2019

# ANNUAL REPORT

farmaindustria

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# A Word
## from the President

**Martín Sellés Fort**

PRESIDENT OF FARMAINDUSTRIA

The severe health crisis in which we remain embroiled eclipses everything, because of its tragic impact on so many thousands of people, and its extraordinary nature. One cannot look back, as in this Report, which records the activities of FARMAINDUSTRIA during 2019, without the coronavirus crisis distorting everything and demanding priority attention.

Let us, then, give it the attention it calls for. Beyond the personal and social tragedies, the pandemic has shown the Spanish society the commitment and the responsiveness of our member companies.

It is when we were most needed that we have acted with the greatest speed and diligence. We have in this regard addressed the two main demands arising from this drastic situation: to find a treatment for coronavirus as soon as possible, and to guarantee the supply of medicines in such a challenging environment.

In the former case, the worldwide response is unprecedented. It is unlikely that so many scientific and economic resources have ever been mobilised to research one single disease.

And Spain is playing a prominent role in this sphere. As confirmed during this crisis, work conducted over many years of partnership between the health authorities, hospitals, researchers, patients and pharmaceutical companies has made Spain a leading international player in clinical research: **we are Europe's leading country and the fourth-ranked in the world in terms of clinical trials**. A success for everyone.

What remains is the challenge to play an active role in the development and production of vaccines being researched at the international level. Now that some of them are embarking on the clinical phase, Spain - through our companies - can also play a remarkable role. Nor should we rule out the possibility of involvement at some stage of production of those vaccines that prove successful.

The rapid deployment of clinical trials for medicines against coronavirus has taken place in parallel with the demanding efforts swiftly to normalise trials in progress for other conditions, which have of course been affected by overwhelmed hospitals and the increased risks for patients and researchers. Activity has clearly been affected, but in partnership with the **AEMPS (Spanish Medicines and Healthcare Products Agency)**, managers and researchers have little by little been able to restore normality.

A similar circumstance has occurred with the supply of medicines. This was one of the highest risk areas, given the hugely difficult situation that the crisis and the measures that needed to be taken led to both within Spain and abroad. Once again, we responded as was expected from us, aware of the vital importance of medication. Companies swiftly and rigorously applied contingency plans, manufacturing sites responded (including by doubling shifts to increase the production of critical medicines), teams ensured the arrival of supplies from other countries…

At FARMAINDUSTRIA we coordinated efforts with the health authorities via the **AEMPS**, and with distributors and pharmaceutical manufacturers. There was no shortage of medicines in ICUs, and the 25 million patients in Spain who take at least one pharmaceutical product every day were able to continue doing so as normal.

Beyond these essential demands, our pharmaceutical companies also helped to support the healthcare system and NGOs in addressing the pandemic on the ground. Donations of medicines and other healthcare products and materials, direct grants to hospitals and social organisations and even the mobilisation of volunteers likewise demonstrated our sector's commitment to people and our capacity to respond to urgent needs.

We got the job done. We responded as expected of such a socially important sector as ours. But it is also important that this has been noted and recognised, and the repeated congratulations from Health Minister Salvador Illa in a number of his public addresses serve as proof of this.

## R&D INVESTMENT

**20%**

OF THE SPANISH INDUSTRIAL TOTAL COMES FROM PHARMACEUTICAL COMPANIES

Society has once again looked to us, calling for solutions, and we have provided them or are on our way to doing so. This is vital for us, since it gives us the opportunity to present our reality, which often, to our bewilderment, seems not to be appreciated.

We know that this is no coincidence, or the result of an isolated effort. It is the outcome of many years of work, of the progress made by a sector which has consolidated its importance in medical and economic terms, and which is steadily evolving in its social commitments through dialogue and cooperation, good practices and transparency.

We have substantially increased employment. We now create more than **42,500 direct jobs**, rising to 215,000 if one includes indirect and induced employment. And this is quality work (almost always on permanent contracts), highly qualified **(two thirds are university graduates)** and diverse (**more than half are women**, and two thirds, as stated, in the case of research).

**PRODUCTION IN SPAIN**

**15,200**

MILLION EUROS

**EXPORTS**

**12,100**

MILLION EUROS

**23%**

OF ALL HIGH-TECH EXPORTS

And we are increasing our **production capacity (€15.2 billion)**, above all in the field of exports. In 2019 we set an all-time record for **exports** with an increase of **13.2%** to a level of more than **€12.1 billion**, i.e. 4.2% of all Spanish exports. And with **23% of high-tech exports,** we have become leaders in this sphere, alongside the aerospace industry.

These are powerful figures, even more so because they are born out of evolution and consolidated growth. But our strength does not simply lie in these numbers.

Last year, we made contributions for the first time (implemented in January 2020) to the healthcare system through application of the Collaboration Agreement with the Spanish Government for sustainability and access to innovation, one of the clearest examples of our capacity for cooperation.

Similarly, it was also the year when **SEVeM (the Spanish Medicines Verification System)** linked up with Europe, the result of our efforts and collaboration with all other agents involved in the medicine supply chain.

Society has once again looked to us, calling for solutions, and we have provided them or are on our way to doing so.

**Martín Sellés**
PRESIDENT OF FARMAINDUSTRIA

All in the year of the challenge raised by Brexit abroad, and domestically the **AIReF** report into public expenditure on medication via retail pharmacies (with the hospital version planned for this autumn), and the Plan to promote generics and biosimilars (not yet applied). These are major challenges for us, as they are based on the misconception that medication is an expense, rather than an investment, and that innovation rarely contributes additional value, which prompts the proposal of measures that are so unnecessary and unjust at this stage such as privileges for generics (when for years branded medicines have had the same price), or practices that could serve as barriers preventing patients from accessing new medicines.

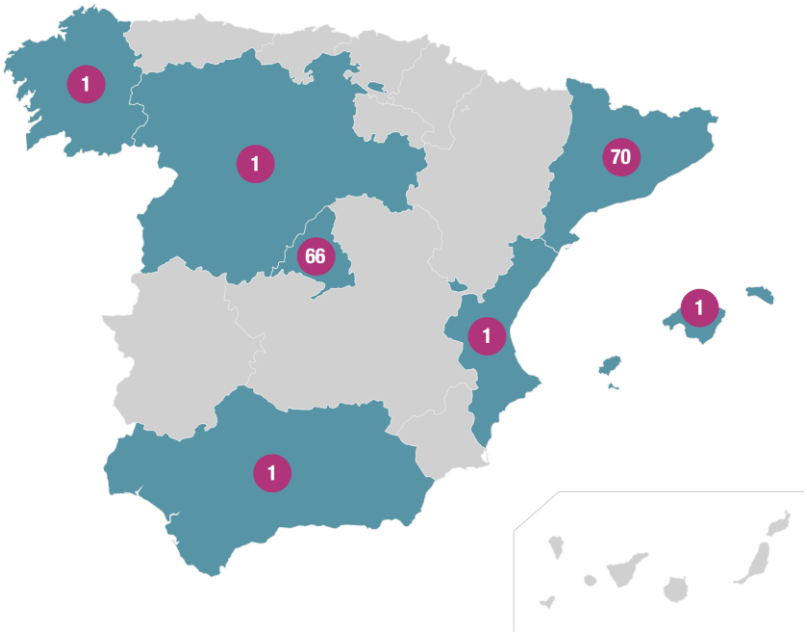
This gives us some idea of how far we still have to go, of the need for us to continue our efforts to demonstrate the value of medicines, of innovation, and of the industry that makes them possible. The figures back us up in this regard, and our actions in particular, such as the response to the remarkable trial of strength represented by the coronavirus crisis. This is the way forward: to show that our sector is the solution for this country from the threefold medical, economic and social perspective. Above all as we face a severe economic and social crisis, and Spain needs to find reliable sectors based on innovation and knowledge to provide the support in reactivating the economy as required.

We are working on that. If the health crisis has taught us anything, aside from the need to reinforce our healthcare system, which has on occasion been overwhelmed by the scale of the pandemic, it is that Spain needs to cherish such sectors as the pharmaceutical industry. Because biomedical research is the response to this and to future health crises, and because we must as a country reconsider whether we can depend so much on third parties, and in particular Asian countries, in order to obtain raw materials and for the manufacture of such vital goods as medication.

This is the operational approach we have adopted, backed up by our own facts and figures. We are part of the solution that Spain needs for its future, and we will work with the public authorities and with society as a whole to provide the medical, economic and social impetus that we want for our country.


01
MEMBERS

By the time this Annual Report was finalised, the number of member companies of FARMAINDUSTRIA amounted to **141**, with the following geographical distribution.




**PHARMACEUTICAL MANUFACTURERS BY GROUP**

| National: 45 | | International: 96 | | |
|---|---|---|---|---|
| | | American | European | |
| **Total** | **45** | **16** | **80** | |
| Large | 5 | | Germany | 7 |
| SMEs (Small and Medium) | 40 | | France | 10 |
| | | | Mixed | 35 |
| | | | United Kingdom | 18 |
| | | | Switzerland | 10 |

In terms of sales, FARMAINDUSTRIA'S members represent 75% of the total prescription market in Spain (retail pharmacies and hospitals).

02

# ORGANISATION

**2.1 Governing Bodies**

2.2 Executive Organisation

# 2.1 Governing Bodies

The General Assembly comprises all Association members and is the supreme governing body of FARMAINDUSTRIA, expressing the companies' collective wishes.

Governance of the Association comprises:

1. **The Executive Board,** made up of the President and 33 representatives of member companies (nine representatives from domestically owned companies and 24 from foreign owned companies, of which 15 are European/international companies and nine are American companies).
2. **The Governing Council,** made up of the President and 22 Members appointed by the Executive Board from among its members, of whom 10 are Vice-Presidents (three from the sector of domestically owned companies, three from the sector of American-owned companies four from the sector of European/internationally and companies), the remaining 12 being Members with the following origins: three with domestically owned capital, three from companies with American-owned capital, and six from companies with European/internationally owned capital.

At the meeting of the Executive Board held on 27 February 2020, a resolution was passed on the initiative of the European International Group to add a new member to the Group of Vice-Presidents to represent said grouping. As this appointment requires approval by the Assembly of a reform of Article 38 of the Articles of Association, it was decided to recruit this fifth representative on an interim basis.

The composition of the Governing Bodies of FARMAINDUSTRIA on the date of this Report is as follows:

| BOARD OF GOVERNANCE | |
|---|---|
| **PRESIDENT** | |
| Mr Martín Sellés Fort | |
| **VICE-PRESIDENTS** | |
| Mr Juan Carlos Aguilera Rodríguez | Mr Federico Plaza Piñol |
| Mr Nabil Daoud | Mr Eduardo Recoder de la Cuadra |
| Mr Jorge Gallardo Ballart | Mr Sergio Rodríguez Márquez |
| Mr Bernardo Kanahuati | Mr David Solanes López |
| Ms Margarita López-Acosta | Mr Roberto J. Urbez Plasencia |
| Mr Juan López-Belmonte Encina | |
| **MEMBERS** | |
| Ms Ana Argelich Hesse | Mr Felipe Pastrana Molina |
| Mr Sergi Aulinas Guillaumes | Mr Peter Plöger |
| Ms Cristina Henríquez de Luna Basagoiti | Mr Jesús Ponce Sancho |
| Ms Fina Lladós Canela | Mr Francisco Quintanilla Guerra |
| Mr José María Martín Dueñas | Mr Mario Rovirosa Escosura |
| Mr Jordi Muntañola Prat | |

## EXECUTIVE BOARD

### PRESIDENT

Mr Martín Sellés Fort
**JANSSEN CILAG, S.A.**

### VICE-PRESIDENTS

| | | | |
|---|---|---|---|
| Mr Jorge Gallardo Ballart<br>**ALMIRALL, S.A.** | Mr Roberto J. Urbez Plasencia<br>**BRISTOL-MYERS SQUIBB, S.A.** | Mr Nabil Daoud<br>**LILLY, S.A.** | Mr Juan López-Belmonte Encina<br>**LABORATORIOS FCOS. ROVI, S.A.** |
| Mr Eduardo Recoder de la Cuadra<br>**ASTRAZENECA FARMACEUTICA SPAIN, S.A.** | Mr David Solanes López<br>**LABORATORIOS ERN, S.A.** | Mr Sergio Rodríguez Márquez<br>**PFIZER, S.L.U.** | Ms Margarita López-Acosta<br>**SANOFI-AVENTIS, S.A.** |
| Mr Bernardo Kanahuati<br>**BAYER HISPANIA, S.L.** | Mr Juan Carlos Aguilera Rodríguez<br>**FERRING, S.A.U.** | Mr Federico Plaza Piñol<br>**ROCHE FARMA, S.A.** | |

### MEMBERS

| | | | |
|---|---|---|---|
| Mr Felipe Pastrana Molina<br>**ABBVIE SPAIN, S.L.U.** | Mr Juan José F. Polledo<br>**CELGENE, S.L.** | Ms Cristina Henríquez de Luna Basagoiti<br>**GLAXOSMITHKLINE, S.A.** | Mr Jesús Ponce Sancho<br>**NOVARTIS FARMACEUTICA, S.A.** |
| Mr Jesús Marcilla<br>**ALCON CUSI, S.A.** | Mr Jordi Muntañola Prat<br>**ESTEVE PHARMACEUTICALS, S.A.** | Mr Joao Simoes<br>**GRÜNENTHAL PHARMA, S.A.** | Mr Ignasi Biosca Reig<br>**LABORATORIO REIG JOFRE, S.A.** |
| Ms Fina Lladós Canela<br>**AMGEN, S.A.** | Mr Francisco Quintanilla Guerra<br>**FAES FARMA, S.A.** | Ms Aurora Berra de Unamuno<br>**IPSEN PHARMA, S.A.** | Mr Guillermo de Juan Echávarri<br>**SMITHKLINE BEECHAM, S.A.** |
| Mr José María Martín Dueñas<br>**ASTELLAS PHARMA, S.A.** | Mr Tomás Olleros Izard<br>**GRUPO FARMASIERRA, S.L.** | Mr Ignacio González Casteleiro<br>**LABORATORIOS MENARINI, S.A.** | Mr Antonio Buxadé Viñas<br>**LABORATORIOS VIÑAS, S.A.** |
| Mr Sergio Teixeira<br>**BIOGEN SPAIN, S.L.U.** | Mr Mario Rovirosa Escosura<br>**FERRER INTERNACIONAL, S.A.** | Ms Ana Argelich Hesse<br>**MERCK SHARP & DOHME DE ESPAÑA, S.A.** | |
| Mr Peter Plöger<br>**BOEHRINGER INGELHEIM ESPAÑA, S.A.** | Mr Sergi Aulinas Guillaumes<br>**LABORATORIOS GEBRO PHARMA, S.A.** | Mr Francisco Javier Alvarado García<br>**MUNDIPHARMA PHARMACEUTICALS, S.L.** | |

02

# ORGANISATION

2.1 Governing Bodies

**2.2 Executive Organisation**

# 2.2 Executive Organisation

THE FARMAINDUSTRIA Director-General is the head of the executive organisation, which in turn has a structure of functional departments. The Association headquarters are in Madrid, and it also has a delegation in Barcelona.

Since January 2020, Ms Ana Bosch has held the position of General Secretary and Director of Legal Affairs and Human Resources, following the departure of Ms Lourdes Fraguas.

The FARMAINDUSTRIA functional organizational chart at the date of finalisation of this Annual Report is as follows:

**Humberto Arnés**
Director-General

**Javier Urzay**
Deputy Director-General

**Ana Bosch**
General Secretary and Director of Legal Affairs and Human Resources

**Pedro Luis Sánchez**
Director of the Studies Department

**Emili Esteve**
Director of the Technical Department

**Iciar Sanz de Madrid**
Director of the International Department

**José Ramón Luis-Yagüe**
Director for Relations with the Spanish Regions

**Francisco J. Fernández**
Director of the Communication Department

# 03

# INSTITUTIONAL ACTIVITY

**3.1 Market Regulation and Relations with Public Authorities**

3.2 Communication

3.3. International Relations

3.4 The Pharmaceutical Industry in Spain and Worldwide

# 3.1 Market Regulation and Relations with Public Authorities

The Collaboration Agreement between the Government (Ministries of Public Finance and Health) and FARMAINDUSTRIA was signed in late 2015 for the 2016 financial year, and was subsequently subject to annual extensions up until 2019.

The aim of the Agreement is collaboration between the parties as regards sustainability, access to innovation and a predictable regulatory environment. From a sustainability standpoint, the main commitment given by the industry is to make monetary compensations in favour of the Spanish National Health Service (NHS) if public pharmaceutical expenditure on originator medicines (excluding generics and biosimilars) rises in any given year above the increase in Spanish GDP in real terms. The compensation would be equivalent to the industrial element of the surplus increase in pharmaceutical expenditure.

The Agreement makes provision for a Monitoring Committee comprising the Ministries of Health and Public Finance and FARMAINDUSTRIA, along with those Spanish regions adhering to the Agreement.

In the first two years covered by the Agreement (2016 and 2017) the rate of increase in public pharmaceutical expenditure on originator medicines (not generics or biosimilars) was lower than the real rise in GDP. It was only from 2018 onwards that surplus growth did occur, thereby triggering the monetary compensation clause.

The procedure established for payments is that, with the initial data on expenditure and real GDP figures available in the month of April each year, an initial advance payment for the previous financial year is calculated, corresponding to 75% of the compensation. The final payment would be required following the definitive expenditure and GDP data published by the Government in the month of September/October.

However, this calendar could not be fulfilled at the close of the 2018 financial year as an interim Government was in place, and because of other administrative issues. It was therefore not until December 2019 that the amount of the monetary compensation for the 2018 financial year was defined (€190.5 million) and the green light was given for the first interim payment of an amount of €121 million, which the industry settled in the month of January 2020.

At the time when this Annual Report was drawn up, the settlement of the final payment corresponding to 2018 remained pending a series of administrative procedures. Likewise, the definitive data for the close of the 2019 financial year are not yet available, and so we do not yet know the definitive amount of the surplus increase in public pharmaceutical expenditure on originator medicines over and above the real increase in Spanish GDP for the year in question.

The health crisis caused by Covid-19 is having a profound impact on the economy of our country and of the whole world, generating a huge degree of uncertainty. FARMAINDUSTRIA has made itself available to the public authorities to reflect on a new Agreement for this situation, and to study what terms might be agreed to contribute towards sustainability while allowing for the balanced development of an opportune sector for economic recovery such as the pharmaceutical industry, within a stable and predictable environment.



# 3.1.1 REGULATORY FRAMEWORK

## Reference Pricing

The consultation process began in May 2019 for the Order to update the Reference Pricing System, maintaining the same criteria as the order for the previous year in terms of the group composition.

Arguments were submitted insistently calling both for the exclusion of those groups comprising one single medicine marketed under two brands held by the same proprietor, and the need to create separate groupings to cover medicines with different therapeutic purposes, along with other issues regarding the lack of commercial viability of certain presentation and calculation errors.

Not all of these arguments were taken on board in the order published in the month of September, and the Association therefore appealed against it under public authority law.



Among other aspects, FARMAINDUSTRIA argued in its appeal against the heterogeneity of the groupings, which could give rise to an interruption of supply, and for the first time against the inclusion of an orphan medicine within the reference pricing system, which presents a contradiction while said status continues to be granted under European law (Regulation (CREC) 141/2000 of the European Parliament and of the Council, of 16 December 1999, on orphan medicines), and such medicines enjoy exclusive commercial rights.

In this regard, on 3 March 2020 the Council of Ministers agreed a measure intended to incentivise investment by the pharmaceutical industry in research, development and subsequent commercial release of orphan medicines, acknowledging this circumstance by stating:

*"This measure comprises the provision that orphan medicines included within the service portfolio of the NHS should benefit from a specific economic regime and not be governed by the Reference Pricing System applied to other medicines funded by the NHS once their patent has expired. This serves to maintain a distinction in setting the price thereof in Spain".*

## SERIALISATION

Last year's Report made mention of the consultation process for the proposed Royal Decree to adapt the management of NHS pharmaceutical provision in accordance with the regulatory context of the verification and authentication of medicines, establishing the conditions for the continuation and subsequent elimination of the coupon seal, as requested by the Association, and application of Article 94.7 (prices outside the NHS system) via SEVeM.

Following this procedure, at the hearing before the Council of State on the proposed Royal Decree modifying Royal Decree 1345/2007, on Registers, access was given to a text merging the two projects and including a chapter dedicated to the system for the verification and authentication of medicines, a text on which FARMAINDUSTRIA likewise made its observations.

In December 2019, Royal Decree 717/2019 was thus published, modifying Royal Decree 1345/2007, on Registers, with the inclusion of the chapter governing the entire medicines verification and authentication system and developing Article 94.7 of the Guarantees Act (prices outside the NHS system).

Among other aspects, the new Royal Decree establishes the NHS-Pharma Node, which will form part of the National Repository managed by SEVeM and will apply to all medicines that include the unique ID and are dispensed under the NHS budget. Integration with the National Repository will be conducted by means of an agreement between SEVeM and the Ministry of Health.

Meanwhile, Royal Decree 717/2019 develops Article 94.7 of the Guarantees Act (prices outside the NHS), establishing that SEVeM provide information for: i) reimbursement within the context of NHS pharmaceutical provision; and ii) reimbursement from pharmacies to the manufacturers and distributors of medicines dispensed outside the NHS system at a price other than the financed price.

## SUPPLY GUARANTEE PLAN

In the month of March 2019, the AEMPS presented the draft 2019-2022 Medicine Supply Guarantee Plan. The text covered three general objectives to improve prevention, management and information about supply problems. There is also a fourth, cross-cutting objective, namely coordination with other European Union (EU) countries, and participation and involvement by stakeholders (patients, healthcare professionals, health authorities, distributors and the industry), along with continuous evaluation of the Plan. Each of the general aims will give rise to specific measures advancing in parallel to deal with situations of medicine supply interruption.

FARMAINDUSTRIA presented its observations on: i) the reasons for a lack of supply of medicines with healthcare impacts; ii) participation by pharmaceutical manufacturers in the prevention plan; iii) the proportionality of the disciplinary measures applied to agents in the supply chain; and iv) measures to guarantee the viability of essential medicines.

At its meeting held in May 2019, the Inter-Territorial Council of the NHS issued a favourable report on the aforementioned 2019-2022 Strategic Plan devised by the AEMPS, which was published on the AEMPS' website on 5 May.

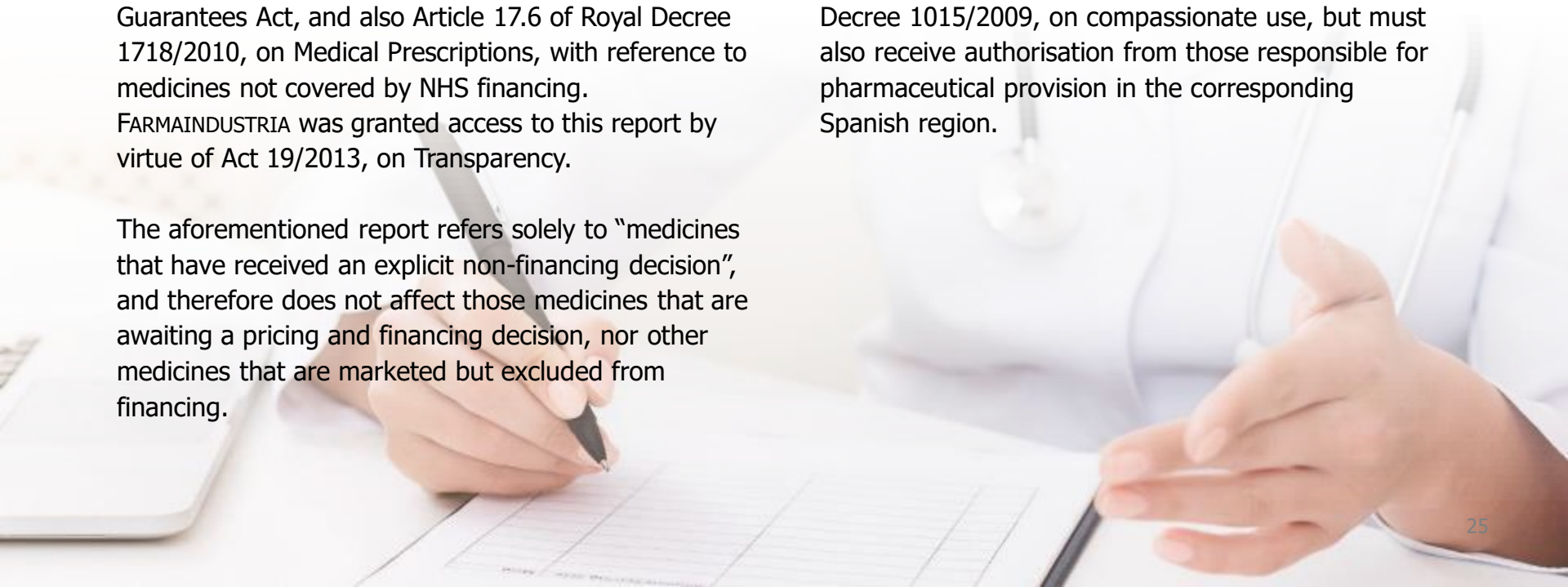
As in other fields, the outbreak of the Covid-19 crisis had a significant impact on actions in the field of medicine supply. Nonetheless, the balance is more than satisfactory, since during the months of the health crisis and up to the date of the finalisation of this Annual Report, the Spanish population continued to enjoy access to medication thanks to the ongoing collaboration between the AEMPS and FARMAINDUSTRIA.

## NOTE FROM THE DIRECTORATE-GENERAL FOR THE BASIC PORTFOLIO OF NHS AND PHARMACY SERVICES AS TO MEDICINES WITH AN EXPLICIT NON-FINANCING DECISION

In April 2019 the Directorate-General for the Basic Portfolio of NHS and Pharmacy Services (DGCBSF) issued a note indicating that medicines with an explicit decision not to be included within NHS pharmaceutical provision cannot be financed by the Spanish regions as a supplementary portfolio. The aforementioned note, distributed internally to all Spanish regions, draws on a report by State Legal Services, based on Articles 91.5 (fairness) and 92 (individual reserves) of the Guarantees Act, and also Article 17.6 of Royal Decree 1718/2010, on Medical Prescriptions, with reference to medicines not covered by NHS financing. FARMAINDUSTRIA was granted access to this report by virtue of Act 19/2013, on Transparency.

The aforementioned report refers solely to "medicines that have received an explicit non-financing decision", and therefore does not affect those medicines that are awaiting a pricing and financing decision, nor other medicines that are marketed but excluded from financing.

The AEMPS informed the Association that ongoing treatments with medicines subject to an explicit non-financing decision would be maintained for patients already receiving the medication (clinical trials, extended access, treatment begun prior to the DGCBSF report). For new treatments, however, the pharmacy services of public hospitals (or public-private partnership hospitals for NHS patients) will not only be required to comply with the demands of Royal Decree 1015/2009, on compassionate use, but must also receive authorisation from those responsible for pharmaceutical provision in the corresponding Spanish region.



FARMAINDUSTRIA is of the opinion that in this case the doctrine of the Constitutional Court would apply (Constitutional Court Judgment 98/2004, of 25 May 2004, and the Judgment of 15 December 2016) in interpreting Article 8 of Act 16/2003, of 28 May 2003, on the Cohesion and Quality of the NHS, which clearly establishes the possibility for the Spanish regions to improve on the minimum of medicines financed by the NHS if they have budgetary availability, invoking the principle of solidarity on a generic basis. Solidarity in the sense that citizens must have access to a "common minimum", but not as justification to eliminate improvements on said minimum.

## PLAN TO PROMOTE GENERICS AND BIOSIMILARS

The draft Plan was presented under the title: 'Action plan to promote the use of market-regulating medicines in the NHS: biosimilar and generic medicines', and was approved by the Pharmacy Standing Commission of the Inter-Territorial Council of the NHS in April 2019, and published on the Ministry website for the presentation of submissions up to 10 November the same year.

The first draft of this Plan included, among other measures, prescription by active substance, prioritisation of the generics on criteria of efficiency, and replacement with the lowest-priced medicine. In July, a report was published by the National Markets and Competition Commission (the CNMC) at the request of the Ministry of Health, supporting the measures and proposing others, such as preferential dispensation of generics and a reform of the reference pricing system to include ATC4-based groupings in certain treatment areas.

The report by the Steering Council for the Financing of Pharmaceutical Provision (the CAPF) was likewise published, and this: i) supported prescription by active substance, while acknowledging the impact on adherence, requesting as far as possible that continuous changes to medication be avoided, and ii) sketched out a position as to the interchangeability of biotherapeutic products, with the knowledge and approval of the prescriber, either at the individual level, or agreed through a pharmacotherapy commission.

At the time when this Annual Report was drawn up, the plan in question was still at the draft stage.



## TRANSPARENCY

The Association has been very closely following all the regulations passed in this sphere. On 13 March 2019, the Business Secrets Act 1/2019, of 20 February 2019, took effect, transposing into the Spanish legal system Directive (EU) 2016/943, of the European Parliament and of the Council, of 8 June 2016, on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. During the consultation process of the Act, arguments were submitted with the aim of maintaining the confidentiality of medicine prices in agreements between public authorities and companies.

FARMAINDUSTRIA was also involved in the public consultation process for the Transparency Act Implementing Regulation, and made submissions to the Council of State with the aim of underpinning the prevalence of confidential information protected by some other specific regulations, such as the Guarantees Act or the Business Secrets Act.

In 2019, the **CTBG (Transparency and Good Governance Council)** also issued a decision on 26 September (0478/2019), denying access to information as to the financing conditions of a medicine, holding that the confidentiality of said information is in the public interest, by allowing better economic conditions to be obtained in accordance with national circumstances.

It likewise issued its interpretation criterion 1/2019, of 24 September 2019, acknowledging with regard to the application of Article 14.1(h) of the Transparency Act that the right of access may be limited, if access to the information would be to the detriment of economic and commercial interests, and the implications thereof in connection with Articles 133 and 154.7 of Public Sector Procurement Act 9/2017, and Article 97.3 of the Guarantees Act.

## PUBLIC PROCUREMENT

As a result of the experience registered following the entry into force of the new national legislation on public procurement, the CNMC began a public consultation in late 2019 with the aim of updating the Public Procurement and Competition Guide, which dates back to 2011. The Guide will be updated in phases, beginning with the public purchasing planning phase.

The aim of the Guide is to provide indications for public purchasing managers in order to foster conditions of competition throughout the entire procurement process.

It should likewise be mentioned in this sphere that the first final provision of Royal Decree-Act 3/2020, of 4 February 2020, on urgent measures incorporating various EU Directives in the field of public procurement in certain sectors within the Spanish legal structure, made a modification to Article 118 of the Public Sector Procurement Act 9/2017, of 8 November 2017, regarding the procedure for minor contract procurement. Said modification does away with the obligation to justify in the procedure that the contractor has not signed additional minor contracts that would individually or jointly exceed the thresholds established for such contracts.

Lastly, Article 81.3 of Royal Decree 1345/2007 (the Royal Decree on Registers), incorporated by Royal Decree 717/2019, of 5 December 2019, governs in its second paragraph the aggregation of unique IDs within the context of hospital supplies.

Given the doubts as to the possible demand for said aggregation in public tenders, the Association analysed the issue, concluding that the literal terms of the aforementioned article and the interpretation given to it by the Ministry of Health (the author of the provision) and the Council of State, asserting the voluntary status of aggregation, indicates that

Public Authorities cannot impose said demand as a criterion for exclusion in public tenders that they arrange for the supply of medicines, but at the most it could be included as an additional criterion for appraisal when awarding the contract.

## DATA PROTECTION

Without prejudice to the contents of the subsection dedicated to the new Code of Conduct in this Annual Report, mention should be made of the European Commission's Q&A document with regard to Opinion 3/2019 of the EDPB (European Data Protection Board) on the interplay between the Clinical Trials Regulation (CTR) and the **GDPR**, in addition to Annex VIII to the instructions document for the updating of the personal data protection section on the patient information sheet (HIP/CI) regarding Regulation (EU) 2016/679, the GDPR, as published by the AEMPS on its website, said documents acknowledging the roles previously assigned to the the centre and promoter under the earlier Standard Code, without making any modifications to the current regulations.

In turn, in July 2019 the European Commission published a report on the first year of implementation of the GDPR in the EU, and the possible mechanisms to improve its application. Most of the Member States have updated their national legislation in line with the GDPR, Spain being one of the pioneering countries in implementing the regulation.

In December 2019, in accordance with the deadline established in the second transitional provision of Spain's Personal Data Protection and Guarantee of Digital Rights Act 3/2018, of 5 December 2018, FARMAINDUSTRIA submitted a draft Code of Conduct governing the processing of personal data within the context of clinical trials and other clinical research and pharmacovigilance, in addition to its explanatory Report, to be admitted to and subsequently approved by the Spanish Data Protection Agency.

## COVID-19 – STATE OF EMERGENCY

The exceptional circumstances caused by Covid-19 prompted extensive regulatory actions and institutional initiatives, headed by the declaration of a state of emergency. However, prior to said declaration, a series of measures with far-reaching implications for the pharmaceutical industry had already taken place.

In this regard, on 3 March the Ministry of Health recommended the suspension of medical congresses, in order to ensure that healthcare professionals would be in optimal condition and available to deal with Covid-19. In line with these recommendations, the Spanish regions issued instructions cancelling all leave to attend scientific or similar gatherings at which a large number of healthcare professionals were expected to attend. FARMAINDUSTRIA immediately espoused the Ministry of Health recommendation, scrupulously following all instructions and recommendations issued by the healthcare authorities.

Many of the Spanish regions subsequently issued instructions suspending medical visits in general.

A few days later, the seriousness of the situation prompted the issuance of Royal Decree 463/2020, declaring a state of emergency to address the health crisis caused by Covid-19. This took effect on 14 March, recognising the Ministry of Health as one of the competent authorities.

Three ministerial Orders were issued on said date by the Ministry of Health, of which we would highlight:

- **Order SND/232/2020, of 15 March,** adopting measures with regard to human resources and means to manage the health crisis situation caused by Covid-19, containing measures for the hiring and rehiring of healthcare professionals and even medical and nursing students, and healthcare resources and means made available to the Spanish regions by other Public Authorities and private healthcare establishments and sites, among other measures.

- **Order SND/233/2020,** of 15 March, establishing certain reporting obligations in accordance with the provisions of **Royal Decree 463/2020,** establishing reporting obligations of legal entities involved in the manufacture and/or import or development capacity of certain products, in particular face masks, tests, protective glasses, gloves, hydroalcoholic solutions and their raw materials, invasive mechanical ventilation (IMV) devices, among others, without this Order affecting equipment/products held on a user basis, rather than as manufacturers/importers, in which case they would not be affected.

- **Order INT/226/2020,** of 15 March, establishing operational criteria for State Law Enforcement Agencies in connection with **Royal Decree 463/2020,** in particular the powers vested in the Ministry of Health which would allow orders to be issued to ensure market supply and the functioning of the services of production sites affected by interruptions to the supply of products required to protect public health, and to requisition and temporarily occupy industrial facilities, factories, workshops, operations or premises of any kind, including privately owned healthcare establishments, services and sites, in addition to the pharmaceutical industry, and to perform temporary requisitions of all manner of goods, and impose mandatory staffing provisions, in those cases where this would prove necessary for the appropriate protection of public health within the context of this health crisis.

The regulatory activity derived from the crisis furthermore focused on issues of public health and employment measures, given the interruption of a large part of national economic activity, as highlighted in other subsections of this Annual Report.

Most of these measures, however, in turn have major repercussions in other spheres. We would in this regard highlight Royal Decree-Act 8/2020, of 17 March, to address the economic and social impact, and specifically measures in the field of public procurement, and in particular Article 34, decreeing the suspension of contracts in force upon declaration of the state of emergency, the execution of which

has become impossible, although these public procurement measures in no way apply to health or pharmaceutical supply or service contracts, or any others whose objective is connected with the health crisis.

Substantial measures to support research into Covid-19 were also included.

The aforementioned regulations were followed by **Royal Decree-Act 9/2020,** of 27 March, on supplementary measures in the field of employment, in particular the following:

- The measures intended to amend Article 16 of **Royal Decree-Act 7/2020,** of 12 March, subject to Article 120 of Public Sector Procurement Act 9/2017, of 8 November 2017, such that all contracts to be arranged by public sector organisations would be subject to the application of emergency procedures.

- **Order INT/262/2020,** of 20 March, with regard to the traffic and circulation of motor vehicles, allowing an exception from the traffic restriction measures for vehicles distributing healthcare materials and medicines.

- **Order SND/276/2020,** of 23 March, the purpose of which was, among other matters, for companies to guarantee information and sufficient supply of presentations of medicines declared essential, including at weekends and during holiday periods, as a result of which companies are required to put in place plans to comply with these new obligations.

- **Order SND/271/2020,** of 19 March, on waste management, establishing instructions as to the management of waste from homes, hospitals, ambulances, health centres, laboratories and similar establishments.

- **Order SND/293/2020,** of 25 March, establishing conditions for the dispensation and administration of medicines, indicating that hospital pharmacy services may not dispense outpatient medicines for more than two months of treatment, with the AEMPS being entitled to reduce this period to one month, without this limit applying to medication dispensed in clinical trials.

**Royal Decree-Act 10/2020,** of 29 March, was subsequently issued regarding recoverable paid leave. This legal provision would not apply to sectors classified as essential, as listed in the Annex to the Decree, including the medicine supply chain. Nor would it apply to those individuals covered by a company 'ERTE' furlough scheme, those temporarily unfit for work or with a contractual suspension, or those able to continue working from home.

Continuing with national regulations, at the end of March **Royal Decree-Act 11/2020,** of 31 March, was issued, adopting urgent supplementary measures in the social and economic sphere to address Covid-19, which, among other measures, highlights those governing donations, deferral of debts derived from customs declarations, suspension of taxation deadlines, measures with regard to public grants and subsidies, extensions to the deadline for appeals, taxation measures, and the amendment to Royal Decree-Act 8/2020, on public procurement, the formulation of annual accounts and other matters.

In April, **Royal Decree-Act 13/2020,** of 7 April, was issued, adopting certain urgent measures in the field of agrarian employment, said regulation including, among other measures, an exemption from fees as a result of the health crisis caused by Covid-19 (clinical trials authorisation procedures where there is no profit motive), and modifications to Royal Decree-Act 6/2020, of 10 March 2020, and Royal Decree-Act 11/2020, of 31 March 2020, adopting urgent supplementary measures in the social and economic sphere to address Covid-19.

Various ministerial orders were likewise issued, including the following up to the date of authoring of this Annual Report:

- **Order SND 319/2020,** of 1 April, modifying Order SND 232/2020, of 15 March, adopting measures with regard to human resources and means to address the health crisis situation caused by Covid-19.

- **Order SND 321/2020,** of 3 April, establishing special measures for the use of bioethanol in the production of hydroalcoholic gels and solutions for hand sterilisation as a result of the health crisis caused by Covid-19.

- **Order SND 325/2020,** of 6 April, establishing interpretation criteria and extending the validity of verification and preventive maintenance certificates established in the regulation of industrial and metrological security.

- **Order SND 326/2020,** of 6 April, establishing special measures for the granting of prior operational licences for installations and the initial operation of certain healthcare products without a CE marking as a result of the health crisis caused by Covid-19.

Lastly, **Royal Decree-Act 14/2020,** of 14 April, was published, extending the deadline for the presentation and deposit of certain tax returns and self-assessed settlements, along with **Royal Decree-Act 15/2020,** of 21 April, on urgent supplementary measures to support the economy and employment, with measures on VAT for deliveries, imports and intra-EU acquisitions of goods required to combat the effects of Covid-19, among others.

## 3.1.2 THE SPANISH REGIONS

During the 2019 financial year elections were held for the regional parliaments of 13 Spanish regions, with the corresponding impact on the composition of their regional governments. On 28 April, then, elections were held in Valencia, and on 26 May in the Spanish regions of Aragón, Asturias, Islas Baleares, Islas Canarias, Cantabria, Castilla La Mancha, Castilla y León, Extremadura, La Rioja, Madrid, Murcia and Navarra.

The autonomous region of Andalucía had held elections on 2 December 2018; Cataluña on 21 December 2017, Andalucía and the País Vasco on 25 September 2016. The last two regions announced that elections would be held in 2020, although as a result of the Covid-19 health crisis, the precise date was not yet known by the time that this Annual Report was drawn up.

During 2019, FARMAINDUSTRIA continued its institutional activities with the regional health authorities, scientific societies, scientific societies and institutions with the aim of underpinning our sector's positioning as a strategic ally and partner of the health system in improving the levels of health of the population. The innovative pharmaceutical industry is committed to the sustainability of the healthcare system and fair patient access to pharmaceutical innovation.

With the collaboration of the **Working Groups** for the **Spanish Regions** (GT-CCAA) and the **Hospital Market** (GT-MH), FARMAINDUSTRIA has been monitoring regional initiatives connected with health policy and pharmaceutical provision, informing the companies of the most significant aspects in this regard.

## FARMAINDUSTRIA – SPANISH REGIONS

On 10 and 11 October 2019, Ávila was the venue for the 22nd edition of the FARMAINDUSTRIA-Spanish Regions Forum, which was formally opened on behalf of the Regional Minister of Health by the Director-General for Information Systems, Quality and Pharmaceutical Provision of Castilla y León. The Forum involved 13 Spanish regions and the INGESA (National Institute of Healthcare Management). The meeting addressed the following topics:

1. **The Public Sector Procurement Act,** 18 months following its entry into force.
2. **Public pharmaceutical provision,** budgets and expenditure.
3. **Innovation radar,** anticipating the arrival of new medicines.
4. How to incorporate **therapeutic innovation** within the NHS?

## PARTICIPATION BY THE SPANISH REGIONS IN THE PHARMACEUTICAL POLICY OF THE NHS

Over the course of 2019, an increasingly prominent role was seen on the part of the Spanish autonomous regions in the processes of financing and pricing medicines, with an extension of their involvement in the CIPM (Inter-Ministerial Medicine Prices Commission), and greater activity on the part of the CPF (Pharmacy Standing Commission) of the NHS Inter-Territorial Council.

With regard to the CIPM, in May 2019 the Plenary of the CISNS (NHS Inter-Territorial Council) resolved to increase the number of Spanish regions taking part at the plenary sessions of said body with the right to speak but not to vote, so as to include all Spain's regions. Ever since, the Commission has thus involved three regions as full members with voting and speaking rights, and the remaining 14 regions as observers.

This entailed a modification to Article 3.3 of the CIPM's internal regulation, establishing that "simultaneously upon the appointment of the three full members representing the Spanish regions, the observer members shall likewise be appointed, as the representatives of all Spanish regions that are not full members".

The CIPM, attached to the Secretariat-General for Health and Consumer Affairs, is the body responsible for the setting of the manufacturers' sales price for each medicinal presentation to be included, or already included, within the NHS pharmaceutical provision.

Meanwhile, within the context of price-setting procedures, the CIPM may propose to the body responsible for NHS pharmaceutical provision: i) the financing of medicines with public funds and, where applicable, the conditions under which this is to occur; and ii) the establishment of one-off reserves or special financing conditions for medicines financed with public funds.

In 2019 the CIPM met on 10 occasions, in accordance with the terms established by point 1 of Article 9 of its Internal Regulations, on the calling and holding of meetings.

## ADVISORY COMMITTEE FOR THE FINANCING OF NHS PHARMACEUTICAL PROVISION

Royal Legislative Decree 1/2015, of 24 July 2015, approved the recast text of the Guarantees and Rational Use of Medicines and Healthcare Products Act. Article 95 of this Royal Legislative Decree regarding the Advisory Committee for the Financing of the NHS' Pharmaceutical Provision established that this is a collegiate body of a scientific and technical nature, attached to the ministerial body responsible for the area of pharmaceutical provision, with the task of providing advice, appraisal and consultation as to the propriety, improvement and monitoring of the economic appraisal needed in support of the decisions of the Inter-Ministerial Medicine Prices Commission.

On 22 March 2019, the Council of Ministers agreed to create the Advisory Committee for the Financing of NHS pharmaceutical provision, with the following legally established functions:

1. **Advise on the economic appraisals** required in support of the decisions of the CIPM (Inter-Ministerial Medicine Prices Commission).
2. **Appraise the outcome of measures** currently established, and propose improvements in furtherance of the sustainability and efficiency of NHS pharmaceutical provision.

The Order of 1 April 2019 served to appoint the members of this Advisory Committee, as follows: Mr Félix Lobo as President, Ms Ana Ortega as Vice-President, and Mr Jaume Puig-Junoy, Ms Marta Trapero, Ms Ana Clopés, Mr Emilio Alegre and Mr Roberto Sabrido as members.

## E-HEALTH PROJECTS IN THE NHS

The **development of information and communication technologies** in the field of health has enabled the introduction of extremely useful applications such as digital clinical records, electronic prescriptions and electronic approval in an attempt to improve the service offered to the general public and to reduce waiting times and medical appointments. Faced with this scenario, the Government has promoted a number of initiatives in order to progress towards interoperable systems within the NHS as a whole.

### Electronic Prescription. Situation in the Spanish Regions

In 2019, electronic prescriptions had been fully implemented at all healthcare levels (health centres, general practices, hospitals and retail pharmacies) in all Spanish regions except for Asturias, where they had not yet been implemented at hospitals, and in Castilla y León, where implementation at hospitals is only partial. According to the Ministry of Health, the percentage of electronically dispensed prescriptions across the NHS as a whole in September 2019 (figures for June 2019) was above 94%.

In order to facilitate the interoperability of electronic prescriptions between Spanish regions, the RESNS (NHS Electronic Prescription) project began in 2015, coordinated by the Ministry of Health, and comprising: i) a series of internal tasks applied to the IT systems of the Spanish regions, allowing them to transfer the information contained in each medical prescription in an interoperable manner; ii) analysis conducted of shared criteria and adaptation of prescription and dispensation systems to incorporate these; and iii) development of the processes required in order to allow patient incorporation.

The project was completed in April 2019 with certification by the Ministry of Health of Madrid (the last region to join the system) as issuer and receiver of interoperable electronic prescriptions. This final certification served to complete the project, with all 17 Spanish regions and INGESA now being interoperable.

## NHS Digital Clinical Records

The HCD (Digital Clinical Record) project within the NHS was defined in the early months of 2006 in order to allow patients to be treated by any service of the NHS, guaranteeing the availability of their prior clinical information.

Each Spanish region had, within its own territorial confines, implemented automated systems to gather and manage individual health data providing support for healthcare processes, among other services, thereby improving healthcare quality through better access to information.

This HCD project, headed by the Ministry of Health, is intended to ensure that healthcare professionals and the general public have access to the most significant clinical documentation for the treatment of each patient, including documentation available in electronic format anywhere within the NHS, providing citizens with the guarantee that their data can be consulted only by those holding the corresponding authorisation.

By late 2019, all the regional health services had managed to position themselves as information issuers and recipients, except for Cataluña, which is only an issuer. As a result, NHS digital clinical records now cover nearly 94% of the population with an individual health card, according to Ministry of Health figures.

Meanwhile, over the course of 2019 a number of Spanish regions began to regulate the content of digital clinical records and the corresponding access conditions on the part of healthcare professionals, in order to improve the protection of patients' clinical data and increase security for professionals in exercising their responsibilities.

## REGULATORY INITIATIVES IN THE REGIONAL FIELD

### Asturias. Health Act 7/2019 of Asturias, of 29 March 2019

The 155 articles describe the aim of the Act and its scope, the subjective extent of application and its guiding principles, including a holistic vision of health initiatives and the values governing the Public Health Service of Asturias.

With regard to pharmaceutical provision, Article 178 of Title V, on the rational use of medicines and healthcare products, establishes the creation of the Commission for the Rational Use of Medicines and Healthcare Products of Asturias, the functions, composition, organisation and functioning of which will be defined by regulation.

Meanwhile, Title III covers the Health System Asturias, incorporating the concept of the Integrated Service Network; Title VII focuses on training, research and innovation; Title VIII sets out the key aspects for the configuration and development of the Health Information System, while Title IX governs the Health Service of Asturias (SESPA).

FARMAINDUSTRIA set out its arguments regarding this legislation at the Green Paper stage, emphasising:

1. Fair access.
2. The need to guarantee the common service portfolio.
3. The advisory status of the Commission for the Rational Use of Medicines created by the legislation.
4. The right of patients to decide from among different treatment options.

## Andalucía. Competitive Tenders for Medicines

Following the regional elections held in December 2018, Mr Juan Manuel Moreno Bonilla was sworn in as President of the Regional Government of Andalucía in January 2019.

The healthcare measures agreed and included in the agreements signed with the various political parties that facilitated his investiture include the reversal of the model for competitive tenders for medicines promoted by the Health Service of Andalucía in 2012.

To this end, the regional government announced that new auctions would not be held, while maintaining those in force up until the expiry of the contracts signed.

The 2019 Health Service Inspection Plan, then, approved by means of the Order of 20 February 2019, addresses this approach, including within the pharmacy area such goals as the appraisal of the distribution and supply of medicines selected in tenders, among other objectives.

## País Vasco. Decree 29/2019, Governing Pharmacy Services and Pharmaceutical Stockpiles at Care Homes

According to the provisions of this decree, medicines prescribed by authorised medical services at social and health care homes within the region, whether publicly or privately owned, will be dispensed via the authorised pharmacy services and pharmaceutical stockpiles at such establishments.

At establishments with a hundred or more beds, an internal pharmacy service or pharmaceutical stockpiles linked to the pharmacy service of a hospital within the public network will be put in place, while at those with fewer than a hundred beds, a pharmaceutical stockpile linked to a hospital pharmacy service must be made available at publicly owned establishments, or a retail pharmacy operation if privately owned.

Article 6 of the Decree governs the common functional standards of pharmacy services and pharmaceutical stockpiling that:

1. Will be involved in the selection of the specific medicines required for the pharmaceutical care of the institutionalised population, based on criteria of efficacy, safety, quality and cost.
2. Will have personalised dosing systems in place.
3. Will cooperate with the healthcare team at the residential establishment and with all other healthcare structures to optimise the pharmacotherapy treatments established for the population cared for, among other aspects.

The development of this regulation will implement new processes for stockpiling and preparation of medicines via a centralised purchasing system in accordance with a standardised pharmacotherapy guide for the 249 care homes covered, tending to a total of 19,560 people.

By the date when this Annual Report was authored, the Council of Official Associations of Pharmacists of País Vasco had lodged an appeal against said Decree under public authority jurisdiction.

## Other Regional Initiatives. Cantabria, Castilla y León, Castilla La Mancha, Cataluña, Murcia, Navarra, País Vasco and Valencia

In February, the Official Gazette of Cantabria published Order SAN/18/2020, creating and governing the **Corporate Pharmacy Committee of the Region of Cantabria** as the collegiate consultancy, advice and support body for pharmaceutical provision attached to the Regional Health Department, via the Directorate-General for Regulation, Pharmacy and Inspection. The legislation incorporates a great many of the arguments made by FARMAINDUSTRIA during the consultation stage.

The functions of this Committee include:

1. Promote the proper usage of pharmacotherapy resources.
2. Monitor the budgetary impact of proposals for the inclusion of new medicines.
3. Make recommendations as to pharmacotherapy treatments or conditions that, because of their high level of health, social or economic impact require particular supervision and monitoring.
4. Provide technical advice for the establishment of criteria intended to optimise joint acquisitions of medicines.
5. Propose prescription support systems integrated with electronic clinical records.

**Meanwhile, the Health Service of Castilla y León** issued its Decision of 24 April, creating the **Pharmacotherapy Advisory Commission**. This body, dependent on the Directorate-General for Healthcare, has the priority aim of establishing recommendations as to usage and clinical monitoring criteria for medicines with a high health, social and/or economic impact. The Commission will comprise, among others, nine pharmaceutical members, nine medical members and a medical director, engaged in healthcare practice at any of the healthcare establishments of the Regional Health Department.

By the date when this Annual Report went to press, the **Health Service of Castilla La Mancha** (SESCAM) had begun the prior public consultation process for the proposed Decree to create the **Central Pharmacy and Therapy Commission (CCFT) of the SESCAM**. According to the proposal, the Commission will be given the function of coordinating the various Pharmacy and Therapy Commissions and Rational Use of Medicines Commissions in place at the different Health Service Departments, along with the establishment of standardised criteria for the acquisition and prescription of medicines.

Meanwhile, the **Health Service of Cataluña (CatSalut)** established its Advisory Council for Medicines in Special Situations (CAMSE), with the following functions: i) the appraisal and generation of coordinated proposals or recommendations regarding the use of medicines in special situations for healthcare centres, and ii) advice on the standardisation of the management of such medicines at hospitals.

It should be recalled that, according to Royal Decree 1015/2009, medicines in special situations are to be understood as those used in research or for compassionate use under conditions other than those authorised, in addition to foreign medicines.

At the start of the financial year the procurement model of the CSC (Health and Social Consortium) was presented, with the aim of developing a procurement strategy based on value (health outcomes) and the acquisition of "complete" services (including logistical processes, coverage and effectiveness). The CSC has announced that future procurement of exclusive medicines will be conducted by means of the dynamic acquisition system (electronic procedure open to bidders).

In the **Region of Murcia,** the Health Service of Murcia issued an Instruction establishing the procedure for the prescription and dispensation of medicines to outpatients via hospital pharmacy services. This affects:

1. Medicines for hospital use.
2. Medicines with individual dispensation reserves.
3. Foreign medicines.
4. Medicines for compassionate use.
5. Investigational medicines.
6. Medicines for clinical trials to be administered at home.

These medicines can only be prescribed by hospital specialists, following the protocols established by the Regional Pharmacy Commission or the Area Pharmacy Commissions. The Association has been monitoring this initiative, in case it could limit patient access to medicines included within public pharmaceutical provision.

**Navarra** approved the Devolved Public Contract Act 15/2019, amending Devolved Act 2/2018, and incorporating a series of specifications as to the formalisation of contracts and the elimination of resolution of the case from the outset in procedures negotiated without publication. Although initially this does not have any significant impact on the sector, it is nonetheless being monitored.

As for **Valencia,** Instruction 6/2019 was published in May 2019, modifying the approach of the PAISE (High Health and/or Economic Impact Medicines Programme) for oncological treatments, with the following aims:

1. **Update the procedures** established in decisions and instructions issued at the proposal of the Subcommittee for the Appraisal and Monitoring of Oncology Treatments.

2. **Establish access to** and usage of medicines /indications that are not financed and medicines in special situations (compassionate use, use under conditions other than those authorised, and foreign medicines).

Furthermore, FARMAINDUSTRIA also lodged a procurement appeal in the same region in response to the competitive tender for methotrexate, challenging the aim of the competitive tender and the conditions, which were in breach of various regulations in the field of medicines and represented a de facto amendment to the dispensation regime for this medicine by transferring it from retail pharmacies to hospital pharmacies.

**País Vasco** published the Order of 10 February, regulating **medical visits** at organisations of the healthcare services of the Health System of País Vasco.

The regulation serves to order and plan medical visits and interactions with healthcare service organisations dependent on Osakidetza and privately-owned healthcare establishments that have signed agreements for the provision of healthcare services, while also governing the handling of free samples of medicines. This Order, for which a consultation process was staged only with the medical visitor trade unions in the three provinces, was being analysed by FARMAINDUSTRIA when this Annual Report went to press.

## PURCHASING PLATFORM OF THE NHS

In 2019 the Ministry of Health reiterated its interest in promoting centralised purchasing via INGESA.

The following table provides an updated summary of the basic aspects of centralised competitive purchase tenders for the NHS announced by INGESA to date, along with the Spanish regions and other public authority bodies in favour of these procedures.

During 2019, renewals of those framework agreements that had ended were announced, using the same format of competitive tenders seen previously (a negotiated procedure without publication, thereby continuing the problem of price transparency). There were no advances in the new framework agreements on which INGESA was working: antineoplastics and age-related macular degeneration.

| MEDICINES TENDERED | PROCEDURE | PROCUREMENT AUTHORITIES | COMPOSITION OF BATCHES | No. OF BATCHES OFFERED | No. OF BATCHES AWARDED |
|---|---|---|---|---|---|
| **CLOTTING FACTOR XIII** (Year 2015) | Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act) | 10 Regions (Asturias, Islas Baleares, Cantabria, Castilla-La Mancha, Castilla y León, Extremadura, Galicia, Murcia, Navarra and La Rioja) and INGESA | Brand | 4 | 4 |
| **EPOETINS** (Year 2015) | Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act) | 7 Regions (Asturias, Islas Baleares, Cantabria, Castilla-La Mancha, Extremadura, Madrid, Murcia), INGESA and Ministry of Defence | Active Substance | 5 | 4 |
| **IMMUNOSUPPRESSANTS** (Year 2013) | Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act) | 10 Regions (Aragón, Asturias, Cantabria, Castilla-La Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja and Valencia), INGESA, Ministry of Interior and Ministry of Defence | Active Substance | 9 | 6 |
| **MEDICINES WITH GENERIC COMPETITION** (Year 2015) | Open procedure by ordinary processing and subject to harmonised regulation (Articles 196 to 198 Consolidated Text of the Public Sector Procurement Act) | 11 Regions (Aragón, Asturias, Islas Baleares, Castilla-La Mancha, Cantabria, Extremadura, Galicia, Madrid, Murcia, Navarra and La Rioja), INGESA, Ministry of the Interior and Ministry of Defence | Active Substance includes two biosimilars, which share batch with the reference biotherapeutic | 20 | 20 |
| **CLOTTING FACTOR VIII** (2019) | Negotiated without public notice (Art. 170.d of the Consolidated Text Act of Public Sector Contracts | 11 Autonomous Regions (Aragón, Islas Baleares, Cantabria, Castile-La Mancha, Castilla y León, Extremadura, Galicia, Murcia, Navarra, La Rioja and Valencia) and INGESA (Ceuta and Melilla) | Brand | 9 | 9 |
| **EPOETINS** (Year 2019) | Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act) | 9 regions (Aragón, Asturias, Islas Baleares, Cantabria, Castilla-La Mancha, Extremadura, La Rioja, Murcia and Valencia), INGESA and Ministry of Defence | Active Substance | 5 | 4 |
| **IMMUNOSUPPRESSANTS** (Year 2015) | Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act) | 11 Regions (Aragón, Asturias, Islas Baleares, Cantabria, Castilla-La Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja, Valencia), INGESA, Ministry of Defence and Prison Institutions | Active Substance | 9 | 9 |
| **ANTI-RETROVIRALS** (Year 2015) | Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act) | 10 Regions (Aragón, Asturias, Islas Baleares, Cantabria, Castilla-La Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja), INGESA, Ministry of Defence and Ministry of the Interior | Active Substance | 26 | 12 |
| **BIOTHERAPUETICS-BIOSIMILARS** (Year 2020) | Negotiated without public notice (Article 168 of the Public Sector Procurement Act) | 10 Regions (Aragón, Asturias, Cantabria, Castilla-La Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja and Valencia), INGESA, Ministry of Interior and Ministry of Defence | Active Substance | 9 | Pending |

As for the framework agreement for biotherapeutic products that have biosimilars, this was authorised by the Council of Ministers in February 2020. The agreement has the following characteristics:

1. Nine batches per active pharmaceutical ingredient and route of administration, including the reference biotherapeutic and biosimilars.
2. Various pharmaceutical manufacturers chosen per batches.
3. Purchasing by those Spanish regions signing up to the system will be assigned to the manufacturer offering the best economic offer, although purchases may be made from other manufacturers on the basis of clinical, logistical or other criteria.
4. No second round in the Spanish regions or hospitals.
5. Two-year duration plus a one-year extension.

Lastly, it is worth noting that the Catalogue of Goods and Services for Centralised Procurement has been presented and added to the NHS' purchasing portal, including general information about the available medicines and healthcare products, and specific information about those that have been the object of centralised purchasing procedures: contract status, participating regions, chosen pharmaceutical manufacturer, tender price and award price. Provision is made for three levels of access to this information:

1. General
2. Participating regions
3. Chosen pharmaceutical manufacturer

At the time when this Annual Report was drawn up, the procedure had been suspended due to the Covid-19 health crisis.



# 3.1.3 ADVISORY AND GUIDANCE COMMITTEES

## ADVISORY COMMITTEE OF THE INTER-TERRITORIAL COUNCIL OF THE NHS

Chaired by the Secretary-General for Health and Consumption, and attended by all the Directors-General of the Ministry, this committee is made up of other representatives of public authorities (regional and local), trade unions and business organisations, including FARMAINDUSTRIA, which holds the vice-presidency corresponding to the last of these groups.

The Advisory Committee of the Inter-Territorial Council of the NHS met on four occasions in 2019, in the months of February, April, May and October. The Committee's mandate is to rule on regulatory projects in progress, and it therefore reviewed, among others, the proposed Royal Decree governing observational studies with medicines, and the proposed Royal Decree for the adaptation of management of NHS' pharmaceutical provision in accordance with the regulatory framework for verification and authentication of medicines (the contents of which were ultimately incorporated within the Royal Decree on Registration).

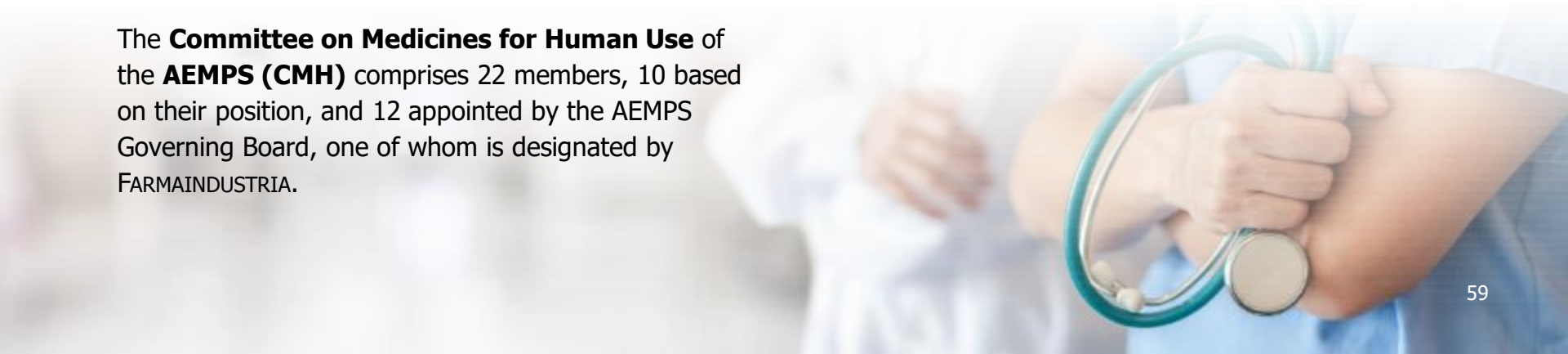
In addition to these aspects, the Committee was aware of other issues in the healthcare sphere, such as the contingency plan and the situation regarding Brexit, corporate information systems in the field of pharmaceutical policy: Valtermed and the search engine for the financing status of medicines within the NHS, interoperable e-prescription data within the NHS, 2019-2020 flu vaccination recommendations, plan for medicine supply interruption, plan to address advanced therapies within the NHS : CAR-T medicines, composition of the Inter-Ministerial Medicines Pricing Commission, and the updating of the National Plan to Combat Antibiotic Resistance (2019-2021).

## AEMPS COMMITTEE ON MEDICINES FOR HUMAN USE

The **Committee on Medicines for Human Use** of the **AEMPS (CMH)** comprises 22 members, 10 based on their position, and 12 appointed by the AEMPS Governing Board, one of whom is designated by FARMAINDUSTRIA.

The CMH has 11 ordinary meetings per year, in which the assessment reports on medicines processed through a centralised procedure are presented and discussed, with Spain acting as rapporteur or co-rapporteur, as well as other medicines or groups of medicines which, due to their special interest for the AEMPS, are included on the Committee's agenda.

Aside from regular matters regarding the evaluation of medicines handled via a centralised procedure in which Spain acts as a rapporteur or co-rapporteur, the Committee also addresses single-issue aspects such as the 2019-2022 medicines supply guarantee plan, the withdrawal of certain medicines containing nitrosamines, the repositioning of medicines, the European project on electronic information for medicines, and the coronavirus situation.



## 3.1.4 COLLECTIVE AGREEMENT

During 2019, the 19th Negotiating Committee for the General Chemical Industry Collective Agreement remained in force, having been published on 8 August 2018 in the Official State Gazette, applicable to the pharmaceutical industry and scheduled to run until 31 December 2020. It should be recalled that one of the key issues addressed by the Collective Agreement was the pay rise, improvements in the field of professional classification and flexibility mechanisms (time credits); the inclusion of a new article allowing for mandatory attendance by workers at training courses outside their regular working hours, along with the inclusion of a new public holiday bonus for each Sunday and/or public holiday worked; or novel aspects in the field of equality.

By the date when this Annual Report was drawn up, no plans had been made with regard to the negotiation of the next Collective Agreement, especially following the current health crisis, which could affect both the deadlines and the contents of the negotiation.

# 03

# INSTITUTIONAL ACTIVITY

3.1 Market Regulation and Relations with Public Authorities
**3.2 Communication**
3.3. International Relations
3.4 The Pharmaceutical Industry in Spain and Worldwide

# 3.2 Communication

IN 2019, FARMAINDUSTRIA maintained its **commitment to communication** in pursuit of the essential aim to continue enabling society at large to understand as clearly as possible what the innovative pharmaceutical sector does, how it does it, and why.

This led to the generation of **informative content** released via all available channels: website, social media, traditional and online media, gatherings, forums, etc.

In accordance with the **Association's Strategic Plan,** the published content focused on on explaining:

1. How the pharmaceutical industry helps to **improve the health** of the population and underpin the quality and sustainability of the NHS.
2. Why it is an **industrial leader** in Spain in terms of R&D investment.
3. Why it is a **byword for transparency** and the generation of wealth and quality employment.
4. The reasons why it must take its place at the **cutting edge of the new productive model** that Spain needs.

Intense communication activities were at all times structured through rigorous information based on provable data and reliable sources, with the goal of explaining to society at large the efforts and motivations of pharmaceutical companies, with FARMAINDUSTRIA spokespeople constantly made available to the media, online platforms, and forums for information and debate.

## NEWSLETTER

FARMAINDUSTRIA began 2019 with a major new development in its online communication strategy. On Monday, 21 January, the Association began publishing a weekly newsletter bringing together the most notable news about the industry and medicines. The overriding aim of this new communication tool is to **underpin the commitment** shown by FARMAINDUSTRIA to information and transparency.

This digital publication, which is sent out by email and via the FARMAINDUSTRIA website, also covers the key impacts in the media regarding the Association's activities, such as editorial publications, interviews, features and other types of press. It likewise offers an agenda service featuring events, courses, forums and happenings in the healthcare sector, along with data of interest and statements by representatives and spokespeople for the sector connected with current affairs issues.

The newsletter has now become an additional channel **to help spread information and understanding about the pharmaceutical industry** medicines among professionals in the healthcare and pharmaceutical sector, the media, and society at large.

Its straightforward design provides up-to-date information about current issues in the pharmaceutical field, along with a direct insight into the positioning of FARMAINDUSTRIA and its member companies regarding these issues. In its first year in operation it attracted over 5,000 subscribers.


## MEDIA

In 2019, FARMAINDUSTRIA generated a substantial amount of new content, both internally and via the **media** in an attempt to reach out to the population as a whole. To this end, it provided information to all **media channels and platforms** (print and digital, television and radio) in all spheres (national, regional, local) and all relevant specialist fields (general interest, economy, healthcare and individual sectors). This in addition to various media collaboration projects via sponsorships of information platforms, supplements on health and the generation of debates, which likewise helped to drive a greater understanding about the work done by the pharmaceutical industry.

At the same time, senior Association figures were encouraged to appear in the media in the form of interviews with FARMAINDUSTRIA spokespeople, along with around a dozen opinion pieces, with the aim of narrating first-hand the **sector's positioning and priorities**. Such activities served to generate more than 4,500 media impacts in 2019.


## INTERNET AND SOCIAL MEDIA

Alongside media contact and partnerships, and with the aim of achieving constant and direct communication with society at large, one of the strategic approaches adopted by FARMAINDUSTRIA over recent years has been to **underpin the information delivered via social media**. This serves to gain interaction with the population, detect possible sources of misinformation, and make a greater and more precise contribution to how society understands the sector.

2019 was a year of consolidation and growth along the path embarked on in previous years, with an exponential improvement in the number of followers, page views and interactions with users across the five social media networks where the Association has a presence: Twitter, LinkedIn, Facebook, Instagram and YouTube.

Similarly, over the year the Association's website (farmaindustria.es) once again proved itself to be a key instrument in compiling all the information generated. In this regard, FARMAINDUSTRIA published 164 information pieces in 2019, of which 139 were online news items, 19 were press releases and 6 in-depth features.


## FEATURES

The FARMAINDUSTRIA website launched a new section in 2019 entitled "Features". The aim of this new platform is to **supplement the news items and press releases** issued by the Association with in-depth information pieces that are essentially educational in nature, giving the population a better understanding of certain aspects of the sector, from how medication prices are regulated in Spain, to the process of R&D for medicines, or the value contributed by a medicine from the economic and social perspective, beyond its medical worth. Six features were published in 2019.

All these information efforts using all online channels generated highly positive results last year. In specific terms, the website ended 2019 with more than **81,000 unique users**. The FARMAINDUSTRIA profile on Twitter registered annual growth of more than 7%, amounting over the year to a figure of **30,000 followers**.

LinkedIn numbers also improved in 2019, registering the most significant growth of all social media platforms, rising by nearly 50% to a level of 29,000 followers. FARMAINDUSTRIA is at present the second-largest pharmaceutical business association in the world in terms of its number of followers on the two networks, behind the US association on one network and the French association on the other.

## EVENTS WITH INFORMATIVE IMPACT

Last year FARMAINDUSTRIA was involved in some 50 forums, both its own and those organised by other bodies (public institutions, associations, scientific societies, universities, media, etc.), with a major media and/or social media impact.

These are listed below:

- 1st International Gathering *Better Data, Best Health*
- Debate on *Access to Innovation in Health. Is Sustainability a Problem?*
- Seminar on *Haematological Cancer: from Clinical Research to Access to Medication*
- 1st Health Forum of the *El Economista* newspaper
- 16th Health Data Protection and Security Forum
- 1st edition of the *POP Patient Organisations Platform Breakfasts*
- Forbes Healthcare Summit
- 9th Biotechnology and Venture Capital Forum
- 7th Forum of the Foundation for Excellence and Quality in Oncology
- National Congress of Institutional Relations
- 12th Annual Conference on Biomedical Research Technology Platforms
- Seminar: *Towards Excellence in Biomedical Innovation*
- Seminar on clinical trials at La Paz Hospital, Madrid

- Seminar on the European Paediatric Translational Research Infrastructure (EPTRI) project
- 2nd Post-ISPOR Seminar
- Seminar on *University Research and GDPR Regulatory Compliance*
- Seminar: *In a Global World, Vaccines Matter*
- Industry - SIGRE Meeting 2019
- 82nd Seminar of the Health Research Foundation (FUINSA)
- 4th Seminar on Phase I Clinical Trials in Spain
- 3rd Pharmaceutical Law Seminar
- Seminar: *Cancer without Hoaxes*


- Annual gathering: *Innovation and Fairness in Oncological Care; Precision Medicine as a Challenge for the National Health Service*
- 3rd Protagonists Forum
- Infosec Health Seminar
- 19th Meeting of the Spanish Pharmaceutical Industry
- 3rd Congress of the Patient Organisations Platform
- ISPOR Europe 2019 Symposium
- Symposium: *Hacking Healthcare*
- 26th Pharmaceutical Forum of the National Association of Business Owners of Colombia
- 41st National Congress of the Spanish Society of Primary Care Physicians (Semergen)

- Seminar on Authorisation of Clinical Trials with Genetically Modified Organisms
- Annual Forum with the Spanish Regions
- 2nd National Meeting with the Spanish Network of Paediatric Clinical Trials
- 16th Pharmaceutical Industry & Media Seminar
- 7th '*Somos Pacientes*' Seminar
- Innova Health Congress 2019
- National Haematology Congress
- 14th Scientific Meeting of the Spanish Health Technology Assessment Association
- 120th Anniversary of the Official Association of Pharmacists of Badajoz
- 2019 Healthcare Sector Gathering
- 'Bringing Science into Schools' at the Malaga Maternity and Infant Hospital and the Jiménez Díaz Foundation in Madrid
- Explanatory Forum on *The Role of Hospital Pharmacies in Clinical Trials*
- *'Reinventing Spain'* Forum
- 2nd Seminar on Incremental Innovation of Medicines
- Preparatory Seminar for the pharmaceutical sector in response to Brexit

## KEY INFORMATION MILESTONES IN 2019

In January, FARMAINDUSTRIA dedicated two of its information initiatives for the month to areas of developing medicines that are setting the trend for the future of innovation: gene and cell therapies, and cancer treatments, which have become one of the major challenges for health systems, and are positioning themselves as one of the major R&D areas promoted by pharmaceutical manufacturers. Given the social, medical and scientific interest in both topics, many media platforms made mention of the figures provided by the Association.


In February, the new Europe-wide anti-falsification system for medicines became operational, along with patient safety measures established by **SEVeM (Spanish Medicines Verification System)** to which FARMAINDUSTRIA belongs, in the role of president. The press release, jointly organised with the representatives of professional associations of pharmacists, wholesalers and the generics industry, was extensively covered by the general interest and specialist media, and also via social media.

In March, Madrid was the venue for the **12th edition of the Annual Conference on Technological Biomedical Research Platforms,** organised by FARMAINDUSTRIA together with Fenin, Asebio and Nanomed, whose message focused on the expansion of clinical trials undertaken in Spain and the considerable investment made by the pharmaceutical industry in the entire innovation process involved in bringing a new medicine to market.

One of the aspects generating the most headlines in the media and interactions via social media in 2019 concerned the problems of medicine supply, to which the Association dedicated a press release in March after having subscribed to the *2019-2022 Medicines Supply Guarantee Plan* launched by the Ministry of Health.

This topic was covered by a number of information releases over the course of the year, leading to an **increase in the presence of Association spokespeople across the media spectrum,** in particular radio broadcasters, with as many as 300 impacts during 2019.

In April, to mark **International Health Day** FARMAINDUSTRIA updated its report on The Value of Medicines, produced by the **Weber Foundation**. The primary aim of this reference document is to offer an overview of the economic, clinical and social value delivered by medicines in Western societies. The pages of the study summarise much of the extensive scientific evidence published in this regard in recent literature, setting out illustrative examples of the contributions made by the most innovative medicines over the years.

Likewise, the **Extraordinary General Assembly** of FARMAINDUSTRIA held in late April in Barcelona unanimously ratified the agreement reached by the Executive Board with the Government to extend throughout 2019 the Collaboration Agreement for access and sustainability, which had already been extended for the first three months of the year. As was explained to the media, the Agreement provides a robust guarantee to ensure that patients, healthcare professionals and managers will have agile access to the most novel and appropriate pharmacological treatments. It in turn recognises the value of innovation, commits the Government and pharmaceutical industry to a structural policy rather than cyclical approaches, and underpins Spain's position as the destination for biomedical R&D investment.

In May, the financial newspaper Expansión published an opinion piece by the President of FARMAINDUSTRIA, Martín Sellés, entitled *Biomedical R&D: The Chance for Leadership*, which highlights the historic opportunity available for Spain to become a leading country in biomedical R&D on the international stage.

By June, the Association was taking part in the **Industry-Sigre 2019 Gathering** to convey the increasing efforts by the pharmaceutical industry to innovate, to reconcile access to medicines with the sustainability of the health system, the generation of high-quality employment and a pioneering commitment to transparency.

I+D biomédica: La ocasión del liderazgo



Martín Sellés
Presidente de Farmaindustria

La historia de España está repleta de oportunidades que no supimos o no pudimos aprovechar como país. Afortunadamente, las cosas han ido cambiando en las últimas décadas y España es hoy un país moderno que cuenta con un sistema sanitario de cobertura universal cuyos estándares de calidad asistencial y acceso a la innovación lo sitúan en el grupo de cabeza a escala global.

España figura a la vanguardia en investigación clínica, y lo hace gra-



directos que genera el sector son indefinidos, dos de cada tres son titulados universitarios y más de la mitad son femeninos) o el volumen de producción y exportación: el 28% de la alta tecnología que se produce y exporta en España.

Esta apuesta de la industria farmacéutica por España, junto a su capacidad para movilizar el tejido investigador biomédico del país, la experiencia de colaboración consolidada en las últimas décadas y la configuración y solidez del sistema sanitario constatan que estamos ante una gran oportunidad, que se abre además en un ámbito, vinculado a la innovación, representativo del cambio de modelo productivo al que aspiran las sociedades más modernas.

Los ensayos clínicos, por concretar con ejemplos, generan un círculo virtuoso con efectos muy positivos en múltiples ámbitos para el sistema sanitario, porque atraen inversiones y ahorros para los costos sanitarios y permiten mejorar la calidad asis-

During the same month, **AIReF** published a report on medicines dispensed by medical prescription in Spain, including proposals for pharmaceutical policies negatively impacting the innovative industry. FARMAINDUSTRIA sent out a press release conducting an initial analysis of these proposals, rebutting some of them and conveying the Association's willingness to continue working with the public authorities in order to improve the efficiency of investment in health and medication.

Subsequently, on 20 June the **Association's Annual General Assembly** was held, in which FARMAINDUSTRIA's **Annual Report** for the previous year is traditionally approved. After the gathering, a press release was sent out to the media and published on the website, setting out the key messages launched by the President and in the Annual Report itself, along with a summary of the contents in an attractive and dynamic format for easy consultation by the media and society at large.

On 25 June, FARMAINDUSTRIA staged an information gathering for the media with the President, which was attended by journalists from 23 different publications. At this forum, the Association's President reasserted the firm commitment of the innovative pharmaceutical sector to the sustainability of the healthcare system, highlighting the importance of maintaining open channels for dialogue and cooperation with the various public authorities so as to sustain healthcare quality and efficiency, and to ensure patient access to innovation.

On 27 June, the media were sent a press release containing the transfers of value from pharmaceutical companies to agents in the sector, by way of grants to healthcare organisations and for the training of professionals. These figures were published as a result of the transparency initiative of the pharmaceutical industry in Europe, included in 2014 in the **Pharmaceutical Industry Code of Good Practice** in Spain, as seen in the initial publication made in June 2016.

In July, FARMAINDUSTRIA embarked on a series of contributions to the radio programmes 'Es la tarde de Dieter' on **EsRadio**. The first feature addressed the importance of patient involvement in clinical trials and the role that Spain is playing as a leading country in this field. In subsequent contributions over the course of the year, the programme played host to a number of spokespeople from the Association along with other experts to cover a range of strategic issues for the sector, such as transparency, the economic and social value of innovative medicines, and incremental innovation.

On 11 July, the Association organised a working meeting for the advancement of excellence in clinical research in Spain, at which more than 120 healthcare professionals, researchers and managers of public and private hospitals and establishments gathered. Some days later, the **magazine Dirigentes** published a video interview with the President of FARMAINDUSTRIA to analyse why Spain has become one of the leading clinical research countries worldwide.

FARMAINDUSTRIA also contributed two articles to a special edition of the **journal Papeles de Economía Española** dedicated to the health economy, addressing the problem of measuring results in health, and estimating the medical, economic and social value of new medicines.

On 5 and 6 September **Menéndez Pelayo International University** in Santander played host to the **19th Meeting of the Spanish Pharmaceutical Industry,** focused on biomedical advances and their incorporation within the NHS. Over the course of the seminars and during the following week, a total of 144 articles were published on the seminars in the general interest, economic and specialist media.

Aside from press releases, FARMAINDUSTRIA was very active on social media, with a particular impact on Twitter, where the various posts published by the FARMAINDUSTRIA account and the different participants at the event, as well as journalists, generated 5.6 million views under the #UIMPFarma19 hashtag. On Facebook, a video by the Minister of Industry emphasising the positive efforts of the pharmaceutical industry in Spain reached more than 82,000 users.

On 11 October the city of **Ávila** played host to the **22nd FARMAINDUSTRIA-Spanish Regions Forum**, a now traditional gathering for dialogue between the Association and those responsible for medicines at the regional level in order to analyse a great many of the current issues connected with health policy and pharmaceutical provision under the NHS. The **Public Sector Procurement Act,** the budget and investment in pharmaceutical provision in the regions, and how to incorporate innovation within the NHS, were among the topics discussed.

Likewise in October, the Director-General of the Association took part at the **41st National Congress of the Spanish Society of Primary Care Physicians (Semergen),** at a panel debate on partnership between the pharmaceutical industry and medical professionals, conveying the need to foster and protect this relationship, not only because it is legitimate and transparent, but also because it is essential in order to make progress in the research and development of new medicines, to guarantee the ongoing training of medical professionals, and to improve the life expectancy and quality of life of patients through scientific progress.

This congress, which in 2019 was held in Gijón, achieves considerable impact in both conventional and social media.

On 28 October, the British Embassy in Madrid and FARMAINDUSTRIA, together with the **ICEX** and the Ministry of Industry, Trade and Tourism, organised a working meeting in Madrid for companies in the pharmaceutical sector to review the guidelines in order to ensure they are prepared for *Brexit*, while likewise debating the need for the future cooperation agreement between the EU and the UK to guarantee collaboration in the field of medicines.

During the latter part of the year, FARMAINDUSTRIA once again partnered the **Jiménez Díaz Foundation** (Madrid), the **Sant Joan de Deu Hospital** (Barcelona) and the **IBIMA (Biomedical Research Institute of Malaga)** in organising three workshops focused on providing baccalaureate students with information and knowledge about biomedical research. Under the title *Bringing Science into Schools*, youngsters from a number of high schools were given an opportunity to discover what the R&D for medicines involves, how much it costs, and how a clinical trial is set up in Spain.

On 5 November, the town of Chinchón in the Madrid region held the **16th Pharmaceutical Industry & Media Seminar,** organised each year by FARMAINDUSTRIA and attracting specialist health journalists from 33 media and communication groups. The Plan for promoting generics and biosimilars, addressing supply interruptions, the Agreement between FARMAINDUSTRIA and the Government, investment in R&D, the sustainability of the NHS and the price of innovation were the key topics addressed in the media headlines.

The seminar was staged over successive days, during which 150 reports were published in general interest, economic and specialist media across all platforms. As for social media, the impact on Twitter was the most notable, with more than 200 mentions, while the seminar was likewise reflected on Facebook and LinkedIn.

On 20 November, the prestigious business school IESE held its **2019 Healthcare Sector Forum** in Barcelona under the slogan *Healthcare First*. The Director-General of FARMAINDUSTRIA participated in the opening event, who analysed the challenge of placing health centre stage in the mind of the society at large.

In information terms, the year ended with the staging of the **7th 'Somos Pacientes' Seminar** organised by the **Somos Pacientes** platform and the FARMAINDUSTRIA Foundation, which also featured the prize-giving ceremony for the fifth edition of the **Somos Pacientes Awards**.

The event was held in Madrid, with the central theme of how the roles of the patient and of patients' associations have evolved within healthcare systems.

The closing address was given by the then Minister of Health, Ms María Luisa Carcedo, and the event attracted more than 200 people, including healthcare authorities, representatives of patients' associations, healthcare professionals, pharmaceutical companies and the media.


El Periódico de Catalunya
Especial

10 Diciembre, 2019

# La industria farmacéutica es clave en el desarrollo de los ODS

**El sector juega un papel protagonista en la lucha contra las principales causas de muerte**

**La innovación farmacéutica ha alargado la esperanza de vida 1,27 años en la OCDE**


ABC

6 Noviembre, 2019

# La patronal farmacéutica propone fabricar más fármacos en España

Farmaindustria plantea soluciones contra el desabastecimiento

**Sin 25 medicamentos**

**Antihipertensivos**

**Antibióticos**

**Ansiolíticos**

**Contra la degeneración macular**

## INTERNAL COMMUNICATION

Internal communication remains an important operational area for FARMAINDUSTRIA. The **Communication Working Group** held four meetings over the course of the year, one per quarter, attended by a great many representatives of the member companies. These meetings addressed issues of interest for the sector, and gave the attendees an account of all the key activities undertaken by the Association.

Similarly, operational approaches focused on improving internal communication with members were strengthened in 2019, through an increase in the volume of information shared about the Association's activities, including data, key information and strategic positioning, so as to help convey a greater understanding to the general population as to the specific experience of the companies and their staff.

## PATIENTS

In 2019, FARMAINDUSTRIA continued to promote relationships and partnerships with patients' groups and their representative associations. Since the pharmaceutical industry researches, develops and markets medicines to cure or avoid illness and increase patients' **life expectancy and quality of life,** the relationship between companies and patients' associations is vital.

Last year FARMAINDUSTRIA organised partnership, dialogue and working initiatives with patients' organisations in various spheres, via two essential channels:

1 | **Dialogue with associations,** both directly and through FARMAINDUSTRIA's Standing Dialogue Panel with Patients' Organisations.

2 | **The management and promotion** of the online community Somos Pacientes, which provides information, training, services and collaborative working tools for organisations of patients, relatives, disabled people and carers, along with society at large.

The Association also held quarterly meetings in 2019 (a total of four) of the **Patients Working Group,** made up of the heads of this area at member companies, who over the course of the year addressed key issues in the relationship between patients' organisations and pharmaceutical manufacturers.

## Dialogue with Patients' Associations

In 2019, FARMAINDUSTRIA took part in numerous gatherings, meetings, training days, seminars and other activities with patients' organisations to share experiences and support their efforts. One of the most notable was the **3rd Congress of the Patients' Organisations Platform,** held in October in Madrid and empathised the commitment of the pharmaceutical industry through research and patient access to medicines.

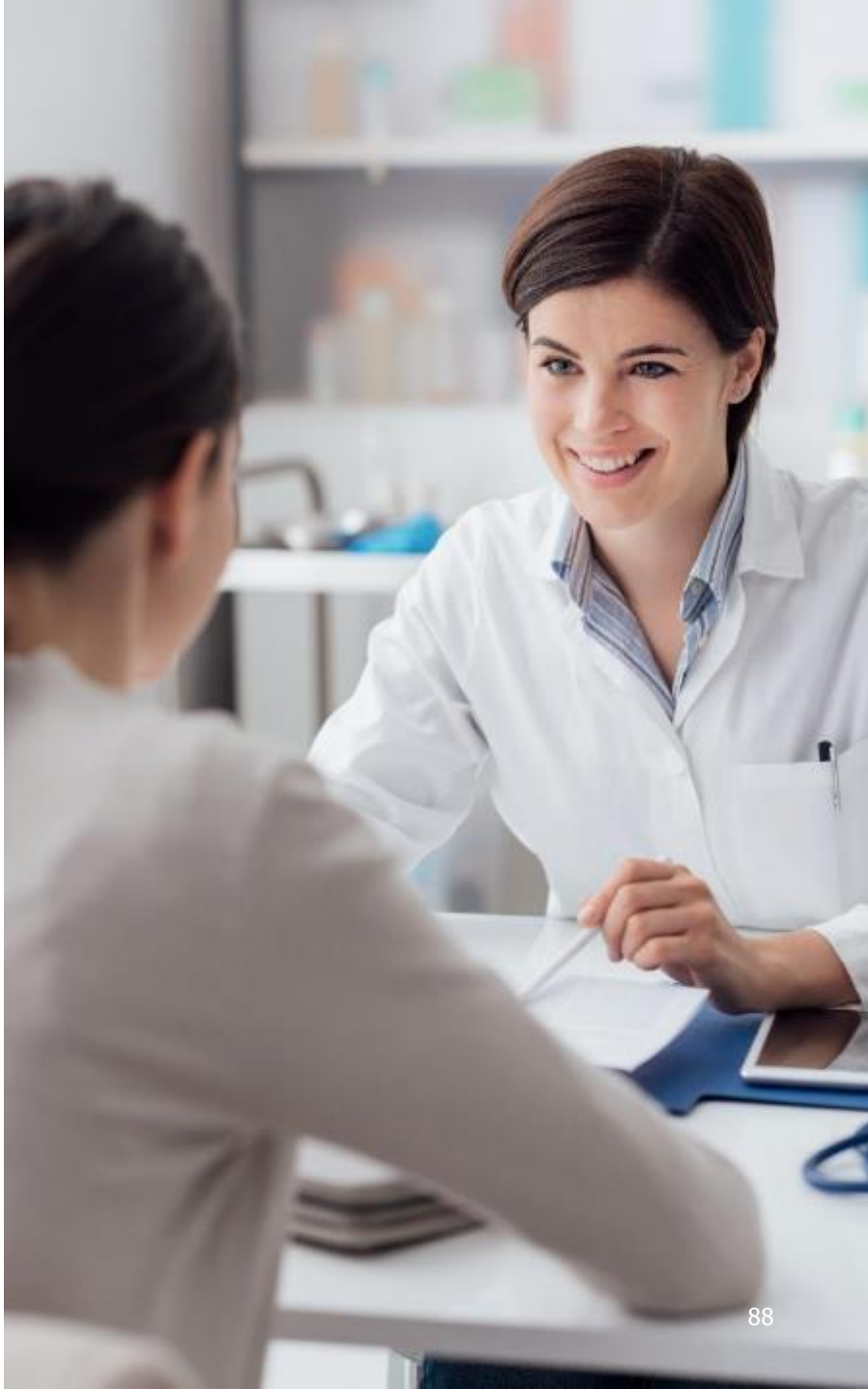
FARMAINDUSTRIA maintained its channels of collaboration both with the Patients' Organisations Platform and the **Spanish Patients' Forum,** the two main bodies representing patients as a group in Spain, alongside other organisations such as **Eupati,** which focuses on training to involve patients in clinical research.

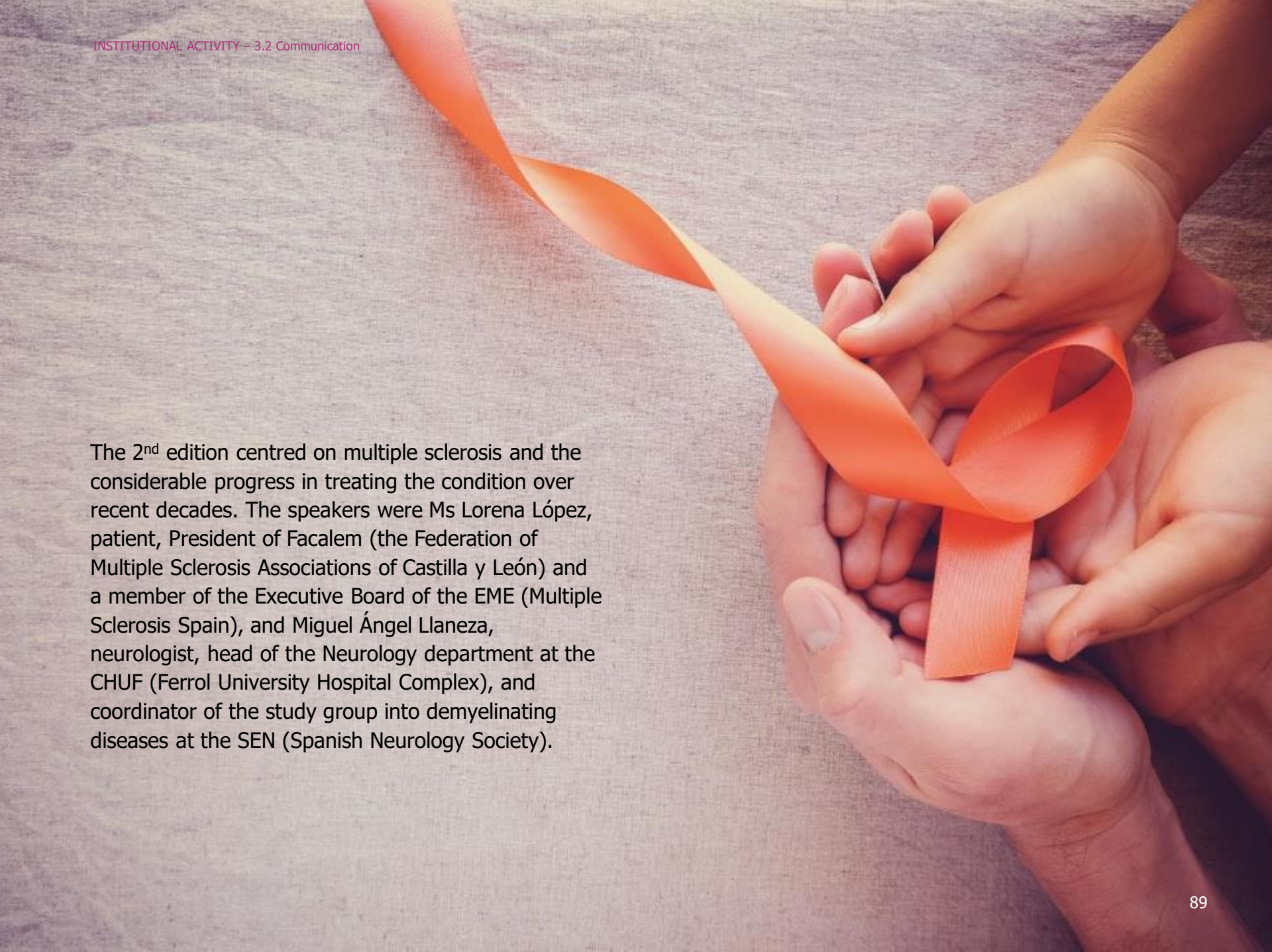
As for the FARMAINDUSTRIA's **Standing Dialogue Panel** with Patients' Organisations, it continued its activities during 2019 as a forum for information and debate, with a group representing more than **20 federations and confederations** of patients' associations to address current issues of shared interest. Two gatherings were held last year to keep the patients' representatives up to date as to the Association's activities, the current situation of the pharmaceutical sector and the process of involving patients in clinical trials, while also listening to what patients' representatives had to say as to their projects and concerns.

In 2019, however, communication with patients went a step further with the launch in May of the **"Doctor-Patient Dialogues"** initiative promoted by the FARMAINDUSTRIA Foundation and the platform Somos Pacientes. This initiative comprises a series of videos which aim to explain to the general public, through a first-hand, educational approach, the challenge involved in dealing with illness from the human perspective as represented by patient and doctor.

As explained by the President of the Association, Martín Sellés, "the FARMAINDUSTRIA Foundation is committed to this project for two fundamental reasons: The first is to give a face to the battle against illness today, and to adopt an educational approach in explaining to society at large how this challenge has evolved over recent decades, as we gain ground day by day". The aim is also to "raise the profile of patients' perceptions, needs and proposals, a goal to which we have been committed for over a decade now".

2019 saw the launch of three videos produced in partnership with scientific societies and patients' organisations. The evolution seen in diagnosis, care and treatment for breast cancer, and the personal, health and social impact that the disease has, were at the heart of the first of the dialogues, courtesy of Olga Cantera, patient and Vice-President of the Rosae Association and member of Fecma (the Spanish Breast Cancer Federation), and Álvaro Rodríguez-Lescure, Oncologist and the then Vice-President of the SEOM (Spanish Medical Oncology Society).





The 2nd edition centred on multiple sclerosis and the considerable progress in treating the condition over recent decades. The speakers were Ms Lorena López, patient, President of Facalem (the Federation of Multiple Sclerosis Associations of Castilla y León) and a member of the Executive Board of the EME (Multiple Sclerosis Spain), and Miguel Ángel Llaneza, neurologist, head of the Neurology department at the CHUF (Ferrol University Hospital Complex), and coordinator of the study group into demyelinating diseases at the SEN (Spanish Neurology Society).

A lack of understanding of rheumatoid arthritis among healthcare professionals and the general population, the importance of early diagnosis, the arrival of **biotherapeutic medicines** which have changed patients' lives, and the importance of adherence to the treatment, were among the most notable topics addressed in the third dialogue: a conversation between rheumatologist José María Álvaro-Gracia, President-Elect of the SER (Spanish Rheumatology Society), and Laly Alcaide, Director of the National Coordination Body for Arthritis, ConArtritis.

The usefulness, interest and novelty of this initiative achieved recognition upon receiving an 'A tu salud' Health Award from the **La Razón** newspaper, along with an accolade from the specialist publication **Diario Médico,** which recognised the venture as one of **The Best Ideas of 2019**.


## Somos Pacientes

The online platform **Somos Pacientes** (somospacientes.com), which has now been in operation for seven years, saw an increase of over 8% during 2019 in the number of registered bodies and associations, totalling 1,837, as reflected on the **National Map of Patients' Organisations,** the most complete database of patient groups in Spain.

The main aim of the platform is to provide a shared forum for information, participation, training, services and collaborative efforts, and during 2019 it achieved a significant level of activity, above all in the sphere of information. The editorial team at Somos Pacientes published nearly a thousand news items, features, interviews, documents, videos, opinion pieces, etc. over the course of the year. Patients' organisations themselves likewise uploaded content to the platform in the form of statements, announcements, editorials, photographs and videos.

One of the most notable activities of all was the staging of the **7th edition of the Somos Pacientes Seminar** in Madrid in late November. The event also featured the 5th Somos Pacientes Awards Ceremony.

Over a hundred entries were submitted for the six categories into which the accolades are divided. An expert jury chose the winner in five of the categories, while the last was decided by users of the website themselves. Nearly 14,000 people selected the winning project from among all the finalists.

As for the **7th Somos Pacientes Seminar,** the programme was entitled "New Patients, New Needs", and spent a whole morning exploring in greater depth the current relationship between patients and the healthcare professionals who tend to them, the health system itself, and society as a whole.

A number of patients' organisations also had the chance to share various innovative services that they make available to their members.

One change seen in the 2019 edition was the involvement of a number of dignitaries from various fields belonging to the patient association movement, whose public profile helped to convey the needs of the groups they represent, as in the case of the journalist Juan Ramón Lucas, the President of the Bertín Osborne Foundation Ms Fabiola Martínez, and athlete Ms Elena Román.

In 2019 the **Somos Pacientes** website registered a significant increase in interactions via both the Internet and social media. On Twitter it amassed more than 19,000 followers, while the Facebook community includes over 4,500, 30% higher than in 2018.

Somos Pacientes offers a weekly newsletter recording the main information content published on the platform. In 2019 this newsletter had **14,000 subscribers,** 47% higher than in 2018.

# 03

# INSTITUTIONAL ACTIVITY

3.1 Market Regulation and Relations with Public Authorities
3.2 Communication
**3.3. International Relations**
3.4 The Pharmaceutical Industry in Spain and Worldwide

# 3.3. International Relations

FARMAINDUSTRIA'S international activity revolves around three key aspects:

1 | **Development of stable relationships** with international pharmaceutical industry federations and associations.

2 | **Positioning of** FARMAINDUSTRIA and the Spanish-based pharmaceutical industry before international bodies and institutions to uphold the interests of the sector.

3 | **Maximisation the presence of Spanish companies** in third-country markets, mainly in emerging countries.

The positioning and practices of the pharmaceutical industry at the international level represent a valuable reference point in defining the different actions of FARMAINDUSTRIA'S **Strategic Plan**. This makes it essential to achieve interaction and participation in the:

1. **European Federation of Pharmaceutical Industries and Associations (EFPIA)**

2. **International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)**

FARMAINDUSTRIA also maintains numerous bilateral and multilateral relations with other national associations in the sector.

# 3.3.1 EUROPEAN CONTEXT

## ACTIVITIES WITHIN THE EFPIA FRAMEWORK

FARMAINDUSTRIA'S activities at European level are aligned with the priorities and themes addressed by **EFPIA,** the organisation representing **36 national associations** and **39 pharmaceutical companies in Europe**.

These links are consolidated through active participation by FARMAINDUSTRIA on most of the governing bodies, strategic committees and working groups of the European Federation.

## EFPIA General Assembly and Annual Conference

**EFPIA's General Assembly** was held in Brussels on 27 June 2019, analysing the progress made in the different matters addressed by the Federation's strategic committees:

1. **Patients and access**
2. **Innovation**
3. **International markets**
4. **Finance**

During the Assembly, the priorities for 2019 were reviewed, including:

1. The new **EFPIA action plan** in response to the difficulty in finalising the proposed European Regulation on health technology assessment (HTA).
2. The **strategy to address the forthcoming review of incentives** in the field of intellectual property (orphan and paediatric medicines) by the European Commission.
3. **Positioning in terms of transparency** on net prices and costs of R&D.
4. **Communication** with the new representatives at the European Parliament.
5. The **digital transformation of the pharmaceutical sector** and the standardisation of technological structures.

The appointment of Mr Jean-Christophe Tellier (UCB) as the new President of **EFPIA** was also ratified**,** taking over in this role from Mr Stefan Oschmann (Merck KGaA).

**EFPIA's 2019 Annual Conference** took place in parallel under the title *"Connecting Healthcare"*, bringing together experts from the health sector to debate and analyse how "connected" healthcare at a time of major changes in the EU can facilitate research, improve the management of health systems and underpin economic growth.

## EFPIA Board

In coordination with its strategic committees, EFPIA's Board approved the following priority issues in 2019:

1. The **analysis of the European Commission** as to intellectual property incentives and the potential review of the European pharmaceutical legislation.
2. The elections to the European Parliament and the renewal of European institutions.
3. The **measurement and analysis** of health outcome data.
4. The **UK's** exit from the EU.
5. **EU trade policy** with third countries.
6. The **operational principles** for implementation of the public-private partnership agenda.

## Meetings of EFPIA's European Markets Committee (EMC)

Over the course of 2019, under the presidency of Sanofi and the vice-presidency of Servier and FARMAINDUSTRIA, meetings of the **European Markets Committee** *(EMC)* continued, made up of the pharmaceutical companies' ***Heads of Europe*** and the Director Generals of the national associations. The primary objective of this Committee is to monitor national implementation of the decisions made by **EFPIA** governing bodies, as well as early detection of risks and threats to the pharmaceutical industry in Member States.

The **EMC** very closely followed the major European and national developments in pharmaceutical policy, paying particular attention to the following topics:

- Progress in the field of the joint assessment of efficacy regarding medicines at the European level
- Developments at the national level in the implementation of the Falsified Medicines Directive
- The possible review by the European institutions of intellectual property incentives
- The impact of the UK leaving the EU (Brexit)
- Regional initiatives for collaboration among European countries on prices and access
- The analysis of the availability and average time to access new medicines in European countries
- The renewal of the EU institutions (Parliament and Commission)



## National Association Meetings (G1 and G2 Groups)

During 2019 there were **two meetings of national associations of the main European markets,** including the group known as G1 (France, Germany, Italy, Spain, Switzerland and United Kingdom) and group G2 (the aforementioned countries in addition to Belgium, Denmark, Netherlands and Sweden), involving representatives from **EFPIA** and **IFPMA**.

These meetings analysed in depth the main developments in pharmaceutical policy affecting each country, stating the shared concern of **balancing innovation and intellectual property rights with equitable access,** the availability of new medicines, and the sustainability of healthcare systems. Other issues addressed included the growing interest of national governments in the field of price transparency, medicines shortages, etc.

## MAIN AREAS OF FARMAINDUSTRIA ACTION IN EUROPE

### New Parliament and European Commission 2019-2024

The European Parliament elections were held in May 2019, thereby launching the process for the renewal of the European Commission for the 2019-2024 period. In November, the new Parliament approved the proposal for the new composition of the College of Commissioners presented by the new Commission President, Ursula von der Leyen, who was officially invested on 1 December 2019 for a period of five years.

Among the highest-impact changes for the pharmaceutical industry are the **reinstatement of all health portfolios** at the Directorate-General for Health (during the previous legislature they were shared with the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs), and the **assignment** to the Executive Vice-President of the European Commission, Margrethe Vestager, **of coordinating the portfolios** covering competition and digital transformation.

One new development was that the President of the Commission sent a letter to each Commissioner describing their mandate and goals. The sphere of responsibility of the Health Commissioner, Stella Kyriakides, includes sustainable access to medicines, while at the same time promoting **innovative activity by the pharmaceutical industry and the digital transformation of health systems,** by developing an interoperable infrastructure at the European level, along with the launch of an agenda to combat antimicrobial resistance and prevention, and care against cancer.

With the aim of reflecting the priorities of the pharmaceutical industry on the European agenda, and in support of the activities undertaken by **EFPIA,** FARMAINDUSTRIA met with the new Spanish representatives of the different political parties at the European Parliament. In this regard, the MEPs proved to be highly receptive to the industry's messages, recognising the value and strategic importance of this sector in terms of healthcare, the economy and employment, opening up a channel for dialogue to address all initiatives impacting the sphere of medication over the course of the new legislature.

## Exit of the UK from the EU (Brexit)

On 29 March 2017 the UK informed the European Council of its intention to **leave the EU** by activating Article 50 of the Lisbon Treaty, as a consequence of the result of the referendum held in the country in June 2016.

The activation of Article 50 triggered the start of a two-year transitional period, during which the UK and the EU would be required to establish the terms of Brexit.

**Phase 1**

**This ended on 8 December 2017** following the agreement reached between the EU and the UK with regard to the Brexit bill, conditions for residence and employment, and the handling of the borders of Northern Ireland and Gibraltar.

**Phase 2**

**The process was concluded on 17 October 2019** when the Heads of State ratified the UK Withdrawal Agreement, establishing the conditions for the relationship between the two parties during the transition period, along with the Political Declaration annexed to the Withdrawal Agreement, which lays out the foundations for the future relationship once the transition period has ended. Although the date of departure was delayed several times, on 31 January 2020 the UK ceased to be a member of the EU, marking the start of the transition period.

Given the unique status of the health sector, the innovative pharmaceutical industry finds it necessary to maintain **the utmost cooperation and regulatory alignment,** preventing any change in the relationship between the EU and the UK from having a negative impact on R&D, the intellectual property regime and the manufacture and supply of medicines.

To this end, so as to prevent possible disruption to the supply chain and to ensure the highest level of readiness to deal with any scenario, the pharmaceutical industry implemented a series of **contingency plans** during the transition period in order to ensure the continuity of supply and patient safety after Brexit.

With this goal in mind, FARMAINDUSTRIA has maintained a constant channel of dialogue with the AEMPS and other competent authorities in Spain, requesting their support for the sector's demands, addressing such various issues as:

- Regulatory alignment
- Promotion of R&D
- Intellectual property
- Supply of pharmaceuticals
- Data flow
- Trade
- Movement of labour

This activity was supplemented by information to pharmaceutical companies as to the scope and consequences of Brexit.

## The Pharmaceutical R&D Model and the Defence of Intellectual Property Rights

**The political debate within the European Council of Health Ministers** as to the pharmaceutical R&D model and its impact on prices has led the European Commission to conduct an analysis of the impact of intellectual property incentives and market exclusivity on prices, access to innovations and the sustainability of national health services. To this end, the Commission published two studies in 2018 analysing the economic impact of intellectual property incentives, and in particular the Supplementary Protection Certificate **(SPC)** in the EU.

The Commission likewise called for an external analysis of legislation on orphan and paediatric medicines, and launched a public consultation in this regard.

The expectation is that over the course of 2020 the **European Commission** and the **Council of Health Ministers of the EU (EPSCO)** will decide whether the intellectual property incentives system should be reviewed, and if so the extent of such a review.

In this regard, and in anticipation of a possible amendment to European pharmaceutical legislation (Directive 2001/83/EC and Regulation (CREC) 726/2004), the governing bodies of **EFPIA** agreed to develop a suite of proposals to jointly improve access to innovation in all Member States, thus guaranteeing the sustainability of their healthcare services.

With this aim in mind, **EFPIA** has been working on the launch of a **high-level forum** which would involve the European Commission, the European Parliament, Member States and all agents in the medicine supply chain, setting out a raft of initiatives:

1. **Measurement of results** in health and associated costs.
2. **Transparency** regarding investment in R&D.
3. **Measurement of time** for access to and availability of medicines.

## Initiatives for Collaboration among European Countries on Pricing and Access to Innovation

The price of medicines and patient access to innovations represent a **political priority** in all European countries. In fact, several voluntary collaboration initiatives among European countries have been implemented in recent years in order to jointly respond to pricing transparency, innovation radar, public purchasing and access to medicines.

These collaboration initiatives are at different development stages and their approach is still to be defined in many cases. The most notable initiatives include:

1 | **Valletta Declaration,** comprising Croatia, Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Slovenia and Spain. This is a declaration of voluntary adhesion to advance in the exchange of information on prices and the design of potential joint medicine purchasing mechanisms. This initiative is supplemented, in the case of Spain, by the Spain-Portugal bilateral agreement aimed at making joint public purchases and exchanging information on medicine prices.

2 | **BeneluxAI Cooperation,** initially comprising Belgium, the Netherlands and Luxembourg, with the subsequent incorporation of Austria, Ireland and Switzerland. Its operational approach *Horizon Scanning for Pharmaceuticals* is particularly notable for its potential scope.

3 | **Nordic Council,** involving Denmark, Finland, Iceland, Norway and Sweden. This initiative includes the launch of a pilot scheme for competitive joint-procurement tenders covering 11 mature medicines so as to explore the possibilities and confirm the security of supply, bearing in mind potential logistics problems and the compatibility between this initiative and domestic legislation. The pilot ended in August 2019 with the signature of a number of agreements.

## Transparency in Pricing

Price transparency of medicines is becoming increasingly important among public pharmaceutical and healthcare managers. Over the course of 2019, a number of initiatives arose within the context of international bodies (**WHO's** resolution on the transparency of markets for medicines), European consortia (**EURIPID** and **Valletta**) and national governments (France, Italy and Norway), reflecting the will of governments to encourage greater transparency in the field of medicines' pricing.

Particular mention should be made of **EURIPID** *(European Integrated Price Information Database),* an initiative intended to increase pricing transparency, which with the support of the European Commission began in 2019 to expand its database by including volumes of sales of medicines and information about market access agreements.

In September, EURIPID set up a Dialogue Platform to allow stakeholders to provide information on a voluntary basis as to the availability of medicines, so as to create a technical guide on international price references and facilitate the exchange of information between countries as to net prices.

Meanwhile, the **Valletta Technical Committee** (to which Spain belongs) included transparency as a fixed item on its agenda in 2019, based on the belief that the exchange of information in the field of pricing is a vital tool in its price-setting procedures.

FARMAINDUSTRIA closely monitors these initiatives, analysing their progress in coordination with **EFPIA**.

## EU Industrial Policy Strategy for 2030

In May 2019, the EU's Council of Ministers adopted a raft of conclusions on the new EU Industrial Policy Strategy: a Vision for 2030, which argues for a decisive, global and long-term strategy to be implemented within the new institutional cycle of the EU.

The Council included two conclusions with a direct and positive impact on the pharmaceutical sector:

1. The recognition of the importance of having a properly functioning system of **intellectual property rights protection** that would be effective for the sustained growth of the EU.

2. The work performed by the European Commission, identifying **strategic value chains,** including in particular Smart Health.

**EFPIA** published a position paper on the **EU Industrial Strategy,** calling on the European institutions to explicitly include the pharmaceutical sector because of its positive impact on health and as a key sector in driving the competitiveness of European industry.

In this regard, the document indicates the importance of creating a stable, predictable, robust and adaptive regulatory context, with intellectual property policies that promote R&D and foster digital transformation.

**EFPIA** also proposes continued efforts to promote free trade treaties and support for the sector's initiatives focused on protecting the environment, in line with the European Commission's Green Europe programme.

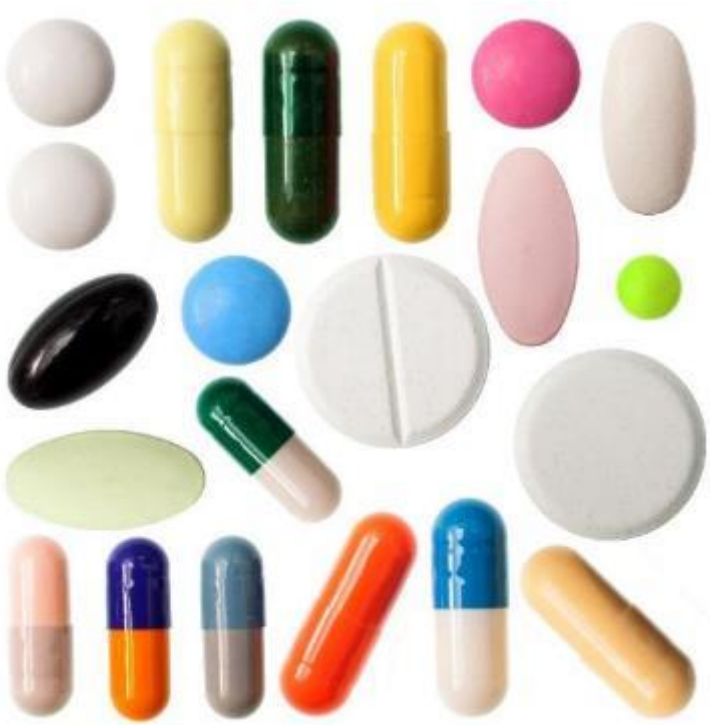
## Support for the Economy of Well-Being and the European Pharmaceutical Policy

The **Employment, Social Policy, Health and Consumer Affairs Council (EPSCO),** which met in December 2019 under the Finnish Presidency of the EU, adopted two documents: one addressing the Economy of Well-Being, and another on the European Pharmaceutical Policy.

The document on the **Economy of Well-Being** highlights the contribution made to the economy by national health services guaranteeing universal access to healthcare, and calls for both inter-sectoral cooperation and the coordination of initiatives at the national and European level. The document in turn spotlights the role that digital transformation and artificial intelligence could play in increasing the efficiency of national health services.

Meanwhile, the **European Pharmaceutical Policy** document argues, in response to the challenges of availability and supply, for the strengthening of cooperation and coordination among member states to improve access to medicines.

**EFPIA** and the national associations have closely monitored the potential impacts that certain measures that might be designed to address the content of these two documents could have on the innovative pharmaceutical industry.

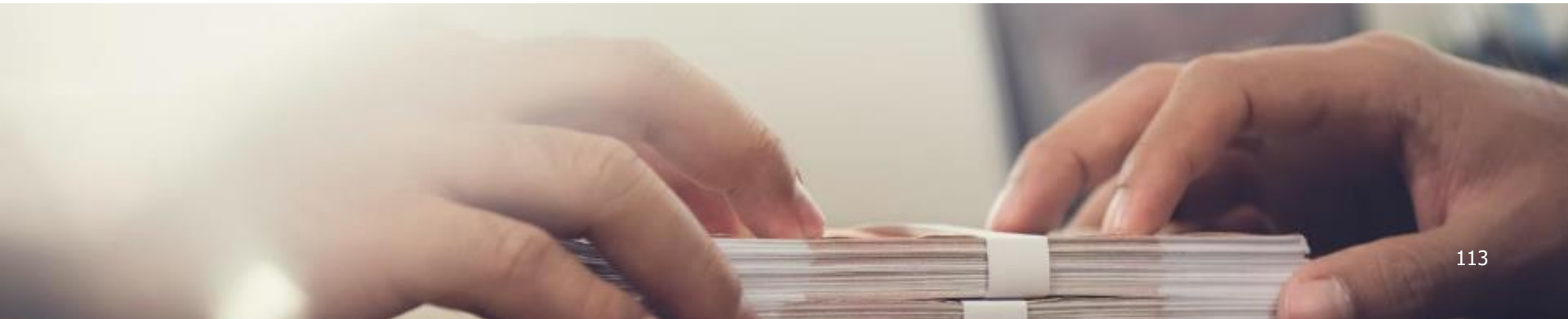


## New Access Models

The growing existence of increasingly complex and personalised treatments is giving rise to **new challenges** for the EU's healthcare systems, and has prompted the launch of innovative models in the field of pricing and reimbursement, with the aim of accelerating patient access and maintaining incentives for the industry to continue innovating, while assisting payers in handling clinical uncertainty and guaranteeing the sustainability of health systems.

In this regard, and in order to facilitate dialogue between companies and national associations and their respective competent authorities, in 2019 **EFPIA** drew up a technical document describing these new payment models, requiring fulfilment of a series of principles based on access, value, cooperation, transparency and data management.

The document acknowledges the difficulty of implementing some of these new models, given the lack of infrastructure for the digitalisation of health data, the existence of legal barriers and the reluctance to incorporate such models, indicating the need to engage in dialogue so as to identify the main barriers preventing the implementation of such models and to cooperate in the creation of a platform to gather data on health outcomes so as to foster optimal conditions for development.





## Incremental Innovation

With the aim of raising awareness of the value and the contribution made by incremental innovation to patients and to society, **EFPIA** commissioned **IQVIA** to prepare a study based on the opinion held by the main stakeholders in the health sector (decision-makers, payers, healthcare professionals, patients and academics) as to this type of innovation.

The study reflects a discrepancy in the perception of the value of incremental innovation between regulators and payers, on the one hand, and patients and professionals on the other. This study in turn analyses **various cases** of pharmaceutical innovations in **six treatment areas** (oncology, antivirals, diabetes, respiratory diseases, multiple sclerosis and the nervous system) in **eight countries** (including Spain) as the baseline to establish a position on the part of the pharmaceutical industry as to the value contributed by incremental innovation. In this regard, FARMAINDUSTRIA has extensively disseminated the conclusions of the study by setting up a working group to develop and implement an action plan focused on the contribution of such innovation.

## LEGISLATIVE INITIATIVES IN EUROPE

### Modification of the Supplementary Protection Certificate (SPC) Regulation

Within the context of the global analysis of intellectual property incentives, in May 2018 the **European Commission** published a proposal for the amendment of the Regulation on the SPC, incorporating an exemption to the rights derived from this intellectual property title known as the **manufacturing waiver,** allowing the manufacturing of generics and biosimilars during its period of validity, purely for the purposes of export to third countries where there is no legislation regarding the intellectual property rights, or where the exclusive status of these rights is expired.

Although the European Commission justified this proposal as a way of establishing a framework of equality between companies manufacturing generics and biosimilars in the EU and their competitors in third markets, the Commission's proposal has a highly negative impact on the research-based pharmaceutical industry by limiting the rights granted by the **SPC,** which were established as a tool to offset the loss of the effective period of protection granted by patents and to allow companies to recoup the resources invested in R&D.

Ultimately, the proposed amendment to Commission Regulation (CE) 469/2009 on the **SPC** was passed by the European Parliament on 17 April 2019, ratified by the EU Council of Ministers on 14 May, and took effect from 1 July 2019.

Despite the arguments raised by the research-based pharmaceutical industry, the adopted text establishes an exemption for manufacturers of generic and biosimilar medicines to manufacture medicines protected by an SPC within the EU either for exportation to third countries and/or for stockpiling during the six months prior to the expiry of the **SPC**.

The amendment to the Regulation affects **SPCs** applied for from 1 July 2019 and also **SPCs** applied for prior to 1 July 2019 and which take effect beyond said date (i.e., from 2 July 2022 onwards). Manufacturers of generics and biosimilars will be entitled to make use of the waiver provided that at least three months in advance they notify national patent offices and the holder of the **SPC** of their intention to manufacture.

It should be pointed out that following the adoption of the text, Belgium, France, Ireland, the Netherlands, Portugal and Spain issued a joint declaration underlining their support for the Regulation, while in turn highlighting that the proposal preserves incentives to encourage R&D. Denmark, Malta, Sweden and the UK, meanwhile, declared that they did not support the proposal.

## Regulation on Health Technology Assessment (HTA)

The European Commission published in January 2018 a legislative proposal of the Parliament and the European Council on **health technology assessment (HTA)**.

The proposed Regulation included a joint clinical assessment of the relative efficacy of medicines as a fundamental element, which would be adopted on a mandatory basis by all countries of the EU, following a transitional period of three years.

The aim pursued by the Commission was to:

1. **Guarantee** fulfilment of the objectives of the internal market.
2. **Overcome** the inefficient overlapping of evaluations taking place in different Member States.

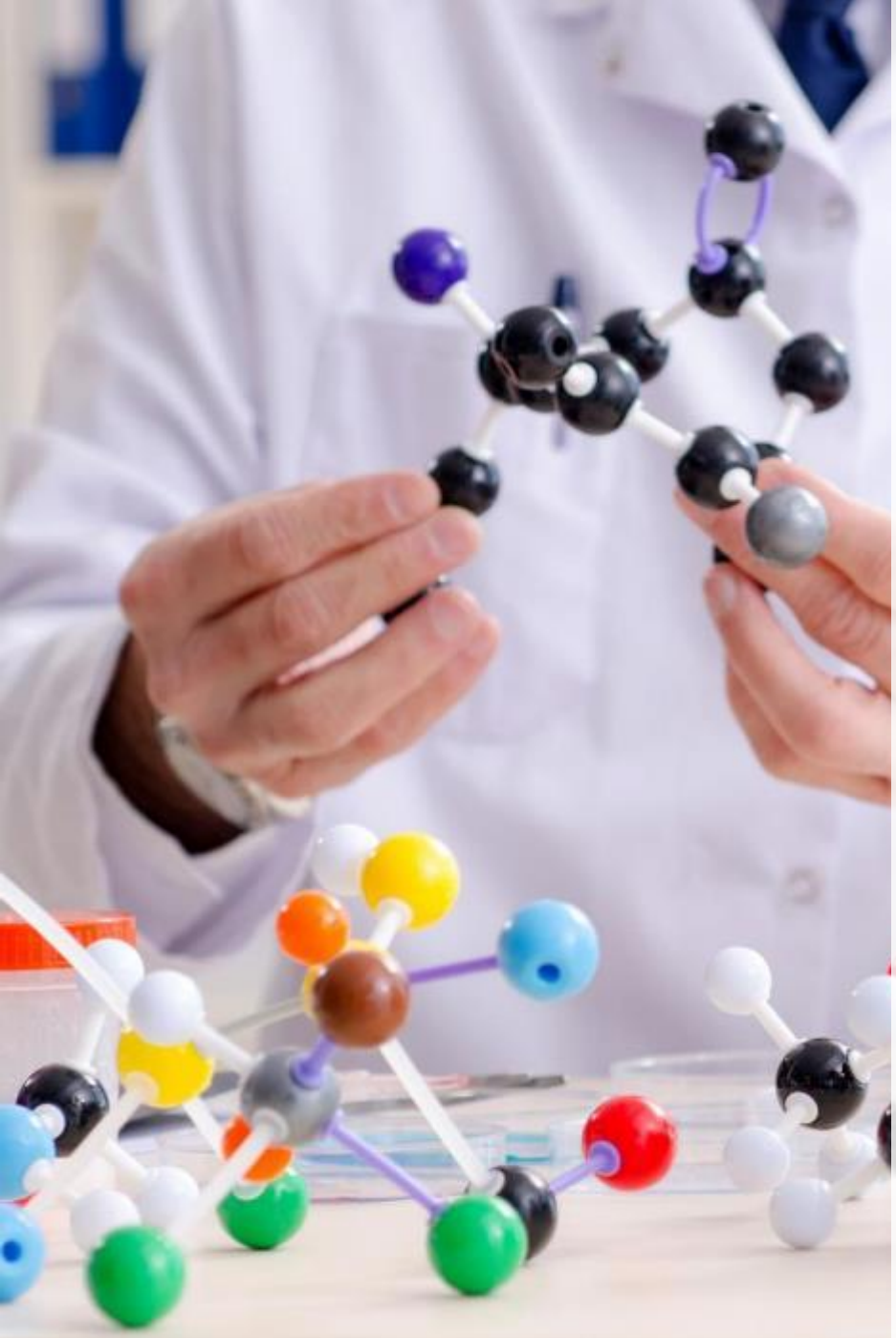
In October 2018 the European Parliament brought in a set of amendments to the proposed Regulation, highlighting the possibility that Member States could conduct a national assessment supplementary to the joint assessment of clinical efficacy, provided that this would be justified.

The incorporation of this amendment was decisive in achieving approval of the proposed Regulation by the European Parliament in February 2019.

Despite the attempts of the EU presidencies of Romania and Finland in 2019 to reach a consensus, the differing positions among **Member States** on the use of joint assessments of relative clinical efficacy (mandatory versus voluntary) remained.

The opposition to mandatory status, headed by Germany and France (and supported by the Czech Republic, Poland and Spain), alongside the reluctance of the European Parliament to change its position, mean that it has so far proved impossible to finalise this procedure.

In line with **EFPIA,** FARMAINDUSTRIA supports European regulation in the field of HTA based on centralised clinical assessment which will avoid inefficient re-assessments at national level, as well as barriers and delays in the access of European patients to innovation.





## Directive 2011/62/EU (Falsified Medicines). Delegated Regulation (EU) 2016/16

Publication in the OJEU on 9 February 2016 of **Delegated Regulation** (EU) 2016/161 officially marked the start of the three-year period established for full compliance, requiring that all prescription medicines be fitted with security and anti-tampering devices allowing their authenticity to be verified.

Within this period, the Member States would be required to set up national verification systems responsible for managing the repositories storing information on these security devices.

Within this context, in July 2016 Spain established its **Spanish Medicines Verification System (SEVeM)** comprising FARMAINDUSTRIA (holding the presidency), the AESEG (Spanish Association of Generic Medicines), the CGCOF (General Council of Official Associations of Pharmacists) and the FEDIFAR (National Federation of Associations of Wholesale Distribution of Medicinal and Para-pharmaceutical Products).

From 9 February 2019 onwards, the Spanish system has been fully operational in connection with the European hub and in accordance with the EU Delegated Regulation. As a member of EFPIA's Supply Chain Working Group, FARMAINDUSTRIA conducts regular and close monitoring of the operational developments of the verification system.

# 3.3.2 INTERNATIONAL CONTEXT

## ACTIVITIES WITHIN THE IFPMA FRAMEWORK

FARMAINDUSTRIA channels a substantial part of its activities at the international level through its involvement in **IFPMA (International Federation of Pharmaceutical Manufacturers & Associations),** an organisation comprising 50 associations (47 national and three regional), 37 pharmaceutical companies and five affiliated federations in fields associated with the sector.

FARMAINDUSTRIA is represented on the governing bodies of **IFPMA** (Council and General Assembly) as well as the Committee of Heads of Associations.

IFPMA's activity revolves around various strategic committees and working groups of which FARMAINDUSTRIA is also a member participating actively and regularly.

## Meetings of the IFPMA Governing Bodies

The meetings of the **IFPMA Council** during 2019 addressed the Federation's priorities in the field of intellectual property, innovation and access.

Meanwhile, the meetings of the Committee of Heads of Associations centred above all on the exchange of information as to pharmaceutical policies in their respective countries, and the debate concerning access and transparency.

## 2nd WHO Fair Pricing Forum

In April 2019 the WHO staged its ***Fair Pricing Forum*** in Johannesburg in collaboration with the South African Government, continuing the debate as to the concept of **"fair pricing"** of medicines in the form of expert panel discussions, debates and group sessions. As in 2017, the Forum proved critical of the innovative pharmaceutical industry, questioning its productive model, the concept of value-based pricing, and ultimately supporting the proposed resolution on transparency forwarded by Italy for debate at the World Health Assembly in May 2019.

Against this background of opposing positions, **IFPMA** coordinated with its member associations in presenting figures on the value contributed by the innovative pharmaceutical industry in medical, economic and social terms, emphasising its value proposition and thereby anticipating its posture in the debates that were to take place a month later during the **World Health Assembly** with regard to transparency, access and sustainability of national health services.

## Resolution of the World Health Assembly on Transparency

At the **World Health Assembly** in May, **WHO's** member states, with the exception of Germany, Hungary and the UK, passed a resolution proposed by Italy with the support of 19 countries (including Spain) on **Improved Transparency in Markets for Medicines, Vaccines and Other Healthcare Products**.

Although the Resolution is not binding, the final text, which proved difficult to pass and was not without its controversy, argues for transparency in the field of net pricing of medicines throughout the value chain (not simply referring to the manufacturer), along with transparency of the costs of clinical trials, wherever these are publicly available or provided voluntarily.

The support lent by a group of countries headed by Germany, the UK and Japan to the objections of the innovative pharmaceutical industry regarding the subsections of the proposal that could jeopardise the pharmaceutical R&D model proved decisive reducing the claims of the more contentious delegations.

## Publication of the WHO Essential Medicines List

In July 2019 the WHO published its 21st **Essential Medicines List,** including 28 new medicines for adults and 23 paediatric products.

Since it was first published in 1977, this list has been revised and updated every two years by WHO's **Expert Committee** for the Selection and Use of Essential Medicines, with the aim of providing national health services (in particular in countries with more limited resources) with a selection of "essential" medicines to cover their citizens' health needs.

The medicines placed on the 2019 WHO list include in particular certain oncological medicines, along with three antibiotics and biosimilar medicines.



## Intellectual Property

On 3 October 2017, **IFPMA** and the **World Intellectual Property Organization** (WIPO) signed a partnership agreement under the Patent Information Initiative for Medicines *(Pat-INFORMED)*. The aim of the initiative is to provide access to public information on pharmaceutical patents via a portal. The portal has been in operation since 25 September 2018, coinciding with the General Assembly of the **WIPO**.

In response to the constant attacks on the productive model of the innovative pharmaceutical industry, and the ongoing emergence of initiatives undermining the intellectual property system, the governing bodies of **IFPMA** in December 2018 approved the launch of an action plan focused on preparing a narrative based on the generation of evidence as to the importance of intellectual property for advances in treatment.

Over the course of 2019, **IFPMA** developed a communication plan to showcase the value proposition of the research-based pharmaceutical industry on numerous forums, debates and round tables, highlighting the need for high levels of intellectual property protection so as to encourage biomedical innovation for the benefit of patients. In parallel, **IFPMA** established a channel for dialogue with the federations at the international level (IGBA) and in Europe *(Medicines for Europe)* for generic medicines.

## Proposed Contribution by the OECD to Increase the Transparency of the Pharmaceutical Market

In response to the request by a number of Member States and the adoption at the **World Health Assembly** of the aforementioned transparency resolution, the **OECD** Health Committee presented a document in December 2019 with proposals for various projects to increase **transparency in the pharmaceutical market**.

In principle, the contribution by the **OECD** was confined to an evaluation of two of these projects. The first of them centred on analysing the performance of the pharmaceutical industry, and the second focused on an examination of the viability and impact of the exchange of pricing information.

In this regard, **IFPMA** submitted a note to the **OECD** indicating that the proposal explores complex and multidimensional issues, which demand prior assessment of the improvements that these proposals would generate in terms of market efficiency and the contribution of value to patients and to public health systems.

## COMPETITIVENESS AND INTERNATIONALISATION

Within the context of overseas trade, FARMAINDUSTRIA acts in coordination with **EFPIA** through working groups, the ultimate aim being to improve the presence of its member companies in international markets.

The EU is currently engaged in negotiations to reach association agreements affecting the commercial activity of the Spanish pharmaceutical companies with various countries and regions.

## EU-US Mutual Recognition Agreement on the Inspection of Medicines

11 July 2019 marked the end of the process of implementing the **Mutual Recognition Agreement on the Inspection of Medicines** signed by the EU and the United States in January 2017, thereby concluding the recognition assessments conducted by the FDA on the regulatory authorities of the EU Member States. This Agreement **allows automatic recognition of inspections conducted at production plants of medicines for human use** in the EU and the USA, avoiding duplication of inspections and thereby facilitating access to medicines.

The most notable next steps include the possible expansion of the scope of application of the Agreement (a decision that the EU and USA must take by 15 July 2022) to incorporate vaccines and plasma derivatives, products which are not yet covered.

## EU-Canada Free Trade Agreement (CETA)

After final adoption and signing on 30 October 2016, the EU-Canada Free Trade Agreement entered into force provisionally on 21 September 2017.

As this is a **mixed agreement,** it must be ratified by the national Parliaments of all EU Member States in order to enter fully into force.

By the date when this Annual Report went to press, 14 Member States had already ratified the Agreement, including Spain.

## EU-Japan Economic Partnership Agreement (EPA)

On 8 December 2017 the negotiations for the **Economic Partnership Agreement** between the EU and Japan were concluded. The Agreement was ratified by the European Parliament on 12 December 2018, and took effect on 1 February 2019.

The aim of this agreement is to remove barriers to trade, with a potential impact on the pharmaceutical sector since:

1. It does away with the regulatory barriers to the implementation of mutual recognition agreements.
2. It strengthens intellectual property rights and establishes shared regulations regarding pharmaceutical patents.
3. It recognises the equivalence of the data protection systems of the EU and Japan.

## EU-MERCOSUR Partnership Agreement

In 2015, the EU and Mercosur (Argentina, Brazil, Paraguay and Uruguay) relaunched their negotiations for this **Partnership Agreement,** which began in 1999 and was suspended in 2004, with the aim of **promoting trade relations between the two blocs**. Between 2017 and 2019 the negotiation rounds intensified, and on 28 June 2019 the EU and MERCOSUR laid the foundations for a trade agreement which, among other commitments, will serve to eliminate tariffs over the next 10 years on 91% of the products that the EU exports to the region.

The trade agreement will have a considerable impact on the pharmaceutical sector since:

1. **It will eliminate** 90% of tariffs on pharmaceutical products.
2. **It will reinforce** compliance with intellectual property rights.
3. **It will adapt** the patent regime in accordance with the legal framework of the TRIPS agreements within the context of the World Trade Organization.
4. **It will establish** a platform for dialogue and cooperation in combating anti-microbial resistance.

The text of the trade agreement is being analysed in connection with legal aspects with a view to finalising the **Partnership Agreement** for ratification by all member states of MERCOSUR, the parliaments of the EU Member States, and the European Parliament.

## Modernisation of the EU-Mexico Global Agreement

In May 2016, the EU and Mexico began negotiations to update the agreement signed in 2001. As a result of these negotiations, the political agreement was signed on 21 April 2018, while practically all the remaining technical and legal aspects were finalised by late 2019, except for the section concerning **public procurement**.

The noteworthy clauses established for the agreement include:

1. The **simplification** of customs procedures and rules of origin for European companies.
2. The **strengthening** of intellectual property rights, giving greater protection to European R&D.

## EU-Australia and New Zealand Free Trade Agreements

In June 2018 the EU began negotiations for **free trade agreements with Australia and New Zealand**. Following the first six rounds of negotiations held by 2019, efforts are achieving positive progress, with a specific textual proposals already in place.

# 03

# INSTITUTIONAL ACTIVITY

3.1 Market Regulation and Relations with Public Authorities
3.2 Communication
3.3. International Relations
**3.4 The Pharmaceutical Industry in Spain and Worldwide**

# 3.4 The Pharmaceutical Industry in Spain and Worldwide

## 3.4.1 THE PHARMACEUTICAL INDUSTRY IN EUROPE

An analysis of the progress of a business sector during a particular time period must be placed within the context of the general evolution of the economy during that period.

In this regard, in 2019 the EU economy **grew by 1.5%,** marking a slowdown compared with the previous year's growth.

2019 was nonetheless the sixth consecutive year of European economic growth, with increases ranging from +1.5% to +2.4%. This economic boom period has led to **greater job creation,** as reflected in the downturn in the unemployment rate in the EU, ending 2019 at 6.4% of the active population, the lowest rate of unemployment in Europe since the year 2000.

The trend of **budgetary consolidation** has likewise continued, with the deficit of the EU Governments as a whole remaining at 2018 levels following eight consecutive years of reduction, with the deficit dropping from 6.9% of GDP in 2009, to 0.6% by 2019.

Meanwhile, the EU-27 managed to reduce its level of financial debt from 79.6% to 77.8% of GDP, the lowest level since 2009.

However, all these advances were curtailed by the economic impact of the health crisis caused by the spread of Covid-19, which battered the European (and global) economy from March 2020 onwards. The most recent European Commission forecasts[1] thus suggest a substantial downturn in the real GDP of the EU-27, from +1.5% in 2019 to -7.4% in 2020, which would be partially offset in 2021 with an upturn of +6.1%.

The substantial impact that the health crisis will have on the public finances of European countries is likewise significant. For the EU-27 as a whole, then, the Commission expects the deficit to go from -0.6% of GDP in 2019 to -8.3% of GDP in 2020, followed by a deficit of -3.6% in 2021. As for public debt in the EU-27, this is expected to rise from 77.6% of GDP in 2019 to 95.1% by 2020, with a slight reduction in 2021 (92.0%).

[1] European Economic Forecast – Spring 2020. European Commission. Published on 6 May 2020, available at https://ec.europa.eu/info/business-economy-euro/economic-performance-and-forecasts/economic-forecasts/spring-2020-economic-forecast-deep-and-uneven-recession-uncertain-recovery_en.


The European Commission itself notes in its report that its forecast scenario could worsen given the uncertainties surrounding the progress of the pandemic, and specifically the possibility of the emergence of a second wave of the disease in the latter part of the year.

Regarding the pharmaceutical industry, it should be remembered that despite the reduction of the deficit, healthcare budgets in member countries continue to be tightly controlled, resulting in certain containment measures on public health and pharmaceutical spending being adopted each year. This inevitably has an effect on the evolution of a market such as the pharmaceutical sector that is strongly regulated and highly dependent on public budgets. In addition, these measures can often lead to restricted market access for certain products and growing pressure on medicine prices, which in turn results in a cascading effect on countries whose reference prices are dependent on each other.

Although the above factors will limit the growth of the European pharmaceutical market over the coming years, there are other elements that will drive sales upwards, such as an ageing population and the chronic status that certain conditions are acquiring. The forecasts by IQVIA[2] thus place the average pace of annual growth for the five main European markets over the period 2020-2024 within the range of +3% / +6%, equivalent to the growth expected in the sector worldwide and the expected growth in the USA (+3% / +6%). Within the main five European markets, France will register the smallest average annual growth over 2020-2024 (0% / +3%), while the forecasts for Germany and the UK are the highest, with a pace of growth of +4% / +7%.

Spain and Italy, meanwhile, will register average growth rates of between +3% and +6% per year. It is in any event important to highlight that the forecasts were made prior to the emergence of Covid-19, and will therefore be subject to thorough review.

Lastly, and regardless of growth, it is important to emphasise the significance of Spain within the European pharmaceutical context. In this regard, as shown in the table below, **Spain is the fifth most important pharmaceutical market in Europe by sales volume and generation of employment** (behind France, Germany, Italy and the UK) and the sixth European market in terms of production (after the previous four countries and Ireland).

[2] Market Prognosis, September 2019. Figures for the total pharmaceutical market in each country (outpatient plus hospital).

## GENERAL DATA FROM THE PHARMACEUTICAL INDUSTRY IN THE UE-13 (2017)

| Country | Number of manufacturers (1) | Output (€ million) (2) | Employment | Domestic Sales (MSP) (€ million) (3) | Foreign Trade (MSP) (€ million) (4) | |
|---|---|---|---|---|---|---|
| | | | | | Imports | Exports |
| Germany | 104 | 30,555 | 117,013 | 32,525 | 47,672 | 75,118 |
| Austria | 250 | 2,712 | 14,860 | 4,213 | 8,976 | 9,942 |
| Belgium | 130 | 10,768 | 35,711 | 5,067 | 32,663 | 40,294 |
| Denmark | 33 | 14,391 | 26,963 | 2,584 | 3,829 | 12,496 |
| **Spain** | **155** | **15,199** | **42,687** | **16,028** | **13,190** | **10,740** |
| Finland | 40 | 1,766 | 4,722 | 2,373 | 1,918 | 752 |
| France | 255 | 21,900 | 98,786 | 28,419 | 24,694 | 28,653 |
| Greece | 62 | 954 | 19,700 | 5,141 | 3,092 | 1,190 |
| Netherlands | 44 | 6,180 | 17,900 | 5,086 | 23,520 | 31,729 |
| Ireland | 50 | 19,305 | 29,766 | 2,013 | 9,540 | 35,451 |
| Italy | 200 | 31,200 | 65,400 | 26,945 | 23,390 | 23,855 |
| Portugal | 111 | 1,694 | 7,700 | 3,056 | 2,442 | 1,081 |
| Sweden | 90 | 7,686 | 11,012 | 3,990 | 3,850 | 7,556 |
| **Total EU-13*** | **1,524** | **164,310** | **492,220** | **137,440** | **198,776** | **278,857** |

*(*) Although previous editions of the Report provided this information with reference to the "fifteen" members of the European Union (EU-15), from this edition onwards the data reported will be for the EU-13, since from 31 January 2020 onwards the United Kingdom no longer belongs to the EU, and data are not available for Luxembourg.*

*(1) Pharmaceutical companies that are members of EFPIA Associations.*

*(2) The data refer to production activities for proprietary medicines and raw materials for human and veterinary use, except Germany, Spain and Ireland where they refer only to the activity intended for human use.*

*(3) Includes sales through retail pharmacies, hospitals and other distribution channels.*

*(4) Foreign pharmaceutical trade (SITC 54). Includes veterinary products.*

**Source:** FARMAINDUSTRIA from EFPIA and Eurostat (Comext Database).

## 3.4.2 THE PHARMACEUTICAL INDUSTRY IN SPAIN

**R&D+i**

"Knowledge and innovation are critical factors to guarantee economic growth and promote the competitiveness and productivity of a country. Closing the virtuous circle between quality public universities and equal opportunities, scientific and technical research and the transfer of knowledge to companies is a priority for a reform agenda that will achieve true consolidation and place the society and economy of Spain on the track to the future."

The above assertion represents one of the fundamental principles of the document entitled **Agenda for Change: 2030 Objective,** highlighting how research, development and innovation activities (R&D+i) form a central part of a sustainable, competitive, high-quality growth model and are key to creating employment and improving the productivity and competitiveness of an economy.

To promote such activities, the Spanish Science, Technology and Innovation Strategy 2013-2020 is currently in place, and alongside the **Europe 2020 Strategy** this makes up the backbone of the country's R&D policy.

The document sets out a series of objectives to be achieved over the coming years in terms of the R&D spending of our economy in relation to GDP and how it is distributed between the public and private sectors. These objectives are summarised in the following table:[3]

| INDICATORS OF THE SPANISH SCIENCE, TECHNOLOGY AND INNOVATION STRATEGY | | | |
|---|---|---|---|
| **Effort Indicators** | **2010** | **2016** | **2020** |
| **R&D spending in relation to Gross Domestic Product (%)** Source: INE | 1.39% | 1.48% | 2.00% |
| **Private sector R&D spending in relation to Gross Domestic Product (%)** Source: INE | 0.60% | 0.73% | 1.20% |
| **Ratio between private and public funding of R&D spending** Source: INE | 0.86% | 1.06% | 1.70% |
| **% foreign funding for R&D spending** Source: INE | 5.70% | 9.60% | 15.00% |

[3] Spanish Science, Technology and Innovation Strategy 2013-2020 (page 40). Secretary of State for Research, Development and Innovation. Ministry of Economy and Competition. Available at: http://www.idi.mineco.gob.es/stfls/MICINN/Investigacion/FICHEROS/Estrategia_espanola_ciencia_tecnologia_Innovacion.pdf

Nonetheless, the most recent figures published by the INE (Spanish National Statistics Institute) for the year 2018 indicate that the actual evolution of expenditure on R&D in the country has progressively diverged from the above goals, seriously compromising the achievement of the targets set for 2020. The weighting of R&D spending over national GDP thus fell from 1.39% in 2010 to 1.24% in 2018, well below the 2.00% target set for 2020.

In terms of R&D expenditure funded by the private sector, this increased from 0.60% in 2010 to 0.70% in 2018, and the volume would therefore still need to increase significantly over the period 2019-2020 to achieve the targets agreed with Brussels (1.2% of GDP by 2020), which would be a real challenge.

**The 2017-2020 National Scientific and Technical Research and Innovation Plan** establishes the operational framework with a view to achieving the objectives set by the 2013-2020 Spanish Science, Technology and Innovation Strategy, and the European 2020 Strategy.

This Plan contains a specific programme to promote R&D carried out by the private sector since, as literally cited in the Plan:[4]

**"Business investment in R&D in Spain, representing 0.64% of GDP in 2016,[5] is almost half the EU-28 average (1.30%) and is one of the most notable structural weaknesses of the Spanish Science, Technology and Innovation System".**

[4] Page 6 of the 2019 National Reform Programme of the Kingdom of Spain. April 2019. Available at: http://www.mineco.gob.es/stfls/mineco/comun/pdf/190430_np_programa.pdf.
[5] This percentage (0.64%) refers to R&D conducted in 2016 by the private sector, while R&D funded by the sector represented 0.55% of GDP in the same year.

In this regard, the CES (Economic and Social Council), one of the Government's main consultancy bodies in the field of socio-economic and employment matters, recommended in a recent report[6] the creation of a new R&D strategy that would essentially involve **"increasing public and private investment in this field to converge with the European average"** while calling on the Government to build a National Agreement for Industry, since **"the strengthening of industry is an essential precondition to combine growth, employment, environmental sustainability, social cohesion and territorial structuring"**.

[6] "La Industria en España. Propuestas para su desarrollo". CES. January 2020. Available at: http://www.ces.es/documents/10180/5209150/Inf0419.pdf. Further information at: https://www.farmaindustria.es/web/reportaje/la-industria-farmaceutica-pieza-clave-en-un-nuevo-modelo-productivo-basado-en-la-id



To improve in this area, it will be essential to boost and promote the participation of the pharmaceutical industry in its role as leading industrial sector in research, as demonstrated by the data of the INE, which may be summarised as follows:

**1**

According to figures from the INE, the pharmaceutical industry invested 1.026 billion euros in research and development in 2018, almost 20% of the total investment in R&D by the Spanish industry, making it the leading industrial sector alongside automotive in terms of the volume of expenditure in absolute terms assigned to research and development activities.

This is also a particularly significant percentage if one bears in mind that the turnover of pharmaceutical companies in 2017 (the last figure available) represented just 2.7% of all Spanish industry, which means that the pharmaceutical industry is likewise the leader, alongside aerospace, in "R&D intensity".[7]

[7] This term refers to the proportion of turnover that each sector assigns to R&D.

**2**

When analysing how R&D spending breaks down into phases, the pharmaceutical sector once again leads the industrial ranking for volume of resources intended for basic or fundamental research, where it accounts for almost half of the total spending of the industrial sector in Spain (45%), and a third of the overall figure for industrial applied research.

**3**

Meanwhile, the pharmaceutical industrial sector is the leader in research conducted internally at company-owned centres (18.8% of the total industrial sector) and the second, after automotive, in research contracted with third parties (universities, hospitals, public or private centres, etc.) where it accounts for 19.0% of the total for Spanish industry.

**4**

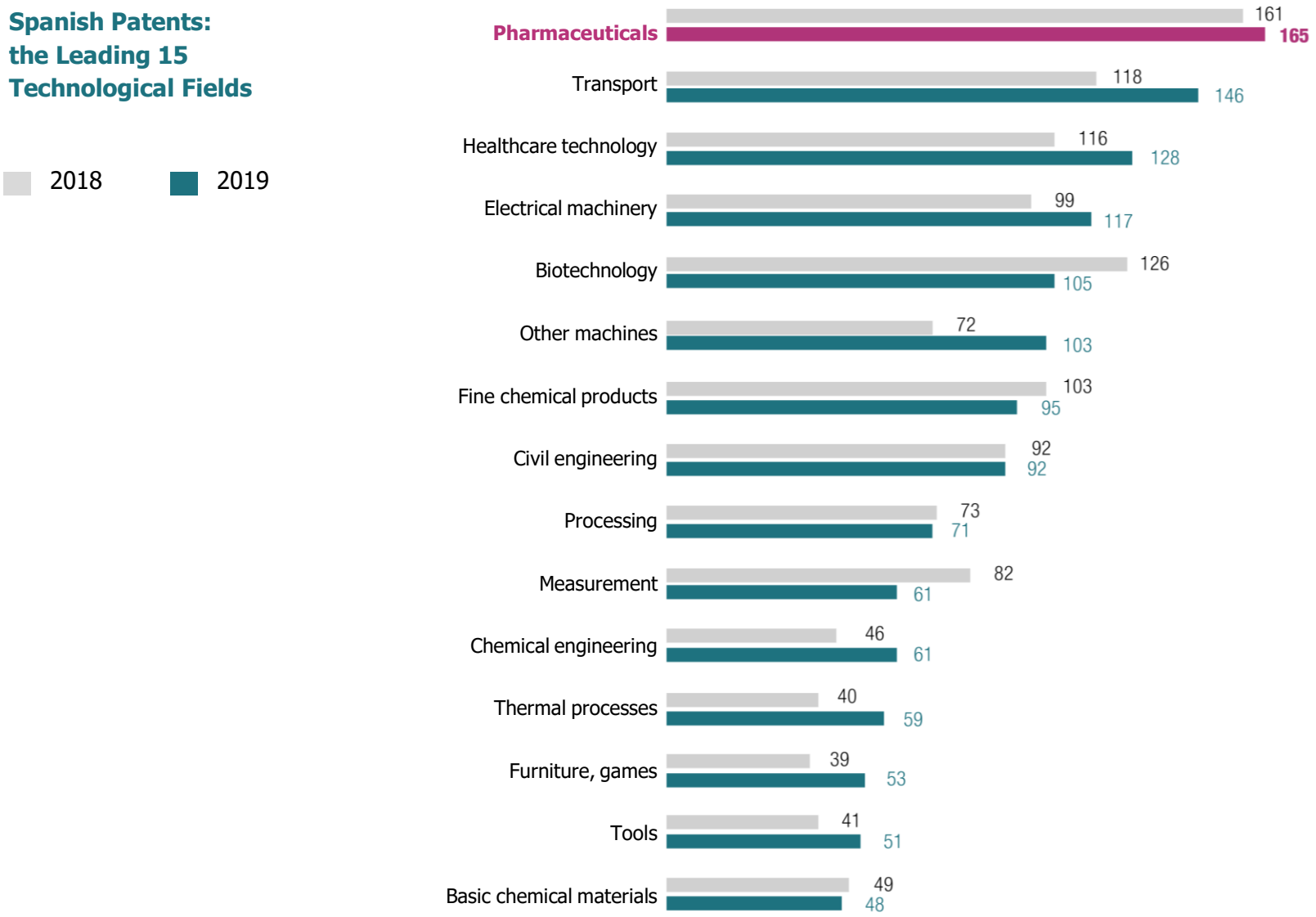
The pharmaceutical industry's leadership is not confined simply to the volume of resources invested in R&D activities, but it is also the sector that generates the most employment in this area, with 5,844 professionals working on these tasks full time. Meanwhile, two thirds of these jobs are held by women (3,849), which means that at present one in every three female researchers employed by the industrial sector in Spain works for a pharmaceutical company.

**5 |**

The aspects cited above make pharmaceuticals a **key strategic sector in terms of research,** with considerable efforts in both absolute and relative terms. From the socio-economic perspective, though, it is extremely important that these efforts should be effective and should generate results that can be seen in new treatments for patients. In this regard, according to the European Patent Office, in 2019 the pharmaceutical industry was for the second year running the industrial sector filing the greatest number of patent applications in Spain (165), followed by transport and healthcare technology. Pharmaceutical patent applications account for 9% of all those filed in Spain, placing the sector at the head of the 35 existing technological fields.[8]

[8] Further information at: https://www.farmaindustria.es/web/otra-noticia/las-solicitudes-de-patentes-farmaceuticas-impulsan-la-innovacion-en-espana.

## Spanish Patents: the Leading 15 Technological Fields



All these potentialities of the pharmaceutical industry as a cutting-edge research sector have once again been highlighted by the response given to the greatest public health challenge that our country has faced in recent decades: the health crisis caused by Covid-19.

In this regard, according to the figures for May 2020 **58 clinical trials had begun in Spain** to evaluate the efficacy of potential treatments for coronavirus, involving more than 332 participations by Spanish hospitals, with up to 28,000 patients expected to benefit from access to these trials in the country. According to the most recent information from the World Health Organization, the figures make Spain the fourth-ranked country in the world in terms of the number of clinical trials being conducted with medication to test the efficacy of potential coronavirus treatments. This ranking, which includes trials up to 5 May 2020, positions China as the country with the most clinical trials involving patients (154), followed by the USA (109) and Iran (63).

Spain follows these three countries on the table with 51 clinical trials (according to the Spanish Register of Clinical Trials, the figure is 58 as stated above).

In Europe, Spain is followed in numbers of clinical trials by

France **51**

UK **17**

Germany **16**

Denmark **13**

Italy **11**

[9] Further information at: https://www.farmaindustria.es/web/otra-noticia/espana-cuarto-pais-del-mundo-y-primero-de-europa-en-ensayos-clinicos-de-tratamientos-contra-el-coronavirus.

In short, the above figures highlight the leading position of the pharmaceutical industry in the field of research and its strategic importance in shaping a new model for growth in this country, allowing us to overcome the economic effects of the health crisis we are suffering. As a result, and in order to progress towards this goal, it would be helpful to see the development of policies that, without compromising savings targets or the need for fiscal consolidation within the various spheres of governmental expenditure, nonetheless serve to balance these goals with the development of the industrial sectors destined to lead the recovery in our country, allowing them as soon as possible to resume the trend of economic growth seen in recent years.

## DOMESTIC MARKET

In 2019, according to data published by the Ministry of Public Finance, public hospital pharmaceutical spending grew by **+7.5%**.

In turn, according to FARMAINDUSTRIA's own estimations, sales of medicines at retail pharmacies in 2019, in net figures after the deductions set out in Royal Decree-Act 8/2010, increased by **+2.3%**.

As a result of the evolution of both segments, total sales of medicines in 2019 increased by **+4.4%** from 2018.

**DOMESTIC MARKET FOR MEDICINES (MSP, million €)**

| | Retail pharmacies (1) | Increase (%) | Hospitals (2) | Increase (%) | Total | Increase (%) |
|---|---|---|---|---|---|---|
| **2015** | 8,957 | +1.3% | 6,386 | +26.4% | 15,343 | +10.4% |
| **2016** | 9,361 | +4.5% | 6,002 | -6.0% | 15,603 | +0.1% |
| **2017** | 9,579 | +2.3% | 6,168 | +2.8% | 15,747 | +2.5% |
| **2018** | 9,756 | +1.8% | 6,624 | +7.3% | 16,375 | +4.0% |
| **2019** | 9,982 | +2.3% | 7,123 | +7.5% | 17,105 | +4.4% |

*(1) Sales of medicines at retail pharmacies, after deductions (RDL 8/2010).*

*(2) Provisional data on public hospital spending for regions, civil service mutual insurers and prison institutions published by Ministry of Public Finance.*

***Source:***

*Retail Pharmacies: FARMAINDUSTRIA based on IQVIA figures and internal estimates.*

*Hospitals: Hospital pharmaceutical expenditure, Ministry of Public Finance. Updated March 2019.*

## Retail Pharmacy Market

The total market via retail pharmacies registered an **increase in sales of +2.1%** in 2019 as a result of the +1.4% rise in the number of units sold and a +0.8% increase in the average price.

Nonetheless, as shown in the following table, the number of units of medicines open to reimbursement through the NHS, accounting for 87% of the total, grew by +2.3%, while the average price increased by +0.1%.

In turn, the units of medicines not covered by reimbursement fell by -4.3%, and the average price rose by +4.4%.

**MARKET STRUCTURE AT RETAIL PHARMACIES**

| | Units (million) | Share | Increase (%) | MSP Sales (million €) | Share | Increase (%) | Average MSP (€) | Increase (%) |
|---|---|---|---|---|---|---|---|---|
| **Market subject to reimbursement** | 1,150 | 86.6% | +2.3% | 9,067 | 88.2% | +2.6% | 7.9 | +0.1% |
| **Non-reimbursed market** | 178 | 13.4% | -4.3% | 1,215 | 11.8% | -1.2% | 6.9 | +4.4% |
| **Total market** | **1,328** | **100%** | **+1.4%** | **10,282** | **100%** | **+2.1%** | **7.7** | **+0.8%** |

**Source:** FARMAINDUSTRIA from IQVIA data and own estimations.

In September 2019 a new reference price order was published, creating 18 new groups and eliminating 11. As a result, the Reference Pricing System groups within the scope of **retail pharmacies rose to 437,** of which 150 have a composition without any generic medicine (three of them with a biosimilar medicine). The new order took effect for expenditure purposes in November 2019.

Updating of homogeneous groupings, along with the creation of new reference groups has led to the situation at the end of 2019 that 82.8% of units sold in the retail pharmacies market are sold at the same price level as their corresponding generic medicine.

In 2019, a total of **268 new medicines** were launched in the retail pharmacies channel, with **total sales of €76.6 million** in the year. Of these, 133 are generic medicines, 27 are OTC medicines, seven are medicines containing a new active substance, and the remainder are medicines with active substances or combinations of active substances already on the market.

## Therapeutic Groups

In 2019, based on IQVIA data, **total sales of medicines** via retail pharmacies by therapeutic group were distributed as shown in the following table.

**TOTAL SALES OF MEDICINES VIA RETAIL PHARMACIES BY THERAPEUTIC GROUP (2019)**

| Therapeutic group | Units (thousands) | Share (%) | Increase (%) | MSP values (thousands) | Share (%) | Increase (%) | Average MSP (€) | Increase (%) |
|---|---|---|---|---|---|---|---|---|
| **N** Nervous System | 351,018 | 26.4% | 2.6% | 2,353,621 | 22.9% | 0.8% | 6.71 | -1.8% |
| **C** Cardiovascular system | 263,292 | 19.8% | 2.8% | 1,543,217 | 15.0% | 2.0% | 5.86 | -0.8% |
| **A** Alimentary tract and Metabolism | 209,967 | 15.8% | 2.1% | 1,965,752 | 19.1% | 6.3% | 9.36 | 4.1% |
| **R** Respiratory system | 123,471 | 9.3% | -0.7% | 1,079,588 | 10.5% | 0.6% | 8.74 | 1.3% |
| **M** Musculoskeletal system | 83,344 | 6.3% | -1.3% | 437,284 | 4.3% | -2.0% | 5.25 | -0.6% |
| **B** Blood and blood forming organs | 68,077 | 5.1% | 1.3% | 726,365 | 7.1% | 9.3% | 10.67 | 7.9% |
| **G** Genitourinary system | 54,423 | 4.1% | 0.8% | 656,024 | 6.4% | -3.3% | 12.05 | -4.0% |
| **D** Dermatologicals | 47,003 | 3.6% | -3.5% | 352,325 | 3.5% | -15.9% | 7.50 | -12.9% |
| **L** Antineoplastic and immunomodulating agents | 6,788 | 0.5% | 3.5% | 350,350 | 3.5% | -2.3% | 51.61 | -5.6% |
| **D** Dermatologicals | 48,285 | 3.6% | -1.2% | 291,621 | 2.8% | 1.0% | 6.04 | 2.2% |
| **J** Anti-infectives for systemic use | 45,695 | 3.4% | -2.8% | 349,626 | 3.4% | -0.8% | 7.65 | 2.0% |
| **S** Sensory organs | 42,606 | 3.2% | -1.3% | 229,029 | 2.2% | 0.7% | 5.38 | -2.1% |
| **H** Hormones | 23,564 | 1.8% | 1.9% | 221,051 | 2.1% | 2.3% | 9.38 | 0.3% |
| **L** Antineoplastic and immunomodulating agents | 7,485 | 0.6% | 5.7% | 366,863 | 3.6% | 2.1% | 49.01 | -3.4% |
| **K** Hospital solutions | 3,427 | 0.3% | 2.4% | 4,244 | 0.0% | 3.2% | 1.24 | 0.8% |
| **V** Various | 1486 | 0.1% | -1.3% | 46,993 | 0.5% | 5.8% | 31.63 | 7.3% |
| **T** Diagnostic agents | 16 | 0.0% | -12.5% | 277 | 0.0% | -8.7% | 17.31 | 4.4% |
| **TOTAL** | **1,327,952** | **100%** | **1.4%** | **10,282,045** | **100%** | **2.2%** | **7.74** | **0.8%** |

The **Central Nervous System group,** accounting for more than a quarter of the pharmaceutical market in unit terms, registered a decline in the average price of -1.8%, while units grew by **+2.6%,** influenced in part by the increase in painkillers, which account for 50% of units in this group.

As for **Cardiovascular Apparatus,** this group registered a drop in the average price of -0.8%, affected by the lower price of certain medicines in this group within the dynamic of Homogeneous Groupings. Around 90% of the units in this therapeutic group lie within the Homogeneous Groupings and/or Reference Pricing System segment.

With regard to the **Digestive Apparatus,** the average price of medicines in this group rose above the average level, in part because of the introduction of innovative treatments.

Lastly, the set of medicines corresponding to the **Respiratory Apparatus** revealed an increase in sales of **+0.6%,** influenced by a rise in the average price of +1.3%. In this group, only 62% of the units sold are subject to reimbursement and their average price recorded a fall of -2.6% as a result of the impact of reference prices.

## Hospital Market

In the hospital market, according to IQVIA data for 2019, 66.3% of sales are concentrated in two therapeutic groups:

1. **Group L.** Antineoplastic and immunomodulatory agents, among which antineoplastic agents account for 67%, and immunosuppressants 28%.

2. **Group J.** General anti-infectives, a group in which systemic antivirals account for 70% of sales.

The new reference price order published on 19 September 2019 created 16 new groups in the hospital setting and eliminated 11, so that **the current number of reference groups amounts to 223** (101 correspond to clinical packaging formats) of which 52 were created without a generic medicine and 10 have a biosimilar.

As of December 2019 there were **30 biosimilars on the market,** with a market share of **35%** of the total sales of the 12 active substances that have a biosimilar equivalent.

During 2019, **113 new medicines** were added to the hospital market, of which 50 are generic medicines, nine are biosimilar medicines, 24 are new active substances (eight of which are orphan medicines), and the rest are medicines with active substances or combinations of active substances already on the market.

## PHARMACEUTICAL FOREIGN TRADE[10]

The **productive structure of the Spanish economy** has traditionally meant that our country has been a clear importer in net terms. In other words, Spain depends on purchasing more abroad than it produces for foreign markets, giving rise to a **trade deficit** as a regular imbalance in the national economy.

This trend is heightened during economic boom times, when dynamic internal demand strongly drives imports, while being more moderate at times of an economic slowdown, when foreign purchases decline, and companies based in Spain find themselves forced to place their surplus output on foreign markets, thereby leading to an increase in exports.

The above behaviour, together with the increased competitiveness of the Spanish economy seen in recent years, explains how the trade deficit in the country changed from 9.5% of GDP before the start of the crisis (2007) to 1.6% of GDP in the last year of recession (2013).

[10] The data in this section are confined to foreign trade in pharmaceutical products. The 2019 data are provisional, subject to subsequent review, and should therefore be interpreted with caution.

Success was subsequently achieved in containing the traditional pattern of behaviour of Spain's trade balance during boom periods since, despite the **upturn seen in the Spanish economy** over the last five years (2015-2019), the trade deficit by late 2019 stood at 2.7% of GDP, in other words just +1.1 percentage points higher than the level in 2013, which remains (in relative terms) Spain's best balance of trade figure since 1995.

Meanwhile, the coverage ratio (the ratio of exports to imports) stood at 90.1% at the close of 2019, a very similar figure to the record maximums seen in 2013 and 2016 (93.4% and 93.6%, respectively). Compared with the previous year, the coverage ratio for 2019 rose by +0.9 percentage points, much higher than the levels seen in the economy prior to the crisis, when the percentage stood at around 70%, indicating a paradigm shift and the country's evolution towards **a more export-focused productive model**.

As for the evolution of the pharmaceutical export trade in 2019, particular mention should be made of the highly dynamic situation in **exports, which grew by +13.2% to a level of €12.104 billion,** the highest figure in the history of the sector in Spain.

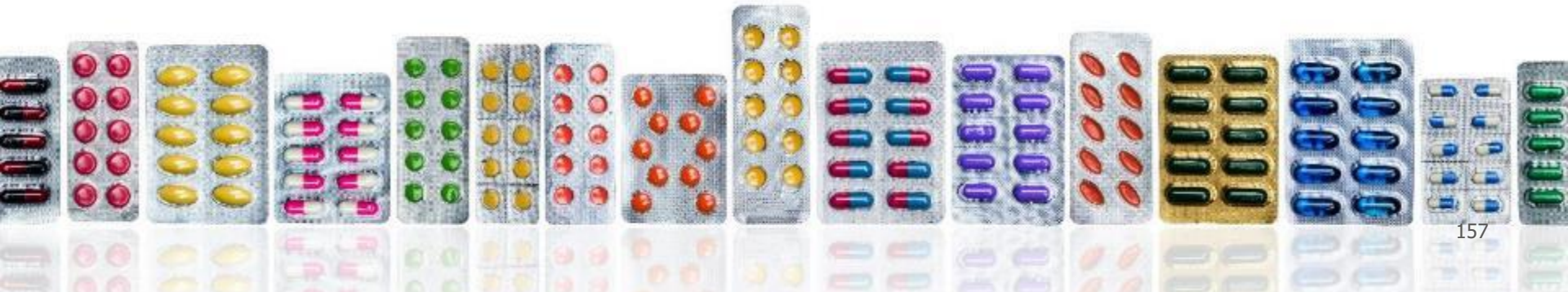
This positive shift is more than 11.4 percentage points higher than the overall figure for Spanish exports (+1.8%), and as a result pharmaceutical exports grew from 3.7% of the total in 2018 to 4.2% in 2019, as Spain's fifth most exported product by tariff category.

Meanwhile, imports registered rather more moderate growth (+10.3%), leading to an increase in the coverage rate of the pharmaceutical sector from 71.5% in 2018 73.3% in 2019.

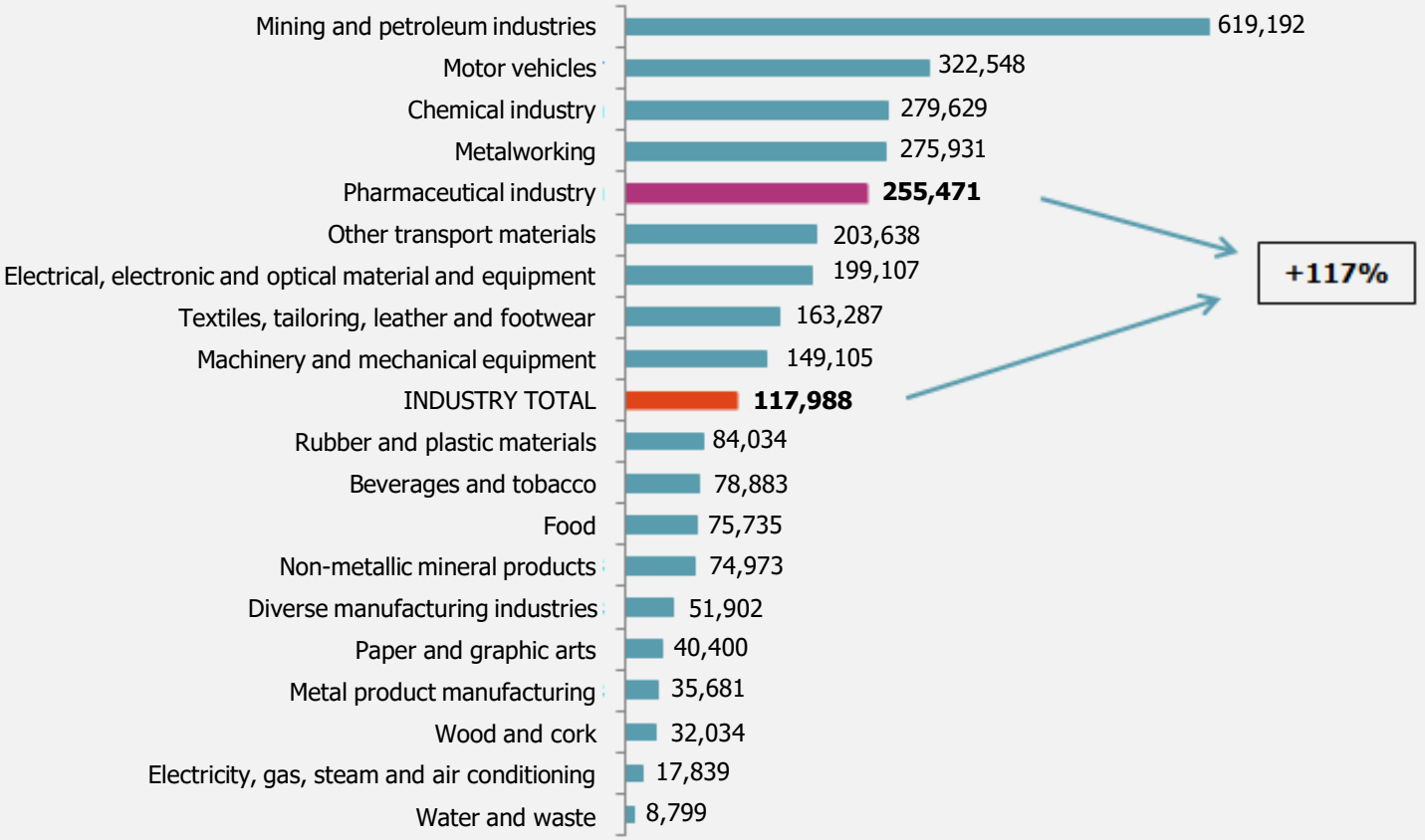
The above figures highlight the significance of the pharmaceutical industry for Spanish overseas trade through an export contribution that is much higher than one would expect according to its size. However, the significance of the industry in the exports sector is not only quantitative but also qualitative, as demonstrated by the fact that, according to INE figures for 2017 (the most recent available), **pharmaceutical exports represent 23% of all domestic exports of high-tech products**, making it the most important sector in this field, alongside the aerospace industry.

In order to complete this analysis of the contribution made by the pharmaceutical industry to the country's export sector, one must also assess the external competitiveness of the sector, serving to measure relative indicators which highlight the volume of exports by a sector in comparison with its turnover, number of employees, etc.

An analysis of the export indicator in terms of turnover using the figures for 2017 (the most recent available) shows that the pharmaceutical industry achieves twice the average for industrial sectors as a whole (81% vs. 41%). Meanwhile, if one uses the indicator of exports over employment, the difference is even more significant, making the pharmaceutical sector the fifth-ranked in the country in terms of overseas competitiveness, with exports of more than €255,000 per employee in 2017, more than twice the average for Spanish industry, as shown in the following graph.



# Main Sectors of the National Economy in Exports Per Employee (2017)




**Source:** FARMAINDUSTRIA based on data from the Department of Trade and INE.

As for the geographical distribution of the pharmaceutical export trade, it should be noted that in 2019 the EU continued to be our leading trade partner, despite the approval of the UK withdrawal agreement which took effect on 31 January 2020, following which the EU now has 27 members.

Nonetheless, 50.3% of Spanish imports of pharmaceutical products come from our EU-27 partners and 46.1% of exports head to them. Within EU countries, Germany remains the main destination for Spanish pharmaceutical output (26.8% of all exports to the EU), followed by France (14.6%), Italy (11.4%) and the Netherlands (9.2%).

Nonetheless, the destination registering the greatest growth is unquestionably Ireland, where Spain has tripled its sales of pharmaceutical products in recent years, from accounting for just 1.1% of exports in 2016 to a level of 3.7% in 2019.

As for the UK, there was a very significant increase (+25.0%) in exports to the country (possibly because of the stockpiling effect), which accounted for 4.6% of Spanish export sales, five tenths higher than in 2018, making it the sixth-biggest global destination in terms of the volume of Spanish pharmaceutical exports.

As for other non-EU markets, which now account for over half of all Spanish pharmaceutical exports, the main destinations are, in this order:

Switzerland **21.4%**

United States **5.3%**

Japan **2.9%**

China **2.2%**

Alongside the UK, these four countries account for two thirds of all pharmaceutical exports destined for countries outside the European Union.

| Economic Area | 2018 | | 2019 (p) | |
|---|---|---|---|---|
| | Export | Import | Export | Import |
| **World Total** | 100% | 100% | 100% | 100% |
| **EU-27** | 45.7% | 53.5% | 46.1% | 50.3% |
| Germany | 12.2% | 16.6% | 12.4% | 15.7% |
| Belgium | 2.0% | 5.2% | 2.1% | 5.7% |
| France | 6.4% | 8.1% | 6.8% | 7.3% |
| Netherlands | 4.8% | 7.6% | 4.2% | 7.8% |
| Ireland | 3.4% | 4.2% | 3.7% | 2.6% |
| Italy | 5.1% | 5.2% | 5.3% | 4.6% |
| **Rest of Europe** | **23.7%** | **17.5%** | 27.8% | 13.4% |
| UK | 4.1% | 6.2% | 4.6% | 4.9% |
| Switzerland | 17.7% | 11.0% | 21.4% | 8.1% |
| **Rest of World** | **30.5%** | **29.0%** | 26.0% | 36.3% |
| China | 2.5% | 2.9% | 2.2% | 2.6% |
| United States | 6.6% | 16.9% | 5.3% | 17.4% |
| India | 0.4% | 1.1% | 0.3% | 1.1% |
| Japan | 3.6% | 0.5% | 2.9% | 0.5% |

**Source:** Ministry of Economy, Industry and Competitiveness. Department for Trade.

**Note:** (p) provisional.

| NHS SPENDING ON PRESCRIPTIONS DISPENSED AT PHARMACIES | | | | | | |
|---|---|---|---|---|---|---|
| **Year** | **Spending** (€ Million RRP VAT) | **Increase** (%) | **No. of Prescriptions** (Millions) | **Increase** (%) | **Spending per Prescription** (€) | **Increase** (%) |
| **2010** | 12,207.7 | -2.4% | 957.7 | 2.5% | 12.7 | -4.8% |
| **2011** | 11,135.4 | -8.8% | 973.2 | 1.6% | 11.4 | -10.2% |
| **2012** | 9,770.9 | -12.0% | 913.8 | -6.1% | 10.6 | -6.6% |
| **2013** | 9,183.2 | -6.0% | 859.6 | -5.9% | 10.6 | -0.1% |
| **2014** | 9,360.5 | 1.9% | 868.6 | 1.1% | 10.7 | 0.9% |
| **2015** | 9,535.1 | 1.9% | 882.1 | 1.6% | 10.8 | 0.3% |
| **2016** | 9,912.8 | 4.0% | 901.6 | 2.2% | 10.9 | 1.7% |
| **2017** | 10,170.8 | 2.6% | 908.5 | 0.8% | 11.1 | 1.8% |
| **2018** | 10,481.9 | 3.0% | 945.8 | 4.1% | 11.0 | -0.9% |
| **2019** | 10,793.9 | 2.9% | 971.2 | 2.6% | 11.1 | 0.2% |

**Source:** Medical Prescription Invoicing. Ministry of Health.

## Public Pharmaceutical Expenditure on Official NHS Prescriptions

The Ministry of Health figures for 2019 indicate **an increase in public pharmaceutical expenditure at retail pharmacies of +2.9%,** amounting to 10.794 billion euros. This change in the level of expenditure is the consequence of a +2.6% increase in the number of prescriptions and a +0.2% increase in the average cost per prescription.

## Regional Distribution of Public Pharmaceutical Spending Per Capita

In 2019, public pharmaceutical expenditure through official NHS prescriptions stood at **229.5 euros per inhabitant,** equivalent to an increase of +2.3% compared with 2018.

At the regional level, the regions revealing the highest pharmaceutical expenditure figures per capita were: Extremadura (€303.1 per person), Asturias (€277.2 per person) and Galicia (€266.3 per person), while the lowest figures corresponded to the two regions with the greatest overall expenditure: Cataluña (€195.7 per person) and Madrid (€192.1 per person).

**Most Spanish regions saw an increase in pharmaceutical expenditure** per capita in 2019, except for Navarra (-1.2%) and the País Vasco (-2.0%). Those regions with the greatest growth rates were the Islas Baleares (+7.8%) and Murcia (+7.4%), while the smallest increases were in Aragón (+0.5%) and La Rioja (+0.3%).

**PHARMACEUTICAL SPENDING PER CAPITA BY REGION (2019)**

| Region | Spending share (%) | € per capita | Increase (%) |
|---|---|---|---|
| Extremadura | 3.0% | 303.1 | 1.6% |
| Asturias | 2.6% | 277.1 | 2.2% |
| Galicia | 6.6% | 266.3 | 1.3% |
| Castilla y León | 5.8% | 263.2 | 3.0% |
| Cantabria | 1.3% | 258.4 | 2.5% |
| Castilla La Mancha | 4.8% | 257.9 | 2.3% |
| Cantabria | 1.3% | 258.4 | 2.5% |
| Valencia | 11.9% | 257.9 | 1.1% |
| Aragón | 3.1% | 253.2 | 0.5% |
| Murcia | 3.4% | 252.4 | 7.4% |
| Islas Canarias | 4.9% | 246.1 | 6.3% |
| La Rioja | 0.6% | 231.8 | 0.3% |
| **Total Spain** | **100%** | **229.5** | **2.3%** |
| Andalucía | 17.6% | 225.9 | 3.3% |
| País Vasco | 4.4% | 217.1 | -2.0% |
| Navarra | 1.2% | 208.4 | -1.2% |
| Islas Baleares | 2.1% | 197.0 | 7.8% |
| Cataluña | 13.9% | 195.7 | 1.9% |
| Madrid | 11.8% | 192.0 | 1.9% |

**Source:** Medical prescription invoicing (MSSSI) and municipal electoral roll figures (INE).

# 04

# MEMBER SERVICES

# 4.1 Online Services

Both the management procedures and communications services of FARMAINDUSTRIA are integrated within a network of portals, giving FARMAINDUSTRIA speedy access to its member companies and the general public.

To begin with, our general interest portals (Members' Intranet, Public Portal and Self-Regulatory System), along with our focused sites (Innovative Medicines Platform, Proprietary Medicine Classification, Series and Tables, and the Cybersecurity site) serve to filter and channel any quality information that could be of value to our member companies.

FARMAINDUSTRIA meanwhile maintains a number of internal management tools to handle membership processes and to administer regulatory procedures, along with the application of deductions derived from Royal Decree-Act 8/2010, or the refunds caused by differences between the prices notified and financed.

## Corporate Website. Intranet with the Industry. Working Groups.

For the exclusive use of **member companies,** this contains over 90,000 documents grouped into over 50 categories, including circulars, publications, departmental areas, flashes, newsletters, regulations, etc.

It has a personalised home page for each of the **2,000 registered users** in the industry, allowing them to choose what should be summarised on their home page and what they can access with a single click.

Each of the working groups run by FARMAINDUSTRIA has a private space, providing fast, secure and orderly access for over 1,400 members. This also includes documentation repositories for the **Association's Statutory Groups**.

The key improvements and additions made during the year featured a complete overhaul of the search engine, two new working groups, and various revisions of the departmental working areas.

## Public Website

The FARMAINDUSTRIA public website is especially designed to **convey information clearly, quickly and openly** to anyone interested in the Spanish pharmaceutical industry.

A new weekly newsletter was added last year, with the most prominent information about the industry and medicines, reaching more than **5,000 subscribers**.

## New Concept for the Innovative Medicines Site

Over the year, the **Spanish Technological Platform for Innovative Medicines** site was completely overhauled, adding new information areas and new means of communication.

There was likewise a complete redesign of the monthly newsletter to give it a more streamlined and modern format, highlighting its technical and informative nature. This newsletter reaches over **1,200 subscribers**.

## Somos Pacientes

Somos Pacientes is a community providing a shared forum for information, participation, training, services and collaborative efforts**, intended for all patient (and disabled) associations** in Spain.

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

## Self-Regulatory System Website

The **pharmaceutical industry self-regulatory system** represents the response of 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.

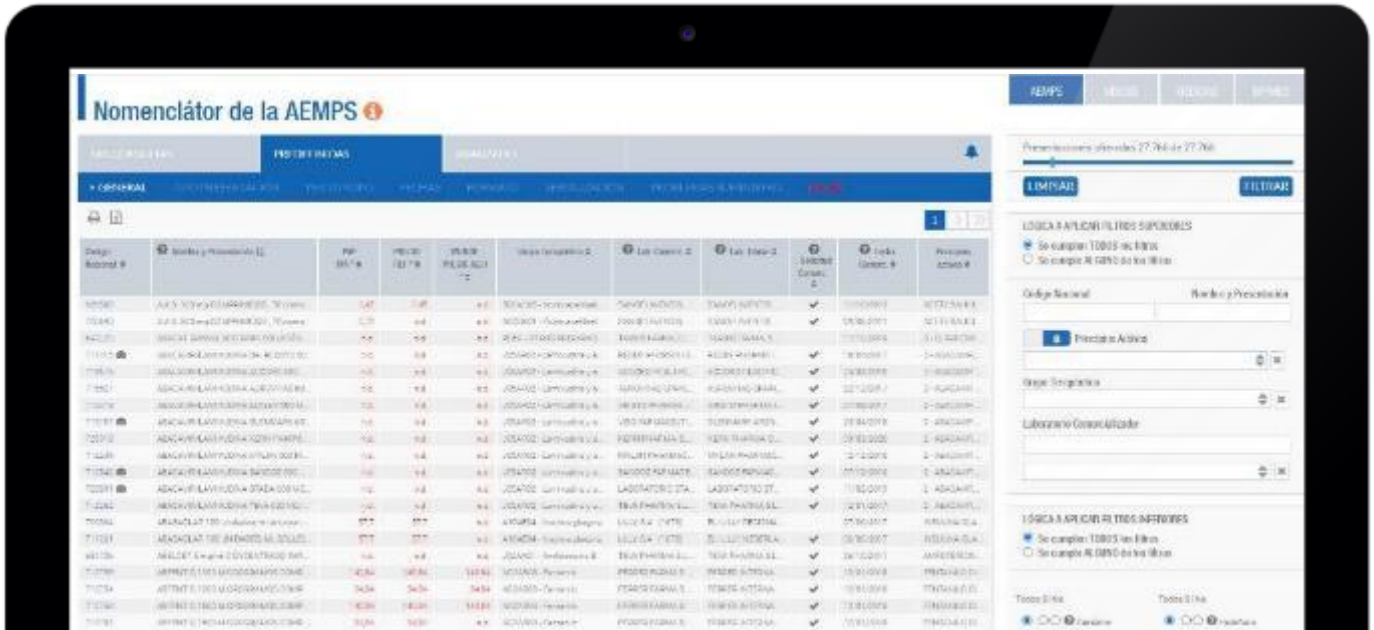
With the aim of supporting the establishment of these standards and criteria of conduct, the portal and its microsite developed the **Code of Good Practice**.

This website provides access not only to the **Code of Good Practice** and the **Practical Case Test,** but also to full information on transparency, control bodies, regulatory framework, a list of training activities, as well as an area reserved for the management and reporting of events and scientific meetings.

## Four Microsites for Proprietary Medicines Classification

In order to facilitate access by member companies' technical teams to the Ministry of Health and the AEMPS' Invoicing and Prescription Classification, FARMAINDUSTRIA has developed four analytical microportals.

This is a **consultation and filtering tool handling all information** submitted by the two institutions. During 2019 a new database provided publicly by the Ministry of Health **(BIFIMED)** was added, simplifying access to information about the financing of medicines.



## Series and Tables Portal

This is a proposal to organise and provide access to the data series on **Expenditure, Personnel, GDP, Demographics and Spanish Regions** most used by our sector.

It contains more than **3,000 data series,** grouped into some 100 categories, including sources and information of value regarding the origin of each series and how it was obtained.


## Deduction-Management Portals

These are four portals allowing the application of deductions derived from the application of Royal Decrees-Acts 8/2010 and 10/2010.

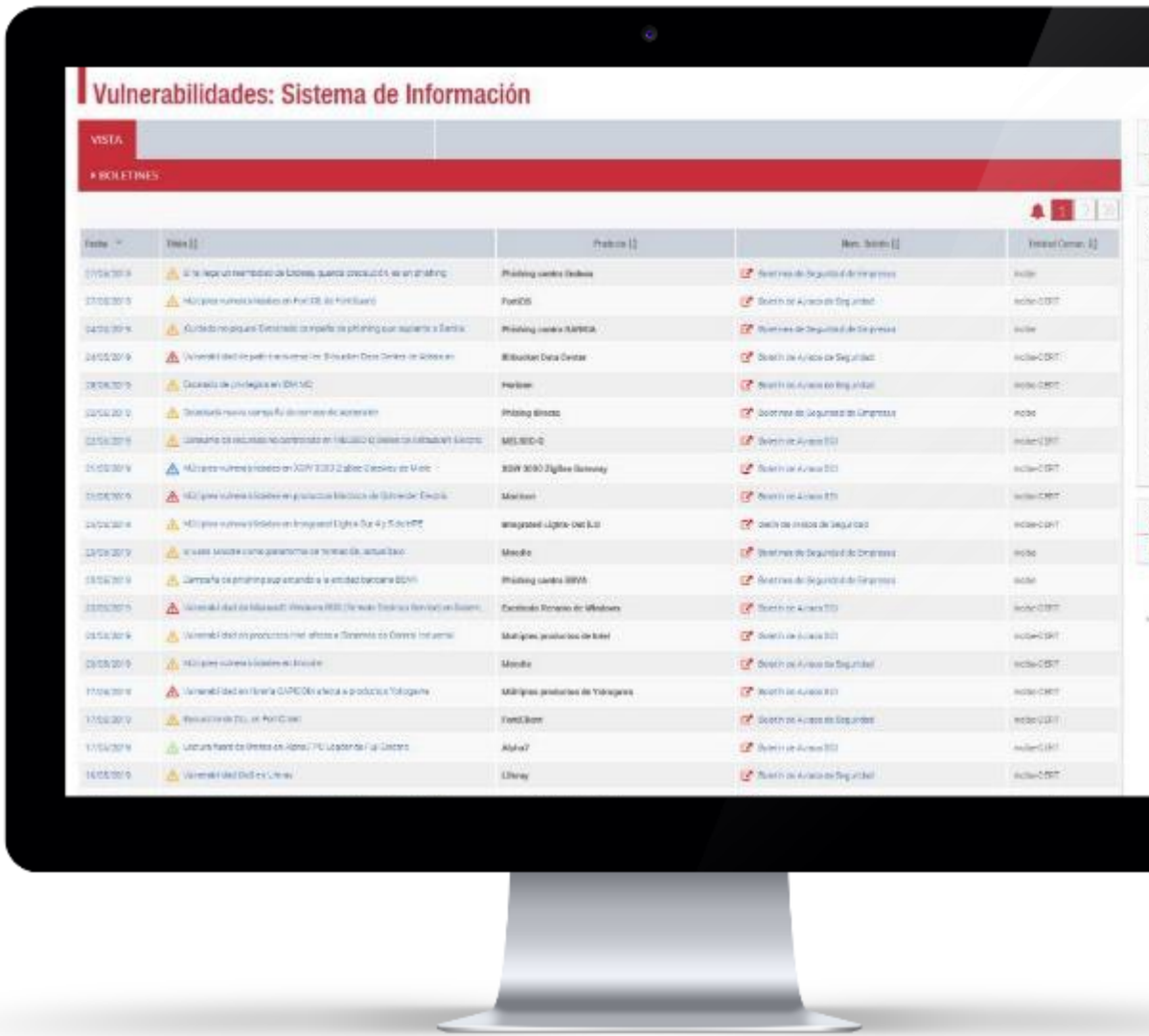
Through these **four tools,** Official Associations of Pharmacists, pharmaceutical manufacturers, the General Council of Official Associations of Pharmacists **(CGCOF)** and the bank involved can all comply with the agreed procedure.

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

## Cybersecurity Vulnerabilities Website

As part of the FARMAINDUSTRIA project to support improvements in the security of our information systems, aside from the creation of a specific Cybersecurity Working Group at the Association, in 2019 a website was set up with **information about vulnerabilities in the different** hardware and software that the companies use.

It receives security alerts that the various agents provide openly, reflecting the type of report currently in demand from the Working Group.



# 04

# MEMBER SERVICES

4.1 Online Services

**4.2 Working Groups/Barcelona Office**

4.3 Spanish Technological Platform for Innovative Medicines (PTEMI)

4.4 Self-Regulatory Systems

# 4.2 Working Groups

Having been set up by the governing bodies of the Association, the working groups **help to serve members** by providing up-to-date information on the topics covered by each group. Coordinated by the different FARMAINDUSTRIA departments and organised into topics of interest to the pharmaceutical industry, the purpose of the working groups is to foster companies' active participation in the work of the Association, to explain the legislative or regulatory initiatives of the various **public authorities,** and to draw up sectoral arguments or follow up on action plans addressing issues of relevance for the industry in order for the Association to pass on information to the corresponding authorities and interlocutors in due time.

The working groups are governed by specific operational guidelines, the overriding principles being regulatory compliance in the field of competition (the contents of which preside over all the groups' meetings), **confidentiality, personal data protection and legal compliance**.

There are currently **24 working groups in operation** at FARMAINDUSTRIA:

1. Sustainability and Economic Regulation
2. Health Technology Assessment (HTA)
3. Hospital Debt
4. Hospital Market
5. Technical Regulation of Medicines
6. Biotherapeutic Medicines
7. Manufacturing and Traceability
8. Environment
9. Pharmacovigilance
10. Vaccines
11. Pharma-Biotech
12. Medical and Research Directors (BEST)
13. Clinical Research
14. Legal Services
15. Taxation
16. Human Resources
17. Code of Good Practice
18. International
19. Relationships with Spanish Regions
20. Trademark Protection
21. Communication and Corporate Social Responsibility
22. Patients
23. Incremental Innovation
24. Cybersecurity

In addition, with the aim of **adopting a more in-depth approach to various aspects,** a number of *ad hoc* groups have been set up, with their results being referred to the plenary working group to which they are attached.

The activities of the various FARMAINDUSTRIA working parties over the course of 2019 are summarised below.

## Sustainability and Economic Regulation Working Group

Over the course of the year this Working Group **(GT-ECO)** continued to analyse Parliamentary initiatives and regulations connected with **economic regulations in the sphere of the pharmaceutical sector,** along with the key developments in this field.

FARMAINDUSTRIA has provided the groups with regular information as to the indicators and development of the **Collaboration Agreement with the Spanish Government,** in force since 2015, with the shared aim of guaranteeing the sustainability of the NHS and providing citizens with access to innovations.

This Working Group receives detailed information on the monitoring of access to innovations and related indicators generated by the Association, monitoring in particular the publication and case study of the **'IPT' Treatment Positioning Reports**.

In this regard, an ad hoc group comprising members of the GT-ECO and GT-HTA groups worked on the preparation of **various IPT proposals** so as to streamline the preparation process, improve the procedure and achieve greater coordination with the pricing and public financing procedures for new medicines.

In turn, regular reports were provided to the group as to the contents of updates to the 2019-2022 **Stability Programme,** along with the proposals made by the **AIReF** in this field within the context of the Spending Review.

The group has over the course of its meetings addressed a series of significant issues connected with the decisions of the **CTBG (Transparency and Good Governance Council),** the public financing of medicines with an explicit decision of non-inclusion under the pharmaceutical provision of the NHS, the information system for the measurement of therapeutic value in actual clinical practice of medicines with a high medical and economic impact on the NHS *(Valtermed),* and accreditation of patent protection of medicines affected by the deductions established in Royal Decree-Act 9/2011, among others.

The group meanwhile conducted an analysis of the action plan to promote generic and biosimilar medicines drawn up by the Ministry of Health, after FARMAINDUSTRIA had conveyed its observations on this text.

This Working Group's members conducted detailed monitoring of the processing of the regulatory project, arguments and subsequent publication of Order SCB/953/2019, of 13 November 2019, implementing the update of the **NHS** medicine pricing reference system.

In turn, in coordination with the Manufacturing and Traceability Working Group, the GT-ECO closely monitored the work conducted by FARMAINDUSTRIA and SEVeM to comply with the provisions of the Falsified Medicines Directive and the Delegated Regulation by the specified deadline of 9 February 2019. Regarding this matter, on 6 December 2019 the Official State Gazette published Royal Decree 717/2019, amending Royal Decree 1345/2007, of 11 October 2007, regulating the procedure for the authorisation, registration and dispensation conditions of industrially-manufactured medicines for human use, one of the purposes thereof being to adapt Spanish regulations in accordance with the European regulatory framework for the verification and authentication of medicines.

## Health Technology Assessment (HTA) Working Group

This Working Group was set up at FARMAINDUSTRIA with the aim of issuing proposals and developing technical documents regarding the main aspects affecting procedures for the economic assessment of medicines, such as: relative effectiveness, therapeutic positioning, degree of innovation, selective financing, measurement, analysis and usage of health outcomes in healthcare decision-making, etc.

The GT-HTA has representatives from some 50 companies, with a membership profile centred very much on market access and health economics & research outcomes. During 2019, monitoring continued of the main initiatives in progress in the field of measuring health outcomes, both nationally and internationally, with a particular emphasis on the ICHOM project and the ***Do-It*** programme under the initiative ***IMI 2 Big Data for Better Outcomes*** **(BD4BO),** conducted between 31 January 2017 and 31 January 2019, in which FARMAINDUSTRIA was involved.

At the domestic level, analyses were conducted of the main national and regional initiatives in the field of assessment of new medicines, with a particular emphasis on **Therapeutic Positioning Reports** and their subsequent implementation in the Spanish regions, as well as the **GENESIS Reports**.

Lastly, at the international level the Group closely followed the advances in the (still ongoing) processing of the **Proposed European Commission Regulation** in the field of **HTA,** which promotes a joint, binding clinical assessment of new medicines for all EU countries, and the main implications of this for Spain.

## Hospital Debt Working Group

The GT-DH analyses the evolution of the commercial debt entered into by NHS hospitals as a result of the supply of medicines, by means of monthly monitoring of balances receivable from regional Health Services and the average payment periods **(DSOs)**. Future forecasts are likewise made in accordance with the evolution of the different macroeconomic variables, the extraordinary liquidity mechanisms established by the **Government,** and the information obtained from the Spanish regions themselves.

During 2019 the group very closely followed the key events in terms of payment default, such as the work in progress to reform the regional financing system, the processing of the **General State Budget** and the regional budgets, the resources provided by the **Financing Fund** to the Spanish regions (FLA and FFF), the processing of the AIReF Report on hospital pharmacy expenditure, and monitoring of the average paymentperiods, published monthly by the **MINHAC,** and their implications as regards the Public Sector Commercial Debt Supervisory Act, without overlooking the processing of other regulatory proposals in progress, intended to combat late payment in trade operations.

The GT-DH is mainly made up of the financial directors of almost 60 companies which make up the body, its functions having included since 2016 the monitoring and analysis of all financial developments connected with the Collaboration Agreement signed by FARMAINDUSTRIA with the Government, through the Ministries of Public Finance and Health.

Lastly, since mandatory implementation of the system in January 2015, the group has monitored in detail all the developments in terms of electronic invoicing with the public sector through the **Electronic Invoicing Ad Hoc Subgroup (SG-FAC)**.

Over the course of 2019, the **SG-FAC** continued to monitor advances in this field, establishing direct dialogue with the **Ministry of Regional Policy and Civil Service,** the Inspectorates-General of the Spanish regions, health services and healthcare centres in order to rectify any incidents that might arise in this field, in accordance with electronic-invoicing regulations.

In turn, the Association continued to participate on the various forums connected with electronic invoicing:

- The e-invoice Forum of the Ministry of Regional Policy and the Civil Service
- B2B FACe Working Group
- CEOE Digital Society Commission

## Hospital Market Working Group

In 2019 this Working Group, made up of **52 companies,** continued to analyse the hospital market by monitoring and studying the various initiatives undertaken at the national and regional levels, above all the key developments in the sphere of **public hospital procurement**.

This Working Group constantly monitors access to innovations in the various Spanish regions, and any policies that might limit the offering of and access to innovative medicines or freedom of prescription.

In accordance with its purpose, this Working Group also coordinates closely with the working groups on Hospital Debt, Biotherapeutic Medicines, Trademark Protection, Relationships with Spanish Regions and Economic Regulation.

## Technical Regulation of Medicines Working Group

The main activities of this Working Group centre on analysing and making contributions to prepare the industry's posture with regard to regulations issued by European institutions and any published by the Ministry of Health and the **AEMPS** with regard to procedures for the authorisation, registration and marketing of medicines. This Working Group focuses on an analysis of matters with a substantial technical component, such as levies, labelling and information leaflets, authorisation applications and modifications, approval of authorisations, classification of medicines with no commercial interest, etc. The group likewise conducts constant monitoring of the functioning and decision-making periods of the **AEMPS**. Ad hoc parties are also set up where necessary to address specific issues.

In 2019, the Working Group analysed, among other issues:

1. **Access to and usage of medicines** in special situations with an explicit decision not to finance.
2. **The future national regulations** which will incorporate certain aspects regarding the serial numbering and verification of medicines and will modify certain aspects of the authorisation and registration procedure of industrially-manufactured medicines for human use, as well as the aggregation of codes for hospitals to facilitate the reading and verification of the unique IDs.
3. **Preparations by pharmaceutical companies** in advance of *Brexit*, given the substantial changes in the pipeline with regard to the registration of medicines.
4. The **Plan to Promote Biosimilars and Generics**.
5. **Interruption of supply of submissions,** an absence of which could have healthcare impacts.
6. **Incremental innovation,** in order to highlight the importance of the continuous improvement of off-patent medicines.
7. **The presentation of conclusions** of the risk analysis on the formation and presence of nitrosamine impurities in medicines containing chemically-synthesised active substances.

## Biotherapeutic Medicines Working Group

Given the importance and distinctive features of biotherapeutic medicines, FARMAINDUSTRIA set up this Working Group in order to specifically monitor the key aspects affecting this category of medicines in terms of regulation, authorisation processes and access both nationally and internationally. The agenda of its meetings also always includes an analysis of the issue of **orphan medicines**.

Biotherapeutic medicines have distinctive characteristics that set them apart from chemical medicines. From a regulatory point of view, the uniqueness of **biotherapeutic medicines** determines their prescription by trade name (trademark), with notification likewise by trademark and batch number.

They are also considered medicines that require special monitoring for the purposes of pharmacovigilance (in accordance with Article 3 of Royal Decree 1718/2010, on medical prescriptions, and Article 5 of Royal Decree 577/2013, on pharmacovigilance). The group monitors public initiatives, studies competitive procurement tenders, and analyses the international situation in this field.

One of the main aspects addressed during the year was the publication of the draft paper entitled "Action plan to promote the use of market-regulating medicines in the **NHS**: biosimilar and generic medicines". This plan includes the definition of a national positioning in terms of the interchangeability of biosimilar medicines in the **NHS**, which would be developed by the Standing Pharmacy Commission, and approved by the **NHS Inter-Territorial Council**. As FARMAINDUSTRIA set out in the comments made on the draft text, a positioning in the field of interchangeability of biosimilar medicines would be difficult to tally with the responsibilities of the Commission and of the aforementioned **Inter-Territorial Council**.

The interchangeability of medicines demands specific regulations which must be drawn up on a scientific basis confirmed by the corresponding studies and with the participation of all agents involved, respecting patient rights and the responsible practice of the different healthcare professionals.

## Manufacturing and Traceability Working Group

This group monitored the field of manufacturing and distribution of medicines, as well as the proper application of the serial numbering demands set out in **Commission Delegated Regulation (EU) 2016/161**. The dynamic of this group's meetings increased considerably following the declaration of the state of emergency caused by the Covid-19 health crisis, focusing on issues of the supply of essential medicines which require daily accounting by the holder of the marketing authorisation.

Over the course of March and April 2020, the companies' contingency plans were successfully applied, guaranteeing the supply of the medicines required by the country. Meetings became weekly, allowing for the monitoring of incidents and providing a much more intense collaboration within the Working Group, which was extended to include representatives of all member companies with manufacturing sites in Spain.

## Environment Working Group

During 2019 this Working Group collaborated closely with SIGRE in monitoring national and European legislation in the environmental field connected with the pharmaceutical sector: waste, circular economy, climate change, environmental responsibility, energy efficiency, European Green Deal, potential soil-polluting activities and discharges.

FARMAINDUSTRIA likewise continues to be represented on the Environmental Commissions of **CEOE and FEIQUE/FEDEQUIM**.

## Pharmacovigilance Working Group

This Working Group **channels the main questions and clarifications derived from both national and European pharmacovigilance provisions**.

In 2019, the development of the Royal Decree on Pharmacovigilance was monitored. As for future regulations, the following should be noted:

1. The **monitoring of the future Royal Decree** governing observational studies with medicines and the possible discontinuation of certain types of *Patient Support Programmes*, as it is anticipated that only those developed within the context of an observational study with medicines may be conducted in Spain.
2. The **monitoring of the guidelines** to be covered by the future Code of Conduct in the sphere of pharmacovigilance following the publication of Regulation (EU) 2016/679, of the European Parliament and of the Council, of 27 April 2016, on the protection of natural persons with regard to personal data and on the free movement of such data, and the Spanish Personal Data Protection and Guarantee of Digital Rights Act 3/2018.

3 The monitoring of the planned circular regarding materials for the prevention of risks in medicines for human use that will allow distribution thereof with due authorisation by the **AEMPS** through scientific societies, as currently occurs with the safety letters sent to healthcare professionals **(DHPCs)**.

The meetings of the Working Group also address **six clearly defined topics**:

- Inspection and audits
- Risk-management plans
- Master file
- Expedited reporting
- Periodic safety reports
- Pharmacovigilance PSPs and solutions

## Vaccines Working Group

The key issues addressed by this Working Group in 2019 include in particular the need for continued cooperation with scientific societies and authorities in the dissemination of messages as to the value of vaccines. In this regard, the **Director General for Public Health at the Ministry of Health** was invited to one of the meetings in order to gain a first-hand insight into the Government's initiatives, and to convey the companies' main concerns to her in this field.

The Working Group likewise collaborated on initiatives to communicate the value of vaccines promoted by *Vaccines Europe.* The future approach to vaccination will, of course, this year be impacted by the outbreak of Covid-19. In turn, it is also unknown whether the health crisis will lead to a substantial change in the demand for respiratory vaccines (such as the flu and pneumococcus vaccines), and the monitoring efforts of this Working Group over the coming months will therefore be of particular relevance in the field of both public health and vaccine supply.

## Pharma-Biotech Working Group

This Working Group, made up of 39 companies, works on goals such as promoting cooperation between the pharmaceutical industry, small biotechnology companies and public research centres, highlighting the differential, complementary aspect that FARMAINDUSTRIA can contribute.

In 2011, FARMAINDUSTRIA launched the *Pharma-Biotech* cooperation programme and since then 18 interactive meetings have been held between the two sectors in the areas of the central nervous system, oncology, respiratory system, inflammation and autoimmune diseases, among others.

42 companies and 31 research centres and hospitals participated in these meetings, presenting the advanced research projects selected for their potential for innovation. The various gatherings featured representatives of more than 116 public and private sector agents. Since it was launched in 2011, this programme has analysed **543 R&D projects** for new medicines, of which **133 were presented** to pharmaceutical companies, to date generating 44 new molecules in the development phase.

The most significant aspect of this initiative is that it has built a bridge between researchers and small biotech companies working on highly promising projects, and pharmaceutical companies that have the required resources and technology to embark on clinical research in an attempt to deliver new medicines to patients.

This Working Group likewise aims to **promote instruments for public-private cooperation** in R&D, hence the various meetings conducted with the **CDTI (Centre for Technological and Industrial Development)**.

This Working Group also seeks to stimulate the participation of companies in national and international pharmaceutical R&D programmes, especially the ***Innovative Medicines Initiative*** **(IMI)** and the actions of the **Spanish Technological Platform for Innovative Medicines (PTEMI)**. One particularly important aspect here has been the engagement by companies in the various calls for international public-private cooperation launched to combine efforts in researching Covid-19.

## Medical and Research Directors (BEST Project) Working Group

This Working Group, set up 14 years ago as a platform for excellence in clinical research, falls within the scope of the **Spanish Technological Platform for Innovative Medicines (PTEMI)** and is focused on the strategy and promotion of competitiveness in clinical research in Spain, facilitating processes and improving performance indicators (time, recruitment, international comparison) to achieve the best environment for conducting clinical trials in this country, with particular emphasis on early phases.

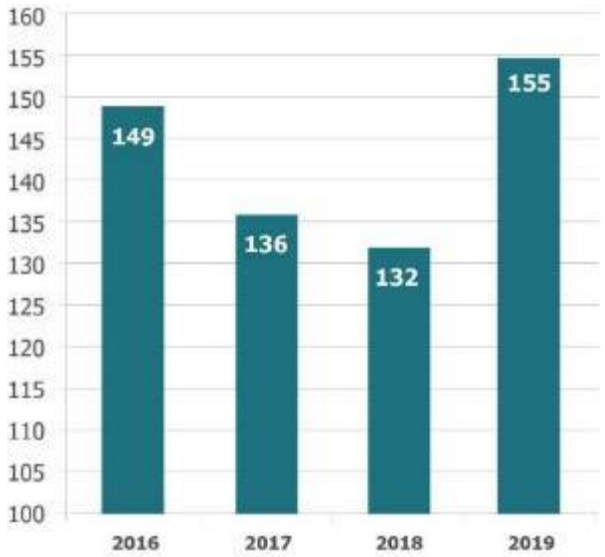
Spain has managed to position itself at the forefront of European clinical research (with Spanish involvement in three out of every ten trials on the continent) with the following highlights:

- Increased **involvement** by stakeholders (hospitals, researchers, scientific societies, patients, Medicinal Research Ethics Committees (CEIM), etc.)
- Spain's greater international **competitiveness** in the field of clinical research
- **Improved dialogue** between strategic agents (industry, research sites and Spanish regions)
- **Pioneer regulations** at the European level with the aim of promoting clinical research

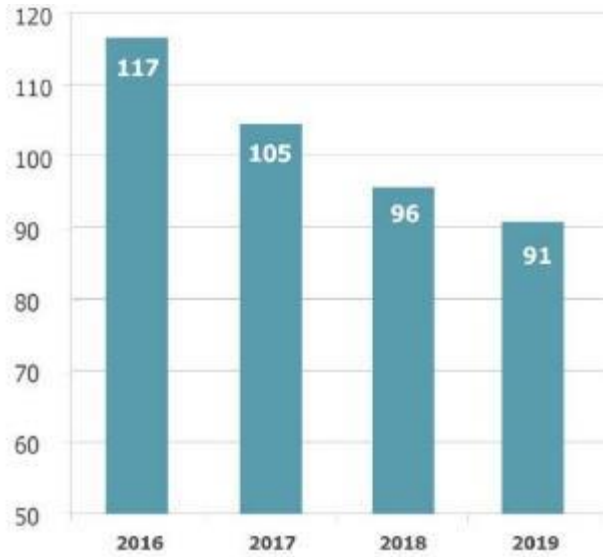
During 2019 and in early 2020, the research sphere highlighted the need to redesign new strategies so as to maintain and underpin Spain's progress in this field, against an international backdrop of considerable competition. Over the period 2016-2018 the average time to launch a clinical trial was 140 days, which had been brought down to 132 days by the end of 2018.

The figures for 2019 indicate that the waiting time has increased to 155 days. FARMAINDUSTRIA is advocating for a reinforced role by the **AEMPS** in order to maintain our country's competitiveness in biomedical R&D.

**LAUNCH**




**AGREEMENT**




**Advance Figures from the 28th Publication. Data as at 31 December 2019**

The lead times for the launch of clinical trials are a decisive factor in achieving investment in this field, and had furthermore been substantially reduced following the entry into force of the **2015 Royal Decree on Clinical Trials**. Particular mention should also be made of the centres' efforts to cut the time it takes to sign the agreements needed to launch such trials, with continuous reductions over the period 2016-2019.

During 2019, within the context of the **BEST Project,** a working sub-group on Early Phases was set up and has begun to review and design the process of updating the Guide on Early Phase Clinical Research Units. Work was also performed over the course of the year on the definition of excellence criteria for the selection of sites to perform clinical trials.

In July 2019 a workshop was staged in Madrid, bringing together sponsors, clinical researchers and trial organisers, to debate in depth the increasingly demanding requirements for cutting-edge clinical research, and the challenges in maintaining and improving Spain's competitiveness in the field of clinical trials.

The efforts of the 120 experts who took part at the workshop resulted in the publication of a list of excellence criteria in clinical research. The document sets out the need to encourage the generation of new clinical trial designs so as to improve timing in clinical development and the incorporation of quantitative and qualitative metrics serving to identify areas for improvement to which efforts could be dedicated so as to improve competitiveness.

There also needs to be a commitment to increased flexibility in adapting to new monitoring procedures, which will require mechanisms for remote monitoring, as highlighted during the management of the Covid-19 crisis, a field in which FARMAINDUSTRIA is working with the **AEMPS** and the **AEPD (Spanish Data Protection Agency)** to establish such monitoring through the adoption of appropriate security measures and guarantees.

During 2019 work continued with patients' associations, including the staging of workshops, the last of these taking place in webinar format in April 2020, organised by the **European Patients' Academy in Spain (EUPATI Spain)**. The webinar served to explain that the difficult situation throughout the health system in general, in particular hospitals, generated by the Covid-19 pandemic had exerted considerable tension on research activities, given the need to focus the bulk of resources at sites to address the urgency of the crisis, along with such added difficulties as the increased risk of contagion for patients participating in trials when visiting the hospital.

Active efforts were made during 2019 to encourage biomedical research in Spain, with a high level of involvement at a range of forums, seminars and workshops organised by public and private bodies. Likewise, in October 2019 FARMAINDUSTRIA took part as a guest at the Health Forum and the **26th Pharmaceutical Forum of the National Business Association of Colombia,** held in Cartagena de Indias and bringing together more than 1,400 representatives of the health sector and pharmaceutical industry in the field of clinical research in Iberia and Latin America. The **BEST** project was presented at this forum as a success story of public-private partnership in Spain for biomedical research.

## Clinical Research Working Group

Over the last year, this group carried out intense monitoring of Spanish and European legislative initiatives regarding clinical research, in particular Regulation 536/2014, of the European Parliament and of the Council of 16 April 2014, published in the OJEU on 27 May 2014, and Royal Decree 1090/2015, of 4 December 2015, regulating clinical trials with medicines, medicinal research ethics committees and the Spanish Clinical Studies Register.

Both texts pursue **greater transparency, simplification and harmonisation of processes,** in order to make clinical research more competitive. Spain was the first country in the EU to implement the new European regulation on clinical trials.

During 2019 a number of meetings were held within the context of this Working Group with representatives of the **AEMPS**. During 2019, FARMAINDUSTRIA also made strenuous efforts for the Supplemental Instructions Document of Royal Decree 1090/2015, of 4 December, to respond to the sector's needs and likewise worked with the **AEMPS** and **Medicine Research Ethics Committees** to align the annexes to this document with the demands of the pharmaceutical industry, with a translation into English. All this information is available on the AEMPS website.

Likewise, progress was made over the course of last year on updated work on the new code of conduct to protect data in clinical research and pharmacovigilance, presented to the AEPD in December 2019. Meanwhile, at the meeting of the Working Group on **Data Governance** held at **EFPIA** in December 2019, FARMAINDUSTRIA presented its 10 years of experience in this field and the key developments in the new Code, to a very positive reception. **EFPIA** in fact resolved to analyse the new Spanish code so as to assess whether it could be adapted at the European level, with a flexible and dynamic approach given the nature of the topic addressed.

Work was furthermore performed with the Working Group for **Medicines Research Ethics Committees** and with patients in an attempt to adapt informed consent forms in line with the new European and national data protection regulations. Various meetings were held in this regard with all the groupings involved.

During 2019 the Working Group comprising representatives of the parties for **Patients, BEST** and **Clinical Research** at FARMAINDUSTRIA, together with the representatives of patient associations **(EUPATI and the Patients' Organisations Platform),** produced a document entitled "Recommendations for the Integration of Patient & Patient Associations' Participation in the Pharmaceutical R&D Process", with the working group involved in this initiative concluding, among other aspects, that at least eight spheres could be identified for the effective and valuable integration of patient participation and contributions in the process of biomedical R&D:

- **Identification** of unmet needs and definition of research priorities
- **Generation** of materials for patient information and education about medicinal R&D
- **Awareness outreach** of pharmaceutical R&D for patients and society at large
- **Participation** in the authoring of protocols for clinical trials and informed consent forms
- **Exploration and dissemination** of clinical trials of interest for each pathology
- **Contribution** to the drafting of executive lay summaries of clinical trials
- **Collaboration** in the recruitment of patients to take part in clinical trials
- **Identification of patient associations** with an interest in participating in industry R&D activities

In the month of November 2019 FARMAINDUSTRIA staged its Explanatory Forum on Understanding "The Role of Hospital Pharmacy in Clinical Trials" at the **RANF (Royal National Pharmacy Academy),** with the aim of exchanging experience and know-how, the ultimate goal being continued progress in improving the quantity and quality of clinical trials conducted in Spain, in which hospital pharmacists play an important role.

Since the outbreak of the Covid-19 health crisis in March 2020, this Working Group has, together with the Medical and Research Directors (BEST) Working Group, been comprehensively monitoring the status of clinical trials in progress and their continuation, alongside the AEMPS, the **Medicine Research Ethics Committees Group,** the AEPD, hospital centres and patients' associations, with the main focus on collaboration to ensure that sponsors can conduct remote monitoring in certain types of trials, monitor digitalisation measures for the management of clinical trials adopted by hospitals, and report to patients' representatives as to the status of those clinical trials in progress. Active efforts are also being made to facilitate the swift approval of new trials focused on Covid-19.

## Legal Services Working Group

During the period covered by this **Annual Report,** this Working Group's activities centred on monitoring all those aspects that because of their legal implications are of relevance to its members, along with other company departments receiving legal support.

As is now traditional, and notwithstanding any developments that might be so required (such as the recent regulations adopted as a result of the Covid-19 health crisis), meetings continue to be conducted twice per year, along with fluid communication by email regarding all aspects impacting on the pursuit of company activities.

All those issues involving our regulatory framework, as detailed in other subsections of this Annual Report, as well as case law and key reports with repercussions for the sector, have been featured on the regular agenda at the meetings of this Working Group.

By way of example, mention might be made of the following:

1. **Note from the DGCBSF** on public financing of medicines with an explicit decision for non-inclusion under pharmaceutical provision, this note being based on a report by the State Legal Services Office, accessed under the terms of the Transparency Act.

2 **AIReF Spending Review Report** in connection with pharmaceutical expenditure at retail pharmacies, including such measures as the possible widespread application of competitive tenders at the national level, the modification of the deductions under Royal Decree Act 8/2010, and modification of the Reference Pricing System.

3 **Transparency Regulation,** with a number of appeals being submitted so as to resolve the debate on confidentiality and transparency, requesting the explicit inclusion that information protected as confidential by some other specific guarantee (Article 97.3, Guarantees Act) or that could be protected by the Business Secrets Act (Article 3.2) would take priority over transparency. Mention should be made in this sphere of the decision of the CTBG of 26 September 2019, denying access to information on the financing conditions of a medicine, holding that the confidentiality of said information is in the public interest, along with Interpretation Criterion 1/2019, of 24 September 2019, in connection with Article 14.1(h) of the Business Secrets Act, when access to the information would be to the detriment of economic and commercial interests.

4 **Plan for promotion of generics and biosimilars,** covering initiatives such as prescription by active substance and prioritisation of generics based on criteria of efficiency and substitution for the lowest-priced medicine, among other aspects, regarding which pronouncements have been issued by the CNMC and the Advisory Committee for the Financing of NHS Pharmaceutical Provision, concerning which the relevant arguments were submitted, emphasising that such actions could distort competition without generating savings for the NHS, clearly to the detriment both of the innovative pharmaceutical industry operating in Spain, and to the national economy.

## Taxation Working Group

This Working Group's priorities focus on the **analysis and monitoring** of issues with taxation implications for the pharmaceutical sector.

At the beginning of 2019, the traditional Annual Taxation Changes Seminar was held, open to all member companies and attended by numerous managers in charge of tax and finances from the pharmaceutical companies. Over the course of the event, statements and legal theory in the field of medical congresses were shared, following the reform of Article 44 of the Spanish Personal Income Tax Regulation. Other topics of interest were likewise addressed, such as a status report on the first year in operation of the **SII (Immediate VAT Information Provision System)** and the transfer of this system to the Islas Canarias, regulations in the field of good taxation practice, and taxation measures planned in the General State Budget Act for 2019.

The Group has likewise monitored and analysed the handling for VAT purposes of the amounts payable to the NHS under the terms of the Collaboration Agreement signed by the Government and FARMAINDUSTRIA.

Meanwhile, the group received individual reports on case-law and legal theory published over the course of the year in connection with transfer pricing, the regularisation of related-party operations, the handling of personal income tax on the minimum compensation for the discharge of senior executives, and the **Tax on the Increased Value of Urban Land**.

Lastly, when this Annual Report went to press, the Working Group was conducting a detailed analysis of the various regulatory provisions and measures introduced in the field of taxation and customs as a result of the health crisis caused by Covid-19.

## Human Resources Working Group

Major reforms took place during the month of March 2019 within the context of employment on the initiative of the interim Government by means of Royal Decree-Acts, which were covered by the 2018 Annual Report. Nonetheless, one of these Royal Decree-Acts, specifically 8/2019, of 8 March 2019, on urgent measures for social protection and to combat precarious employment in terms of working hours, became particularly significant for all sectors, above all with regard to the new obligation for companies to have a daily record of when workers clock in and out each day, a requirement from May 2019 onwards and which influenced the Working Group's efforts.

The Group has likewise received ongoing reports on the various Royal Decree-Acts published over the course of the year, including **Royal Decree-Act 18/2019,** of 27 December 2019, adopting certain measures in the field of taxation, the land survey and Social Security, and **Royal Decree-Act 1/2020,** of 14 January 2020, establishing the re-evaluation and maintenance of pensions and public benefits under the Social Security system, and **Royal Decree-Act 4/2020,** of 18 February 2020, repealing objective dismissal because of non-attendance at work.

Lastly, the Covid-19 crisis brought with it the introduction of a homeworking model, and so far the authoring of this Annual Report has been conducted by means of three videoconference group meetings.

These meetings analysed numerous topics:

1. The **volunteering schemes** being undertaken by the industry.

2. **Royal Decree-Act 8/2020, of 17 March 2020,** on urgent and extraordinary measures to address the economic and social impact of Covid-19, including significant measures in the field of **ERTE** furlough schemes, flexibility, adaptation of working hours, mobility/attendance at workplaces.

3. **Royal Decree-Act 9/2020, of 27 March 2020,** adopting supplementary measures in the field of employment to offset the effects derived from Covid-19, according to which force majeure, economic, technical, organisational and production causes covering measures for the suspension of contracts and reduction of working hours, cannot be deemed as justifiable reasons for the termination of employment contract or redundancy.

4. **Royal Decree-Act 10/2020, of 29 March 2020,** governing recoverable paid leave for employed workers not providing essential services, in order to reduce the mobility of the population within the context of combating Covid-19, under which the main activities of the pharmaceutical industry were considered to be essential.

5. **Royal Decree-Act 11/2020, of 31 March 2020,** adopting urgent supplementary measures in the social and economic sphere to address Covid-19.

The group has likewise received regular reports as to the various initiatives of public authorities, institutions and bodies, including the **General Treasury and the National Institute of Social Security,** the **Directorate-General for Employment, CEOE, CGPJ, SEPE and AEPD**.

## Code of Good Practice Working Group

2019 began with the effective entry into force of the new version of the **IFPMA** code, along with the consolidation in one single document of the three pre-existing **EFPIA** codes. This last initiative, while as far as possible conducted in accordance with the current text of the terms and conditions of each of them, includes changes which must necessarily be transposed in the **Code of Good Practice** of FARMAINDUSTRIA.

In 2019, then, the process of revising, updating and improving the national Code began, and will need to conclude with the approval of a new version to take effect from 1 January 2021, save for exceptional circumstances. The **main improvements to the Code** comprise:

- The **revision of key concepts**, such as "information" and "marketing authorisation"
- The **binding inclusion** of the existing guidance regarding the interrelationship with the media and use of social media and in the field of the interrelationship with patients as an integral part of the Code
- **Greater objectivity in the conditions** and requirements applicable in the provision of services by healthcare professionals and organisations
- **Optimisation of the procedures** currently in place for communication

The main medical and scientific societies in Spain were specifically invited through meetings held by their representatives with the **Ethics Supervision Unit (USD),** allowing them to play a direct and active role in the process of updating, revising and improving the Code.

The most notable legislative initiatives in this field include in particular the draft **Royal Decree on Observational Studies,** and the expected update to **Royal Decree 1416/94** on the advertising and promotion of medicines for human use. With regard to the former, the explicit reference that it makes to patient support programmes is particularly significant, limiting and restricting the authorisation of those considered to be observational studies connected with medicines. FARMAINDUSTRIA submitted its written arguments. The final draft has been brought before the Council of State and is pending approval.

In addition, representatives of the main healthcare authorities reported that during 2019, work and preliminary meetings began on updating **Royal Decree 1416/94** in the field of promotion of medicines. This is one of the main regulations on which the Pharmaceutical Industry **Code of Good Practice** is based, and with which it will need to be aligned. As a result, and as far as is permitted, FARMAINDUSTRIA plans to play an active part in the process of revision and improvement.

In line with the model adopted the previous year, and bearing in mind that compliance with the Code of Good Practice remains one of the Association's primary objectives, the decision was taken to maintain the existence of a **Strategic Committee** set up within the context of the FARMAINDUSTRIA **2018-2019 Strategic Plan,** regularly reporting its decisions to the **Working Group on the Code of Good Practice**.

The collaboration and dedication provided by the members of the Committee proved fundamental not only in such significant aspects as those detailed above, but also issues of a more institutional and strategic nature.

## International Working Group

This Working Group was set up for the purpose of conducting an analysis at FARMAINDUSTRIA of the priorities and positioning of **EFPIA** and **IFPMA** and contributing to the design of the strategy and action plan of the pharmaceutical industry in Spain to champion these priorities.

The issues addressed by this Working Group, regarding which information was provided in previous sections of this Annual Report, include in particular:

1. **European and international initiatives** affecting the productive model of the innovative pharmaceutical industry, including the modification to the Regulation on the SPC, the European Commission's analysis of incentives for the industry in the field of intellectual property and exclusive market rights, the adoption of the **Resolution on Pricing Transparency** at the **2019 World Health Assembly,** and collaboration among European countries in the field of pricing and access to medicines.
2. **Brexit.**
3. Proposal for a European Commission Regulation on **HTA**.
4. Monitoring of the **meetings of the EPSCO** Council and the initiatives of the Directorates-General for Health, Internal Market, Competition, and the working agenda of the new European Commission.

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## Relations with Spanish Regions Working Group

This Working Group comprises 63 companies, and its objectives include:

- **Monitor the different initiatives in healthcare and pharmaceutical policy**, particularly those of a regulatory nature or technical reports affecting the pharmaceutical provision and freedom of prescription in terms of equality in each region
- **Strengthen dialogue** and collaboration with public authorities
- **Promote balance** in the healthcare system to allow patient access to medicines and the development of industrial activity
- **Consolidate alliances** with the different agents of the healthcare sector to achieve common goals, with a special focus on healthcare professionals
- **Set up a regional early-warning system** to detect and monitor regional prescription-dispensing policies

The Working Group receives detailed information of interest regarding all aspects of healthcare and pharmaceutical policy occurring both nationally and regionally, and their impact on access to pharmaceutical provision, such as budgets, healthcare and pharmaceutical expenditure, prescription and dispensation policies, R&D and innovation, composition of regional governments, etc.

Meanwhile, the Working Group collaborates in the preparation of **topical and situational reports in the Spanish regions,** information and consultation tools regarding the regional situation which are available to members in online format.

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## Trademark Protection Working Group

This Working Group focuses its efforts on showcasing the value of trademarked medicines, which offer significant advantage to prescribers and to patients.

The group has helped to produce a bullet-point list about the values of trademarked products, giving rise to the publication of various articles, interviews and other informative pieces in the media, as well as the launch of the information initiative **#LaMarcaTeCuida ('TheTrademarkLooksAfterYou').**

One of the initiatives generating greatest concern within this Working Group was the renewed momentum for prescription based on active substance as championed by the draft text entitled "Action plan to promote the use of market-regulating medicines in the NHS: biosimilar and generic medicines".

The Working Group's proposal was that the law should not be changed, and that no actions should be taken in the Spanish regions to make prescription based on active substance more widespread, since the prescription of trademarked products has numerous positive effects for patients, healthcare professionals and the health system itself, by encouraging adherence to the treatment, avoiding changes in dispensation, facilitating pharmacovigilance and entailing no additional cost to public funds or patients, since trademarked medicines are priced the same as the corresponding generics in Spain.

## Incremental Innovation Working Group

In January 2020 this Working Group met for the first time, having been convened by resolution of the Executive Board, in view of the interest of many member companies in this facet of innovation in medicines.

The group's purpose is to **set out proposals for the governing bodies** and to monitor an action plan so as to showcase the value of incremental therapeutic innovations.

Such innovations focus on fulfilling or improving the needs of certain patient organisations, using pre-existing, off-patent medicines, by means of modifications to the active substance, new formulas, new combinations of active substances, addition of technological devices to facilitate administration and/or monitoring, repositioning medicines for different indications, etc.

The group established **three objectives**:

- **Properly define** incremental innovation
- **Promote** a modification to the regulations allowing certain incremental innovation to be classified as of interest to the NHS
- **Publicise** the significance of incremental innovation across society so that a greater number of healthcare professionals and patients' representatives are aware of its benefits

## Cybersecurity Working Groups

This Group was set up in 2019 with the main aim of providing a forum for the IT managers of pharmaceutical companies. Its goal is to provide the industry with a shared platform where they can pool their problems, incidents and solutions, in particular from the perspective of cybersecurity. The group also proposes the creation of channels for communication with the institutions responsible for **National Cybersecurity** (INCIBE, CCN, etc.) with the possibility of sectoral collaboration.

Each meeting addresses a single-issue subsection exploring in greater depth topics of particular interest, such as awareness raising, directed attacks, vulnerabilities, supercomputing, artificial intelligence, digital transformation, etc.

## BARCELONA DELEGATION

FARMAINDUSTRIA's delegation in Barcelona, in coordination with various departmental areas within the Association, provides **support and consulting** functions across a range of matters, mainly for those pharmaceutical member companies based in Cataluña. It provides both horizontal and subject-based functions for the other member companies, and collaborates in the coordination of the various working groups in place at FARMAINDUSTRIA.

In turn, the Delegation provides a venue for meetings of the governing bodies of FARMAINDUSTRIA, the various statutory groups and other organisations in the healthcare sector.

In this regard it continued working closely with the FARMAINDUSTRIA National Statutory Group, taking on the role of technical secretary at its bimonthly meetings, coordinating the Group's own initiatives and managing information of interest for national companies that are members of the Association. It also continued to provide technical and logistical support for the other FARMAINDUSTRIA statutory groups.

Lastly, the delegation continued to maintain active dialogue with the public health authorities in Cataluña in various spheres, along with ongoing contact with a number of academic institutions and organisations connected with the pharmaceutical sector at the regional level, playing an active role in the Fedequim Mixed Delegated Commission for Cataluña, as well as this federation's Social and Employment Commission.

# 04

# MEMBER SERVICES

4.1 Online Services
4.2 Working Groups/Barcelona Office
**4.3 Spanish Technological Platform for Innovative Medicines (PTEMI)**
4.4 Self-Regulatory Systems

After running for over 14 years, the **Spanish Technological Platform for Innovative Medicines (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.

The PTEMI is the Spanish reference point for the ***Innovative Medicines Initiative*** (IMI), an initiative of **EFPIA** and the **European Commission** to promote research into new medicines, which seeks to strengthen Europe's position in pharmaceutical research, make Europe more attractive for research investment, and, in the long term, provide European citizens with faster access to better quality medicines.

The key activities undertaken by the PTEMI in 2019 include the **BEST Project** for excellence in clinical research, which proved a fundamental tool in making Spain one of the leading European countries for conducting clinical trials (see the subsection on the BEST Working Group in this Annual Report), alongside the *Pharma-Biotech* Cooperation Programme launched in February 2011 with the aim of facilitating collaboration between the pharmaceutical industry and the biotech sector in Spain.


Between 2011 and 2019 there were 18 interactive meetings, mainly in the areas of the central nervous system, oncology, respiratory system, inflammation and autoimmune diseases. In this period, it received **543 project applications** from which **133 projects** were selected and presented to biopharmaceutical companies. The *Pharma-Biotech* Cooperation Programme is discussed in greater detail in the *Pharma-Biotech* Working Group section of this Annual Report.

The **PTEMI** dedicates much of its activity to the field of publicising and promoting actions addressing all agents in the science-technology-enterprise system, so as to showcase the results of research initiatives and of public and private actions of interest to the sector, with the aim of fostering cooperation among such agents.

Over the course of 2019, intense efforts were made to update the innovative medicines website, making it a go-to source for information about research and development of medicines in Spain. The new medicamentos-innovadores.org website features information about the different stages covering the research and development of new medicines, from pre-clinical to the clinical phase. The website is easy to consult and focuses on explaining what the development of new medicines entails, how it is carried out, and the constituent phases involved in their development, as well as what the R&D of new medicines means to society at large.

It likewise provides comprehensive information as to Spanish and European personal data protection regulations in biomedical research.

A newsletter is issued monthly and is sent to over 1,200 people interested in **PTEMI** activities. By March 2019, 105 editions of this newsletter had been published.

The **Annual Technology Platform Conference** was scheduled for 9 and 10 March 2020 in Barcelona, but was suspended as a result of the Covid-19 health crisis.

Work was conducted in various spheres within the context of the **BEST Project**. The process of updating the Guide for Early Phase Clinical Research Units will make this more functional, while at the same time creating a web application expected to be available over the course of 2020.

The **Clinical Research Excellence Criteria Rulebook** was also published, setting out the need to foster the generation of new designs for clinical trials so as to improve clinical development lead times and incorporate metrics serving to identify areas for improvement to be addressed, and so help increase predictability and gain competitiveness. The action plan to publicise the rulebook includes the staging of workshops in various Spanish regions where clinical research plays an important role (Andalucía, Cataluña, Madrid and Valencia).

Lastly, work will continue with public and private stakeholders for the full application of **Regulation (EU) 536/2014** on clinical trials.

Within the scope of pre-clinical research, the **PTEMI** collaborates with **REDEFAR (Spanish Medicine Discovery Network)** on the start-up of the strategic plan for the network to consolidate this as an inclusive and cross-functional platform. **REDEFAR** is a network of excellence of the Ministry of Economy and Enterprise, with the mission of serving as an instrument to create a coordinated structure within Spain covering the different stages of the early discovery of pharmaceutical products, seeking to add value at each stage and to reduce the risk intrinsic to this type of activity, with an innovative approach aligned with the demands of the pharmaceutical and biotech industry, streamlining the process of discovering new medicines.

In the field of pre-clinical research, the **PTEMI** also collaborates with the **KÆRTOR Foundation**. The Foundation pursues a model of open innovation and public-private co-development to facilitate the reciprocal transfer of knowledge in the discovery of new medicines. The I2D2 *(Incubation Innovation in Medicine Discovery)* programme has been developed as an incubator for the early development of medicines in collaboration with the pharmaceutical industry.

In the field of the interrelationship with patient organisations, extensive work has been performed on the document of recommendations for integrating participation by patients and patients' associations in the process of pharmaceutical R&D.

The working team involved in this initiative concluded, among other aspects, that at least **eight areas** can be identified for the effective and valuable integration of patient participation and contributions in the process of biomedical R&D:


1. **Identification of unmet needs** and definition of research priorities.
2. **Generation of materials** for patient information and education about medicinal R&D.
3. **Awareness outreach of medicinal R&D** for patients and society at large.
4. **Participation in the authoring** of protocols for clinical trials and informed consent forms.
5. **Exploration and dissemination of clinical** trials of interest for each pathology.
6. **Contribution to the drafting** of executive lay summaries of clinical trials.
7. **Collaboration in the recruitment** of patients to take part in clinical trials.
8. **Identification of patient associations with an interest** in participating in industry R&D activities.

Meanwhile, efforts were made to update the **Code of Conduct for Data Protection in Clinical Research and Pharmacovigilance,** in accordance with the Spanish Personal Data Protection and Guarantee of Digital Rights Act, the second transitional provision of which establishes a timeframe of one year from its entry into force for the sponsors of the Codes of Conduct entered in the register of the **AEPD** to adapt their contents in accordance with the provisions of Article 40 of the **GDPR**. **The new Code will interpret the law in accordance with the GDPR** with regard to:

- **Data processing** in biomedical research
- Extensive **consent forms**
- **Reuse**
- **Legal bases** for processing of personal data connected with the clinical trial, within the protocol, or future uses outside the protocol

In December 2019 it was presented to the **AEPD** for evaluation.

Meanwhile, during 2019 the Platform achieved a high level of participation on various national and international forums addressing support for biomedical R&D, such as the early phase **clinical research promotion seminars** for rare or paediatric diseases.

In turn, the Platform has organised specific seminars and workshops addressing topics of interest for agents in the science-technology-enterprise system within the sector. With the idea of increasing the number of private establishments taking part in clinical research, then, a specific seminar addressing this topic was held on 4 April 2019, entitled "Towards excellence in biomedical innovation".

Meanwhile, on 11 July Madrid was the venue for a workshop on excellence criteria for the staging of clinical trials, which brought together 120 experts from hospitals and pharmaceutical companies participating in the BEST project of the **Spanish Technological Platform for Innovative Medicines (PTEMI)**.

Sponsors, clinical researchers and trial organisers debated in depth the increasingly demanding requirements involved in cutting-edge clinical research and the challenges that we face in maintaining and improving Spain's competitiveness in hosting trials.

This workshop resulted in agreement as to the document mentioned above, setting out criteria and priorities to boost Spain's competitiveness as a leading country for clinical research worldwide.

On 6 November, 20 November and 13 December, Barcelona, Malaga and Madrid, respectively, hosted seminars intended for baccalaureate students, with the aim of explaining what R&D for new medicines is, how it is conducted, its constituent phases, and what it means for society. The scheme, entitled Bringing Science into Schools, is meant for baccalaureate students and addresses the issues of R&D of medicines from the threefold perspective of the manufacturer, the researcher and the patient.

With regard to the 2020 working plan for the **PTEMI,** provision has been made for the continuation of a number of lines begun in 2019:

1. **Implementation** of European legislation and improvement of procedures.
2. **Dissemination** of the rulebook of criteria for excellence in conducting clinical trials in the different Spanish regions.
3. **Update** to the early phases guide.
4. **Approval and distribution** of the Code of Conduct.
5. **Intensification of efforts** with patient associations in the process of bio-pharmaceutical R&D.
6. **Promotion of Spanish participation** at IMI.
7. **Active participation** at forums, seminars and workshops to make Spain one of the leading nodes to attract international biomedical innovation projects.

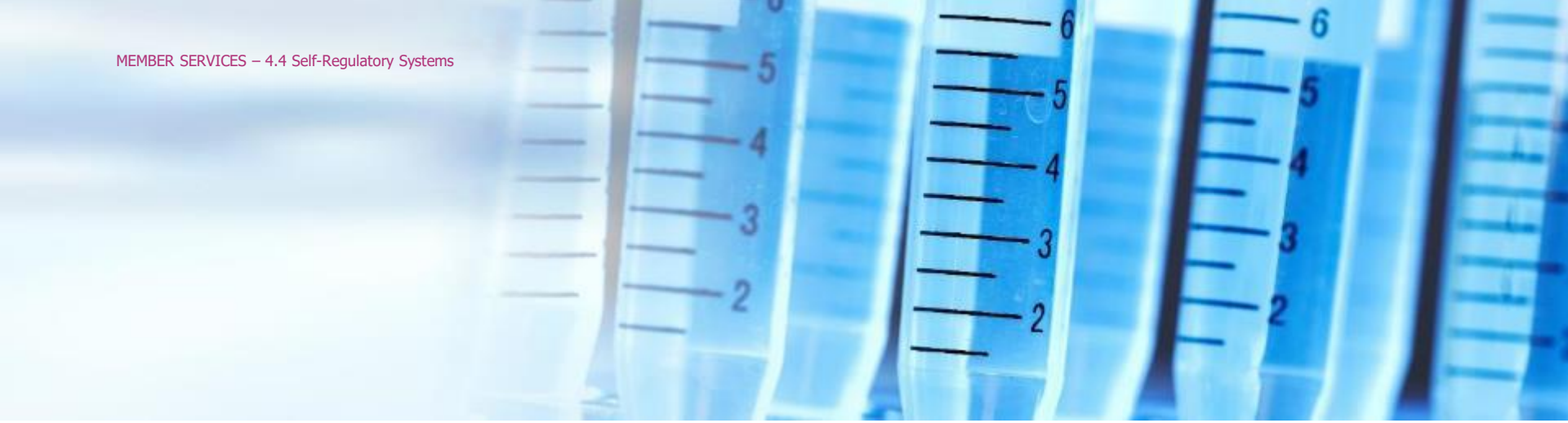
We should lastly mention that the European Parliament and EU Council reached a provisional agreement in April 2019 as to the **Research and Innovation Framework Programme** for the period 2021-2027, ***Horizon Europe***.

The scheme will include research and innovation missions to increase the efficacy of funding through the search for clearly-defined objectives. One of the five missions focuses on cancer, and in the months of June and December 2019 the **Carlos III Health Institute** staged meetings with a number of agents from the public and private sector (involving FARMAINDUSTRIA) to define the content and schedule.

# 04

# MEMBER SERVICES

4.1 Online Services
4.2 Working Groups/Barcelona Office
4.3 Spanish Technological Platform for Innovative Medicines (PTEMI)
**4.4 Self-Regulatory Systems**



## SELF-REGULATION SYSTEM OF THE PHARMACEUTICAL INDUSTRY IN SPAIN

In accordance with the transparency obligations set out in the Code, for the fourth year running, pharmaceutical manufacturers in 2019 published their transfers of value to healthcare professionals and organisations made during 2018.

This was the second consecutive year in which all transfers of value made to healthcare professionals were published individually.

In comparison with the initial data published for 2015, those corresponding to 2018 reveal an increase in the total volume of transfers of value made by pharmaceutical manufacturers in two categories:

1. **Transfers to healthcare organisations** by way of collaboration with scientific meetings and professionals, rising from €66 million in 2015 to €98.5 million in 2018.

2. **Transfers by way of R&D,** rising from €190 million in 2015 to €259 million in 2018.

In the remaining figures published, amounting to a total of **€597 million** (which was the overall figure 2018), there were no significant variations. Transfers of value to healthcare professionals amounted to **€118 million** by way of **collaboration** in their attendance at scientific meetings (€119 million in 2015) and **€72 million** by way of **services provided** (75 million in 2015).

As for healthcare organisations, aside from the aforementioned figures the following were published:

- €37.5 million by way of **donations** (33 million in 2015)
- €12 million by way of **services provided** (13 million in 2015)

The continuity, consistency and coherence of the data published over the last four years demonstrate, reinforce and consolidate the existing model in Spain for the interrelationship between the pharmaceutical industry and healthcare professionals and organisations. A model of interrelationship based essentially on principles of trust, integrity, respect, legality and transparency.

At the international level we would emphasise that on 1 January 2019 the new version of the **IFPMA Code** took effect, the main changes being:

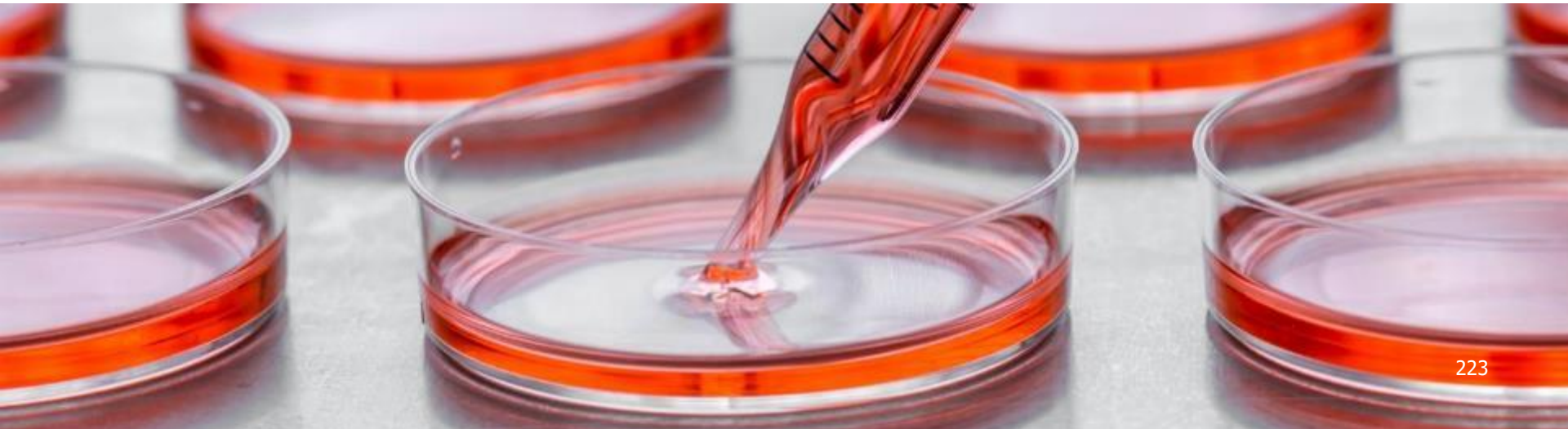
1. The **inclusion** of operational ethical principles based on "trust".
2. A **ban** on the distribution of promotional gifts and gratuities.
3. **Procedural technical improvements,** minor changes and updates to guides.

Meanwhile, the **EFPIA General Assembly** in June 2019 approved a new consolidated version of its Code, combining the codes previously in place in the fields of:

- **Promotion of medicines** and interrelationship with healthcare professionals and organisations.
- **Interrelationship with patient organisations**.
- **Transparency** in transfers of value.

This new version of the **EFPIA Code** includes modifications and improvements with regard to concepts and definitions, eliminates overlapping articles, and clarifies and develops aspects connected with its content. Since its approval, the national associations belonging to **EFPIA** have had a year to adapt and transpose into their national codes the changes made to the **EFPIA Code**. They must in any event be implemented and in force from 1 January 2021 onwards.

We would lastly emphasise the collaboration given by pharmaceutical manufacturers through the **Strategic Transparency Committee** at FARMAINDUSTRIA, and the Working Group for the Code of Good Practice, the functions of which are explained in greater detail in other subsections of this Annual Report.



## Ethics Supervision Unit (USD) Actions

With regard to the dissemination of our self-regulatory system, the following key points should be made:

- **Participation in the Code of Good Practice Working Group** at FARMAINDUSTRIA to update, report and monitor any issue connected with the transparency initiative and the individualised publication of transfers of value, and active monitoring of the self-regulatory system.
- **Meetings with pharmaceutical manufacturers** to monitor and support transparency projects.
- **Meetings with the Health Departments of the Spanish Regions** to address issues connected with the transparency initiative and the self-regulatory system in general.
- **Meetings with Scientific Societies** for more in-depth analysis and resolution of queries regarding transparency matters, and to pursue and approve the basis for collaboration in the sphere of ongoing medical training.
- **Delivery of training sessions** specifically designed to meet needs and demands of pharmaceutical manufacturers (in-company training).
- **Participation at** FARMAINDUSTRIA seminars on "Pharmaceutical Industry and Media".
- **Attendance at** FARMAINDUSTRIA seminars with leaders from the Spanish regions.
- **Participation in EFPIA working groups** responsible for ensuring transposition and implementation of the approved standards to the applicable codes in each national association.
- **Active member of** the *Codes Committee* (Chair), *Strategic Committee*, *Ethics & Compliance Committee* (Vice-Chair), of the *Medical Education Working Group*, and EFPIA's *Validation Team* (e4ethics).

- **Continuous collaboration** with IFPMA: Chair of **IFPMA Code** Grievances Procedure Appeal Group, involvement in the working groups on "Patient Centricity", "Training in the Code", "Innovation Models", "New Technologies", "Responsible interrelationship with key stakeholders" and "Scientific meetings and congresses"; support in various translations of materials into Spanish, and in the process of updating the **IFPMA** Code of Good Practice.

With regard to relationships with **Patients' Organisations,** one essential USD role is to ensure that pharmaceutical companies comply with the commitment to provide updated information on the joint projects carried out during the year (available at www.codigofarmaindustria.es).

## Consultancy and Joint Projects

The **Unit** continued its collaboration and support tasks through:

- **Review, adaptation and improvement** of the internal procedures implemented by pharmaceutical manufacturers to ensure compliance with both the Code and regulations in force on the promotion of medicines.
- **Continuous and ongoing support** for pharmaceutical manufacturers and third parties involved, mainly scientific societies, technical secretariats and service providers in general.
- **Active participation at meetings** and forums organised by FARMAINDUSTRIA and attendance at international meetings and forums organised by **EFPIA** and **IFPMA**.

During 2019, three circulars related to the Pharmaceutical Industry **Code of Good Practice** were published.

## Monitoring and Prevention

The number of preventive actions carried out in 2019 was **1,633** (an increase of 120 compared with the previous year). Three grievances were also filed in 2019 on the initiative of the Unit. These grievances were based on activities or practices allegedly in breach of the provisions of the Code concerning: **distribution of promotional material** (Article 7) and **guarantees of independence** (Article 10). Two of these were shelved at the request of the USD, while the other is being processed by the Professional Ethics Commission.

It should be recalled that from 1 February 2018, the USD decided to publish on the online platform of third-party events only those gatherings of greater scope and scale (attended by at least 200 healthcare professionals).

In 2019 the number of **scientific professional meetings** analysed and verified totalled **3,884** (10 fewer than in 2018). In percentage terms, the **level of compliance** of the meetings was **97.1%** (compared with 96.2% in 2018). Meanwhile, there was an increase both in the number of **market research studies** notified (**310.48 more** than in 2018), and the number of **projects notified** (**373.83 more** than in 2018). Both activities revealed a relative increase in the level of compliance: in the case of studies, rising from 95% in 2018 to 96.8% in 2019, and in the case of projects, from 93.1% in 2018 to 94.9% in 2019.

**3,884**

Scientific and professional meetings

**97.1%**

Level of compliance

**310**

Market research studies communicated

**373**

Projects communicated

## EFPIA e4ethics Platform

As active members of the "*Validation Team*" of EFPIA's platform **e4ethics,** 155 scientific professional meetings were reviewed at the European international level (45 with one single review, and 110 with two or more reviews) in 2019.

As a consequence of the internal organisational changes approved by **EFPIA,** from September 2019 onwards FARMAINDUSTRIA once again took charge of direct management of the **e4ethics** platform on behalf of **EFPIA**.

**Note:** The table below summarises the figures for the Professional Ethics Supervision Unit (yearly and cumulative) from when it began operations up until 31 December 2019.

| | | **USD ACTIVITY** (1 January to 31 December 2019) | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **2004** Apr-Dec | **2005** | **2006** | **2007** | **2008** | **2009** (a) | **2010** | **2011** (b) | **2012** | **2013** | **2014** | **2015** | **2016** | **2017** | **2018** (c) | **2019** | **Cumulative** |
| **EVENTS** | **ANALYSED** | **945** | **1,747** | **2,199** | **2,926** | **3,388** | **3,878** | **5,080** | **5,335** | **5,003** | **4,954** | **5,566** | **5,337** | **5,382** | **5,377** | **3,894** | **3,884** | **64,895** |
| | No incidents | 718 | 1,390 | 1,909 | 2,616 | 3,087 | 3,345 | 4,383 | 4,862 | 4,389 | 4,412 | 5,124 | 4,867 | 5,110 | 5,084 | 3,747 | 3,772 | 58,815 |
| | % Compliance | 75.98% | 79.56% | 86.81% | 89.41% | 91.12% | 86.26% | 86.28% | 91.13% | 87.73% | 89.06% | 92.06% | 91.19% | 94.95% | 94.55% | 96.22% | 97.12% | 90.63% |
| **STUDIES (a)** | **ANALYSED** | | | | | | **687** | **724** | **626** | **512** | **400** | **449** | **300** | **317** | **293** | **262** | **310** | **4,880** |
| | No incidents | | | | | | 397 | 546 | 565 | 416 | 332 | 368 | 251 | 280 | 271 | 249 | 300 | 3,975 |
| | % Compliance | | | | | | 57.79% | 75.41% | 90.26% | 81.25% | 83.00% | 81.96% | 83.67% | 88.33% | 92.49% | 95.04% | 96.77% | 81.45% |
| **SERVICES (b)** | **ANALYSED** | | | | | | | | **357** | **330** | **306** | **350** | **368** | **363** | **364** | **290** | **373** | **3,101** |
| | No incidents | | | | | | | | 282 | 272 | 230 | 292 | 301 | 274 | 321 | 270 | 354 | 2,596 |
| | % Compliance | | | | | | | | 78.99% | 82.42% | 75.16% | 83.43% | 81.79% | 75.48% | 88.19% | 93.10% | 94.91% | 83.71% |
| **PREVENTIVE ACTIONS** | | 814 | 1,801 | 1,376 | 2,092 | 2,440 | 2,670 | 3,482 | 3,131 | 2,488 | 2,112 | 2,180 | 2,138 | 1,483 | 1,674 | 1,513 | 1,633 | 33,027 |
| **USD COMPLAINTS** | | 18 | 11 | 9 | 18 | 8 | 12 | 4 | 3 | 1 | 9 | 7 | 7 | 2 | 3 | 3 | 3 | 118 |

(a) System for Communicating Studies approved under the 2008 Code.
(b) System for Communicating Services approved under the 2010 Code.
(c) Change in the procedures for publication of Third-party Events (Circular USD 2/18) in force since February 2018.

7 Cases resolved in the Courts.
6 Binding decisions by the Self-Regulation Jury in favour of the USD.
88 Resolved by mediation before the Ethics Commission, acknowledging the infraction and accepting corrective measures.
14 Shelved at the request of the USD.
2 Not upheld by the Self-Regulation Jury.
1 Under evaluation by the Professional Ethics Commission.

## ACTIONS OF THE PROFESSIONAL ETHICS COMMISSION

In 2019, 11 meetings of the **Professional Ethics Commission** were held, focusing in particular on issues of mediation and the referral to the Self-Regulatory Jury of those matters on which a reconciliation agreement could not be reached.

As for the mediation cases, 10 grievances were filed in 2019 with the **Professional Ethics Commission,** and these were processed in accordance with the ordinary procedure set out in Article 32.2 of the Code.

30% of the grievances were filed by the USD (Professional Ethics Supervision Unit), mainly citing promotional activities, promotional materials, or breaches of articles of the Code.

The following layout summarises the grievances, grouped according to classification criteria.

| **TOTAL** | **10** |
|---|---|
| **PROFESSIONAL ETHICS COMMISSION** | **10** |
| Case Shelved | 2 |
| Commission Mediation | 3 |
| *Agreement* | *2* |
| *Agreement + contribution* | *1* |
| Self-Regulation Jury | 5 |
| *Pending* | *2* |
| *Economic sanctions* | *3* |
| **PLAINTIFFS** | |
| USD | 30% |
| Member companies | 50% |
| Adhering companies | 20% |
| **DEFENDANTS** | |
| Member companies | 80% |
| Adhering companies | 20% |
| **CONTRIBUTION AGREEMENTS** | |
| 1 of €6,000 | |
| **SELF-REGULATORY PENALTIES** | |
| 1 of €25,000 | |
| 1 of €50,000 | |
| 1 of €60,000 | |

Aside from the above, other matters of interest were also addressed, in the main a range of communication initiatives by pharmaceutical manufacturers which, given the channel, means and platform employed, could entail the potential risk of a breach of the Code. In these cases the USD sent letters to the manufacturers and informed the **Professional Ethics Commission**.

The Commission was likewise informed of the monitoring of the document on Patient Remuneration Principles approved at **EFPIA** referring to the ban on any interrelationship with patients for promotional purposes.

Meanwhile, the **Secretariat of the Professional Ethics Commission** presented the report on the Commission's activities in 2017, 2018, and the period January-May 2019.

Lastly, with regard to the **Covid-19** crisis and the declaration of the state of emergency, the **Secretariat of the Professional Ethics Commission** informed those parties subject to the Code that on 10 March 2020, Autocontrol published its Contingency Plan to address the situation created in connection with the pandemic.

For its part, the **Professional Ethics Commission** decided, in line with the measures adopted by Royal Decree 463/2020, that the grievances procedure would suspend the established deadlines, with timeframes being recalculated once Royal Decree 463/2020, of 14 March 2020, or any extensions thereto, no longer applied.

In accordance with the above, grievances received during the period will be registered and conveyed to the defendant, although the deadline for the presentation of arguments (five business days from receipt) will not be calculated until the aforementioned Royal Decree or any extensions thereto cease to have effect.

In any event, the **Professional Ethics Commission** has continued to fulfil the functions entrusted to it, and maintained the schedule of meetings planned for 2020. It was likewise announced the USD will continue to fulfil and exercise the functions and powers entrusted to it, with the three notification procedures set out in the Code remaining available and fully functional.

## Code of Conduct for Data Protection in Clinical Research and Pharmacovigilance

Over the course of 2019 there were meetings of the ad hoc working groups made up of representatives of the clinical research, pharmacovigilance and legal departments responsible for efforts to adapt the new Code of Conduct in accordance with the regulatory reference framework.

In the field of data protection, it has become apparent that consent is not the only legitimate basis for data processing.

In the field of clinical research, efforts centred on:

1. The need for extensive **consent forms**.
2. The **recognition of clinical research** as a general interest activity.
3. The **inclusion of biomedical research** among those purposes considered compatible with the adoption of adequate guarantees for the compatibility of such purposes without the need for consent, said guarantees including the possibility of working with encoded data, impact assessments, good clinical practice standards or review by an ethics committee.

In the field of **pharmacovigilance,** emphasis is placed on the lawfulness of personal data processing, since pharmacovigilance is considered to be a public health safeguard, and therefore constitutes a public interest activity which allows processing to be performed where necessary so as to guarantee said activity.

In December 2019, in accordance with the deadline established by the national data protection regulations, the **AEPD** was informally sent a draft of the **Code of Conduct** governing personal data processing in the field of clinical trials and other clinical research endeavours and pharmacovigilance, to be admitted and subsequently approved.

05

# ANNEX I

**SIGRE Medicine and Environment**




## THE LARGEST COLLABORATIVE PROJECT IN THE PHARMACEUTICAL SECTOR

**SIGRE Medicine and Environment** is the non-profit entity set up by the pharmaceutical industry to guarantee the proper environmental processing of medicinal waste and packaging of household origin.

Made up of all agents in the medicine supply chain, SIGRE has become the largest collaborative project in the Spanish pharmaceutical sector. Cooperation among pharmaceutical manufacturers, pharmacies and distribution companies has been vital over the years in achieving the success of this management system, and serves as an example of the alliances that need to be implemented if we are to continue advancing towards a more sustainable planet.

Through SIGRE, the pharmaceutical industry pursues a twofold objective:

**1** Environmental, minimising the environmental impact of empty packaging or leftover medicines of household origin.

**2** Public health, removing medicines that have expired or that are no longer needed from private homes, thus preventing accidents resulting from inappropriate use.

## COMMITMENT TO CONTINUOUS IMPROVEMENT AND QUALITY

In 2019 the organisation updated its certificates issued by AENOR for its Quality Management (ISO 9001:2015), Environmental Management (ISO 14001:2015), Energy Management (ISO 50001:2011) and Health and Safety at Work Systems (OHSAS 18001:2007).

By updating these certificates, SIGRE demonstrates its commitment to innovation and continuous improvement in all its services and processes, with the clear aim of continuing to contribute value to the pharmaceutical sector and to society at large.


## CONTRIBUTION TO THE SDGs

Through SIGRE the pharmaceutical industry contributes to achievement of the Sustainable Development Goals (SDGs) belonging to the United Nations 2030 Agenda.[11] Support is in particular given for the SDGs corresponding to "Good Health and Well-Being" (SDG 3), "Quality Education" (SDG 4), "Clean Water and Sanitation" (SDG 6), "Industry, Innovation and Infrastructure" (SDG 9), "Sustainable cities and communities" (SDG 11), "Responsible Consumption and Production" (SDG 12), "Climate Action" (SDG 13), and "Partnerships to Achieve the Goals" (SDG 17).

SIGRE was one of the first organisations to sign up to the Circular Economy Pact,[12] and as a member of the Executive Committee of the Spanish UN Global Compact Network (REPM)[13] it helps raise social awareness as to the importance of joining forces to achieve the 2030 Agenda Goals.

In 2019, to mark the fourth anniversary of the adoption and approval of the SDGs, the Spanish Network published the document "SDG, YEAR 4. Business Leadership in the 2030 Agenda: From Theory to Action". The commitments given by Spanish companies to transform the planet over the coming years include those espoused by SIGRE, comprising the development of 10 awareness-raising initiatives among its stakeholders to combat bacterial resistance, one of the greatest health threats worldwide.

(11) https://www.un.org/sustainabledevelopment/es/2015/09/la-asamblea-general-adopta-la-agenda-2030-para-el-desarrollo-sostenible/

(12) https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/economia-circular/pacto/

(13) https://www.pactomundial.org/

## AN INTERNATIONAL MODEL

SIGRE belongs to the Ibero-American Network of Post-Consumption Medicine Programme (RIPPM),[14] an organisation set up to facilitate the exchange of experiences and serving to identify advantages and drawbacks of the different post-consumption medicine programmes in operation in Ibero-American countries.

In 2019 the RIPPM promoted the creation of the Medicines Post-Consumption Platform (PPM),[15] a forum intended to promote the creation of post-consumption programmes, by organising initiatives to encourage an understanding of best practices in the handling of expired or unused medicines, to ensure that such waste is given appropriate environmental treatment, and to combat falsification and the illicit use of medicines.

The creation of this Platform is supported by the EAMI (Network of Medicine Authorities of Ibero-America,[16] made up of the agencies or departments for medicines linked to the Ministries of Health or public health research institutions in Ibero-American countries.

(14) https://www.redippm.org/

(15) https://www.redippm.org/plataforma-posconsumo-de-medicamentos-ppm/

(16) https://www.redeami.net/web/noticias_y_alertas/noticias/2019/contenedor_noticias/eami_conten_NI-06-Red-EAMI-plataforma-gestion-ambiental.htm

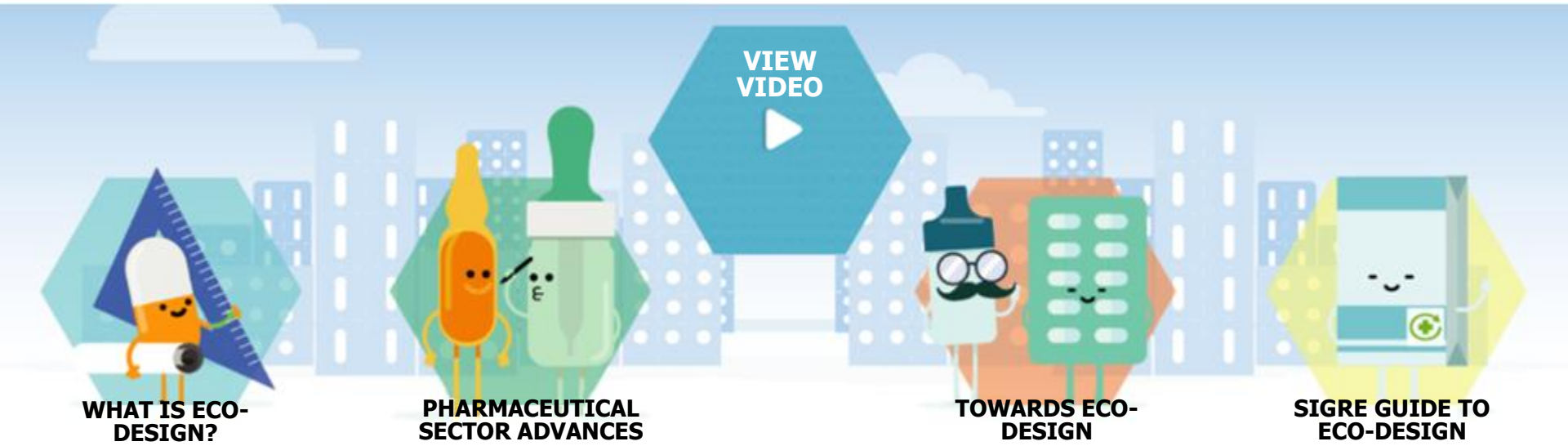
## THE PHARMACEUTICAL INDUSTRY IN SIGRE

### Eco-Design, Cornerstone of the Circular Economy

SIGRE has updated its Eco-design website[17] (www.sigre-ecodiseno.es) to include the latest advances achieved by the pharmaceutical industry in this sphere. The additional content includes the results achieved in the 2015-2017 Company Waste Prevention Plan ('PEP'), and the objectives set for the new 2018-2020 Plan, among others.

Since it was launched the website has built up more than 4,000 users, making it one of the main sources of information about eco-design in the pharmaceutical sector, one of the cornerstones on which the new circular economy model is based.

(17) http://www.sigre-ecodiseno.es/



**Training and Information for the Subscribing Pharmaceutical Manufacturers**

SIGRE organises training sessions every year to explain to pharmaceutical manufacturers the functionality of the SIGRELAB Form, the IT application used to compile information about units, weights and materials of all medicinal packaging released to market during the previous year, along with the packaging prevention measures applied. In 2019, some 60 representatives of pharmaceutical manufacturers attended.

Likewise, with the aim of creating a forum for information and debate with the pharmaceutical industry, SIGRE organises a number of seminars each year in Madrid and Barcelona to address those environmental topics of greatest relevance for the sector. This year, there was an analysis of the EU's strategic focus for pharmaceutical products in an environmental context, the latest environmental and healthcare legislative developments, CSR in the pharmaceutical industry, and examples of the prevention measures recently applied by a number of pharmaceutical manufacturers.

**Waste management in the pharmaceutical industry**

SIGRE worked together AEFI (the Spanish Industry Pharmacists Association) on preparing the *"Manual for Waste Management in the Pharmaceutical Industry"*, a document offering a practical approach to the steps to be followed to ensure proper environmental management of any waste that might be generated at a pharmaceutical facility, along with the different environmental solutions that can be applied according to the type of waste and current waste management processes.

## 2019 RESULTS

### Company Waste Prevention Plans

In order to comply with the obligations set out in the current packaging regulations, SIGRE is the body responsible for preparing and coordinating the Company Waste Prevention Plans (PEP) for the pharmaceutical sector. These plans set out the objectives of the pharmaceutical industry to ensure that the packaging and containers used for medicines are increasingly sustainable and environmentally friendly, promoting to this end the application of a circular economy model that will minimise environmental impacts throughout its life cycle.

The seven PEPs approved since the year 2000 have allowed the industry to reduce the overall weight of pharmaceutical packaging by over 25%, as a further demonstration of its commitment to the circular economy.

### Annual Pharmaceutical Sector Packaging Declaration

SIGRE is the organisation responsible for presenting the 'DAE' Annual Packaging Declaration to the environmental authorities. The document compiles information on which medicines are sold each year on the Spanish market (type of pharmaceutical presentation, weight and materials used), along with the environmental management applied to waste packaging and leftover medicines generated by consumption in Spanish households.

According to the contents of the DAE for 2019, during the year the SIGRE system collected an average of 102.84g per inhabitant of empty packaging or containing leftover medication, successfully recycling 55.21% of the packaging materials recovered.

To this end, the waste medicines deposited by the general public at the 21,900 SIGRE Points available throughout Spain are sent to the Packaging and Waste Medicines Treatment Plant located in Tudela de Duero, Valladolid. This facility, which began operating in 2012, is a worldwide pioneer and was designed exclusively for the appropriate environmental treatment of this type of waste.

In the second half of the year numerous devices and technological improvements were added to the facility, and these will begin operating next year in the classification process, serving to improve the quality and quantity of the proportions recovered. Meanwhile, control and traceability of waste throughout the logistical process is being strengthened thanks to the development of specific radiofrequency reading and automatic registration technology.


## Awareness-Raising Campaigns

Citizen engagement is essential in order to achieve the proper management of waste medicines. To get the public to cooperate, SIGRE launches awareness-raising campaigns every year to publicise the importance of properly recycling empty packaging and leftover medicines via a SIGRE Point.

Last year, SIGRE presented the environmental authorities with its 2019-2021 Three-Year Communication Plan, setting out the strategic objectives and specific messages for each of its stakeholders. The key concept serving as the fulcrum for all initiatives and campaigns conducted during the period will be the responsibility that each of us must take on board if we are to progress towards a sustainable planet.

2019 saw the launch of a campaign entitled "Say yes to SIGRE. Say yes to the environment", the aim of which is to remind the general public of the importance of properly recycling empty packaging or any containing leftover medication, to protect public health and care for the natural world. The campaign also calls for particular emphasis to be placed on antibiotics, which must be properly used and correctly disposed of at a SIGRE Point in order to prevent the generation and spread of antimicrobial resistance.

## Participation at Environmental and Healthcare Forums

SIGRE actively collaborates with a number of environmental and social/healthcare forums in order to continue showcasing the benefits of its operations, and to highlight the environmental contribution made by the pharmaceutical sector.

Notable events during 2019 include participation at the 39th Symposium of the AEFI (Spanish Industry Pharmacists Association), at the 31st edition of INFARMA, the 17th National Forum for Environmental Management and Sustainability, organised by the ANAVAM (National Association of Environmental Auditors and Verifiers), and the 7th Seminar on Pharmaceutical Cooperation staged by Pharmacists Without Borders.

SIGRE was also involved at meetings and gatherings of the Advisory Council and Assembly of Packnet, the Environment Commission of the CEOE, the Foundation for the Circular Economy, the Executive Committee of the Spanish Global Compact Network, the Assembly of the CEMA (Spanish Environment Club), the 13th National Environmental Journalism Congress, and the General Assembly of the RIPPM (Ibero-American Network of Post-Consumption Medicine Programmes).

## Performance Awards

Last year the Spanish United Nations Global Compact Network recognised four good practices implemented by SIGRE for their contribution to achieving the Sustainable Development Goals.

Under SDG 3 "Good Health and Well-Being" there were accolades for the ecoFARMACIA interactive website, under SDG 12 "Responsible Production and Consumption", the 5th Catalogue of Eco-design Initiatives for pharmaceutical sector packaging,[18] and the Practical and Technical Eco-design Guide,[19] and under SDG 13 "Climate Action", the reverse logistics model provided for SIGRE by the distribution channel to collect the waste deposited at the SIGRE Points at pharmacies.

#PorElClima (#ForTheClimate) Community recognised the SIGRE ecoFARMACIA website as an example of environmental action to combat climate change, including it in its publication on the 101 Best Business Practices presented at the United Nations Conference on Climate Change (COP 25), staged last December in Madrid.

Likewise, the 5th Catalogue of Eco-design Initiatives[20] published by SIGRE was honoured at the 18th edition of the Fundamed & wecare-u Awards in the Corporate Reputation category, thanks to its efforts in supporting eco-design, the circular economy and recycling of medicine packaging.


Lastly, in 2019 SIGRE once again renewed its commitment to the Global Compact through the 2018 Progress Report, distinguished for the ninth year running at the GC Advanced Level, the highest rating granted by this international body, which evaluates the alignment and dissemination of its 10 principles, transparency, and the degree of information provided.

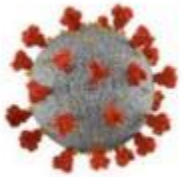
(18) https://www.sigre.es/wp-content/uploads/2018/04/ECODIS_2018.pdf

(19) http://www.sigre-ecodiseno.es/guia-de-ecodiseno.html

(20) https://www.sigre.es/wp-content/uploads/2018/04/ECODIS_2018.pdf

## FUTURE CHALLENGES

The pandemic caused by Covid-19 is generating considerable uncertainty for all organisations, which are finding themselves forced to anticipate scenarios and adopt measures in an attempt to minimise harm and to maintain activity and employment. Within this new context, SIGRE is firmly committed to collaboration, innovation and continuous improvement. Given the above, all our actions are focused on achieving the 10 Principles of the Global Compact and the United Nations Sustainable Development Goals (SDGs).



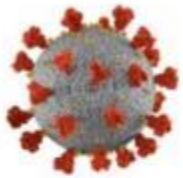
These principles and goals will define the organisation's actions in response to the main challenges that will need to be addressed in the future:

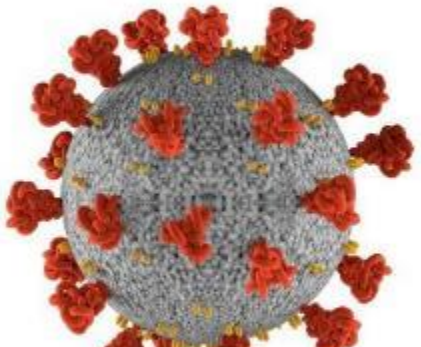
**For as long as the Covid-19 pandemic lasts:**

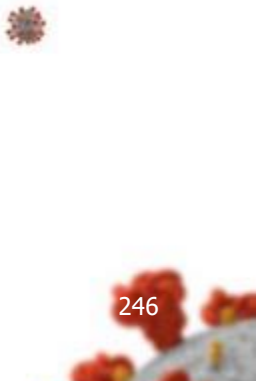
- Maintain the SIGRE system: collection and management of waste medicines and packaging have been declared an "essential service"
- Protect the health of professionals: constant updating of the safety protocols for waste-management activities and the promotion of homeworking
- Cybersecurity: guarantee our communication networks and confidentiality
- Continuous dialogue and transparency: keep all stakeholders informed about the results of our activity

**In parallel with the management of this crisis:**

- Search for synergies and efforts based on transparency, ethical management and innovation as mechanisms for continuous improvement
- Commitment to eco-design and recycling within the context of a Circular Economy
- Contribution to the Sustainable Development Goals linked to our activity
- Support training for healthcare professionals and environmental awareness-raising across society







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# ANNEX II

**SEVEM (Spanish Medicines Verification System)**



## BACKGROUND

In 2008, the European Commission presented a legislative proposal amending Directive 2001/83/EC, by incorporating measures intended to prevent falsified medicines from entering the legal medicine supply chain. This initiative was in response to concern over the public health threat that could result from an increase in falsified medicines in terms of their identity, record and origin within the EU.

The Falsified Medicines Directive, Directive 2011/62, governs the inclusion of security devices required in order to verify the authenticity and identification of individual packaging units, and to ascertain whether they have been tampered with. The Directive establishes that medicines subject to medical prescription must be equipped with safety devices. It nonetheless allows for certain medicines or categories of medicine to be exempt from the obligation to be equipped with these devices, while also, on an exceptional basis and in exceptional circumstances, allowing for the possibility of safety devices being added to medicines not subject to medical prescription.

The detailed implementation of the provisions included in the Falsified Medicines Directive is delegated to the European Commission which, in accordance with this mandate, in October 2015 issued Delegated Regulation (EU) 2016/161, applicable on a mandatory basis since 9 February 2019, thus making it a decisive year for the entire European Medicines Verification System.

## OBJECTIVES AND COMPOSITION

The Spanish Medicines Verification System, SEVeM, was founded on 21 July 2016 and began operations on 1 September the same year as a not-for-profit limited liability company, in order to develop, implement and administer the Spanish medicines verification system in accordance with the terms of Directive 2011/62 (the Falsified Medicines Directive). 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 medicine 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 involved in 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 Board** comprises the SEVeM members (FARMAINDUSTRIA, AESEG, the General Council of Official Associations of Pharmacists and FEDIFAR). SEVeM's governing body is its Board of Directors, made up in 2019 as follows:

### PRESIDENT

- Mr Humberto Arnés Corellano

### DIRECTORS

- Mr Jesús María Aguilar Santamaría
- Mr Luis Amaro Cendón
- Mr Francisco José Aranda Campos
- Ms Ana Bosch Jiménez
- Mr Emili Esteve Sala
- Mr Eladio González Miñor
- Ms Raquel Martínez García
- Mr Ángel Luis Rodríguez de la Cuerda
- Ms María Iciar Sanz de Madrid Ibrán
- Mr Javier Urzay Ramírez

### NON-DIRECTORIAL SECRETARY

- Mr Pedro Yanes Yanes

### NON-DIRECTORIAL VICE-SECRETARY

- Mr Miguel Valdés Garaizabal

In addition, and in accordance with the articles of association of **SEVeM,** the **AEMPS** is also invited whenever the Board of Directors addresses issues concerning the development and functioning of the Spanish repository.

## 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 (AESEG, FARMAINDUSTRIA, FEDIFAR and CGCOF) and representatives of the authorities (AEMPS, DGCBSF, and the Spanish Regions). During 2019 the Operations Committee met on nine occasions to address topics connected with:

1. Regulatory provisions under way in the field of falsified medicines.
2. Criteria for the management of system users.
3. System stabilisation period.
4. Operational protocols in the event of alerts at pharmacies and in distribution.
5. Working plan for the integration of the NHS Node.
6. Development of system reports for the competent authorities.
7. Packaging to oversee system functions.
8. Management of deactivated medicines returned by pharmacies to wholesalers.
9. Management of packaging with damaged tamper-proof devices.
10. Management of alerts and advanced algorithm for the end user software.
11. Voluntary aggregation of codes for hospitals.
12. Monitoring of connected agents.

The Audit Committee, which comprises representatives of the four members as established in the **SEVeM** articles of association, met on three occasions during 2019 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.

## COMMUNICATION

Ever since it was founded, **SEVeM** has had a website (www.sevem.es) to provide the general public and stakeholders with an insight into the activities performed by the organisation, ensuring that information connected with the project is available and kept up-to-date.

The executive team of SEVeM also plays an active role at numerous conferences, seminars and courses to explain its activities, and the progress and results achieved through the various phases of the project. In 2019 the appearance of SEVeM on various media platforms (press, radio and television) was particularly notable, coinciding with the mandatory application of the Delegated Regulation on 9 February.

## REGULATORY FRAMEWORK

### Procedure for Authorisation, Registration and Conditions for Dispensing of Medicines for Human Use

In January 2019, the public consultation process began for the Royal Decree modifying Royal Decree 1345/2007, of 11 October 2007, governing the procedure for authorisation, registration and conditions for dispensing of industrially-manufactured medicines for human use. SEVeM submitted arguments as to the project on two occasions, and these were in part taken into account in the final text of Royal Decree 717/2019, of 5 December 2019.

This Royal Decree adds a new Chapter IX to Royal Decree 1345/2007, specifying the regulation of those aspects that Delegated Regulation (EU) 2016/161 leaves to the decision of the Member States. It furthermore identifies the competent authorities in the various aspects covered by the Delegated Regulation, and establishes a specific node for the NHS, known as the NHS Pharma Node, as an instrument for technological integration and information exchange with the national repository of which it will form part, for all medicines with a unique ID dispensed under the budget of the National Health System.

## PROJECT PROGRESS

2019 was a particularly important year for SEVeM, as on 9 February the medicines verification system was required to be fully operational so as to comply with the obligations set out in the European regulations. One week prior to this date, more than 11,400 pharmaceutical SKUs intended for the Spanish market had been uploaded to the system, with some 70% of medicine distribution warehouses located in the country being connected. In just five days, more than 8,000 pharmacies received accreditation to access the system. During the first month that the system was operational, more than 3.6 million deactivations were clocked up.

By the end of 2019, SEVeM had signed 324 connection agreements via the European platform, with 471 holders of commercial authorisations for medicines within the Spanish medicines verification system. Likewise, 302 distribution warehouses were connected, along with all retail pharmacies and 179 private hospital pharmacy services. The connection of public hospitals remains pending up until completion of implementation and integration of the NHS Pharma Node.

In 2019 more than 15,000 pharmaceutical SKUs and 1.35 billion unique IDs were uploaded to the system, while during the first year in operation over 420 million unique IDs were verified within the system, and over 280 million were deactivated.

Other significant activities undertaken by SEVeM during 2019 included:

- The introduction of improvements to the stabilisation of the system and optimised performance.
- Implementation of the reports platform integrated with the main repository and Nodofarma Verification.
- Coordination and support for the Ministry of Health in the development of the NHS Pharma Node, allowing connection by public hospitals.
- Coordination with the AEMPS in investigations of potential falsification alerts and the resolution of serial numbering incidents.
- Agents and authorities for the aggregation of codes in the establishment of a common standard for all hospitals.
- Development of the platform with the initial system supervision reports for the authorities.

SEVeM likewise made great efforts to identify and reduce false alerts derived from the learning curve of thousands of connected users. To this end, tools were developed internally to allow the analysis of large volumes of alerts, with support being given to pharmaceutical manufacturers by identifying batches and codes not uploaded to the system, along with false Datamatrix elements, as well as detecting software and scanner configuration failures at end users.

This served to reduce false alerts from 16.2% of all operations, to 3.7%.

Nonetheless, the reduction of false alerts will remain a priority target for SEVeM in 2020.


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