

ANNUAL REPORT

2020

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A Word from the President



Juan López-Belmonte

PRESIDENT OF FARMAINDUSTRIA

Never has our sector been so much in the social spotlight as in 2020, which has been such a hard year for everyone as a result of the pandemic. Never, perhaps, has more been expected of us as a pharmaceutical industry. Ever since the outbreak of the health crisis, the world has turned to us for solutions in the form of effective treatments and vaccines.

And I believe that we have responded. Our sector mobilised immediately - opening up collaboration between companies and governments, the scientific community and regulatory authorities - allowing us to deliver safe and effective vaccines in less than a year.

The World Health Organisation officially declared a pandemic on 11 March, and less than nine months later, on 8 December, a British woman was administered the first vaccine. An unprecedented achievement.

These efforts have been global, and here in Spain we have made a significant contribution. We have made use of our renowned capacity for clinical research, making Spain the leading country in Europe and the fourth in the world in terms of trials to combat Covid-19.

We acted swiftly in our research to fight against coronavirus, and with the support of the Spanish Medicines and Healthcare Products Agency (AEMPS) we were able to find solutions to normalise non-Covid clinical trials at the earliest opportunity, after they were suspended during the most difficult points in the crisis due to lockdowns and overwhelmed hospitals. And these solutions proved so effective that in 2020 Spain set a new record for approved trials, with more than a thousand.

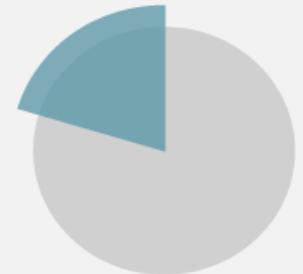
We also made great efforts to ensure that at the most challenging times the supply of medicines was never interrupted, as well as mobilised in support of the healthcare system and other social organisations in response to the many needs generated by the pandemic. Our work was perhaps less noticeable than that of other sectors and professionals. But it was rigorous, altruistic and necessary, and we should congratulate ourselves on that. We demonstrated our commitment to society and our reliability and capacity responding to an emergency situation.

As this Report shows, the pharmaceutical industry has considerable weight. We are the leaders in industrial R&D investment, alongside the automotive sector, accounting for almost 19% of the total. This commitment to research in Spain has, as I mentioned, placed us in the international vanguard for clinical trials: there are at present over 3,400 trials in progress in Spain, involving 145,000 patients. We applied for more patents than any other sector last year, and serve as the main catalyst for public and private biomedical research, since almost half of the R&D investment by pharmaceutical companies takes the form of contracts with third parties.

R&D INVESTMENT

19%

OF THE SPANISH INDUSTRIAL
TOTAL COMES FROM
PHARMACEUTICAL COMPANIES





PRODUCTION IN SPAIN

14,900

MILLION EUROS



EXPORTS

12,800

MILLION EUROS

22%

OF ALL HIGH-TECH
EXPORTS

We represent a powerful driving force in the economy. We generate 14.9 billion euros of value, and set a new export record of almost 12.8 billion euros - accounting for over 22% of high-tech exports and almost 5% of all Spanish exports. These figures take on even greater significance given the gravitational pull of the pharmaceutical industry: every euro invested in our industry generates between one and two more in other sectors. Furthermore, in a country facing the major challenge of precarious employment, we are a leading sector for quality employment, in terms of permanent contracts (94%), qualifications (62% are university graduates) and gender diversity (52% are women).

And beyond these figures, we are today a sector that is more open to society; more committed to good practices, having made a pioneering dedication to transparency; a sector striving to achieve a closer relationship with patients and healthcare professionals so as to understand their needs and try to respond to them; a sector fully immersed in dialogue with public authorities in pursuit of solutions to promote healthcare and to balance patient access to innovation with the financial sustainability of the healthcare system. A sector, in short, with a long track record of commitment to caring for the environment: we have now marked the twentieth anniversary of SIGRE, the first major collaboration project between the pharmaceutical industry, distributors and pharmacies, to reduce our environmental footprint to a minimum.

We are beginning to see the end of the crisis. The vaccines are arriving and the pharmaceutical industry is to this end making global efforts to mobilise worldwide vaccine production capacity, and provide enough in 2021 in order to at least achieve the prized goal of herd immunity. Agreements between development companies and those with the capacity to participate in the complex production process through the transfer of technology and knowledge are working, and various institutions calculate that by the end of the year there will be more than 11 billion doses available. International cooperation will be vital in distributing them fairly around the whole world.

The end of the crisis which we can now begin to glimpse is for us, to a degree, a beginning. This tragedy has allowed us to forge a closer relationship with society, making us even more aware of our responsibility.



The population as a whole, all of us, have seen the extent to which health, biomedical research and the medicines resulting from it are critical for the prosperity and future of a modern society.

Juan López-Belmonte

PRESIDENT OF FARMAINDUSTRIA



At FARMAINDUSTRIA we are convinced that our sector is strategic to emerging from the economic, social and health crisis in which we still find ourselves, and in helping to enrich the productive model that Spain needs for its future. Traditional sectors such as tourism and construction must be complemented by others that will increase opportunities for growth.

FARMAINDUSTRIA has embarked on two approaches:

- Production
- Research

Under the former, we have already presented the Government with an initiative to reinforce the production of essential medicines in Spain which, given that many of these medicines are now mainly being produced in Asian countries, is a necessary step toward Spain reshoring part of that production and underpinning our productive network for a greater strategic protection.

As for research, we aim to leverage our position as an international benchmark for clinical research of medicines, and the boost given to biomedicine worldwide, so as to take a further step forward and make our country an international node for biomedical research investment.

In both cases, we are talking of real needs and of genuine opportunities for the future of Spain, given our advantageous starting position compared with other neighbouring countries.

All of this, though, entails close cooperation with the Government and the creation of an ambitious, medium-term strategic framework which allows us to develop our full potential as a cutting-edge sector for Spain. A change of vision on the part of our authorities is necessary, who need to see medicines not as an expense, but as the investment that it is, with clear returns from the threefold perspective of health, the economy and society. We will be unable to maximise our value contribution in the field of R&D, production, exports and job creation without a genuine commitment to the best possible patient access to innovative medicines.

The figures from the WAIT Indicator, the report by the IQVIA consultancy, show that access to innovation in Spain has worsened, and now lags far behind such nearby countries as Germany, Italy, England and France.

We must remain on a par with such countries, in terms of both approval times and availability, so that Spanish patients can benefit from a faster access to the value delivered by therapeutic innovations.

We also need genuine recognition of what is known as incremental innovation, which provides valuable enhancements to pre-existing medicines, and is hardwired into much of our sector in Spain. This delivers tangible value for doctors, patients and the health system, and needs to be properly valued in a way that the reference pricing system fails to do. Meanwhile, with regard to the off-patent market as a whole (in other words those medicines that no longer have industrial protection) it is vital to ensure a framework guaranteeing open competition between originator, generic and biosimilar medicines.

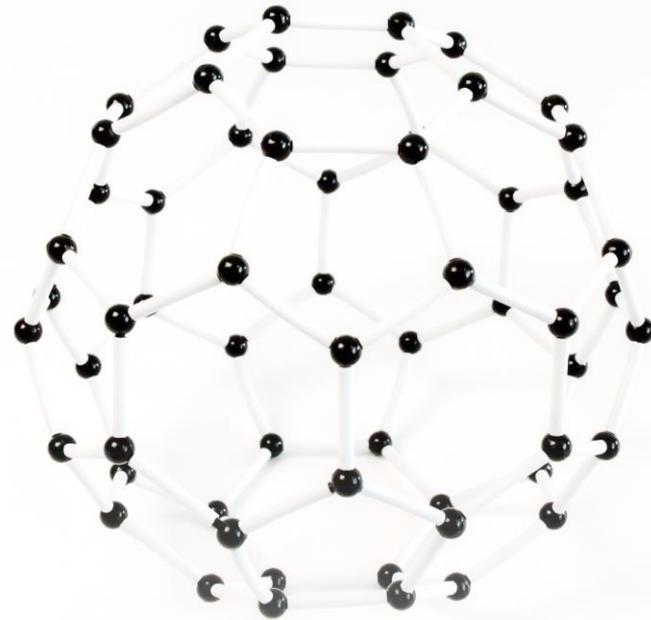
Nor can we overlook the European scenario to which we belong. Europe has over the last two decades lost its leading position in the development of new medicines. Today barely 23% come from Europe, compared with 47% from the United States. And Asia is gaining ground. The roadmap for the Pharmaceutical Strategy for Europe is now under discussion, and should serve to place the European Union (EU) where it deserves to be. However, some of the measures on the horizon, such as the revision of incentives for private investment in R&D, raise numerous doubts.

Europe must resolutely commit to the scientific cutting edge and the pharmaceutical industry, which means a clear positioning as to support for public-private partnership and in favour of the protection of intellectual property, which serve as the foundation underpinning a successful biomedical R&D model which, over recent decades, has delivered unprecedented levels of quality of life and longevity. And Spain must vociferously champion this approach within Europe.

'España Puede' ('Spain Can') Plan recently published by the Government makes provision for a Strategic Pharmaceutical Industry Plan with three pillars:

- 1 Patient access and sustainability of the National Health System (NHS).
- 2 Supporting competitiveness, innovation and development.
- 3 Ensuring a sound, resilient and eco-sustainable supply chain.

This Industrial Plan must provide the framework for moving forward, setting these priorities and defining the actions so as to achieve our goals. Anything else would lead to lost opportunities for our country's future. As far as the pharmaceutical industry is concerned, there will be no lack of commitment.



01

MEMBERS

By the time when this Annual Report was finalised, the number of member companies of FARMAINDUSTRIA amounted to 137, with the following geographical distribution:



PHARMACEUTICAL MANUFACTURERS BY GROUP

National: 44		International: 93	
		American	European
Total	44	17	76
Large	5		Germany 7
SMEs (Small and Medium)	39		France 10
			Mixed 34
			United Kingdom 16
			Switzerland 9

The members of FARMAINDUSTRIA represent, in terms of sales, 75% of the total prescription market (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 11 are Vice-Presidents (three from the sector of domestically-owned companies, three from the sector of American-owned companies, and five from the sector of European/internationally-owned companies), the remaining 11 being Members with

the following origins: three with domestically owned capital, three from companies with American-owned capital, and five from companies with European/internationally owned capital.

Elections were held in October 2020 to renew the Governing Bodies of the Association. In fulfilment of the statutory provision establishing the rotation of the Presidency every two years. Mr Juan López-Belmonte Encina, of LABORATORIOS FCOS. ROVI, S.A., a company belonging to the National Group, was appointed as President replacing Mr Martín Sellés Fort, who had been the previous President, representing a company from the American Group.

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

BOARD OF GOVERNANCE	
PRESIDENT	
Mr Juan López-Belmonte Encina	
VICE-PRESIDENTS	
Mr Nabil Daoud	Mr Federico Plaza Piñol
Mr Jorge Gallardo Ballart	Mr Francisco Quintanilla Guerra
Ms Cristina Henríquez de Luna Basagoiti	Mr Sergio Rodríguez Márquez
Mr Bernardo Kanahuati	Mr David Solanes López
Ms Margarita López-Acosta	Mr Roberto J. Urbez Plasencia
Mr José María Martín Dueñas	
MEMBERS	
Mr Juan Carlos Aguilera Rodríguez	Mr Jordi Muntañola Prat
Ms Ana Argelich Hesse	Mr Felipe Pastrana Molina
Mr Sergi Aulinas Guillaumes	Mr Peter Plöger
Mr Ignasi Biosca Reig	Mr Jesús Ponce Sancho
Mr Ricardo Jorge Castrillo Pelaz	Mr Rick Suárez
Ms Fina Lladós Canela	

EXECUTIVE BOARD

PRESIDENT

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

VICE-PRESIDENTS

Mr Jorge Gallardo Ballart
ALMIRALL, S.A.

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

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

Mr Federico Plaza Piñol
ROCHE FARMA, S.A.

Mr José María Martín Dueñas
ASTELLAS PHARMA, S.A.

Mr David Solanes López
LABORATORIOS ERN, S.A.

Mr Nabil Daoud
LILLY, S.A.

Ms Margarita López-Acosta
SANOFI-AVENTIS, S.A.

Mr Bernardo Kanahuati
BAYER HISPANIA, S.L.

Mr Francisco Quintanilla Guerra
FAES FARMA, S.A.

Mr Sergio Rodríguez Márquez
PFIZER, S.L.U.

MEMBERS

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

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

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

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

Ms Fina Lladós Canela
AMGEN, S.A.

Mr Jordi Muntañola Prat
ESTEVE PHARMACEUTICALS, S.A.

Mr Luis Díaz-Rubio Amate
JANSSEN CILAG, S.A.

Mr Carlos Rubió Badía
LABORATORIOS RUBIO, S.A.

Mr José Francisco Marcilla Molina
ARTIS PHARMA, S.L.

Mr Tomás Olleros Izard
GRUPO FARMASIERRA, S.L.

Mr Miguel Fernández Alcalde
MERCK, S.L.

Mr Guillermo de Juan Echávarri
SMITHKLINE BEECHAM, S.A.

Mr Rick Suárez
ASTRAZENECA FARMACEUTICA SPAIN, S.A.

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

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

Mr Antonio Buxadé Viñas
LABORATORIOS VIÑAS, S.A.

Mr Sergio Teixeira
BIOGEN SPAIN, S.L.U.

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

Mr Francisco Javier Alvarado García
MUNDIPHARMA PHARMACEUTICALS, S.L.

Mr Peter Plöger
BOEHRINGER INGELHEIM ESPAÑA, S.A.

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

Mr Jesús Ponce Sancho
NOVARTIS FARMACEUTICA, S.A.

02

ORGANISATION

2.1 Governing Bodies

2.2 Executive Organisation

2.2 Executive Organisation

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

On 1 February 2021, Ms Isabel Pineros joined FARMAINDUSTRIA as Director of the newly-created Access Department.

FARMAINDUSTRIA's 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
Director of the
Legal Department



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



Isabel Pineros
Director of the Access
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

3.1.1 REGULATORY FRAMEWORK

COVID-19 – STATE OF EMERGENCY

March 2020 marked the onset of the pandemic in Spain, and the corresponding proliferation of rules which have completely changed the way of life of citizens and companies. The pharmaceutical industry was one of the first sectors to suffer the consequences. Days before the state of emergency was declared, the Minister of Health recommended the suspension of medical congresses, an approach continued by the Spanish regions, which issued the corresponding instructions, along with the suspension of medical visits. FARMAINDUSTRIA reiterated these recommendations.



The declaration of the state of emergency a few days later, through the publication of Royal Decree (RD) 463/2020, provided confirmation of the new scenario with which the country would subsequently be faced. The Ministry of Health thus became one of the competent authorities, and the entire media spotlight was focused on this department and, in particular, the Interterritorial Council of the National Health System (CISNS).

In parallel, a series of ministerial orders were issued, with a substantial impact on the health industry, such as Order SND/233/2020, of 15 March, establishing certain reporting obligations of companies with manufacturing and/or import activities or the capacity to develop certain healthcare products, and Order INT/226/2020, of 15 March which, among other matters, granted powers to the Minister of Health to

ensure market supply and the service functionality of manufacturing sites affected by the interruption to the supply of products for public health, along with the temporary occupation and control of industrial facilities, factories and similar, including privately-owned healthcare establishments, as well as the pharmaceutical industry, and the implementation of temporary requisitions of all manner of goods. Specific mention should be made of Order SND/276/2020, of 23 March, on obligations for the provision of information, supply and manufacture of certain medicines, which, among other matters, established that companies must guarantee information and a sufficient supply of sensitive products; as well as Order SND/293/2020, of 25 March, establishing conditions for the dispensing and administration of medicines.





The regulations issued during the state of emergency focused in the main on establishing mobility restrictions so as to contain the pandemic and also to offset the effects of the crisis on companies and workers. We would highlight in this regard Royal Decree-Law (RDL) 8/2020, of 17 March, to address economic and social impacts, RDL 9/2020, of 27 March, adopting complementary measures to alleviate the effects of Covid-19, and RDL 10/2020, of 29 March, on recoverable paid leave which did not apply to sectors classified as essential, including the medicine supply chain.

Likewise in the month of March, we should cite RDL 11/2020, of 31 March, adopting urgent complementary measures in the social and economic sphere to address Covid-19, and Order SND/307/2020, of 30 March, establishing the interpretation criteria for the application of RDL 10/2020, and the affidavit template, to facilitate required travel between home and work. Lastly, RD 476/2020, of 27 March, was issued at the end of the month, extending the state of emergency up until 12 April 2020.

Meanwhile, in February, RDL 13/2020, of 7 April was issued, adopting certain urgent measures in the sphere of agricultural employment, and RD 15/2020, of 21 April, on urgent complementary measures to support the economy and employment, with two new RDs being issued to extend the state of emergency up until 10 May.

In May, the state of emergency was again extended up until 7 June, given the continuation of the pandemic. On this occasion the Ministry of Health was designated as the delegated competent authority which, should the Spanish regions so propose, could agree to the measures applicable and the progression of phases within particular regional confines.

Prior to the extension of the state of emergency, we should highlight RDL 17/2020, of 5 May, approving measures to support the cultural sector, and taxation measures to address the economic and social impact of Covid-19, and RDL 18/2020, of 12 May, on social

measures to protect employment, establishing specific aspects applicable to temporary workforce adjustment procedures based on force majeure (Article 1), extending 'ERTE' furlough schemes up until 30 June 2020 for those companies that had been unable to resume operations because of force majeure. Furthermore, partial force majeure ERTE furlough schemes could also be extended up until 30 June 2020. As for procedures to suspend and reduce working hours on economic, technical, organisational and production reasons declared after the month of lockdown (Article 2), it was ruled that these could be initiated while a force majeure ERTE was in place. In addition to the above, among other measures, the Sixth Additional Provision established a commitment on the part of the company to maintain employment for six months after the date of resumption of operations.



Lastly, in the month of May we would highlight RDL 19/2020, of 26 May, adopting complementary measures in the agricultural, scientific, economic, employment, Social Security and taxation spheres to alleviate the effects of Covid-19, in particular the classification as a professional contingency resulting from an occupational accident applied to illness suffered by staff working at social and healthcare establishments as a consequence of infection with the virus during the state of emergency.

Furthermore, an amendment was made to the orders governing Phases I and II by means of Order SND/442/2020, of 23 May, amending Order SND/399/2020, of 9 May, to increase the flexibility of certain nationwide restrictions established after the declaration of the state of emergency through application of Phase 1 of the Plan for the transition towards a new normality, and Order SND/414/2020, of 16 May, to increase the flexibility of certain nationwide restrictions established after the declaration of the state of emergency through application of Phase 2. Subsequently, Order SND/458/2020, of 30 May, was issued to increase the flexibility of certain nationwide restrictions established after the declaration of the state of emergency through application of Phase 3 of the Plan for the transition towards a new normality. Lastly, we would similarly highlight during the same month Order SND/403/2020, of 11 May, on the quarantine conditions required of persons arriving in Spain from other countries.



June began with a new extension to the state of emergency up until 21 June, and RD 21/2020, of 9 June, on urgent prevention, containment and coordination measures to address the health crisis caused by Covid-19, establishing prevention and hygiene measures, in particular Article 19, which established measures regarding medicines, meaning that manufacturers and holders of marketing authorisations for those medicines considered essential were required to inform the AEMPS of the available stock, the quantity supplied during the past week and the forecast release and reception of batches, including the estimated dates and quantities. They were furthermore required to establish the necessary measures and to activate protocols serving to guarantee supply.

Moreover, it was established that where an exceptional healthcare situation existed, the bodies or authorities responsible for administration of the pharmaceutical provision of the Spanish regions could establish the relevant measures to dispense medicines other than through the in-person method, guaranteeing optimal care where necessary through the distribution of medicines at healthcare centres or healthcare establishments authorised for dispensation near to the patient's home address, or at their home. Lastly, a provision was included amending Article 65(d), with a new Article 65(bis) being added to the Cohesion Law. An amendment was also made to Article 93.3 of the Guarantees and Rational Use of Medicines and Healthcare Products Act (the 'Ley de Garantías y Uso Racional de los Medicamentos y Productos Sanitarios', or 'LGURMPS'), such that the procedure for setting the maximum retail price would be agreed at the Inter-ministerial Commission for Pharmaceutical Prices ('Comisión Interministerial de Precios de los Medicamentos', or 'CIPM').



Noteworthy legislation in June would also include RDL 22/2020, of 16 June, governing the creation of the Covid-19 Fund and establishing rules regarding distribution and issuance, which entailed authorisation for an extraordinary credit facility to finance the Covid-19 Fund totalling €16 billion, which would be used to make the corresponding transfers to the Spanish regions in order to provide them with greater finance so as to address the budgetary impact resulting from the Covid-19 crisis, and to allow them to establish budgetary credits in their expenditure budget.

We must finally mention RDL 24/2020, of 26 June, on social measures to reactivate employment and protect self-employment and competitiveness of the industrial sector, which for the first time established exemptions equal to those applicable to partial force majeure for ERTE furlough schemes based on economic, technical, organisational and production grounds ('ERTE ETOP') as a result of Covid-19, while extending up until 30 September the ban on dismissal and redundancy because of Covid-19, among other measures. Lastly, the successful completion of phases of the Restriction Relaxation Plan approved on 28 April 2020 meant that the measures associated with the declaration of the state of emergency were repealed in the corresponding provinces, islands or territorial units.



In July, we would in particular cite RDL 26/2020, of 7 July, on economic reactivation measures to address the impact of Covid-19 in the spheres of transport and housing, containing an amendment to RDL 21/2020, of 9 June, entitling Works Inspectorate officials to monitor and serve demands and, where applicable, to issue infringement notices, with regard to compliance with public health measures by employers, this entitlement being extended to the public officials of the Spanish regions.

The last quarter of the year stood out for the intensity of legislative activity within the context of the health crisis. 19 September saw the publication of Law 3/2020, of 18 September, on procedural and organisational measures to address Covid-19 within the context of the Justice Administration, with the aim of streamlining the handling of proceedings, by reducing deadlines or through the use of remote electronic means. In the field of employment, the measures introduced included RDL 28/2020, of 22 September, on remote working; RDL 29/2020, of 29 September, on urgent remote working measures in public authorities and human resources of the National Health System to address the health crisis caused by Covid-19; and RDL 30/2020, of 29 September, on social measures to protect employment, to which reference is made in another section of this Annual Report.



October began with the Plenary of the CISNS passing a resolution with the declaration of coordinated public health actions in response to situations of particular risk because of the uncontrolled transmission of infections caused by SARS-CoV-2, published by means of the Resolution of 30 September 2020 of the Secretary of State for Health. Lastly, the Resolution of 29 October 2020 of the Spanish National Congress ordered the publication of the Decision to authorise the extension of the state of emergency declared by RD 926/2020, of 25 October 2020, declaring the state of emergency to contain the spread of infections caused by SARS-CoV-2, up until 9 May 2021.

November saw the approval of RDL 32/2020, of 3 November, approving complementary social measures to provide unemployment protection and support for the cultural sector, to make provision for those whose benefits expired between 14 March and 30 June 2020 and who had no access to any further support nor any opportunity to join the labour market, by including facilities for the processing and improvement of discontinuous permanent contracts. Meanwhile, the Resolution of 11 November 2020 of the Directorate-General for Public Health established the health controls to be applied at points of entry into Spain, in fulfilment of the Sixth Additional Provision of RDL 23/2020, of 23 June 2020.



For its part, the Inter-ministerial Commission for Pharmaceutical Prices adopted a decision on 12 November 2020 revising the maximum retail prices through application of the provisions of Article 94.3 of the recast text of the LGURMPS, implemented through the Resolution of 13 November 2020 of the Directorate-General for the Basic Portfolio of NHS and Pharmacy Services (the 'Dirección General de Cartera Común de Servicios del Sistema Nacional de Salud y Farmacia', or 'DGCCSF'), for disposable surgical face masks, this amount subsequently being revised through a further decision adopted by the Inter-ministerial Commission for Pharmaceutical Prices on 18 November.

In addition to the above, 17 November saw the issuance of RDL 34/2020, on urgent measures to support business solvency and the energy sector and in the sphere of taxation, Article 6 of which, with effect from 1 November 2020 until 30 April 2021, applied a 0% Value Added Tax rate to deliveries of goods, imports and intra-EU acquisitions of goods referred to in the annex to the Royal Decree-Law, including two medicines.



Particular mention should also be made of Order INT/1119/2020, of 27 November, extending until 31 December the effectiveness of Order INT/657/2020, of 17 July, amending the criteria for the application of a temporary restriction on non-essential travel from third countries to the EU and associated Schengen countries on grounds of public order and public health, as a result of the health crisis caused by Covid-19. This type of order was a constant throughout the year, since in order to control the pandemic and avoid the spread of some of the most dangerous strains which were developing in other countries throughout the year, other measures were also issued, such as those ruling the limitation of direct flights and passenger ships between the United Kingdom (UK) and Spanish ports and airports, the establishment of controls on the internal land border with Portugal, limitations on flights between Brazil/South Africa and Spain, and health control measures on people arriving in Spain from France by land, among other provisions.

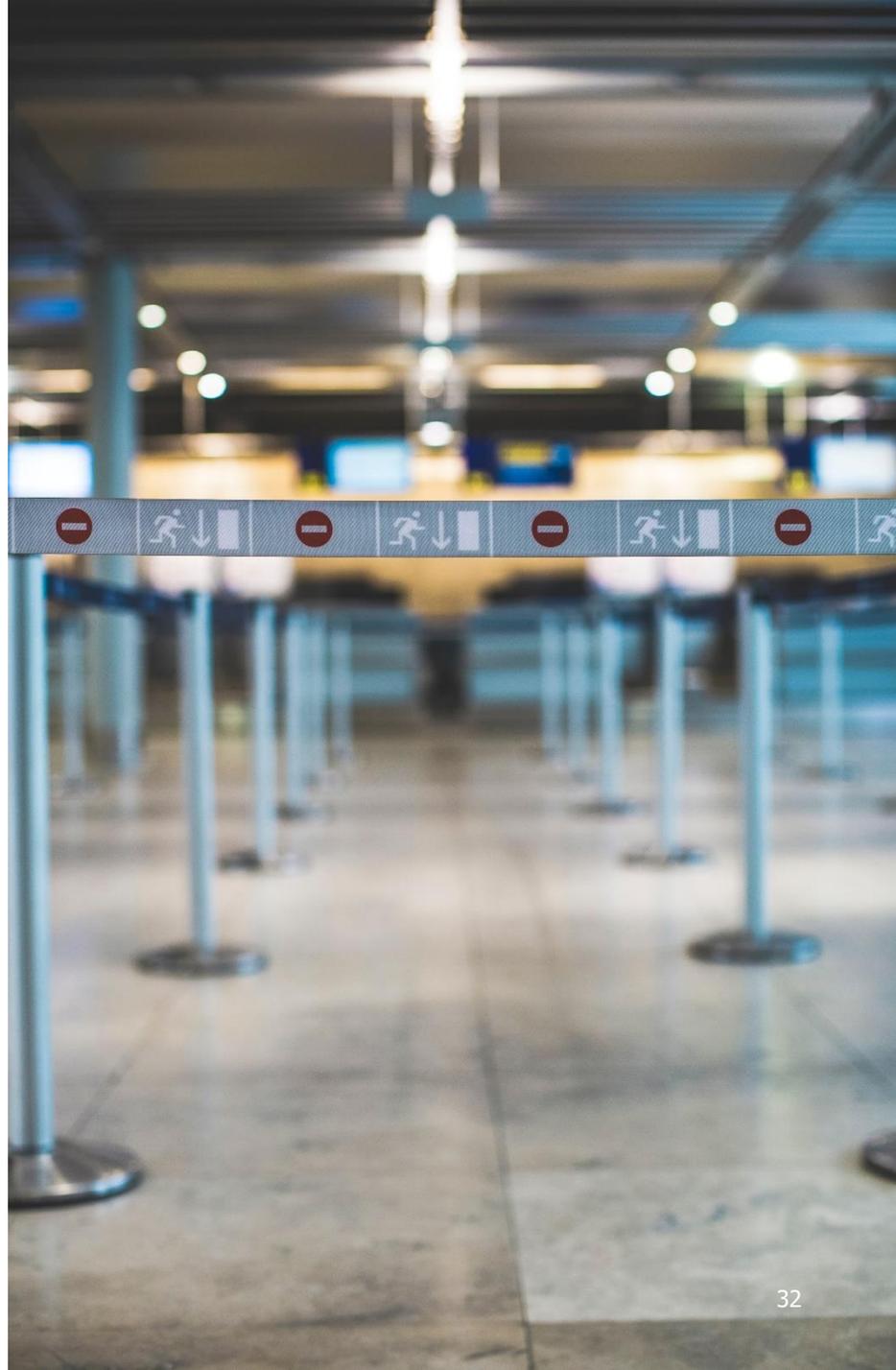
Once again, in fulfilment of the Sixth Additional Provision of RDL 23/2020, of 23 June, in its Resolution of 9 December 2020 the Directorate-General for Public Health established the formats for Active Infection Diagnostic Tests for SARS-CoV-2 permitted in connection with the health controls to be performed at points of entry into Spain. Meanwhile, the Seventh Final Provision of RDL 35/2020, of 22 December, on urgent measures to support the tourism, hospitality and retail sector, and in the sphere of taxation, made provision from the entry into force of said RDL, and up until 31 December 2022, for a 0% VAT rate to be applied to deliveries, imports and intra-EU acquisitions of certain goods and the provision of services required in order to combat the effects of SARS-CoV-2 and the effects of the special equivalence surcharge regime, including deliveries of vaccines against SARS-CoV-2 authorised by the European Commission.



Moreover, in late December two ministerial orders were published, adopting restrictive measures with regard to access controls, particularly Order INT/1236/2020, of 22 December, and Order PCM/1237/2020, of 22 December, publishing the Decision adopted by the Council of Ministers of 22 December 2020, establishing exceptional measures to limit the spread and contagion of Covid-19 by limiting direct flights and passenger ships between the UK and Spanish ports and airports.

The year ended with the adoption of RDL 36/2020, of 30 December, approving urgent measures for the modernisation of Public Administration and for the implementation of the Recovery, Transformation and Resilience Plan. This RDL served to adopt urgent measures intended to structure a model of governance for the selection, monitoring, evaluation and coordination of investment programmes and projects under the aforementioned Plan, and to implement regulatory reforms that would serve to improve agility in the operational start-up of projects, and procedural simplification. The most notable changes include the creation of a new public-private partnership concept: Strategic Recovery and Economic Transformation Projects ('Proyectos Estratégicos para la Recuperación y Transformación Económica', or 'PERTE'), which will play a key role in the implementation of catalyst projects. The creation of a register at the Ministry of Finance will serve to identify those operators with an interest in a PERTE in order to facilitate administration.

Aside from the above, during 2020 a whole series of regulations were issued by Spain's regions, setting out prevention, containment and coordination measures to address the health crisis. Of particular note would be limitations on geographical mobility and opening hours, the number of people who could meet both indoors and outdoors, exceptions to these limitations, and safety and prevention measures at workplaces. With regard to healthcare centres, services and establishments, provision was likewise made for the adoption of organisational, prevention and hygiene measures to ensure the well-being of workers and patients, in addition to the availability of the required protective materials, the cleaning and disinfection of the areas used and the elimination of waste, along with appropriate maintenance of equipment and premises. Some of these provisions have also served to regulate the conditions for the staging of congresses, meetings, conferences, seminars and workshops within the sphere of innovation and scientific research.



REFERENCE PRICING

On 22 September 2020, the Directorate-General for the Basic Portfolio of NHS and Pharmacy Services (DGCSF) launched the public consultation procedure on the Order to update the Reference Pricing System for the year 2020. Unlike previous orders, the use of the ATC5 classification as the sole criterion to make up certain reference groupings was abandoned, in accordance with the existing case-law.

In this case, FARMAINDUSTRIA's main focus was on its opinion regarding incorrect grouping where the active pharmaceutical ingredient of the presentations included in the group do not fully coincide and therefore should not be considered, as the Law requires, as the same active pharmaceutical ingredient or when an orphan medicine presentation is included.

Since these arguments were not incorporated in SND/1121/2020, of 27 November, FARMAINDUSTRIA filed a legal appeal on the basis of the arguments advanced at the public hearing stage, namely the inclusion of incorrect grouping, i.e., orphan medicines, same medicine with different trademarks, medicines with ATC5 classification or paediatric medicines with indications for adults and children where the formulation had only been developed only for children.





Within the context of the legal appeal proceedings, we should highlight the partial climbdown by the public authorities in the two appeals lodged by the Association against the reference pricing Orders for the years 2018 and 2019. These concessions correspond to the improper creation of certain groupings on the basis of ATC5 classification. On 22 December 2020, the National Court upheld the legal appeal lodged by FARMAINDUSTRIA against the 2018 Reference Price Order was upheld, eliminating the groupings challenged on the basis of the reference criterion (groupings made up by ATC5 classification).

However, this criterion was recently included in the recast text of Article 98 of the LGURMPS, by means of the amendment applied to this article by General State Budget Law 11/2020, of 30 December 2020, for the year 2021 (35th Final Provision), in force from 1 January 2021 onwards.

IPT CONSOLIDATION PLAN

On 26 November the Ministry of Health published the Plan for the Consolidation of Therapeutic Positioning Reports ('Informes de Posicionamiento Terapéutico', or 'IPT') on medicines within the National Health System, developed by the Standing Pharmacy Commission of the NHS Inter-territorial Council.

The structure of the Plan comprises three strands of action:

- 1** The evaluation network (REvalMed NHS), comprising the DGCCSF, the AEMPS and the Spanish regions, which will have a therapeutic evaluation team (headed by the AEMPS), another pharmaco-economic evaluation team (headed by the DGCCSF), and seven evaluation nodes corresponding to therapeutic areas, comprising more than 120 experts appointed by the Spanish regions.
- 2** The methodology for the design and approval of the IPTs, according to which the IPTs will be prioritised in accordance with the therapeutic positioning, the potential incremental clinical benefit, new indications and potential interest for the NHS. A process is established for the generation of IPTs with milestones and deadlines, the provision being for full completion in 90 business days, with the publication of a Standardised Operating Procedure (SOP) for the evaluation, and the development of specific guides comprising annexes to the general SOP. The main change lies in the inclusion of the pharmaco-economic evaluation and information as to therapeutic alternatives. The participation of scientific societies and patient organisations will remain unchanged, and a hearing will be granted to the pharmaceutical manufacturers that are the owners of active ingredients cited in the IPT.

3 | A dashboard will allow users to ascertain the current phase of each IPT, the timings of each phase, the degree to which deadlines are fulfilled, and hence the time elapsing from the marketing authorisation up until conclusion of the IPT and the decision regarding its inclusion for reimbursement is made.



Given the overarching significance of the document, FARMAINDUSTRIA has announced a legal appeal since the IPT had been regulated without considering that it is part of the reimbursement procedure for medicines with multiple recipients and ad extra effects, and was issued without having followed the legally-established procedure for this purpose.

ORPHAN MEDICINES

At its meeting on 3 March 2020, the Council of Ministers approved the economic framework for orphan medicines, in response to the problems resulting from the most recent Reference Pricing Order, which had for the first time included an orphan medicine with a known active pharmaceutical ingredient, this circumstance having been appealed.

In fulfilment of this governmental Decision, the DGCCSF published its Resolution of 2 June 2020, establishing the exemption of orphan medicines from the Reference Pricing System, while making this exemption subject first of all to the fulfilment of conditional factors, such as the absence of a therapeutic alternative within the pharmaceutical provision of the NHS, or if such an alternative did exist, that the orphan medicine offered a significant clinical benefit, as agreed within the context of the Standing Pharmacy Commission of the CISNS, ratified at the Inter-ministerial Commission for Pharmaceutical Prices, with consideration of this aspect being based on the available scientific knowledge and evidence, and any Therapeutic Positioning Report that might exist.

Furthermore, the price of the exempted medicine will be subject to review if it is found that it is economically viable or if any of the circumstances set out in Article 96 of the recast text of the LGURMPS are fulfilled. This review provision will be included in the decision to include the medicine within the pharmaceutical provision of the NHS, issued under the terms of Article 92 of the aforementioned recast text.

Since this exemption is made subject to the fulfilment of these requirements, FARMAINDUSTRIA has announced a legal appeal, based on a breach of the provisions of the applicable domestic and European regulations.



OBSERVATIONAL STUDIES

RD 957/2020, of 3 November, governing observational studies with medicines for human use, was published towards the end of the year. Observational studies with medicines are an essential instrument to obtain data as to their conditions of use, safety and effectiveness within the actual context of healthcare. This new provision is justified on the one hand by the emergence of EU provisions affecting pharmacovigilance, and on the other by the domestic regulations governing clinical trials, assigning medicinal Research Ethics Committees (CEIm) the function of evaluating the methodological, ethical and legal aspects of clinical studies, be they clinical trials or observational studies with medicines.

With the entry into force of the aforementioned RD on 2 January, the aim is to simplify the current processes governed by Order SAS/3470/2009, so as to limit the requirements prior to the commencement of observational studies with medicines to a favourable opinion by the CEIm and the agreement of the healthcare establishment where the participant subjects are treated. There is also an amendment to the Bylaws of the AEMPS, eliminating the Post-authorisation Study Coordination Committee, including patient representatives on various committees of the Agency, and creating the Technical Certification Area Committee. RD 1090/2015, of 4 December 2015, is also amended in order to specify the composition of the CEIm.



One of the aspects of concern during the processing of the regulation was the treatment given to Patient Support Programmes (PSP) in the initial drafts, the baseline position being an absolute prohibition of PSP other than observational studies aligned with the provisions of the RD. However, following the arguments made by FARMAINDUSTRIA, the text indicates that the regulation affects those PSP that fulfil the criteria to be considered an observational study with medicines, and that will therefore need to be conducted in accordance with the provisions of this RD.

An FAQ document was recently published in this sphere to establish the guidelines to be followed with the monitoring of post-authorisation studies prior to the entry into force of the RD, and this document will gradually be updated as new questions arise. The AEMPS has issued a note of information with regard to the publication of information about studies conducted in Spain in the Spanish Clinical Studies Register (the 'Registro Español de estudios clínicos', or 'REec'). Publication of information in the REec is mandatory for observational studies with medicines for prospective monitoring, and voluntary for all other such studies. In order to comply with this obligation, the AEMPS has provided the sponsors of the studies with access to the GESTO Administration of Observational Studies with Medicines platform, allowing this information to be registered, and which can be consulted via the REec.



Law 2/2021, on urgent prevention, containment and coordination measures

The Law - derived from RDL 21/2020, which was treated as a draft bill upon its ratification – includes some issues related to medicines, healthcare products and products required for health protection, including information obligations concerning essential medicines, the need to establish the necessary measures and to enable protocols serving to guarantee the supply of those medicines determined by the Director of the AEMPS for healthcare services and establishments in accordance with their needs, and the possibility for the Minister of Health to order the prioritisation of manufacture of medicines.

Likewise, the Seventh Additional Provision incorporates the suspension of medical inspection approval for access to triple therapy for COPD throughout the duration of the Covid-19 health emergency, and the amendment of the recast text of the Guarantees Law of the Third Final Provision, specifically Article 94.3, which allows the Government to regulate the price-setting mechanism for healthcare products and medicines not subject to medical prescription, as well as other products required to protect the health of the population.



Popular Legislative Initiative on fairly priced medicines

This Popular Legislative Initiative, which was admitted for processing by the board of the Congress of Deputies in September 2019, concluded its parliamentary procedures following expiry of the deadline for signatures to be gathered in support of the initiative. Conclusion of the process was the result of the withdrawal by the proposers of the initiative, which was intended to amend certain articles of the LGURMPS, so as to address pricing transparency and to implement the 'cost-plus' system for price setting, as well as support public research of medicines and independent training of healthcare professionals.



Proposal for a Royal Decree on the availability of medicines in special situations

The Ministry of Health is working on the text of the aforementioned RD Proposal, the purpose of which is better to define the various existing circumstances for access to medicines in special situations, and the different categories included under each of them, as well as the healthcare context within which they may be used.

It is similarly intended to improve the access process by simplifying administrative workloads for the applicants, taking advantage of the benefits offered by information and communication technologies - in the field of both administration and transparency - as well as increasing communication among public authorities and the generation of knowledge associated with the use of medicines in such situations.

The intention is likewise to define the actions and responsibilities of the subjects involved, and to incorporate elements ensuring that the use of medicines in special situations does not become routine, by establishing measures to encourage the marketing and use of medicines via the channels established under ordinary legislation.



TRANSPARENCY

Particular mention should be made in this subsection of Decree 76/2020, of 9 September, on a Governing Council for the creation of the Transparency Register for Madrid, and approving the Regulations governing its organisation, legal regime and functionality. This is a mandatory, public register operating free of charge, for the purpose of registration of those conducting any activity the purpose of which is directly or indirectly to influence the generation of legal regulations and general provisions and the preparation and application of public policy and, in particular, those activities set out in Article 65 of the Law, which include contact with officials, executives, professionals, statutory personnel, consultants or other parties belonging to regional and local public authorities, for the aforementioned purpose.

Following the consultation conducted in the Madrid, the governing bodies would, for the purposes provided in the regulations, be the Directors-General of Specialist- and Primary-Care Cost Centres, as well as Deputy Managers and Directors and Deputy Directors of Divisions, although the Transparency Law does not affect ordinary contacts inherent in the client-supplier relationship.

In turn, the Regional Government of Cataluña has likewise drawn up a regulatory provision in partial implementation of Law 19/2014, of 29 December 2014, on transparency, access to public information and good governance, which is pending publication. Justification for the adoption of this regulation is to be found in the need to guarantee implementation of the Law in a more uniform, effective and comprehensive manner, to clarify undefined legal concepts and settle queries of interpretation, by drawing on the experience built up by public authorities in Cataluña.

PUBLIC PROCUREMENT

The Islas Baleares passed Decree-Law 8/2020, of 13 May 2020, on urgent and extraordinary measures to promote economic activity and achieve administrative simplification in the sphere of public authorities so as to alleviate the effects of the crisis caused by Covid-19. This Decree-Law, approved and processed as a draft bill, gave rise to Law 2/2020, of 15 October 2020.

The reactivation measures include a provision system for medicines without tendering, based on the fact that there is already a price defined by means of an administrative procedure, negotiated between the public authority and the pharmaceutical manufacturer, and which applies to medicines with a manufacturer sale price established in an administrative procedure for the NHS, or with a reference price, which may be purchased by the public hospital system outside the confines of public procurement procedures.

Regulations are likewise established for the purchase of medicines for hospital use, establishing a system serving to define general conditions, which may or may not include reductions on the administratively established price for reimbursement through the NHS, open to multiple suppliers, with the possibility of the subsequent inclusion of other economic operators, in accordance with the case-law established by the Court of Justice of the EU in its judgment of 2 June 2016 (Dr. Falk Pharma GmbH v. DAK-Gesundheit, Case C-410/14, points 41 and 42).

DATA PROTECTION

On 16 July 2020 the Grand Chamber of the Court of Justice of the European Union (CJEU) issued a judgment in the request for a preliminary ruling submitted by the High Court of Ireland in the proceedings between Data Protection Commissioner and Facebook Ireland Ltd and Maximilian Schrems (Case C 311/18), nullifying the Privacy Shield, the framework allowing international transfers of data between Europe and the USA.

The CJEU based its position on the fact that access to the data of European citizens by public authorities constitutes an intrusion on fundamental rights, which should be provided for in a regulation of legislative rank with clear and precise guidelines governing the scope and application of the limitation in question, and providing safeguards for data subjects.

With regard to the standard contractual clauses approved by the European Commission, which were likewise challenged, it holds that they are valid to the extent that they provide effective mechanisms serving in practice to ensure fulfilment of the level of protection required by EU Law, including the possibility that the transfer of personal data to a third country on the basis of such clauses may be forbidden or suspended if the recipient thereof does not or might not comply with the terms of the clauses. However, in accordance with the regulations and practices in force in the third country that receives the data, the adoption of additional guarantees may be necessary in order to allow a transfer to be performed.



Lastly, the CJEU asserts that given the inherent characteristics of the legislation and practices in force in the USA, it would be unlikely that the inadequacy of contractual clauses could be supplemented by means of the adoption of such additional guarantees that are not binding on the public authorities in said country. As a consequence, transfers of personal data to the USA will require a prior case-by-case analysis serving to determine which of the mechanisms provided for in Article 46 of the General Data Protection Regulation may be applied to such transfers so as to ensure an adequate level of data protection.

In this regard, the Spanish Data Protection Agency (the 'Agencia Española de Protección de Datos', or 'AEPD') published a note indicating the importance of the judgment with regard to the fundamental right of data protection within the context of international transfers to third countries, in addition to an FAQ document produced by the European Data Protection Committee regarding the same matter, to be developed in accordance with ongoing examination and evaluation of the pronouncement, the aim being to provide initial clarification and preliminary guidance for the parties concerned as to the use of legal instruments for the transfer of personal data to third countries, including the USA.

Regarding other matters, it should be mentioned that FARMAINDUSTRIA has subscribed to the AEPD Digital Compact for the protection of persons, for the promotion of a major agreement for the coexistence of citizens in the digital sphere, the purpose of which is both to encourage a commitment to privacy in the business models of companies and organisations, by balancing the right of data protection with innovation, ethics and competitiveness in business, and also to raise public awareness, in particular among children, as to the consequences of distributing sensitive content via the Internet.

The compact contains an action plan with 103 initiatives in spheres such as education and children, gender equality, innovation and enterprise, the environment, good governance and transparency, and workers. All these initiatives are fully aligned with the Sustainable Development Goals (SDG) of the UN's 2030 Agenda.

By subscribing to this compact, FARMAINDUSTRIA commits to implement the principles and recommendations it contains, and to inform its members and employees of the Agency's Priority Channel to request the urgent elimination of sexual and violent content distributed without consent via the Internet, in addition to other AEPD resources and tools, to help raise awareness as to the value of privacy and the importance of personal data processing. It likewise commits to promote the recommendations of the AEPD to prevent digital sexual harassment in the workplace, and firmly rejects the use and distribution of personal data that would constitute unlawful data processing and could undermine the privacy rights of its employees.



ENVIRONMENT

In June 2020, the Council of Ministers approved the public consultation procedure for the Green Paper on Waste, with the aim of transposing into Spanish law the Waste and Single-Use Plastics Directives, while also taking the opportunity to revise certain aspects of Waste Law 22/2011.

The changes incorporated include in particular the introduction of a new levy on non-reusable plastic packaging, with an exemption applying to "the manufacture, import or intra-EU acquisition of non-reusable plastic packaging used for the primary packaging of medicines", and the revision of the regulations as to extended producer responsibility, in accordance with EU regulations.



Regarding this point, in fulfilment of Waste and Contaminated Soil Law 8/2019, of 19 February 2019, the Islas Baleares recently sent a communication to suppliers reminding them of the obligation contained in the Law that all types of packaging (domestic or household, commercial, industrial, primary, collective or secondary, tertiary or for transport, etc.) must be covered by an extended producer responsibility (EPR) system for the packaging. In the case of the pharmaceutical industry, this provision would not affect the packaging of medicines dispensed at retail pharmacies, with the waste being managed by SIGRE, but would affect packaging of hospital medicines and cardboard shipping boxes, pallets, etc.

Although the extended responsibility system must be incorporated into Spanish law through transposition of an EU Directive by the end of 2024, the responsibility for drawing up the regulations would lie solely with the State, and the Islas Baleares would therefore have overreached its powers by including this obligation in the aforementioned Law, a matter being analysed by the Association at the time when this Annual Report went to press.



COMPETITION

The Competition Promotion Department of the National Markets and Competition Commission (the 'Comisión Nacional de Mercados y Competencia', or 'CNMC') launched a public consultation as to the marketing and wholesale distribution of dispensable medicines via retail pharmacies in Spain.

The consultation has a twofold aim: first of all, to compile the opinions of the key stakeholders in the sector, and furthermore to address the final considerations of the market study being conducted in this sector, a continuation of the study published in 2015 on the retail sector.

By the time when this Annual Report went to press, the CNMC was still preparing its study.



INTELLECTUAL PROPERTY

The Spanish Patents and Trademarks Office published the public consultation procedure prior to the preparation of a Green Paper to amend Trademarks Law 17/2001, of 7 December 2001, Legal Protection of Industrial Designs Law 20/2003, of 7 July 2003, and Patents Law 24/2015, of 24 July 2015.

FARMAINDUSTRIA has once again stressed the need to guarantee adequate level of protection in the field of intellectual property so as to preserve the legal certainty of the medicinal R&D model which relies on such a structure. The ability to attract foreign investment to Spain (and hence the EU) depends on levels of protection afforded in the sphere of intellectual property (patents and supplementary protection certificates). Patents contribute to scientific knowledge and are the cornerstone of the global biomedical R&D model, allowing pharmaceutical companies to develop 95% of the medicines currently available.

PLAN TO PROMOTE GENERIC AND BIOSIMILAR MEDICINES

As initially indicated in the 2019 Annual Report, in May this year we learned of the first draft Plan to Promote Generics and Biosimilars. Following the reports by the CNMC and the Advisory Board for the Financing of Pharmaceutical Provision of the NHS (CAPF), at the meeting of the Standing Pharmacy Commission of the CISNS held on 24 September 2019, a resolution was passed to approve the update to the "Action Plan to promote the use of market-regulating medicines within the NHS: biosimilar and generic medicines", along with a resolution to initiate a period of public presentation so as to elicit contributions from stakeholders, via the organisations or associations representing them. On 10 October 2019 the Ministry of Health website published a new version of the Plan for contributions to be submitted.



Both FARMAINDUSTRIA and a number of scientific societies and patient associations have conveyed their contributions to the Ministry of Health, highlighting the negative effects of this plan. Specific reference has been made to the negative impact that the plan would have for the sector if approved on the terms as known, emphasising that the approach is misguided, and could cause almost irreparable harm to the innovative industry. These considerations were likewise sent both to scientific societies and to the Regional Health Ministers, with whom a series of meetings was conducted so as to explain the effects on the sector in detail.

By the time when this Annual Report was drawn up, possible approval of this initiative by the CISNS remained pending, and FARMAINDUSTRIA has been closely monitoring this matter given the numerous negative repercussions it would have for the sector.

ADVISORY COMMITTEE FOR THE FINANCING OF NHS PHARMACEUTICAL PROVISION

In March 2019, the Council of Ministers ordered the creation of the Advisory Committee for the Financing of the National Health System Pharmaceutical Provision (CAPF). Over the course of 2020, the CAPF published a consensus document containing five strategic operational approaches for the period 2020-2021:

- 1 Budgetary and personal resources.
- 2 Policies to encourage competition.
- 3 Criteria and procedures for price setting and the reimbursement of new medicines and indications within a comprehensive evaluation and positioning procedure.
- 4 Recommendations for the generation, revision or adoption of support tools (guides and procedures) for the evaluation and positioning of medicines.
- 5 Recommendations for the development of a dynamic evaluation system.



The aims of the CAPF through the strategic approach "Criteria and procedures for price setting and reimbursement of new medicines and indications within a comprehensive evaluation and positioning procedure" are twofold:

- 1 Analyse the criteria and procedure to focus the negotiation and setting of prices, taking into account the incremental clinical benefit and the incremental cost-effectiveness relationship.
- 2 Analyse the criteria and procedure for the inclusion and exclusion of a medicine within public coverage (upon market release or subsequently).
- 3 Analyse and set out recommendations as to the criteria and procedure for decision-making regarding prices and the reimbursement of medicines subject to conditional marketing authorisation by the EMA.
- 4 Draw up recommendations to prepare a methodological guide to establish the price and reimbursement of the medicine in accordance with the degree of uncertainty as to its efficacy, safety and efficiency.
- 5 Establish recommendations to set the cost by QALY (maximum provision payable per QALY) for use in pricing and reimbursement decisions.



For the development of the objectives of this operational strand, CAPF technical support groups were set up, comprising doctors, health economists, pharmacists and healthcare decision-makers/planners, with the resolution to appoint the members being published on 24 November 2020.

Additionally, over the course of 2020 the CAPF produced other documents:

- 1 Comments on the Action Plan to promote the use of market-regulating medicines within the NHS: biosimilar and generic medicines.
- 2 Opinion on the need to reform the current co-payment system for medicines.
- 3 Therapeutic positioning reports on medicines within the National Health System.



3.1.2 THE SPANISH REGIONS

Political scenario. Elections and significant changes in regional governments



Galicia and the País Vasco held their regional elections on 12 July 2020. Polling was initially scheduled for 5 April 2020, but as a result of the health crisis caused by the coronavirus pandemic and the state of emergency decreed by the Spanish Government, the polling date was postponed until the month of July. This resulted in the Partido Popular renewing its absolute majority in Galicia, while the Partido Nacionalista Vasco was the winner in the País Vasco, although it was forced to continue the governing coalition in the region with the Partido Nacionalista Vasco.



Cataluña, meanwhile, held early elections on 14 February 2021. This resulted in the PSC (Partido Socialista de Cataluña) and ERC (Esquerra Republicana de Cataluña) both gaining 33 seats. By the date when this Annual Report went to press, no regional government had yet been formed.

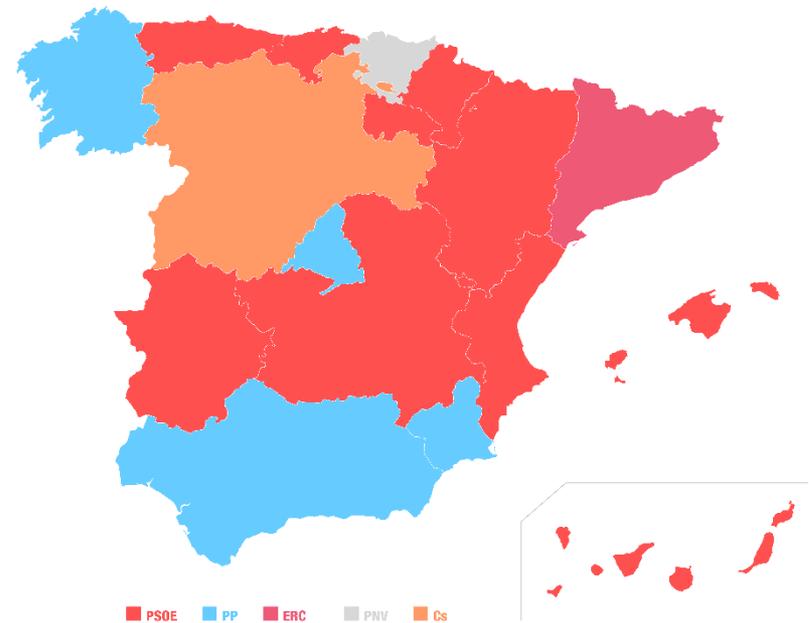


Lastly, Madrid held early elections on 4 May 2021, which resulted in a victory for the Partido Popular, although it did not achieve an outright majority. By the date when this Annual Report went to press, no regional government had yet been formed in Madrid.

Regional Health Ministers

ANDALUCÍA Jesús Aguirre Muñoz (PP)	EXTREMADURA Jose María Vergeles (PSOE)
ARAGÓN Sira Repollés (PSOE)	GALICIA Julio García Comesaña (PP)
ASTURIAS Pablo Fernández (PSOE)	LA RIOJA Sara Alba (PSOE)
ISLAS BALEARES Patricia Gómez Picard (PSOE)	MADRID Enrique Ruiz Escudero (PP)
ISLAS CANARIAS Blas Gabriel Trujillo (PSOE)	MURCIA Juan José Pedreño (PP)
CANTABRIA Miguel Rodríguez (PSOE)	NAVARRA Santos Induráin (PSOE)
CASTILLA LA MANCHA Jesús Fernández (PSOE)	PAÍS VASCO Gotzone Sagardui (PNV)
CASTILLA Y LEÓN Verónica Casado (Cs)	VALENCIA Ana Barceló Chico (PSOE)
CATALUÑA Alba Vergés Bosch (ERC)	

Regional Health Departments according to the most recent electoral results



FARMAINDUSTRIA-SPANISH REGIONS FORUMS

As a consequence of the Covid-19 pandemic situation and the lockdown and restrictions on mobility decreed by the health authorities, in 2020 it was not possible to hold the Farmaindustria-Spanish Regions Forum, initially scheduled for the first four months of the year in Palma de Mallorca, following the invitation that the regional authorities had sent out. We trust that the evolution of the epidemiological situation and pressure on healthcare facilities will allow this traditional gathering with those in charge of pharmacy and research in the Spanish regions to be held once again in 2021.



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

2020 continued to provide evidence of the role of the Spanish regions in pricing and reimbursement processes of medicines, given their significant involvement in the CIPM and the activity of the Standing Pharmacy Commission (the 'Comisión Permanente de Farmacia', or 'CPF') of the CISNS.

It should in this regard be recalled that in May 2019 the CISNS Plenary passed a resolution to increase the number of Spanish regions involved at the plenary sessions of the CIPM with observer status (in other words with the right to speak but not to vote) to cover all the regions. As a result, three Spanish regions have since that date participated as members, with the right to speak and vote, while the remaining 14 regions have observer status.

The CIPM, which corresponds to the Secretary of State for Health, is the body responsible for setting the manufacturers' sale price (PVL) for each pharmaceutical presentation to be included or already included within the pharmaceutical provision of the NHS.

In 2020 the CIPM met on nine occasions (4 February; 4 March; 1 April; 6 May; 17 June; 15 September; 14 October; 12 November, and 17 December).



E-HEALTH PROJECTS IN THE NATIONAL HEALTH SYSTEM

The development of information and communication technologies (ICT) 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 Spanish Government has promoted a number of initiatives in order to progress towards interoperable systems within the NHS as a whole.





Electronic prescription and Interoperable electronic prescription. Situation in the Spanish Regions

According to the information provided by the Ministry of Health, in late 2020 all the Spanish regions had fully implemented electronic prescriptions at all healthcare levels (health centres, clinics, hospitals and retail pharmacies). The percentage of electronically dispensed prescriptions for the NHS as a whole in December 2020 amounted to almost 98%, with Cataluña the region with the highest percentage of dispensation via this system, at 99.96%.

Since Law 16/2003, on the cohesion and quality of the National Health System was introduced, a series of operational approaches have been developed across the NHS as a whole with the aim of responding to the general public's need for healthcare information when travelling from one region to another and healthcare provision is required.

Electronic prescription systems are currently interoperable across the 17 autonomous regions and INGESA. According to the most recent data published by the Ministry of Health, in 2020 there were 310,758 acts of dispensation, with 793,182 units dispensed to 217,434 different citizens via interoperable electronic prescription.

Work is currently ongoing to include mutual insurers offering public provision within the NHS interoperable electronic prescriptions system. By the date when this Annual Report was drawn up, 12 regions (Andalucía, Asturias, Aragón, Islas Baleares, Islas Canarias, Cantabria, Extremadura, La Rioja, Murcia, Navarra, País Vasco and Valencia) had incorporated MUFACE (the General Mutual Insurer for State Civil Servants), the MUGEJU (General Judicial Mutual Insurer) and the ISFAS (Armed Forces Social Institute) within their interoperable electronic prescriptions systems. Extremadura has incorporated MUFACE, while Cataluña, Castilla y León, Castilla La Mancha and Galicia have not yet begun the incorporation of these mutual insurers within their system interoperability.



National Health System digital clinical records

The 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 National Health System, guaranteeing the availability of their prior clinical information. Each Spanish region had within its territorial scope implemented automated systems to gather and administer individual health data, providing support for healthcare processes, among other services, although citizen mobility is often accompanied by the need for healthcare provision outside their area of residence because of problems which arise, and information must therefore accompany patients at all times.

This required the adoption of interoperability elements across all the Health Services. The application of information standardisation criteria, together with the development of a healthcare intranet within the National Health System, helps to protect public health at all times, irrespective of where citizens might require healthcare provision.





The NHS digital clinical record aims to ensure access for citizens and healthcare professionals to the relevant clinical documentation in order to provide healthcare for a patient from any NHS location, while providing citizens with a guarantee that their data can only be accessed by those with authorisation for this purpose.

This project was headed by the Ministry of Health within the context of the Online Health Programme - in collaboration with the Public Commercial Enterprise red.es, the 17 Spanish regions and the INGESA - and by late 2020 all the regional health services had been certified as issuers and recipients of information, except for Cataluña, which remains just an issuer. As a result, according to data from the Ministry of Health, the NHS digital clinical record now covers some 93% of the population with an individual healthcare card.

REGULATORY INITIATIVES IN THE REGIONAL FIELD

In the field of healthcare, 2020 was a year defined by the handling of the Covid-19 pandemic. From the month of March, when the state of emergency was decreed, the Spanish regions embarked within the scope of their responsibilities on extraordinary healthcare efforts focused on an attempt to arrest the pandemic's spread and care for patients, which represented a real challenge for the regional health services and for society as a whole. Most regional regulatory initiatives in progress were therefore interrupted, with the focus being shifted to others involved in the handling of this healthcare crisis. We may nonetheless highlight the following:

Andalucía. Tenders

Following the regional elections in December 2018, the Partido Popular and Ciudadanos formed a coalition government with the support of the 12 Vox representatives. The healthcare measures agreed and included in the agreements signed by the three political parties included the reversal of the tender model for medicines in force in Andalucía since 2012. The new regional Government thus announced that no new tenders would be held when the contracts corresponding to the tenders in progress expired.

On 28 December 2020, the final two-year deadline of the 14th and last tender in force in Andalucía expired, at which point the Andalusian Government confirmed that tenders had ended, and would not be replaced with a similar formula.



Cantabria. Order SAN/18/2020, creating and regulating the Corporate Pharmacy Committee of Cantabria

In February 2020 the Official Gazette of Cantabria published Order SAN/18/2020, creating and regulating the Corporate Pharmacy Committee of Cantabria, as a collegiate consultative, advisory and support body with regard to pharmaceutical provision, attached to the Regional Health Department via the Directorate-General for Regulations, Pharmacies 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, including those approved under risk management programmes that would require particular monitoring, extended access, or otherwise those under conditional approval.
- 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 purchases of medicines.
- 5 Propose prescription support systems integrated with electronic clinical records.
- 6 Coordinate the actions of the area of pharmacy and therapeutic committees.

This Order was processed as a consequence of Judgment 266/2017, of 27 July 2017, which became binding by means of the Ruling of 9 March 2018 of the High Court of Justice of Cantabria, declaring Order SAN/31/2016, of 23 June 2016, creating and regulating the Corporate Pharmacy Committee within the context of the SCS as invalid, by upholding the legal appeal lodged against the Order by FARMAINDUSTRIA.

Castilla La Mancha. Decree 25/2021, of 23 March 2021, creating and regulating the Central Pharmacy and Therapeutic Committee of the Health Service of Castilla La Mancha.

In December 2018 the Regional Government of Castilla-La Mancha launched the public consultation procedure to establish the Regional Committee for the Rational Use of Medicines, as provided in Pharmaceutical Service Regulatory Law 2/2015, on Pharmaceutical Provision Ordinances which did not continue the procedural stages.

The Health Service of Castilla La Mancha published Decree 25/2021, of 23 March 2021, creating and regulating the Central Pharmacy and Therapeutic Committee (CCFT) of the Health Service of Castilla La Mancha (SESCAM). The Committee, which is attached to the SESCAM, and answers in functional terms to the Directorate-General for Healthcare, has been created in order to coordinate the functioning of the different Pharmacy and Therapeutic Committees (CFT) and Rational Use of Medicines Committees (CURM) existing at the SESCAM's Managerial Departments, and also to establish common criteria serving to address the uniform optimisation of pharmaceutical provision across all sites.



According to Article 4, the Committee will, among others, perform the following functions:

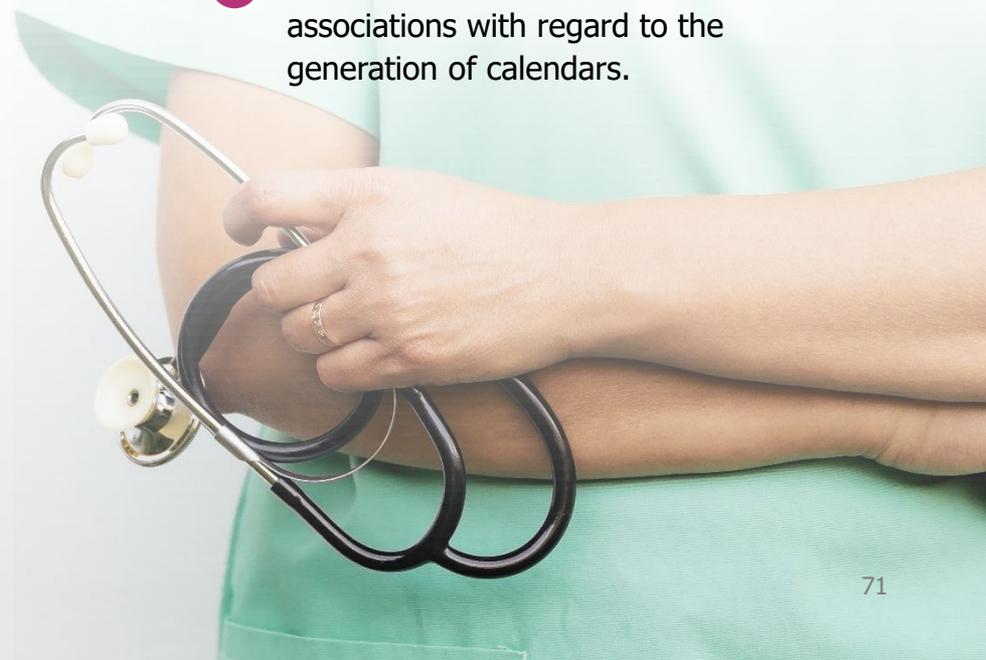
- 1 Propose evaluation and selection criteria for medicines, to be followed by the CFT and CURM.
- 2 Propose the generation of protocols, clinical guidance and consensus documents for those conditions which, given their health, social or economic impact, or their variability in the usage of medicines, would require application throughout the Region.
- 3 Recommend therapeutic usage criteria for those medicines deemed necessary by the CCFT to allow them to be applied at the healthcare centres of the SESCAM.
- 4 Agree which medicines not covered by public reimbursement may be purchased and used by hospitals.
- 5 Agree on criteria for the use of medicines on conditions other than those authorised.
- 6 Propose and monitor the quality objectives and indicators in the sphere of rational use of medicines for management contracts.
- 7 Coordinate the generation of a pharmacotherapy guide for prescriptions, as a system to offer support and guidance in clinical decisions, and for integration with the electronic clinical record.

País Vasco. Order of 10 February 2020 governing medical visits at organisations of the health services of the Basque Health System

The Official Gazette of the País Vasco published its Order of 10 February 2020, governing medical visits at organisations of the health services of the Basque Health System. According to the explanatory memorandum, the aim is to update the regulations issued in this sphere (Instruction 5/2000, regulating medical visits by pharmaceutical manufacturer representatives to health service organisations dependent on the Osakidetza). 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. Training and educational programmes are not considered to be medical visits.

In October 2020, following authorisation by the Governing Bodies of FARMAINDUSTRIA, it was announced that a legal appeal would be filed against this, among other matters because of:

- 1 The presumed equivalence of in-person and remote digital calls.
- 2 The role attributed to visitor associations with regard to the generation of calendars.



Order of 13 October 2020, governing the recognition of healthcare interest for scientific events taking place in the País Vasco

The purpose of this Order is to govern the procedure for the recognition of the healthcare interest of scientific events such as conferences, congresses, meetings, seminars and symposia conducted both remotely and in-person within the confines of the País Vasco for the purpose of the promotion, application and dissemination of health-related sciences and techniques. The scope of this recognition does not extend to courses and other activities the main purpose of which is training.

Recognition of healthcare interest will result in a series of benefits, including in particular:

- 1 Use of this title in the documentation of the activity, allowing this to be publicised once the signed concession document has been obtained.
- 2 Tax benefits and exemptions as established by law for this type of recognition.
- 3 Receipt of any technical assistance and advice that the Secretary of State for Health might be able to provide.
- 4 Inclusion in the list of events that have been granted the recognition on the Secretary of State for Health's website.

Madrid. Scientific-Technical Advisory Committee

The Region of Madrid published an Order creating the Scientific-Technical Advisory Committee for Research and Healthcare Innovation. The Committee will exercise the following functions:

- 1 Provide scientific-technical advice for the responsible body in the field of research and innovation in all matters requested with regard to health research and innovation.
- 2 Issue proposals and recommendations regarding health research and innovation affecting the health services of Madrid.

This Committee will comprise at least 12 members, including:

- 1 The scientific directors of the public health research institutes of Madrid accredited by the Carlos III Health Institute.
- 2 The head of the Primary Healthcare Management Research Unit.
- 3 At least two external experts of established standing in the field of health research and innovation.
- 4 A representative of the most representative patient associations in Madrid.

Other regional initiatives

Nursing indication

The indication, use and authorisation for dispensation by nurses of medicines subject to medical prescription, in accordance with clinical and healthcare practice guides or protocols, is governed by Royal Decree 954/2015, of 23 October 2015, amended by Royal Decree 1302/2018, of 22 October 2018. According to Article 3 of said RD, two requirements are established to undertake these actions:

- 1 Nursing professionals may indicate, use and authorise the dispensation of medicines subject to medical prescription in accordance with the clinical and healthcare practice guides or protocols.
- 2 In order to undertake such actions, nurses must hold the corresponding accreditation issued by the competent body in the Region in question.



The generation of clinical and healthcare practice guides and protocols as described in Article 6 of the RD is performed within the context of the Standing Pharmacy Commission of the NHS Inter-territorial Council, and must be validated by the Directorate-General for Public Health. At the time when this Annual Report was drawn up, the only approved guide was the Guide for the indication, use and authorisation of dispensation of medicines subject to medical prescription for wounds (Resolution of 20 October 2020 of the Directorate-General for Public Health). It describes the general and specific criteria taken into account for the selection of the list of active ingredients included, and the conditions under which such activity may be performed. The Spanish regions develop their own specific clinical or healthcare practice guides and/or protocols on the basis of this guide, tailored to their own context.

With regard to the accreditation of nurses, FARMAINDUSTRIA is monitoring regulatory developments in this sphere in each Region. By the time when this Annual Report was drawn up, 14 Spanish regions (Andalucía, Aragón, Asturias, Islas Baleares, Islas Canarias, Cantabria, Castilla La Mancha, Castilla y León, Cataluña, Extremadura, Murcia, Navarra, País Vasco and Valencia) and INGESA had regulated this procedure, while La Rioja and Madrid were at the processing stage, with regulation pending in only Galicia.



Covid-19 pandemic. Collaboration with the Spanish regions

Over the course of 2020, FARMAINDUSTRIA intensified its institutional activity with regional health authorities, scientific societies, professional organisations and institutions in order to underpin collaboration by our sector as a strategic ally, in particular from the perspective of health crisis management and the availability of medicines, both at retail pharmacies and health centres and hospitals.

Within this context, there was an intensification of contact with the health authorities, which were provided with timely information as to:

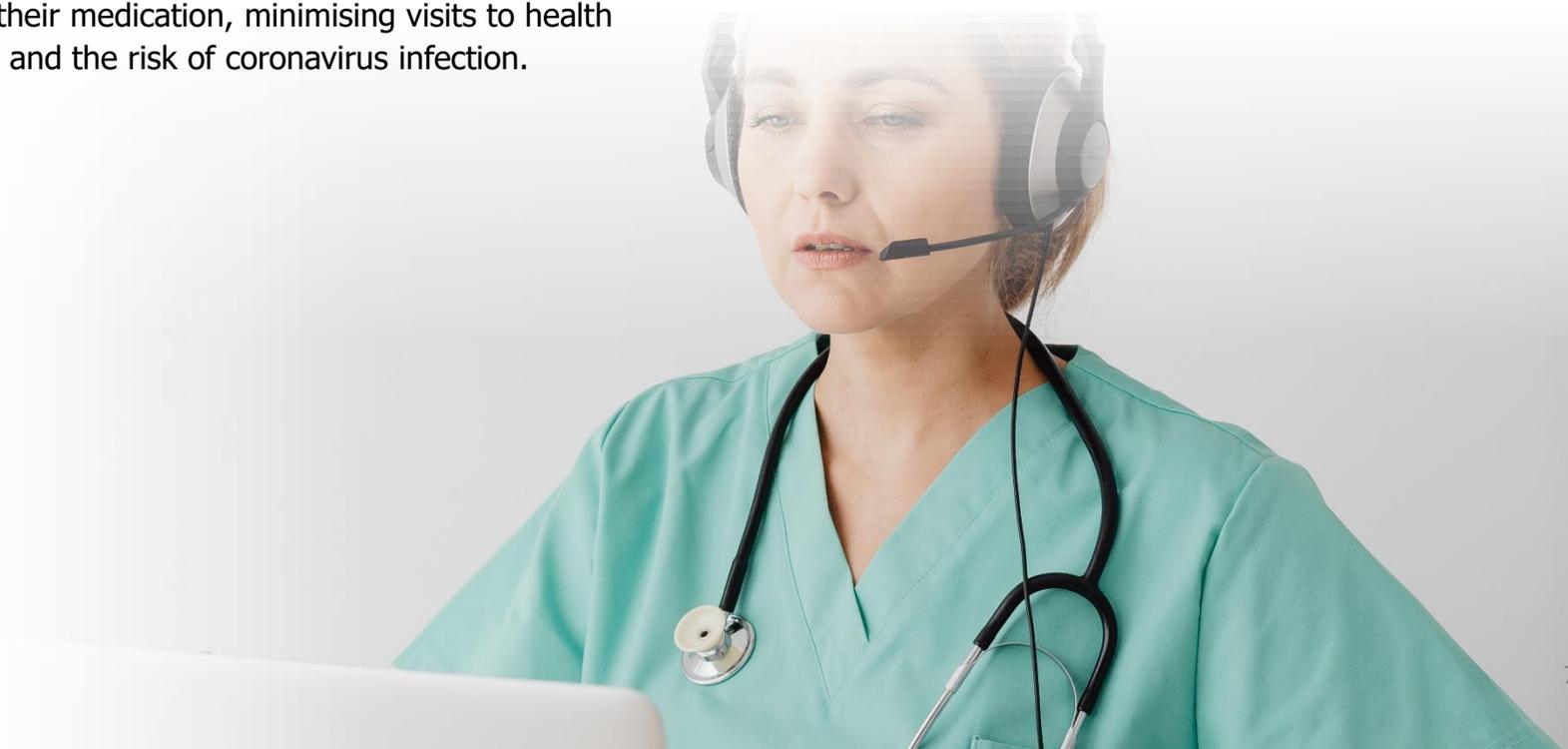
- 1 The efforts taken by the pharmaceutical industry during the months of the pandemic to ensure the supply of medicines, both for use at ICUs and for the treatment of chronic patients.
- 2 The coordination established with the AEMPS, distributors and the General Council of Official Associations of Pharmacists (the 'Consejo General de Colegios Oficiales de Farmacéuticos', or 'CGCOF'), helping to avoid any significant supply interruption problems.
- 3 Clinical trials in progress for the development of treatments and vaccines to combat coronavirus, with Spain taking on a key role, along with the challenges that would be involved in ensuring availability of a vaccine once it had been produced.



The Spanish regions developed different strategies to minimise travel by patients to collect their medication, at both the hospital and the community level.

Within the context of retail pharmacies, then, modifications were made to prescription renewal procedures to avoid patients with chronic treatments and those with medication subject to prescription approval from being required to go to their health centres to renew their prescriptions. This measure allowed patients to go directly to the pharmacy to collect their medication, minimising visits to health centres and the risk of coronavirus infection.

FARMAINDUSTRIA maintained close contact with pharmacy supervisors in the Spanish regions to ascertain the changes made to electronic prescriptions systems and to suggest that the option of collecting more medication than normal from pharmacies should not be enabled, since this could have consequences on supply and lead to supply interruptions. Modifications made to the electronic prescription systems in the different Regions were set out in a situational report which has been progressively updated.



In the hospital sphere, in accordance with Order SND/293/2020, of 25 March 2020, establishing conditions for the dispensation and administration of medicines within the context of the National Health System, in response to the health crisis caused by Covid-19, the different regions began to establish measures to guarantee outpatient access to hospital medicines ('DHDH') without the need to retrieve them on hospital premises. FARMAINDUSTRIA then established a channel for dialogue with the Spanish regions and the AEMPS to ensure that this practice would not lead to an increase in the number of units dispensed, since this could give rise to a market supply problem. With the collaboration of the Association's Hospital Market Working Group, the situation was actively monitored and a report was drawn up.

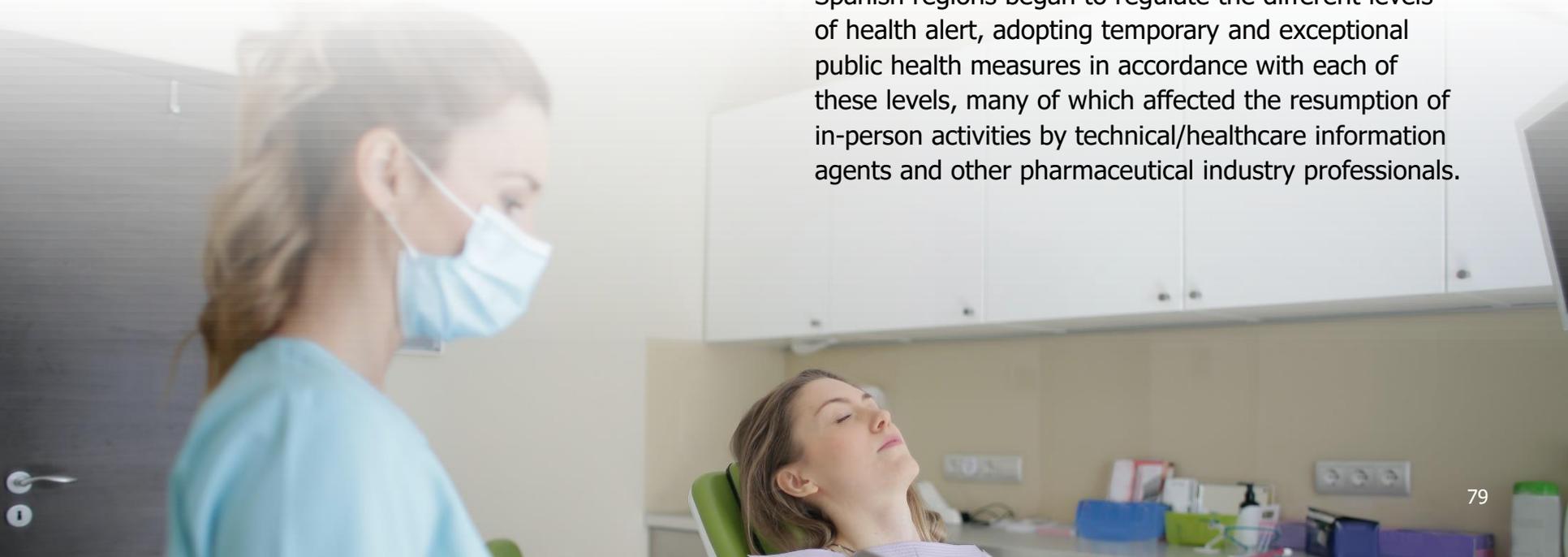
Meanwhile, with the aim of freeing up the congestion resulting in a huge amount of healthcare pressure at medical facilities, a number of Spanish regions converted conference halls and hotels to admit patients referred from the public hospital network. FARMAINDUSTRIA offered its collaboration to the Regions in order to facilitate the supply of medicines, while also analysing the implications that these provisions could entail with regard to the medicines supply circuit (from ordering to invoicing), so as to provide the necessary information for both the health authorities and the associated pharmaceutical manufacturers.

Another of the aspects constantly monitored with the health authorities during this period was the resumption of in-person activity by industry representatives working on medical visits and the monitoring of clinical trials.

Medical Visits

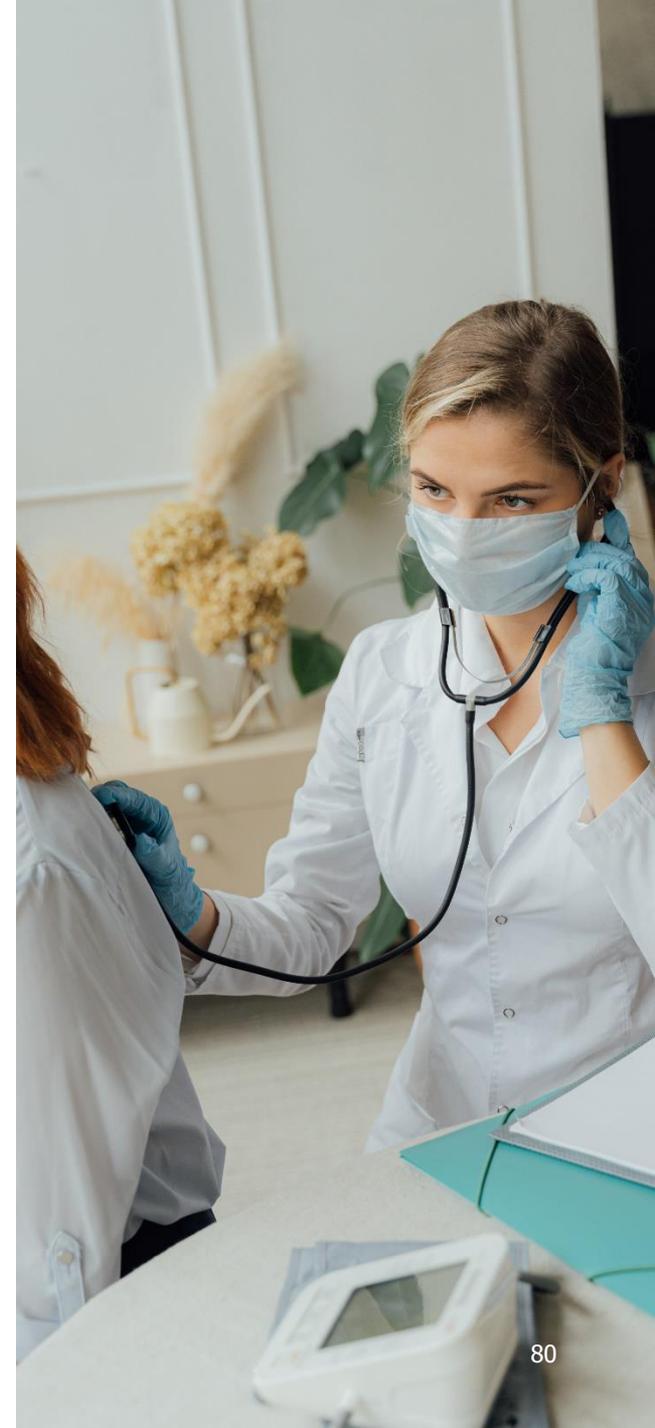
Given the evolution of the Covid-19 pandemic, throughout the first fortnight of March 2020 all Spanish regions except for the Islas Baleares restricted medical visits to healthcare establishments and services. This restriction affected some 12,000 technical healthcare information agents from FARMAINDUSTRIA's member companies, a figure that could be increased to 20,000 if one takes into account all pharmaceutical and medical device industry representatives interacting with healthcare professionals.

On 28 April, the Council of Ministers approved the Plan for the Transition to a New Normality, which determined the key parameters, instruments and phases for lifting the measures under the state of emergency, establishing a gradual process of easing restrictions in three phases, in which, with certain limitations and while ensuring compliance with safety protocols, authorisation could be granted for scientific, information and scientific/technical presentation activities to be conducted. Within this context, the Spanish regions began to regulate the different levels of health alert, adopting temporary and exceptional public health measures in accordance with each of these levels, many of which affected the resumption of in-person activities by technical/healthcare information agents and other pharmaceutical industry professionals.



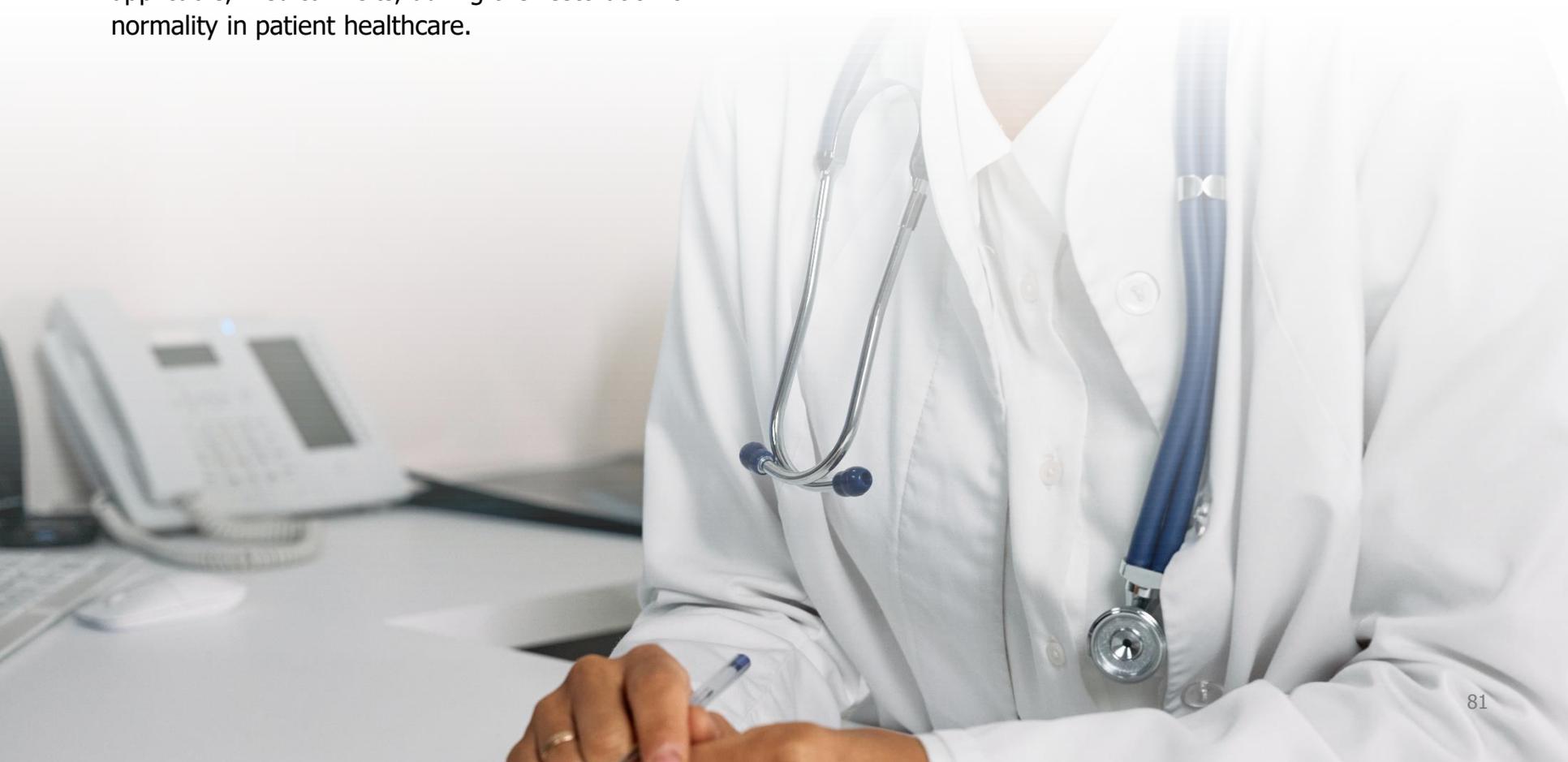
With the aim of facilitating the resumption of such activity with the necessary safety and traceability guarantees demanded by the Government, the Association set up its ad hoc Medical Visit Working Group, with the goal of producing and implementing a Safety Protocol for the reincorporation of industry professionals to such activities, and to monitor their resumption.

The Protocol, which proved vitally important in the progressive resumption of medical visits, was drawn up with the support and collaboration of Dr Rafael Cantón Moreno, Head of the Microbiology Service at Ramón y Cajal University Hospital in Madrid, and researcher at the Ramón y Cajal Healthcare Research Institute, as well as the scientific societies covering primary care (SEMG, SEMERGEN, SemFYC), Pulmonology and Thoracic Surgery (SEPAR), Internal Medicine (SEMI) and Healthcare Executives (SEDISA). The General Councils of Professional Associations of Physicians, Pharmacists and Nurses were also involved. The Protocol, to which other business associations have also subscribed, was made available to all members on 5 June and was submitted to the Ministry of Health, the health departments of the Spanish regions and professional associations for their information.



It is important to point out that the Protocol specifically establishes respect on the part of all industry personnel for any standards or instructions issued by the health authorities of the Regions or the healthcare establishments themselves with regard to the organisation of healthcare activity and, where applicable, medical visits, during the restoration of normality in patient healthcare.

FARMAINDUSTRIA closely monitored the situation with medical visits over the course of 2020, and drew up a situational matrix, which is periodically updated, covering the restrictions in place for the staging of congresses and scientific meetings, and the situation regarding medical visits in each Spanish region.



NATIONAL HEALTH SYSTEM PURCHASING PLATFORM

As we have indicated in previous Reports, the Ministry of Health has repeatedly shown an interest in promoting centralised purchasing via the INGESA. In this regard, at the proposal of the Minister of Health the Council of Ministers gave authorisation on 11 February 2020 for the arrangement of a competitive tender (Framework Agreement ('Acuerdo Marco', or 'AM')) for the purchase of biotherapeutic medicines having a biosimilar, to which 10 Spanish regions initially subscribed: Aragón, Asturias, Islas Baleares, Cantabria, Castilla y León, Extremadura, Galicia, La Rioja, Murcia and Valencia. The INGESA and the Ministry of Defence were also involved.

The outbreak of the Covid-19 pandemic and the corresponding declaration of the state of emergency prompted health authorities to focus all their efforts on responding to the grave threat which had been unleashed, prioritising the acquisition of healthcare materials and medicines for Covid-19, and this AM was therefore not ultimately tendered in 2020.

By the time this Annual Report was drawn up, the INGESA had resumed preliminary work to process the AM, initiating a round of contacts with the Spanish regions and other public authorities, as well as the pharmaceutical manufacturers affected by it, so as to confirm their interest in participating in this procedure.



In the contacts that FARMAINDUSTRIA has had with INGESA, the latter has indicated that the plan is for the AM to be awarded in the last four months of the year, involving 14 entities (including Spanish regions and national government). The AM will comprise a tender for 10 batches, established by active pharmaceutical ingredient (adalimumab, bevacizumab, etanercept, infliximab, rituximab, trastuzumab, somatropine, pegfilgastrim, epoetin alfa and filgastrim), with the previously planned specifications being maintained:

- 1 Batches formed by active pharmaceutical ingredient.
- 2 No second round in the Spanish regions.
- 3 Provision for the possibility of awards based on justified clinical need.
- 4 2-year duration plus a 1-year extension.

FARMAINDUSTRIA has in this regard reiterated the importance of defining batches by trade name, in order to facilitate the continuation of treatment that has already begun, and pharmacovigilance, in accordance with the regulations currently in force, as well as the need to safeguard the confidentiality of the prices awarded.

Meanwhile, INGESA has begun administrative procedures for the extension of the Factor VIII AM, which expires in June 2021, although the plan is to arrange a new AM for this medicine, on which work is already taking place.

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 covered by these procedures.



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 Pharmaceutical Ingredient	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 Pharmaceutical Ingredient	9	6
MEDICINES WITH GENERIC COMPETITION (2015)	Open procedure by ordinary processing and subject to harmonised regulation (Articles 196 and 198, recast Text of the Public Sector Procurement Law)	11 Regions (Aragon, 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 Pharmaceutical Ingredient Includes two biosimilars, which share batch with reference biological	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, Castilla La Mancha, Castilla y León, Extremadura, Galicia Murcia, Navarre, La Rioja and Valencia) and INGESA (Ceuta and Melilla)	Brand	9	9
EPOETINS (2019)	Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act)	9 regions (Aragon, Asturias, Islas Baleares, Cantabria, Castilla La Mancha, Extremadura, La Rioja, Murcia and Valencia), INGESA and Ministry of Defence	Active Pharmaceutical Ingredient	5	4
IMMUNOSUPPRESSANTS (2015)	Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act)	11 Regions (Aragon, Asturias, Islas Baleares, Cantabria, Castilla La Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja, Valencia), INGESA, Ministry of Defence and Prison Institutions	Active Pharmaceutical Ingredient	9	9
ANTI-RETROVIRALS (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 Pharmaceutical Ingredient	26	12

3.1.3 ADVISORY AND GUIDANCE COMMITTEES

ADVISORY COMMITTEE OF THE INTER-TERRITORIAL COUNCIL OF THE NATIONAL HEALTH SYSTEM

The Advisory Committee of the Inter-territorial Council of the National Health System met on four occasions in 2019, but did not hold any meetings during 2020. The situation caused by the pandemic meant that all meetings of the Inter-territorial Council of the National Health System were conducted on an extraordinary basis, without the need for any prior action by the Advisory Committee. In any event, the approval of future regulatory provisions will, as is known, require an opinion from the Committee, which is expected to resume the pace of its meetings in 2021.



AEMPS COMMITTEE ON MEDICINES FOR HUMAN USE

The Committee for Medicines for Human Use ('CMH') is the collegiate body of the AEMPS representing the interests of society and overseeing transparency, objectivity, and scientific rigour in the Agency's decisions regarding the marketing of medicines. The Committee is composed of 23 members, 10 by reason of their position and 13 appointed by the the AEMPS' Governing Board, one of them 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.

During the last financial year, aspects connected with the evaluation of the different Covid-19 vaccines accounted for the bulk of the non-ordinary matters addressed by the Committee.



3.1.4 GENERAL AGREEMENT OF THE SPANISH CHEMICAL INDUSTRY

2020 was the last year for which the 19th General Agreement of the Spanish Chemical Industry published on 8 August 2018 in the Official State Gazette remained in force, with an agreement for a pay rise of +2.5% each year covered by the agreement.

From June 2020 onwards, the Socio-Employment Committee of the Spanish Chemical Industry Association (Feique) began preparatory work for the negotiation of the twentieth General Agreement of the Spanish Chemical Industry. This preliminary work comprised, among other matters, an analysis of the legal reforms occurring during the term of validity of the 19th Agreement with a direct impact on its contents, as well as those legislative bills being processed or that were expected, and the articles of the Collective Agreement that they would affect. These legal reforms are in particular the result of:

- 1 Royal Decree-Law 6/2019, of 1 March 2019, on urgent measures to guarantee equal treatment and opportunities for women and men in work and employment.
- 2 Royal Decree-Act 8/2019, of 8 March 2019, on urgent measures for social protection and to combat precarious employment in terms of working hours
- 3 Royal Decree-Law 28/2020, of 22 September 2020, on remote working.
- 4 Royal Decree-Law 902/2020, of 13 October 2020, on equal pay for women and men.
- 5 Royal Decree-Law 901/2020, of 13 October 2020, regulating equality plans and their registration, and amending Royal Decree 713/2010, of 28 May 2010, on the registration and filing of collective employment agreements.

In order to organise the preparation of the future negotiations in greater detail, the Social-Employment Committee of Feique set up two working groups to address the most significant matters with regard to negotiations, specifically a Working Group on Remote Working, Registration and Digital Disconnection, the spokesperson being FARMAINDUSTRIA, and a Working Group on Equality, likewise involving the Association. The proposals for the negotiations were issued by these Working Parties.

Finally, on 11 January 2021 a Collective Bargaining Agreement Negotiation Committee was established, comprising on the trade union side the Industry Workers' Commission and UGT-FICA, and Feique representing the employers. The Negotiation Committee comprises seven members of the Industry Workers' Commission, seven of UGT-FICA and one of CIG Industria, and fifteen members of Feique.



Following the creation of the Negotiation Committee, a total of seven negotiation meetings were held on 12 January; 2, 9 and 16 February; and 11 and 24 March. The weightiest matters discussed in the negotiations included the pay rise and duration of the agreement, remote working (compensation for expenses, reversibility), registration of working hours, digital disconnection, retirement, absence because of Covid-19, leave of absence, equality, and occupational health and safety.

Ultimately, on 7 April 2021 the negotiation parties signed the corresponding preliminary agreement, which by the date when this Report was drawn up was pending the definitive text of the General Agreement of the Spanish Chemical Industry which must subsequently be published in the Official State Gazette.



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 2020, FARMAINDUSTRIA saw unprecedented deployment of communication efforts as a consequence of the coronavirus pandemic. The Association maintained a constant and proactive presence in the media and through its Internet and social media channels, providing clear, quality, reliable information about the health and economic crisis caused by Covid-19.

Research into medicines and vaccines to halt the pandemic provided, from the communication perspective, the opportunity to inform society of how the medicines sector and the pharmaceutical industry in general normally work.



From the very outset, communication efforts focused on informing public opinion of four major challenges impacting our sector from the outbreak of the health crisis:

- 1** | The guarantee to supply medicines during the most difficult weeks of the pandemic.
- 2** | The intense global research efforts to find an effective vaccine or medication, together with the prominent role played by Spain in clinical trials addressing coronavirus.
- 3** | The resumption of normality in non-Covid clinical trials.
- 4** | The commitment shown by our companies in helping those affected by the pandemic.

From the outbreak of the pandemic, then, the Association strove to provide reliable information about the pharmaceutical industry's response to the challenge. The FARMAINDUSTRIA information channels thus became during 2020 a source of trustworthy, verified and updated information both for the media and for society as a whole. This led to the generation of informative content released via all available channels: website, social media, traditional and online media outlets, gatherings, forums, etc.

Likewise, throughout the year the Association made FARMAINDUSTRIA spokespeople continuously available to both the media and the information and debate forums conducted as a result of the pandemic.

Specifically, in 2020 FARMAINDUSTRIA generated more than 220 of its own information releases for the media, over 80 of which were connected with the pandemic. This meant an average of more than four internally generated information releases each week, giving some idea of the extensive information and communication efforts deployed by the Association during the year.

Of all the information releases generated, 27 were institutional press releases, 160 news information items, along with 15 in-depth features on the website. FARMAINDUSTRIA spokespeople were also interviewed 12 times on the radio and six times on television, representing a substantial increase in the Association's presence on this type of media platform: currently 11% of our audience is via radio and TV.

This extensive activity also led to more than 6,000 media impacts in 2020, an increase of more than 30% compared with the coverage generated in 2019. The figure represents an average of more than 100 media impacts per week.

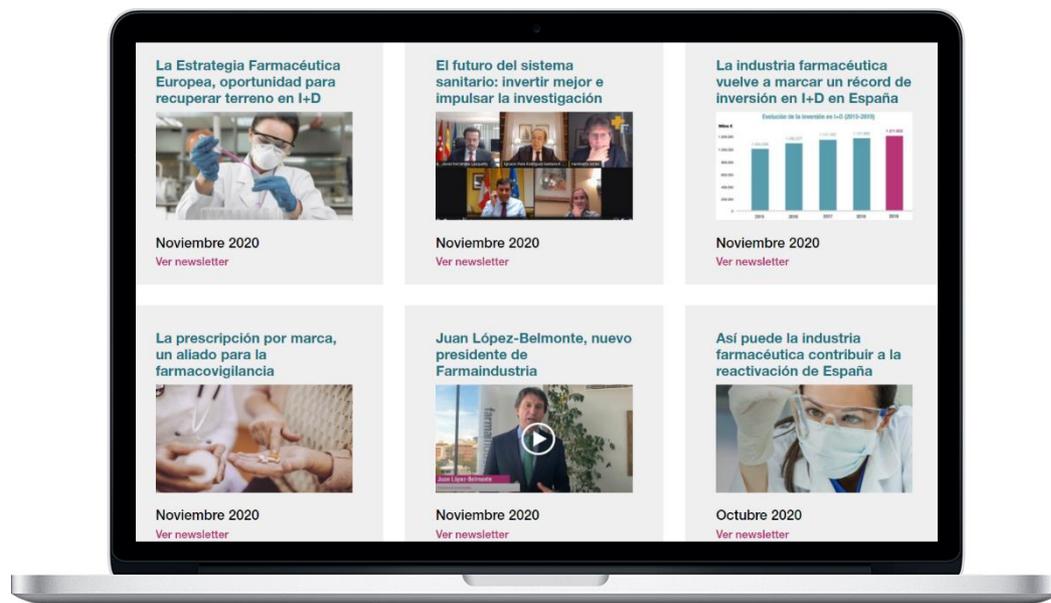
Meanwhile, the trend begun in 2017 of replacing advertising-type artwork with a new infographic design approach presenting purely informative content was maintained, featuring key figures on the sector and reflecting the reality of the pharmaceutical industry based in Spain.



NEWSLETTER

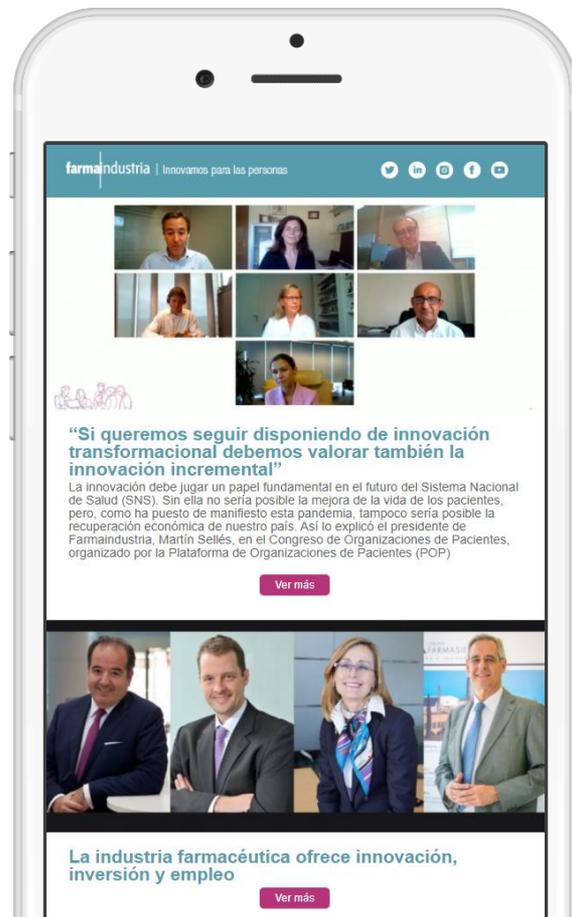
In 2020 the FARMAINDUSTRIA newsletter marked its second anniversary, and did so by reaching the figure of 7,000 subscribed users, almost three times the number of readers registering since January 2019. The weekly information bulletin of the research-based pharmaceutical industry in Spain is sent free of charge every Monday to subscribed users' email addresses, and contains key information about medicines, the industry, biomedical innovation and health.

Through this digital newsletter, FARMAINDUSTRIA aims to facilitate dissemination of information about the sector and medicines among professionals in the healthcare and pharmaceutical sector, and above all to provide the media and society at large with a better understanding of the industry.



WEBSITE

The Association's website (www.farmaindustria.es) once again proved a flagship vehicle during the year. In total, more than 210,500 users visited the FARMAINDUSTRIA website in 2020, compared with 80,200 in 2019, an increase of +162%.



SOCIAL MEDIA

In a year marked by the Covid-19 pandemic, FARMAINDUSTRIA successfully shouldered its responsibility as a key player, in the world of social media as well, obtaining unprecedented results via these communication channels. 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 increase the information delivered via social media. This serves to gain interaction with the population, and contribute to society's greater and more precise understanding of the sector.

2020 was the year when the path embarked on in previous years bore fruit, 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.

In fact, all the social media platforms of FARMAINDUSTRIA registered substantial growth in terms of both users and engagement. Particular mention should be made of LinkedIn, with an increase in user numbers of +47.4% compared with 2019, and +287% more interactions. With over 40,000 followers, FARMAINDUSTRIA is the second-ranked pharmaceutical industry association in the world on this social media platform, behind only France.



Twitter saw an increase of +12.3% to a figure of 34,000 followers during 2020. In comparison with other industry associations in other countries, FARMAINDUSTRIA is ranked second in the world in terms of follower numbers, behind only the USA.

On Facebook there was a +33% increase in the number of followers in 2020, and with figures close to 3,000 it is the fourth-ranked industry association worldwide, as is also the case of Instagram, adding 1,231 followers this year, +50% more than in 2019.

All this growing and innovative information activity for the sector via all online channels generated highly positive results last year. In total, FARMAINDUSTRIA social media posts were displayed to users (page views) more than 17 million times in 2020.



FEATURES AND FAQs

On its website, FARMAINDUSTRIA has a Features section and another with an FAQ format, with the aim of supplementing the news items and press releases sent out by the Association by means of analytical information articles which are essentially explanatory in nature, helping the general population to better understand certain aspects of the sector, from how prices are set for medicines in Spain, to the nature of the R&D process for a medicine, or the benefits that medicines offer from the economic and social perspective, beyond their core value as healthcare assets.

In 2020, fifteen of these information articles were published (compared with six in 2019), including such notable titles as: "How the pharmaceutical industry can contribute to Spain's economic recovery"; "The pandemic which has triggered the greatest research race in history"; "Orphan drugs: two decades of progress in clinical research and new treatments"; "How long does it take to develop a medicine (and why)?"; "Medicines manufacturing sites: how they guarantee supply", and "How to achieve a safe, affordable vaccine for all".



What was achieved in 2020?



Inform society about how the pharmaceutical sector functions and works, given the demand for information generated by the pandemic.

Expand the Association's communication efforts, reaching out to all our stakeholders and to society at large.

Consolidate FARMAINDUSTRIA as a reliable source, by conveying clear, trustworthy information.

Underpin communication initiatives with the media, online and at in-person forums, using the social media channel to convey our messages.

Multiply communication impacts by using appropriate formats (texts, infographics, animations, videos, etc.) for different audience profiles.

Feed trustworthy information about the pharmaceutical industry, research and medicines into the online conversation.

Listen to our stakeholders and society, so as better to adapt our communication to society's demands and queries.

Strengthen the sectoral commitment to transparency.

EVENTS WITH INFORMATIVE IMPACT

Although for many months of 2020 events and forums were suspended as a result of the pandemic, FARMAINDUSTRIA continued to participate at numerous happenings and webinars online. These events, whether organised internally or by other entities (public institutions, associations, scientific societies, universities, media, etc.), had a significant impact in conventional and/or social media. The main information events in which FARMAINDUSTRIA was involved in 2020 are listed below:

- Post-ISPOR 2019 Seminar on *Digital Transformation in Health. New Roles and Shared Responsibilities*
- Lung cancer forum: *Challenges and Solutions*
- Seminar: *Future of Clinical Research in Spain*, organised by AMIFE (Pharmaceutical Industry Medical Association)
- 9th European Forum for Science, Technology and Innovation (Transfiere)
- 2nd Spanish Anti-Cancer Summit, organised by GEPAC (Spanish Group of Cancer Patients)
- Seminar: *40 Years of the Constitution: 40 Years of Health. Witness Accounts by Key Figures*
- Forbes Healthcare Summit
- Seminar on clinical trials organised by the Spanish association of EUPATI (European Patients' Academy on Therapeutic Innovation)

- Webinar by the European Patients Academy in Spain regarding clinical trials and the pandemic
- Webinar on transparency organised by the Bar Association of Barcelona
- Seminar: *How to Promote Research in Spain*, organised by the New Medical Economics journal
- Online seminar: *How to Measure Online Influence When Talking about Health*, organised by the communication agency Burson Cohn & Wolfe (BCW)
- Forum: *Impact of the Covid-19 Crisis on Professionals and the Industry. What Have We Learned?*, organised by the Spanish Cardiology Society
- Webinar: *The Event Value chain in Health*, organised by Eventoplus
- Information session with the President of FARMAINDUSTRIA, organised by Nueva Economía Fórum
- Forum: COVID-19. *Strategies for Health Research*, of the University of Valencia, Microsoft and the Spanish Professional Privacy Association
- Fundamed & Wecare-u Awards handed out by the newspapers El Global and Gaceta Médica, and La Razón Awards in tribute to the healthcare sector during the pandemic
- Webinar organised by the consultancy Atrevia and the Talento-Ephos school, on the lessons of the pandemic
- Health Monitor of the newspaper El Español
- 4th Congress of the Patients Organisations Platform
- Seminar: *The Health of the Future: Challenges and Trends in the Covid-19 Era*, organised by the IDIS Foundation
- Meeting of the Permanent Dialogue Board of FARMAINDUSTRIA-Patients Organisations

- Workshop: *Digital Challenges in the Administration of Clinical Trials*, organised by FARMAINDUSTRIA
- Institutional Strategic Forum of SEPAR (Spanish Pulmonology and Thoracic Surgery Society)
- Annual congress of the Spanish Society of Medical Oncology (SEOM)
- Congress of the Spanish Society of Primary Care Physicians (SEMERGEN)
- Global Meeting of Health and Medical Reporting Executives and SEDISA
- Online seminar of the CAEME (Argentinian Chamber of Medicinal Specialties)
- 2nd Global Social Responsibility Week
- Virtual forum: *Health Funding in Times of Crisis*, organised by the Bamberg Foundation
- Pharma-Biotech meeting, organised by FARMAINDUSTRIA
- Two seminars: *Bringing Science into Schools*, organised by the Sant Joan de Déu Maternity and Infant Hospital in Barcelona and the Jiménez Díaz Foundation in Madrid, with the collaboration of FARMAINDUSTRIA
- Digital gathering to mark Chemistry Day, organised by the Chemistry and Society Forum
- Online training workshop: *The Patient: Manager of Their Data in the Digital Transformation of Clinical Trials*, by FARMAINDUSTRIA and Sant Joan de Déu Hospital



IV CONGRESO DE ORGANIZACIONES DE PACIENTES /online/



- 8th edition of the 'Somos Pacientes' Seminar, organised by FARMAINDUSTRIA
- Involvement by FARMAINDUSTRIA in the Committee for Social and Economic Reconstruction of the Congress of Deputies' Healthcare Working Group
- Video press conference with the media to discuss the pharmaceutical industry's response to the pandemic
- Business Summit: *Spanish Companies Leading the Future*, by CEOE
- FARMAINDUSTRIA online seminar addressing lessons learnt in the pandemic in the field of clinical research
- Annual gathering of the Spanish Pharmaceutical Industry at Menéndez Pelayo International University
- Digital gathering: *The Pharmaceutical Industry's Role in the Economic Recovery*, organised by FARMAINDUSTRIA with the support of the APIE (Association of Economic Information Journalists)

KEY INFORMATION MILESTONES IN 2020

January

In January, FARMAINDUSTRIA presented the media with the key figures both from the annual report of the European Medicines Agency (EMA) and of the US Food and Drug Administration (FDA) as to medicines approved in 2019. In specific terms, the EMA gave the greenlight to 30 new medicines, and the FDA, 48. The area accounting for the greatest number of innovations was haematology, followed by cancer, infectious diseases and endocrinology. Meanwhile, in the case of Europe it was emphasised that of the 30 approvals, seven were considered orphan therapies.

Furthermore, it was announced during the month that cancer mortality in Europe in real terms has dropped significantly over the last 20 years, as reflected in the publication: *Comparator Report on Cancer in Europe 2020*, a study conducted by the Swedish Health Economy Institute and commissioned by EFPIA, the European Federation of Pharmaceutical Industries and Associations, to which FARMAINDUSTRIA belongs.



February

On 4 February FARMAINDUSTRIA published its first information about coronavirus, announcing that EFPIA had called on pharmaceutical companies to identify which treatments already in use or under investigation could be effective in halting the virus. The aim of the request was to obtain new treatments and a better diagnosis in order to address the epidemic.

FARMAINDUSTRIA launched the #LaMarcaTeCuida (#TheBrandCaresForYou) initiative on social media with the aim of informing society of the benefits of branded medication. The campaign employed a graphical approach with straightforward, real examples to remind patients, families and carers, and healthcare professionals alike that branded medicines can be requested at retail pharmacies and that doctors can prescribe either by the trade name or by active pharmaceutical ingredient, at no greater cost to the patient and the health system, since originator medicines and their generics have the same pricing within the public system. FARMAINDUSTRIA shared this initiative across Twitter, Instagram and LinkedIn, where the Association has a particularly active presence, attracting tens of thousands of followers.



During the month FARMAINDUSTRIA also took part in the seminar “*40 years of the Constitution: 40 Years of Health*”, held at the Congress of Deputies, and featured a book presentation which involved the Director-General of the Association, presenting the medical, economic and social value contributed by the sector through research on medicines.

On 24 February FARMAINDUSTRIA launched an updated version of the website Medicamentos-innovadores.org, the portal of the Spanish Technological Platform for Innovative Medicines (PTEMI). The platform was set up in 2005 as a project sponsored by Farmaindustria and involving industry and public authority experts to boost research into new medicines through cooperation among all agents. The coordination committee of the Platform is in fact made up of equal numbers of public and private sector representatives (10 members each).

To mark World Rare Disease Day, held on 29 February, FARMAINDUSTRIA reminded its audience in an information release that research into uncommon or rare diseases registered a turning point in the year 2000, when the EU adopted its orphan drugs regulation, establishing incentives for the research, development and marketing of treatments for such conditions, suffered by 30 million people in Europe. The regulation catalysed work by pharmaceutical companies in this field, and between the years 2000 and 2020 the treatments available for rare diseases have increased 20 times over, allowing some 90 conditions to be treated.



March

To mark International Women's Day, on 8 March FARMAINDUSTRIA launched the #MiHistoriaHaceHistoria (#MyStoryMakesHistory) campaign on social media, in which women working at innovative companies gave their first-hand account of triumph over adversity, development and future in what is a cutting-edge sector in terms of equality. As confirmed by the figures: half of the jobs in the pharmaceutical industry are held by women, a figure which rises to 64% at R&D departments (the highest figure anywhere in the Spanish economy); 41% of the steering committee members at pharmaceutical companies are women (far higher than the average for IBEX blue-chip companies). In similar terms, the proportion of female chief executives is 22%, likewise much higher than that of major listed companies.

During the month the Director-General of the Association participated in the Forbes Healthcare Summit 2020, emphasising that efficiency and fairness were the two major challenges for the healthcare system, and championing the use of big data and cooperation among agents as two instruments to address these challenges. He furthermore highlighted Spain's potential in clinical trials, and the sector's capacity to drive the country towards an innovation-based productive model.



On 9 March it was announced that the pharmaceutical industry had as many as thirty medicines and four vaccines being researched to combat Covid-19. As soon as coronavirus disease emerged, numerous pharmaceutical companies worldwide mobilised their research teams in pursuit of a potential treatment to contain the pandemic.

On 23 March, FARMAINDUSTRIA announced that the pharmaceutical companies based in Spain were achieving full performance levels to guarantee production and to deliver medicines to all the country's hospitals and pharmacies. The Association had received this information over the previous days from the more than 140 pharmaceutical companies that are members of FARMAINDUSTRIA. Manufacturing sites and warehousing facilities had also established contingency plans and were working in close cooperation with the AEMPS to share information in case any alteration was detected with regard to the pharmaceutical supply, so as to be able to organise the relevant measures to guarantee patient care.





A few days later, the Association published a feature on its website about how warehouse, distribution, production and manufacturing staff, as well as quality and distributor or pharmacy response departments belonging to pharmaceutical companies, had been turning up for work every day since the Government declared a state of emergency, so as to guarantee supplies for hospitals, retail pharmacies and healthcare establishments. The feature included videos and photographs of these industry professionals working on the shop floor in the most difficult weeks of the pandemic.

On 26 March it was announced that there were already 20 vaccines being researched across the pharmaceutical industry to combat coronavirus. It was similarly stated that hospitals and pharmaceutical companies in Spain were already playing a leading role in some of this research, with clinical trials in progress for these potential treatments.

April

In early April, FARMAINDUSTRIA announced that its companies were at the service of public authorities, medical societies and social organisations to help fulfil their most urgent needs in combating the pandemic, mobilising more than eight million euros in direct grants during the first three weeks of the crisis. Some of our companies' manufacture sites adapted their production lines to manufacture large quantities of hand sanitiser gel to be delivered to the health authorities, while other manufacturers were working on making Covid-19 diagnostic tests and respirators for hospital ICUs available to the Ministry of Health. Companies had also mobilised the staff at their manufacture sites to collaborate in the development of prototype respirators intended for the seriously ill, while others were using 3D printers to urgently manufacture personal protective equipment (PPE).

During this period the Deputy Director-General of FARMAINDUSTRIA appeared on the Ana Rosa TV programme on Telecinco and on España Direct on TVE, to explain that the pharmaceutical industry, both in Spain and worldwide, had mobilised to guarantee production of medicines and patient supply. During the interviews, work being performed by "pharmaceutical companies as a whole in the field of research to find a treatment to combat the virus, involving the search for both medication and an effective vaccine" was emphasised.



To mark World Parkinson's Day, it was announced that pharmaceutical companies were currently working on more than thirty medicines to combat the disease. Furthermore, the Spanish Register of Clinical Trials had more than 60 Parkinson's studies on record, according to the information reported.

Likewise during the month, FARMAINDUSTRIA distributed a document in which 120 experts from hospitals and pharmaceutical companies proposed their measures to drive Spanish leadership in the research of new medicines, and to attract greater investment. The document: *Criteria of Excellence to Conduct Clinical Trials*, is available on the Association website.



FARMAINDUSTRIA wished to inform Spanish society as a whole of the recognition expressed by its member companies for healthcare professionals and their dedication in helping patients and the general population in the unprecedented and challenging situation caused by the Covid-19 pandemic. To supplement the information efforts that had been conducted via conventional media outlets and social media, the Association thus launched a campaign which was publicised for two weeks both via the leading radio stations and online, using the hashtag *#CuidateEnCasa* (*#StaySafeAtHome*). The advertisement reminded audiences of the two key commitments that pharmaceutical companies had given in response to the health crisis: to focus on discovering an effective treatment for Covid-19, and to ensure that there would be no problems in the supply of medicines to treat any type of illness. "It is our responsibility as the pharmaceutical industry to ensure that both healthcare professionals and patients alike keep caring for their health now more than ever," the campaign asserted.

Two days later, Their Royal Majesties held a videoconference meeting with the President of FARMAINDUSTRIA, Mr Martín Sellés, and the Director-General, Mr Humberto Arnés, who explained the fundamental role being played by pharmaceutical companies in the Covid-19 crisis. The most senior figures at FARMAINDUSTRIA gave King Felipe and Queen Letizia details as to how the pharmaceutical industry had committed to working with the authorities and the rest of Spanish society to deal with the situation in unison.



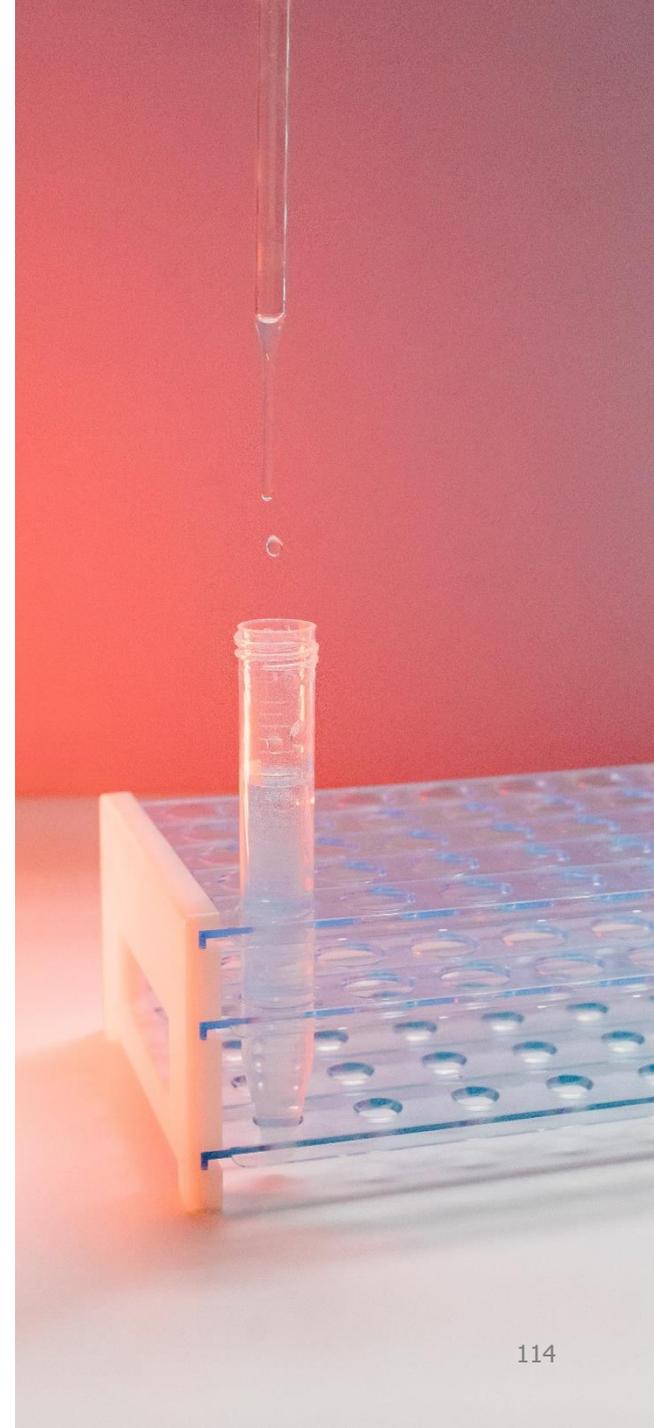
In late April, it was announced that IFPMA (the International Federation of Pharmaceutical Manufacturers & Associations) had joined forces as a founding member of the global alliance led by the World Health Organization (WHO) to speed up the development and production of treatments and vaccines against Covid-19, and to ensure that these treatments would be affordable and fairly available. The alliance, which goes by the name of *ACT Accelerator*, was presented at WHO headquarters in Geneva, the other founding partners being the Bill and Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI), the GAVI Vaccine Alliance, the Global Fund, UNITAID, the Wellcome Trust, the International Red Cross and Red Crescent Movement, the Developing Countries Vaccine Manufacturers Network, and the International Generic and Biosimilar Medicines Association. The alliance was also joined by the main governments in Latin America, Africa, Asia, and Europe, including the Spanish Government.

May

Early this month the Minister of Health, Mr Salvador Illa, highlighted in his weekly appearance before the Health Committee of Congress, the example of "commitment, coordination and dutiful effort" by pharmaceutical companies in combating the pandemic. This willingness to collaborate under the leadership of the AEMPS had, according to the minister, ensured "that supply of medicines has been guaranteed at all times", even at the most difficult points of the crisis.

An information release publicised the fact that Spain had become one of the world's leading countries in conducting clinical trials. Specifically, according to WHO data, Spain was as of 5 May the world's fourth-ranked country and the first in Europe in terms of the greatest number of clinical trials being conducted on medicines to study their efficacy against Covid-19.

During the month, FARMAINDUSTRIA marked World Clinical Trials Day by releasing an explanatory video which in three minutes explains what this type of study is, what it is for, how it is undertaken, the necessary requirements and timings, and those involved in the process.



June

Explanations were presented in June as to how pharmaceutical companies contribute to the Sustainable Development Goals. A series of micro-videos were used to explain via social media the main contributions made by pharmaceutical companies, as an educational initiative likewise intended to focus attention on the importance of progress towards these goals, for everyone's future.



On 12 June the FARMAINDUSTRIA President Mr Martín Sellés gave a presentation to the members of the Health Working Group of the Committee for Social and Economic Reconstruction at the Congress of Deputies as to the main operational approaches that the Association aims to pursue with Government in order to help refloat the Spanish economy and improve the National Health System.



On 22 June, the FARMAINDUSTRIA President, Mr Martín Sellés, and Vice-President, Mr Juan López-Belmonte took part at the *Business Summit of Spanish Companies Leading the Future* organised by CEOE, at which they asserted that the pharmaceutical companies based in Spain are one of the strategic sectors capable of helping to refloat the nation's economy after the Covid-19 crisis. FARMAINDUSTRIA representatives presented a battery of proposals to create jobs and increase investment in R&D and manufacturing of medicines in Spain.

Also in June, FARMAINDUSTRIA organised an online seminar addressing the lessons learned during the pandemic in the field of clinical research. The virtual gathering, which brought together more than 500 people, involved researchers, pharmaceutical companies and health authorities, who shared their experiences and the measures adopted to ensure that during the pandemic no patient participating in a clinical trial would be left without their treatment.



July

On 8 July the President of FARMAINDUSTRIA, Mr Martín Sellés, was the key figure at an informative session organised by Nueva Economía Fórum, at which he highlighted the fact that the pharmaceutical companies involved in research into a possible Covid-19 vaccine were taking on substantial financial risks in carrying out all their research and future development and that they were committed to making vaccines universally available at an affordable price once developed.

During the month, a report by the Royal Elcano Institute cited the pharmaceutical industry as one of the cornerstones in emerging from the crisis, alongside the agri-food, cyber-security and automotive sectors. The report emphasised Spain's potential to serve as an investment hub in the pharmaceutical sector, proposing that a national strategy be devised to make use of the European funds for industrial conversion following the crisis.

Likewise in July, at events paying tribute to the entire healthcare sector, FARMAINDUSTRIA received two accolades for its efforts during the pandemic. First of all, the newspaper La Razón highlighted the work by pharmaceutical companies both in research and in guaranteeing supply of medicines. FARMAINDUSTRIA companies also received the Fundamed Award from the El Global and Gaceta Médica publishing group, this time honouring the healthcare institutions and professionals that had played the most significant role during the Covid-19 crisis.



September

The 20th edition of the Spanish Pharmaceutical Industry Gathering was held in September, during the summer courses at Menéndez Pelayo International University. This year the lectures and debates were conducted via the university's online channel (uimptv.es), under the title: *The Role of the Pharmaceutical Industry in Response to the SARS-CoV-2 Pandemic*. The two-day event involved the Minister of Industry, Ms Reyes Maroto; the Director-General for the Basic Portfolio of NHS and Pharmacy Services, Ms Patricia Lacruz; and the Director of the AEMPS, Ms María Jesús Lamas, as well as researchers, clinicians, parliamentarians and representatives of the pharmaceutical industry.

During the month, the Director-General of FARMAINDUSTRIA took part in the 1st Health Observatory organised by the newspaper El Español, under the title: *Limits to Combating the Virus*, to state that the Spain needed strategic sectors to refloat its economy, and that the pharmaceutical industry could be one of the key players in the social and economic rebuilding process currently required by the country.

The Director-General also explained some days later in an interview on TVE's Canal 24h the process behind the international race to develop and manufacture a safe and effective Covid-19 vaccine in the shortest time possible. "There is very close international collaboration between pharmaceutical companies, research centres and authorities to provide an effective vaccine as soon as possible," he emphasised.



October

In October, the President of FARMAINDUSTRIA, Mr Martín Sellés, took part at the 4th Congress of the Patients Organisations Platform, reminding delegates that patients are the very reason why the pharmaceutical industry exists, hence the fact that companies in the sector invest 150 billion euros worldwide each year in the R&D that allows them to develop medicines and vaccines to improve patients' lives.

During the month a digital forum was staged to discuss *The Role of the Pharmaceutical Industry in the Economic Recovery*, organised by FARMAINDUSTRIA with the support of the APIE (Association of Economic Information Journalists). The gathering involved Antón Costas, former President of Cercle d'Economía and Professor of Economic Policy at Barcelona University; Mariano Barbacid, Professor of Molecular Oncology and former Director of the CNIO (National Oncological Research Centre), and Javier Urzay, Deputy Director-General of FARMAINDUSTRIA.

On 29 October the Extraordinary General Assembly of FARMAINDUSTRIA was held digitally, unanimously electing Mr Juan López-Belmonte as the Association's new president for the next two years. Mr López-Belmonte, CEO of Rovi and one of the Vice-Presidents of the Association over recent years, replaced Mr Martín Sellés in the presidential role he had held for the two previous years, in fulfilment of the provisions of the FARMAINDUSTRIA bylaws, which establish that the presidency of the Association must rotate among the three statutory groups of companies in accordance with the source of their capital: Spanish, European/International, and American. Over the next two years, the presidency of FARMAINDUSTRIA is assigned to the Spanish-owned group of companies.



November

A further gathering took place during the month in the Pharma-Biotech programme, this time online, bringing start-ups and research groups into contact with national and international pharmaceutical companies to promote research of medicines in Spain. On this occasion as many as eight new research projects led by small enterprises and Spanish public research centres attracted the interest of pharmaceutical companies.

During the month the results of the R&D Activity Survey conducted every year by FARMAINDUSTRIA among its members were published. In 2019, investment in R&D of medicines by the pharmaceutical industry in Spain amounted to 1.211 billion euros, +5.2% up on 2018, representing a new all-time record for the sector, and confirming the upward trend in this budgetary item over recent years.

In November the fourth of the Doctor-Patient Dialogues was also presented, an initiative promoted by the FARMAINDUSTRIA Foundation and the Somos Pacientes platform, comprising a video conversation between a doctor and a patient with the aim of presenting society with a first-hand account of the challenge involved in addressing various illnesses. On this occasion the initiative focused on diabetes, and the video featured the endocrinologist Dr Antonio Pérez, President of the SED (Spanish Diabetes Society), and Ms Ana Belén Torrijos, President of the Federation of Diabetics Associations of Madrid. The Director-General of FARMAINDUSTRIA, Mr Humberto Arnés, and the acting President of the FEDE (Spanish Diabetes Federation), Mr Aureliano Ruiz, participated in the presentation of this initiative to the media.



December

In early December, FARMAINDUSTRIA released an infographic highlighting the achievements of the last two decades in R&D into orphan treatments for rare diseases, and the challenge faced by Europe in maintaining progress in this sphere. The number of orphan drugs developed by pharmaceutical companies has increased more than 20 times over since 2000, when the European Regulations for this type of treatment was introduced.

15 December saw the 8th edition of the Somos Pacientes Seminar promoted each year by the FARMAINDUSTRIA Foundation and the Somos Pacientes virtual community. In fulfilment of the recommendations to combat the pandemic, the 8th Somos Pacientes Seminar was held in an online format. The event was staged under the title: *Future of the Associative Movement: Lessons from the Pandemic*, with representatives of patient associations, healthcare professionals, authorities and the pharmaceutical industry addressing matters including the main future challenges for patient associations and the role that they should play in the R&D process for new medicines, among other matters. The gathering ended with the 6th Somos Pacientes Awards Ceremony, to present accolades honouring the most notable activities and projects launched by patient associations and public and private institutions over the past year, with a focus on providing quality services for patients, people with disability, relatives and carers, with a particular emphasis on initiatives linked to innovation in the sphere of new technologies and communication tools.



INTERNAL COMMUNICATION

Internal communication remains an important operational area for FARMAINDUSTRIA. The Communication Working Group held quarterly meetings attended by a great many representatives of member companies. Following the lockdown imposed as a result of the Covid-19 pandemic, all meetings were conducted remotely. These meetings addressed issues of particular interest for the sector, and gave the attendees an account of all the key activities undertaken by the Association.

Similarly, in 2020 internal communication with members was strengthened, through more and better information shared as to FARMAINDUSTRIA activities, including data, significant information and strategic positions, as well as an invitation for pharmaceutical manufacturers to participate in the communication initiatives led by the Association, so as to help provide the general population with a better understanding of the specific experience of the companies and their professionals.



PATIENTS

In 2020 FARMAINDUSTRIA continued to promote relationships and its dedication to collaboration and partnership with groupings of patients and their representative associations. In the sense that the pharmaceutical industry researches, develops and markets medicines that cure or avoid illness and increase patients' life expectancy and quality of life, the relationship between companies and patient associations is vital. Furthermore, as a result of the pandemic one of the Farmaindustria member companies' main goals was to ensure supplies for the 25 million people in Spain who need to take at least one medicine each day so as to lead a normal life. In turn, another of the challenges following the onset of the health crisis was to try to ensure that it would have the least possible impact on chemical trials in progress at Spanish hospitals. Collaboration with the Government and constant communication with patient associations served to guarantee that in no case would patients involved in clinical trials be left without their treatment during the pandemic.

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

- 1** | Dialogue with associations, both directly and through FARMAINDUSTRIA'S Standing Dialogue Panel with patient organisations.
- 2** | The management and promotion of the online community Somos Pacientes, providing information, training, services and collaborative working tools for organisations of patients, relatives, disabled people and carers, along with society at large.

Dialogue with patient associations

In 2020, FARMAINDUSTRIA participated in numerous gatherings, meetings, conferences, seminars and other activities with patient organisations to share experiences and support their efforts. One of the most notable was the 4th Congress of the Patients Organisations Platform, which was conducted online in October.

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 such other organisations as EUPATI, which focuses on training to involve patients in clinical research.



As for the Standing Dialogue Panel linking FARMAINDUSTRIA to patients' organisations, it continued its activities during 2020 as a forum for information and debate, with a group representing more than 20 federations and confederations of patient associations to address current issues of shared interest. In October 2020 a gathering was held, focused on advances in research to combat the Covid-19 pandemic, and the future Pharmaceutical Strategy for Europe.

In addition, as mentioned previously, the fourth edition of the Doctor-Patient Dialogues was staged. On this occasion the dialogue focused on diabetes, one of the most prevalent chronic diseases in our society, which entails major complications unless accompanied by healthy lifestyles, prevention, appropriate treatments and adherence to the prescribed treatment.

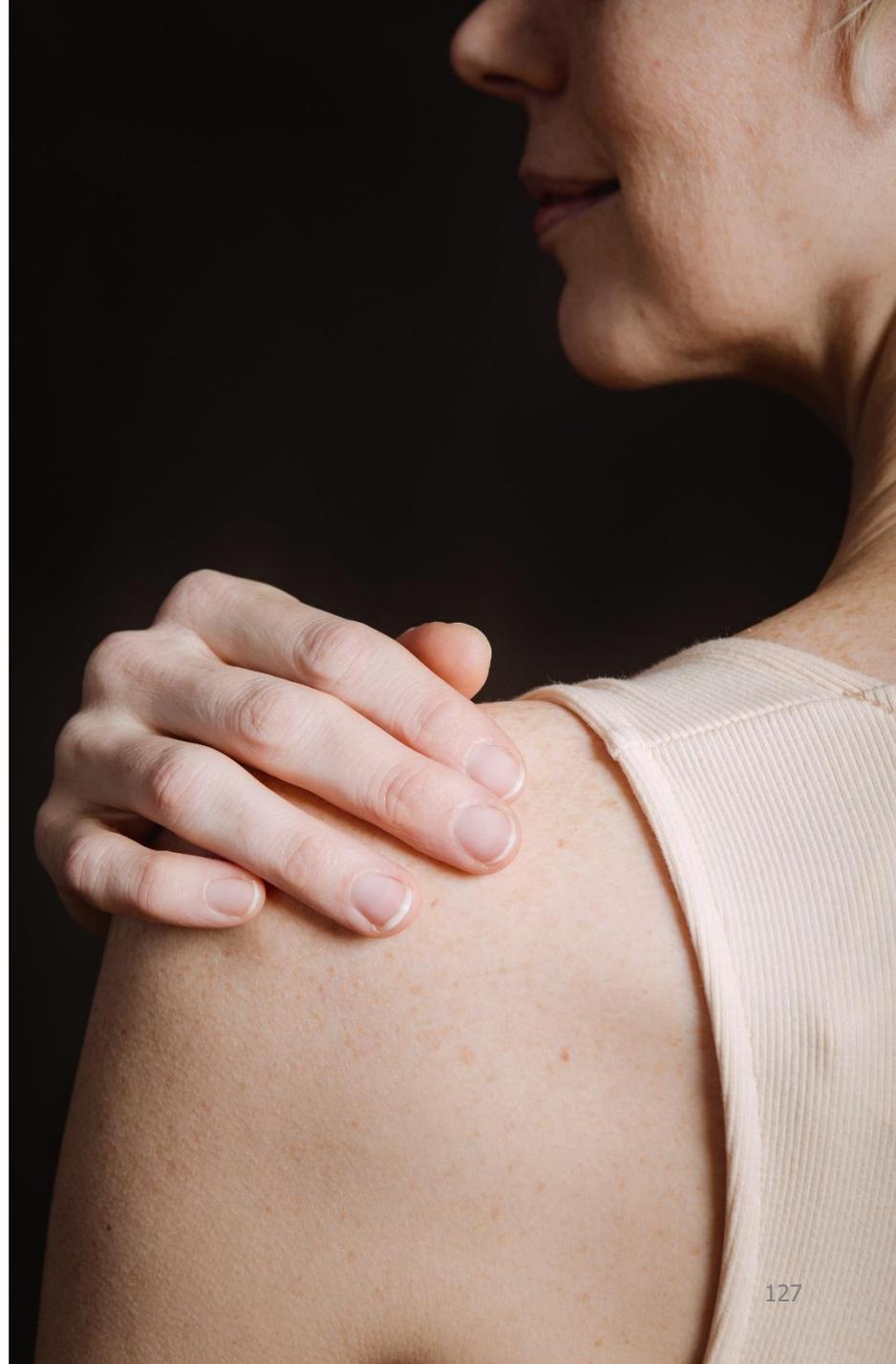


Somos Pacientes

The Somos Pacientes online platform (somospacientes.com), in operation for eight years now, has continued to increase the number of registered patient organisations, amounting to 1,900, as shown on the National Map of Patients Organisations, the most complete database of patient bodies in Spain.

Meanwhile, the Somos Pacientes weekly newsletter saw its database almost double in 2020, to a figure of almost 28,000 subscribers.

The main aim of the platform is to provide a shared forum for information, participation, training, services and collaborative efforts, and during 2020 it achieved a significant level of activity. The editorial team at Somos Pacientes published nearly a thousand news items, features, interviews, documents, videos, opinion pieces, etc. last year. Patient organisations themselves likewise uploaded content to the platform in the form of press releases, announcements, editorials, photographs, videos and other items.



Another notable activity during the year was again the 8th edition of the Somos Pacientes Seminar held in mid-December in Madrid. The event was for the first time conducted in semi-online format because of the pandemic health situation, and was broadcast live via the Somos Pacientes YouTube channel. On this occasion under the title: *Future of the Associative Movement: Lessons from the Pandemic*, representatives of patient associations, healthcare professionals, authorities and the pharmaceutical industry addressed matters including the main future challenges for patient associations, and how they should be involved in the R&D process for new medicines.



The closing address at the seminar was delivered by the Minister of Health, Mr Salvador Illa, followed by the 6th Somos Pacientes Awards Ceremony. Over 100 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. Almost 80,000 people chose the winning project from among all the finalists, an all-time record to date for these awards.



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

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 markets.



The positioning and practices of the pharmaceutical industry at the international level represent a valuable reference point in defining the different actions of the FARMAINDUSTRIA Strategic Plan. One fundamental requirement in this process is the Association's interaction and participation at EFPIA (European Federation of Pharmaceutical Industries and Associations) and IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), along with the numerous bilateral and multilateral relationships that FARMAINDUSTRIA maintains with other national associations in the sector.

3.3.1 EUROPEAN CONTEXT

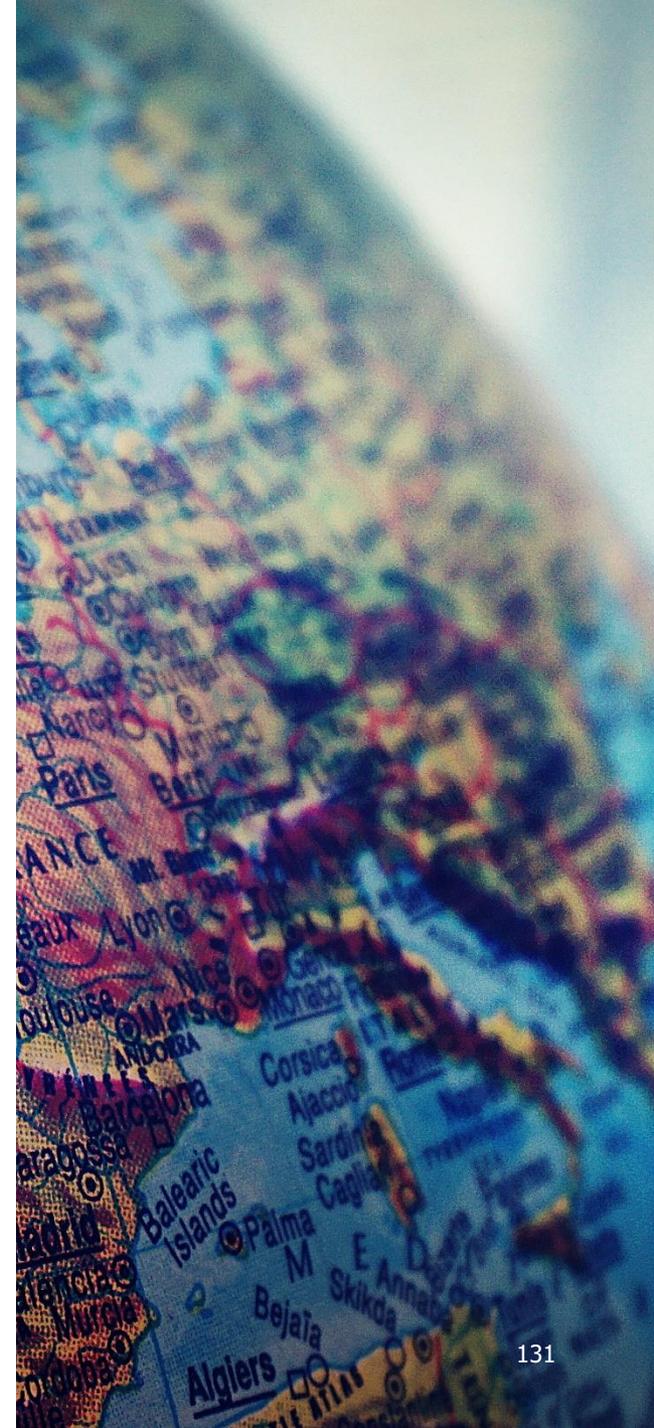
ACTIVITIES WITHIN THE EFPIA FRAMEWORK

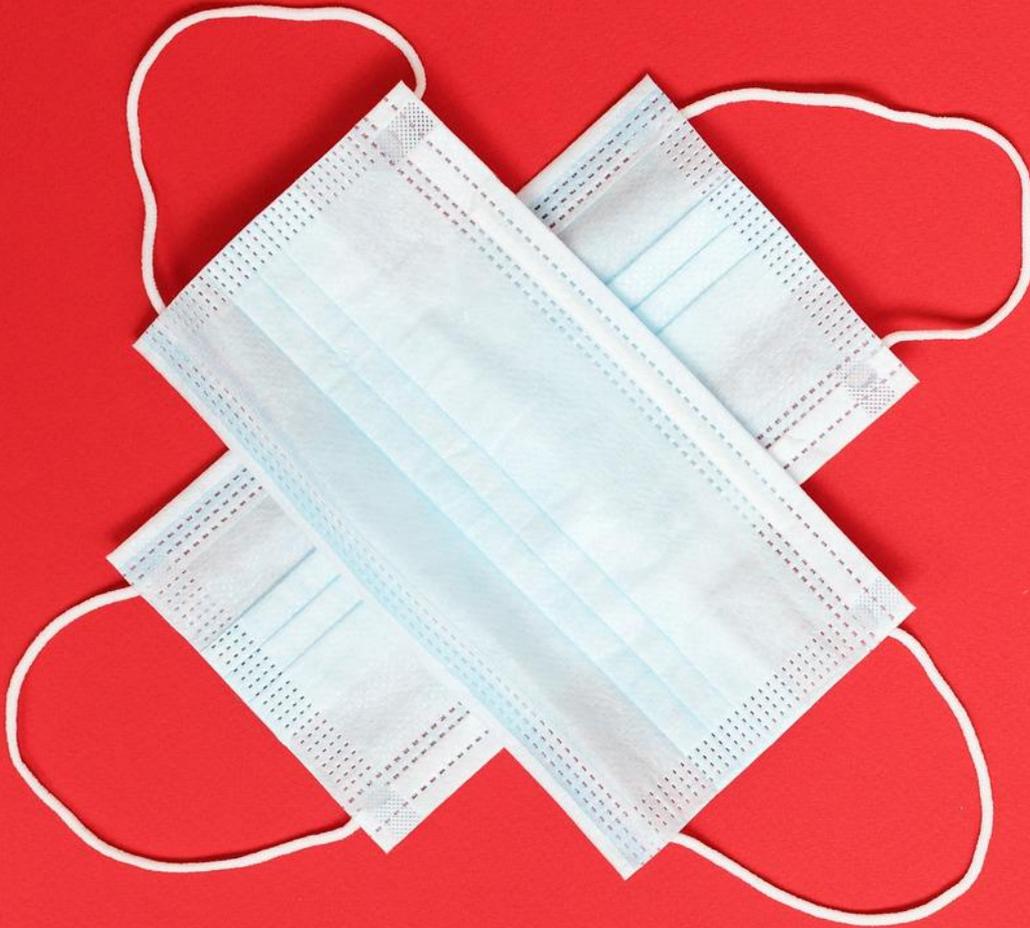
FARMAINDUSTRIA's activities at the European level are aligned with the priorities addressed by EFPIA, the organisation representing 36 national pharmaceutical industry associations and 39 companies in Europe. These links are consolidated through active participation by FARMAINDUSTRIA in most of the governing bodies, strategic committees and working groups of the European Federation.

EFPIA General Assembly

EFPIA held its General Assembly on 30 June 2020, ratifying the priorities of the European Federation for 2020, approving the 2019 accounts, the budget for 2020 and an advance on 2021, along with an analysis of the progress achieved in the different matters addressed by its four strategic committees:

- 1 Innovation
- 2 Access
- 3 European Markets
- 4 Finance





In parallel, the President and the Director General of EFPIA emphasised the key role of the pharmaceutical industry during the Covid-19 crisis and its potential to contribute to the recovery of the European economy. They likewise indicated the sector's willingness to work with all stakeholders in shaping the Pharmaceutical Strategy for Europe and to seek out joint solutions to improve, facilitate and strength equity of access to new treatments, in turn establishing a regulatory framework underpinning pharmaceutical industry's role as a global leader in biomedical research.

EFPIA Board

In coordination with its strategic committees, over the course of 2020 the EFPIA Board addressed the following priorities, among others:

- 1** | The Pharmaceutical Strategy for Europe and the pharmaceutical industry's response through the Country Engagement Efforts.
- 2** | R&D into Covid-19 vaccines.
- 3** | The evolution of the proposed Regulation on Health Technology Assessment (HTA).
- 4** | The negotiation of a trade and partnership agreement between the UK and the EU.
- 5** | The operational principles for implementation of the public-private partnership agenda.



Meetings of the EFPIA European Markets Committee

Over the course of 2020, under the presidency of Sanofi and the vice-presidencies of Servier and FARMAINDUSTRIA, meetings of the European Markets Committee (EMC) continued, which is integrated by the pharmaceutical companies' Heads of Europe and the Directors-General of the national associations. The primary objective of this Committee is to monitor national implementation of the decisions made by EFPIA's Governing Bodies, as well as early detection of risks and threats to the pharmaceutical industry in the various Member States.

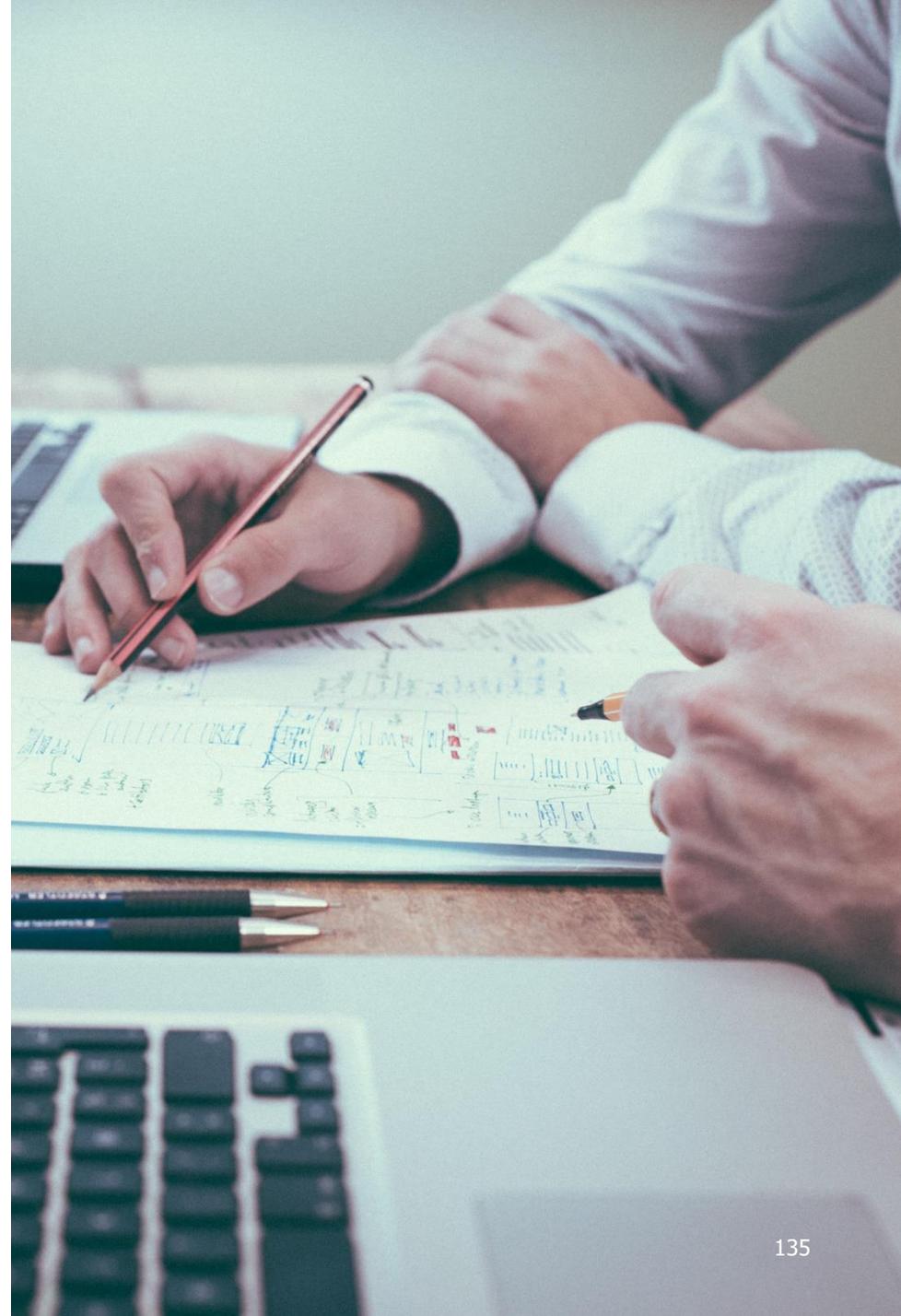
The EMC closely followed the major European and national developments in pharmaceutical policy, paying particular attention to the following topics:

- 1 | Monitoring of the development and publication of the Pharmaceutical Strategy for Europe, as well as of the various activities and actions identified and implemented by EFPIA and its members within the Country Engagement Efforts.
- 2 | Response from the industry to the challenges resulting from the Covid-19 pandemic in connection with supply interruptions and vaccines.
- 3 | Advances regarding the EU-Relative Efficacy Assessment (EU-REA).
- 4 | Regional initiatives for collaboration among European countries on prices and access (Cross-Country Collaborations).
- 5 | Analysis of the situation regarding access to innovation in Europe, through the elaboration of the W.A.I.T. indicator, which compiles the rate of availability and the average time to access of new medicines in European countries.

National Associations Meetings (G1 and G2 Groups)

During 2020 there were two meetings of national associations of the main European markets, including the groups known as G1 (Germany, Spain, France, Italy, UK and Switzerland) and G2 (Belgium, Denmark, Netherlands and Sweden), involving the representatives of EFPIA and IFPMA.

These meetings conducted an in-depth analysis of the impact that the Covid-19 pandemic has had on national health systems, and how this has affected the pharmaceutical industry in the field of health policy, in particular in terms of access to and manufacture of medicines. Various agenda items of the meetings focused on the Pharmaceutical Strategy for Europe published by the European Commission, as well as the various actions conducted with reference to the Country Engagement Efforts, as a proactive response by the industry to the actions set out in the Pharmaceutical Strategy for Europe.

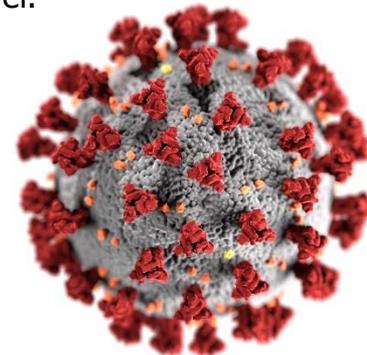


COVID-19 AND THE PHARMACEUTICAL STRATEGY FOR EUROPE

Among the goals set by the European Commission President Ursula von der Leyen for her term in office, the field of health included "sustainable access to medicines, while at the same time promoting innovative activity by the pharmaceutical industry, the digital transformation of national health systems, developing an interoperable infrastructure at the European level, along with the launch of the agenda to fight antimicrobial resistance". In order to fulfil this challenge, the European Commission identified as key elements the establishment of a Pharmaceutical Strategy for Europe and the creation of the European Health Union (EU Health).

The outbreak of the Covid-19 pandemic and the resulting health crisis highlighted the weaknesses of the national health systems of the Member States, prompting a rethink of the direction that both the Pharmaceutical Strategy for Europe and European Health Union should take, along with other healthcare policies.

To this effect, it is essential to strengthen national health systems and ensure they best provide the guarantees for which they have been created, capable of withstanding pandemics and other unforeseen events. The achievement of this objective requires the establishment of a biomedical research ecosystem equipped with an infrastructure facilitating new technological developments and scientific advances. This means providing the regulatory framework with a first-class, predictable, flexible and adaptive regulatory system to support the new generation of medicines. An agile and attractive system operating with high levels of security, quality and efficacy, promoting the regulatory convergence which is essential in order to allow the European pharmaceutical industry to recover the position of leadership it has lost over recent decades, and to compete on equal terms at the international level.



The European pharmaceutical industry is a fundamental cornerstone in realising the European Commission's vision for the future and in achieving more resilient national health systems. The aim of the industry is to protect patient health by improving availability and fair access to safe and effective medicines without delay, at affordable prices, aiming for the sustainability of national health systems, as well as focusing research on unmet medical needs so as to improve health outcomes for the population.

Within this context, the Pharmaceutical Strategy for Europe must be aligned with other European initiatives, such as:

- 1 The proposed health data regulations.
- 2 The establishment of the European Health Emergency Preparedness and Response Authority (HERA).
- 3 The broadening of the powers of the European Medicines Agency (EMA).
- 4 The revision of the legal framework regarding serious threats to cross-border public health.
- 5 The European Green Deal.
- 6 Commercial policy.
- 7 Industrial policy.
- 8 The new mechanisms for the control and management of supply interruptions, developing the strategic autonomy term.
- 9 The implementation of an HTA Regulation to assist Member States in decisions in this field and provide the European pharmaceutical industry with a more predictable procedure for the assessment of the clinical benefit offered by new medicines.



The Pharmaceutical Strategy for Europe comprises a total of 55 actions. Of these actions, the revision of the regulations for orphan and paediatric medicines, and the modification of the European pharmaceutical legislation, are the most advanced in terms of implementation.

Economic Recovery Plan and Multiannual Financial Framework

As part of its package of measures for the recovery of the EU, on 27 May 2020 the European Commission published its Economic Recovery Plan (Next Generation EU) and its proposed Multiannual Financial Framework 2021-2027. The Economic Recovery Plan was assigned a budget of 750 billion euros, of which 390 billion would be assigned in the form of non-reimbursable transfers, and 360 billion as loans to the Member States. Meanwhile, the Multiannual Financial Framework was assigned 1.0743 trillion euros, in addition to the three safety nets for workers, companies and Member States totalling €540 billion already agreed by the European Council and Parliament.

The Economic Recovery Plan funds were distributed across three pillars:

- 1 | A first pillar comprising investments and reforms, divided into the Recovery and Resilience Facility, and a supplement known as React-EU.
- 2 | A second pillar for the reactivation of the economy, comprising the update of the InvestEU Programme and a Solvency Support Instrument intended for companies in those regions most affected by Covid-19.



3 A third pillar, focused on lessons learned after the crisis, incorporating, among other aspects:

- A new, independent health programme (EU4Health) to underpin healthcare systems, immediately addressing the crisis resulting from Covid-19 and future pandemics, and funding the required infrastructure to monitor the forecasting of new outbreaks, the supply of personal protective equipment and potential vaccines against Covid-19.
- An expansion of the EU Civil Protection and Emergency Mechanism (rescEU) launched by the EU to address the current healthcare crisis and guarantee the supply of medicines.
- A reinforcement of the programme Horizon Europe to fund research in the fields of health, resilience as well as the green and digital transitions.

At the insistence of various countries (Austria, Denmark, Finland, the Netherlands and Sweden), the European Council of Heads of State and Government of 21 July 2020 agreed to incorporate greater supervision of direct grants, requiring that the Member States present a programme of reforms for the period 2021-2023 in line with the priorities and recommendations of the European Semester. These national reform plans must be approved by qualified majority, and the subsequent disbursements will depend on compliance with a series of pre-established objectives. The instrument to be used for the disbursement of the bulk of the Recovery Plan is the Recovery and Resilience Mechanism, with a budget of 672.5 billion euros and a duration of three years.

In the longer term, both the Recovery Plan and the Multiannual Financial Framework include a section indicating the importance of using part of the funds assigned to the EU4Health programme to improve preparedness for potential future healthcare crises by strengthening the EMA, reinforcing the European Centre for Disease Prevention and Control (ECDC), facilitation of public procurement (in particular for vaccines), and the creation of a European Health Data Space to support research.

The Economic Recovery Plan and the proposed Multiannual Financial Framework ultimately received the support of the European Council in December 2020, allowing the launch of the European budget for the period 2021-2027.



EU4Health - European Health Programme

As part of the package of measures for the economic recovery of the EU in response to the crisis caused by the Covid-19 pandemic, the European Commission published a proposed Regulation on 27 May 2020 establishing a specific programme in the field of health named EU4Health, for the period 2021-2027. Following intense negotiations between the European Parliament and the EU Council, on 14 December 2020 consensus was reached, and on 26 March 2021 EU4Health took effect.

EU4Health comprises three general objectives:

- 1 Protect European citizens from serious cross-border threats to health.
- 2 Improve the availability of medicines, medical devices and other relevant healthcare products for the crisis, contributing to their affordability and supporting innovation.
- 3 Strengthen national health systems and healthcare professionals, including digital transformation, data transfer, interoperability and coordination among Member States.

These more general objectives are in turn supplemented by 10 specific objectives resulting in 11 possible actions eligible for funding, which could have a substantial impact on R&D activity in the pharmaceutical industry.

From a longer-term perspective, EU4Health has the aim of complementing policies already put in place by the European Commission, such as the Beating Cancer Plan and the digital transformation of national health systems, while also serving as a platform to tackle other healthcare challenges, such as inequalities in this sphere between countries, regions and certain population groups, and the configuration of high-quality, sustainable healthcare systems.



European Health Union

On the basis of the lessons learned, and with the aim of dealing with other pandemics, as well as serious cross-border public health threats, in a comprehensive and consistent manner with clear principles of cooperation and coordination among the Member States, the European Commission published a package of proposals on 11 November 2020 laying the foundations for a "European Health Union". The package is made up of a Communication accompanied by three legislative proposals developing its contents in greater detail.

The Communication explains the objectives of the European Health Union, including:

- 1 Strengthen EU planning for preparedness, response and resilience to combat threats to public health in a coordinated manner.
- 2 Improve monitoring and surveillance systems for infectious diseases, by incorporating artificial intelligence and electronic patient records.
- 3 Align testing methods to avoid different approaches at the national and regional level.
- 4 Authorise the Health Security Committee to draw up guidelines developing on the recommendations of the Commission, ensuring coordination of measures in the Member States.
- 5 Facilitate international collaboration in response to viral threats, reforming the WHO and allowing non-European countries to participate in the Health Security Committee.
- 6 Create an early warning system for public health emergencies in coordination with the WHO.

- 
- 7 Promote a platform for the exchange of information between the EMA and the ECDC regarding the safety and efficacy of vaccines.
 - 8 Improve the administration of medicines and medical devices to monitor and mitigate supply interruptions, in coordination with the pharmaceutical industry.
 - 9 Formalise procedures to speed up the development of treatments.
 - 10 Establish permanent mechanisms to promote dialogue and coordination in clinical trials.
 - 11 Create a European version of the United States BARDA (*Biomedical Advanced R&D Authority*) named the Health Emergency Preparedness and Response Authority (HERA).

The legislative proposals contained in the package are as follows:

- 1** Regulation to Expand the Mandate of the ECDC. The expansion of the ECDC's mandate will allow it to:
- Supervise outbreaks of infectious diseases on the basis of shared standards and definitions.
 - Improve risk analysis, modelling and evaluation of healthcare capabilities for specialist treatments.
 - Draw up response recommendations.
 - Mobilise and deploy an EU Health Working Group to assist the Member States in their response at the local level.

- 2** Regulations to Expand the Mandate of the EMA. The role of the EMA in crisis management will comprise:
- Monitor and mitigate a lack of medicines and medical devices.
 - Coordinate and advise as to the medicines that could treat, prevent or diagnose illnesses giving rise to health crises.
 - Coordinate studies and clinical trials to supervise the efficacy and safety of vaccines.



3 Regulation on Serious Cross-Border Threats to Health. The Regulation repeals Decision 1082/2013/EU, on the understanding that, despite the instruments available, such as for emergency support, the EU is not in a state of preparedness to make efficient purchases of treatments, joint purchase agreements having been one of the weak points at the outset of Covid-19. Article 12 includes new provisions to improve the European procurement process (likewise providing for an exclusivity clause with regard to negotiation and procurement), to ensure that the participating countries align themselves with this process, so as to prevent parallel negotiations.



EU strategy for vaccines against Covid-19

On 17 June 2020 the European Commission published a Communication to the European Parliament, European Council and European Investment Bank with a specific strategy for Covid-19 vaccines, with the aim of accelerating development, manufacture and supply, so as to inoculate the European population against the virus.

The strategy comprises three objectives:

- 1 Ensure the quality, safety and efficacy of vaccines.
- 2 Secure timely access to vaccines for the Member States, while leading the global solidarity effort established within the context of access collaboration.
- 3 Ensure equitable and affordable access as early as possible.





The strategy in turn rests on two pillars:

- 1 Adapt the European regulatory framework, making use of existing regulatory flexibility to facilitate the research and production of healthcare products to combat Covid-19.
- 2 Ensure vaccine production and supply in the EU through Advance Purchase Agreements.

Regarding this latter pillar, in order to support companies in accelerating the development and production of Covid-19 vaccines, and aware of the risk of failure during clinical trials, the European Commission has, in the name of the Member States, signed individual agreements with vaccine manufacturers, committing to finance part of the initial costs in exchange for the right to purchase a specified number of doses over a given period at an affordable price. The financing provided was considered an advance payment towards the vaccines purchased by the Member States.

Pharmaceutical Strategy for Europe

On the basis of the feedback contained in the Roadmap and Public Consultation launched in June 2020 (consultation processes in which FARMAINDUSTRIA was involved in coordination with EFPIA), on 25 November the European Commission published the Pharmaceutical Strategy for Europe, which will play a key role in the creation of the European Health Union, and will define the future of the European pharmaceutical industry over the next 20 years.

The publication of the Pharmaceutical Strategy for Europe marks the start of a process which includes an ambitious programme of legislative initiatives (revision of Europe's basic pharmaceutical legislation, Directive 2001/83/EC and Regulation (EC) 726/2004), as well as non-legislative initiatives that will be launched over the next three years and will cover the entire medicine life-cycle, in turn creating synergies with the Green Deal, the European Digital Strategy, Europe's Beating Cancer Plan, the European Industrial and Trade strategies, and the Action Plan on Intellectual Property. In this regard, on 30 March 2021 the European Commission published the Roadmap and Inception Impact Assessment for the Revision of the EU Pharmaceuticals Legislation, opening up the process for the publication of a revision proposal in early 2022.



The main goals of the Strategy are:

- 1 Protect patients by responding to unmet medical needs and guaranteeing access to medicines at affordable prices.
- 2 Support the European pharmaceutical industry to be more competitive and innovative.
- 3 Increase resilience through diversified and secure supply chains, with environmentally-sustainable pharmaceutical products, and the implementation of mechanisms to prepare and allow a response to potential health crises.
- 4 Make the European regulatory system a global flagship, promoting cooperation and regulatory convergence to allow the European pharmaceutical industry to compete on equal terms internationally.

Since the publication of the Roadmap and Public Consultation, FARMAINDUSTRIA has intensified its dialogue both with the Spanish authorities at the national level and Spanish representatives before European institutions, emphasising the importance of promoting and maintaining the necessary incentives in the field of R&D so that the EU does not lose competitiveness in the international context, and can thus position itself as a global leader in biomedical research.



With the aim of establishing a platform which allows EFPIA member associations to complement the actions of the European Federation at the local level, and so provide a proactive response to the Pharmaceutical Strategy for Europe, the Country Engagement Efforts were set up in June 2020, resting on three pillars:

- 1 Organisation of a High-Level Forum with the involvement of the European and national authorities, patients, pharmaceutical industry and other relevant stakeholders.
- 2 Incentives.
- 3 Early patient access to innovations.

In parallel, and given the vital importance that the Pharmaceutical Strategy for Europe will have in the future of the sector, FARMAINDUSTRIA has set up a Strategic Committee, comprising 10 members of its Governing Bodies (representing the Association's three statutory groups), the objectives and action plan of which are closely aligned with EFPIA's Country Engagement Efforts.



Inception Impact Assessment for Orphan and Paediatric Medicines

As part of the Pharmaceutical Strategy for Europe, on 24 November 2020 the European Commission published a Roadmap for the Inception Impact Assessment for Orphan and Paediatric Medicines, with the aim of addressing the deficiencies identified by the Commission in its assessment report published in August 2020. These deficiencies include:

- 1 Presence of incentives in orphan and paediatric medicine regulations which may not be the most appropriate to promote the development of medicines intended for unmet medical needs.
- 2 Disparity in the availability of medicines and inequitable access across Member States.
- 3 Need to adapt the regulatory framework to incorporate technological and scientific advances.
- 4 Existence of inefficient and cumbersome processes which hamper the analysis and authorisation of orphan and paediatric medicines.



In this regard, the Inception Impact Assessment presents different options to tackle each of these deficiencies.

With the aim of conveying the opinion of the research-based pharmaceutical industry for consideration in the drafting of the public consultation text (the European Commission is expected to open this process in the second quarter of 2021), FARMAINDUSTRIA submitted its response to the Roadmap which had been drawn up. The Commission will subsequently proceed to draw up a Final Impact Assessment, taking into account the responses, and may present a legislative proposal in early 2022.



Publication of the European Industrial Strategy

In March 2020, the European Commission published its Industrial Strategy, establishing the path to be followed by Europe's industrial sector to address the digital and green transformations, while at the same time maintaining the leadership and competitiveness of European industry at a time of great geopolitical uncertainty. In the pharmaceutical sphere, the Strategy emphasises the importance of underpinning industrial autonomy and the strategic value of this sector in guaranteeing the supply of active pharmaceutical ingredients through a specific action plan for pharmaceutical products, based on the Pharmaceutical Strategy for Europe.

In parallel, the Commission published an Industrial Strategy for Small and Medium Enterprises tailored to the reality of this business grouping, and providing support to allow these companies to maximise their productive potential. In this regard, the Commission calls on the Member States to use the flexibility offered by the new European procurement framework in order to:

- 1 Increase opportunities for SMEs through the use of digital tools and platforms, thereby intensifying cross-border public procurement.
- 2 Divide large contracts into smaller batches.
- 3 Increase use of strategic procurement (in particular for innovation).
- 4 Complete the digital transformation of procurement processes.

In response to the publication of the Industrial Strategy, EFPIA published a document indicating that since the 1990s the EU has gradually lost its leading position in pharmaceutical R&D, having been overtaken by the United States, and imminently by China if the Commission does not adopt urgent measures. In this regard, EFPIA proposed a series of recommendations to ensure that the industrial and pharmaceutical strategies would facilitate the creation of a flexible and adaptive regulatory framework, with a favourable climate in terms of intellectual property and accelerated access, which would allow the research-based pharmaceutical industry (as a strategic sector) to continue helping to improve the health of European citizens, boost R&D activity, drive economic growth and contribute to the digital transformation of the EU through the European Health Data Space.

At the time when this Annual Report went to press, the European Commission was reviewing the text of the Industrial Strategy to incorporate the lessons learned from the Covid-19 pandemic and adapt the strategy to the new post-pandemic context, in line with the Pharmaceutical Strategy for Europe.



Pilot project on Market Launch Intentions of Centrally Authorised Products

On 22 June 2020 the European Commission launched a public consultation for a pilot project on Market Launch Intentions of Centrally Authorised Products (CAP), designed by the Human Medicines Division of the Directorate-General for Health of the European Commission. FARMAINDUSTRIA, in coordination with EFPIA, participated in the public consultation in order for its observations and comments to be included in the pilot design.

The pilot project forms part of the initiatives included in the Pharmaceutical Strategy for Europe, in response to the existing inequalities in access across Member States, the aim being to inform the regulatory authorities of the marketing intentions of CAPs and the reasons for possible delays in their market launch. Participation in the pilot by the holders of marketing authorisations is voluntary, with guarantees of confidentiality on the part of the European Commission, and with the focus on oncology and orphan medicines, both in the phase prior to authorisation by the EMA and for new authorisations.



The analysis of the data gathered via this project will serve to:

- 1** | Identify the reasons for inequalities in access in the Member States.
- 2** | Determine possible actions to achieve the objectives of the Pharmaceutical Strategy for Europe.

On 4 March 2021, the European Commission published an information document detailing the objective and the key characteristics of the project, allowing the pilot to begin on 25 March, for a period of 18 months.



Action Plan on Intellectual Property Rights

On 25 November 2020 the Commission adopted an Action Plan on Intellectual Property Rights, with a general scope, since it affects not only the pharmaceutical sector but all industrial sectors as a whole, the aim being to help European innovative industry players maintain global leadership, while at the same time speeding up the green and digital transition in the EU.

To achieve this aim, the Plan includes a raft of measures intended to:

- 1 Improve the protection of intellectual property.
- 2 Drive the implementation of intellectual property by SMEs.
- 3 Facilitate exchanges in the field of intellectual property.
- 4 Combat counterfeiting and improve respect for intellectual property rights.
- 5 Promote fair competition conditions worldwide.



With regard to the references that the Plan contains for the pharmaceutical sector, it emphasises the launch of a unitary mechanism for the granting of supplementary protection certificates and the creation of a unified patent title.

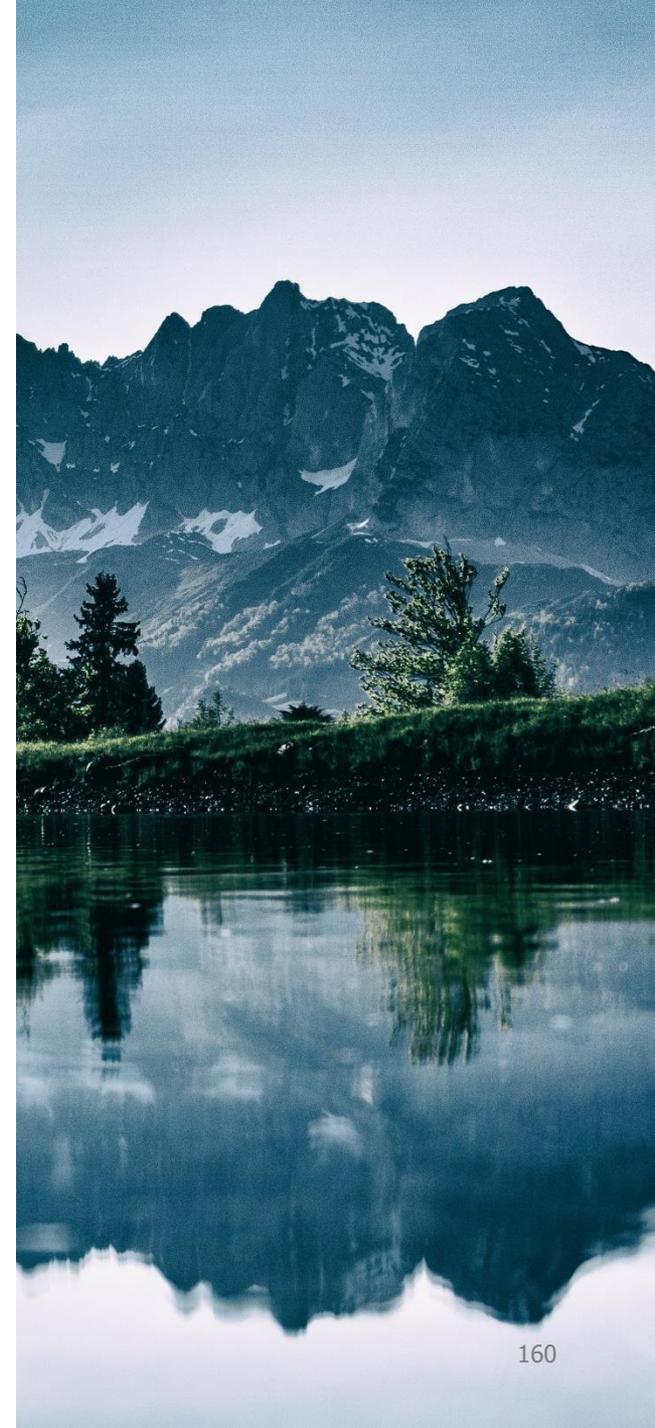
In this regard, EFPIA published a press release welcoming the Commission's commitment in this sphere, since this will result in greater predictability and savings when researching and developing medicines in the EU. Nonetheless, EFPIA registered its concern at the mention in the document (as a consequence of the Covid-19 pandemic) of the possibility of coordinating the granting of compulsory licences at the European level for medicines in health emergency situations, as this jeopardises incentives for research.



Strategic Approach to Pharmaceuticals in the Environment

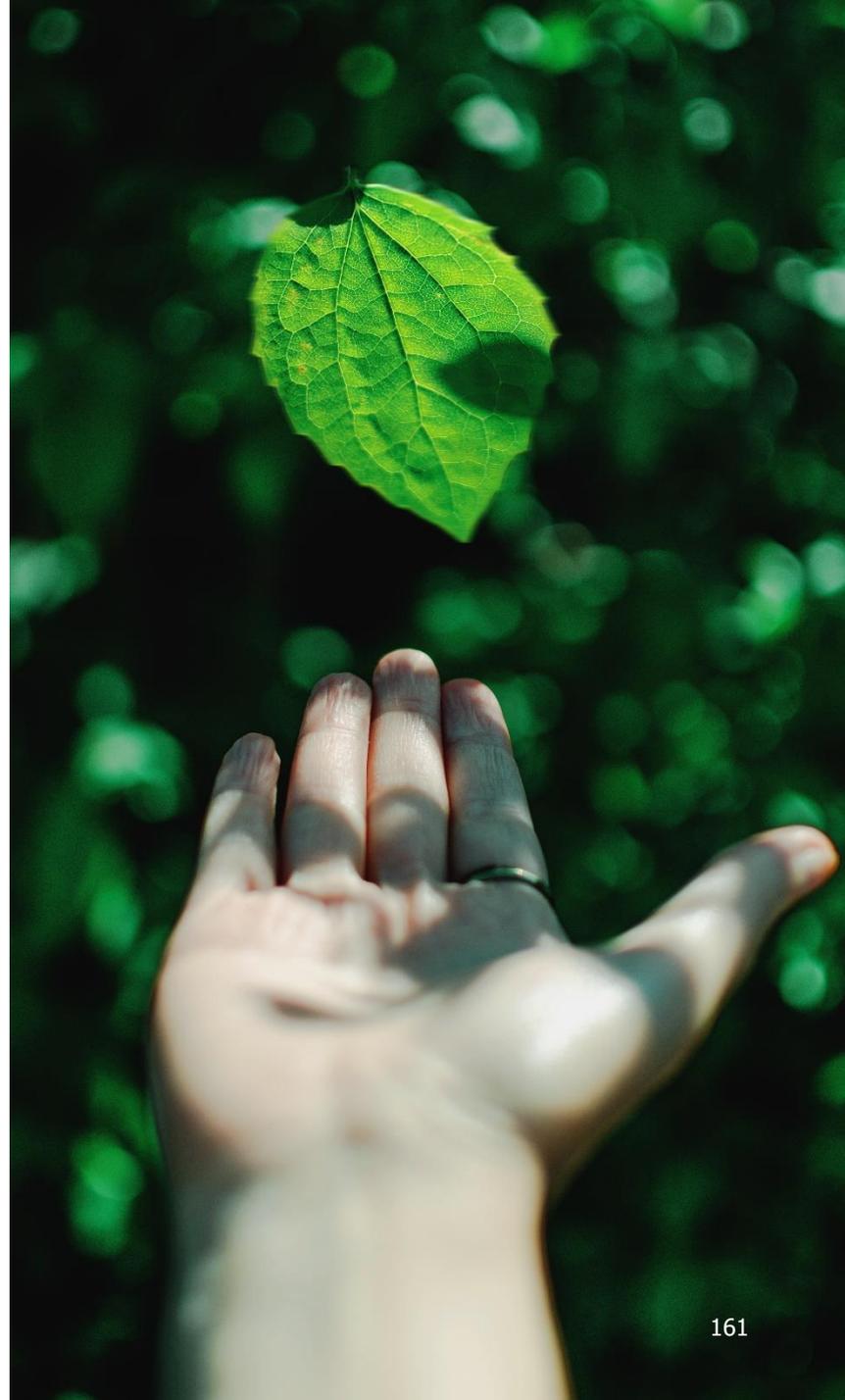
In March 2019 the European Commission presented the Strategic Approach to Pharmaceuticals in the Environment, including actions to counteract the effects of pharmaceuticals throughout their life-cycle: from design and production, through their use, and up to their elimination. The Strategic Approach identifies more than 30 individual actions classified in six areas:

- 1 Raise awareness and promote prudent use.
- 2 Improve expertise and risk assessment.
- 3 Gather monitoring data.
- 4 Incentivise environmentally-sustainable design.
- 5 Reduce manufacturing emissions.
- 6 Improve the treatment of waste water and other waste materials.



To mark the first anniversary of the launch of the Strategic Approach, the European Commission published a report detailing the progress achieved in application of the strategy, the conclusion being that the process was on the right track given the significant progress attained in implementing certain actions:

- 1** Adoption of the revised Surface Water Watch list, to which new pharmaceutical products have been added.
- 2** Authoring of legal acts as a result of the Regulation on Veterinary Medicines, with the aim of promoting more prudent use of antibiotics in animals, and applying a wide range of specific measures to fight antimicrobial resistance.
- 3** Drafting of new guidelines on hazardous domestic waste, taking into account the incorporation of pharmaceutical products in the impact assessment for the possible revision of the Directive on urban waste water treatment.



- 4** | Generation of the most recent "LUCAS" topsoil survey, with results scheduled for 2022, which will include a sampling of pharmaceutical concentration and antimicrobial genes in topsoil.
- 5** | Awareness-raising actions among healthcare professionals as to the environmental impact of medicines.
- 6** | Funding of various research projects into pharmaceuticals and the environment.

The report also indicates that the achievement of the remaining actions will be strongly driven by both the European Green Deal and the Pharmaceutical Strategy for Europe.



MAIN AREAS OF FARMINDUSTRIA ACTION IN EUROPE

Exit of the United Kingdom from the EU (Brexit) and the Trade and Cooperation Agreement

On 29 March 2017, the UK notified the European Council of its intention to leave the EU through activation of Article 50 of the Lisbon Treaty, launching a period of two years during which the UK and the EU would be required to define the terms of Brexit.

Phase 1

This ended on 8 December 2017 with the agreement reached regarding the Brexit financial settlement, the 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 with the ratification of the United Kingdom Withdrawal Agreement, establishing the conditions for the relationship between the two parties during the transition period, along with the Political Declaration attached to the Agreement, laying the foundations for the future relationship once the transition period ended.





Although there were various delays to the exit date, ultimately on 31 January 2020, following ratification on 29 January of the Withdrawal Agreement by the British and European parliaments, the UK ceased to be a member of the EU, beginning the Transition Period (up until 31 December 2020).

Following intense negotiations over the course of 2020, on 24 December the EU and the UK finalised a Trade and Cooperation Agreement comprising three pillars:

- 1 A Free Trade Agreement.
- 2 A new framework for law enforcement and judicial cooperation.
- 3 A horizontal agreement on governance, guaranteeing the utmost legal certainty for businesses, consumers and citizens.

The Free Trade Agreement achieved goes beyond the traditional agreements, covering a range of spheres which lie outside the scope of trade in goods and services, such as investment, competition, data protection and Social Security coordination. With regard to free movement (of goods, services, capital and people), since the EU and the UK have become independent markets, the framework will be more restrictive, and the export and import of goods will therefore be subject to customs procedures, although to facilitate trade an exemption from tariffs and quotas has been established for all goods that comply with appropriate rules of origin. In the field of competition, both parties committed to guarantee fair conditions. As for Social Security coordination, the Agreement aspires to guarantee a set of rights for EU and UK citizens working, travelling or moving in both directions. Lastly, the Agreement allows the UK to continue participating in various landmark EU programmes over the period 2021-2027, such as Horizon Europe, on condition of a financial contribution to the EU budget.



In the field of health, the Agreement includes a specific annex on medicines, establishing the conditions for the mutual recognition of inspections and certifications. The annex determines the framework which will govern mutual recognition, establishing specific articles which stipulate how modifications to legal and regulatory provisions must be conducted in the sphere of good manufacturing practice, the potential suspension of mutual recognition, cooperation in the regulatory field, and the establishment of a Working Group on Medicines, which will supervise the proper application of the annex.

The inclusion in the Agreement of a specific annex regarding medicines was welcomed by the pharmaceutical industry, as it covers one of the industry's main requests, avoiding duplication of workload and preventing potential disruptions of the supply chain. The Agreement likewise indicates the intention of the EU and the UK to work together in the field of health security, allowing the UK to access the Early Warning and Response System of the EU, while also making provision for cooperation for the prevention and control of disease.



On 1 May 2021 the Trade and Cooperation Agreement took full effect following ratification by the European Council and Parliament, and by the corresponding British institutions.

At the domestic level, particular mention should be made of the publication of Royal Decree-Law 38/2020, of 29 December 2020, adopting measures to adapt to the third country status of the UK following the expiry of the transition period established in the Withdrawal Agreement.

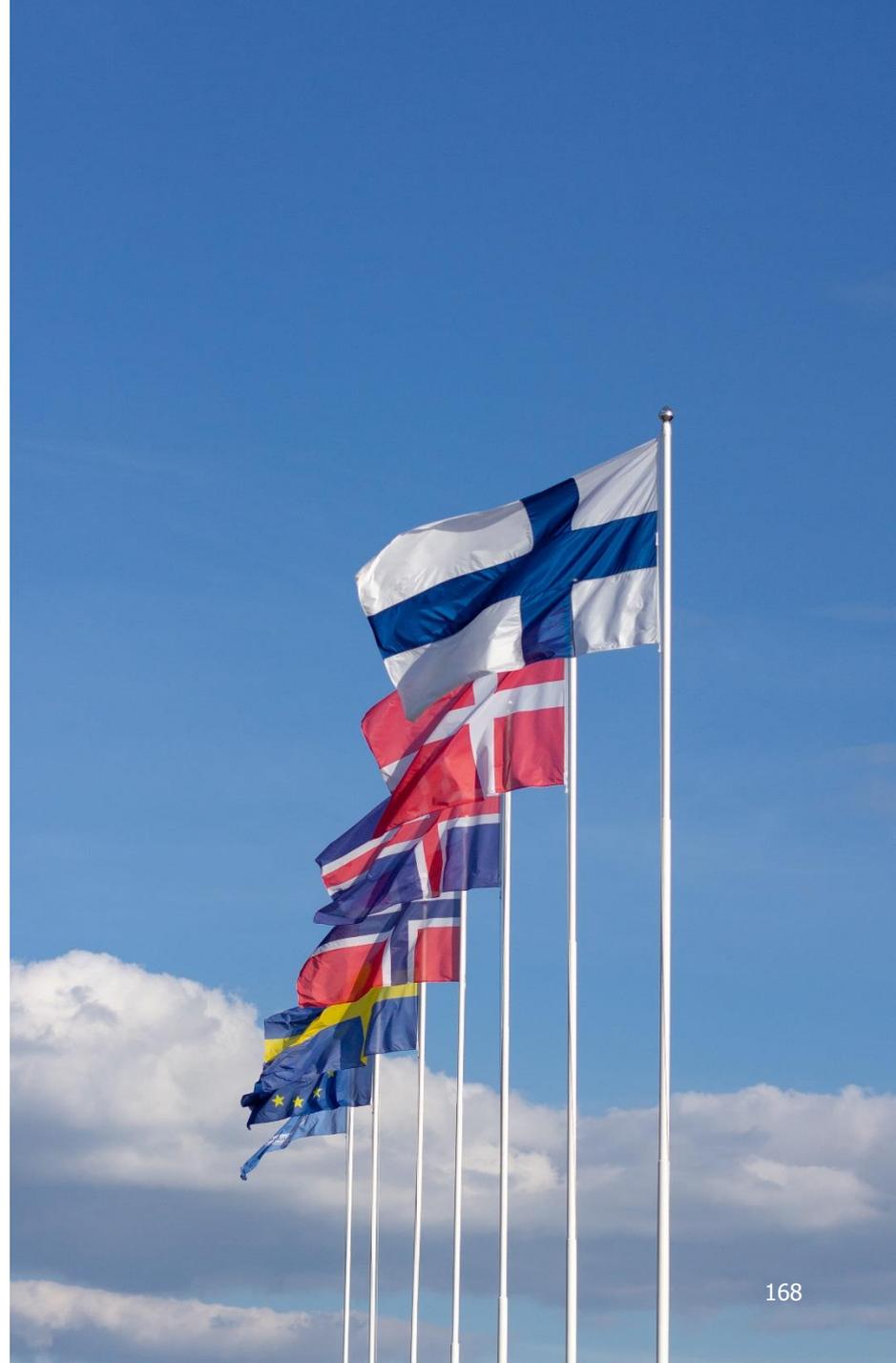


Regulation on Health Technology Assessment

The European Commission published in January 2018 a legislative proposal of the European Parliament and the European Council on health technology assessment (HTA). The proposed Regulation included as one fundamental element a joint clinical assessment of the relative efficacy of medicines, which would be adopted on a mandatory basis by all countries of the EU, following a 3-year transitional period.

The aim pursued by the Commission was to:

- 1** | Guarantee fulfilment of the internal-market objectives.
- 2** | Overcome inefficiencies resulting from the duplication of assessments taking place in the 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, under certain circumstances and provided that this would be duly 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 in 2019 and early 2020 to reach a consensus, the differing positions of the Member States (mandatory vs. voluntary approaches) as to the use of joint clinical assessments remained clear.

It was not until the German presidency in the second half of 2020 that progress was finally achieved in the negotiations. The text presented by the German presidency highlights:

- 1 The need to strengthen the role of the Member States.
- 2 The consideration of joint clinical assessments in national procedures (non-mandatory).
- 3 The expansion of the Regulation's scope of application in a progressive manner (beginning with oncology medicines and others for which there is unanimity among EU countries).
- 4 Flexibility with regard to the technologies evaluated.



Finally, in March 2021 under the Portuguese presidency, the EU Council reached a consensus as to the text, allowing the start of conversations between the European Council, Commission and Parliament. The expectation is that the negotiations among the three institutions would be concluded in the second half of the year, allowing a text to be finalised for the Regulation in late 2021 or early 2022.

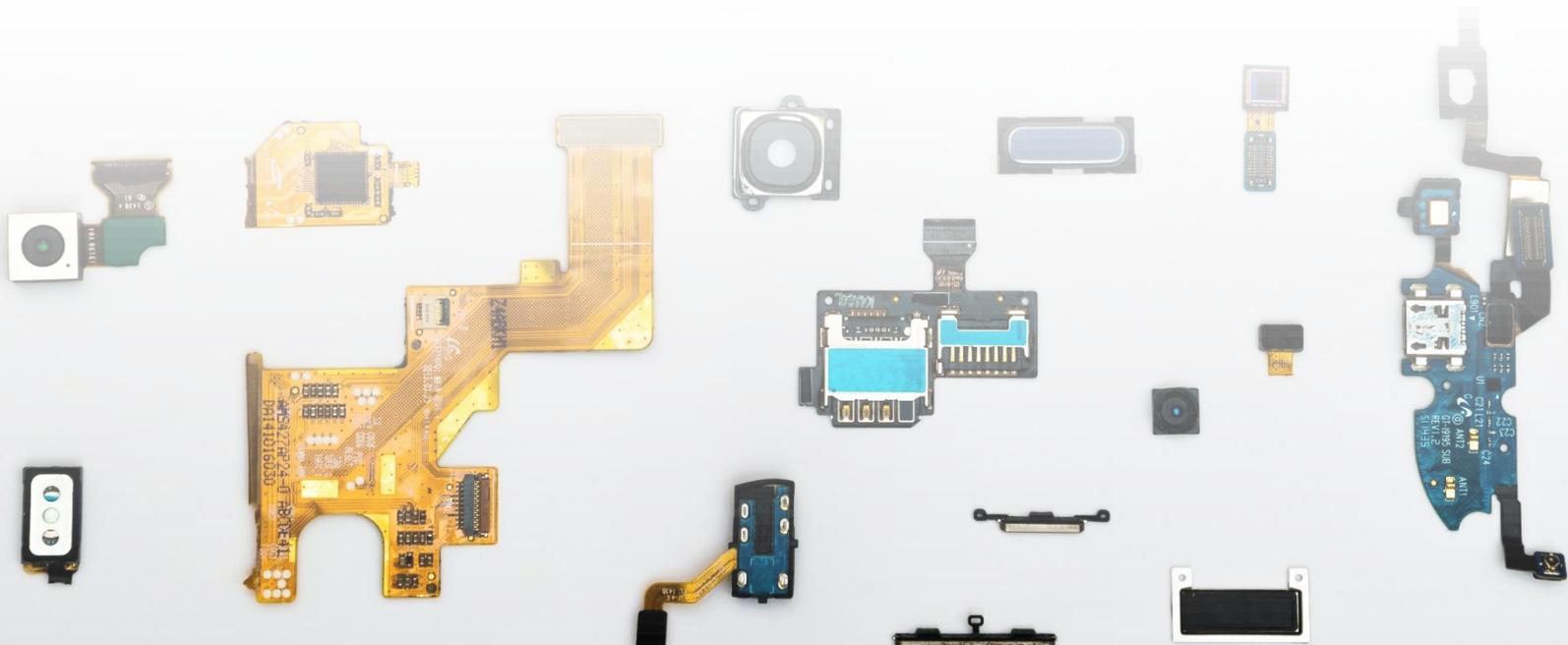
In line with EFPIA, FARMAINDUSTRIA supports a future European regulation in the field of HTA based on centralised clinical assessment which will avoid inefficient re-assessments at the national level as well as the barriers and delays in access to innovations affecting European patients.



European Commission Digital Strategy

On 19 February 2020 the European Commission published a set of documents revealing the digital transformation strategy for the 2019-2024 term. These documents include:

- 1** A roadmap, in which the Commission describes its digital strategy and the actions that it will implement over the next five years.
- 2** The European Data Strategy, with the legislative measures that need to be adopted in order to create a European Data Space.
- 3** A white paper on artificial intelligence, proposing a regulatory framework serving to guarantee reliable and secure use of artificial intelligence.



In the field of health, the Commission's digital strategy includes a raft of actions, including:

Create a European Health Data Space to improve access to such data so as to allow faster and more precise research, diagnosis and treatment.

2 | Promote electronic clinical records with a format guaranteeing access and transfer of health data throughout the EU.

3 | Embark on an open dialogue with the health sector to generate an action plan facilitating the development, experimentation and adoption of artificial intelligence in healthcare.



Europe's Beating Cancer Plan

On 4 February 2020 the European Commission launched a Public Consultation and Roadmap with the aim of serving as the basis to establish Europe's Beating Cancer Plan, defining its key spheres of action, and studying potential future measures in each phase of the disease. In parallel, the Commission published a Q&A document setting out detailed information as to both the objectives and the operational framework of the Plan.

Europe's Beating Cancer Plan is one of the six policy priorities identified by the President of the Commission for the 2019-2024 term, arising with the aim of assisting the Member States in improving cancer control and care, given the constant increase in incidence, the high mortality rate and the disparities which exist between European countries in the fields of prevention, detection, treatment and patient quality of life.

In this regard, FARMAINDUSTRIA sent the Commission a response document with observations on the Roadmap (in coordination with EFPIA), emphasising the commitment of the pharmaceutical industry to continue researching and developing new medicines that would reduce cancer mortality and improve patient quality of life. FARMAINDUSTRIA likewise indicated that in order for the industry to be able to fulfil this commitment, it is vital that there should be coordination of health policies, collaboration on initiatives such as the cancer mission area within the Horizon Europe context, as well as public-private partnerships and support for the pharmaceutical industry through a regulatory framework encouraging R&D in this sphere.

The European Beating Cancer Plan was adopted in February 2021.



Antimicrobial Resistance: publication of the progress report

In December 2020 the European Commission published its fifth progress report on the implementation of the *European One Health Action Plan against Antimicrobial Resistance*, adopted in June 2017.

The main goals of this Plan are:

- 1 Position the EU as a standard-setting region for best practice in this field.
- 2 Promote R&D for new antibiotics.
- 3 Influence the global agenda in combating microbial infection.

The progress report indicates the advances achieved since the previous review, in particular the adoption of the EU "Farm to Fork" Strategy, the aim of which is to reduce total sales of antimicrobial medicines for farm animals and aquaculture in the EU by 2030, in addition to the inclusion of the fight against antimicrobial resistance as a key objective in the Pharmaceutical Strategy for Europe adopted in November 2020.



3.3.2 INTERNATIONAL CONTEXT

ACTIVITIES WITHIN THE IFPMA FRAMEWORK

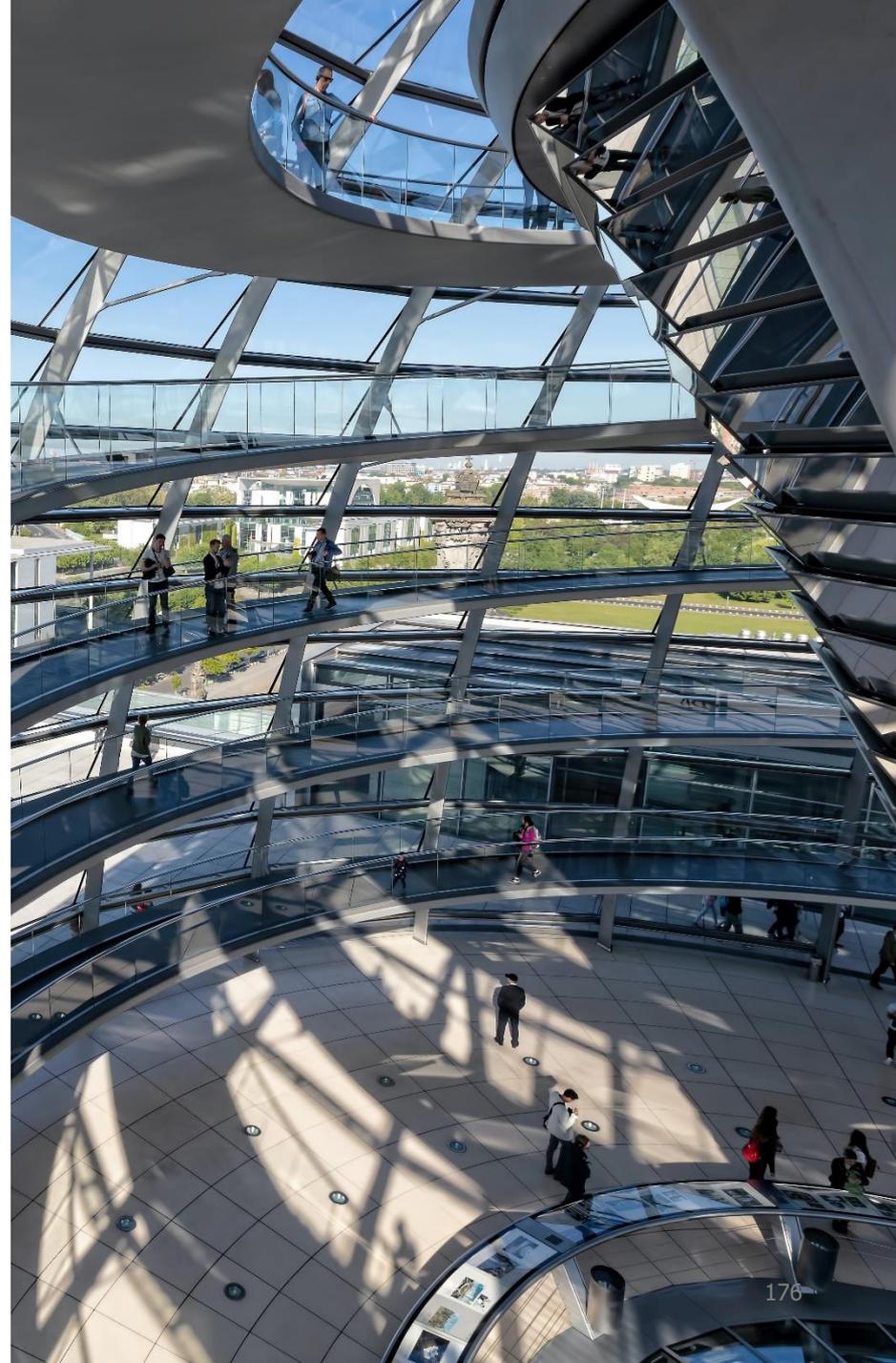
FARMAINDUSTRIA channels a substantial part of its activities at the international level through its involvement in IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), an organisation comprising 50 associations (47 national and 3 regional), 37 pharmaceutical companies and 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 National Associations.

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



Meetings of the IFPMA Governing Bodies

FARMAINDUSTRIA participated in IFPMA's Council meetings held in June and November 2020, which addressed the priorities of the International Federation in the field of intellectual property, innovation and access, as well as the pharmaceutical industry's response to the Covid-19 pandemic. The meetings of the Committee of Heads of National Associations centred above all on the exchange of information as to pharmaceutical policies in their respective countries, and the debate concerning access and transparency. Lastly, the General Assembly ratified the appointment of Jean-Christophe Tellier (UCB) as the new President of IFPMA, taking over the role from David Ricks (Eli Lilly).



Global response to the Covid-19 crisis: *Access Accelerator Alliance*

As a result of the health crisis caused by Covid-19, 24 April 2020 saw the launch of a global collaboration project, *Access Accelerator (ACT-A)*, to accelerate R&D and production of vaccines, medicines and diagnoses to combat Covid-19 that would be safe, effective, affordable and high-quality, while in turn guaranteeing fair global access. ACT-A is an alliance headed by the WHO, with a group of founding members that includes: Gavi the Vaccine Alliance, UNITAID, Wellcome Trust, the Bill & Melinda Gates Foundation, and the research-based pharmaceutical industry, represented by IFPMA.

ACT-A has five commitments:

- 1** | Achieve fair global access to new vaccines, medicines and diagnoses to combat Covid-19.
- 2** | Create an unprecedented global partnership based on transparency and science to align and coordinate research efforts, taking advantage of existing collaboration mechanisms.
- 3** | Devise collective solutions, providing a response to the pandemic through interconnection and inclusion, allowing stakeholders to benefit from the experience, knowledge and activities of this shared platform.
- 4** | Learn from the past experiences and adapt the global response to ensure that all activities performed take into account fair global access.
- 5** | Take on responsibilities for the most vulnerable communities and the entire world, through a principle of solidarity and of serving humanity.



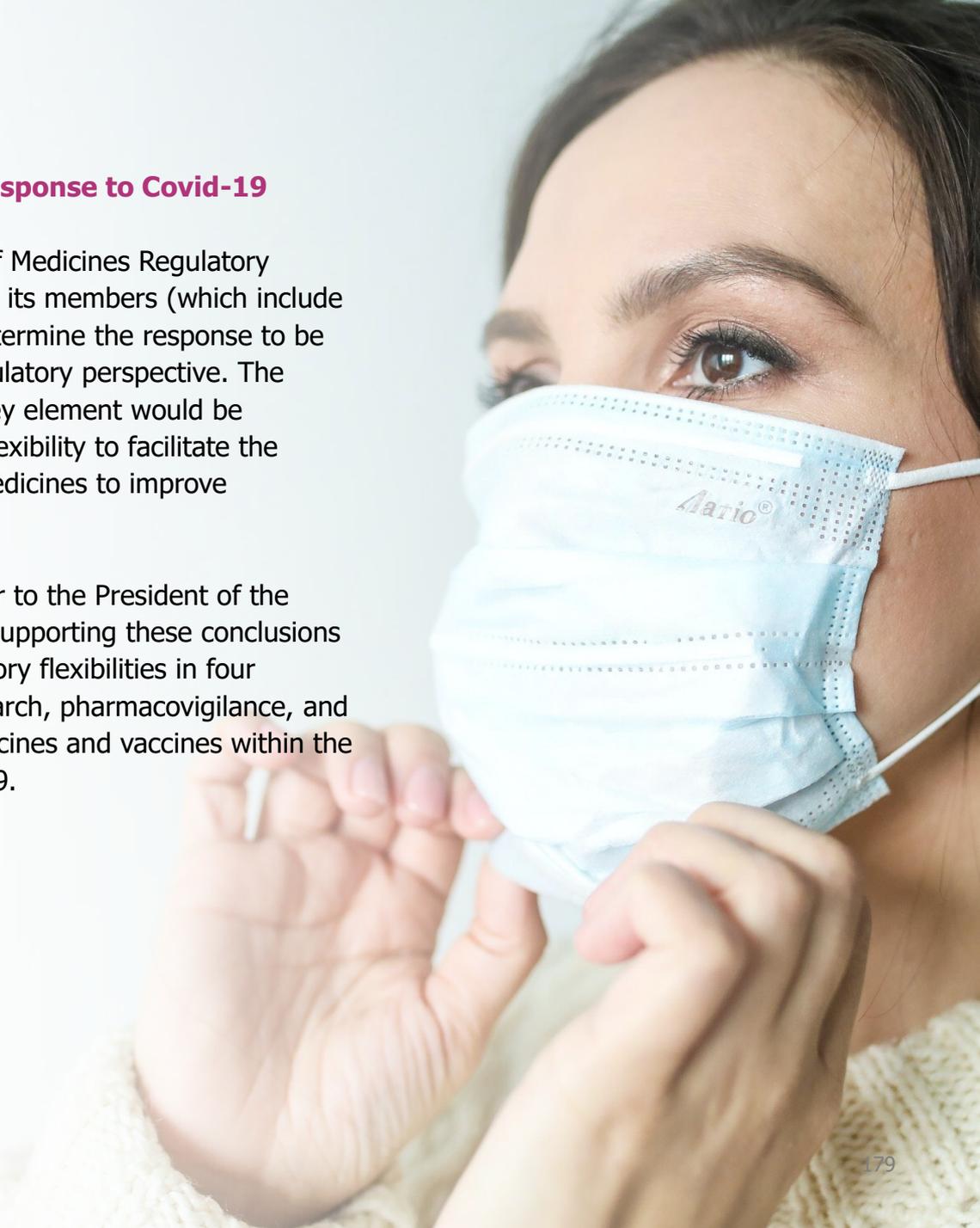
In turn, the ACT-A conceptual document which establishes the framework for the global response to the pandemic, identifies three different and autonomous partnerships: vaccines, medicines and diagnoses, which are under the supervision of the *Global Stewardship Council*.

When ACT-A was launched, the founding members called on the global community, political leaders and donors to support this alliance and contribute the necessary resources in order to accelerate the achievement of its goals. In this regard, on 4 May 2020 the EU staged an event involving countries and organisations from all round the world to mobilise funds in support of this initiative, raising more than 7.5 billion euros for the initial funding of ACT-A.

Alignment and regulatory flexibility in response to Covid-19

On 16 April 2020 the International Coalition of Medicines Regulatory Authorities (ICMRA) organised a meeting with its members (which include the AEMPS and EMA) and WHO experts to determine the response to be adopted in combating Covid-19, from the regulatory perspective. The authorities determined in this regard that a key element would be regulatory alignment at the global level and flexibility to facilitate the development, evaluation and availability of medicines to improve prevention and treatment of the pandemic.

As a result of the meeting, IFPMA sent a letter to the President of the ICMRA, Guido Rasi, the Director of the EMA, supporting these conclusions and requesting the implementation of regulatory flexibilities in four spheres: international alignment, clinical research, pharmacovigilance, and quality, so as to guarantee the supply of medicines and vaccines within the context of the health crisis caused by Covid-19.



Antimicrobial Resistance Action Fund

Given the importance that antimicrobial resistance has taken on over recent years on the agendas of governments worldwide and the organisations belonging to the United Nations, along with the growing call for the pharmaceutical industry to take action in this regard, in July 2020 the research-based pharmaceutical industry launched the Antimicrobial Resistance Action Fund, under the umbrella of IFPMA. The main aim of the Fund is to promote the creation of a sustainable antibiotics market, in parallel with governmental commitments in this sphere. The Fund likewise serves as a bridge to address antibiotic pipeline deficiencies, while also demonstrating the commitment of the pharmaceutical industry in fighting against antimicrobial resistance.



WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

During the 146th meeting of the Executive Council of the WHO, one of the points discussed with the greatest impact on the pharmaceutical sector was the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI). The purpose of this agenda item was to examine the progress made by the WHO in applying the recommendations of this strategy, although it ultimately led to a debate focused on access and pricing transparency.

Although the decision which was adopted to a great extent maintained the status quo and did not extend the mandate of the WHO in the sphere of intellectual property, a point was included making reference to pricing transparency, confirming the growing desire on the part of Member States to include this issue in the debates of their governing bodies. In this regard, IFPMA pointed out in a letter addressed to the WHO that the direction of the GSPA-PHI had over recent years deviated from its original mandate and spirit, leading to confusion, a slowdown in the implementation of the strategy and the establishment of recommendations in the field of intellectual property that could weaken the framework of incentives for R&D.

OECD report on challenges in access to oncology medicines

In April 2020 the OECD published a report which focused on addressing challenges in access to oncology medicines. The report is based on the information gathered through various interviews with national authorities of OECD member states, concluding in an analytical study setting out the challenges faced by national health systems in order to incorporate new oncology treatments and the measures implemented by these authorities to address these issues.

The OECD proposes two types of action in its conclusions for consideration by countries:

- 1** | Enable traceability of use by indication through systematic data gathering, records or market release studies.
- 2** | Improve the design of results-based access agreements to support the generation and gathering of market evidence.

Although the report is in general characterised by its neutral tone (furthermore acknowledging that access is a multidimensional concept which can be analysed from various perspectives, taking into account the differences between health systems), some sections have a less balanced focus, as IFPMA expressed in a note which it submitted to the OECD.



COMPETITIVENESS AND INTERNATIONALISATION

Within the context of overseas trade, FARMAINDUSTRIA acts in coordination with EFPIA through specialist working groups, the ultimate aim being to improve the presence of its member companies in international markets. In 2020, the European Commission reviewed its European trade policy, following up on the association agreements in force and continuing progress on negotiations for those agreements pending finalisation.

EU Trade Policy Review

In June 2020 the European Commission began a major review of EU trade policy by launching a public consultation with the aim of achieving a consensus as to a medium-term trade focus that would respond to new global challenges, incorporate lessons learned through the Covid-19 crisis, and help drive economic recovery by preserving and creating quality jobs, protecting European businesses from unfair practices, and guaranteeing fulfilment of broader priorities in the spheres of the digital economy, climate change, sustainability and security.



The consultation covered all relevant aspects of EU trade policy, with a particular focus on the following:

- 1 The development of a resilient and sustainable post-Covid-19 European economy.
- 2 The reform of the World Trade Organization.
- 3 The creation of global commercial opportunities for companies, and in particular for SMEs.
- 4 The optimisation of contributions by trade policy to address key global challenges such as digital transition and sustainable development.
- 5 The consolidation of trade and investment relations with the EU's main trading partners.
- 6 Greater equality of conditions and protection for European companies and citizens.

On the basis of the observations proposed by the European Parliament, the Member States and the stakeholders, the European Commission published a new strategy in February 2021, reflecting a new focus for EU trade policy over the coming years.



Free Trade Agreement (CETA) EU - Canada

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, 16 Member States had already ratified the Agreement, including Spain.

Economic Partnership Agreement EU - Japan

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 patents of medicines.
- 3 It recognises as 'equivalent' the data protection systems of the EU and Japan.

Partnership Agreement EU - Mercosur

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 undergoing legal analysis 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 Global Agreement signed in 2001. As a result of these negotiations, on 21 April 2018 the political agreement was signed, with the negotiations for the agreement being concluded on 29 April 2020.

The agreed clauses include in particular the following:

- 1 Elimination of customs procedures for practically all trade in goods and simplification of rules of origin, with one of the beneficiary sectors being pharmaceuticals.
- 2 Strengthening of intellectual property rights and greater protection for investments, boosting protection for European R&D.
- 3 Opening up of public procurement markets, while also guaranteeing their predictability and transparency.

In order to advance towards signature and ratification of the Agreement, the text is being reviewed with regard to its legal aspects.

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 rounds of negotiations held by 2020, efforts are achieving positive progress, with specific textual proposals already in place.

03

INSTITUTIONAL ACTIVITY

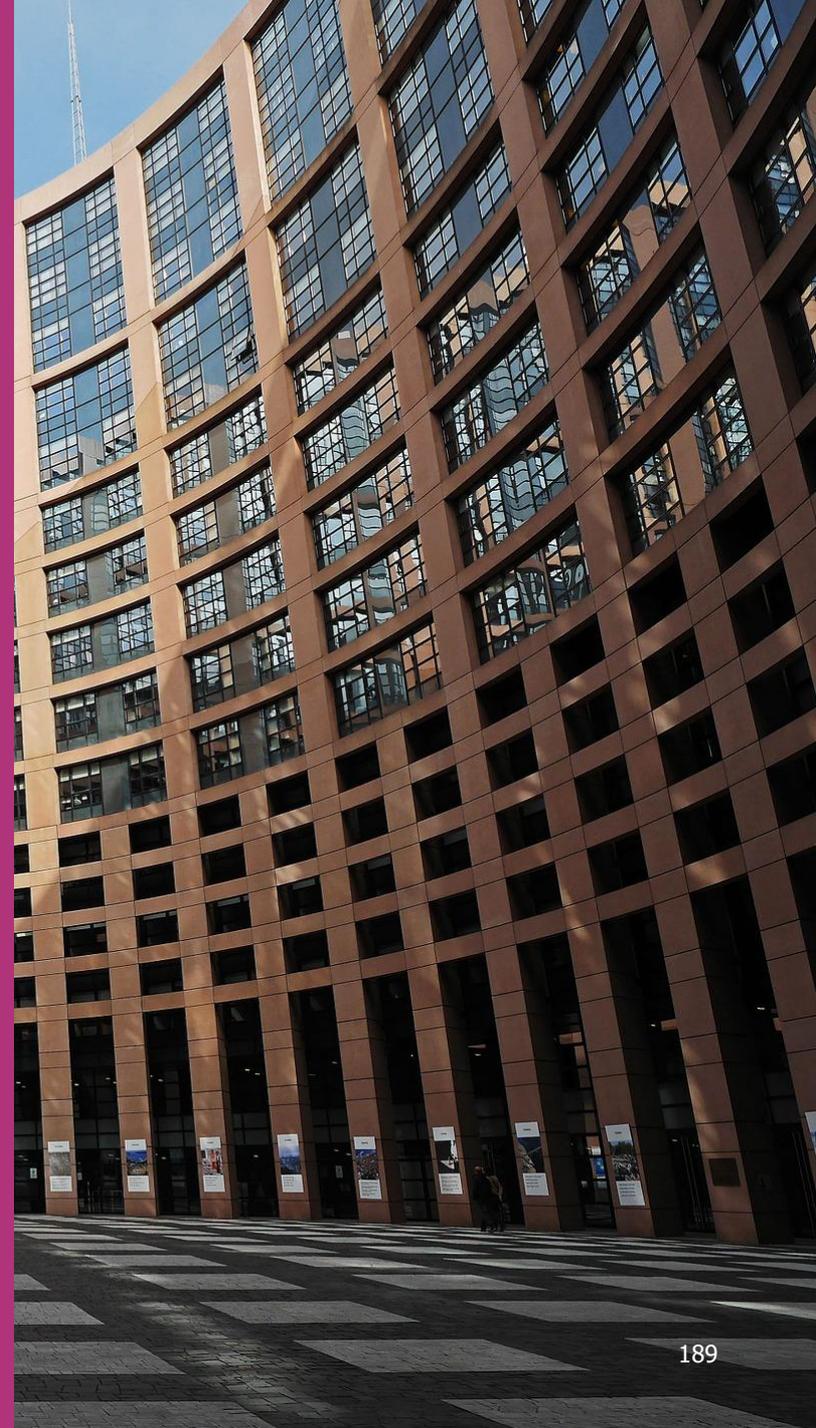
- 3.1 Market Regulation and Relations with Public Authorities
- 3.2 Communication
- 3.3 International Relations
- 3.4 The Pharmaceutical Industry in Spain and Worldwide**

3.4 The Pharmaceutical Industry in Spain and Worldwide

3.4.1 THE PHARMACEUTICAL INDUSTRY IN EUROPE

An analysis of the evolution of a business sector over a given period of time must be contextualised within the general evolution of the economy during that period, above all amid a pandemic such as that experienced in 2020, which triggered a widespread recession throughout Europe after six consecutive years of economic growth (2014-2019). In 2020 the economy of the EU-27 registered a drop of 6.1%.

Within this context, and although the various Member States managed in part to mitigate job losses through the legal instruments available to them, the downturn in economic activity caused the unemployment rate in the EU to increase in 2020 to 7.1% of the active population, although it will be in 2021 that the full effects of the crisis are noted, with the unemployment rate expected to rise to 7.6%.



The health crisis likewise had a substantial impact on the public accounts of European countries, following a number of years marked by a process of budgetary consolidation serving to reduce the public deficit in the EU from 6.9% of GDP in 2009 to 0.6% in 2019. The outbreak of the health crisis caused by Covid-19 in March 2020 thus simultaneously led to a substantial increase in public expenditure and a reduction in tax revenues, causing the EU's public deficit to rise from 0.6% of GDP in 2019 to 6.9% in 2020, the greatest deficit increase in one year. This upturn in the deficit caused public debt in the EU-27 to shoot up from a level of 77.5% of European GDP in 2019, to 90.7% in 2020.

Looking ahead to the future, the improvement in health indicators is expected to go hand-in-hand with a progressive recovery in economic activity in 2021 and 2022, with GDP growth of +4.2% and +4.4, respectively, and a public deficit which would drop considerably from 2022 onwards.

With regard to the pharmaceutical sector, it should be recalled that despite the increase in the deficit registered in 2020 and the suspension of fiscal rules in various countries of the EU, the health budgets of the Member States will remain subject to strict control, in particular from 2022 onwards, which could result in the adoption of public health and pharmaceutical expenditure containment measures, which would impact the evolution of a market such as pharmaceuticals, which is heavily dependent on public budgets and economic regulations.

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 certain conditions becoming chronic. The forecasts by the consultancy IQVIA in 2019 (prior to the pandemic) thus placed 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 at the global level and the expected growth in the USA. Among the five largest European markets, France would see the smallest annual average growth over the period 2020-2024 (0%/+3%), while the forecasts was higher for Germany and the UK, with a rate of growth of +4%/+7%. Spain and Italy, meanwhile, would register average growth rates of between +3% and +6% per year. It is in any event important to mention that the profound impact of the pandemic on the pharmaceutical market at the global level makes it very likely that these forecasts will be revised in subsequent updates.

Lastly, and regardless of the rate of growth, it is important to emphasise the significance of Spain within the European pharmaceutical context. In this regard, and as shown in the following table, Spain is the fourth most significant pharmaceutical market in the EU by volume of sales and job creation (behind Germany, France and Italy), and the fifth in the EU in terms of production (following the aforementioned three countries and Ireland).



GENERAL DATA FROM THE PHARMACEUTICAL INDUSTRY IN THE UE-13 (2018)						
Country	Number of manufacturers (1)	Production (million €) (2)	Employment	Domestic Sales (MSP) (million €) (3)	Foreign Trade (MSP) (€ million) (4)	
					Imports	Exports
Germany	104	32,905	119,535	38,531	49,398	82,609
Austria	250	2,775	15,411	4,393	9,036	9,363
Belgium	130	13,312	37,073	5,047	36,169	42,801
Denmark	36	14,391	24,875	2,807	4,020	13,489
Spain	141	14,970	42,653	16,375	14,088	10,478
Finland	40	1,773	4,715	2,570	1,973	740
France	255	23,213	98,528	28,897	24,831	29,450
Greece	62	996	21,739	4,806	3,209	1,475
Netherlands	42	6,180	15,000	5,358	25,259	38,633
Ireland	50	19,305	29,766	2,137	11,963	46,199
Italy	200	32,200	66,500	23,769	25,563	24,906
Portugal	115	1,514	7,900	3,230	2,635	979
Sweden	90	8,153	11,012	4,137	3,970	7,987
Total EU-13*	1,515	171,687	494,707	142,057	212,114	309,109

(* Although previous editions of the Report provided this information with reference to the "fifteen" members of the European Union (EU-15), from the 2019 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 activity for 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).



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 Spanish society and economy 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 that 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.

In order to promote such activities, the 2021-2027 EECTI (Spanish Science, Technology and Innovation Strategy) has been put in place, as the central plank of Spain's R&D policy. It sets out a series of objectives to be achieved over the coming six years in terms of the R&D spending of the Spanish economy in relation to GDP and how it is distributed between the public and private sectors, as summarised in the table below:³

Indicator	Year available	Data for most recent year	EU data	Real value 2027
Percentage of national GDP spent on R&D	2018	1.24%	2.12 %	2.12 %
% internal R&D expenditure funded by the business sector	2018	49.5 %	58 % (2017)	58 %
% internal R&D expenditure funded by the public sector	2018	37.6 %	29.3 % (2017)	30.0 %
Percentage of GDP spent on R&D within the business sector	2018	0.7 %	1.4 %	1.5 %
Percentage R&D expenditure of SMEs	2018	46.9 %	-	50.0 %
Percentage R&D expenditure of public authorities funded by the business sector	2018	6.9 %	8.3 % (2016)	8.0 %

³ 2021-2027 Spanish Science, Technology and Innovation Strategy (page 51). Ministry of Science and Innovation Available at: <https://www.ciencia.gob.es/stfls/MICINN/Ministerio/FICHEROS/EECTI-2021-2027.pdf>

As the above table shows, one of the priority areas for action under the 2021-2027 EECTI involves strengthening and boosting the role of the private sector in Spanish R&D, by setting the target of increasing its participation in overall R&D expenditure from 49.5% at present, to 58% in 2027. To achieve this, and given that the overall aim is for Spain to spend 2.12% of its GDP on R&D in 2027, there would need to be an increase in R&D expenditure by the Spanish business sector from the current 0.7% of GDP to 1.5% in 2027.

In order to achieve these goals, the EECTI sets out seven fundamental objectives, the last three of which are closely tied to the business sector:



As a consequence, in order to achieve improvements in these spheres, and given that the EECTI acknowledges that in the short-term (2021-2023) "it will be essential to provide clear and decisive support for R&D+i in the field of health"⁴, it is seen as vital to the success of the strategy that the participation of the pharmaceutical industry be facilitated and promoted, given its role as the leading industrial sector in terms of research, as highlighted in the data below from the Spanish statistics agency (INE):

1 The pharmaceutical industry invested €1.025 billion in R&D in 2019, 18.5% of the total R&D investment by Spanish industry, which makes it, alongside the automotive industry, the leading industrial sector by volume of spending on research. The figure is also particularly significant if one bears in mind that pharmaceutical companies' turnover accounts for just 2.2% of all Spanish industry, which means that, in this case, the pharmaceutical industry is, in relative terms ("R&D intensity")⁵, the leading Spanish industrial sector, alongside aerospace.

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

⁴ 2021-2027 Spanish Science, Technology and Innovation Strategy. Executive Summary. Ministry of Science and Innovation

⁵ The term "R&D intensity" refers to the proportion of turnover that each sector assigns to R&D.

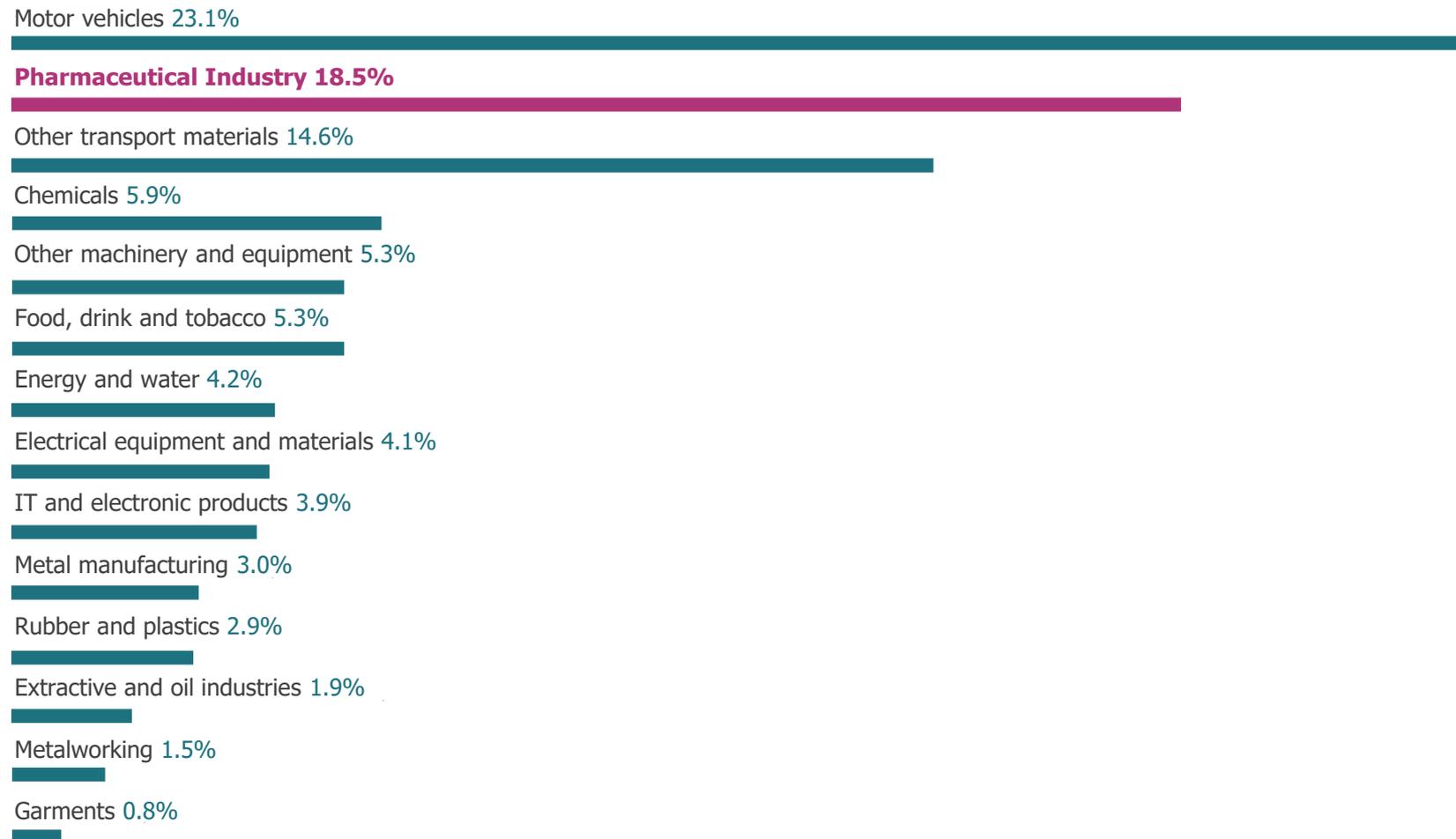


3 The pharmaceutical industrial sector is the leader in internally-conducted research at company-owned centres (19.5% of the total industrial sector) and the second, after automotive, in research contracted with third parties (universities, hospitals, public or private centres, etc.) where it accounts for 15.8% 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 5,965 professionals dedicated to these tasks. Meanwhile, two thirds of these jobs are held by women (3,961), which means that at present one in every three female researchers employed by the industrial sector in Spain works for a pharmaceutical company.



Leading Industrial Sectors by Investment in R&D in Spain, 2019 (as % of industry total)



Source: FARMAINDUSTRIA from INE figures (Survey on innovation at companies).

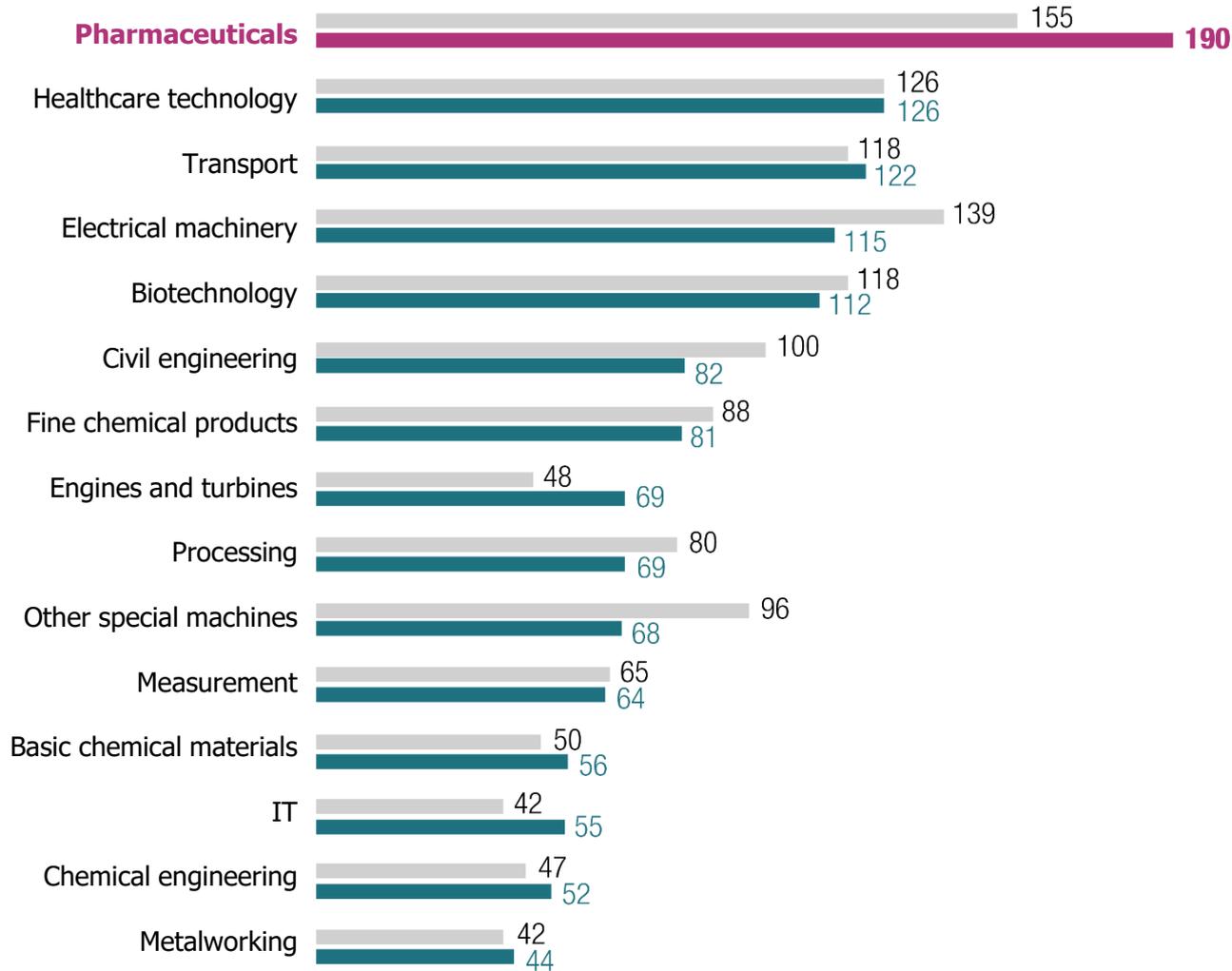
Reflecting further on the above figures, it should be emphasised that according to the European Patent Office, the pharmaceutical industry was in 2020, for the third year running, the industrial sector filing the greatest number of patent applications in Spain (190), followed by the health technology industry. Pharmaceutical patent applications account for 10.7% of all those filed in Spain, placing the sector at the head of all technological fields.⁶



⁶ Source: FARMAINDUSTRIA based on European Patent Office (www.epo.org)

Spanish Patents: The 15 Leading Technological Fields

■ 2019 ■ 2020



All these data emphasise the leadership of the pharmaceutical industry in the field of research in Spain, and its strategic importance in shaping a new productive model in the country which would serve to overcome the effects of the health crisis which devastated global economies in 2020 in the first half of 2021. In order to advance towards this goal, establishing policies encouraging the development of those industrial sectors destined to lead Spain's economic recovery and to consolidate stable and lasting growth is needed.



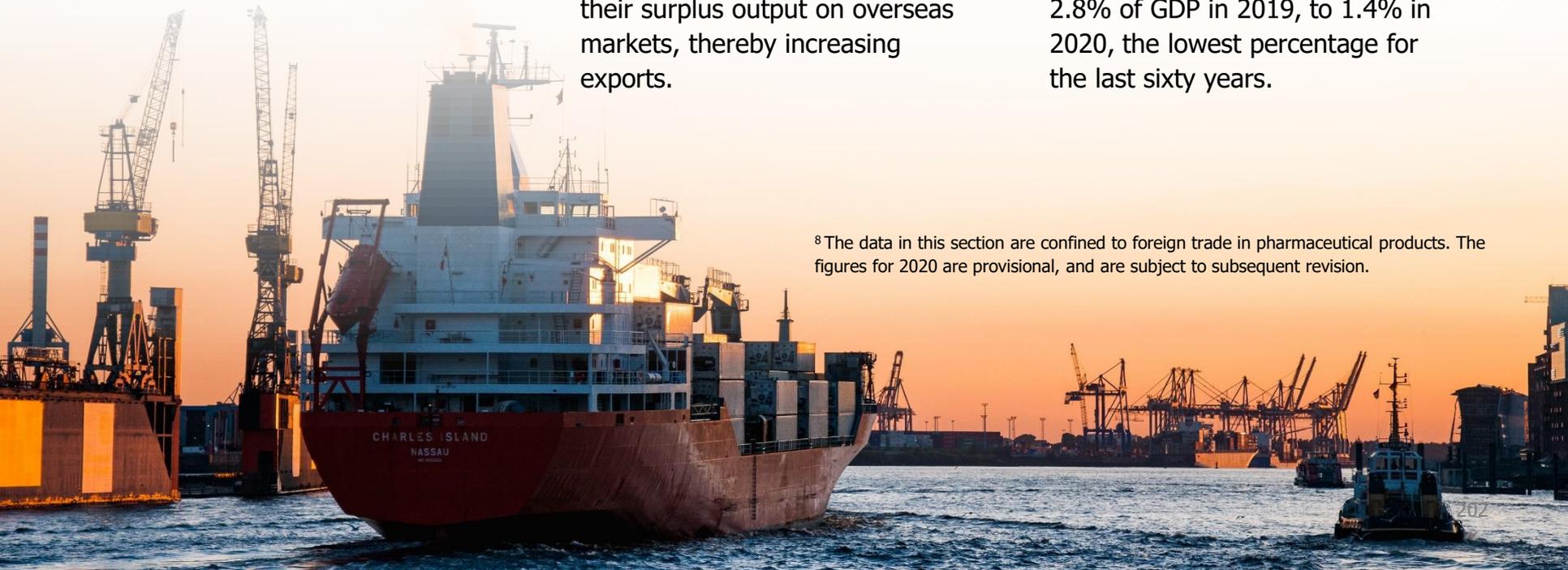
PHARMACEUTICAL FOREIGN TRADE⁸

The productive structure of the Spanish economy has traditionally meant that the country has been a net importer; 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 tendency towards Spain's uneven trade balance is heightened during economic booms, when the dynamism of domestic demand gives a particular boost to imports, while being more moderate at times of economic slowdown, when foreign purchases decline and companies based in Spain manage to place their surplus output on overseas markets, thereby increasing exports.

Within the context of the severe economic recession experienced by Spain in 2020, with a record drop in GDP (-10.8%), the aforementioned behaviour, combined with the increased competitiveness achieved by the Spanish economy over recent years, explains the reduction in Spain's trade balance deficit from 2.8% of GDP in 2019, to 1.4% in 2020, the lowest percentage for the last sixty years.

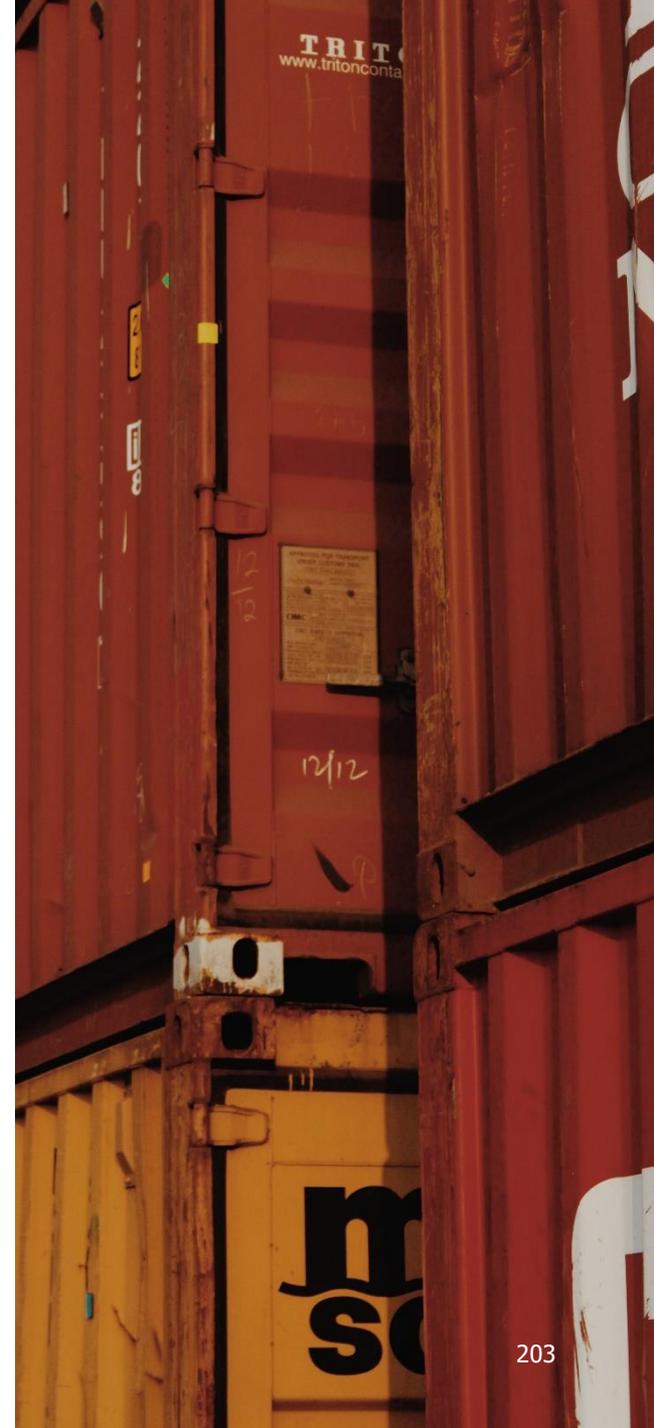
⁸ The data in this section are confined to foreign trade in pharmaceutical products. The figures for 2020 are provisional, and are subject to subsequent revision.



Meanwhile, the coverage ratio (the ratio of exports to imports) stood at 94.3% at the close of 2020, 2.1 percentage points higher than the figure for the previous year and well above the levels registered by the Spanish economy prior to the 2008 crisis, when the figure stood at around 70%, demonstrating the country's evolution towards a more export-focused productive model.

As for overseas trade in the pharmaceutical sector, particular mention should be made of the highly dynamic performance of pharmaceutical exports, rising by +5.6% in 2020 to a figure of 12.777 billion euros, an all-time record for the sector. This means that pharmaceutical exports rose from 4.2% of all Spanish exports in 2019 to 4.9% in 2020, placing them fourth in the rankings of Spanish exports by tariff category.

In turn, pharmaceutical exports also registered a substantial rise (+7.1%), resulting in a coverage ratio in the pharmaceutical sector of 72% in 2020, a similar level to recent years (71% in 2018, and 73% in 2019).

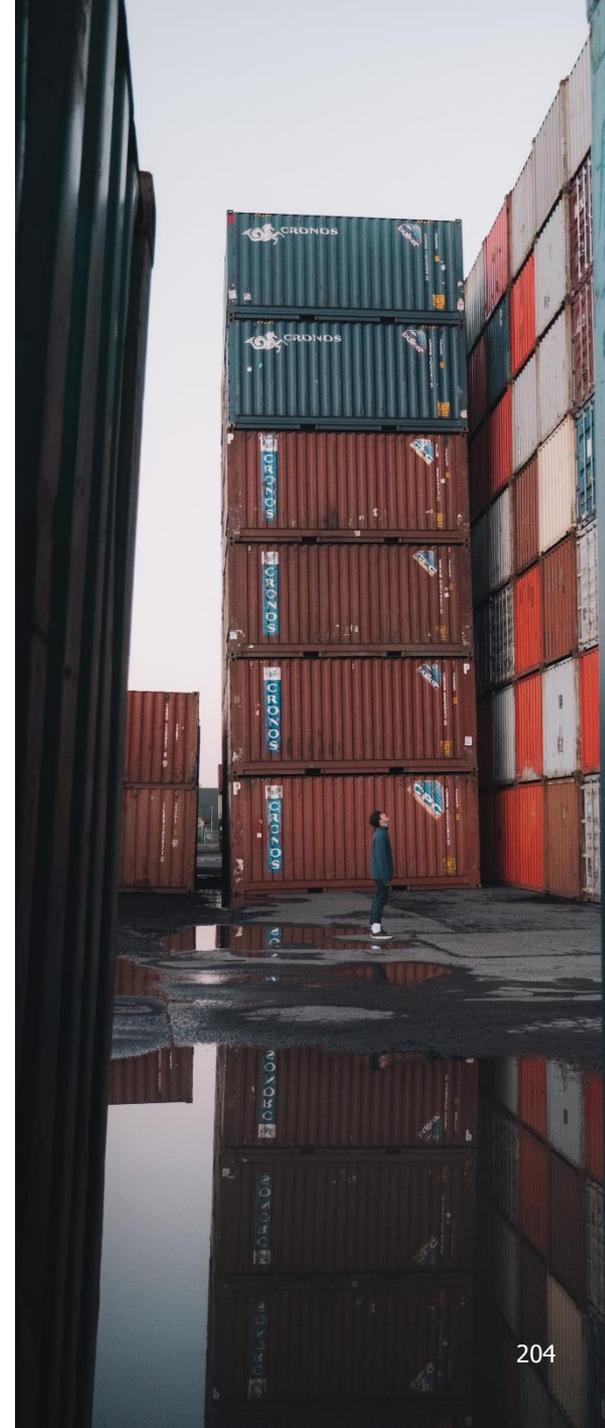


The above figures highlight the significance of the pharmaceutical industry in Spain's overseas trade, a significance which is not just quantitative but also qualitative, as demonstrated by the fact that according to INE data for 2018 (the most recent figures available), pharmaceutical exports accounted for 22.3% of all national high-tech product exports, making the pharmaceutical industry the most important sector in this sphere, alongside aerospace.

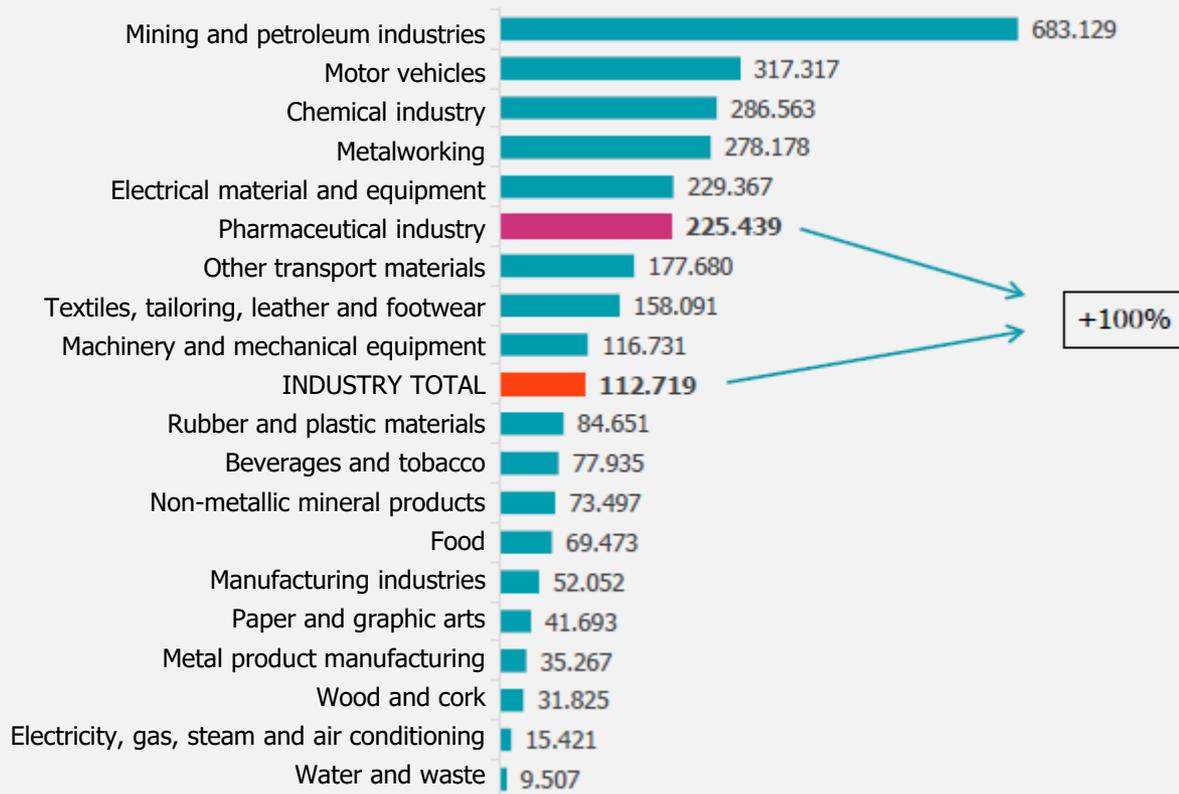
To round off the analysis of the pharmaceutical industry's contribution to the export sector in Spain, one must consider the external competitiveness of the sector with different ratios.

An analysis of the export indicator in terms of turnover using the figures for 2018 (the most recent available) shows that the pharmaceutical industry achieves twice the average for industrial sectors as a whole (73% vs. 38%).

Likewise, if one uses the indicator of exports over volume of employment, the difference is even more significant, with pharmaceutical exports in excess of €225,000 per employee in 2018, twice the Spanish industrial average, as shown in the following graph.



Main Sectors of the National Economy in Exports Per Employee (2018)



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

With regard to the geographical distribution of pharmaceutical foreign trade, it should be noted that in 2020 the EU continued to be Spain's main business partner:

Despite the UK's departure from the EU, which took effect in January 2020, 55% of Spanish purchases of pharmaceutical products from abroad come from our EU-27 partners, while 52% of Spain's exports flow to these same countries. Among EU nations, Germany remains the main destination for Spanish pharmaceutical output (accounting for 26% of all medicinal exports to the EU), followed by France (14%), Italy (slightly over 10%) and the Netherlands (7.2%).

As for the UK, following the substantial increase in exports to the country in 2019 (+25%, possibly because of the stockpiling effect), in 2020 there was a rise of +0.6%, accounting for 4.3% of Spain's overseas sales, as the sixth most significant global destination in terms of volume of Spanish pharmaceutical exports.

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

Switzerland 21.2 %

United States 5.3%

China 2.9 %

Japan 2.3 %

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

Economic Area	2019		2020 (p)	
	Export	Import	Export	Import
World Total	100.0 %	100.0 %	100.0 %	100.0 %
EU-27	50.4 %	54.7 %	51.8 %	55.3 %
Germany	12.4 %	15.5 %	13.6 %	15.3 %
Belgium	2.1 %	5.7 %	1.6 %	5.5 %
France	6.7 %	7.2 %	7.3 %	7.3 %
Netherlands	4.2 %	7.8 %	3.7 %	8.2 %
Ireland	3.6 %	2.6 %	3.8 %	2.7 %
Italy	5.3 %	4.6 %	5.4 %	4.9 %
Rest of Europe	23.4 %	8.5 %	22.9 %	12.1 %
United Kingdom	4.6 %	4.9 %	4.3 %	3.9 %
Switzerland	21.4 %	8.1 %	21.2 %	11.7 %
Rest of World	26.2 %	36.8 %	25.3 %	32.6 %
China	2.2 %	2.6 %	2.9 %	2.8 %
United States	5.3 %	17.8 %	5.3 %	16.9 %
India	0.3 %	1.1 %	0.3 %	1.2 %
Japan	2.9 %	0.5 %	2.3 %	0.5 %

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

Note: (p) provisional.

DOMESTIC MARKET

In 2020, according to data published by the Ministry of Public Finance, public hospital pharmaceutical spending grew by 5.6%.

In turn, according to FARMAINDUSTRIA's own estimations, sales of medicines at retail pharmacies in 2020, in net figures after the deductions set out in Royal Decree-Law 8/2010, will have increased by 0.7%.

As a result of the evolution of both segments, total sales of medicines in 2020 will have increased by 2.8% from 2019.

DOMESTIC MARKET FOR MEDICINES (MSP, million €)						
	Retail Pharmacies ⁽¹⁾	Increase (%)	Hospitals ⁽²⁾	Increase (%)	Total	Increase (%)
2016	9,361	+4.5 %	5,962	-5.3 %	15,323	+0.5 %
2017	9,579	+2.3 %	6,157	+3.3 %	15,736	+2.7 %
2018	9,756	+1.8 %	6,629	+7.7 %	16,385	+4.1 %
2019	9,982	+2.3 %	7,149	+7.8 %	17,131	+4.6 %
2020	10,054	+0.7 %	7,550	+5.6 %	17,604	+2.8 %

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

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

Source:

Retail pharmacies: FARMAINDUSTRIA from IQVIA data and own estimations.

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 +0.6 % in 2020 as a result of the -2.2% drop in the number of units sold and a +2.9% increase in the average price.

A breakdown of the above figure into medicines eligible for public reimbursement (88% of all sales in terms of units) and pharmaceuticals not subject to

reimbursement (the remaining 12%) reveals that in the former case (medicines eligible for reimbursement) the number of units dropped by -1.0% in 2020, while the average price increased by +2.8%.

In the case of medicines not covered by public reimbursement, the number of units fell by -10.1%, while the average price increased by +2.3% in 2020.

MARKET STRUCTURE AT RETAIL PHARMACIES

	Units (million)	Share	Increase (%)	MSP Sales (million €)	Share	Increase (%)	Average MSP (€)	Increase (%)
Market subject to reimbursement	1,138	87.7 %	-1.0 %	9,218	89.1 %	+1.7 %	8.1	+2.8 %
Non-reimbursed market	160	12.3 %	-10.1 %	1,126	10.9 %	-8.0 %	7.0	+2.3 %
Total market	1,298	100.0 %	-2.2 %	10,344	100.0 %	+0.6 %	8.0	+2.9 %

Source: FARMAINDUSTRIA from IQVIA data and own estimations.



A new Reference Price Order was published in November 2020, modifying the criteria applied in previous orders, with groups being defined on the basis of the same active pharmaceutical ingredient, rather than the ATC5 classification. This resulted in the elimination of 437 groups included in the previous order and the creation of 452 new groups of presentations dispensed at retail pharmacies, 33% of them created without a generic medicine and five created as a result of the existence of a biosimilar medicine.

The updating of homogeneous groupings, along with the creation of new reference groups led to 84% of units sold in the retail pharmacies market being sold at the same price level as their corresponding generic medicine at year end 2020.

Therapeutic groups

In 2020 there was a drop in the consumption of most therapeutic groups, with those registering the most pronounced downturns being:

- 1 Anti-infectives.
- 2 Respiratory system.
- 3 Musculoskeletal system.

Only these groups registered an increase in the number of units:

- 1 Central nervous system.
- 2 Cardiovascular system.
- 3 Antineoplastic.

According to IQVIA data, total sales of medicines via retail pharmacies were distributed by therapeutic group as shown in the following table.



TOTAL SALES OF MEDICINES VIA RETAIL PHARMACIES BY THERAPEUTIC GROUP (2020)								
Therapeutic group	Units (thousands)	Share (%)	Increase (%)	MSP values (thousands)	Share (%)	Increase (%)	Average MSP (€)	Increase (%)
N Nervous System	363,952	28.0 %	+3.7 %	2,443,587	23.6 %	+3.9 %	6.7	+0.2 %
C Cardiovascular system	269,391	20.8 %	+2.4 %	1,587,726	15.3 %	+2.9 %	5.9	+0.5 %
A Alimentary tract and Metabolism	207,911	16.0 %	-0.9 %	2,061,495	19.9 %	+4.9 %	9.9	+5.9 %
R Respiratory system	107,407	8.3 %	-13.0 %	1,012,969	9.8 %	-6.1 %	9.4	+7.8 %
M Musculoskeletal system	72,479	5.6 %	-12.9 %	417,700	4.0 %	-5.9 %	5.8	+8.1 %
B Blood and blood forming organs	67,829	5.2 %	-0.1 %	783,879	7.6 %	+8.1 %	11.6	+8.1 %
G Genitourinary system	53,007	4.1 %	-2.6 %	608,174	5.9 %	-7.3 %	11.5	-4.8 %
D Dermatologicals	45,762	3.5 %	-5.2 %	281,846	2.7 %	-3.3 %	6.2	+2.0 %
J General Anti-infectious Agents	35,488	2.7 %	-22.3%	294,642	2.8 %	-15.7 %	8.3	+8.5 %
S Sensory organs	38,635	3.0 %	-9.3 %	217,069	2.1 %	-5.2 %	5.6	+4.5 %
H Hormones	21,863	1.7 %	-7.2 %	201,491	1.9 %	-8.7 %	9.2	-1.6 %
L Antineoplastic and Immuno-modular Agents	7,569	0.6 %	+1.1 %	370,571	3.6 %	+1.0 %	49.0	-0.1 %
K Hospital solutions	3,132	0.2 %	-8.6 %	3,880	0.1 %	-8.6 %	1.2	+0.1 %
P Anti-parasitics	1,623	0.1 %	-9.7 %	7,981	0.1 %	-23.9 %	4.9	-15.7 %
V Various	1,467	0.1 %	-3.6%	50,410	0.2 %	+4.8 %	34.4	+21.4 %
T Diagnostic agents	12.18	0.0 %	-21.6 %	215	0.0 %	-22.2 %	17.7	-0.7 %
TOTAL	1,297,530	100 %	-2.2 %	10,343,637	100 %	+0.6 %	8.0	+2.9 %

The Central Nervous System group, which accounts for slightly more than a quarter of the pharmaceutical market in terms of units, is the group registering the greatest increase in unit consumption (+3.7%), influenced by the increase in the consumption of analgesics, tranquillisers and antidepressants, which in combination represent just over than 70% of the units in this group. The increase in the consumption of the nicotine anti-addiction sub-group, with these medicines being reimbursed for the first time in January 2020, likewise led to an increase in units within this group.

The Cardiovascular System group registered the second-greatest increase in units (+2.4%), in part as a consequence of the increase in the consumption of lipid modifying agents, where units increased by 5.5%. This is the group representing the greatest percentage of units within the reference pricing system and/or homogeneous groupings.

The consumption of units within the Digestive System group fell by 0.9%, while the average price registered an above-average increase, influenced by the increase in the consumption of the new anti-diabetic drugs.

The Respiratory and Musculoskeletal groups reveal similar behaviour, both with substantial drops in the number of units of around 13% resulting from, in the former case, a reduction in the consumption of expectorants and antivirals; and in the latter, because of the 21% drop in non-steroidal anti-rheumatic drugs.

We should lastly emphasise the substantial downturn in the consumption of anti-infectious drugs, where the number of units have been falling over recent years because of campaigns as to the rational use of antibiotics, with this subgroup registering a drop of 24% in 2020.



Hospital Market

In the hospital market, according to IQVIA data for 2020, 66% of sales are concentrated in two therapeutic groups:

- 1** Group L - Antineoplastic agents and immunomodulatory agents, in which antineoplastic agents account for 69% and immunosuppressive agents for 27%.
- 2** Group J - General anti-infectives, a group in which systemic antivirals account for 66% of sales.

With the new Reference Price Order published on 28 November 2020, and on the basis of the new criterion for the definition of groups, 223 over those existing to date were eliminated and 237 new groupings were created, 11 of them on the basis of a biosimilar medicine, and 42 with no generic or biosimilar product.

During 2020, 76 new medicines were included on the hospital market, of which 48 (63%) are generics, 10 (or 13%) are medicines with new active ingredients being marketed for the first time (three of which are orphan drugs), four (or 5%) are biosimilar medicines, and the remaining 14 (or 18%) are medicines with active ingredients or combinations thereof which are already existed on the market.

By December 2020 there were 30 biosimilar medicines being sold on the Spanish hospital market, corresponding to 14 active ingredients. Among these active ingredients, the biosimilar quota amounts to 58% in terms of units.



New Launches

In 2020, a total of 232 new medicines were launched within the national market in the retail pharmacies channel, with total sales of €76.6 million. Of these, 126 (or 54%) correspond to generic medicines, 51 (22%) to parallel imports, 18 (or 8%) are over-the-counter medicines, and the remaining 37 (or 16%) are medicines with active ingredients or combinations already existing on the market.

In 2020 no medicine with a new active pharmaceutical ingredient was marketed at retail pharmacies.



Public pharmaceutical expenditure on official NHS prescriptions

The Ministry of Health figures for 2020 indicate an increase in public pharmaceutical expenditure at retail pharmacies of 2.6%, amounting to €11.077 billion. This change in the level of expenditure is the consequence of a 0.8 % increase in the number of prescriptions and a 1.8 % increase in the average cost per prescription.

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	10,794.0	+2.9 %	971.2	+2.6 %	11.1	+0.2 %
2020	11,077.3	+2.6 %	979.2	+0.8 %	11.3	+1.8 %

Source: Medical Prescription Invoicing. Ministry of Health

Regional distribution of public pharmaceutical expenditure

In 2020, public pharmaceutical expenditure through official NHS prescriptions stood at €233.9 per inhabitant, an increase of 1.9% compared with 2019.

In most Spanish regions there was an increase in per capita pharmaceutical expenditure in 2020, except for Valencia (-0.1%) and Islas Baleares (-1.9%).

PHARMACEUTICAL EXPENDITURE BY REGION (2020)			
Region	Spending share(%)	€ per capita	Increase (%)
Andalucía	17.9 %	233.5	+3.3 %
Aragón	3.1 %	255.4	+0.8 %
Asturias	2.6 %	284.5	+2.6 %
Islas Baleares	2.1 %	193.4	-1.9 %
Islas Canarias	5.0 %	248.1	+0.8 %
Cantabria	1.4 %	268.6	+3.9 %
Castilla La Mancha	4.9 %	265.5	+2.9 %
Castilla y León	5.9 %	274.3	+4.2 %
Cataluña	13.8 %	199.6	+2.0 %
Valencia	11.7 %	257.6	-0.1 %
Extremadura	3.0 %	313.9	+3.6 %
Galicia	6.7 %	273.3	+2.6 %
La Rioja	0.7 %	233.1	+0.6 %
Madrid	11.8 %	193.1	+0.5 %
Murcia	3.5 %	260.0	+3.0 %
Navarra	1.2 %	210.1	+0.8 %
País Vasco	4.4 %	222.3	+2.4 %
Total Spain	100 %	233.9	+1.9 %

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

04

MEMBER SERVICES

- 4.1 Online Services**
- 4.2 Working Groups / Barcelona Delegation
- 4.3 Spanish Technological Platform for Innovative Medicines
- 4.4 Self-Regulation System

4.1 Online Services

It is now 20 years since FARMAINDUSTRIA resolutely committed to the digital transformation of its information systems, by promoting remote electronic methods. We are now able swiftly to reach out to our members and the general public via our network of portals.

Both our general interest portals (Member Intranet, Public Portal and Self-regulatory System) and our focused sites (Innovative Medicines Platform and Presentation Catalogue) serve to filter and channel all forms of quality information that could be of value to our members.

We also maintain a number of internal tools to handle membership processes, and also to administer regulatory procedures, such as the application of deductions derived from RDL 8/2010.

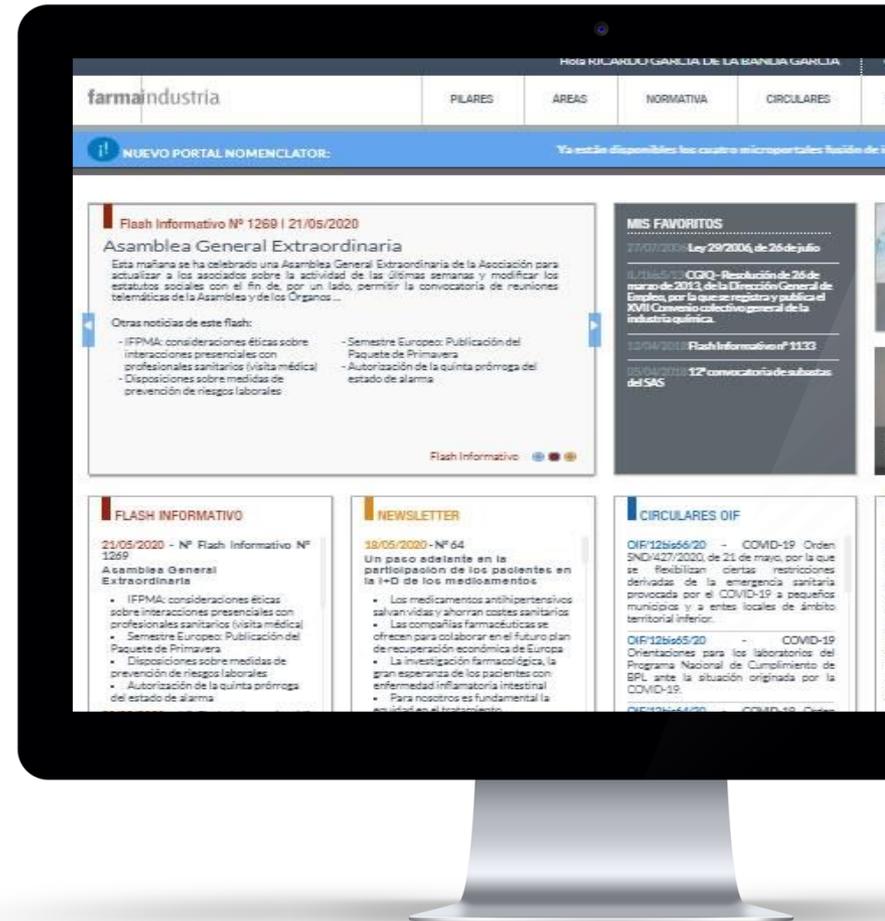


Corporate Portal - Industry Intranet <https://www.farmaindustria.org>

For the exclusive use of member companies, this contains some 95,000 documents grouped into over 50 categories, including circulars, flashes, departmental areas, flashes, newsletters, regulations, etc.

This supports an individualised home page for each of the 2,000 registered industry users, allowing them to decide the information that will be displayed on their page.

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

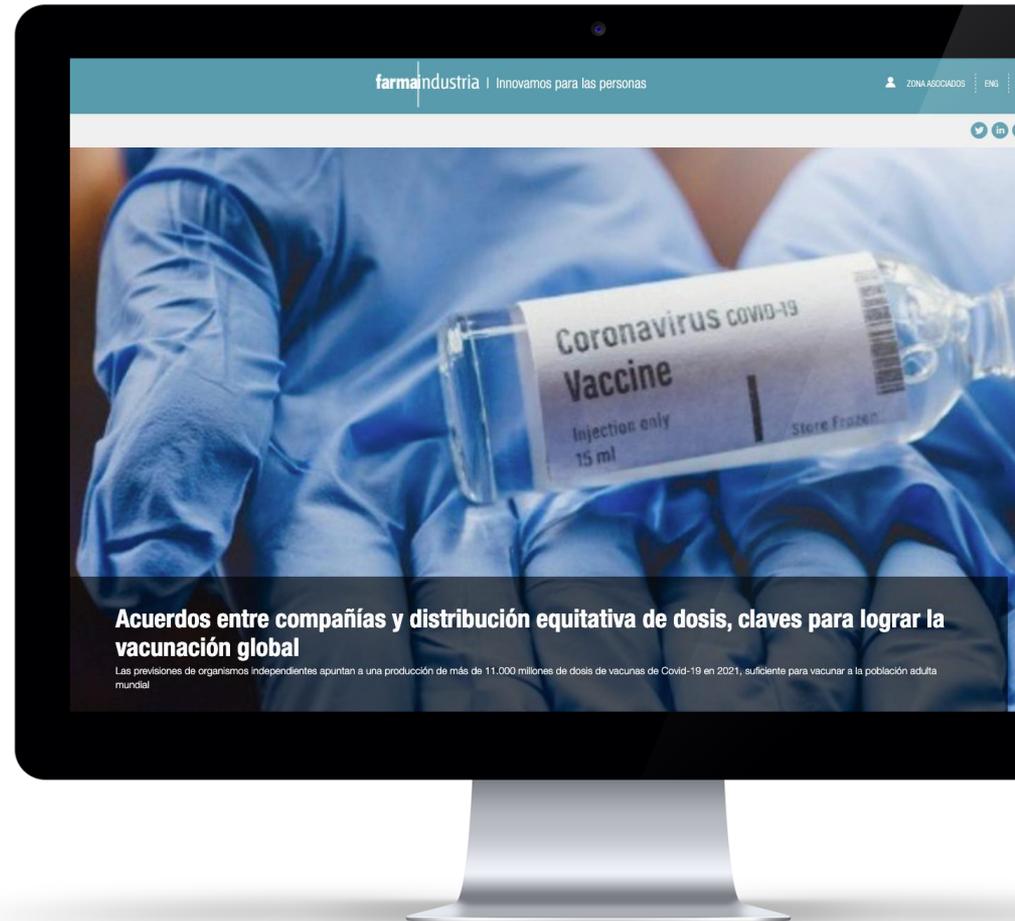


Public website

<http://www.farmaindustria.es>

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 relevant information about the industry and medicines, reaching nearly 8,000 subscribers.



Innovative Medicines

<https://www.medicamentos-innovadores.org/>

Following last year's complete revamp of the portal, this portal is now a consolidated dissemination tool.

In 2020 the new portal received more than 30,000 queries from 6,500 different addresses. "Webinar on Clinical Trials; Lessons Learnt through Covid-19" was the most commonly consulted document, with more than 1,500 hits.

The monthly newsletter has likewise established its position, with the number of subscribers having increased to a level of 2,000 by the end of the year.



Somos Pacientes

<https://www.somospacientes.com>

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 patients' 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

<https://www.codigofarmaindustria.org>

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.

The portal was developed with this idea in mind, along with the Code of Good Practice micro-site.

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



Four Microsites for Proprietary Medicines Classification

<http://nomenclator.farmaindustria.org>

FARMAINDUSTRIA has developed these four analytical micro-portals in order to provide the technical teams at pharmaceutical manufacturers with access to the nomenclature of both the Ministry of Health and the AEMPS.

This is a consultation and filtering tool handling all information submitted by the two institutions. It likewise provides oversight of changes to the AEMPS nomenclature, to ascertain any changes between uploads, including presentations that have been "Incorporated" and "Eliminated".

During 2020, in addition to numerous minor changes, changes to the Ministry of Health's nomenclature were included within this oversight process.

Websites for management of Royal Decree-Laws 8/2010 and 10/2010

These are four portals for managing the control procedures of the deductions resulting from the application of Royal Decrees-Acts 8/2010 and 10/2010. These four tools mean that the Official Associations of Pharmacists, pharmaceutical manufacturers, the General Council of Official Associations of Pharmacists and the bank involved can all comply with the procedure.

Código Nacional	Nombre y Presentación	PVP IVA	PRECIO RES	MEMOR PRECIO AG	Grupo Terapéutico	Lab. Comerc.	Lab. Titular	Solicitud Comerc.	Fecha Comerc.	Principios activos
68580	A.A.S. 100 mg COMPRIMIDOS, 30.	1,45	1,45	n.d.	B01AC05 - Ácido acetil.	OPELLA HEALTH.	OPELLA HEALTH.	✓	11/10/2012	ACETILSAL.
700693	A.A.S. 500 mg COMPRIMIDOS, 20.	2,5	2,5	n.d.	N02BA01 - Ácido acetil.	OPELLA HEALTH.	OPELLA HEALTH.	✓	09/06/2011	ACETILSAL.
692223	ABACAT GRANULADO PARA SOLU.	n.d.	n.d.	n.d.	R05X - OTROS PREPA.	TARBIS FARMA.	TARBIS FARMA.	✓	29/10/2020	3 - CLORFE.
729072	ABACAVIR ACCORD 300 mg COMP.	n.d.	n.d.	n.d.	J05AF06 - Abacavir	ACCORD HEALTH.	ACCORD HEALTH.	✓	17/05/2021	ABACAVIR
727637	ABACAVIR TARBIS 300 MG COMP.	n.d.	n.d.	n.d.	J05AF06 - Abacavir	TARBIS FARMA.	TARBIS FARMA.	✓	28/07/2020	ABACAVIR
711415	ABACAVIR/LAMIVUDINA DR. REDD.	n.d.	n.d.	n.d.	J05AR02 - Lamivudina	REDDY PHARM.	REDDY PHARM.	✓	18/04/2017	2 - ABACAVI.
719675	ABACAVIR/LAMIVUDINA ACCORD.	n.d.	n.d.	n.d.	J05AR02 - Lamivudina	ACCORD HEALTH.	ACCORD HEALTH.	✓	34/04/2018	2 - ABACAVI.
715527	ABACAVIR/LAMIVUDINA ALROVIT.	n.d.	n.d.	n.d.	J05AR02 - Lamivudina	AUROVITAS SPA.	AUROVITAS SPA.	✓	22/12/2017	2 - ABACAVI.
712373	ABACAVIR/LAMIVUDINA EDGEN 5.	n.d.	n.d.	n.d.	J05AR02 - Lamivudina	ARISTO PHARM.	ARISTO PHARM.	✓	07/08/2017	2 - ABACAVI.
719707	ABACAVIR/LAMIVUDINA GLENMARK.	n.d.	n.d.	n.d.	J05AR02 - Lamivudina	VISO FARMACE.	GLENMARK AR.	✓	23/04/2018	2 - ABACAVI.
723918	ABACAVIR/LAMIVUDINA KERN PH.	n.d.	n.d.	n.d.	J05AR02 - Lamivudina	KERN PHARMA.	KERN PHARMA.	✓	09/03/2020	2 - ABACAVI.
712249	ABACAVIR/LAMIVUDINA MYLAN 6.	n.d.	n.d.	n.d.	J05AR02 - Lamivudina	MYLAN PHARM.	MYLAN PHARM.	✓	12/12/2016	2 - ABACAVI.

04

MEMBER SERVICES

- 4.1 Online Services
- 4.2 Working Groups / Barcelona Delegation**
- 4.3 Spanish Technological Platform for Innovative Medicines
- 4.4 Self-Regulation System

4.2 Working Groups / Barcelona Delegation

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 active participation by companies in the work of the Association, to explain the legislative or regulatory initiatives of the various Public Authorities, draw up sectoral arguments or follow up on action plans addressing issues of relevance for the sector, to allow the Association to pass on the information to the corresponding authorities and interlocutors.

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

In October 2020, the renewal of FARMAINDUSTRIA's Governing Bodies also coincided with the updating of the working groups for a new 2-year period. This renewal resulted in the merging and renaming of some of the working groups with the twofold aim of adapting to current circumstances and covering the needs arising among members.



The current list of working groups in operation at FARMAINDUSTRIA is as follows:

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

A number of *ad hoc* groups are also in operation with a more restricted scope, their purpose being to explore a range of aspects in greater depth, with the results being brought before the plenary sessions of the working group to which they are assigned.

The activities of the various FARMAINDUSTRIA working groups over the course of 2020 are summarised below.

Access Working Group (former Sustainability and Economic Regulation Working Group)

The analysis of parliamentary initiatives and legislation related to economic regulations in the sphere of the pharmaceutical sector remained the focus of the content covered by this working group throughout 2020.

As a result of the Covid-19 crisis, FARMAINDUSTRIA provided the group with timely information as to the Association's priorities in this difficult climate for health and the economy, focusing efforts on ensuring continuity in both the manufacturing and supply of medicines, and clinical trials and research to combat coronavirus.

Meanwhile, the group received updated information as to the contact maintained with the Government, both in connection with the indicators and development of the Collaboration Agreement with the Government, and progress in institutional dialogue for the structuring of a Multiannual Strategic Plan for the pharmaceutical industry, aligned with the Recovery, Transformation and Resilience Plan for the Spanish Economy recently presented by the Government.

Furthermore, the group monitored access indicators for innovations, the IPT Consolidation Plan for medicines within the NHS, and the Ministry of Health's draft Action Plan to promote generic and biosimilar medicines.

Regarding other matters, over a series of meetings the group addressed relevant matters connected with the processing of the proposed Regulation on HTA fostered by the European Commission, the work of the Advisory Committee for the Financing of the NHS Pharmaceutical Provision, and the information system for the measurement of the therapeutic value in real clinical practice of medicines with a high health and economic impact for the NHS (Valtermed).

This working group 's members have also conducted detailed monitoring of the processing of the regulatory project, arguments and subsequent publication of Order SND/1121/2020, of 27 November 2020, implementing the 2020 update of the National Health System reference pricing system for medicines.

Lastly, the Access Working Group received timely information on progress made by the HTA Working Group, and the Incremental Innovation (INI) Working Group.

Health Technology Assessment (HTA) Working Group

This working group was set up at FARMAINDUSTRIA with the aim of making 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 working group has representatives from some 50 companies, with a membership profile centred very much on Market Access and Health Economics & Outcomes Research. During 2020, monitoring continued of the main initiatives in progress in the field of measuring health outcomes, both nationally and internationally. 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.

Lastly, at the international level the working group closely followed progress in the processing (which is still ongoing) of the European Commission's Proposal for a Regulation on HTA, promoting joint clinical assessment for the EU, analysing the potential implications in the process of price setting and reimbursement of medicines in Spain.

Financial Directors and Collections Working Group

In late 2020, given the background of the majority of members and the content addressed by the group, the decision was taken to rename the Hospital Debt Working Group, now the Financial Directors and Collections Working Group.

This working group mainly comprises the financial directors of the nearly 60 constituent companies, as well as financial controlling and cash-management personnel and credit and collections managers.

The group monitors financial and accounting aspects connected with the Collaboration Agreement signed with the Government, as well as any new agreements that might arise with the public authorities in the field of financial sustainability.

It also analyses the evolution of the debt incurred 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.

During the 2020 financial year the working group very closely followed the key milestones in the field of payment default, such as the processing of the General State Budget and regional budgets, the resources activated under the Financing Fund for Spanish Regions (the Autonomous Liquidity Fund, or FLA, and the Financial Facility Fund, or FFF), the processing of the AIREF report on hospital pharmacy expenditure, and the monitoring of the average payment periods published each month by the Ministry of Finance, and their implications with regard to the Organic Law on the Control of Commercial Debt in the Public Sector.

Regarding other matters, over the course of 2020 the Electronic Invoicing (FAC) ad hoc Sub-Group continued its detailed review of all

the latest developments and national and regional legislation in the field of electronic invoicing with the public sector, which has been mandatory since January 2015.

Furthermore, within the context of the pandemic the group monitored the outfitting of medicalised hotels and conference centres in a number of Spanish regions, to analyse the implications of this matter with regard to the medicinal supply circuit and electronic invoicing, and to rectify any incidents that might arise.

In turn, the Association continued its involvement in the CEOE Digital Society Committee, addressing occasional matters connected with this field.

Lastly, at the time when this Annual Report went to press, the FAC Working Sub-Group was closely monitoring a number of regional initiatives:

- In Cataluña, the imminent implementation of electronic data exchange (EDI) for the pharmacy purchases of hospitals belonging to the ICS (Catalan Health Institute).
- In Andalucía, the completion of integration of all SAS (Andalusian Health Service) pharmacies within the SIGLO system, and the incorporation of Public Health Enterprise Agencies within the model of entities with public budgetary accounting.

Hospital Market Working Group

In 2020 this working group, which works in close coordination with other FARMAINDUSTRIA working groups (such as Financial Directors and Collections, Biotherapeutic and Orphan Drugs, Trademark Protection, Relations with Spanish Regions and Access), continued to analyse the hospital market by monitoring and studying the various initiatives undertaken at the national and regional levels, in particular the most notable developments in the field of public hospital procurement.

This working group receives information from the monitoring conducted by FARMAINDUSTRIA as to access to innovations in the different Spanish regions and any policies that could limit the supply of and access to innovative medicines or freedom of prescription.

In this regard, during the year there was a particular emphasis on the supply of hospital ('DHDH') medicines, since as a result of the pandemic - and in accordance with Order SND/293/2020, of 25 March, establishing conditions for the dispensation and administration of medicines within the context of the National Health System, in response to the health crisis caused by Covid-19 - the different Spanish regions began to establish the relevant measures to ensure the dispensation of outpatient medicines without the need to retrieve them on hospital premises.

Regarding other matters, given the situation caused by Covid-19, and with the aim of alleviating the pressure on health centres, some regions equipped conference centres and hotels to receive patient admissions referred from public network hospitals. In this regard, Farmaindustria in collaboration with the Hospital Market Working Group monitored the situation in order to ascertain the potential implications of such deployments for pharmaceutical suppliers with regard to the medicinal supply circuit (from order to invoicing). In general the supply of medicines to these medicalised hotels or conference centres was established from the pharmacy service of the reference hospital referring the patient, although there were certain exceptions, such as the IFEMA conference centre hospital in Madrid.



Technical Regulation of Medicines Working Group

The main activities of this working group focus on analysis and contributions to prepare the industry's position with regard to the regulations issued by European institutions and published by the Ministry of Health and the AEMPS with regard to procedures for the authorisation, registration and marketing of medicines, in particular the implementing provisions of Royal Legislative Decree 1/2015, approving the recast text of the Guarantees and Rational Use of Medicinal and Healthcare Products Law.

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, the Sunset clause and classification of medicines with no commercial interest, etc. The party likewise conducts constant monitoring of the AEMPS' operating and decision-making periods.

In 2020, the working group analysed, among other issues:

- 1 The Pharmaceutical Strategy for Europe, developed by the European Commission and the challenge it faces in minimising the complexity of pharmaceutical regulations in order to shorten time to authorisation, among other aspects.
- 2 Preparation by pharmaceutical companies for Brexit.
- 3 The alerts received by SEVeM (the Spanish Medicines Verification System).
- 4 The new procedure for the generation of therapeutic positioning reports ('IPT') on medicines within the NHS.
- 5 The implementation of Instruction 1/2020 of the AEMPS with regard to materials concerning risk prevention.

In all its meetings, this working group discusses eight specific subject areas:

- 1 Therapeutic Positioning Reports
- 2 Early access
- 3 Product information
- 4 Biotherapeutic medicines
- 5 National procedure and management
- 6 Quality regulation
- 7 Risk-management plan
- 8 European procedures

In 2020 an ad hoc group was set up to promote a pilot scheme overseen by the AEMPS for the implementation of electronic information leaflets for medicines used in a hospital setting, so as thereby to eliminate paper leaflets.

Lastly, a number of meetings of this working group were attended by various representatives of the AEMPS in order to explain both the main measures agreed by the Agency to facilitate the management of authorisations and modifications of medicines for human use deemed essential during the Covid-19 pandemic, and the procedural method for Therapeutic Positioning Reports ('IPT').

Biotherapeutic and Orphan Medicines Working Group

This working group regularly analyses legislative initiatives at both the national and European levels, along with the issues associated with these types of medicines, given their unique characteristics.

In 2020, aside from the usual matters, the group addressed certain issues directly related to the situation concerning the supply of medicines at hospitals (many of them biotherapeutics) and for outpatient use which, as a result of the pandemic, was subject to a special home-supply system which differed in each Spanish region, so as to prevent patients retrieving their medicines at hospital premises. A number of aspects concerning the availability of medicines in special situations were also debated (many of them biotherapeutic or orphan medicines, or from both categories), with the regulations being announced by means of a prior public consultation.

In the case of orphan medicines, one of the aspects generating the greatest debate at the meetings of the working group was the content of the Resolution passed by the Council of Ministers regarding the economic regime for orphan medicines, establishing a conditional release from the inclusion of such medicines within the Reference Pricing System. Although this release is possible in certain cases, it does not simply correspond to orphan designation, but it additionally requires that the orphan medicine offer a relevant clinical benefit, with such an agreement being established by the Standing Pharmacy Commission of the Interterritorial Council of the NHS, which must then be ratified by the

Inter-ministerial Commission for Pharmaceutical Prices, taking into account for this purpose the available scientific knowledge and evidence, and any Therapeutic Positioning Report that might exist. In the opinion of the working group, this type of conditional factor clashes with the spirit of the European Regulations governing orphan medicines, which grants them commercial exclusivity incompatible with their inclusion within the Reference Pricing System, as they are directly tied to the orphan medicine designation, rather than being dependent on a subsequent evaluation.

Manufacturing and Traceability Working Group

This group was kept very busy during the past year as a result of the major role guaranteeing supply of medicines played during the pandemic. The group was expanded to all companies within the Association that have manufacturing sites in Spain, in order to ensure they received timely information. A total of 10 meetings were held in 2020 in order to closely monitor the supply of those medicine presentations declared by the AEMPS to be essential, in particular during the state of emergency.

Unlike the case of other healthcare products, there was no interruption of supply of medicines, although the AEMPS had to inform companies directly of the required destination for the limited units available of certain presentations needed at hospital ICUs. Particular mention should be made of the conduct and pragmatism of the AEMPS during the peak moments of the pandemic, as they held weekly meetings with all agents in the supply chain to ensure particularly close monitoring. The Agency's flexibility and dedication in addressing requests from companies focused on resolving special situations should likewise receive special mention, as this allowed for the continued supply of certain medicines deemed at the time to be vital.

Aside from supply-related issues, the group continued to work on other subjects such as serialisation, maintaining one item on the agenda to address actions by the various agents in connection with their obligations to include unit codes, verification, deactivation and alert information. Another of the regular agenda items of this working group is code aggregation at hospital level, a subject which is currently pending, since public hospitals are not deactivating codes.

Lastly, the working group addressed a range of specific issues such as airborne transportation of medicines under special temperature conditions, and the pilot initiative to include a datamatrix code in the primary packaging of medicines in a hospital setting, scheduled for development in late 2021, so as to be able to eliminate the information leaflet from such packaging, as it is possible to access all information from the leaflet and other characteristics of the medicinal presentation by scanning this code.

Environment Working Group

During 2020 the working group collaborated closely with SIGRE in monitoring national and European legislation in the environmental field connected with the pharmaceutical sector: circular economy, waste and soil contamination, climate change, environmental responsibility, environmental quality, water, energy transition, requirement by the Balearic Government regarding the expansion of extended producer responsibility for commercial and industrial packaging, and the future excise tax on non-reusable plastic packaging included in the Waste and Soil Contamination Bill.

FARMAINDUSTRIA also still sits on Environmental Commissions of the CEOE and FEIQUÉ/FEDEQUIM.

Pharmacovigilance Working Group

This working group channels the main questions and clarifications derived from both national and European pharmacovigilance provisions.

We would highlight the following provisions and actions from 2020:

- 1 AEMPS Instruction 1/2020, on Materials for the prevention of risk in medicines for human use, and Note of Information MUH 32/2020, on Instructions for the pharmaceutical industry regarding materials for the prevention of risk in medicines for human use, enabling distribution thereof, duly authorised by the AEMPS, via Scientific Societies, as currently occurs with healthcare professional safety letters (DHPC). FARMAINDUSTRIA has in this regard formalised the signature of a Collaboration Agreement with 51 Scientific Societies, both for the distribution of medicinal safety information and the distribution of risk prevention materials.

- 2 With regard to data protection, the guidelines to be covered by the future regulatory code of conduct for personal data processing in the field of clinical trials and other clinical research activities, and pharmacovigilance.
- 3 The Royal Decree regulating observational studies with medicines for human use and the corresponding implementation instructions, which will serve to progressively update the requirements, aligning them with the reality of the different agents, including the pharmaceutical industry.

All 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.

One of the working group's meetings involved the Head of the Pharmacovigilance and Pharmacovigilance Division and the Head of the Pharmacovigilance Area of the AEMPS, who presented the plan for overseeing the safety of Covid-19 vaccines, and responded to questions regarding Royal Decree 957/2020, on observational studies with medicines.

Vaccines Working Group

This working group played a particularly important role during the past year, given the primordial significance of Covid-19 vaccines. The matters discussed by this working group correspond to purely technical aspects.

Aside from issues regarding the supply of Covid-19 vaccines or the monitoring of population rates for remaining vaccination calendars, the working group focused part of its efforts on the exchange of information regarding documents and recommendations drawn up by Vaccines Europe.

Pharma-Biotech Working Group

This working group 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 19 interactive meetings have been held between the two sectors, mainly in such areas as the central nervous system, oncology, respiratory system, inflammation and autoimmune diseases.

Following a careful study, the most advanced projects were selected and invited to take part at a seminar to discuss the results obtained with various interested pharmaceutical companies. These seminars are of particular relevance both for pharmaceutical companies and for research groups.

The 19 meetings held to date involved 42 companies and 31 research centres and hospitals, presenting the advanced research projects selected for their innovation potential, while another 44 pharmaceutical companies with an interest in the projects will also be represented totalling participation of over 116 public and private sector agents.

Since the launch in 2011, 592 biomedical research projects have been analysed, with a total of 118 projects being selected, 56 of them promoted by Spanish start-up companies, and 62 by research centres and hospitals. This collaboration initiative has driven advances in more than 45 new molecules which are at the development stage and are protected by patents to date.

The most recent gathering, which was held remotely, took place on 18 November 2020 with the presentation of as many as eight new research projects led by small companies and Spanish public research centres, which could be further developed through collaboration with pharmaceutical companies.

This initiative has bridged the gap 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). Meanwhile, a very close eye is kept on all new calls launched by the AEI (State Research Agency), as well as grants for R&D+i projects under the 2021 Strategic Lines.

This working group also seeks to boost participation of companies in national and international pharmaceutical R&D programs, 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 at the various international public-private cooperation procedures launched to combine efforts in researching Covid-19.

Similarly close monitoring is maintained of the new Horizon Europe Framework Programme (2021-2027), which will involve a key role for public-private partnerships such as the Innovative Health Initiative-IHI, the successor of IMI, but extended to other health sectors. This future intersectoral partnership includes the pharmaceutical industry, represented by the EFPIA, Vaccines Europe and EuropaBio, together with medical technologies represented by the COCIR and MedTech Europe. Initially, a harmonised set of standards will be established, while at the same time guaranteeing processes which allow a degree of flexibility in intersectoral cooperation, provided that this serves to foster an ecosystem based on research and innovation in the field of health, so as to improve patients' lives in Europe. Lastly, IHI will be aligned with other programmes, and will contribute to the achievement of the objectives of the Europe's Beating Cancer Plan and Pharmaceutical Strategy for Europe. FARMAINDUSTRIA is working with EFPIA on the monitoring and implementation of this new initiative.

BEST for Excellence in Clinical Research Working Group

This working group, made up of over 60 companies, focuses on strategic aspects and the promotion of competitiveness in clinical research in Spain by facilitating processes and enhancing performance indicators under the terms of Royal Decree 1090/2015, on Clinical Trials.

The working group also focuses on the regulatory and technical aspects of clinical research in connection with the Ministry of Health, the AEMPS and the Spanish regions, as well as outreach in the field of biomedical research in collaboration with hospitals and other organisations. Additionally, a series of recommendations are developed together with the Patients Working Group for participation by adult and paediatric patients in R&D projects.

The BEST Project, headed by FARMAINDUSTRIA, groups together the main public and private agents comprising the system for medicinal knowledge generation and clinical research in Spain. BEST aims to foster R&D investment, monitoring the situation of clinical research processes in Spain, identifying different practices and adopting measures intended to enhance efficiency and competitiveness.

Over the past year, this working group was hard at work monitoring Spanish and European legislative initiatives in the field of clinical research, in particular Regulation 536/2014, and Royal Decree 1090/2015.

The new Regulation establishes harmonised procedures for the authorisation of clinical trials across Europe, urging Member States to cooperate in the assessment by adopting a single, common stance but leaves out of this cooperation inherently national aspects that require assessment by each Member State. The cornerstone for the application of the new principles of this regulation is the development of the Clinical Trials Information System portal managed by the EU which, following various delays, is expected to be operational in January 2022.

In order to ensure that centres, sponsors of clinical trials and regulators are ready to operate under this new framework, and within the context of the collaboration which FARMAINDUSTRIA maintains with the AEMPS, various meetings have been held with representatives from the Agency in order to progressively resolve practical and technical issues, many of which still remain pending. In any event, the legislation allows for a transitional period so that sponsors can progressively adapt new requests for the authorisation of trials in line with the new European regulations.

Meanwhile, during 2020 FARMAINDUSTRIA continued to work actively on ensuring that the Document of Complementary Instructions to Royal Decree 1090/2015, of 4 December 2015, would correspond to the sector's needs, in particular during the Covid-19 pandemic. Work was also conducted with the AEMPS and Medicinal Research Ethics Committees (CEIm) to ensure that the annexes to the document are aligned with the pharmaceutical industry's requests as well as translated into English. All this information is available on the AEMPS' website.

Efforts were similarly made with the CEIm Working Group and patients in an attempt to adapt the informed consent forms to be in line with the new European and national data protection regulations, with a number of meetings having been held with all the groups involved.

The most notable activities undertaken during recent months include the following:

- 1** Update to the Early Stage Clinical Research Units Guide. The decision was taken to improve the operability of this Guide by creating an online application that will facilitate both its edition and future data display and export. This is currently at a highly advanced stage, with information from over 30 units at different public and private hospitals.
- 2** Publication of the criteria guidelines for excellence in clinical research. The document sets out the need to encourage the generation of new clinical trial designs so as to improve clinical development lead times and the incorporation of quantitative and qualitative metrics serving to identify areas for improvement to which efforts could be dedicated so as to gain predictability and competitiveness. The guidelines also recommend 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.
- 3** Implementation of the European Data Protection Regulation and update of the Code of Conduct on Data Protection in Clinical Research and Pharmacovigilance (currently being assessed by the Spanish Data Protection Agency). Over the last year, progress has also been made in updating the new code of conduct to protect data in clinical research and pharmacovigilance, presented to the AEPD in December 2020. A number of different meetings have also been held with public and private stakeholders to explain the fundamental principles of the Code. Meanwhile, at the meetings of the EFPIA Data Governance Working Group, FARMAINDUSTRIA presented its 10 years of experience in the field and the key developments in the new Code. This provided the basis for work to begin at the EFPIA to prepare a Code of Conduct in this sphere at the European level.

4 We would emphasise the creation of a working group with representatives of the SEFH (Spanish Hospital Pharmacy Society) and FARMAINDUSTRIA member companies to advance a joint work plan so as to draw up Guidelines on "challenges, criteria and priorities of hospital pharmacy services to foster contribution to excellence in conducting clinical trials". The main issues to be addressed in this document are:

- Aspects for improvement in sponsor-pharmacy service communication.
- Harmonised documents and standardised operating procedures.
- Standardisation of accredited and connected platforms for the administration of medicines under investigation.
- Improvements in kick-off processes, patient recruitment and close-out of the trial.
- Procedures for the acquisition of comparators.
- Measures for the implementation of remote monitoring in hospital pharmacy services.

These efforts are being made within a context of the greatest collaboration among the parties with the aim of improving the efficiency of processes and pursuing excellence in order to maintain and improve the competitiveness of clinical research in Spain. The Guidelines are expected to be ready for publication in the coming months.

5 Within the realm of the interrelationship with patient groups, numerous activities have been developed, as described in the subsection on the PTEMI (Spanish Technological Platform for Innovative Medicines) in the subsequent sections of this Annual Report.

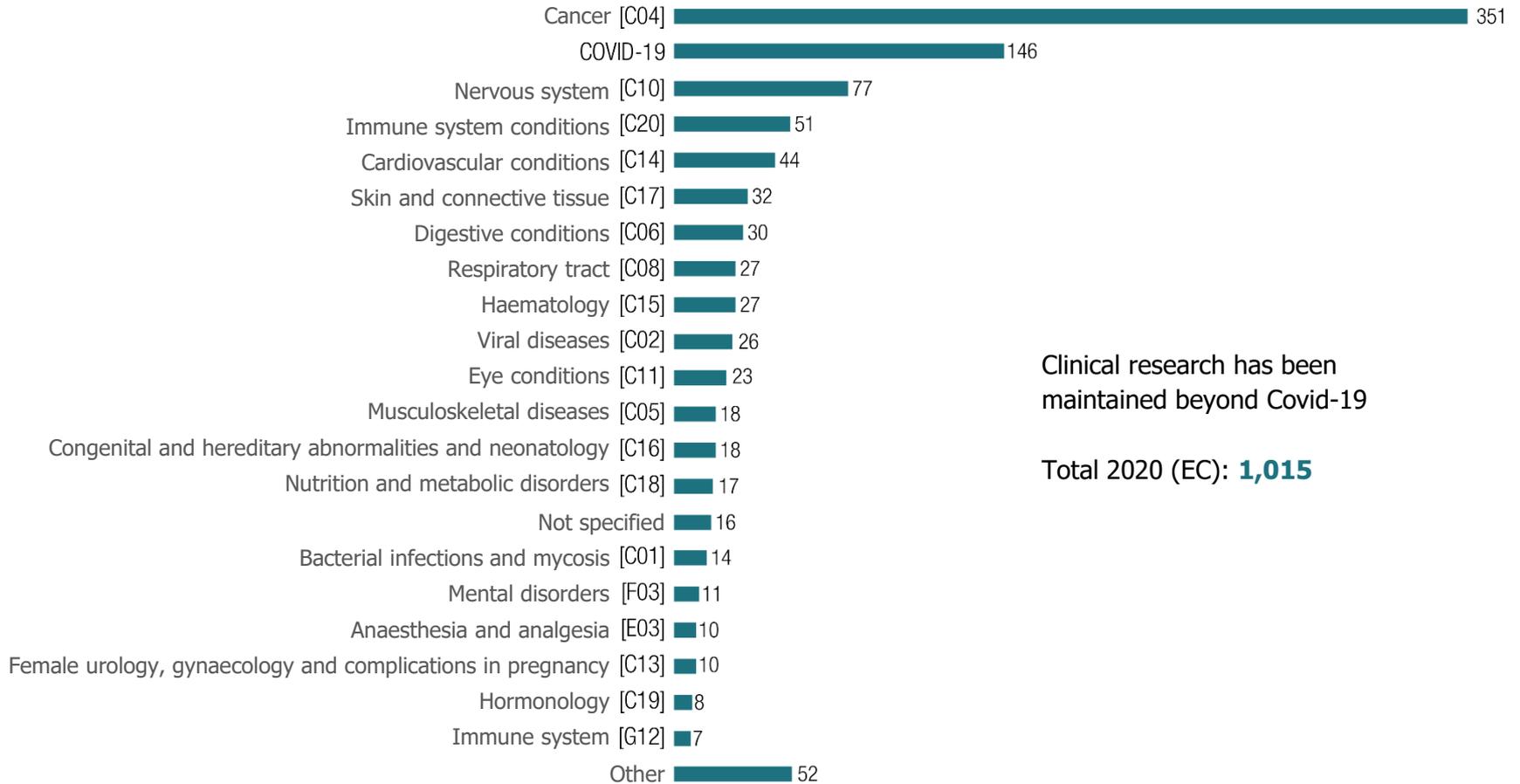
Spain is already one of the world's leading countries in research of medicines (Spain participates in three out of every ten clinical trials on the continent of Europe), thanks to the collaborative efforts made over the years by health authorities, hospitals, researchers, patients and the pharmaceutical industry, allowing the country to take part in the most cutting-edge international clinical trials, benefiting patients above all.

The coronavirus pandemic has further highlighted the importance of biomedical research around the world, with Spain taking up a key role in the field of clinical trials into Covid-19 treatments and vaccines. Spain has since the onset of the pandemic launched more than 150 clinical trials to test effective treatments. Nearly thirty of them are testing new molecules; more than a hundred are therapeutic repositioning of existing molecules, while seven are treatments involving cellular therapies. Nearly twenty FARMAINDUSTRIA member companies, both national and international, are taking part in many of these clinical trials and

collaborating in other publicly-sponsored initiatives, by providing the required medication. These trials involve professionals at more than 200 Spanish hospitals, with 28,000 patients expected to participate and benefit from them.

Aside from the above figures, more than one thousand new clinical trials were authorised in Spain in 2020. This significant figure demonstrates that for the various stakeholders involved in research, the priority has been both to provide a response to the new disease, and to maintain activity in clinical trials studying other conditions.

Clinical Research - During the Covid-19 Pandemic



Number of Clinical Trials in the different therapeutic areas. 2020 REec data (according to AEMPS authorisation date), considering Covid-19 as a therapeutic area.

The Covid-19 Health Crisis has also placed emphasis on the digital transformation of healthcare. Digital transformation has only just begun in this sector, and the way that this complements many in-person activities will progressively be improved and adapted as the various technologies are developed. In this regard, particular mention should be made the Spanish Data Protection Agency's activities, which in May 2020 worked together with the AEMPS and FARMAINDUSTRIA to seek out a solution for the remote monitoring of trials, guaranteeing their continuity as in some cases they are the only therapy option available to patients.

Many of these research activities require constant contact with hospital personnel in order to ensure that the trial is properly conducted and documented. This aspect demands that the validity of data and scientific integrity of the clinical trial be guaranteed. The adoption of ethical and legal measures allowing such activities to be conducted remotely serves to ensure that in such an adverse epidemiological situation the research does not need to be suspended.

In all these initiatives - coordinated by FARMAINDUSTRIA - pharmaceutical professionals' support was crucial, as they shared their concerns as to the continuity of clinical research, and worked in harmony at both the national and international levels. All within a context of constant adaptability to the situation so as to offer the best solution for patients in a highly challenging healthcare context.

Legal Services Working Group

The activity of this working group focused once again this year on monitoring all matters which would be of relevance to the member companies because of their legal implications.

The intense legislative activity undertaken throughout the last year meant that meetings were held monthly, along with daily communication regarding all matters with an impact on our regulatory framework, as well as case-law and reports of relevance for our sector.

Notwithstanding the regulations adopted as a result of the health crisis, this working group also provided information regarding the following matters, among others:

- 1 Orphan medicines. Resolution of 2 June 2020 of the Directorate-General for the Basic Portfolio of NHS and Pharmacy Services (DGCFYF), publishing the Decision of the Council of Ministers of 3 March 2020, establishing the economic framework for orphan medicines, comprising an exemption from the reference pricing system if there is no therapeutic alternative within National Health System's pharmaceutical provision or, if a therapeutic alternative does exist the orphan medicine must offer a significant clinical benefit, as agreed at the Standing Pharmacy Standing Commission of the NHS Inter-territorial Council, ratified at the Inter-ministerial Commission for Pharmaceutical Pricing, taking into consideration for this purpose the available scientific knowledge and evidence, and any therapeutic positioning report that might exist. Likewise, and in accordance with the provisions of Article 96 of the Recast Text of the Guarantees and Rational Use of Medicinal and Healthcare Products Law, the price of the exempted medicine will be subject to review if it is found to be economically viable or if any of the circumstances set out in the article in question are fulfilled. Lastly, the aforementioned Resolution states that the Ministry of Health will submit a report on its effects to the Delegated Government Committee for Economic Affairs.

- 2 IPT Consolidation Plan. Official presentation on 26 November via a webinar staged by the Ministry of Health, with the plan structured along three lines of action: a) the evaluation network (REvalMed NHS), comprising the DGCFY, the AEMPS and the Spanish regions, which will have its own therapeutic assessment team (led by the AEMPS), another pharmaco-economic assessment team (led by the DGCFY) and seven assessment nodes corresponding to different therapeutic areas, comprising more than 120 experts designated by the Spanish regions; b) a methodology for the design and approval of therapeutic positioning reports (IPTs); c) a dashboard providing information as to the current stage of each IPT.
- 3 Public consultation by the CNMC into the marketing of medicines. In January 2021 the Competition Promotion Department of the CNMC began a consultation focused on industrially manufactured human use medicines reimbursed by the NHS in Spain and those dispensed at retail pharmacies, excluding the hospital channel. The consultation represents a period of final reflection, the aim of which is to gather the opinions of the main market agents, including economic operators, public institutions, associations, academics, consumers, patients and other experts and agents with an interest in the sector.

- 4 Biosimilars (Andalucía). In August, the Andalusian Health Service published a Framework Agreement ('Acuerdo Marco', or 'AM') for the supply of biosimilar medicines, in order to establish harmonised and uniform approval of the conditions for the purchase of the selected medicines. The aforementioned AM, which comprises nine batches identified by active pharmaceutical ingredient ('denominación oficial Española' or 'DOE'), was appealed by the Association by means of the special procurement appeal mechanism, and also on the basis of the configuration of the contract's purpose, as it included special execution conditions forcing the chosen contractor to adjust the contract price downwards if it offered a lower price in a centralised INGESA framework agreement. This appeal was upheld in part by the Procurement Appeals Tribunal of the Regional Government of Andalucía (the TARCJA), which declared the disputed clauses to be unlawful, ruling the nullification of the procurement specifications challenged, and requiring a new tender to be conducted, where applicable. The nullified clauses include in particular the conditions regarding the award price being linked to prices offered by the same company in procedures organised by the Ministry of Health. The TARCJA declared that this clause went beyond the inherent scope of the execution conditions to be respected in the essential elements of the contract, including the price awarded and agreed.

To the above we would add the consultation procedures regarding reference prices for 2020, the Royal Decree regulating observational studies with medicines, the parliamentary process of various legislative initiatives, the monitoring of cases regarding medicine supply and public procurement legislation, as well as changes to employment law and data protection.

Taxation Working Group

This working group permanently analyses and monitors those issues that have tax implications for the pharmaceutical sector.

At the beginning of 2020, 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 process an analysis was conducted as to the accounting and tax treatment of amounts payable to the NHS under the terms of the Collaboration Agreement signed with the Spanish Government, likewise addressing other aspects connected with the simplification and harmonisation of VAT in the intra-EU trade in goods (entry into force of quick fixes) and the current situation of AEAT (Spanish Tax Agency) inspections in the field of redundancies. In turn, a review was conducted of the provisions of the regulations to avoid double taxation with the USA, and an analysis of the impact of Brexit with regard to customs and VAT. There was lastly a review of the most significant legal theory and judgments for the sector with regard to taxation.

Meanwhile, the working group conducted a detailed analysis of the extensive domestic and EU regulations, AEAT criteria and adoption of multiple measures implemented in the field of taxation and customs as a result of the health crisis caused by Covid-19, in particular monitoring the tax regime for donations of medicines and healthcare materials. In particular, monitoring was conducted of both the various regulations regarding the VAT exemption on deliveries, imports and acquisitions of goods required to combat Covid-19 within the EU, and also the new measures adopted by the European Commission regarding the temporary VAT exemption applicable to Covid-19 diagnostic kits and vaccines, on the established terms.

Given their relevance in this field, we should cite the following, among other provisions:

- At the EU level, European Commission Decision (EU) 2020/491 (and subsequent amendments) and Council Directive (EU) 2020/2020, of 7 December 2020.
- At the domestic level, RDL 15/2020, of 21 April 2020 (and successive extensions to the VAT exemption), RDL 34/2020, of 17 November, and RDL 35/2020, of 22 December.

Over the course of the year the working group received timely information as to all tax-relevant case-law concerning the sector, as well as the criteria published by the AEAT with regard to the applicability of the deduction to avoid international double taxation under Corporation Tax, and all the most significant taxation and customs matters covered by the various Royal Decree-Laws and regulations approved during the Covid-19 crisis, with a particular focus on matters concerning taxation and procedural deadlines, census matters, electronic identification and taxes. Issues regarding transfer pricing and related operations were also monitored, as well as the new validation rules for the Integrated Information Supply System ('SII') in force since January 2021.

There was in turn permanent contact with the CEOE Tax Committee, analysing together with the working group those regulatory projects submitted by the organisation, so as to channel the relevant observations.

Human Resources Working Group

Given the current context, during 2020 this working group significantly increased its activity compared with other years, with the members receiving information by email on a daily basis, as to all regional, national and European regulations of relevance: vaccination and the corresponding strategies, situation regarding medical visits in each Spanish region, circulars, notes of information or initiatives by the CEOE, CEIm, FEDEQUIM, FOMENT DEL TREBALL, FEIQUÉ, etc. The working group also received reports on the employment market, analysing the registered unemployment rate, new contracts and Social Security registration, produced by the CEOE Labour Relations Department.

Meanwhile, an updated document was sent to the working group each month with all occupational risk prevention regulations concerning Covid-19 with an impact on pharmaceutical companies at the domestic and regional levels. This document emphasised in particular the regulations connected with Covid-19 diagnostic tests and temperature checks to enter company workplaces, as well as the Vaccination Strategy in Spain and updates to this. Emphasis was similarly placed on the operational procedure for occupational risk prevention services to address exposure to SARS-CoV-2, and the numerous procedural updates, the different ministerial orders regarding foreign travel restrictions, and continuous updates to the measures and restrictions implemented in each Spanish region.

The working group saw a significant increase in its number of meetings in 2020, with gatherings being held monthly in online format in order to inform members of all relevant aspects in the sphere of labour relations and human resources, as well as aspects concerning the negotiation of the XX General Agreement of the Spanish Chemical Industry, which took place from January 2021 onwards.

The most significant matters addressed by the working group include the following:

- 1 FARMAINDUSTRIA initiatives for the resumption of medical visits following the restrictions imposed by various regulations and instructions of the regional health services, in particular the Protocol on safety and prevention for professionals as a result of the resumption of in-person scientific and technical activities, developed by FARMAINDUSTRIA in collaboration with other sectoral organisations, as discussed in other subsections of this Annual Report.
- 2 The occupational measures approved during the health emergency: absence because of infection, quarantine and complete isolation; 'ERTE' furlough schemes; Social Security contributions deferrals for companies; adapted and reduced working hours to care for people ('Plan Me Cuida'); remote working and the corresponding regulations; the prohibition of dismissals during the health crisis on objective grounds; temporary contractual measures; "recoverable paid leave"; the different subsidies which were approved, etc.
- 3 Access or return to workplaces, and information on the lockdown relaxation phases.
- 4 The regulations on equality plans.
- 5 Occupational risk prevention in connection with Covid-19.
- 6 Negotiation of the Collective Agreement.
- 7 The forthcoming regulations that are to take effect, such as the Royal Decree on Equal Pay, which establishes pay registration at companies, and RDL 28/2020, on remote working.

As for other initiatives undertaken during the year and communicated to the working group, the most notable features are the collaboration between FARMAINDUSTRIA and other associations in the Official Medical Association of Madrid and Organisation of Medical Associations, to establish the most effective way of providing health authorities with access to the capacity available at companies to provide volunteers from their teams of healthcare professionals (above all doctors, but also nursing staff and other health science professionals), in order to support the healthcare system as far as possible at such a critical time. The management of FARMAINDUSTRIA also offered to collaborate with the network of associations of Spanish scientists and researchers abroad (RAICEX).

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Code of Practice Working Group

For the fifth consecutive year, and with the help and collaboration of the members of the group, the transfers of value to healthcare professionals and organisations for the year 2019 are published. It should be noted that, for the third year in a row, 100% of the transfers of value to healthcare professionals are published individually, with no significant differences in terms of volume and amounts with respect to the data published the previous year (relating to the 2018 year) and with no claims in terms of personal data protection arising from the publication of the information individually. This is an initiative that is not only consolidating over the years but is also increasingly welcomed as a matter of course and normality by society as a whole and by the main stakeholders concerned (healthcare professionals and organisations).

The main issue on which the activity of this working group has focused has been the updating, improvement and revision of the Code of Practice for the Pharmaceutical Industry.

This process concluded with the approval and ratification of a new version of the Code of Practice for the Pharmaceutical Industry (Code 2021) at the Board of Directors and General Assembly held in October. This new text, which came into force on 1 January, 2021, incorporates important new features and improvements: (i) reference to the principles and values governing the industry's Self-Regulatory System; (ii) recommendations on information activities on prescription-only medicines and on relations with the media (new Annex III); (iii) clarifies and qualifies the responsibility of pharmaceutical companies in the digital environment and in the use of social networks; (iv) establishes additional criteria and guidelines for action applicable in relation to services provided by healthcare professionals or healthcare organizations (new Annex IV);

(v) Harmonises certain activities or practices in the area of interaction with patient organisations; (vi) updates the procedures for communicating meetings, market research studies and services; and (vii) revises the Queries (questions and answers) document on the interpretation of the Code of Practice, specifically incorporating six new questions and reformulating seven (Annex V).

In line with the model adopted in the previous year and considering that compliance with the Code of Practice is one of the Association's main objectives, maintenance of a Strategic Committee – created within the framework of Dimension IV, relating to Transparency of the 2018-19 FARMAINDUSTRIA Strategic Plan, and whose decisions are promptly reported to the Code of Practice Working Group – was approved. The collaboration and dedication provided by the members of this Committee has been fundamental not only in matters as relevant as those detailed above, but also in matters of a more institutional and strategic nature.

International Working Group

The International Working Group was set up for the purpose of conducting an analysis at the Association 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 The European and international initiatives affecting the productive model of the research-based pharmaceutical industry, including the Pharmaceutical Strategy for Europe, the establishment of a specific health programme (EU4Health), and collaboration among European countries on price and access.
- 2 The Trade and Cooperation Agreement between the EU and the UK, as the end of Brexit.
- 3 The European Commission proposal for an HTA Regulation.
- 4 Monitoring of the meetings of the European Council of Health Ministers (EPSCO Council) and the initiatives of the Directorates-General for Health, the Internal Market, Competition, and the working agenda of the European Commission.
- 5 The measures and initiatives devised and implemented at both the European and international levels by public authorities and the pharmaceutical industry to fight against the Covid-19 pandemic.

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Relationships with Spanish Regions Working Group

The aims of the Working Group on Relationships with Regions, comprising 65 companies, include the following:

- 1 Monitor relevant pharmaceutical and healthcare policy initiatives in the various Spanish regions.
- 2 Strengthen dialogue and collaboration with public authorities.
- 3 Promote balance in the healthcare system to allow patient access to medicines and the development of industrial activity.
- 4 Consolidate alliances with the different agents at the healthcare sector to achieve common goals, with a special focus on healthcare professionals.
- 5 Set up a regional early warning system to detect and monitor regional prescription-dispensing policies.

This 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+i, etc.

During the year, particular emphasis should be placed on the monitoring of the renewal of prescriptions for chronic treatments and medicines subject to approval in the different regions. As a result of the Covid-19 health crisis, the regions made changes to their prescription renewal procedures so that patients with chronic treatment and those requiring medicines subject to prescription approval did not have to visit their health centre in order to renew their prescriptions via an electronic prescription. A report was drawn up covering the modifications made by the various regions to their electronic prescriptions systems in order to achieve this goal.

Meanwhile, this working group collaborates in drawing up thematic and situational reports on the Spanish regions, information and consultation tools as to the regional situation, which are available to members on the FARMAINDUSTRIA website.

Trademark Protection Working Group

Trademark defence remains one of the Association's strategic focuses. During the past year this working group was essentially engaged in the task of monitoring the provisions and plans of the authorities responsible for medicines, ensuring that branded pharmaceutical dispensation and prescription conditions are maintained in accordance with the provisions of the legislation in force.

Aside from promoting articles and interviews in various media outlets, it launched an informative initiative mainly intended for social media (#LaMarcaTeCuida, or '#TheBrandCaresForYou'), using simple, everyday examples to remind patients, relatives and carers, as well as healthcare professionals, that they can request a branded medicine at a pharmacy, which will be at the same price as the corresponding generics, and that prescriptions can be issued either by trade name or by active pharmaceutical ingredient.

Incremental Innovation Working Group

This working group was set up in January 2020 with the aim of highlighting the importance of continued improvements to off-patent medicines. During the past year an action plan was defined, along with the communication strategy to inform society of the importance of incremental innovation as the result of analysis of the use of already-existing medicines, aiming to incorporate modifications or improvements that would benefit patients and the health system. This action plan aims to help make developments to known medicines feasible, and ensure that they do not suffer any negative penalisation effects from inclusion within the Reference Pricing System. Regulatory protection is required in this regard to avoid, in those cases where these medicinal presentations are of interest to the NHS, the arithmetic application of the Reference Pricing System, with the Inter-ministerial Commission for Pharmaceutical Prices establishing the marketing price in such cases.

With regard to communication, a video was produced to explain what incremental innovation is, emphasising that this type of innovation is particularly appreciated by patients and healthcare professionals because it improves both clinical practice and patients' quality of life. Various initiatives were likewise undertaken in the general and specialist media as to the importance of this type of innovation and the desirability of encouraging such developments in Spain.

20

Medical Visit Working Group

This ad hoc working group was set up with the aim of monitoring the situation with medical visits, which, as indicated in other sections of this Annual Report, were subject to an almost total restriction in the Spanish regions from mid-March 2020 onwards.

This working group has, with the support of scientific societies, professional organisations and external experts, drawn up a Safety Protocol for industry professionals to resume medical visits, which was quite favourably received by the regional authorities, and proved a key element in the progressive resumption of medical visits in Spain. The FARMAINDUSTRIA protocol was subscribed to by business associations including FENIN, BIOSIM, ASEBIO, AESEG, ANEFP, AELMHU, FARMAFLUID and AENE.

This working group currently involves 47 pharmaceutical manufacturers, continuing its efforts to monitor the situation with medical visits in the different Spanish regions, along with contact with regional figures of authority and healthcare informer and visitor associations.

Aside from closely monitoring the medical visit situation, the group is also involved in producing and validating a situational chart indicating the main regional restrictions for the staging of congresses, seminars, workshops and scientific meetings, as well as the position regarding medical visits in each region of Spain. These reports are periodically updated and are available to all members via the FARMAINDUSTRIA website.

Communication and Corporate Social Responsibility Working Group

The content of this working group is discussed in the section of this Annual Report addressing Communication.

Patients Working Group

The content of this working group is discussed in the section of this Annual Report addressing Communication.

Cybersecurity Working Group

The main aim of this working group is to serve as a forum for the IT managers of member manufacturers, so as to share problems, incidents and solutions, in particular from the perspective of cybersecurity. It also proposes the creation of channels for communication with the institutions responsible for National Cybersecurity (INCIBE, CNI/CCN, etc.) with the possibility of sectoral collaboration.

Aside from sessions focused on remote working and re-entry resulting from Covid-19, and other seminars delivered by association experts, such as the "Return to the Workplace Action Plan", single-issue presentations were also conducted during 2020, such as "Awareness-raising for Companies" and "Attacks on the CEO", delivered by INCIBE, and "Cybersecurity with R&D Equipment", supported by CCN/CNI.

BARCELONA DELEGATION

The FARMAINDUSTRIA Barcelona Delegation performs institutional representation functions for the Association in Catalunya, along with consultancy in a range of spheres for members based mainly in the region, in coordination with the various departmental areas that make up the Association. In parallel, depending on the subject matter it collaborates on the management and coordination of the various FARMAINDUSTRIA working groups.

In turn, the Delegation performs technical and logistical support functions for various FARMAINDUSTRIA Statutory Groups, including close collaboration with the National Group, performing technical Secretariat functions at its meetings, coordinating the group's own initiatives and administering information of interest for the Association's national member companies.

Lastly, the Delegation has maintained active dialogue with the public healthcare authorities in Catalunya covering a range of topics, along with various academic institutions and organisations connected with the pharmaceutical sector at the regional level, while playing an active role on the Management Council, the Mixed Delegated Committee for Catalunya and the Social and Employment Committee of FedeQuim, along with the General Assembly and a number of working commissions of Foment del Treball Nacional.



04

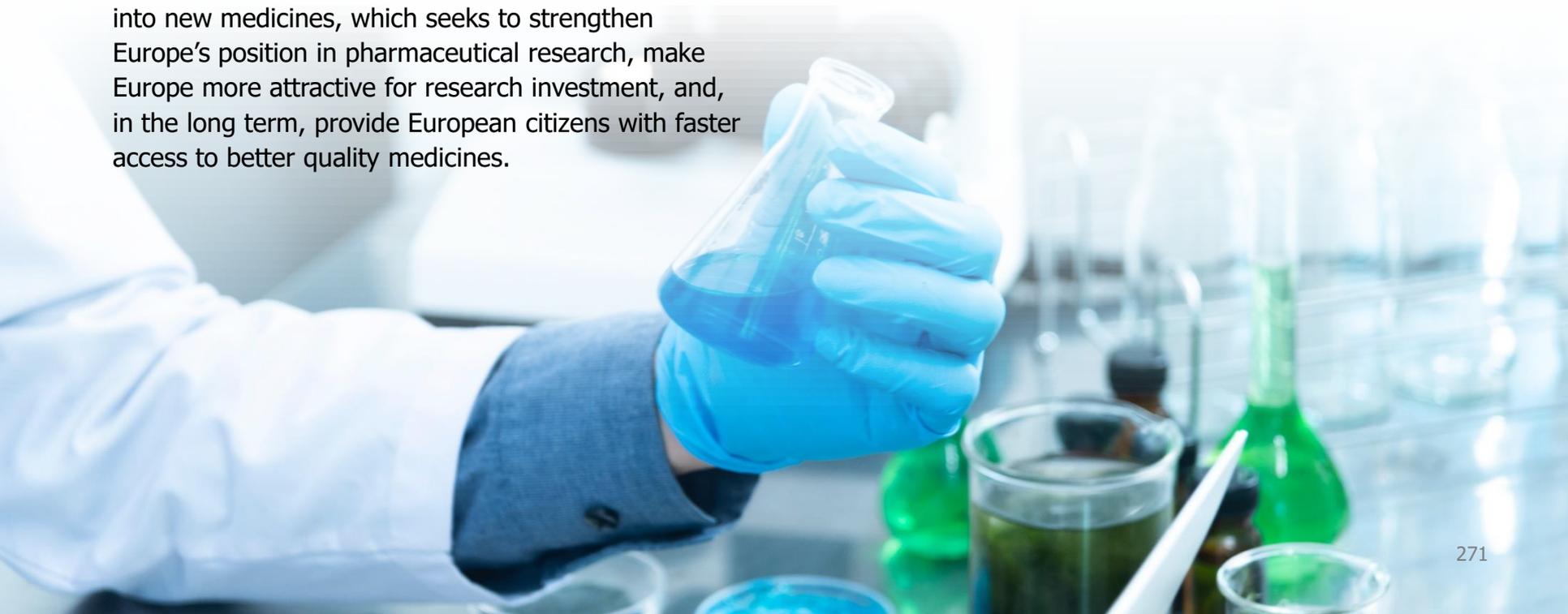
MEMBER SERVICES

- 4.1 Online Services
- 4.2 Working Groups / Barcelona Delegation
- 4.3 Spanish Technological Platform for Innovative Medicines**
- 4.4 Self-Regulation System

After running for over 15 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.

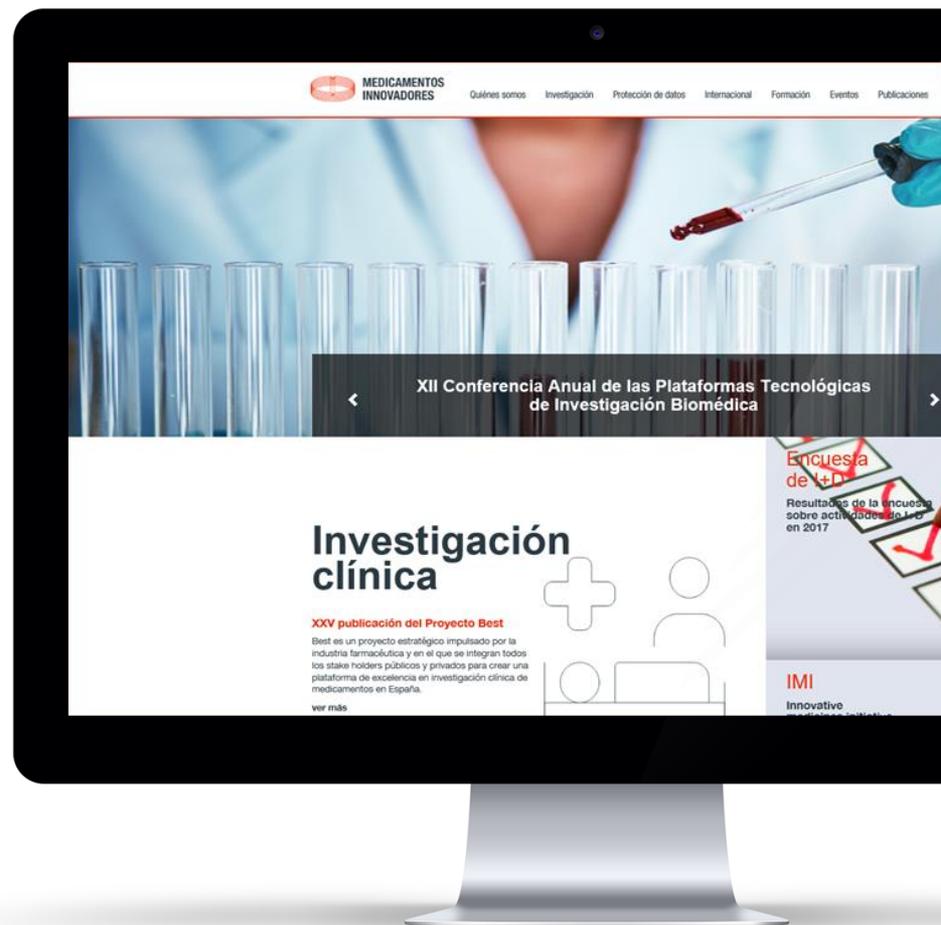
The PTEMI is the Spanish reference point for the Innovative Medicines Initiative (IMI), an initiative of EFPIA and European Commission to promote research into new medicines, which seeks to strengthen Europe's position in pharmaceutical research, make Europe more attractive for research investment, and,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

The key activities undertaken by the PTEMI in 2020 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 for excellence in clinical research of 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, likewise discussed at length in this Report.



The PTEMI performs much of its work in the field of dissemination and promotion of activities addressing all agents in the science-technology-enterprise system via the platform's website, www.medicamentos-innovadores.org, which is updated daily. A monthly newsletter is also published and sent out to the more than 2,000 people expressing an interest in PTEMI activities. 117 editions of this newsletter had been published by April 2021, covering the main news items and events of interest in biomedical research.

The traditional Annual Technological Platform Conference was to be held on 9 and 10 March 2020 in Barcelona. It was, however, suspended as a result of the Covid-19 health crisis. At the time when this Annual Report was drawn up, preparations were being finalised for the 14th Annual Technological Platform Conference, scheduled to be held online on 11 and 12 May 2021, jointly organised by FARMAINDUSTRIA, Asebio, Nanomed, Fenin and Veterindustria, under the title: "Biomedical Research: Opportunity for the Country after the Covid-19 Pandemic".



The coronavirus pandemic has revealed the importance of biomedical research worldwide. Spain was already a leading country in research of medicines, as a result of the joint efforts undertaken for years now by health authorities, hospitals, researchers, patients and the pharmaceutical industry, and remains an opportunity not only in economic sectoral terms but also in national terms. It must not be overlooked that biomedical research, together with green transition and digital transformation, represent key drivers for the future of Spanish society.

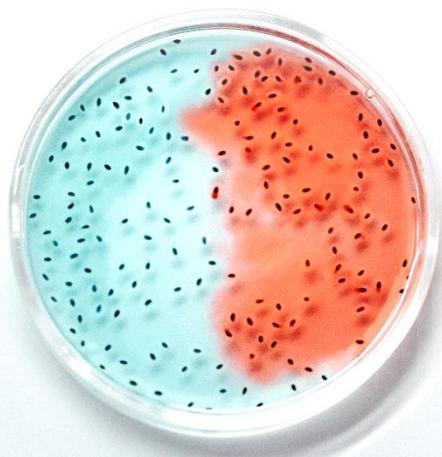
Through BEST, FARMAINDUSTRIA has been working on encouraging investment in R&D, monitoring the situation of clinical research processes in Spain, identifying different practices and adopting measures intended to improve efficiency and competitiveness. Of particular significance in this area were the various seminars, meetings and publications seen in the fields of paediatric research, clinical research at early stages, research into rare diseases, criteria of excellence to conduct clinical trials, as well as recommendations for patient participation in medicine R&D processes.



Initiatives were likewise launched to advance excellence and prove more competitive in response to the full implementation of the EU Regulation on clinical trials, since administrative issues potentially affecting clinical trial launch times often play a critical role. A sub-group has thus been set up to work on analysing a series of common clauses for clinical trial contracts, with the aim of improving harmonisation and streamlining such processes in practice.

Within this context, another sub-group has been set up to address biological samples used in clinical trials, and specifically import/export following the effective application of Brexit.

FARMAINDUSTRIA has maintained an active working approach with the AEPD and AEMPS to make progress on issues concerning remote monitoring with data source verification. FARMAINDUSTRIA thus submitted a consultation to the AEPD in May 2020 regarding remote monitoring of clinical trials, which received a favourable report from the AEPD, and this type of monitoring is therefore now a reality at a number of Spanish hospitals - which unquestionably represents progress in clinical trial control processes.



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 Economic Affairs and Digital Transformation, with the mission of serving as an instrument to create a coordinated structure within Spain covering the different stages of the early discovery of medicines, seeking out added value at each stage and reducing the risk intrinsic to this type of activity, with an innovative approach that is more aligned with the demands of the pharmaceutical and biotech industry, streamlining the process of discovering new medicines.

In 2020 REDEFAR, together with the ES-OPENSOURCE Strategic Network, set up the CO-SYNERGIES initiative, which aims to combine capacities to achieve progress in the fight against Covid-19. The aim of the initiative is to facilitate generational networking and the structuring of programmes for Covid-19 in Spain and to create complementary initiatives generating synergies in projects to discover medicines to combat the pandemic.

Given the importance of pre-clinical research, the PTEMI is intended to continue this line of collaboration and to participate in meetings with different organisations. During 2020 a line of collaboration was begun with the CSIC, enabling the organisation of a Pharma-Biotech cooperation meeting with CSIC research groups in late April 2021.

In the field of the interrelationship with patient groups, extensive work has been performed in the areas described in the document of recommendations for integrating participation by patients and patients' associations in the process of pharmaceutical R&D. The document may be summarised in terms of eight main areas:

- 1 Identification of needs not covered 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.



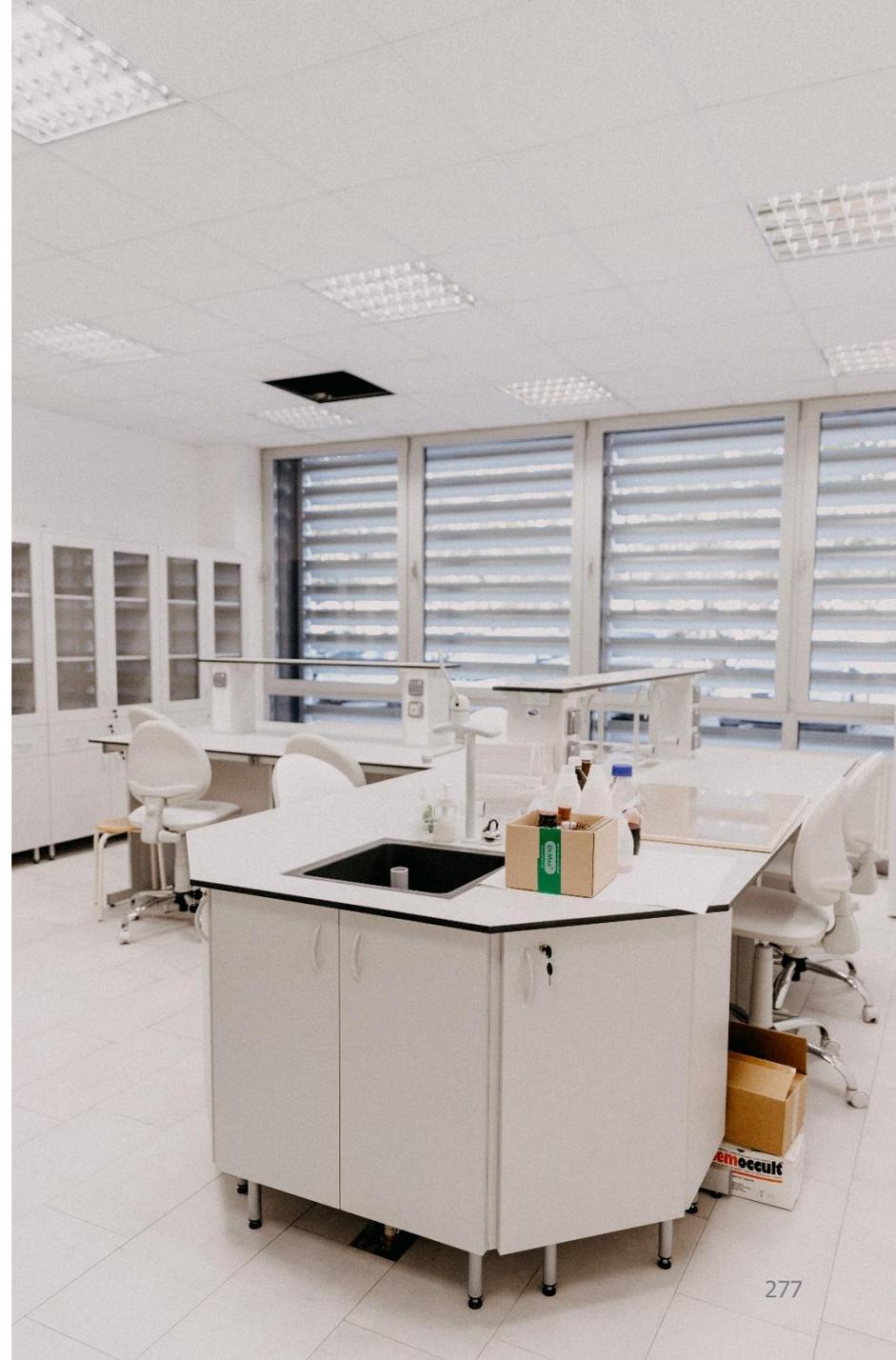
Meanwhile, over recent months a working group was set up to adapt these recommendations to the paediatric population. It involves the Sant Joan de Dèu Hospital and the Kids Barcelona Group, with representatives from Reclip, the Spanish Paediatrics Association, and FARMAINDUSTRIA member companies. The aim is to draw up a set of recommendations shared by the different agents to guarantee a pharmaceutical R&D process focused on paediatric patients and relying on close collaboration with the patients themselves. This is expected to be completed and published in the second half of 2021.

Along similar lines, numerous seminars have been organised and publicised in the field of patient participation in the development of medicines, in particular in paediatric research and rare diseases, as well as the lessons learned regarding Covid-19, with the goal of advancing the digital transformation of clinical trial processes and improving efficiency.

Work was also performed on a new Code of Conduct for Data Protection in Clinical Research and Pharmacovigilance, in accordance with the Spanish Law on Personal Data Protection and Guarantee of Digital Rights. The new Code interprets the law in accordance with the General Data Protection Regulations with regard to:

- 1 Data processing in biomedical research.
- 2 Extensive consent.
- 3 Reuse.
- 4 Legal basis for processing of personal data connected with the clinical trial within the protocol, or uses outside the protocol.

This Code provides a response to the demands of the AEPD in terms of penalties and active responsibility as required by the Regulation. The Code was presented to the AEPD in late December 2020, and is currently being assessed by the regulator.



Furthermore, during 2020 the PTEMI was heavily involved in different national and international forums as to the promotion of biomedical R&D, and organised specific workshops and seminars addressing issues of interest for agents in the sectoral science-technology-enterprise system, including in particular:

1 Digital challenges in the management of clinical trials. The Covid-19 crisis has highlighted the importance of the digital transformation of the health sector, in terms of both healthcare and medical research. Within this sphere, remote monitoring with source data verification has played a vital role, with FARMAINDUSTRIA working together with the AEPD and AEMPS to ensure that such monitoring can be undertaken with full guarantees for patients.

2 Webinar on clinical trials, lessons learnt through the Covid-19 pandemic. FARMAINDUSTRIA organised a webinar with the aim of sharing lessons learned from the Covid-19 pandemic in the sphere of clinical trials. We would emphasise not only the measures adopted by the AEMPS to maintain, as far as possible, trial activities under progress, but also actions by the AEMPS and CEIm to streamline and facilitate clinical trials conducted to deal with coronavirus. A key role was played in the launch of all such measures by researchers, hospital pharmacies, patients, research managers and the pharmaceutical industry.



3 Training of baccalaureate students: "Bringing Science into Schools" programme. Since 2016, in collaboration with the Jiménez Díaz Foundation, Sant Joan de Dèu Hospital and the Málaga Maternity and Infant Hospital, alongside the IBIMA (Málaga Biomedical Research Institute), activities have been conducted to explain medicinal R&D to baccalaureate students. These training days were held in the months of November and December in online format, focusing on the R&D of new Covid-19 vaccines, with more than 1,500 baccalaureate students taking part. The information conveyed through these activities addresses the full extent of the R&D process for new medicines: from the identification of therapeutic targets and animal experimentation to pharmacovigilance, through clinical trial stages, lead times and the required investment. Mention is also made of the need for public-private partnership so as successfully to conclude such research initiatives.



With regard to the work plan for 2021, provision has been made for the continuation of a number of the lines of work that have already begun:

- 1 Implementation of European legislation and improvement of procedures.
- 2 Dissemination of the guidelines 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 groups in the process of biopharmaceutical R&D.
- 6 Promotion of the Spanish participation in calls under the Horizon Europe programme, and in particular the Innovative Health Initiative (formerly the Innovative Medicines Initiative).
- 7 Active participation at forums, seminars and workshops to consolidate Spain as one of the leading nodes to attract international biomedical innovation projects.



Ever since the PTEMI was founded, the Coordination Committee has met on a yearly basis to develop the strategic operational approaches of the Platform, suggesting the periodic action plan and monitoring and overseeing the scheduled initiatives.

The last meeting of the PTEMI Coordination Committee (November 2020) conducted an in-depth review of the Platform's activities in the field of pre-clinical and clinical research, big data, internationalisation and dissemination initiatives. There was also a debate as to the main topics of the Annual Biomedical Research Platform Conference.

The PTEMI stands out for its open nature, allowing access to all interested organisations, through open registration via the Platform website.



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MEMBER SERVICES

- 4.1 Online Services
- 4.2 Working Groups / Barcelona Delegation
- 4.3 Spanish Technological Platform for Innovative Medicines
- 4.4 Self-Regulation System**

SELF-REGULATION SYSTEM, SPANISH PHARMACEUTICAL INDUSTRY

The pandemic caused by Covid-19 has had a very significant impact on the volume of interactions carried out by pharmaceutical companies with their main stakeholders:

- Healthcare professionals, healthcare organisations.
- Patient organisations

During 2020 there has been a notable decrease in the number of activities analyzed by the Code of Practice Surveillance Unit under the three communication procedures provided for in the Code of Practice:

- 1 Scientific and professional meetings.
- 2 Market research studies.
- 3 Services provided by healthcare professionals or healthcare organisations.



Notwithstanding the effects caused by the aforementioned health crisis on the activities and collaborations carried out by pharmaceutical companies, the Code of Practice Surveillance Unit has continued to carry out the functions and powers entrusted to it as normal as one of the control bodies of the Self-Regulation System of the Pharmaceutical Industry, adapting to virtual environments and formats when necessary. As proof of this, it is worth highlighting, on the one hand, the strict compliance with the transparency obligations set forth in article 18 of the Code, and on the other hand, the updating, improvement, and approval of a new version of the Code of Practices, ratified in the Association's Assembly held in October 2020.

In terms of transparency, for the fifth consecutive year, pharmaceutical companies published the transfers of value to healthcare professionals and organizations (the third year in which transfers of value to healthcare professionals are published individually¹). As in previous years, a survey was sent to the pharmaceutical companies beforehand to know sufficiently in advance the information that would be published. This measure made it possible to update and prepare in advance a Communication and Contingency Plan for the publication of the data.

Once again, considering the consistency of the data, in 2020 the media have welcomed with normality, neutrality, recognition and even positively, the transparency initiative taken by the pharmaceutical industry. Comparing the amounts published in June 2020 (relating to transfers of value made in 2019) with those published in June 2019 (relating to transfers of value in 2018), no significant differences are observed.

The continuity and consistency of the data published over the last five years consolidates the existing model in Spain for the interrelationship between the pharmaceutical industry and healthcare professionals and organisations, based essentially on principles of trust, integrity, respect, legality, prevention and transparency.

¹ Spain is the only country in the European Union that, by virtue of a Self-Regulatory System, publishes this information on an individual basis.

Regarding the new version of the Code of Practice (Code 2021), in force as of January 1st, 2021, it should be noted that it incorporates the following new features and improvements:

- 1 Reference to the principles and values that govern the Industry Self-Regulation System.
- 2 A new Annex III that includes recommendations on information activities on prescription-only medicines and relations with the media.
- 3 Clarifies and qualifies the responsibility of pharmaceutical companies in the digital environment and in the use of social networks.
- 4 Establishes additional criteria and guidelines for action applicable in relation to services provided by healthcare professionals or healthcare organizations (new Annex IV).
- 5 Harmonises certain activities or practices in the area of interaction with patient organizations.
- 6 Updates the procedures for communicating meetings, market research studies and services.
- 7 Revises the Queries (questions and answers) document, on the interpretation of the Code of Practice (questions and answers), specifically incorporating six new questions and reformulating seven (Annex V).

The approval of this new version of the Code would not have been possible without the collaboration of the pharmaceutical companies, especially those that form part of the Code Strategic Committee, the Code of Practice Working Group (WG-COD) and the Communication Working Group (WG-COM). More detailed information on the purpose and functions of each of these subgroups is provided in the section of the report dedicated to the working groups.

Finally, with the approval and entry into force of this new version, FARMAINDUSTRIA, as a National Association member of EFPIA, fulfills its ongoing commitment to adapt and transpose its national code to the new developments approved at European level.



ACTIONS OF THE CODE OF PRACTICE SURVEILLANCE UNIT

In relation to the dissemination of our Self-Regulation System, the following activities, among others, should be highlighted:

- Participation in multiple meetings with the working groups concerned with the aim of updating and approving a new version of the Code (Code 2021): Code Strategic Committee (ComEst); group of Compliance officers of ComEst member companies; and FARMAINDUSTRIA Code of Practice WG, Communication WG, Governing Council, Board of Directors and group of Vice Presidents.
- Collaboration and participation in the different FARMAINDUSTRIA working groups to analyze issues related to the Code of Practice
- Meetings with companies to monitor and support transparency projects.
- Meetings with the Health Departments of the Spanish Regions to address issues related to both the transparency initiative and the Self-Regulation System in general
- Meetings with Scientific Societies to share the initiative to update the Code and analyze their possible proposals.
- The delivery of training sessions specifically designed to respond to the needs and demands of the companies ("in-company training").
- Collaboration in the delivery of training sessions related to the Code within the framework of courses, doctorates, and specialized masters.
- Active participation in the EFPIA working groups responsible for ensuring the transposition and implementation of the approved standards into the codes applicable in each national association.
- Active member of the Codes Committee (Chair), of the Strategic Committee, of the Ethics & Compliance Committee (Vice-Chair), of the Medical Education Working Group, and of the Validation Team (e4ethics) of EFPIA.

- Management of the e4ethics platform on behalf of EFPIA (until December 2020) and collaboration and support in the transfer of the management of this platform for its operation through the MedTech platform.
- Continued collaboration with IFPMA: Chair of the Appeal Group of the IFPMA Code complaints procedure (Appeal Group), participation in the "Patient Centricity", "Code Training", "Innovation Models", "New Technologies", "Responsible Interaction with Key Stakeholders", and of "Scientific Meetings and Congresses" working groups.
- Active participation in meetings for the development of guidance guidelines on "service provision", "interaction with patients", "virtual interactions with healthcare professionals (on topics such as sponsorship and collaboration in congresses, hospitality limitations, etc.) motivated by the pandemic situation" (IFPMA; EFPIA and PHARMA).
- Interactions with patient organizations to ensure that companies comply with the commitment to provide updated information regarding the collaborations carried out during 2019 (available through www.codigofarmaindustria.es).



ADVICE AND COLLABORATION

The Unit has maintained its collaboration and assistance tasks through:

- 1 Reviewing, adapting and improving the internal procedures implemented by pharmaceutical companies to ensure compliance with both the Code and the regulations applicable to the promotion of medicines.
- 2 Permanent and continuous support to pharmaceutical companies and third parties involved, mainly scientific societies, technical secretariats and service providers in general.
- 3 Active participation in meetings and forums organized by FARMAINDUSTRIA, attendance at international meetings and forums organized by EFPIA and IFPMA, with the Code of Practice Surveillance Unit remaining an active member of the aforementioned groups.

This work has been particularly intense and relevant in view of the multitude of collaboration initiatives that have arisen as a result of the health crisis and the virtual or telematic nature of many of the interactions derived from them.

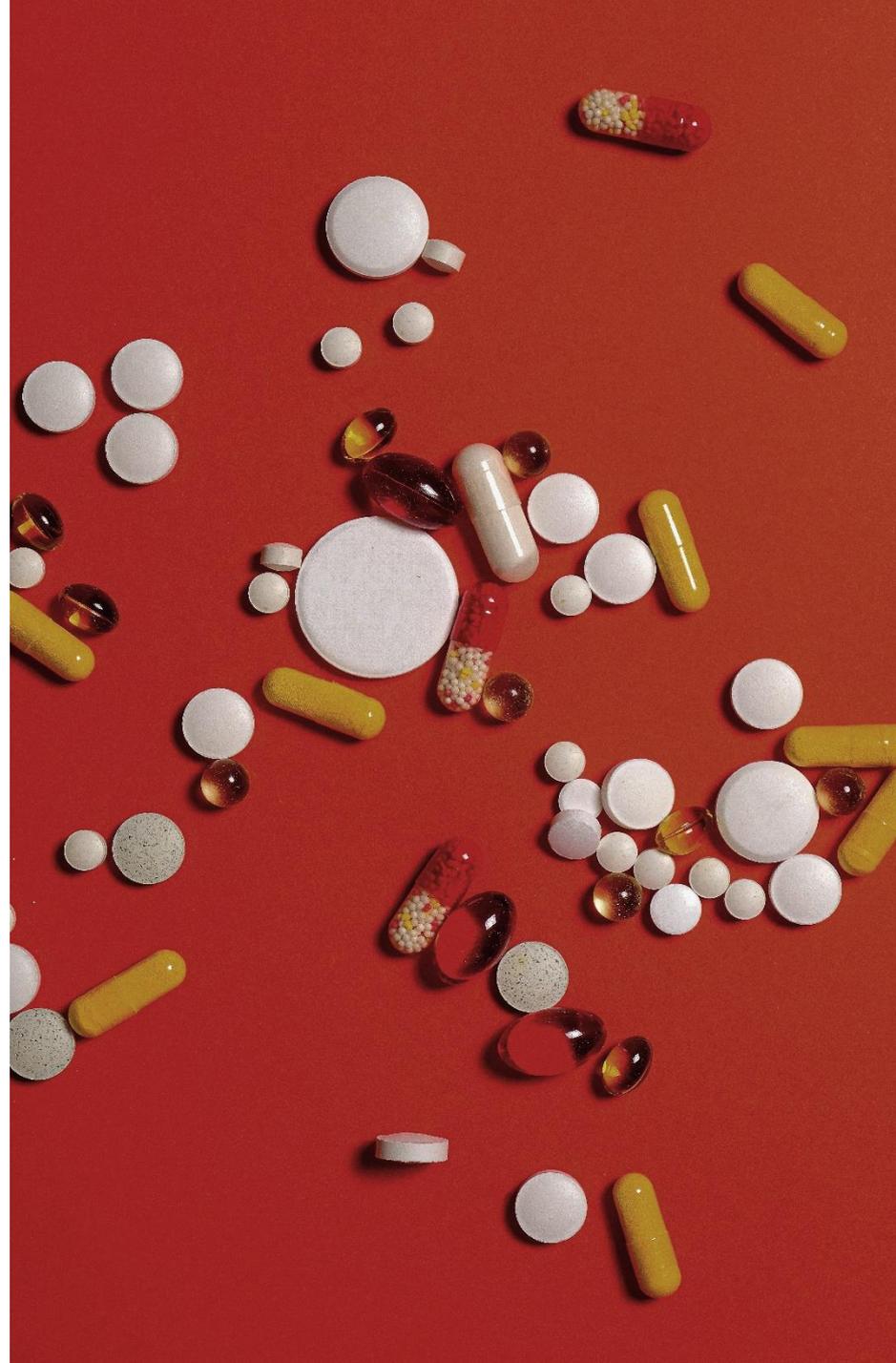
Furthermore, the evolutionary maintenance of the Unit's management software, the updating of the Self-Regulation System website, as well as the monitoring, adaptation and improvement of the internal communication procedures for meetings, market research studies and services have also been carried out.

During 2020, 10 circulars related to the Code of Practice and the Self-Regulation System of the Pharmaceutical Industry were published.

CONTROL AND PREVENTION

The number of preventive actions carried out was 771 (which represents a decrease of more than 50% with respect to the 1,633 carried out in the previous year).

The total number of complaints issued at the initiative of the Unit was four, motivated by activities or practices that allegedly infringed the provisions of the Code regarding: "Information on medicines to be made available" (Article 2), "Transparency in the promotion of medicines" (Article 5), "Distribution of promotional material for medicines" (Article 7), "Digital environment" (Article 8), "Guarantees of Independence" (Article 10) and "Scientific and professional meetings" (Article 11). In two of them, a Mediation Agreement was reached before the Code of Practice Committee and the other two were filed at the request of the USD itself.



In 2020 the number of scientific-professional meetings analyzed and verified was 1,452 (2,432 less than in 2019). In percentage terms, the level of adequacy of the meetings was 90.98% (compared to 97.12% in 2019). In line with the above, it should be noted that a significant percentage of the meetings initially analyzed had to be revised on different occasions due to the unstable situation resulting from the pandemic, which led to postponements, cancellations and, in several cases, their holding in a "virtual" format.

The adaptation, revision and continuous improvement of the USD management procedures and tools provided the companies with a better response to the situation of uncertainty experienced at that time, and the participation and

attendance of USD representatives in scientific-professional meetings held in virtual format, from which a large number of preventive actions and proposals for improvement were derived, aimed at both the pharmaceutical companies and those responsible for their organization, in order to adapt them to the Code and to the new existing reality.

Likewise, there has been a decrease both in the number of market research studies analysed, which has reached 285 (25 less than in 2019), and in the number of services analysed, 303 (70 less than in 2019). In both activities, the level of adequacy remains practically constant in percentage terms, reaching 96.49% in the case of studies (compared to 96.77% in 2019) and 94.06% in the case of services (compared to 94.91% in 2019).

1,452

Scientific-professional meetings analysed and verified

91%

Level of compliance

285

Market research studies analysed

303

Projects analysed

EFPIA'S "e4ethics PLATFORM"

The health crisis caused by COVID-19 resulted in a notable decrease in the number of scientific-professional meetings held during 2020. Many of the planned meetings were cancelled or postponed and others were finally able to be held under a virtual or telematic format.

Given this situation, the review and analysis work carried out through the e4ethics platform was reduced to a total of 84 meetings across Europe (representing 45% less than the number of meetings analysed during 2019), with no need to warn pharmaceutical companies of the existence of elements contrary to the applicable codes in 49 of them (representing 58% adequacy).

For 20 scientific-professional meetings, it was not possible to issue an assessment, as they were postponed to 2021 and even 2022.

As of January 1, 2021, the platform for evaluating scientific-professional meetings launched by EFPIA in 2010 (www.efpia-e4ethics.eu) will be integrated into the Meeting Verification System launched by the European Association of Healthcare Technology Companies MedTech in 2012 (www.ethicalmedtech.eu). In addition to generating efficiencies based on accumulated experience, this initiative aims at consistency and harmonization of criteria within the healthcare industry for the benefit of the different stakeholders concerned.

Since that date and as a consequence of this integration, Farmaindustria has ceased to be part of the Validation Team and to carry out the reviews on behalf of EFPIA. For more information: <http://www.codigofarmaindustria.org>

		USD ACTIVITY (1 January to 31 December 2020)																	
		2004 Apr-Dec	2005	2006	2007	2008	2009 (a)	2010	2011 (b)	2012	2013	2014	2015	2016	2017	2018	2019	2020	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	1,452	66,347
	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	1,321	60,136
	% 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 %	90.98 %	90.64 %
STUDIES (a)	ANALYSED						687	724	626	512	400	449	300	317	293	262	310	285	5,165
	No incidents						397	546	565	416	332	368	251	280	271	249	300	275	4,250
	% Compliance						57.79 %	75.41 %	90.26 %	81.25 %	83.00 %	81.96 %	83.67 %	88.33 %	92.49 %	95.04 %	96.77 %	96.49 %	82.28 %
SERVICES (b)	ANALYSED								357	330	306	350	368	363	364	290	373	303	3,404
	No incidents								282	272	230	292	301	274	321	270	354	285	2,881
	% Compliance								78.99 %	82.42 %	75.16 %	83.43 %	81.79 %	75.48 %	88.19 %	93.10 %	94.91 %	94.06 %	84.64 %
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	771	33,798
USD COMPLAINTS		18	11	9	18	8	12	4	3	1	9	7	7	2	3	3	3	4	122

Note: The above table summarizes the Unit's data (annual and cumulative) from the beginning of its activity until 12/31/2020

(a) System for Communicating Studies approved under the 2008 Code

(b) System for Communicating Services approved under the 2010 Code

7 Cases resolved in the Courts

6 Binding decisions by the Self-Regulation Jury in favour of the USD

90 Resolved by mediation before the Ethics Commission, acknowledging the infraction and accepting corrective measures

15 Shelved at the request of the USD

2 Not upheld by the Self-Regulation Jury

2 Under evaluation by the Professional Ethics Commission

ACTIONS BY THE PROFESSIONAL ETHICS COMMITTEE

As with all other activities, the pandemic shaped the operations of the Professional Ethics Committee, since following the declaration of the state of emergency all in-person meetings were suspended, to be replaced with remote meetings via technological platforms.

This circumstance furthermore meant that the Professional Ethics Committee, in line with the measures adopted by Royal Decree 463/2020, ruled on 23 March 2020 to suspend the deadlines established for the complaints procedure as set out in Article 32 of the Code, to be resumed once Royal Decree 463/2020, or any extensions to it, ceased to have effect.

Nonetheless, this measure did not in any way mean the suspension of efforts by the Professional Ethics Committee, which instead continued to fulfil the functions entrusted to it, and strictly complied with the calendar of meetings scheduled for 2020.

Meanwhile, in the month of March the Self-regulatory Jury informed the Secretariat of the Professional Ethics Committee of its Contingency Plan to address the situation caused by coronavirus, under the terms of which - both with regard to complaints in progress and any new complaints that might be received - those that could be communicated and processed as urgent matters would be resolved. All others would be handled as soon as the contingency period ended. In the case of oral hearings that had already been requested, or any that might subsequently be requested, the Jury offered the possibility of either not holding the oral hearing (with the case being passed on to the Jury for a decision), or otherwise to maintain the oral hearing once the contingency plan had been deactivated.

Subsequently, in the month of May when the Professional Ethics Committee had adapted the procedure for remote digital cases, it was again decided to process any new cases received on a normal basis, in addition to any previous cases that had not been processed during the state of emergency. It was likewise decided that for as long as social distancing recommendations were maintained, in order effectively to conduct the mediation phase indicated in Article 32.3 of the Code, the Secretariat of the Professional Ethics Committee would formally call on the parties to appear at a mediation meeting at least two business days in advance, via remote means. This situation remains in place up until this Annual Report was drawn up.

In line with the above, the Self-regulatory Executive Board ruled in the month of May that new cases would be handled as normal, along with any prior cases that were not processed during the state of emergency through application of the contingency plan, with remote means being used to consider and rule on these cases, for as long as the authorities maintained social distancing recommendations.

Another of the consequences of the health crisis, the declaration of the state of emergency and the corresponding limitation on free movement, was to restrict the possibility of conducting medical congresses, as well as medical visits. With regard to medical congresses, these restrictions were recommended by the Ministry of Health even before the state of emergency was declared. As for medical visits, many of the Spanish regions issued instructions to suspend such visits in general at healthcare establishments.

These circumstances led to a proliferation of virtual medical congresses conducted online, using various digital platforms. These congresses are characterised by the possibility of taking part by means of a profile, which may or may not be associated with a person, allowing interaction on various forums, chats, or even commercial presentations. Given this circumstance, the USD included a new events classification on its third-party events website for such virtual medical congresses.

FARMAINDUSTRIA has been working throughout 2020 and 2021 to ensure that company sales networks can gradually resume normal operations, with medical visits to healthcare establishments once again being permitted as soon as public health circumstances so allow, drawing up a Protocol for this purpose in collaboration with medical organisations and other associations. Work has likewise been performed to ensure that, when circumstances so allow and full guarantees are available for participants, scientific meetings and congresses can once again be held and attended by healthcare professionals.



In 2020 the Professional Ethics Committee held a total of 11 meetings. However, even though mediation meetings continued to be held, agreements continued to be reached and the Self-regulatory Jury continued to be presented with those cases where a reconciliation agreement could be reached, the number of complaints of cases received fell considerably, with the reasons for such complaints notably being restrictions on medical visits and restrictions on the staging of congresses, as established by the various public authorities.

As for the mediation cases, in 2020 five grievances were filed with the Professional Ethics Committee, and these were processed in accordance with the ordinary procedure set out in Article 32.2 of the Code. The following layout summarises the grievances, grouped according to the different classification criteria.

TOTAL	5
PROFESSIONAL ETHICS COMMISSION	5
Case Shelved	2
Commission Mediation	2
<i>Agreement + contribution</i>	2
Self-Regulation Jury	1
<i>Economic sanctions</i>	1
PLAINTIFFS	
USD	80 %
Member companies	20 %
DEFENDANTS	
Member companies	100 %
CONTRIBUTION AGREEMENTS	
1 of €6,000	
1 of € 10,000	
SELF-REGULATORY PENALTIES	
1 of € 30,000	

In addition to the above, during 2020 other matters of interest were discussed involving the Professional Ethics Committee, including in particular the update to the Code of Good Practice, which took effect on 1 January 2021, as a result of the efforts by the USD and an expert committee representing member companies, with this procedure involving the participation of the Secretariat of the Professional Ethics Committee.

Lastly, the USD has been informing the Professional Ethics Committee of its activities in 2020 and 2021.

CODE OF CONDUCT FOR DATA PROTECTION IN CLINICAL RESEARCH AND PHARMACOVIGILANCE

Following the informal presentation to the Spanish Data Protection Agency (AEPD) in December 2019 of the draft Code of Conduct governing the processing of personal data within the context of clinical trials and other clinical research and pharmacovigilance, meetings were held over the course of 2020 by the ad hoc working groups responsible for the efforts to adapt the new Code of Conduct in line with the applicable regulatory framework, with the support of an external consultant specialising in data protection.

These meetings essentially focused on responding to and explaining those matters which, following the demand received from the AEPD in July 2020, would need to be updated and adapted in line with the guidelines of the European Data Protection Committee and the accreditation criteria of supervisory bodies, among other aspects, and subsequently published following the informal presentation of the Code of Conduct in December 2019.

Specifically within the context of clinical research, efforts were made to clarify aspects such as, on the one hand, the legal basis for the processing of personal data, as this is not limited exclusively to consent, on the basis of the provisions of Article 6.1(c) in connection with the terms of Article 9.2(i) and (j) of the European General Data Protection Regulation; and on the other, clarification of the centre and sponsor's responsibilities as the respective data controllers. The sponsor determines the criteria for participants whose encoded data must be included in the data record books for the clinical research, while the centre (and/or the main researcher, where relevant) is the data controller of clinical research participants' data, the aim being to provide appropriate healthcare to those within the context and course of research.

In terms of pharmacovigilance, data processing is mainly conducted with personal data – although there are certain exceptions – and efforts were focused on clarifying the legal basis for processing, processes for collecting data via social media, and describing the coding process and methodology employed.

Likewise, as detailed previously, following on from publication by the AEPD of the accreditation criteria for supervisory bodies, certain points were refined in the subsection of the Code of Conduct regarding governance, with reference to the governing body in terms of its composition and support personnel.

Following completion of this work, a version of the Code of Conduct was then presented in December 2020, which is currently being assessed by the AEPD, thereby fulfilling the demand served on 29 June 2020.



05

ANNEX I

SIGRE Medicines and Environment

A PHARMACEUTICAL INDUSTRY TOOL TO CARE FOR HEALTH AND THE ENVIRONMENT

The crisis caused by the Covid-19 pandemic redoubled the importance of the duality of health and environment in order to guarantee the future of the planet and its population.

Within this context, particular importance should be given to the creation and launch of SIGRE almost 20 years ago, when the pharmaceutical industry voluntarily decided that this non-profit entity should take responsibility not only for the management of packaging, as required by law, but also any surplus medicines that the general public might have at home, in order to process them in an environmentally-appropriate manner.

Through its participation in SIGRE, the pharmaceutical industry actively helps to reinforce environmental aspects connected with the medicine life-cycle, from the eco-design of the packaging of such an essential product for our health, to management of the waste generated by consumption. SIGRE serves to guarantee the control of such waste, avoiding any harm to personal health and the environment.



The largest collaborative project in the pharmaceutical sector

One of the fundamental elements of the SIGRE management model is to generate trust and credibility among all stakeholders, as an essential aspect in creating shared value, both for the pharmaceutical sector and for society as a whole.

The value of collaboration is one of the hallmarks of SIGRE, an initiative which has over the years become the largest collaborative project undertaken by the pharmaceutical sector in Spain, making it an exemplary international flagship initiative. SIGRE receives the support and collaboration of pharmaceutical manufacturers, distributors and pharmacies.



Committed to our environment

Behind every medicine there lies a major industrial sector committed to people's health, innovation, and the sustainability of the healthcare system. A commitment which goes hand-in-hand with concern for protecting the natural world, since health and the environment are intrinsically connected. In fact, the WHO calculates that some 24% of the global level of morbidity and 23% of mortality is attributable to environmental factors. SIGRE's operations therefore pursue a twofold aim:

1 Environmental: prevent surplus medicines and packaging from being thrown into the rubbish or down the drain, with the corresponding risk of polluting rivers, aquifers and the environment in general.

2 Social and healthcare: assist in removing any surplus from completed treatments from homes, as well as medicines that have expired or are in poor condition, so as to avoid accidents and uncontrolled self-medication, thereby encouraging more responsible use of medicines.



Particular mention should be made in this regard of SIGRE's contribution to fighting antibiotic resistance, one of the leading healthcare risks worldwide. The 2019-2021 National Antibiotic Resistance Plan coordinated by the AEMPS includes strategies to be adopted in order to help avoid bacterial resistance, emphasising the importance of using a SIGRE Point to dispose of surplus antibiotics and packaging when the treatment is completed.

In order to achieve these aims, SIGRE works in three operational fields serving to comply with the provisions of environmental and healthcare legislation:

1 Protection of packaging. As the organisation responsible for generating the Business Prevention Plan for pharmaceutical packaging, SIGRE provides consultancy for pharmaceutical manufacturers to ensure that the packaging of their medicines is increasingly ecological and sustainable, overcoming numerous technical, administrative, legal and economic issues resulting from any modification of pharmaceutical packaging.

2 Responsible waste management. The closed reverse logistics system implemented by SIGRE serves to keep waste medicines and packaging under the control of the pharmaceutical channel, until they are handed over to the corresponding authorised waste managers. This entails a series of social and health benefits (avoiding accidents, theft, unlawful trade and counterfeiting) as well as environmental benefits (reduced environmental impact associated with waste transportation). Similarly, the application of artificial intelligence and robotics in waste classification and separation is allowing SIGRE to improve recovery and recycling percentages, helping to advance the circular economy.

3 Environmental awareness-raising. SIGRE conducts initiatives to raise social awareness as to the need for responsible use of pharmaceuticals and the importance of properly closing the medicine life-cycle by using the SIGRE Point at a pharmacy.



COMMITTED TO QUALITY AND CONTINUOUS IMPROVEMENT

In 2020, SIGRE successfully completed the follow-up audit for its four-fold certification for Quality Management (ISO 9001:2015), Environmental Management (ISO 14001:2015), Energy (ISO 50001:2011) and Health and Safety at Work (OHSAS 18001:2007).

At a time when waste management of medicines of household origin via the pharmacy SIGRE Point was declared an essential service during the health crisis, these certifications awarded by AENOR provide accreditation of compliance with the requirements established in the corresponding international standards, demonstrating the organisation's commitment to continuous improvement, correct management of environmental impacts, energy efficiency and the minimisation of occupational risks associated with its activity.

CAN I TAKE SURPLUS MEDICINES TO THE SIGRE POINT DURING THE STATE OF EMERGENCY?



IF YOU DO NOT NEED TO GO TO THE PHARMACY.
NO

We advise the population to stay at home, and only during this period, to **keep** surplus medicines and packaging until the State of Emergency has ended.



IF IT IS **ESSENTIAL** FOR YOU TO GO TO THE PHARMACY.
YES

You should only take empty packaging or surplus medicines to the SIGRE Point if it is **essential for you to go to the pharmacy.**



IF YOU HAVE TESTED **POSITIVE** FOR CORONAVIRUS OR HAVE BEEN IN QUARANTINE.
NO

In the homes of people who have tested positive for Covid-19 or are in quarantine, **such waste must be placed** in the bag for **remainder or rejected waste** (black bag).



AENOR	AENOR	AENOR	AENOR
HEALTH AND SAFETY AT WORK	QUALITY MANAGEMENT	ENVIRONMENTAL MANAGEMENT PLAN	ENERGY MANAGEMENT
OHSAS 18001	ISO 9001	ISO 14001	ISO 50001

THE CONTRIBUTION OF THE PHARMACEUTICAL INDUSTRY TO THE SDGs THROUGH SIGRE

Over the last two decades, the pharmaceutical industry has, through its involvement in SIGRE, contributed to the fulfilment of various Sustainable Development Goals (SDGs) linked to public health and the environment.

In this regard, the recent commemoration of the 5th Anniversary of the SDGs provided the pharmaceutical sector with a new opportunity to work in close collaboration with the Spanish Global Compact Network (REPM), contributing to the ripple effect of familiarity with the SDGs.

Contribution by SIGRE to the SDGs Operations are aligned with the eight highlighted SDGs



The pharmaceutical sector's commitment to sustainability led the SIGRE campaign "*Medicinal Packaging, an Ally for Your Health*" to be recognised as "good practice" by the REPM. The campaign served to inform the general public as to the meaning of the most common symbols, abbreviations and designations found on medicinal packaging and product information leaflets.

Other SIGRE good practices acknowledged by the REPM include the ecoFARMACIA website, thanks to its contribution to SDG 3 Health and Well-being; the publication of the 5th Eco-design Initiatives Catalogue and Practical and Technical Guide in this sphere, thanks to the contribution to SDG 12 Responsible Production and Consumption, and the reverse logistics applied by pharmaceutical distributors to remove waste from SIGRE Points, through the contribution to SDG 13 Climate Action.

Under this SDG 13, with the aim of reducing greenhouse gas emissions at its central offices and contributing to environmental sustainability, SIGRE has renewed its entry in the Register of carbon footprints, compensation and CO2 capture projects of the Ministry for Ecological Transition and Demographic Challenge, earning the Carbon Footprint Calculation Seal.



SIGRE, AN INTERNATIONAL FLAGSHIP

SIGRE currently chairs the RIPPM (Ibero-American Network of Medicine Post-Consumption Programmes), an organisation set up to facilitate the exchange of experiences among Ibero-American countries.

In 2020 the 1st Forum of the Medicine Post-Consumption Platform was held, as a gathering set up by the RIPPM to promote the creation of post-consumption programmes and to organise activities fostering an understanding of best practice in the handling of expired or unused medicines, so as to ensure that such waste receives proper environmental treatment, and to combat counterfeiting and unlawful use of pharmaceuticals.

During the year, SIGRE was also involved in various international conferences, such as the 2E-International Circular Economy Vision Mission, organised by the Blue Point Corporation of Colombia, and the International Medicines Reverse Logistics Forum organised by the Brazil Health Service, involving international logistics and sustainability experts from the healthcare, environmental and high-tech sectors.

SIGRE also worked with the OECD on a project intended to study the environmental management of expired or disused medicinal waste.

Meanwhile, SIGRE has through the AEMPS contributed to the European Commission project to gather information as to best practice in the management of waste medicines, so as to establish recommendations for all countries.



1st Medicine Post-Consumption Platform



TRAINING FOR MEMBER COMPANIES

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 January 2020, Madrid and Barcelona both played host to new training days involving almost a hundred representatives of the pharmaceutical manufacturers which belong to SIGRE. These sessions allowed pharmaceutical companies to review the information that they must provide to SIGRE with regard to products marketed, as well as the packaging used for this purpose, in fulfilment of the packaging regulations in force.





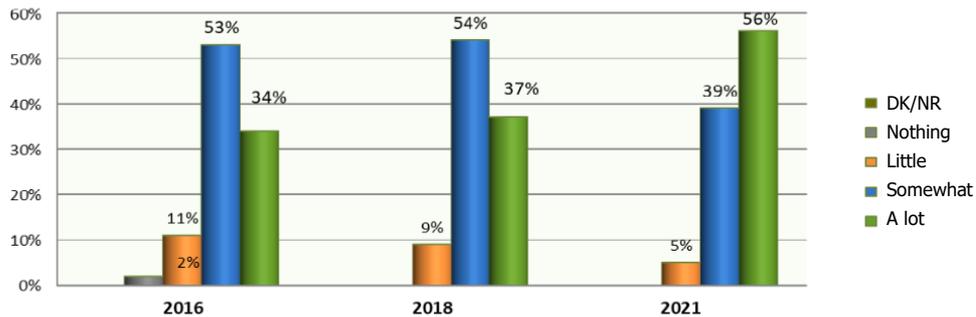
OPINION SURVEYS

SIGRE conducts a periodic opinion survey among the environmental managers of pharmaceutical manufacturers to assess their level of satisfaction with how the organisation functions and the service they receive, and to learn of their expectations and suggestions. These surveys help to identify those aspects offering the greatest value for the pharmaceutical industry. The main conclusions of the 9th survey (covering the years 2020-2021) include in particular the following:

- 1 Almost 90% of pharmaceutical manufacturers rate their level of satisfaction in their relationship with SIGRE as "high".
- 2 The responses that pharmaceutical manufacturers obtain when they submit any query or question to SIGRE are rated as "useful" in 100% of cases. 95% are likewise of the opinion that the information received from SIGRE is of good quality.
- 3 100% believe that SIGRE performs responsible management.
- 4 95% believe that SIGRE operations contribute "greatly" or "moderately" to showing a public commitment to the environment on the part of the pharmaceutical industry.

- 5 Almost 80% of pharmaceutical manufacturers believe that SIGRE's involvement in educational efforts regarding antibiotic resistance is "good" or "vital".
- 6 49% of pharmaceutical manufacturers have made some environmental improvements to their packaging over the past three years, with 80% of cases receiving a "positive" or "very positive" evaluation from company management.

Contribution by SIGRE to Highlight the 2016-2021 Environmental Commitment of the Pharmaceutical Industry



COMPANY WASTE PREVENTION PLAN

In order to comply with the obligations set out in the current packaging regulations, SIGRE prepares and coordinates 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 a medicine's life cycle.

In 2020, the third follow-up report marking the completion of the 2018-2020 Plan revealed highly positive results, reflecting the continuous efforts by manufacturers to make their packaging more eco-friendly, despite the existing difficulties and the exceptional circumstances which shaped the year.





The quantitative reduction goal, set at 1% for the 2018-2020 Plan, was successfully exceeded, with the final reduction being 1.33%.

With regard to preventive measures, particular emphasis should be placed on the high degree of participation by pharmaceutical manufacturers, resulting in the application of a great many improvement initiatives. 2020 saw the registration of 160 initiatives which, together with those from the two previous years, makes for a total of 441 eco-design measures implemented within the context of the Plan.

We would lastly highlight the fact that since 2000 the industry has managed to reduce the overall weight of pharmaceutical packaging by more than 25%, as a demonstration of its commitment to the circular economy.

ANNUAL PACKAGING DECLARATION

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

During the past year, as set out in the 2020 Annual Packaging Declaration presented to the various Departments of the Environment of the Spanish Regions, the 21,958 SIGRE Points collected an average of 91.92 grammes per capita of empty packaging or packaging containing surplus medicines, successfully recycling 59.16% of the packaging materials recovered.

To this end, the waste medicines deposited by the general public at the 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 designed exclusively to guarantee the appropriate environmental treatment of this type of waste.



The results obtained in 2020, despite the 10% reduction of data collected because of the health crisis, demonstrate the public commitment to the environment through SIGRE.

AWARENESS-RAISING CAMPAIGN

Citizen engagement is essential in order to achieve the proper management of waste medicines. To this end SIGRE launches awareness-raising campaigns every year to bring attention to the importance of properly recycling empty packaging and leftover medicines via the SIGRE Point at a pharmacy.

The SIGRE 2020 Communication Plan, which forms part of the 2019-2021 Three-year Communication Plan, focused on emphasising the role played by pharmaceutical sector agents in providing the entire population with access to a convenient and safe system to dispose of waste medicines.

Within the context of this plan, a new campaign was launched in 2020 under the title “*A Step Forward for the Environment*”, with the aim of reminding the general public of the importance of depositing waste medicines at a SIGRE Point to ensure environmentally-sound management.

The campaign likewise emphasised the responsibility shared by all of the society in caring for the environment and public health, stressing the need periodically to check household medicine cabinets, make appropriate use of antibiotics, and to complete each prescribed course of treatment.



A NEW WEBSITE WITH ADDITIONAL CONTENT FOR THE PHARMACEUTICAL INDUSTRY

In 2020 SIGRE renewed its website with a more modern and innovative design, serving to improve the user experience through access to more dynamic and visual content, underpinning transparency and helping the general public to find the most up-to-date information.

Its various sections - About Us, Citizens, Pharmaceutical Sector, Sustainability and Communication - provide information about SIGRE and its organisation, explaining the importance of proper management of waste medicines and packaging, providing specific resources for agents in the pharmaceutical sector involved in SIGRE, demonstrating the organisation's commitment to the criteria and values of sustainability, and publishing communication initiatives and campaigns undertaken to raise environmental awareness.

There is also a section set aside for pharmaceutical manufacturers, designed to include new information subsections while furthermore expanding those already in place with new functionalities and greater ease of use, as a way of assisting members in their relations with SIGRE.



EDUCATION AS THE CORNERSTONE OF A MORE SUSTAINABLE SOCIETY

In order to achieve the Sustainable Development Goals set out in the 2030 Agenda, it is essential that the general public be made aware from their childhood years of their relationship with the environment and the rational use of natural resources.

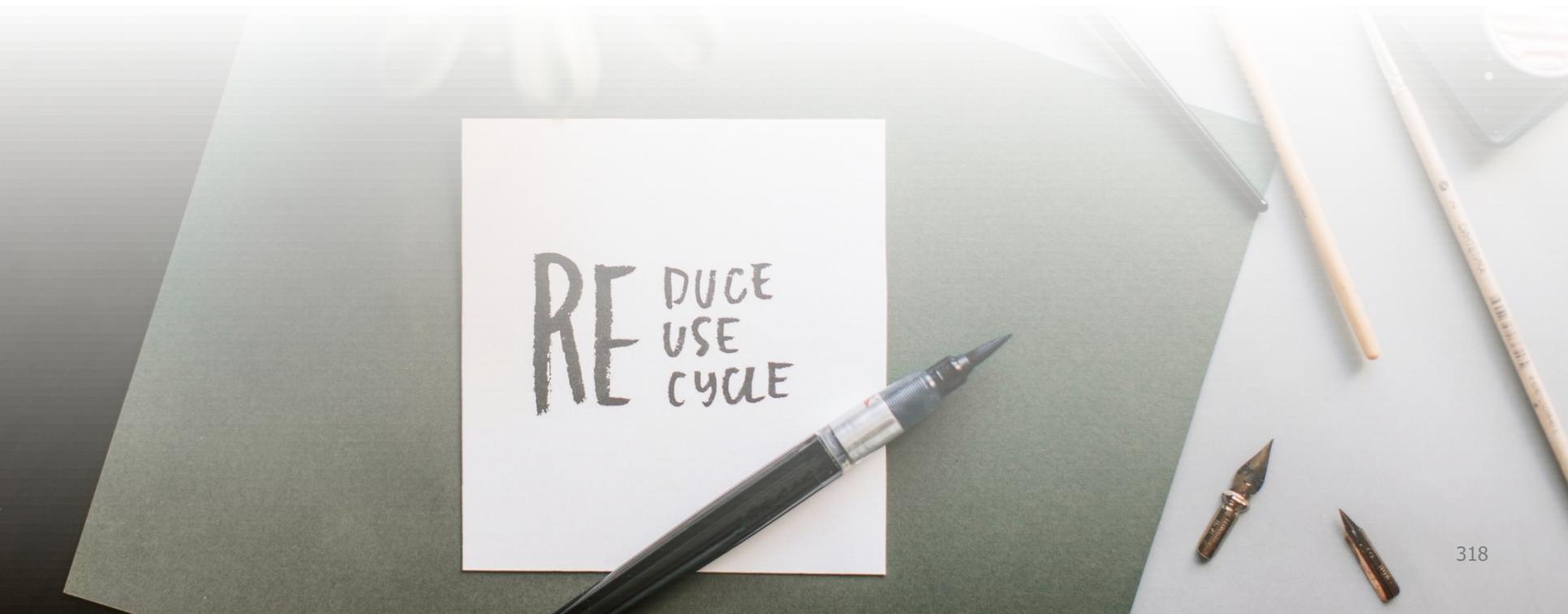
SIGRE is therefore committed to environmental education and to encouraging digital training tools, which were strengthened during the Covid-19 pandemic and proved particularly useful for students, who were forced temporarily to suspend in-school classes.

The SIGRE online educational plan covers all training cycles through various tools, such as teaching materials for children's education; SIGRELANDIA, intended for Primary Education students; the Learning Project "Medicines: Which, When and How" Service, intended for secondary school and baccalaureate students, and the Training Module intended for university students and pharmaceutical sector professionals.



Lastly, to mark European Researchers' Night, the AEMPS launched an educational project last November covering the life-cycle of medicines. The project, which is available on the Association's website and its YouTube channel, explains each of the stages through which a medicine passes, from basic, preclinical and clinical research, through marketing authorisation and subsequent monitoring, the distribution of medicines, inspection and control, and ending with the essential process of environmental management of the waste generated.

For this project SIGRE produced content illustrating the final phase of a medicine's life cycle, with a video providing a straightforward explanation of the activities conducted to design more environmentally friendly packaging, to collect waste, and the treatment applied to each of the constituent fractions, all of which is intended to reduce the environmental impact and contribute to a more circular economy.



RE DUCE
USE
CYCLE

06

ANNEX II

SIGRE (Spanish Medicines Verification System)

Ministerio de Sanidad, Consumo y Bienestar Social
Agencia Española de Medicamentos y Productos Sanitarios

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 that a public health threat 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 safety 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 such 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.



OBJECTIVES AND COMPOSITION

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 corporate purpose of SEVeM likewise includes ensuring that information about SEVeM-authenticated medicines will be used to calculate the reimbursement owed by retail pharmacies to pharmaceutical manufacturers and distribution organisations of those medicines dispensed outside the NHS.

SEVeM was set up by the main agents in the medicinal supply chain: the pharmaceutical industry, distributors and retail pharmacies, which as the shareholders of the entity play a role on its governing bodies. Alongside the technological challenge 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 Assembly is made up of the SEVeM members: AESEG, FARMAINDUSTRIA, General Council of Official Associations of Pharmacists and FEDIFAR, while the governing body of SEVeM is its Board of Directors, which had the following composition in 2020:

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

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, Directorate-General for the Basic Portfolio of National Health System and Pharmacy Services, and the Spanish Regions). During 2020 the Operations Committee met on 10 occasions, mainly by videoconference because of the state of emergency caused by the Covid-19 pandemic, addressing issues connected with the following matters:

- 1 Regulatory provisions underway in the field of falsified medicines.
- 2 Monitoring of key activity indicators and alerts generated by system users.
- 3 Supervision and monitoring in the distribution of credentials for user connection.
- 4 Monitoring of the functionality of Nodofarma Verification.
- 5 Protocols for action in the event of alerts.
- 6 Status of the Agreement between the Ministry of Health and SEVeM and progress with the NHS Pharma Node.
- 7 European change control procedure.
- 8 European Alert Management System.
- 9 Impact of Brexit.

- 10 Status of system reports for the competent authorities.
- 11 Impact of Covid-19 on serialisation.
- 12 Approval of the advanced algorithm for the retail pharmacy software.
- 13 Verification of the Product Code with the National Code.
- 14 Validation of scanners in the Datamatrix reading.
- 15 Detection and disconnection of end users due to sporadic use.
- 16 Aggregation of codes for hospitals.

The Audit Committee, which comprises representatives of the four members, met on two occasions during 2020 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.

A great many events were suspended in all spheres in 2020 because of the pandemic. Nonetheless, it did prove possible to stage some of them remotely, with the involvement of SEVeM. These include, in particular, collaboration in the course on falsified pharmaceutical products and medicines, and the seminar conducted with manufacturers of software for retail pharmacies.



REGULATORY FRAMEWORK

In late 2019 the Spanish Official State Gazette published Royal Decree 717/2019, of 5 December 2019, amending Royal Decree 1345/2007, of 11 October 2007, regulating the procedure for authorisation, registration and conditions for the dispensation of industrially-manufactured medicines for human use. Royal Decree 717/2019 established, among other aspects, a specific node for the Spanish National Health System, known as the NHS-Pharma Node, as an instrument for technological integration and exchange of information with the National Repository managed by SEVeM. To this end, the Royal Decree made provision for an agreement to be established between the Ministry of Health and SEVeM. During 2020, both parties worked together on producing an initial draft text for the agreement, with negotiations expected to continue during 2021 so as to establish a definitive text.

PROJECT PROGRESS

By the end of 2020, SEVeM had signed contracts with 490 marketing authorisations holders for medicines to be connected with the National Repository via the European platform. 325 distribution warehouses were likewise connected, along with 22,100 retail pharmacies and 197 private hospital pharmacy services. The connection of public hospitals remains pending, once the NHS Pharma Node is operational.

In 2020 more than 18,000 SKUs of medicines and 2.7 billion unique IDs were loaded into the system. During this second year in operation, the system verified some 750 million unique IDs, and nearly 500 million were deactivated.

The most important activities within the project during 2020 focused on the following:

- 1 Developing reports allowing the authorities to investigate possible counterfeiting, and to conduct supervision of system users.
- 2 Reducing the generation of false alerts.
- 3 Achieving connection for those end users who had not yet accessed the verification system. Additionally, initial steps were taken to make progress in harmonisation of sending of aggregate codes to hospitals.



SEVeM likewise made great efforts to identify and reduce false alerts resulting from the learning curve by thousands of connected users. Throughout the year operational procedures were progressively developed with a focus on analysing a great many alerts, providing continuous support for pharmaceutical manufacturers, identifying batches and codes not uploaded to the system and false Datamatrix records, while also detecting software and end-user scanner configuration failures. This served to reduce false alerts from 3.66% of all operations, to 1.12%. The aim for 2021 is to reduce the percentage of false alerts to a level below that set by the European Medicines Verification Organisation (EMVO) (0.05%).

With regard to the code aggregation project to facilitate deactivation at hospitals, early 2020 saw completion of the preparation of the consensus document setting out SEVeM's recommendations for aggregation based on international standards. The EMVO was also informed of the standards selected under this Spanish project to serve as the basis for the ultimate solution at the European level to be adopted in the future, while work also began to identify agents interested in conducting an end-to-end pilot.

Meanwhile, as a consequence of the need to facilitate the market release of as many Covid-19 vaccines as possible, a series of exceptions to the standard functionality of verification repositories was agreed. In late 2020, the Spanish Repository was thus selected as one of the 11 national repositories storing unique Covid-19 vaccine IDs to provide the verification/deactivation service for all Member States during the mass vaccination phase.



Other significant activities undertaken by SEVeM during 2020 included:

- Incorporation of new functionalities and improvements in system stabilisation and performance optimisation.
- Participation in different European working groups to address regulatory, operational, technical and quality-assurance matters.
- Generation of proposals to reduce false alerts in the national and European system.
- Generation of guides, functionalities and recommendations for the proper configuration of system user scanners.
- 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.
- Development of procedures to handle alerts within the system.
- Coordination with the AEMPS in investigations of potential falsification alerts and the resolution of serial numbering incidents.
- Coordination with the AEMPS and notification to this agency as to any users with a recurrently high level of false alerts.
- Improvement in the identification of medicines by also sending the National Code to be checked in the system.
- Review and monitoring of the quality of identification data for medicines uploaded by the pharmaceutical manufacturers.
- Planning and design of a technical solution for the incorporation of new functionalities and improvements in Nodofarma Verification, including in particular the implementation of an advanced algorithm, reduction of double dispensation alerts and the sending of the National Code in pharmacy transactions.
- Training and support for authorities in the use of the system supervision reports platform.

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