farmaindustria

2018

Anual Report

A message
from the President

Martín Sellés Fort

PRESIDENT OF FARMAINDUSTRIA

The figures and comments set out in this Annual Report are a true reflection of the reality of Spain's innovative pharmaceutical industry. They reveal an established business sector, generating wealth, high productivity, exports, stable and skilled employment, and above all, one that is tied to R&D and innovation.

They also reveal a sector which is especially important for society, particularly for those who are patients, by focusing on delivering new therapies to resolve the treatment of illnesses and to improve the health and quality of life of the population.

All this, combined with a strict self-regulatory system which we have set up, guarantees the highest levels of ethics and responsibility in our companies' operations, make us a flagship sector for a modern country aiming to achieve the quantum leap towards a new model of production and places the nation at the cutting edge for the near future.

If we combine the reality in terms of healthcare, industry and economics reflected in the figures, with the ideal positioning that Spain has achieved over recent years as a platform for research and for conducting clinical trials within an international context of considerable development in biomedicine, our sector quite rightly represents an irrefutable opportunity that no country should miss out on.

The innovative pharmaceutical industry in Spain generates an **annual output of more than 15 billion euros** (the figure for 2016, which is the most recent one available), with exports in 2018 surpassing 11 billion euros for the second time in its history.

This volume accounts for 3.9% of all goods exported from the country, and 25% of all the nation's exports of high-tech products. These are just some of the numbers I referred to earlier, which demonstrate the reality of a booming and dynamic sector.

PRODUCTION IN SPAIN

15,000

MILLION EUROS

EXPORTS

11,000

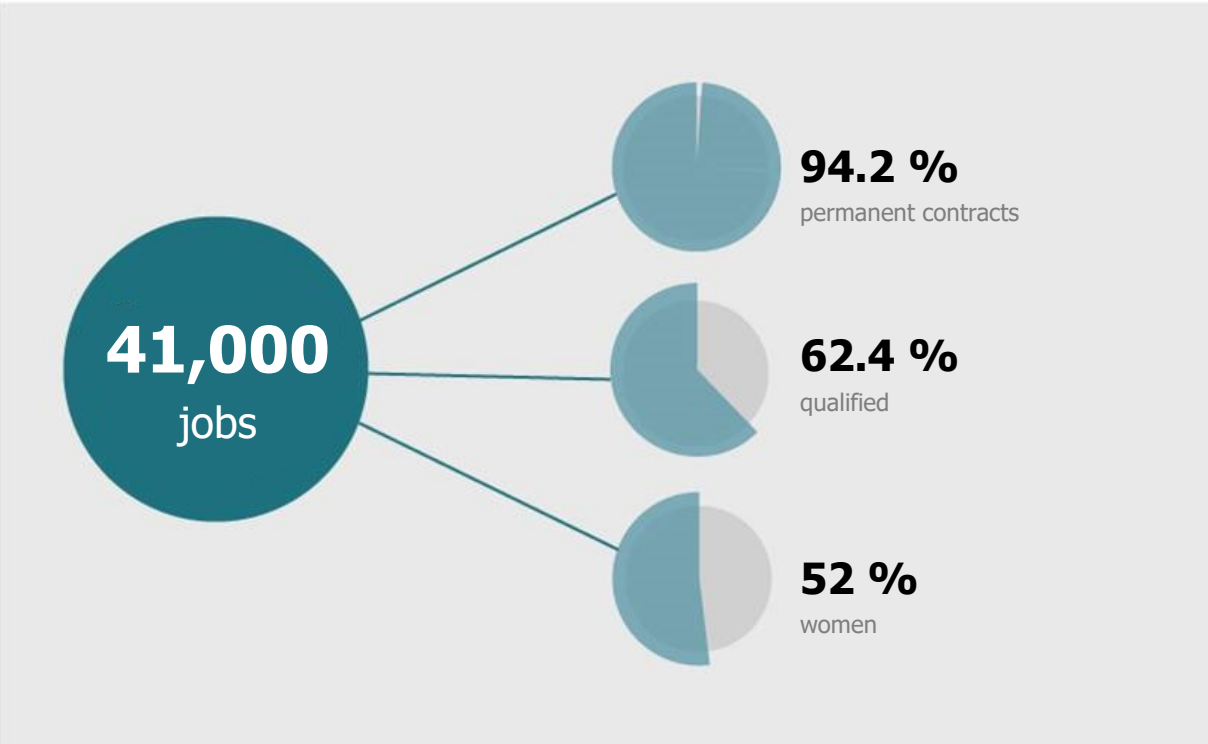
MILLION EUROS

25%

OF ALL HIGH-TECH EXPORTS

In order to drive this huge output and export capacity, as well as research, pharmaceutical manufacturers provide **41,000 direct jobs**, and another 160,000 that are indirect and induced. The outstanding figures for employment stability, qualifications and equality among those who work at our companies are rightly a source of pride: **94.2%** of workers are on **permanent contracts**; **62.4%** have **high-level qualifications**, and **52% are women**, twice the average in the industrial sector in Spain.

The research and development of new medicines, biomedical innovation in the broadest sense, accounts for the bulk of our companies' operations, our raison d'être. Which is why **the pharmaceutical industry creates more employment than any other industrial sector in Spain in the field of R&D**: 4,956 professionals dedicated to such tasks full-time, 65% of whom are women. One in every four female researchers employed in Spanish industry works for a pharmaceutical company.



This figure of nearly 5 thousand workers dedicated to researching new medicines, along with **the 1.15 billion euros that the pharmaceutical industry dedicates every year to R&D activities**, have consolidated our position as the leading sector in terms of the volume of investment dedicated to research: one in every five euros spent on R&D by Spanish industry (20.3%) comes from a pharmaceutical company.

Our turnover represents 2.4% of the national industrial total, but we are the leading industrial sector both in research conducted internally at companies' own centres, making up 18.2% of the total, and research contracted out to third parties, at 29%, in our case a rewarding partnership with hospitals, universities and other establishments that make us the driving force behind both the public and private biomedical research fabric.

This firm commitment by the pharmaceutical industry, alongside the robustness of the National Health System, its highly skilled healthcare professionals, Spain's advanced legislation, as well as growing patient participation and engagement, and a shared willingness on the part of public authorities and managers, all make up the decisive elements which now place Spain at the forefront of the world in the field of clinical research.

R&D INVESTMENT

20.3%

OF THE SPANISH INDUSTRIAL TOTAL COMES FROM PHARMACEUTICAL COMPANIES

Our researchers and centres are already involved in one in every three clinical trials carried out in Europe, and for some of our companies, **Spain is now their preferred destination for investments in clinical research** after the United States. This capacity to attract clinical trials to Spain is a clear and decisive example in helping to bring about a new model of economic growth and society.

This Report does not only contain facts and figures. It also sets out the pharmaceutical industry's commitment to the sustainability of the healthcare system and patient access to the medicines that they need. We are well aware that there would be little point in developing the very best medicines if they do not reach the patients who need them. With this aim in mind, through constant dialogue with public authorities our companies have progressively applied different innovative solutions to provide patients with access to innovation within a context of sustainability.

This is the approach reflected in the FARMAINDUSTRIA Agreement with the Government, which in 2018 marked its third year in force and towards the end of the year was once again extended, under the terms of which the industry undertakes to refund to the State any surplus expenditure on pharmaceuticals if growth is greater than the rise in GDP. **Innovation, accessibility and sustainability** are the goals of this Agreement and are intrinsic elements for us, which is why we constantly work with public authorities to strike a delicate balance which demands the involvement of all players in the sector.

This is an expression not only of our commitment to society, but also our decisive dedication to **transparency**. The publication of transfers of value to healthcare professionals and organisations was further extended some years ago to transparency regarding sanctions and mediation procedures in application of the Pharmaceutical Industry Code of Good Practice, and the publication of collaborations with patients' organisations.

This sector represents a real opportunity to lead the transformation of our country's economic model

Martín Sellés

PRESIDENT OF FARMAINDUSTRIA

In 2018 we became the first country in Europe to publish collaborations with healthcare professionals and scientific societies on a completely individualised basis, a step demonstrating the consistency and strength of our commitment in this field.

And both the constant dedication to dialogue and commitment to patients, in this case patient safety, lie behind the **establishment of SEVeM, the Spanish Medicines Verification System.**

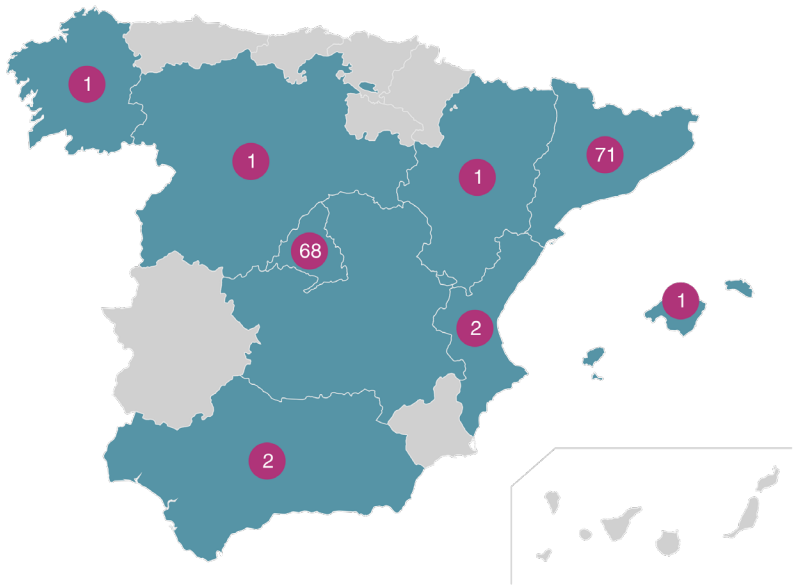
With the leadership of the innovative industry, and in partnership with generics manufacturers, pharmaceutical distributors and retail pharmacies, preparations were made in 2018 for the launch early this year of an ambitious and complex system linked up with the other countries of the European Union, further underpinning medicine traceability controls in order to ensure that falsified products cannot enter official channels.

In short, this Report sets out our reality. And in doing so demonstrates the contributions made to Spain by our sector, as the country maps out its economic and social future on the international stage. The pharmaceutical industry is a cutting-edge, innovation-based sector with an international perspective, committed to good practice and essential for the Welfare State. With medication expenditure fully under control, as at present and as predicted for the future by reputable analyses, far from representing a threat to national budgets, the sector offers a genuine opportunity to lead the transformation of our country's economic model.

To achieve that, we need to help change the focus and see biomedical innovation not as an expense but as an investment that provides solutions for patients, leads to savings in the healthcare system, and generates wealth for Spanish society as a whole. **Our figures, our reality, our commitments vouch for us**. And will provide the basis for our ongoing efforts.

1 Member Services

By the time this Annual Report was finalised, the number of member companies of FARMAINDUSTRIA amounted to **147**, with the following geographical distribution:



PHARMACEUTICAL MANUFACTURERS BY GROUP

National: 47		International: 100		
		American	European	
Total	**47**	**16**	**84**	
Large:	5		Germany	10
SMEs (Small and Medium):	42		France	10
			Mixed	35
			United Kingdom	19
			Switzerland	10

In terms of sales, FARMAINDUSTRIA'S members represent 71% of the total prescription market (retail pharmacies and hospitals).

2 Organisation

2.1 Governing Bodies

2.2 Executive Team

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 (9 representatives from domestically owned companies and 24 from foreign owned companies, of which 15 are European/international companies and 9 are American companies).
2. **The Governing Council,** made up of the President and 22 Members appointed by the Executive Board from among its members, of whom 10 are Vice-Presidents (3 from the sector of domestically owned companies, 3 from the sector of American-owned companies 4 from the sector of European/internationally and companies), the remaining 12 being Members, drawn from the following 3 from companies with domestically owned capital, 3 from companies with American-owned capital, and 6 from companies with European/internationally owned capital.

There is also an additional Vice-President who is the outgoing President of the Association.

Elections were held in October 2018 to renew the governing bodies of the Association. In accordance with the bylaw provision establishing that the Presidency must rotate every two years, Mr Martín Sellés Fort, President of JANSSEN CILAG, S.A., a company of the American Group, was appointed President of FARMAINDUSTRIA to replace Mr Jesús Acebillo Marín, who had previously served as President, representing a European/International company, specifically of the Swiss Group.

The composition of the Governing Bodies of FARMAINDUSTRIA was as follows on 30 April 2019:

BOARD OF GOVERNANCE	
PRESIDENT	
Mr Martín Sellés Fort	
VICE-PRESIDENTS	
Mr Jesús Acebillo Marín	Mr Salvador Pons Ribas
Mr Ángel Fernández García	Mr Eduardo Recoder de la Cuadra
Mr Jorge Gallardo Ballart	Mr Sergio Rodríguez Márquez
Ms Marieta Jiménez Urgal	Mr David Solanes López
Ms Margarita López-Acosta	Mr Roberto J. Urbez Plasencia
Mr Juan López-Belmonte Encina	
MEMBERS	
Mr Juan Carlos Aguilera Rodríguez	Mr José María Martín Dueñas
Mr Antonio Bañares Cañizares	Mr Jordi Muntañola Prat
Mr Nabil Daoud	Mr Federico Plaza Piñol
Ms Cristina Henríquez de Luna Basagoiti	Mr Francisco Quintanilla Guerra
Mr Bernardo Kanahuati	Mr Mario Rovirosa Escosura
Ms Fina Lladós Canela	

EXECUTIVE BOARD

PRESIDENT

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

VICE-PRESIDENTS

Mr Jorge Gallardo Ballart **ALMIRALL, S.A.**	Mr David Solanes López **LABORATORIOS ERN, S.A.**	Mr Angel Fernández García **MERCK SHARP & DOHME DE ESPAÑA, S.A.**	Mr Juan López-Belmonte Encina **LABORATORIOS FCOS. ROVI, S.A.**
Mr Eduardo Recoder de la Cuadra **ASTRAZENECA FARMACEUTICA SPAIN, S.A.**	Mr Salvador Pons Ribas **LABORATORIOS MENARINI, S.A.**	Mr Jesús Acebillo Marín **NOVARTIS FARMACEUTICA, S.A.**	Ms Margarita López-Acosta **SANOFI-AVENTIS, S.A.**
Mr Roberto J. Urbez Plasencia **BRISTOL-MYERS SQUIBB, S.A.**	Ms Marieta Jiménez Urgal **MERCK, S.L.**	Mr Sergio Rodríguez Márquez **PFIZER, S.L.U.**	

MEMBERS

Mr Antonio Bañares Cañizares **ABBVIE SPAIN, S.L.U.**	Mr Peter Plöger **BOEHRINGER INGELHEIM ESPAÑA, S.A.**	Mr Juan Carlos Aguilera Rodríguez **FERRING, S.A.U.**	Mr Ignasi Biosca Reig **LABORATORIO REIG JOFRE, S.A.**
Mr César Concepción **ALCON CUSI, S.A.**	Ms Katherine Stultz **CELGENE, S.L.**	Mr Sergi Aulinas Guillaumes **LABORATORIOS GEBRO PHARMA, S.A.**	Mr Federico Plaza Piñol **ROCHE FARMA, S.A.**
Ms Fina Lladós Canela **AMGEN, S.A.**	Mr Jordi Muntañola Prat **ESTEVE PHARMACEUTICALS, S.A.**	Ms Cristina Henríquez de Luna Basagoiti **GLAXOSMITHKLINE, S.A.**	Mr Guillermo de Juan Echávarri **SMITHKLINE BEECHAM, S.A.**
Mr José María Martín Dueñas **ASTELLAS PHARMA, S.A.**	Mr Francisco Quintanilla Guerra **FAES FARMA, S.A.**	Mr Guillermo Castillo Acero **IPSEN PHARMA, S.A.**	Mr Antonio Buxadé Viñas **LABORATORIOS VIÑAS, S.A.**
Mr Bernardo Kanahuati **BAYER HISPANIA, S.L.**	Mr Tomás Olleros Izard **GRUPO FARMASIERRA, S.L.**	Mr Nabil Daoud **LILLY, S.A.**	
Mr Sergio Teixeira **BIOGEN SPAIN, S.L.U.**	Mr Mario Rovirosa Escosura **FERRER INTERNACIONAL, S.A.**	Mr Francisco Javier Alvarado García **MUNDIPHARMA PHARMACEUTICALS, S.L.**	

2 Organisation

2.1 Governing Bodies

2.2 Executive Team

2.2 Executive Team

THE FARMAINDUSTRIA Director-General is the head of the executive organisation, which in turn has a structured of functional departments.

The Association headquarters are in Madrid and it also has a delegation in Barcelona. The FARMAINDUSTRIA functional organizational chart at the date of finalisation of this Annual Report is as follows:

Humberto Arnés
Director-General

Javier Urzay
Deputy Director-General

Lourdes Fraguas
General Secretary and Director of Legal Affairs and Human Resources

Pedro Luis Sánchez
Director of Studies Department

Emili Esteve
Director of the Technical Department

Iciar Sanz de Madrid
Director of the International Department

José Ramón Luis-Yagüe
Director of Relations with the Spanish Regions

Francisco J. Fernández
Director of the Communication Department

3 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

Reference Prices

As indicated in last year's Report, in January 2018 the **public consultation process** took place prior to a new White Paper for a Royal Decree to amend Royal Decree 177/2014, of 21 March 2014, governing the system of reference prices and uniform groupings of medicines under the National Health System, and certain information systems in the field of funding and prices of medicines and healthcare products, with no further advances having been made in this process.

Meanwhile, the Order to **update the system of reference prices** corresponding to 2018 was published in November, partially upholding

the arguments regarding the Draft Order submitted by FARMAINDUSTRIA and certain companies. It should be highlighted that the Order maintained the price of certain products of interest for the **National Health System** the viability of which would be seriously compromised. With regard to this last aspect, the preamble to the Order makes reference to the non-revision of the **price of essential medicines** the commercialisation of which was not viable because of the continuous reduction of prices.

However, the Ministry of Health did not accept other arguments presented, and continued to maintain the principle of including different active substances with shared classification at the ATC5 level within the same group, contrary to the reasoning of various court judgments. FARMAINDUSTRIA therefore filed an appeal against the Order under public authority litigation, challenging a series of groups which it deemed to be unlawful, the main reason being that the groups challenged are made up of medicines with different active substances, in breach of the legislation and the settled case-law of the Supreme Court in this regard.

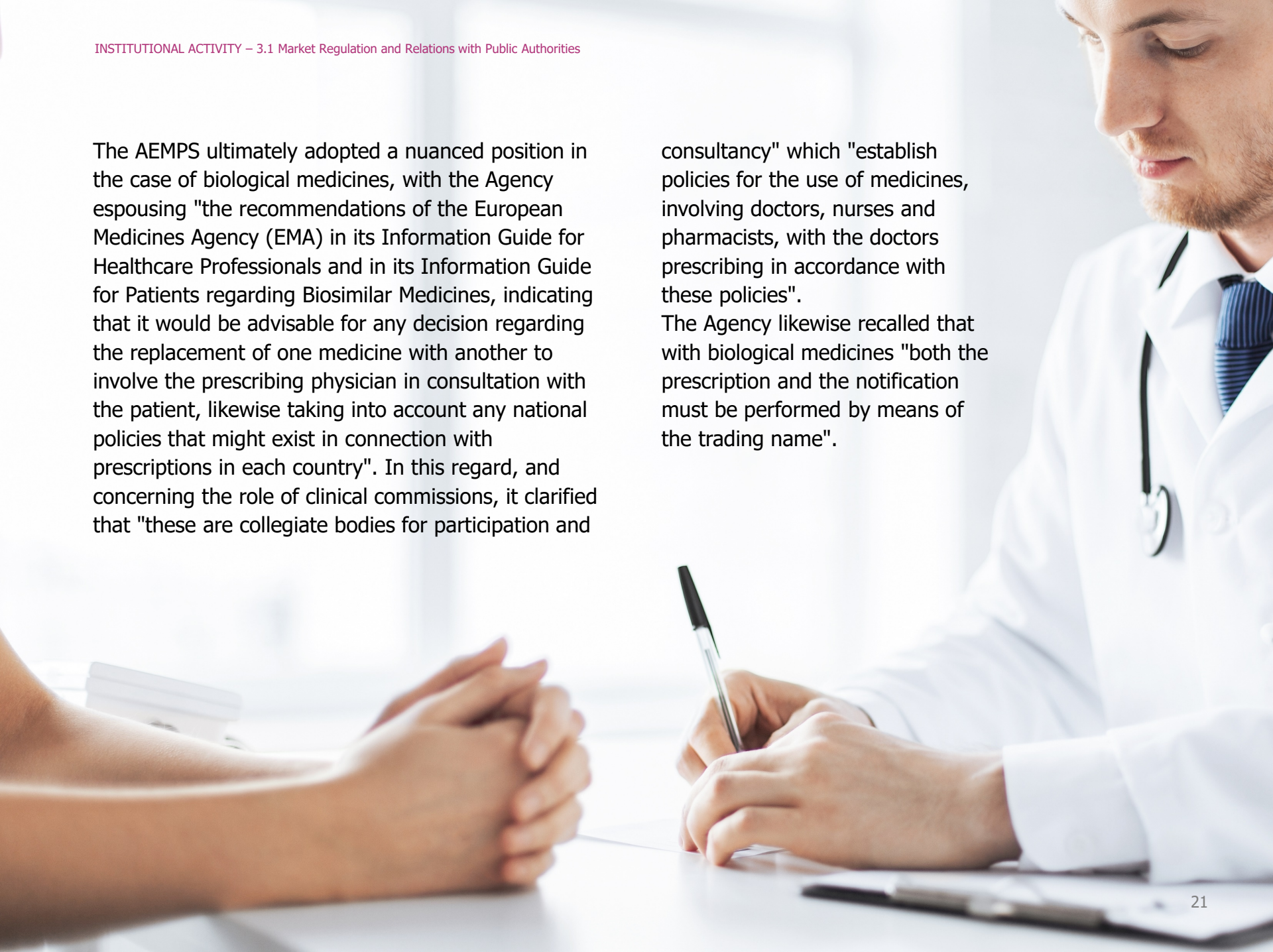
NON-SUBSTITUTION ORDER

In September 2018 the **AEMPS (Spanish Medicines and Healthcare Products Agency)** published on its website a clarification/interpretation regarding Order SCO 2874/2007, establishing those medicines that represent an exception to possible substitution by the pharmacist in accordance with Article 86.4 of Act 26/2006 (now Article 89 of Royal Legislative Decree 1/2015), indicating that said Order would only apply to the scope of retail pharmacies, and indicating that "the policy as to the use of medicines within the sphere of hospitals is established by interdisciplinary commissions which **promote rational use of medication** in accordance with the law and good practice, including therapeutic interchange".

In accordance with the above, FARMAINDUSTRIA informed the Agency of its opposition to this clarification/interpretation, in order for it to reconsider its position and align it with the established legal terms. Alongside FARMAINDUSTRIA, a number of doctors' and patients' groups argued against the AEMPS interpretation.

The AEMPS ultimately adopted a nuanced position in the case of biological medicines, with the Agency espousing "the recommendations of the European Medicines Agency (EMA) in its Information Guide for Healthcare Professionals and in its Information Guide for Patients regarding Biosimilar Medicines, indicating that it would be advisable for any decision regarding the replacement of one medicine with another to involve the prescribing physician in consultation with the patient, likewise taking into account any national policies that might exist in connection with prescriptions in each country". In this regard, and concerning the role of clinical commissions, it clarified that "these are collegiate bodies for participation and consultancy" which "establish policies for the use of medicines, involving doctors, nurses and pharmacists, with the doctors prescribing in accordance with these policies".

The Agency likewise recalled that with biological medicines "both the prescription and the notification must be performed by means of the trading name".



CNMC (NATIONAL MARKETS AND COMPETITION COMMISSION)

With regards to competition, it is important to highlight the Decision of the CNMC (National Markets and Competition Commission) of 30 August 2018, confirming the **legality of a free market price being set** by pharmaceutical manufacturers, adjusted to the regulated price if the distributor can demonstrate that the medicine was ultimately dispensed at the expense of the NHS (National Health System).

Furthermore, said decision contains a reference to the **SEVeM** (**Spanish Medicines Verification System**), validating this in terms of responsibility.

PUBLIC PROCUREMENT

One year after the entry into force of the LCSP (Public Sector Procurement Act 9/2017, of 8 November 2017), transposing the European Directives in this field into the Spanish legal structure, a number of developments occurred as a result of the initial experience of application of the legislation and the queries that certain principles aroused.

In this regard, it should be highlighted that the recommendation by the **Public Procurement Consultative Board** as to the ROLECE (Official State Register of Bidders and Classified Companies), and the publication of Instruction 1/2019, of 28 February 2019, of the **Independent Procurement Regulation and Supervision Office**, published in order to do away with the different interpretations of Article 118 of the LCSP regarding minor contracts, clarified by means of a subsequent note in connection with the request for three price quotations.

Likewise, it is important to highlight the interest registered by the Ministry of Health in order to promote centralised purchasing via the INGESA (National Health Management Institute), as seen in the Catalogue of Goods and Services for Centralised

Procurement, added to the NHS procurement web portal and published in February 2019, along with the launch of a Framework Agreement for the **selection of suppliers** to provide recombinant coagulation factor VIII medicines for various autonomous regions and the INGESA.

TRANSPARENCY

FARMAINDUSTRIA has closely monitored the parliamentary course of the Business Secrets Act, in respect of which the Association submitted a number of arguments at both the Green Paper and White Paper stages and during consideration by the Council of State, in order to underpin the protection afforded to the confidentiality of medicine prices both within the context of public procurement and in exercising the right of access to information by virtue of the Transparency Act.

Meanwhile, in April 2018 the public consultation process began for the **Implementing Regulation of the Transparency Act**, whereby FARMAINDUSTRIA submitted its observations both directly and through the CEOE,

with the aim of **maintaining any non-disclosure obligations** that might be guaranteed by other laws, such as those regarding public procurement, business secrets and the Guarantees Act itself. The Draft Regulation is currently awaiting a decision by the Council of State, before whom FARMAINDUSTRIA has appeared in order to present the arguments it has been championing.

One of the most notable events regarding transparency occurred within the field of the right of access, with reference to requests to access the minutes of the CIPM (Inter-ministerial Medicine Prices Commission) and its resolutions for the years from 2007 to 2017. As the information contained in these minutes could affect economic commercial interests of the owners of medicines subject to the decisions of said Commission during the period in question, the Ministry of Health passed the request on to all the potentially affected parties in order for them to present their arguments. As a result of the above, arguments were presented by FARMAINDUSTRIA and those pharmaceutical manufacturers who saw fit. FARMAINDUSTRIA'S request was that the economic information contained in said minutes be handled on a confidential basis in accordance with the Guarantees Act (Article 97.4), emphasising the existence of grounds for inadmissibility and limits on access to information as established in the Transparency Act, with the information that the Ministry of Health publishes on its website therefore being sufficient.

Ultimately, the **Transparency and Good Governance Council** partially upheld the claim submitted, and called on the Ministry of Health to provide the approved minutes of the meetings of the CIPM, with all resolutions passed between 2007 and 2017, clarifying that any classified matters or others that could not legally be disclosed should be redacted, in accordance with the considered and dutiful judgment of the public authority.

The Transparency and Good Governance Council also issued a Decision on 6 September upholding the claim brought by BIOSIM with regard to the request for access to aggregate information concerning sales of biosimilar medicines, along with another Decision on the **sale price of authorised medicines**, calling on the Ministry of Health to provide the authorised manufacturers' sale prices (or the industrial funding price) of medicines approved in 2017 at the CIPM, although the request did not include access to information about generic medicines, regarding which public information is available on the Ministry of Health website.

With regard to this type of decision, it is important to emphasise a number of those issued at the European level, such as the decisions of the **High Commissioner for Transparency of the Republic of Ireland**, published in April 2018 on requests presented to the Irish Health Service, from which a number of arguments and conclusions opposed to information access may be drawn.

Lastly, in the field of transparency, we should highlight the ECJ Judgment of 5 February 2018 on access to EMA documents presented with the application for commercial authorisation for a medicine, in which the Court upheld the EMA's position in favour of access to information given the existence of a greater public interest in the disclosure of the information, while respecting any confidential commercial information.

DATA PROTECTION

It is first of all worth highlighting with regard to data protection, that on 25 May 2018 Regulation (EU) 2016/679, of the European Parliament and of the Council, of 27 April 2016 took effect, **on the protection of natural persons** with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/CREC (hereinafter, the General Data Protection Regulation, or GDPR).

The steps required in order to adapt to the **GDPR** are essentially:

1. Appointment of a Data Protection Officer.
2. Draw up a register of processing activities.
3. Conduct a risk analysis.
4. Review security measures in light of the results of the risk analyses.
5. Establish mechanisms and procedures to serve notice of security breaches.
6. Where necessary following the risk analysis, conduct the corresponding impact assessment.

In addition, the following simultaneous actions must be taken:

1. Adjust forms (right of information).
2. Adaptive mechanisms and procedures for rights to be exercised.
3. Consider whether data processors provide guarantees and adaptation of contracts.
4. Draw up a privacy policy.

In addition to the entry into force of the GDPR, the **processing of Spain's Organic Act on Personal Data Protection and the Guarantee of Digital Rights** was closely monitored, as the legislation supplementing the GDPR in accordance with the entitlement granted by the Regulation to the Member States to nuance or restrict certain aspects provided in the Regulation.

FARMAINDUSTRIA has been extremely busy at both the national and European levels to ensure that the data protection standards would fulfil the needs of the industry. Numerous initiatives were therefore undertaken with the Government, political groups and sectors and institutions connected with biomedical R&D to present amendments to the White Paper, the ultimate aim of which was to avoid any retrograde measures for biomedical research, in accordance with the terms of the report published by the AEPD (Spanish Data Protection Agency) in March.

Ultimately, FARMAINDUSTRIA'S amendments were given a satisfactory reception, in particular with regard to subsection 2 of Additional Provision 17, which introduces a series of provisions intended to **guarantee the proper development** of research in the field of health, and in particular biomedical research, by balancing the unquestionable benefits that this offers society against due guarantees as to the fundamental right of data protection.

Meanwhile, the Organic Personal Data Protection and Digital Rights Guarantee Act establishes a period of one year from its entry into force for the codes registered with the AEPD, such as the FARMAINDUSTRIA code itself, to adapt to the new regulations. In this regard, FARMAINDUSTRIA is making efforts during 2019 to update a new Code of Conduct which will replace the **Standard Code for Personal Data Protection in Clinical Research** and **Pharmacovigilance**, all of which is being conducted in collaboration with the heads of the clinical research, pharmacovigilance and legal departments of the pharmaceutical manufacturers who belong to the Association.

Modifications to the current informed consent form for participants in clinical trials have also been under consideration, in full coordination with ethics committees and the AEMPS.

We should lastly mention that during the processing of the Data Protection Bill, Royal Decree-Act 5/2018 was passed in July, on urgent measures for the adaptation of Spanish Law to European Union regulations in the field of data protection, which will remain in force until the new Organic Data Protection Act takes effect.

BIOLOGICAL SAMPLES

In September 2018 the public consultation process began for the Draft Royal Decree to modify Royal Decree 65/2006, of 30 January 2006, establishing **requirements for the import and export** of biological samples, without any progress having thus far been made in the process.

PROCEDURE FOR AUTHORISATION, REGISTRATION AND CONDITIONS FOR DISPENSING OF MEDICINES FOR HUMAN USE

In January 2019 the public consultation process began for the Royal Decree modifying Royal Decree 1345/2007, of 11 October 2007, governing the **procedure for authorisation, registration and conditions for dispensing industrially manufactured medicines for human use.**

DRAFT ROYAL DECREE ON ADVERTISING OF MEDICINES

In August 2018 the prior consultation process for the Draft Royal Decree on the advertising of medicines was announced, the main aims being:

1. **Establish comprehensive regulations** for the advertising of medicines both to the general public and to healthcare professionals.
2. **Define the powers** of the State and of the Autonomous Regions.
3. **Update the current regulations**.

FARMAINDUSTRIA presented observations requesting explicit recognition of the Self-regulatory Codes and Systems and the need to avoid different regulations at the regional level. The processing of the Draft Royal Decree is currently suspended.

DRAFT ROYAL DECREE ON HEALTH PRODUCTS

Prior to the announcement of the public consultation regarding this Draft Royal Decree, FARMAINDUSTRIA presented its observations, emphasising among other aspects, the need to preserve the confidentiality of the documentation to be presented in the process of **applying for inclusion of a product** within pharmaceutical provision, and the need for objective and duly founded healthcare reasons to exist in order for singular reservations to be established.

ROYAL DECREE-ACT ON UNIVERSAL ACCESS TO THE NHS

Royal Decree-Act 7/2018 of 27 July 2018 on universal access to the National Health System was passed in July 2018, acknowledging the **right to protection of health and healthcare for those of Spanish nationality and also foreign citizens** resident in Spain. The regulation establishes criteria to avoid the inappropriate use of the right to healthcare to ensure that public funds will not be used wherever a third party is subject to payment obligations or the right can be exported from the country of origin. Within the sphere of their powers, the Autonomous Regions will be required to establish the procedure to apply for and receive an accreditation certificate allowing foreign citizens to receive healthcare provision. The regulation establishes pharmaceutical co-payment of 40% of the RRP for foreign citizens not registered or authorised as resident in Spain.

SERIALISATION

In February 2019 the **SEVeM** (**Spanish Medicines Verification System**) was successfully connected to the European hub on time. The system is now operating as planned. The SEVeM Operations Commission, which together with the members of the System also includes representatives of the Autonomous Regions, the AEMPS and the Directorate-General for the Basic Portfolio of NHS and Pharmacy Services, continues to meet regularly to resolve technical issues as they arise.

Meanwhile, the Ministry of Health has decided to channel the verification and deactivation of medicines reimbursed by the NHS (both via the hospital channel and through retail pharmacies) by means of its own public node ('Nodo NHS'), as the replacement for such medicines of the node of the General Council of Official Associations of Pharmacists ('Nodofarma Verificación') integrated within **SEVeM**. To this end the consultation procedure has begun for a Draft Royal Decree to adapt the administration of NHS pharmaceutical provision in accordance with the regulatory framework for the verification and authentication of medicines, through publication on the website. The draft Royal Decree likewise establishes the conditions for continuation and the subsequent elimination of the coupon seal and, as requested by FARMAINDUSTRIA, the application of Article 94.7 (prices outside the NHS) via **SEVeM**.

COMPLIANCE

In June 2018 the FARMAINDUSTRIA General Assembly approved the **Association Code of Ethics**, which is being distributed to members.

The Code of Ethics **reflects the culture of compliance** in place at FARMAINDUSTRIA, its actions being subject to the strictest ethical and regulatory standards, serving as a mandatory guide for all actions by the personnel of the Association, its governing and executive bodies and the personnel of the Member Companies when performing or participating in activities connected with the object of the Association.

Internal training sessions are being conducted in parallel for the Association's *Criminal Compliance Programme*, of which the Code of Ethics forms an integral part.

3.1.2 THE SPANISH REGIONS

During 2018, FARMAINDUSTRIA continued its institutional activities with the regional health authorities, scientific societies, professional organisations and institutions with the aim of **underpinning our sector's positioning as a strategic ally and partner of the healthcare system** in improving the levels of the population's health. The innovative pharmaceutical industry is committed to equitable patient access to pharmaceutical innovation within a sustainable public health system.

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

FARMAINDUSTRIA - REGIONS FORUM

On 12 and 13 April 2018 Murcia hosted the 21st FARMAINDUSTRIA Regions Forum, which was formally opened by the Regional Health Minister Mr Manuel Villegas García and attended by nine of Spain's Regions and the INGESA. On this occasion the matters addressed were:

1. **Data protection in biomedical research and healthcare.**
2. **The Public Sector Procurement Act** in connection with the purchasing of medicines within the NHS.
3. **The Code of Good Practice of the Pharmaceutical Industry** and the transparency initiative.

E-HEALTH PROJECTS IN THE NHS

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. Nonetheless, the varying pace of development and implementation of these systems across the different regions represents a constraint on NHS operability.

Faced with this scenario, the Central Government has promoted a number of initiatives in order to **progress towards interoperable systems** within the NHS as a whole.

Electronic Prescription. Situation in the regions

By late 2018 electronic prescriptions had been fully implemented at all levels of healthcare in all regions except for Madrid and Asturias, where the system had not yet been implemented at hospitals, and in Aragón and Castilla y León, with only partial implementation at hospitals. The percentage of prescriptions dispensed electronically in the NHS by the end of 2018 was over 91%.

Likewise, by late 2018 16 regions, as well as INGESA, held technical certification from the Ministry of Health both as issuer (issuing electronic prescriptions that can be dispensed in another region) and recipient (receiving and dispensing electronic prescriptions generated in another region). Madrid was the only region that had not joined the system, as it was still at the trial stage. Nonetheless, by the date when this Annual Report was drawn up, the Madrid Region had been certified by the Ministry of Health as an issuer and recipient of interoperable electronic prescriptions, although retail pharmacies in Madrid will gradually be joining the system from March 2019 onwards.

National Health System Digital Clinical Records. Situation in the Autonomous Regions

The NHS Digital Clinical Records project, led by the MSSSI, aims to guarantee **access by citizens and healthcare professionals to the most relevant clinical documentation for the healthcare of each patient** and includes the documentation that is available in electronic format anywhere within the NHS, guaranteeing that the consultation of data is restricted to only those with the corresponding authorisation.

By late 2018 all the regional health services had managed to position themselves as information issuers and recipients, except for Cataluña, which is only an issuer. NHS digital clinical records therefore now **cover some 93% of the population** with an individual health card.

Approval of medicines. NHS

Approval is an administrative and healthcare procedure subject to singular reservation, established by the Guarantees Act and regulated by Royal Decree 618/2007, the purpose being to **verify the conformity of the prescribed treatment** within the NHS against the conditions of use authorised on the technical data sheet for the medicine and the treatment indications and conditions for dispensing and use under which the medicine was included within public pharmaceutical provision.

By September 2018, of the 11,818 presentations of medicines marketed and included under NHS pharmaceutical provision, a total of 1,694 (14% of the total) were subject to approval. Of these, 744 have approval for the population aged over 75, and 28 are funded only for some of their therapeutic indications.

The power to establish the approval of medicines and healthcare products lies solely with the Ministry of Health, acting either ex officio or at the request of the regions. It is nonetheless the regions themselves that administer the approval of medicines.

Each region has therefore established its own administrative procedure, gradually evolving towards electronic approval. The varied pace of the **introduction of information and communication technologies** within the healthcare services of the regions, and differences in administrative procedures, give rise to a considerable lack of uniformity in how this medicines approval process is administered in Spain.

INITIATIVES AT REGIONAL LEVEL

Cataluña. CatSalut Pharmacotherapeutic Harmonization Programme

In May 2017 the Catsalut Pharmacotherapeutic Harmonisation Programme came into force in Cataluña. This programme establishes criteria for use, access and provision of new medicines, new indications, and medicines that were already commercially released and reveal characteristics of particular interest based on:

1. **Incidence and prevalence of the clinical condition for which they are intended.**
2. **Degree of therapeutic innovation and potential clinical benefit** in terms of health outcomes.
3. **Availability** of alternative treatments.
4. **Budgetary impact**.

This programme unifies and integrates the existing therapeutic harmonisation programmes (primary and hospital care), by creating one pharmacotherapeutic commission and two advisory boards (hospital medication, 'CAMH', and medication for primary, community and specialist healthcare, 'CAMAPCE').

Given the queries arising in the application of the programme, FARMAINDUSTRIA contacted the heads of the CatSalut Medicines Area, who indicated the following:

1. This is an **internal document** for the purpose of simplifying pre-existing commissions and processes.
2. The instruction **does not limit the prescription capacity** of healthcare professionals.
3. **The harmonisation criteria** take into account the approved IPTs (Therapeutic Position Reports).

Within the context of this programme and since April 2018, CatSalut has been applying a new classification of prescribed medicines establishing 4 categories (A, B, C and D) for the purpose of evaluation and issuance of recommendations for use in primary care and specialist care:

- **Category A**, first ranked choice of medicines.
- **Category B**, second ranked choice of medicines, or recommended for a sub-group of patients.
- **Category C**, medicines for patients who have exhausted other alternative treatments.
- **Category D**, medicines with no added therapeutic value.

This new categorisation is being used both for new medicines and for medicines that had already been commercially released and classified as 'MATMA' (medicines with more appropriate therapeutic alternatives), which CatSalut is re-evaluating and reclassifying in accordance with the new categories. This categorisation affects the quality indicators for pharmaceutical provision (management contracts), which penalise the prescription of medicines included in the aforementioned categories C and D.

FARMAINDUSTRIA is monitoring the evaluation harmonised reports and resolutions issued on medicines, ascertaining that:

Between April 2018 when the new categories took effect, and late 2018, **evaluation reports and resolutions were published on 39 medicines**, of which eight were categorised, and of these one was classified in category B, 3 in category C and the remaining 4 in category D.

In the first quarter of 2019 **evaluation reports and resolutions were published for 30 medicines**, of which 22 were categorised. Of this latter group, 13 were classified in category C, and the remaining 9 category D.

Andalucía. Competitive tenders for medicines dispensed at retail pharmacies

On 6 June 2018 the SAS (Andalucía's Health Service) announced the 13th competitive tender for medicines, with 337 presentations being tendered corresponding to **163 active substances**, of which 34 active substances were ordered, representing 21% of the active substances tendered through the Decision of 17 July 2018.

The Decision announcing the 14th competitive tender was published on 20 September 2018. This announcement was for the tender of 449 presentations corresponding to **192 active substances**, of which 82 active substances were awarded (43% of those tendered) by means of the Decision of 9 November 2018.

Below is the list of the announcements, active substances tendered, and awards made under the different tenders for the selection of medicines by the Government of Andalucía to date.

Medicine tenders. Announcements and Awards

	ANNOUNCEMENT			AWARD		
	Decision Date	Active Substances Offered	Manufacturers Presented	Decision Date	Active Substances Awarded	Manufacturers Selected
1	25/01/12	18	13	19/03/2012	5	4
2	20/12/2012	330	17	01/02/2013	68	11
3	20/06/2013	288	14	21/11/2013	52	12
4	31/03/2014	251	17	24/07/2014	43	13
5	02/10/2014	214	13	17/11/2014	17	10
6	09/12/2014	243	17	06/02/2015	69	15
7	12/05/2015	249	18	16/07/2015	74	16
8	29/04/2016	210	21	21/06/2016	71	19
9	21/07/2016	156	16	30/09/2016	58	14
10	28/10/2006	178	23	15/12/2016	70	21
11	26/05/2017	208	29	18/07/2017	78	26
12	27/03/2018	212	33	25/05/2018	94	26
13	06/06/2018	163	20	17/07/2018	34	18
14	20/09/2018	192	27	09/11/2018	82	23

Following the regional elections in December 2018, the new executive in Andalucía announced that it would not be staging more competitive tenders, maintaining those in force up until the expiry of the signed contracts. By the date of finalisation of this Annual Report, the **Healthcare Services Inspection Plan** had been published by means of the Order of 20 February 2019. The aims in the pharmacy area include the evaluation of the distribution of medicines selected by the SAS in competitive tenders, and an analysis of inadequate supply arrangements.

Andalucía. Supreme Court Judgment on the Framework Agreement of Andalucía's Health Service by therapeutic indication

In connection with the Framework Agreement of Andalucía's Health Service regarding approval for the selection of active substances for certain indications, grouping together in one single lot medicines with different active substances that share some therapeutic indication (AM 4001/13), to which we made reference in previous annual reports, the Supreme Court indicated in its Judgment 98/2018, of 29 January 2018, that the lots should have been defined by active substance and not by therapeutic indication.

It asserts in this regard that even if the active substances are intended to treat the same pathology, "and could therefore be included in the same ATC classification therapeutic sub-group", they were authorised with different therapeutic indications either because of "the description of the disease to be treated, or the intended population".

This significant judgment espouses the interpretation given by the Central Administrative Contractual Appeals Court in its Decision of 27 March 2013, discussing the **definition of lots by active substance** rather than therapeutic indication, and recalling that Article 86.3 of the TRLCSP (Recast Text of the Public Sector Procurement Act) allows the object of the contract to be subdivided, provided that the functional unit is respected. It does indicate that "the only groupings of medicines provided for in the Act (and hence functional units of medicines) are those indicated in Article 93.2 (now 98.2) of the LGURMPS (Act 29/2006, of 26 July 2006, on **Guarantees and Rational Use of Medicines and Healthcare Products**): groupings for presentations of medicine with the same active substance and identical route of administration; and Additional Provision 14.2: uniform groupings of medicines, with the same active substance and interchangeability".

On 18 May 2018 the High Court of Justice of Andalucía echoed this pronouncement with regard to an appeal lodged by FARMAINDUSTRIA against the aforementioned Framework Agreement, although by the time that this Annual Report was drawn up, said judgment had not become binding, having been appealed by Andalucía's health authority.

Madrid. Pharmacy Green Paper

As mentioned in the 2017 Annual Report, FARMAINDUSTRIA passed on a proposed amendment to this Green Paper, which was taken into consideration. The text of the bill was approved by the Government Council of the Region of Madrid in September 2018 and brought before the Madrid Assembly to be processed, although the text was ultimately not presented for possible approval.

Cantabria. Pharmacy Corporate Committee

In its judgment of 9 March 2018, the Supreme Court rejected the appeal lodged by the Government of Cantabria against the judgment of the High Court of Justice of Cantabria striking out Order SAN/31/2016, of 23 June 2016, of the Regional Health Department, creating and regulating the **Pharmacy Corporate Committee** within the context of Cantabria's Health Service, upholding the public authority litigation appeal brought by FARMAINDUSTRIA against said order.

In its judgment, the High Court of Justice of Cantabria held that the Order, to the extent that it granted said Committee functions such as the preparation of a medicines form and the evaluation of proposals for the inclusion of new medicines, was not merely an organisational regulation, but a **provision that affected third-party rights,** and which therefore could not disregard the consultation procedures required in order to adopt all regulations. Following the Supreme Court's rejection of the appeal by the Government of Cantabria, the judgement of Cantabria's High Court is now binding.

By the time that this Annual Report was drawn up, the SCS (Cantabria's Health Service) had begun a public consultation of a new proposed Order to create and regulate the Pharmacy Corporate Committee, a consultative collegiate, advice and support body assisting the **General Management of the SCS** in the field of pharmaceutical provision, with the aim of promoting measures intended to achieve better usage and prescription of medicines and healthcare products, and to promote pharmaceutical prescription based on the criteria of fairness, efficacy, effectiveness, safety and coordination between levels of healthcare.

FARMAINDUSTRIA submitted arguments regarding this proposal, emphasising:

1. The **advisory** nature of the Commission
2. **Transparency** and participation by all agents involved in its actions
3. The **steering** function of pharmacotherapeutic guides.

Emphasis was likewise placed on the need for public tenders to identify and define Lots by active substance, or trademark, in the case of non-interchangeable medicines.

Other initiatives at regional level. Castilla la Mancha. Canaries and Extremadura

The autonomous region of Castilla la Mancha launched a prior public consultation process to establish its Regional Commission for the Rational Use of Medicines. The Commission, which belongs to the regional health service, SESCAM, will coordinate the various commissions that exist at hospitals with the aim of **unifying and standardising the criteria for the acquisition and prescription of medicines** within the context of the SESCAM. By the time that this Annual Report was finalised, the project had not been presented for public consultation.

The Region of Islas Canarias has for its part announced the creation of a Regional High-Impact Medicines Evaluation Committee ('CAEMAI'), the aim of which will be to provide information and advice as to the therapeutic usage of such medicines, establishing the criteria in order to consider a medicine as "high- impact", and evaluating the effectiveness, safety, usage indications and monitoring of medicines that fulfil these criteria.

It will also be responsible for analysing reports on the evolution of expenditure on medicines and at establishments dependent on the SCS (Islas Canarias' Health Service). This body will depend on the SCS Directorate and will be made up, among others, of the presidents of the pharmacy commissions of the SCS hospitals, along with representatives of the Evaluation and Rational Use of Medicines and Provision Control Services.

By the time that this Annual Report was finalised, the announced project had not been submitted for public consultation.

Meanwhile, the Region of Extremadura has established its **Office for Information and Evaluation of Medicines**, with the following objectives:

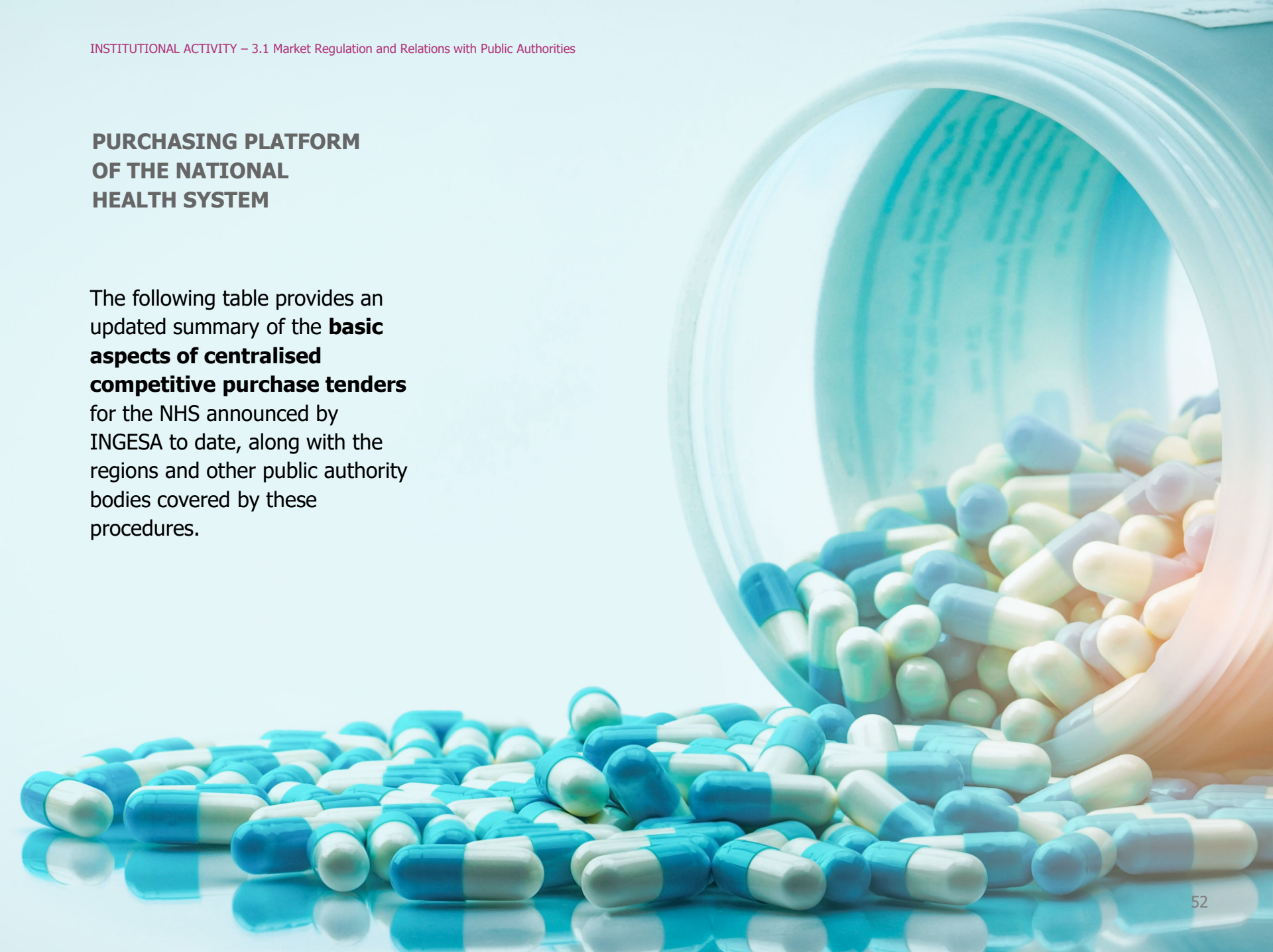
1. **Evaluate** the effectiveness, efficacy and clinical impact of medicines.
2. **Advise** doctors on alternative treatments.
3. **Train** Health Area Pharmacy Commissions and Tumour Committees in the evaluation methodology.

The proposed Order to regulate medical visits at health centres of Extremadura's Health Service has also been submitted for public consultation in the Region, the aim being to establish criteria for the ordering, monitoring and control of such activities at its centres. The proposed Order governs the academic training of the visitor, the quality of information conveyed, and reference to the explicit declaration that they must be performed by pharmaceutical manufacturers that subscribe to the principles of the Spanish Pharmaceutical Industry Code of Good Practice. FARMAINDUSTRIA has submitted its arguments, emphasising that individual visits should be maintained and considered, along with the planning of such activities by pharmaceutical divisions. Meanwhile, with regard to the training given to visitors, the Order should comply with the provisions of Royal Decree 1416/94, since accreditation of a qualification is the exclusive responsibility of national government.

Lastly, over the course of 2018 various regions presented for public consultation their **regulatory proposals for pharmaceutical provision** at social and healthcare centres, with the aim of regulating retail pharmacies and pharmaceutical stocks at such establishments. Several of these projects include, among other initiatives, the creation of social and healthcare pharmacy commissions and the generation of pharmacotherapeutic support guides for prescription. During the public consultation processes, FARMAINDUSTRIA placed particular emphasis on fair access to pharmaceutical provision, the advisory nature of the pharmacy commissions and the steering role of pharmacotherapeutic guides, among other aspects.

PURCHASING PLATFORM OF THE NATIONAL HEALTH SYSTEM

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 regions and other public authority bodies covered by these procedures.



MEDICINES TENDERED	PROCEDURE	PROCUREMENT AUTHORITIES	COMPOSITION OF LOTS	No. OF LOTS OFFERED	No. OF LOTS AWARDED
CLOTTING FACTOR VIII	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	Trademark	4	4
EPOETINS	Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act)	5 Regions (Asturias, Cantabria, Castilla la Mancha, Extremadura and Murcia), INGESA and Ministry of Defence	Active Substance	5	4
IMMUNOSUPPRESSANTS	Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act)	10 Regions (Aragón, Asturias, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja and Valencia), INGESA, Ministry of Interior and Ministry of Defence	Active Substance	9	6
MEDICATIONS WITH GENERIC COMPETITION	Open procedure by ordinary processing and subject to harmonised regulation (Articles 196 to 198 Consolidated Text of the Public Sector Procurement Act)	11 Regions (Aragón, Asturias, Islas Baleares, Castilla la Mancha, Cantabria, Extremadura, Galicia, Madrid, Murcia, Navarra and La Rioja), INGESA, Ministry of the Interior and Ministry of Defence	Active Substance Includes two biosimilars, which share lot with reference biological	20	20
CLOTTING FACTOR VIII	Negotiated without public notice (Art. 170.d of the Consolidated Text Act of Public Sector Contracts	9 Regions (Asturias, Islas Baleares, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra, La Rioja) and INGESA	Trademark	4	4
EPOETINS	Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act)	7 Regions (Asturias, Islas Baleares, Cantabria, Castilla la Mancha, Extremadura, Madrid, Murcia), INGESA and Ministry of Defence	Active Substance	5	4
IMMUNOSUPPRESSANTS	Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act)	11 Regions (Aragón, Asturias, Islas Baleares, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja, Valencia), INGESA, Ministry of Defence and Prison Institutions	Active Substance	9	9
ANTIRETROVIRALS	Negotiated without public notice (Art. 170.d of the Consolidated Text of Public Sector Procurement Act)	10 Regions (Aragón, Asturias, Islas Baleares, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja), INGESA, Ministry of Defence and Ministry of the Interior	Active Substance	26	12
CLOTTING FACTOR VIII	Negotiated without public notice (Article 168 of the Public Sector Procurement Act)	11 Autonomous Regions (Aragón, Islas Baleares, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Galicia Murcia, Navarra, La Rioja and Valencia) and INGESA (Ceuta and Melilla)	Trademark	4	Pending

Over the past year the Government has reiterated its wish to **promote centralised purchasing** through INGESA. In this regard, on 15 November 2018 the Inter-territorial Council of the NHS presented a proposals document which:

1 | **Calls** on the health services to participate in centralised purchasing.

2 | **Considers** the possibility of avoiding price revisions of awarded medicines for the duration of the contract. This latter point incorporates one of the proposals that FARMAINDUSTRIA has been making.

The aforementioned document likewise analyses other aspects of centralised purchasing, highlighting the initiatives undertaken (15 tenders with a value of 2.7 billion euros), the public authorities that have signed up (all the regions except Andalucía, Islas Canarias, Cataluña and País Vasco, INGESA, and the Interior and Defence Ministries), along with the total savings achieved during the period 2013-2017 (amounting to 267 million euros).

During the last financial year, with the contracts under the **Factor VIII Framework Agreement** having ended, a new competitive tender was announced and authorised by the Council of Ministers on 16 November 2018, with the following characteristics:

1. **Division** into 9 lots by trading name.
2. **Negotiated procedure** without publication.
3. **Involving** 11 regions and INGESA.
4. **Duration** of two years with the possibility of a further yearlong extension.
5. Possibility of **termination** of the contract in the event of the effective commercial release of a new generic or biosimilar medicine.

The tender price in accordance with the "general market price" (including the deductions under Royal Decree-Act 8/2010) and with no price revision during the phase of derivative contracts with the regions.

INGESA is also working on the **preparation of new Framework Agreements** (anti-neoplasics and age-related macular degeneration) and to reconvene others that have already ended (epoetins, antivirals), using the same format as previous competitive tenders.

Lastly, it should be noted that the Catalogue of Goods and Services for Centralised Procurement has been presented and added to the NHS purchasing portal, including general information about the available medicines and healthcare products, and specific information about those that have been the object of centralised purchasing procedures, including:

The contract status, participating regions, chosen pharmaceutical manufacturer, tender price and award price. Provision is made for three levels of access to this information:

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

FARMAINDUSTRIA continues to work with INGESA on the **pursuit of formulae** serving to balance the need for transparency under the Procurement Act and the interests of the sector and the NHS.

3.1.3 ADVISORY AND GUIDANCE COMMITTEES

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

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

The Advisory Committee of the Inter-territorial Council of the National Health System met on two occasions in 2018, in March and November, with an agenda which addressed certain aspects of particular interest for the pharmaceutical industry. The Committee is tasked with issuing opinions on regulatory projects in progress, and therefore reviewed the projects for the modification of two royal decrees governing, respectively, pharmaceutical manufacturers

(RD 824/2010) and the procedure for the authorisation and registration of medicines (1345/2017). The Committee also issued a report on the Order regarding homeopathic medicines.

In addition to these aspects, the Committee was informed of other particularly vital matters in the field of healthcare, such as the **approval of the standardised vaccine calendar** throughout a patient's lifespan, which was agreed by the Public Health Commission and is considered a very significant step forward in terms of quality, consistency and equal access. The Committee likewise received information on the proposed update to the strategic plan to address hepatitis C within the NHS.

AEMPS COMMITTEE ON MEDICINAL PRODUCTS FOR HUMAN USE

The **Committee on Medicinal Products for Human Use** of the **AEMPS (CMH)** is made up of 22 members, 10 by reason of their position and 12 appointed by the Governing Board of the AEMPS, one of them designated by FARMAINDUSTRIA.

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

One of the most significant aspects added to the CMH agenda in 2018 was the review of certain matters connected with **use of and appropriate access to medicines**. Aspects such as supply guarantees, in particular as a result of the lack of certain active substances because of quality problems, changes in conditions for prescribing and dispensing medicines, the strategy of the Agency in the field of homeopathic medicines and preparation for Brexit were all addressed by the CMH.

3.1.4 COLLECTIVE AGREEMENT

In December 2017 the Spanish Chemical Industry Business-Trade Union Debate Forum provided the venue for the establishment of the **19th Negotiating Committee for the General Chemical Industry Collective Agreement**, with the negotiations being divided into a four-block structure:

Block 1: Positive Action, Equality and Leave.
Block 2: Occupational Health, Environment And Trade Union Rights.
Block 3: Training, Employment, Professional Classification, Functional and Geographical Mobility.
Block 4: Working Hours and Salaries.

The negotiations were shaped by the general context of economic recovery based on sectoral productivity figures for 2017, recording an increase in turnover and exports.

Another significant contextual event was the **negotiation taking place in parallel for the AENC (Employment and Collective Bargaining Agreement)**, which serves to negotiate, and ultimately agree, an annual salary increase of around 2%, plus a variable element of 1% tied to concepts to be determined in each collective agreement, such as the evolution of productivity, results, unjustified absenteeism and other factors, on the basis of quantified, measurable indicators known to the parties.

Following months of negotiations, on 8 August 2018 the Official State Gazette published the text of the 19th General Chemical Industry Collective Agreement. This was in general terms, held to be a **modernised agreement** (including modifications to as many as 34 articles), championing equality, committed to training (aware of the importance of worker know-how and the investment made in this regard), avoiding the use of the CPI as a reference index, and including changes to the articles regarding working hours and flexibility.

The 19th Collective Agreement is valid for three years (2018-2020), establishing pay rises of +2.5% per year, including an additional salary guarantee clause which would take effect only upon expiry of the term of the agreement in the event that the sum total of the CPI rates during the period was higher than the agreed increases.

With regard to equality plans, they are established as a mandatory requirement to be introduced at companies with more than 150 employees over the course of the three-year term of the agreement. The equality plan will have an **initial diagnostic phase** (presentation of company data) and a **second negotiation phase** (anti-discrimination protocols, equality training, etc.). An Equality Officer will also need to be appointed.

The new agreement likewise provides for improvements in areas that are particularly important companies, such as flexibility and professional classification, and the inclusion of a breach or violation of the codes of compliance in place at companies as a very serious professional offence.

Institutional activity

3

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

During 2018, FARMAINDUSTRIA continued its efforts to develop the **Communication Plan** approved the previous year. The plan maintains the main aim of **disseminating informative content** about the value that innovative medicines offer society, both in terms of health and also with regard to the sustainability of the healthcare system and care quality, with particular reference to the sector's firm commitment to biomedical R&D.

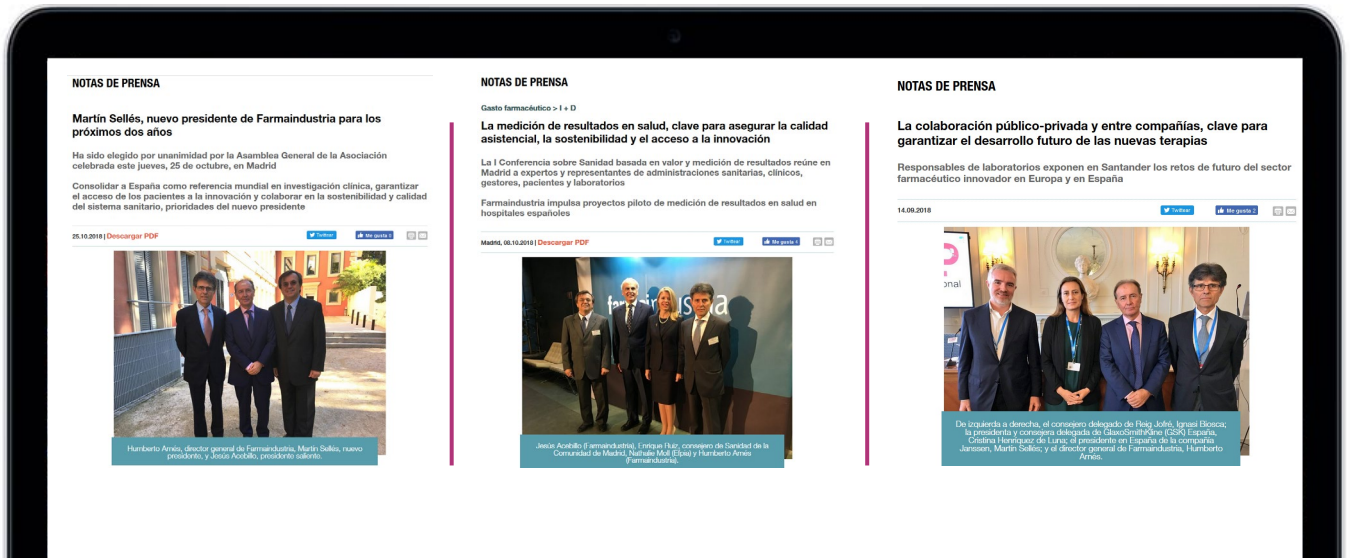
Within this context, FARMAINDUSTRIA made great efforts to inform both via traditional channels (the media) and through the Association's website and its profiles on the various social media platforms (Twitter, LinkedIn, Facebook, Instagram and YouTube). The aim in all cases was to present information of the utmost quality, based at all times on proven data and reliable sources.

With regard to topics, there was more intense publication of information regarding key aspects of pharmaceutical industry operations, such as:

1. The pharmaceutical industry's firm commitment to R&D.
2. Its dedication to society by generating skilled employment.
3. Its status as an economic driver of the national production system.
4. The development of the transparency system.
5. Its responsibility in the sustainability of the National Health System.
6. The added value that innovative medicines generate for society as a whole, among other aspects.

MEDIA

During 2018, FARMAINDUSTRIA set about generating new content, both internally and in collaboration with different media outlets, in order to convey the sector's key messages to the general public and to **encourage the distribution of journalistic information showcasing the importance of innovative medicines**, both for people's health and for the quality of healthcare provision and sustainability of the NHS. This involved working with all types of platform (print and digital media, TV and radio) at every level (national, regional, local) and in all relevant specialist fields (general interest, economic, health and sectoral media). Within this context, in 2018 FARMAINDUSTRIA distributed a total of 110 information releases, 27 of which were official press releases and 83 online news items. The information releases made it possible to raise awareness of the positioning of the pharmaceutical industry on various issues, to recount the Association's role on different forums and to disseminate information content linked to the value of innovative medicines for society, among other aspects.



At the same time, FARMAINDUSTRIA maintained its lines of collaboration with **various media outlets**, exploring different branded content formulae and also using information windows in the online editions of a number of media platforms in order to allow users with an interest in health-related matters and medicine to access the information platforms on the FARMAINDUSTRIA website itself.

The media presence of senior Association representatives has also been encouraged, through interviews and around a dozen editorial pieces published over the course of the year, with the aim of giving a first-hand account of the sector's positions and priorities.

FORO DE EXPERTOS

Humberto Arnés

Director general de Farmaindustria

Compromiso social desde la innovación

SALUD / TRIBUNA

Medicina de precisión, una oportunidad que no podemos desaprovechar

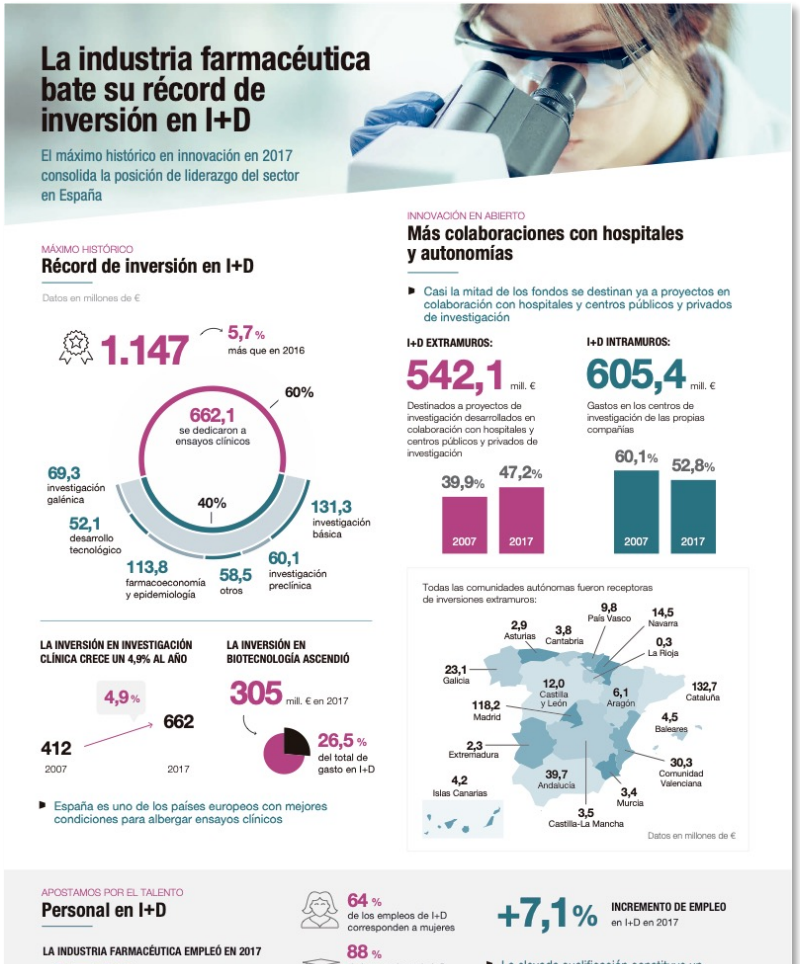
Martín Sellés
Presidente
Farmaindustria

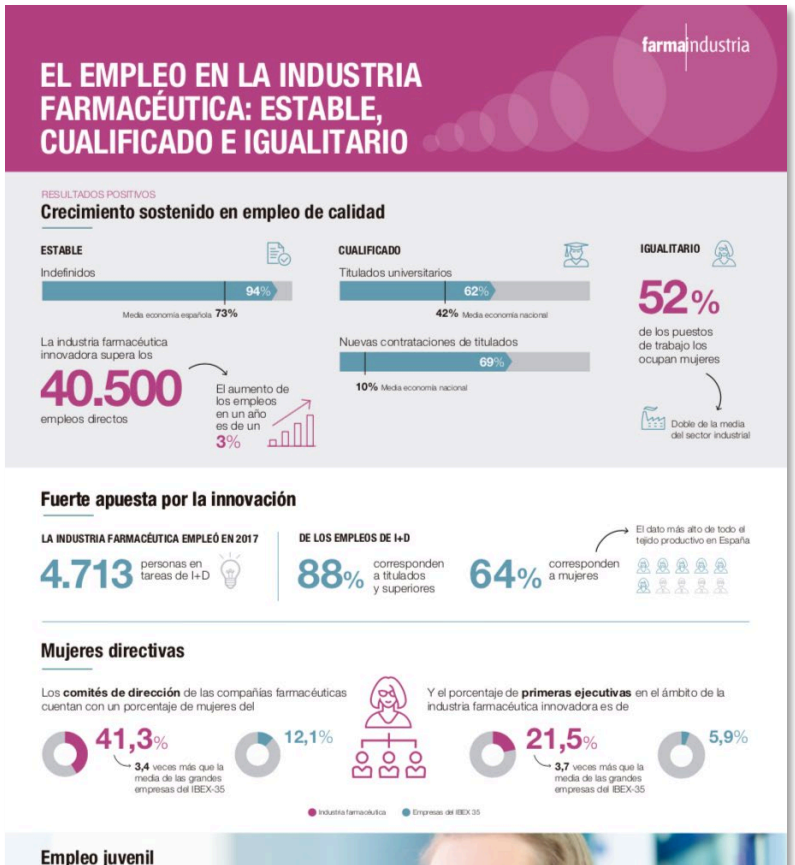
Todo fluye, nada permanece». Si hay un sector donde se cumple esta archiconocida sentencia del filósofo griego

la calidad de la prestación), a los pacientes (beneficiarios últimos) y a la industria farmacéutica, gran movilizadora de esta estructura y figura capaz de sus-

One other significant aspect was the involvement of senior FARMAINDUSTRIA representatives at numerous debates and symposia held by various organisations in the health, economic and social spheres over the course of the year.

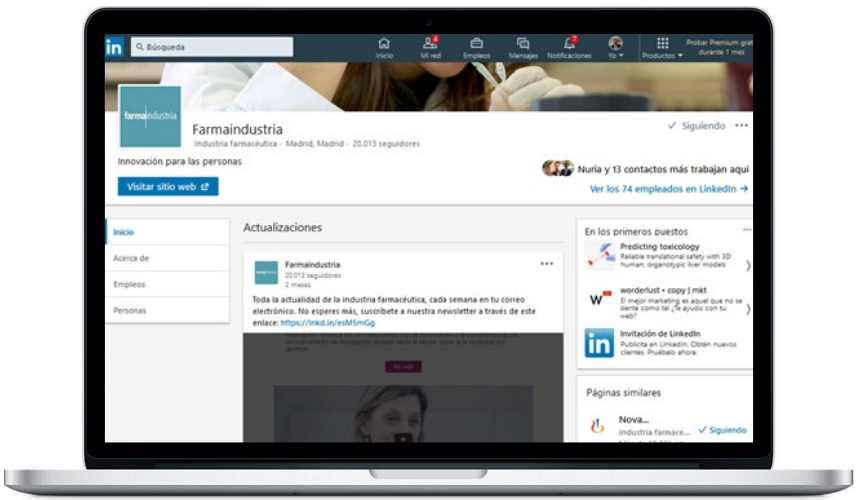
Meanwhile, the trend of replacing advertising-type artwork with a new infographic design approach presenting purely informative content was maintained in 2018, featuring key figures on the sector and reflecting the reality of the pharmaceutical industry based in Spain.

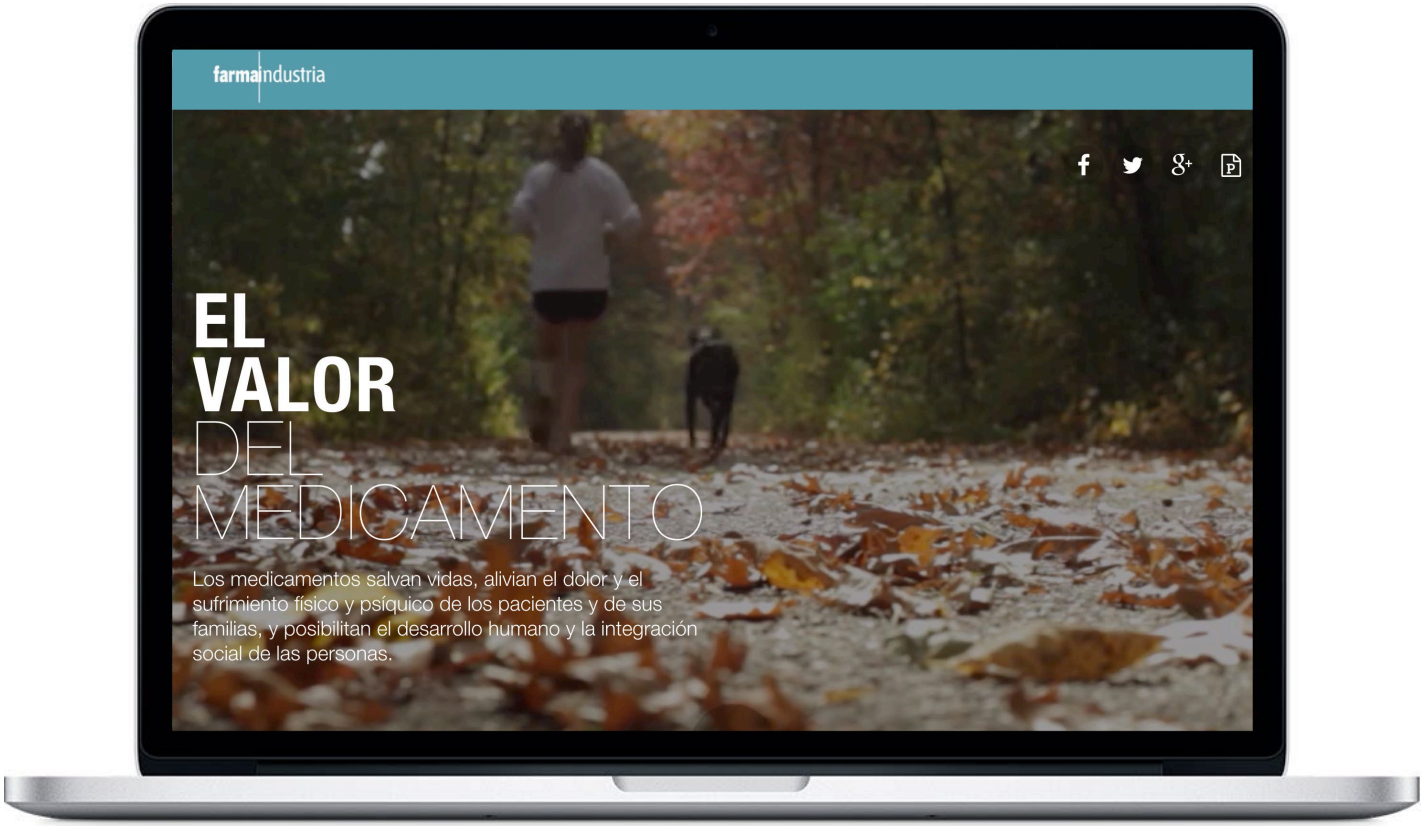




INTERNET AND SOCIAL NETWORKS

The distribution of information via social media was one of the main areas of FARMAINDUSTRIA operations, with the aim of achieving **free-flowing and direct communication** with users present on such networks, while offering society at large a comprehensive and up-to-date information platform about the pharmaceutical industry and medicines. FARMAINDUSTRIA thus registered **growing activity** resulting in a high level of distribution of its own messages via these channels, with clearly positive results in terms of the development of both the profile themselves and their audiences. In specific terms, FARMAINDUSTRIA'S Twitter account, which in 2018 closed with more than 28,000 followers, a registered growth of +6%, consolidated its position as the **Association's key social media platform**. Meanwhile, last year FARMAINDUSTRIA established itself as the third-largest pharmaceutical industry business Association on LinkedIn worldwide, with more than 15,000 followers by the end of the year.





Meanwhile, continuing the operational approach begun after the **renewal of the corporate website** the previous year, when FARMAINDUSTRIA continued to generate online content in a dynamic parallax-scrolling infographic format, along with videos intended for distribution via social media, with the goal of underpinning communication with society and the health sector, and helping to showcase different aspects connected with the **value of innovative medicines** within a multi-platform context and with an informative tone.

Within this context, there was an increase in the number of dynamic infographic features included in the series "The Value of Medicines", adding to the existing titles *The Value of Medicine; The Value of Vaccines; The Value of Medicines in Oncology; The Value of Medicines in Diabetes and The Value of Medicines in Cardiovascular Disease,* a new series focused on *The Value of Medicines in Rheumatic Diseases*.

Furthermore, **Somos Pacientes**, an online community of patients' associations promoted by the FARMAINDUSTRIA Foundation, strengthened its presence and further publicised its activities and Internet and social media content. The platform has a notable presence on both Twitter and Facebook. On Twitter, the Somos Pacientes profile had more than 18,500 followers by the end of 2018. Through this channel, the platform disseminates all its new content and maintains an open dialogue with the more than 1,400 associations followed via this social network. On Facebook, meanwhile, Somos Pacientes has a page used to distribute its content with more than 3,500 followers by the end of 2018. In addition, the community has a YouTube channel in which it posts all reports and video interviews that are published.

The **Somos Pacientes** ['We Are Patients'] newsletter, which distributes a weekly summary of the main content published on the platform, had more than 9,500 subscribers at the end of 2018.

EVENTS WITH INFORMATION IMPACT

Last year FARMAINDUSTRIA took part at numerous forums, both its own and those organised by other bodies, with a significant press and/or social media impact. A number of them are set out below.

- Seminar: *Unique identification of medicines; new scenario in treatments*.
- Seminar: *State health impact; industry perspective.*
- Sedisa - Alsedisa Forum on quality and sustainability. Updates on Data Protection in Healthcare
- 7th European Forum for Science, Technology and Innovation (Transfiere 2018).
- 7th Pharmaceutical Distribution Forum
- 10th Annual Conference on Biomedical Research Technology Platforms. Innovative Medicines, Nanomedicine, Healthcare Technology and Biotech Markets.
- 6th Forum of the Oncology Excellence and Quality Foundation on *Solutions for sustainable oncology.*
- Seminar to present the report *The value of medicines from a social perspective.*
- 21st FARMAINDUSTRIA-Autonomous Regions Forum.
- Seminar of the Royal National Academy of Medicine: *Clinical research - an opportunity for research and patients in Spain.*

- Seminar: *Digital transformation in Biomedical Innovation at Private Centres.*
- 38th Symposium of the AEFI (Spanish Industry Pharmacists Association)
- Seminar: *The challenges of the pharmaceutical industry in the new European context.*
- Biomedical Innovation Gathering: *a revolution in progress.*
- 18th Meeting of the Spanish Pharmaceutical Industry.
- 1st Conference on Value Based Healthcare and Outcomes Measurement
- Seminar marking the 10th Anniversary of the European IMI (Innovative Medicines Initiative).
- Spain Summit 2018 Forum.
- 15th Pharmaceutical Industry & Media Seminar.
- 6th 'Somos Pacientes' Seminar.

KEY INFORMATION MILESTONES IN 2018

In January, senior figures from FARMAINDUSTRIA took part in a number of forums, including the international seminar 'Experiences and Challenges in the Implementation of Codes of Good Practice and Multi-agent Collaboration in the Bio-pharmaceutical Sector', organised by the Chamber of Pharmaceutical Innovation of Chile, and the seminar 'State Health Pact - the Industry Perspective', events which were picked up on by both the press and social media.

In February, to mark World Cancer Day, FARMAINDUSTRIA published information on its website about the new anti-tumour medicines approved in 2017, and clinical trials focused on different types of cancer. The content of the press release, which was also distributed via the FARMAINDUSTRIA social media profiles, was heavily publicised by numerous specialists and also general interest media outlets, such as the newspaper El Mundo, which put the figures provided by the Association on its front page.

Likewise in February, the Director-General of FARMAINDUSTRIA analysed the situation of the sector and the challenges it faces in an editorial piece published in the Yearbook of the newspaper El Global and an extensive interview with the Journal El Médico and its online version El Médico Interactivo.

Other topics of media interest during the month of February included the presentations made by FARMAINDUSTRIA at the **Seminar on Research into Rare Diseases**, in which the Association argued for the need to have networks of centres of excellence in place and to encourage public-private partnership as essential elements in order to promote research into these conditions, as well as the 7th Pharmaceutical Distribution Forum, where FARMAINDUSTRIA championed an increase in the level of transparency across the medicine supply chain as a whole, along with support dialogue and a firm commitment by all agents involved.

On 5 and 6 March FARMAINDUSTRIA joined Fenin and Asebio in staging in Barcelona the **11th Annual Conference of Biomedical Research Technology Platforms: Innovative Medicines, Nanomedicine, Healthcare Technology and Biotech Markets**. The gathering was widely reported in the press and the social media.

R&D

150,000

MILLION EUROS

IN RESEARCH PHASE

7,000

NEW MEDICINES

CANCER TREATMENT

1,900

COMPOUNDS

The different topics addressed at the seminar were featured in over eight hundred journalistic reports, representing a potential OTS (opportunity to see) of 22.7 million impacts. In terms of social media, the take-up on Twitter was particularly notable, with the first seminar of the Conference becoming a national trending topic.

Meanwhile, the Association took part at the 6th Forum of the ECO (Oncology Excellence and Quality) Foundation, held under the title **Solutions for Sustainable Oncology**. FARMAINDUSTRIA published a report on the event on its website, which was picked up on by conventional and social media, focusing on how as a result of the figure of nearly 150 billion euros invested each year in research and development initiatives for new medicines, there are some 7,000 compounds at the research phase around the world, 1,900 of which are intended to treat different types of cancer.

One of the information milestones of the year took place on 20 March with the presentation in Madrid of the report 'The Value of Medicines from a Social Perspective', drawn up by the Weber Foundation with the support of FARMAINDUSTRIA. The seminar, which was formally opened by the Director-General for the Basic Service Portfolio of National Health System and Pharmacy Services, Ms Encarnación Cruz and the Director-General of FARMAINDUSTRIA, Mr Humberto Arnés, attracted a large audience and more than 20 media representatives.

The seminar was **extensively covered on social media**, above all Twitter, where the hashtag #ValordelMedicamento [Value of Medicines] became a trending topic in Spain, with an impact of almost 4 million page views on the social media platform. Content was also distributed via Facebook, LinkedIn and Instagram. The presentation of the document and its contents were likewise reflected in more than 60 general interest in specialist media impacts with a potential OTS (Opportunity to See) of 25.8 million impacts.

In April, FARMAINDUSTRIA began the publication of a series of features based on the scientific evidence contained in the **Weber Foundation Report**. The first was published to coincide with World Health Day (7 April), and was entitled *Innovative Medicines: Story of a Revolution*. The feature focused on the contributions made by innovative treatments in improving health and quality of life over recent decades. The feature was distributed via FARMAINDUSTRIA'S social media profiles and reported on by a number of media outlets.

On 12 and 13 April, the city of Murcia was the venue for the 21st FARMAINDUSTRIA-Regions Forum, the platform for dialogue and collaboration at which senior figures from the Association and healthcare representatives from a number of Spanish regions analysed current issues connected with the **NHS healthcare policy and pharmaceutical provision**. On this occasion the participants at the Forum addressed questions such as data protection in the field of biomedical research and healthcare, legislative developments affecting the sector, such as the new Public Sector Procurement Act, and the **evolution of the transparency initiative**.

Likewise in April, on this occasion to mark World Intellectual Property Day, FARMAINDUSTRIA published a feature on its website accompanied by a video, highlighting the importance of maintaining appropriate protection for intellectual property so as to guarantee the investments made by pharmaceutical companies in biomedical R&D.

On 10 May the Royal National Academy of Medicine hosted a session organised in partnership with FARMAINDUSTRIA on the current situation and future challenges raised by clinical research, a field in which Spain has succeeded in achieving a leading position over recent years, and which is an essential element in **guaranteeing pharmaceutical innovation**, as well as a key factor in driving R&D initiatives across the country as a whole. The seminar was streamed live.

The possibility of reusing clinical data for research purposes within the context of an extensive model of informed consent to take advantage of all the possibilities offered by new big data tools is the main key in **guaranteeing the future development** in Spain of what is known as precision medicine. This was one of the issues addressed at the Seminar on Digital Transformation in Biomedical Innovation at Private Centres organised by the IDIS (Institute for Health Development and Integration), held in the month of May and attended by FARMAINDUSTRIA.

Likewise in May, FARMAINDUSTRIA took part in the 38th Symposium of the AEFI (Spanish Association of Industry Pharmacists), which addressed such topics as the sustainability of the healthcare system, **pricing and funding processes**, early access to new medicines, measures for traceability and to combat falsification, progress in biomedical R&D, the digital transformation process, measurement of health outcomes and the protection of clinical data within the context of the new European regulation. FARMAINDUSTRIA marked the event by publishing two features on its website and via social media, one of which was also issued as a press release.

In May, the publication of a series of features based on the evidence contained in the **Weber Foundation** report continued. On this occasion the reportage focused on the savings for healthcare systems as a result of the **incorporation of innovative** medicines. The article was picked up on by numerous press outlets and social media profiles.

On 13 June the Royal National Academy of Pharmacy hosted a scientific session organised in partnership with FARMAINDUSTRIA on the challenges of Brexit for the pharmaceutical industry. The discussion covered the consequences of the United Kingdom's exit from the European Union for the research, manufacture, distribution, authorisation and pharmacovigilance of medicines in which said country had previously been involved. The seminar was covered by various media outlets.

June, likewise, saw the publication of a new infographic document in parallax-scrolling format as part of the series **The Value of Medicines**. Entitled **"The Value of Medicines in Rheumatic Disease"**, the document sets out an extensive compendium of information about these conditions, and how new treatments are significantly improving the health and quality of life of the patients affected. To mark the publication, FARMAINDUSTRIA issued a press release and two videos, which were reported by numerous press publications and social media profiles.

Around the same time, TVE broadcast an extensive reportage on the latest developments in the fight against cancer, interviewing a number of the top oncology specialists as well as **leading researchers and patients**. The feature, entitled *Cancer: Winning the Battle*, also involved FARMAINDUSTRIA.

One of the most notable milestones during the year was the staging of the **Biomedical Innovation** on 19 June: a revolution in progress, organised by FARMAINDUSTRIA within the context of the #WeWontRest initiative, with the main aim of illustrating the value of the research model led by the pharmaceutical industry, the growing commitment to public-private partnership, and dialogue as a means of including new medicines within healthcare provision without jeopardising **sustainability and fairness**. The session was held at the Canal Foundation and attended by 150 people, including 15 journalists, whose publications reflected the main conclusions of the gathering, the key elements of which were likewise featured in a video produced by Europa Press Television which was broadcast by a number of media outlets over the following days. Around 500 tweets were generated on Twitter in connection with the event, with nearly 3 million page views on the social media platform.

The **FARMAINDUSTRIA ANNUAL GENERAL ASSEMBLY** took place subsequently on the 21st, approving the Annual Report on the Association's activities, along with other business. Following the assembly, FARMAINDUSTRIA posted on its website and issued a press release to the media featuring the speech given by the President of the Association at the time, Mr Jesús Acebillo, along with the Annual Report itself and a summary of the publication in dynamic infographic format.

The month of June ended with the publication of the **transfers of value** corresponding to 2017 on the part of the companies signed up to the Code of Good Practice. FARMAINDUSTRIA issued an extensive press release entitled "The Pharmaceutical Industry Reasserts its Collaboration with the Healthcare System through R&D and Support for *Lifelong Learning*', with the aim of publicising this transparency initiative and detailing its different aspects.

A few days later, the newspaper La Razón paid tribute to the firm commitment of the pharmaceutical industry to transparency in the form of one of it's a Tú Saldud Awards, an accolade serving to highlight the value of a long-term initiative which has made the pharmaceutical industry a beacon in the field of transparency.

To mark the **publication of the pharmaceutical Industry R&D Survey**, in July FARMAINDUSTRIA sent out an extensive press release to the media to publicise the results of the survey, with a breakdown of the different aspects covered. The release was accompanied by a brief explanatory video designed specifically to be distributed via social media, with extensive coverage being given by the general interest, business, regional and specialist press, in both conventional and digital format. In specific terms, **more than 130 journalistic features were generated**, with a potential audience of nearly 25 million users. The social media impact was likewise positive, in particular in the case of Facebook, where the information was seen by more than 17,000 users and the video was played over 8,000 times.

On 19 July the Association published a third feature based on the evidence set out in the **Weber Foundation** report, on this occasion focusing on the contribution made by the innovative pharmaceuticals sector to the national economy and employment. Entitled "*The Pharmaceutical Industry - a Formula 1 for the Economy and Employment",* centred on the reality of the pharmaceutical industry from the perspective of its contribution to productivity and economic growth. The feature was distributed by social media and reported on in a number of press articles.

La industria farmacéutica bate su récord de inversión en I+D en España

Casi la mitad de los fondos se destinaron a colaboraciones con **hospitales y centros públicos y privados** de investigación ● Los nuevos fármacos, llamados a transformar el sistema sanitario

Meanwhile, in late July, FARMAINDUSTRIA took part in the Buenos Días Madrid morning magazine show on Telemadrid in order to explain to the general public the **meaning of the icons, pictograms and texts which appear on pharmaceutical packaging.**

Around the same time the newspaper ABC published a feature produced with the support of FARMAINDUSTRIA on how **progress in genomics and functional proteomics** have over recent years brought medicine to the threshold of a new revolution, precision medicine, characterised by the development of molecular, genetic and cellular therapies which take the form of **specific treatments** for individual patients. This information was also publicised by FARMAINDUSTRIA'S social media profiles.

On 29 August, the President and Director-General of FARMAINDUSTRIA met with the Minister for Science, Innovation and Universities, Pedro Duque, and the Minister for Universities, Research and Innovation, Ángeles Heras.

The Association's leaders shared with the Minister the reality of the innovative pharmaceutical industry in Spain, its firm commitment to investment in biomedical R&D activities and its solid conviction as to the major opportunities that research in this field offers to Spain's economy and society. They likewise reasserted to the minister the commitment on the part of the industry based in Spain to collaborate with the government on a long-term R&D strategy. The Association publicised the content of the meeting in a press release which was widely reported in conventional and social media.

In September, Correo Farmacéutico published an editorial piece by FARMAINDUSTRIA'S Director-General focusing on the importance of measuring the **health outcomes from innovation** as an essential requirement in order to progress along the pathway of precision medicine, a new paradigm in healthcare which must necessarily combine access to innovation and sustainability.

Cinco Días

PÁGINAS: 1,20 · TARIFA: 8230 € · ÁREA: 648 CM² - 54% · O.J.D.: 20314 · E.G.M.: 36000 · SECCIÓN: PORTADA

15 Septiembre, 2018

Farmacia

Los laboratorios españoles piden más apoyo público para crecer en el exterior

El CEO de Reig Jofre destaca el compromiso inversor de la industria

Prevé un alza de 'startups' biotecnológicas

CARLOS MOLINA
SANTANDER

Los laboratorios farmacéuticos miran al futuro con optimismo, pero consideran que necesitan el apoyo de las Administraciones públicas, inédito durante los años de la última crisis económica.

Así lo constataron algunos de los consejeros delegados de los laboratorios integrados dentro de la patronal Farmaindustria, durante la clausura del XVIII Encuentro de la Industria Farmacéutica en Santander. En representación de las compañías con matriz española intervino el consejero delegado de Reig Jofre, Ignasi Biosca, quien consideró que "después de muchos años de centrar todos los esfuerzos en políticas de precios y costes, ha llegado el momento de que la Administración española apueste por el desarrollo de una industria farmacéutica sólida en el mercado interno, pero sobre todo en los mercados internacionales". Frente a esa petición de apoyo público, Biosca vertidos en I+D en 2017 y una generación de empleo de 40.000 puestos de trabajo directos y 200.000 indirectos. "Constituimos una industria con capacidad de comprometerse en inversiones para favorecer el tejido industrial del país, las colaboraciones en investigación y el desarrollo, sin olvidar la innovación aplicada; una industria comprometida con la creación de empleo cualificado y el aumento de las exportaciones de productos farmacéuticos y, en definitiva, comprometida con el crecimiento del PIB nacional", destacó.

Biosca se mostró convencido de que la industria nacional tiene capacidad de optar a la innovación radical, "ejerciendo como tractora de las múltiples iniciativas de nuevos tratamientos farmacológicos que se están desarrollando en pequeñas startups biotecnológicas españolas salidas de la iniciativa privada o de proyectos nacidos en los centros de investigación públicos y hospitales españoles y que

"El mayor reto es la gestión del 'brexit'"

Suministros. Durante su intervención, Cristina Henríquez de Luna, presidenta y consejera delegada de GlaxoSmithKline en España, puso el acento en la importancia de gestionar de forma adecuada, en el ámbito de la industria farmacéutica, el proceso de salida de Reino Unido de la Unión Europea. En su opinión, este es el mayor reto que afrontan en la actualidad las compañías farmacéuticas presentes en Europa (Reino Unido exporta el 45% de su producción en medicamentos a la UE e importa de esta el 70%).

Protección. "En este escenario se hace necesario un pacto que incluya soluciones específicas

Ignasi Biosca (Reig Jofre), Cristina Henriquez de Luna (GSK), Martín Sellés (Janssen) y Humberto Arnés (Farmaindustria).

El sector asegura que un medicamento innovador puede tardar 12 años en salir

se Janssen en España, resaltó que las perspectivas son favorables en España, "un país que cuenta ya con múltiples centros de investigación básica y se ha convertido en una potencia mundial de primer orden en el ámbito de la investigación clínica". Pese a ello, criticó los obstáculos que tienen que enfrentar los la-

"Solo uno de cada 10.000 compuestos que sintetizamos llega a las manos de los médicos y los pacientes. Es un camino largo que cuesta entre 8 y 12 años recorrer, con un coste aproximado de unos 2.400 millones", insistió. En opinión de Sellés, las matrices deben tener "una vocación inversora" a largo plazo, mientras que

On 13 and 14 September, he city of Santander was the venue for the 18th Gathering of the Spanish Pharmaceutical Industry, held under the title "*25 Years of the Single European Pharmaceutical Market: 25 years of Scientific, Therapeutic and Economic Progress".* FARMAINDUSTRIA issued two press releases, one on each day of the gathering.

The forum was another of the key events of the year and was featured in a total of 122 journalistic reports with a potential audience of nearly 27 million users. The social media impact was likewise positive, in particular Twitter, with 362 posts being generated by 111 different users leading to more than three million views of the content featured at the gathering.

Around the same time the business newspaper Cinco Días published a lengthy feature in partnership with FARMAINDUSTRIA as to the importance of immunisation to prevent disease and the need to continue maintaining high rates of vaccination in the country so as to preserve public health.

Subsequently, to mark FARMAINDUSTRIA'S role in Biospain, the Association published extensive information about the FarmaBiotech Programme, highlighting the more than 500 research projects that have been presented for the 16 funding rounds under the programme since it was launched in 2011 with the aim of **promoting collaboration between the pharmaceutical industry and the world of biomedical research** in pursuit of projects with innovative potential.

On 4 October FARMAINDUSTRIA published the results of the **2017-2018 Pharmaceutical Industry Employment Survey**, which revealed that employment in the sector was continuing to register stronger growth, along with a profile of high quality and qualified professionals, with women representing the majority and significant job creation for young people. The Association sent an extensive press release out to the media to cover the story, along with the Survey itself and links to 3 videos explaining the main data from the report. All the content was distributed via FARMAINDUSTRIA'S social media profiles. The press release was widely reported by the media general interest, business and specialist health media outlets, with a total of with 115 articles and a potential audience of more than 33 million. The video clocked up more than 38,000 views on Facebook.

Another event with a major media impact was the **1st Conference on Value Based Healthcare and Outcomes Measurement** held on 8 October in Madrid and attended by more than 300 people, including Spanish and international experts, as well as managers and representatives from health authorities, patients and the pharmaceutical industry. The bodies organising the event (FARMAINDUSTRIA, EFPIA and ICHOM), issued a joint press release which was featured in some 50 reports in a range of general interest, business and specialist media outlets, with a potential audience of more than two million users. Over the course of the session, which was video streamed, 477 tweets were generated by 133 different users.

On 10 October Barcelona was the venue for a **Seminar on Incremental Innovation** organised by FARMAINDUSTRIA. Over the course of the session, leading figures from pharmaceutical companies and the Association itself, alongside other experts, analysed the benefits for patients and healthcare professionals derived from **innovative modifications to medicines that have already been commercially released**, such as increased speed of action, ease of use or improvements to the safety and efficacy of the compound. FARMAINDUSTRIA issued a press release which was reported on by a number of conventional and social media outlets.

On 25 October the General Assembly of FARMAINDUSTRIA met at an extraordinary session to unanimously elect Mr Martín Sellés Fort as the new president of the Association for the following two years. FARMAINDUSTRIA published the election in the form of a press release sent out to the media and posted on the Association's website and social media profiles. The handover at the head of the Association was reported in 67 media articles with a potential audience of more than 10 million users.

In November, seven months prior to the European elections in May 2019, EFPIA published a Manifesto highlighting the sector's priorities to *"build a healthier future for Europe".* These priorities include:

1. The **recognition** of the value of innovation by measuring outcomes in health.
2. The **continuation** of the length of the current European intellectual property protection model.
3. The **desire** to make Europe a world power in clinical research by means of a framework fostering the development of clinical trials and public-private partnership.

FARMAINDUSTRIA published information in this regard on its website and social media, which was picked up on by a number of media outlets.

On 7 November Madrid hosted the seminar to commemorate the 10th Anniversary of the IMI (the European Innovative Medicines Initiative), 50% funded by the European Commission and EFPIA, and which over the last decade has enabled investments totalling more than 5.3 billion euros, promoting 107 public-private projects to foster R&D into innovative medicines around Europe. The seminar clearly demonstrated that over the past decade the pharmaceutical industry operating in Spain has played a decisive role in many of the projects launched by IMI. The Association reflected the content of the day-long event via its social media platforms, and sent out a press release which was reported on by numerous specialist and general interest media outlets.

el Periódico

PÁGINAS: 53

ÁREA: 851 CM² - 80%

O.J.D.: 62555

E.G.M.: 363000

SECCIÓN: PAGINA ESPECIAL

18 Noviembre, 2018

Salud. Informe Farmaindustria

La industria farmacéutica bate su récord de inversión en I+D

La cifra alcanzó los 1.147 millones de euros en el 2017, lo que supone un aumento anual del 5,7%

Casi la mitad de los fondos se destinaron a centros públicos y privados de investigación

Cristina Capdevila

LAS CIFRAS

La inversión en el 2017

662,1 €

Son los millones de euros que se destinaron a ensayos clínicos, la principal partida de inversión de I+D

63,7%

Porcentaje de presencia femenina en puestos de trabajo en el área de I+D

132,7 €

Son los millones de euros que percibió Catalunya, convirtiéndola en la comunidad autónoma donde más invierte la industria farmacéutica

Around the same time, the newspapers La Vanguardia and El Periódico de Cataluña both published editorial features supported by FARMAINDUSTRIA on the **health contribution made by new medicines** and the importance of biomedical R&D, alongside a strong commitment to investment in the industry in Spain. The articles reflected many of the conclusions of the Weber Foundation report "*The Value of Medicines from a Social Perspective*", and highlighted the record of investment in R&D by pharmaceutical companies in Spain.

Likewise in November, FARMAINDUSTRIA took part at *The Spain Summit*, organised by the magazine The Economist. Association President Martín Sellés highlighted how:

1. The improvement of health
2. The generation of quality employment
3. The promotion of biomedical R&D
4. The strengthening of the economy

are the four social spheres in which the pharmaceutical industry acts as a beneficial driver, positioning itself as one of the **most important strategic sectors for the country.** Also involved at the summit was the Director-General of FARMAINDUSTRIA, Mr Humberto Arnés, who emphasised among other matters the way in which the role of the pharmaceutical industry transcends that of a mere supplier for the healthcare system, and is in fact one of the cornerstones of the Spanish National Health System. FARMAINDUSTRIA published a feature on its website and social media profile summarising both their addresses, which were reported on by a number of journalists.

On 27 November FARMAINDUSTRIA held the 15th Pharmaceutical Industry & Media Seminar in Avila, an event attended by 30 journalists each representing a different media outlet. On the part of the Association, all the members of its executive team were involved along with the President himself, Mr Martín Sellés. The content on offer at the seminar was **extensively covered** by the media, generating 164 articles with a potential audience of more than 41 million. The day's events were likewise reported on by the journalists in attendance via social media.

The year ended with the staging in December of the **6th Somos Pacientes Seminar,** which included the prize-giving ceremony for the **4th edition of the Somos Pacientes Awards**. The event was held in Madrid at the Canal Foundation with the central focus on patient participation in biomedical research, and proved a success in terms both of audience, with more than 200 people attending, and also media impact, above all via Twitter, where it became a national trending topic. The seminar was attended by around a dozen journalists, and the content covered was featured in 97 articles with a potential audience of more than 11 million people.

PARTICIPATION IN THE #WEWONTREST INITIATIVE

FARMAINDUSTRIA has been one of the most active organisations in publicising the information initiative #WeWontRest, promoted by EFPIA, with the aims of illustrating how medicinal research has transformed healthcare and life expectancy, and also showcasing the firm **commitment that the innovative pharmaceutical sector** has towards patients, as the main raison d'être of the manufacturers' efforts.

FARMAINDUSTRIA distributed campaign materials throughout the year tailored to a specifically Spanish audience, and also linked various items of information coinciding with the ultimate aims of the #WeWontRest initiative.

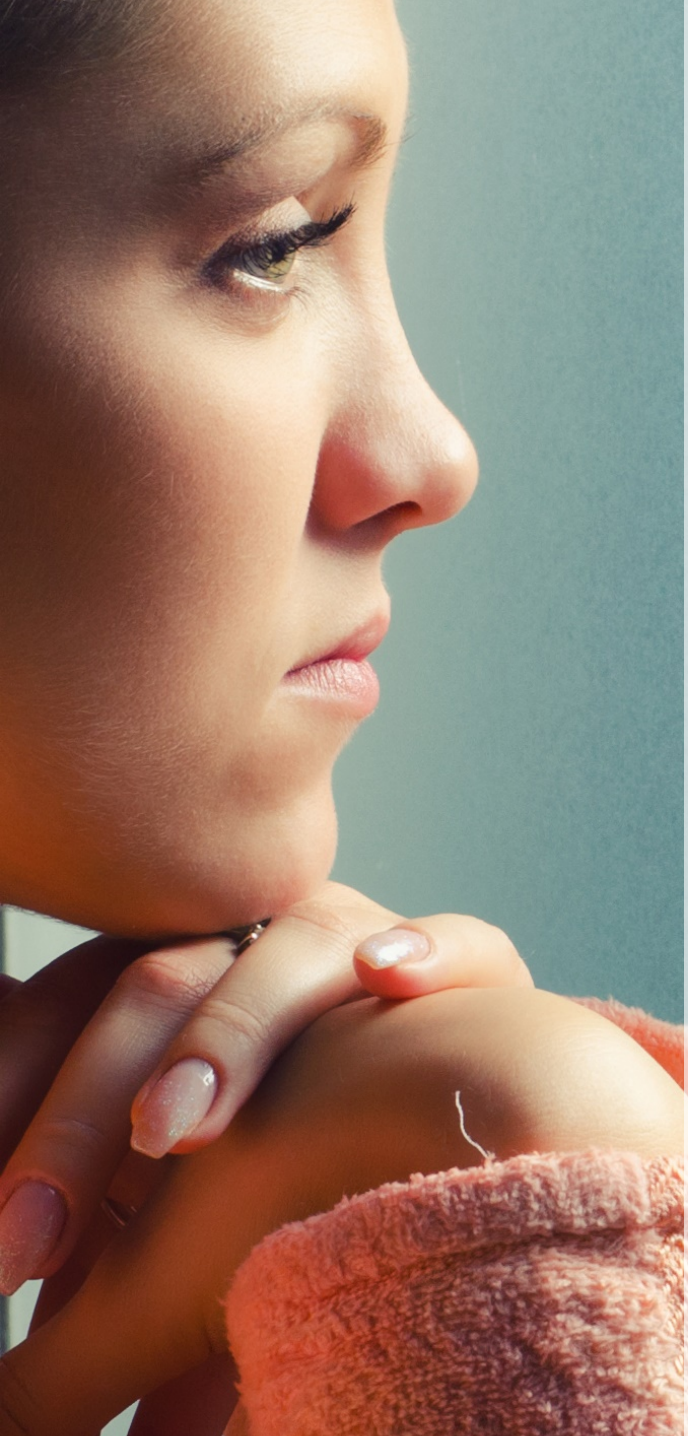
Following an initial phase in which the initiative focused on the commitment of all those working in the pharmaceutical industry to **research and develop** new medicines and collaborate with healthcare professionals and systems to ensure that these medicines reach the patients that need them, the second phase added new content under the hashtag *#BrighterTomorrow*, with the aim of highlighting the commitment of the innovative pharmaceutical industry to offer a better future to patients suffering from serious conditions, and who are gradually seeing substantial improvements to their health and quality of life.

Subsequently, in 2018 and on the basis of the principle that patients should also play a lead role, *#ForTheChance* was launched as a new phase of the initiative. Through this content a number of patients explain individually and in a direct and straightforward manner how pharmaceutical innovation has given them a second opportunity to engage in activities that are particularly motivating for them.

INTERNAL COMMUNICATION

Internal communication remains an important operational area for FARMAINDUSTRIA. The **Communication Working Party** held quarterly meetings attended by a great many manufacturers' representatives.

These meetings addressed the issues of greatest interest for the sector, such as the **challenges of new precision medicine and the sustainability of the healthcare system**, along with an analysis of initiatives in the field of communication.



RELATIONSHIPS WITH PATIENTS' ASSOCIATIONS

In 2018, FARMAINDUSTRIA maintained its dedication to collaboration and service for the benefit of patients' groups and the associations that represent them. The Association sees patients, relatives, disabled people and carers, as a further interlocutor in the health sector through their organisations, aiming to maintain the **best possible relationship** with these bodies and to establish areas of cooperation in those spheres where common or shared interests can be defined. With that goal in mind, action in this area focuses on two distinct lines:

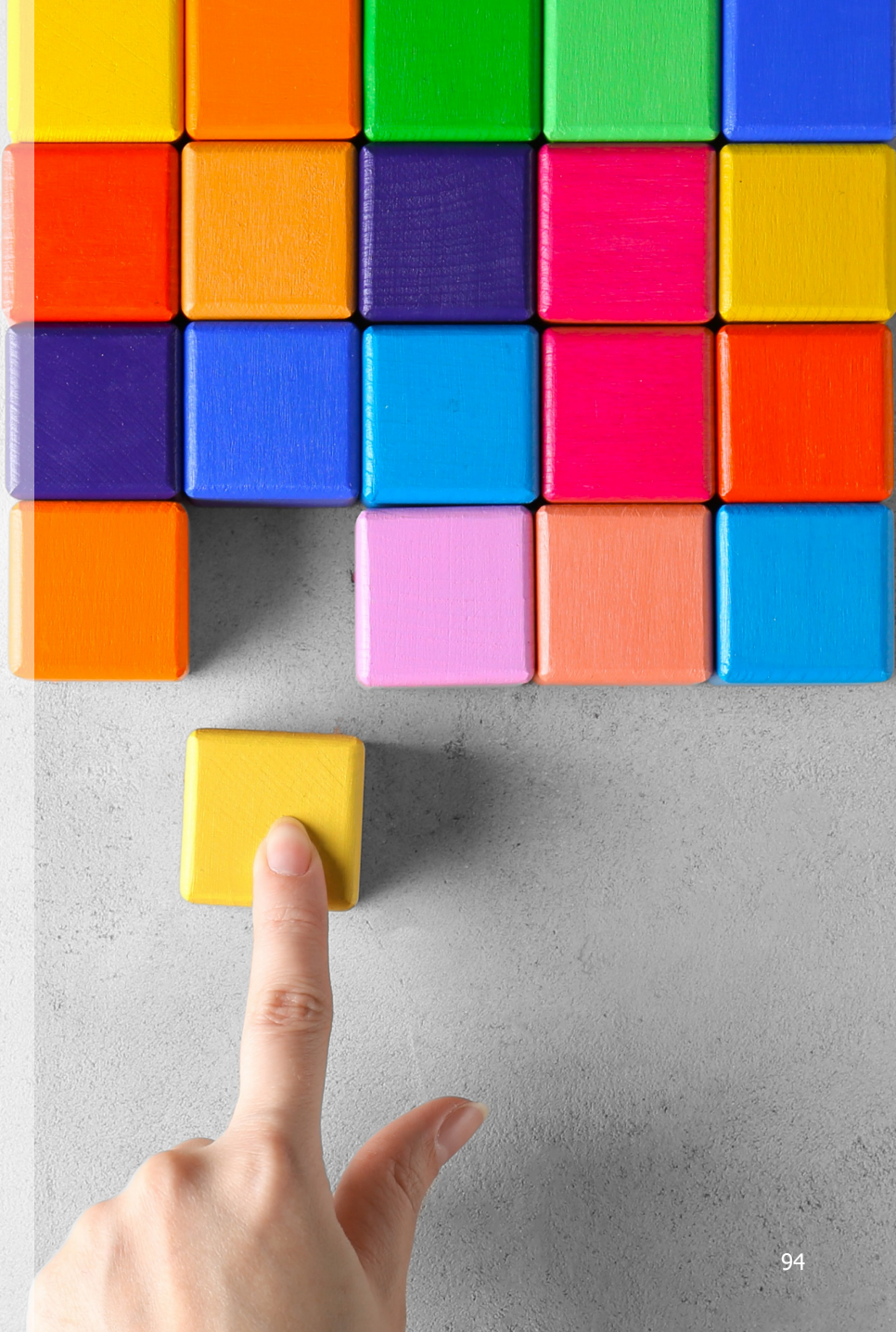
1 | **Dialogue with associations, both directly and through Farmaindustria's** Standing Dialogue Panel with Patients' Organisations.

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

Collaboration with patients' associations

In 2018, FARMAINDUSTRIA took part in numerous gatherings, meetings, training days, seminars and other activities with patients' organisations to **share experiences and support their efforts**. We would highlight in particular in this regard the course organised each year by **FECMA (Spanish Breast Cancer Federation)** at Menéndez Pelayo International University, the 2nd Congress of the Platform of Patients' Organisations, and the radio programme Enfermedades Raras, which focuses on rare diseases.

FARMAINDUSTRIA also maintained its lines of collaboration both with the Platform of Patients' Organisations and the Spanish Patients' Forum, the two main bodies representing patients as a group in Spain.



Standing Dialogue Panel

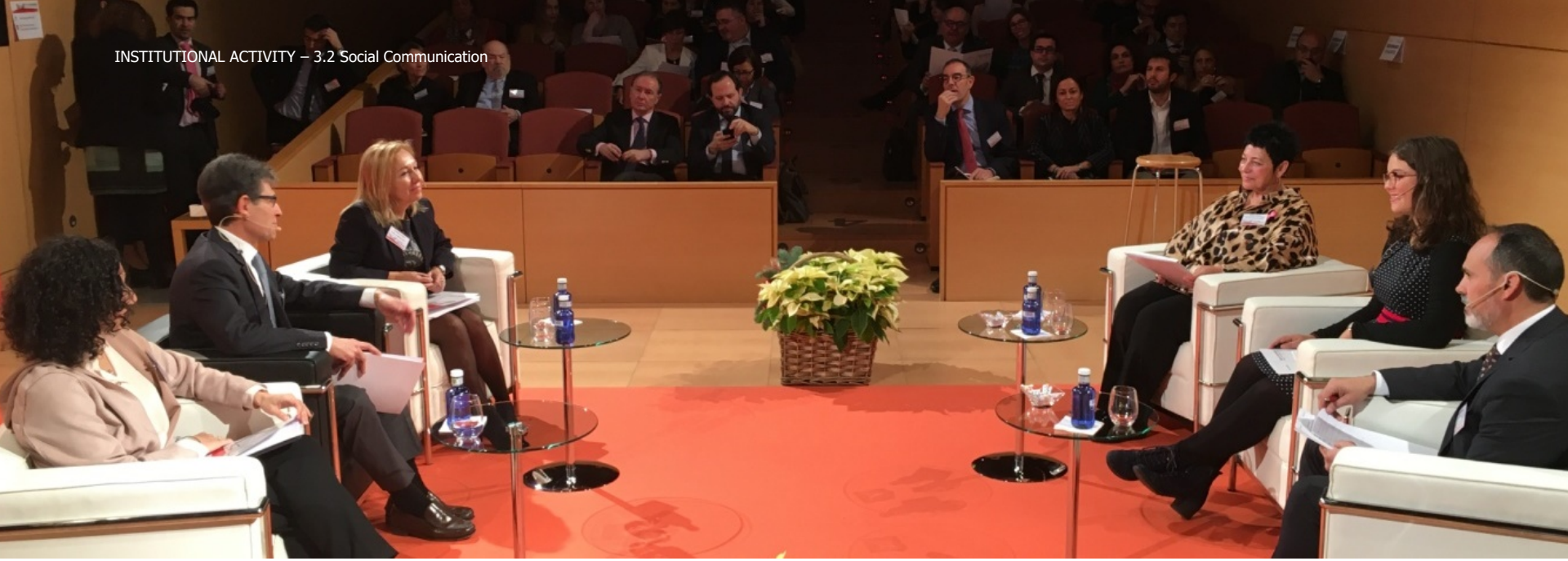
The FARMAINDUSTRIA Standing Dialogue Panel with Patients' Organisations maintained in 2018 its activity as a forum for information and discussion with a representative group of more than 20 federations and confederations of patients' associations to address current and common interest issues with the goal of **securing a relationship of mutual trust** and improving along with recognition of the needs and concerns of this group. The Panel met twice in 2018, addressing among other issues the efforts focused on patients covered by the different initiatives promoted by EFPIA.

Somos Pacientes

By the end of 2018, the online community of patients' associations Somos Pacientes (www.somospacientes.com), set up by FARMAINDUSTRIA in 2012, brought together more than 1,700 organisations registered and included on the **National Map of Patients' Organisations.**

Somos Pacientes offers a shared space for information, participation, training, services and joint efforts for all patients' and disabled people's associations in Spain, as well as for family members, carers and professionals.

Of all the tools available, those most commonly used by associations are the virtual webinar conferences, online meetings and the live audio and video streaming channel. This functionality allowed **Somos Pacientes** to stage a number of activities in 2018 involving various bodies belonging to the community, along with the whole course of the 6th Somos Pacientes Seminar. This last event has now established its position as the ideal forum for representatives of patients' associations, the innovative pharmaceutical industry, health authorities and healthcare research professionals to exchange ideas, needs and projects. The 6th edition focused on participation by representatives of patients' groups in the process of medicinal R&D.



In turn, the **6th Somos Pacientes Seminar** also included the prize-giving ceremony for the 4th edition of the Somos Pacientes Awards, which received over 140 valid nominations across the six categories and subsections covered. A jury of 14 members with extensive knowledge of this area was set up to chose the winning submissions in the different categories and sections of the awards. One of the awards, the website users' favourite initiative, had nearly 40,000 registered votes online.

The three round table debates staged over the course of the seminar involved representatives from patients' associations, healthcare professionals, public authority spokespeople and members of the pharmaceutical industry. The event attracted more than 150 attendees and could be followed via the Somos Pacientes streaming channel, becoming a national trending topic.

EUPATI - European Patients' Academy

This European Commission initiative in which FARMAINDUSTRIA participated ended in February 2017, having met its goal in 2016 to develop training courses and prepare educational materials, in addition to organising a public online library to **train patients' representatives** and the general public in all processes involved in the development of medicines.

At its conclusion, the group of Spanish entities that had participated in the initiative remained active the National EUPATI Platform in Spain and entered into an agreement with the Spanish Agency for Medicinal and Healthcare Products, allowing several training activities for representatives of patients' groups to be staged in 2017 and 2018. Although FARMAINDUSTRIA has not formally been part of the Platform since February 2017, it has maintained its support and assistance by offering advice and providing spaces and tools for its meetings.

3 Institutional activity

3.1 Market Regulation and Relations with Public Authorities

3.2 Communication

3.3 International Relations

3.4 The Pharmaceutical Industry in Spain and Worldwide

3.3. International Relations

FARMAINDUSTRIA'S international activity revolves around three key aspects:

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

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

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

The Association's alignment with the positions and practices of the international pharmaceutical industry remains a horizontal element cutting across the different actions covered by the **Strategic Plan** drawn up by FARMAINDUSTRIA, the aim being to draw on the experience and information built up by the Association both through its interaction and participation at the two major international federations:

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

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

And in the numerous bilateral and multilateral relationships that FARMAINDUSTRIA maintains with other national pharmaceutical industry associations.

3.3.1 EUROPEAN CONTEXT

ACTIVITIES WITHIN THE EFPIA FRAMEWORK

FARMAINDUSTRIA'S activities at the European level are mainly aligned with the priorities and themes addressed by **EFPIA**, the organisation representing **36 national pharmaceutical industry associations** and **40 companies in Europe.**

These links are consolidated through active participation by FARMAINDUSTRIA in most of the strategic committees and working parties of the Federation.

EFPIA General Assembly and Annual Conference

The EFPIA General Assembly was held in Brussels on 28 June 2018, analysing the progress made in the different matters addressed by the Federation's strategic committees:

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

During the Assembly the priorities and targets for 2018 were reviewed, including in particular:

1 | **Funding models** to make sustainability of healthcare systems compatible with patient access to innovations.

2 | **Consolidation of an environment to protect intellectual property rights** in both European and third-country markets.

3 | **Promotion of effective and flexible regulatory environments** that promote R&D for new medicines.

EFPIA Board

In coordination with its strategic committees, the EFPIA Board approved the following priority issues 2018:

1. The European Commission analysis of intellectual property incentives and waiver of the Supplementary Protection Certificate (SPC).
2. The various joint initiatives between Member States on medicine prices and health technology assessment.
3. The measurement and analysis of health outcome data.
4. The UK's exit from the EU.
5. EU trade policy with third party countries.
6. The operational principles for implementation of the public-private partnership agenda.

In parallel, the Board has prioritised **implementation of the General Data Protection Regulation** by EU Member States, focusing its activity on the area of biomedical research and transfers of value.

Meetings of the EFPIA European Markets Committee (EMC)

Over the course of 2018, under the presidency of Sanofi and the vice-presidency of Servier and FARMAINDUSTRIA, meetings of the **European Markets Committee** (EMC) continued, made up of the **pharmaceutical companies' Heads of Europe** and the Director-Generals of the national associations. The primary objective of this Committee is to monitor national implementation of the decisions made by the EFPIA Board and strategic committees, as well as early detection of risks and threats to the pharmaceutical industry in the Member States.

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

- Advances regarding the EU-Relative Efficacy Assessment (EU-REA).
- Developments at the national level of the Falsified Medicines Directive.
- Possible review by the European institutions of the incentives for industrial property and waiver of the SPC for export to third-country markets.
- Impact of the UK's exit from the EU.
- Regional initiatives for collaboration among European countries on prices and access.

The EMC also analysed best practices in health outcome measurement and analysis in various countries, including the projects that FARMAINDUSTRIA is undertaking in this area.

National Association Meetings (G1 and G2 Groups)

Three meetings of the national associations on the main European markets were held during 2018, including the group known as G1 (Germany, Spain, France, Italy, UK and Switzerland), and group G2 (Belgium, Denmark, Netherlands and Sweden).

These meetings analysed in depth the major new developments in pharmaceutical policy affecting each country, stating their common concern to **make access to innovations compatible with sustainability of healthcare systems.**

Various sections of the meetings also focused on an in-depth analysis of the measurement of health outcomes, the assessment of the relative efficacy of medicines at the European level (EU-REA), and an analysis of the different regional initiatives for collaboration among European countries in the field of prices and access.

MAIN AREAS OF FARMAINDUSTRIA ACTION IN EUROPE

Exit of the UK from the EU (Brexit)

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

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

Phase 1

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

Phase 2

The process was concluded on 25 November 2018 when the Heads of State of the EU gave their support to the UK Withdrawal Agreement, setting the conditions for the relationship between the two parties during the transitional period, along with the Political Declaration, laying the foundations for the future relationship once the transitional period had ended.

At the time this Annual Report was finalised, the UK's exit from the EU remained uncertain, with 31 October 2019 having been set as the deadline for the British Parliament to ratify the withdrawal agreement.

Given the singular nature of the sector, the innovative pharmaceutical industry sees the need to maintain cooperation and regulatory alignment, and to prevent any change in the trading relationship between the EU and the UK from having a negative impact on R&D and the manufacture and supply of medicines, to the detriment of patients.

Accordingly, with the aim of preventing potential disruption in the supply chain and ensuring the utmost preparation for any scenario, the pharmaceutical industry has implemented a series of contingency plans with the **adoption of technical and regulatory measures to guarantee patient safety** and public health after Brexit.

In this regard, and since the start of negotiations between the EU and the UK to determine the withdrawal terms, FARMAINDUSTRIA has maintained constant dialogue with the **Spanish Medicines and Healthcare Products Agency** and with the other Spanish authorities with relevant responsibilities, requesting their support for the sector's demands, focused on a number of strands:

- Regulation
- R+D
- Intellectual property
- Movement of labour
- Trade
- Supply of medicines

This activity has been supplemented by information to pharmaceutical companies as to the extent and consequences of Brexit, particular in a no-deal situation, and as to the need to implement contingency plans to address this possible scenario.

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

2018 was a year of intense debate focused on prices and access to innovations. **The political debate on the pharmaceutical R&D** model and its impact on prices has led the European Commission to assess the impact of intellectual property incentives on access to innovations and the sustainability of healthcare systems.

To this end the European Commission published two studies in 2018 analysing the economic impact of incentives on intellectual property and the legal aspects of the supplementary protection certificate (SPC) in the EU.

The Commission also commissioned a consultancy to analyse the current Regulation on Orphan Medicinal Products, and in parallel launched the public consultation about orphan and paediatric medicinal products.

Through these studies, and others such as the conclusions of the public consultation as to how to optimise the **legal framework of intellectual property rights** and the report on the 10 years of application of the **Regulation on Paediatric Medicinal Products**, the European Commission and the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) will decide in 2019 whether there should be a review of the **intellectual property incentives system**, and if so to what extent.

In order to minimise the risk of a review that would limit the system of intellectual property incentives, and the negative effects this would have on biomedical research, the European industry has developed a three-stand strategy:

1. **Demonstrate** the importance of intellectual property rights for therapeutic progress.

2. **Champion** the success of the pharmaceutical R&D model in terms of the number and characteristics of the new medicines authorised.

3. **Communicate** the value of medicines and their contribution to the European economy.

Ministerial round tables on prices, access and sustainability: High-Level Group

The last meeting was held in March 2018, involving representatives of the Member States, patients' associations and the pharmaceutical industry, although the representatives of the **Member States** decided to initiate a new line of work excluding the representatives of the pharmaceutical industry and patients' associations.

Within this context, the various European federations involved in the **High-Level Group** wrote a joint letter calling for the initial inclusive spirit of the Group to be restored.

FARMAINDUSTRIA is, in unison with **EFPIA**, closely monitoring the progress of this initiative.

Initiatives for collaboration among European countries on pricing and access to innovation

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

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

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

2. **BeneluxAI Cooperation**, made up of Belgium, Netherlands, Luxembourg, Austria and Ireland, which is being monitored given the potential impact of its *Horizon Scanning for Pharmaceuticals* initiative, to which Switzerland has also joined up.

3. **Nordic Council**, involving Denmark, Finland, Iceland, Norway and Sweden. This initiative is designing a pilot mature medicine tender project to explore the possibilities and to check safety/supply stability, taking into account the potential logistical problems and the compatibility of national legislation.

EFPIA has published a series of documents, including in particular a legal toolkit, a set of general principles that these collaboration initiatives should respect, and a document regarding horizon scanning, identifying the potential risks and uncertainties of these initiatives.

In parallel FARMAINDUSTRIA, following on from the actions proposed by **EFPIA**, has established a working party with national associations of the countries involved in the Valletta Declaration, which includes Spain, in order to ensure that any possible action with regard to prices respects the **EFPIA** principles.

European Debate on Access to and Availability of Innovations

Europe's Health Ministers met at an informal Council in September 2018 under the auspices of the Austrian Presidency of the EU to debate regulatory and political challenges, and to guarantee the availability of medicines authorised by the centralised procedure, taking as the reference point a document drawn up by the Austrian Presidency.

This document identifies four challenges:

1. **Lack of information** about the medicines to be marketed, including their prices and the public funds invested in their research.
2. **Approval of medicines** with scant evidence as to their safety and the benefits they offer patients, and discrepancy in the results of the clinical assessment (HTA).
3. **Inequalities in access to medicines** among Member States.
4. **Absence of clear requirements** as to regulation and evaluation of orphan medicinal products.

In parallel, the need to promote the digital transformation of national health systems so as to encourage the measurement of health outcomes was also addressed.

For their part, **EFPIA** and the national associations are closely monitoring the progress of this initiative, aware of the need for the current debate so as for innovation availability and access to be an open one, so as to ensure that this complex issue is addressed to its full extent and with a comprehensive overview.

2019 European Elections: EFPIA Manifesto

Looking ahead to the **European elections** in May 2019, **EFPIA** launched a manifesto in Autumn 2018 setting out our sector's vision of three major issues:

1. "**Health for all**: providing innovative health solutions for all patients".
2. "**European excellence**: positioning the EU as a world leader in biomedical R&D".
3. "**Stronger together**: joining forces to speed up results".

The **EFPIA Manifesto** was drawn up with the aim of directly and convincingly share the political perspective of the innovative pharmaceutical industry with regard to health, and positioning the industry as a key partner of health systems, with the aim for the main messages of the **Manifesto** to be reflected in the priorities of the upcoming mandate of the European Parliament and the European Commission (2019-2024). FARMAINDUSTRIA adapted the **EFPIA** Manifesto to the Spanish national context for local use.

Antimicrobial Resistance

In September 2018 the European Parliament adopted a non-binding resolution: **European One Health Action Plan Against Antimicrobial Resistance**, calling on the European Commission to:

1. **Consider** the creation of a legislative framework to stimulate the development of new antibiotics and vaccines through the introduction of new economic and incentives models to combat antimicrobial resistance

2. **Conduct** assessments to measure the progress of the action plan.

3. **Integrate** all stakeholders within this plan.

The European industry, which is very much aware of the issue and is committed to a solution, has within this context undertaken through **EFPIA** and the national associations a number of support activities, highlighting the need to establish different incentives so as to achieve a satisfactory solution to this major problem.

LEGISLATIVE INITIATIVES IN EUROPE

Modification of the Supplementary Protection Certificate (SPC) Regulation

Within the framework of the global analysis of incentives regarding intellectual property, the European Commission published in May 2018 a proposed modification to the Regulation of the **Supplementary Protection Certificate (SPC)**, bringing in an exemption to this protection by allowing the manufacture of generics and biosimilars during the period of validity, purely for the purpose of exports to third countries where there is no legislation regarding intellectual property or where the exclusivity of the rights has expired. This modification is known as a Manufacturing Waiver.

Although the European Commission justifies this proposal through the aim of establishing an equal framework for generic and biosimilar companies in the EU and their competitors in third country markets, the Commission's proposal in fact damages the innovative pharmaceutical industry by **modifying the status of SPCs**, which were established as a tool to guarantee an effective period of protection for patents which would help to recover the resources invested in **R&D** on the part of innovative companies.

This potential modification to the current status quo in the field of intellectual property, which would weaken the rights that the **EU** grants as an incentive for innovation, could have a negative impact on European biomedical **R&D**, not only through a reduction in research efforts, which would mean a smaller volume of resources, but also and strategically a negative impact on **decisions to invest in R&D in the European continent**. A weakening of intellectual property rights would convey a confusing signal about the European commitment to research that would undoubtedly be taken advantage of by other markets.

By the time of this Annual Report was drawn up, the three-way negotiations between the Council, the commission and the European Parliament as to the proposed modification to the **SPC** Regulation had resulted in an agreement approved by the Member States and ratified by the European Parliament.

Despite the industry's efforts, the agreed text serves to erode intellectual property rights, since aside from the export waiver it also allows for six months of stockpiling which will affect both new **SPC** applications once the Regulation takes effect, and those **SPCs** already in force, from 1 July 2022 onwards.

In addition, the agreement includes a three-month notification system both for national patent offices and for the holder of the **SPC**.

Regulation on Health Technology Assessment (HTA)

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

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

The aim pursued by the Commission was to:

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

In October 2018 the European Parliament approved this proposed **HTA Regulation**, bringing in a series of amendments which include in particular the option for Member States to conduct a supplementary assessment in addition to the joint clinical assessment, provided that this would be justified.

By the time that this Annual Report was finalised, the European Parliament had already approved its position and the proposed Regulation is being considered by the European Council, where there is clear opposition from a number of Member States to the mandatory requirement to apply joint assessments at the national level, which could delay final approval of the Regulation.

In line with EFPIA, **FARMAINDUSTRIA** supports a future European regulatory proposal in the field of **HTA** based on centralised clinical assessment which will avoid inefficient re-assessments at the national level, and would prevent barriers and delays in access to innovations on the part of European patients.

Directive 2011/62/EU (falsified medicinal products). Delegated Regulation (EU) 2016/16. Setting up SEVeM in Spain

After publication in the Official Journal of the EU on 9 February 2016 of **Commission Delegated Regulation (EU)** 2016/161, which establishes specific rules on the inclusion of mandatory safety features in medicine packaging (unique identifier and anti-tampering device), the planned three-year period for full compliance officially began, requiring all prescription medicines (with few exceptions) to carry safety and anti-tampering features to verify their authenticity.

During this period the Member States should establish their national verification systems, responsible for managing the repositories storing information about these security devices, which must be fully operational by 9 February 2019, the date of application of the Regulation.

In addition, after the meetings and intense work conducted with all agents in the medicine supply chain, in July 2016 the company managing the **Spanish Medicines Verification System (SEVeM)** was set up, comprising FARMAINDUSTRIA, the Spanish Association of Generic Medicines (AESEG), the General Council of Official Associations of Pharmacists (CGCOF) and the National Federation of Wholesalers Association of Medicinal Products and Parapharmaceutical Products (FEDIFAR).

SEVeM officially came into being in September 2016 with the establishment of its Board of Directors, of which FARMAINDUSTRIA is the President, while meetings also involve AEMPS, which furthermore acts as the system supervisor. The Spanish system has been fully operational in connection with the European hub since 9 February 2019, in accordance with the Delegated Regulation.

3.3.2 INTERNATIONAL CONTEXT

ACTIVITIES WITHIN THE IFPMA FRAMEWORK

FARMAINDUSTRIA channels much of its activity in the international context through its participation in the **International Federation of Pharmaceutical Manufacturers and Associations** (IFPMA), an organisation comprising **50 associations** (47 national and 3 regional) and **37 pharmaceutical companies**.

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 parties of which FARMAINDUSTRIA is also a member and in which it participates actively and regularly.

Meetings of IFPMA's governing bodies

FARMAINDUSTRIA took part in the Board meetings and the **IFPMA** Assembly. These meetings addressed the Federation's priorities with regard to intellectual property, innovation and access.

A number of changes were also made to the **bylaws** regarding association formats and the principles of governance for its committees and operating practices.

Intellectual property

On 3 October 2017, **IFPMA and the World Intellectual Property Organization (WIPO) signed a partnership agreement** through the Patent Information Initiative for Medicines (Pat-INFORMED) to allow access to patent information through a global portal with public information on pharmaceutical patents.

The portal was ultimately launched on 25 September 2018 to coincide with the General Assembly of the **WIPO**.

In parallel, and given the constant emergence on multilateral forums of initiatives hostile to the intellectual property system, the Governing Bodies of **IFPMA** approved in December 2018 the launch of a strategy and action plan focused on developing a narrative based on the generation of evidence as to the **importance of intellectual property, therapeutic progress**, along with the value proposal of the innovative pharmaceutical industry. Both the companies and the associations belonging to the **IFPMA** have signed up to this initiative.

OECD Report on Sustainable Access to Innovative Therapies

In 2017, the **OECD** issued a draft report with recommendations on international price regulation and access to pharmaceutical innovations of great concern for the industry due to the limited focus (based on pricing and spending analysis in a small number of therapeutic areas and the North American market) and its inconsistency with other guidelines of the **OECD** itself on innovation, access and sustainability.

As a result of the joint efforts by **IFPMA** and the contribution of the various working parties involved, the final report (published in late 2018) is more balanced, and includes references that emphasise and acknowledge the **innovative role of the pharmaceutical industry in improving global health.**

UN High-Level Meeting on Tuberculosis and Non-communicable Diseases

In 2018 the United Nations held its High-Level Meetings on Tuberculosis and Non-communicable Diseases, with the aim of seeking solutions and establishing measures to be implemented by its Member States.

In parallel with these meetings, **IFPMA** organised and participated in a number of events where it shared the **importance of R&D in combating tuberculosis and non-transmissible diseases,** and reported on the activities and initiatives led by the industry in these fields.

COMPETITIVENESS AND INTERNATIONALISATION

In the sphere of **overseas trade**, FARMAINDUSTRIA acts in coordination with **EFPIA** through specialist working parties. The ultimate goal is to improve the presence of member pharmaceutical companies in international markets.

Below is a brief summary (focused on the area of medicines) of the current status of the major EU agreements being negotiated with third countries or regions.

EU-US Mutual Recognition Agreement on the Inspection of Medicines

On 1 November 2017 the Mutual Recognition Agreement on the inspection of medicines between the European Union and the USA took effect. This Agreement **allows the automatic recognition of inspections** conducted at plants producing medicines for human use (while for the moment excluding vaccines and plasma derivatives) in the EU and USA, **avoiding duplicate inspections and fast-tracking access to medicines**.

Spain is one of the 22 EU Member States that has since November 2017 passed an audit by the US regulatory agency (the FDA), and which will be in a position to benefit from the advantages offered by the Agreement. All other EU Member States must wait until July 2019 to obtain this recognition.

EU-Canada Comprehensive Economic and Trade Agreement (CETA)

After final adoption and signing on 30 October 2016, the EU-Canada Comprehensive Economic and 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 the EU Member States in order to enter fully into force. To date, **eight Member States have already ratified the Agreement**, including Spain.

Furthermore, a comprehensive follow-up of Law B-30 is being carried out, which will transpose into Canadian legal regulations the **main provisions of CETA** on pharmaceutical intellectual property:

- Right of appeal for innovative manufacturers.
- Patent protection compensation periods.
- Extension of the data protection period.

EU-Japan Economic Partnership Agreement (EPA)

On 8 December 2017, negotiations of the **Economic Partnership Agreement** between the EU and Japan concluded successfully, based on the agreement reached in July 2017. In essence, the agreement aims to **eliminate trade barriers.**

The Agreement was ratified by the European Parliament on 12 December 2018, and took effect on 1 February 2019.

EU-Mercosur Association Agreement

In 2015, the EU and Mercosur (made up of Argentina, Brazil, Paraguay and Uruguay) relaunched the negotiations of the **Association Agreement**, initiated in 1999 and suspended in 2004. Although the negotiation rounds during 2017 and 2018 intensified, a final text could not be established for the Agreement.

Modernisation of the EU-Mexico Global Agreement

In May 2016, the EU and Mexico began negotiations to update the agreement signed in 2001. Negotiations are making positive progress, with a political agreement having been reached in April 2018. Signature of the agreement is expected to be possible in 2019, once the legal review is complete and more technical aspects have been finalised.

The noteworthy clauses established for the agreement include:

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

EU-Australia and New Zealand free trade agreements

On 22 May 2018 the European Council adopted the negotiation guidelines for the **free trade agreements** with Australia and New Zealand.

The negotiations are making positive progress, with reports and draft texts having been published as a result of the initial rounds of negotiations over the course of 2018.

3 Institutional activity

3.1 Market Regulation and Relations with Public Authorities

3.2 Communication

3.3 International Relations

3.4 The Pharmaceutical Industry in Spain and Worldwide

3.4 The Pharmaceutical Industry in Spain and Worldwide

3.4.1 THE PHARMACEUTICAL INDUSTRY IN EUROPE

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

In this regard, in 2018 the EU economy registered **growth of +1.9%**, which although it is undoubtedly a good figure, nonetheless represents a slow-down of five tenths compared with the growth seen the previous year, which would seem to suggest that activity is slacking off to an extent.

Despite the above, 2018 now marks the fifth year of consecutive growth by the European economy, with increases ranging between +1.6% and +2.4%. This economic boom period has led to **greater job creation**, as reflected in the downturn in the unemployment rate in the EU-28, ending at 6.6% of the active population in 2018, the lowest rate of unemployment in Europe since the year 2000.

The pathway towards **budgetary consolidation** likewise continued in 2018, with a reduction for the eighth consecutive year in the overall deficit of public authorities in the EU, dropping from 6.9% of GDP in 2009 0.6% in 2018.

With a view to the future, the European economy will continue to grow, although forecasts would seem to confirm a slowdown in the levels of growth, as indicated above. In its ***European Economic Forecast – Winter 2019***, the European Commission predicted a real GDP growth rate for the EU of +1.5% for 2019.

Regarding the pharmaceutical industry, it should be remembered that despite the reduction of the aforementioned deficit, healthcare budgets in member countries continue to be tightly controlled, resulting in **containment measures on public health and pharmaceutical spending**.

This inevitably has an effect on the evolution of a market such as the pharmaceutical sector that is strongly regulated and highly dependent on public budgets.

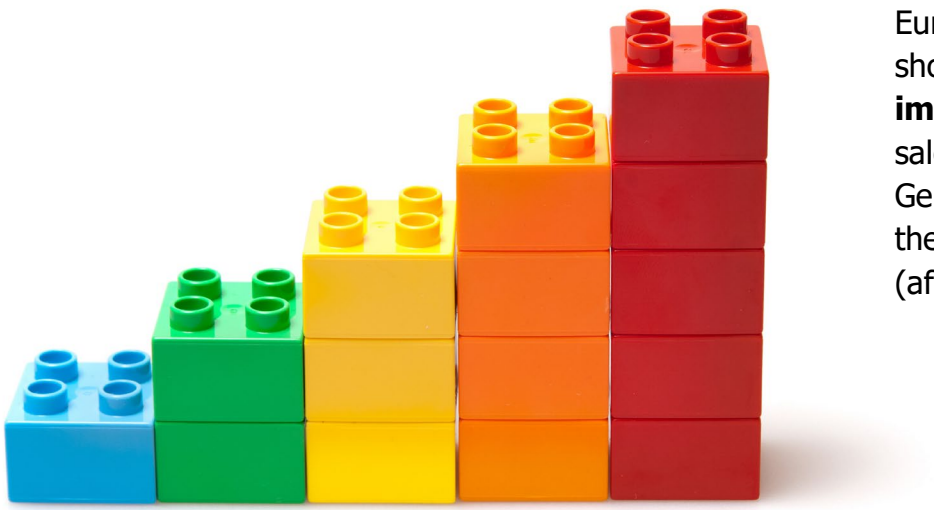
In addition, these measures can often lead to restricted market access for certain products and growing pressure on medicine prices, which in turn results in a cascading effect on countries whose reference prices are dependent on each other.

Although the aforementioned factors will limit the growth of the European pharmaceutical market over the coming years, there are other elements which will drive sales upwards, such as:

1. **An ageing population.**

2. **The chronification of certain conditions.**

The consultancy IQVIA predicts in this regard an average rate of increase for the five main European markets over the period 2019-2023 (in the range of +1%/4%) significantly lower than that predicted worldwide (+3% to 6%) and the growth predicted for the USA (+4%/7%), as well as such emerging markets as Brazil, India and Russia, which will register average annual growth in the range of +7%/10%.



Meanwhile, among the five main European markets, **France (-1%/+2%) and Spain** (+1%/+4%) will be the countries registering the **lowest annual average growth** over the period 2019-23, while the forecast for Germany is for a growth of between +3% and +6%, with Italy and the United Kingdom seeing average growth rates of from +2% to +5% a year.

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

GENERAL DATA FROM THE PHARMACEUTICAL INDUSTRY IN THE UE-15 (2016)						
Country	**Number of manufacturers** (1)	**Output** (million €) (2)	**Employment**	**Domestic Sales** (MSP) (million €) (3)	**Foreign Trade** (MSP) (€ million) (4)	
					Import	Export
Germany	304	29,197	115,663	30,815	44,721	69,513
Austria	116	2,737	14,634	3,657	8,349	8,405
Belgium	122	12,821	35,250	4,771	33,506	40,723
Denmark	33	14,219	26,963	2,446	3,604	12,301
Spain	**183**	**15,144**	**41,102**	**15,595**	**13,201**	**10,497**
Finland	45	1,721	4,792	2,333	2,011	840
France	255	19,040	98,796	28,362	23,141	28,271
Greece	65	895	16,800	4,890	2,853	1,059
Netherlands	43	6,180*	17,900	5,052	21,085	28,495
Ireland	46	19,305*	26,373*	1,977	6,238	30,169
Italy	186	30,010	64,400	25,959	22,124	20,524
Portugal	118	1,686	7,400	2,983	2,429	1,131
United Kingdom	69	22,445	61,000	20,774	30,066	30,318
Sweden	90	7,302	11,012*	2,917	3,923	7,308
Total EU-15	**1,675**	**182,702**	**542,075**	**152,531**	**217,251**	**289,554**

(*) Figures from previous years

Note: Luxembourg is not included due to poor representation.

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

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

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

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

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

3.4.2 THE PHARMACEUTICAL INDUSTRY IN SPAIN

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

The above assertion is one of the fundamental principles of the document entitled **Agenda for Change**, which highlights how research, development and innovation (R&D+i) activities represent a core element for a model of sustainable, competitive high-quality growth, and are vital to create employment and improve the productivity and competitiveness of an economy.

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

The document sets out a series of objectives to be achieved over the coming years in terms of the R&D spending of our economy in relation to GDP and how it is distributed between the public and private sectors. These objectives are summarised in the following table:[2]

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

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

Nonetheless, the most recent figures published by the INE (Spanish National Statistical Institute) for the year 2017 indicate that the actual evolution of expenditure on R&D in the country has progressively diverged from the above goals, seriously compromising the achievement of the targets set for 2020. The weighting of R&D spending over national GDP thus fell from 1.39% in 2010 to 1.20% in 2017, well below the 2.00% target set for 2020.

In terms of R&D expenditure funded by the private sector, far from increasing the proportion of GDP, levels have dropped from 0.60% in 2010 to 0.57% in 2017, and the volume would therefore need to double over the period 2018-2020 to achieve the targets agreed with Brussels (1.2% of GDP by 2020), which would be a real challenge.

With regard to the more immediate future, the **2017-2020 State Scientific and Technical Research and Innovation Plan** establishes the operational framework for the coming years with a view to achieving the goals of the Spanish Science, Technology and Innovation Strategy 2013-2020, and the Europe 2020 Strategy.

This Plan contains a specific programme to promote R&D carried out by the private sector, since as is literally cited in the Plan:[3]

> Business investment in R&D+i in Spain, representing 0.64% of GDP in 2016,[4] is almost half the EU-28 average (1.3%) and is one of the most notable structural weaknesses of the Spanish Science, Technology and Innovation System.

3 Page 6 of the 2019 National Reform Programme of the Kingdom of Spain. April 2019. Available at: http://www.mineco./mineco/comun/pdf/190430_np_programa.pdf

4 This percentage (0.64%) refers to R&D conducted in 2016 by the private sector, while R&D funded by the sector represented 0.55% of GDP in the same year.

Subsequently, the new Government confirmed its commitment to the Europe 2020 objectives, while agreeing to highlight the need to promote private R&D which, it acknowledges, will represent the main goal of the **Spain – Enterprise Nation Strategy**, the design of which is now being finalised.

It is essential with this aim in mind to boost and promote the **participation of the pharmaceutical industry** in its role as leading industrial sector in research, as demonstrated by the data of the INE, which may be summarised as follows:

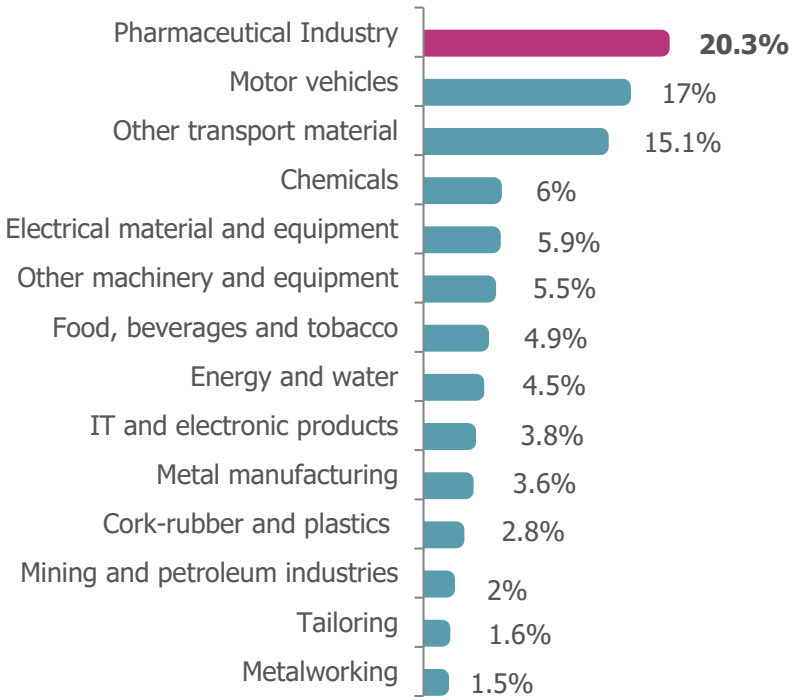
1 |

The pharmaceutical industry invested 966 million euros in research and development in 2016,[5] 20.3% of the total R&D investment in Spanish industry, which makes it the leading industrial sector by volume of spending on research. It is also a particularly significant percentage if one considers that the turnover from pharmaceutical companies only represented 2.4% of Spanish industry overall.

2 |

An analysis of the breakdown of R&D expenditure by sector reveals that the pharmaceutical sector heads the industrial rankings in terms of the volume of resources allocated to applied research, accounting for 31% total.

Main industrial sectors by R&D investment
(as % of industrial total) (2016)



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

[5] By the time that this Annual Report was finalised, the INE had not yet published the 2017 figures for external expenditure in R&D by business sector, and the sectoral evaluations are therefore based on the full information published for 2016.

3

Meanwhile, the pharmaceutical industrial sector is the leader in research conducted internally at company-owned centres (18.2% of the total industrial sector) and above all in research contracted with third parties (universities, hospitals, public or private centres, etc.) where it accounts for 29% 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 4,956 professionals working on these tasks full time.

In addition, two thirds of these posts were occupied by women, meaning that currently one out of every four female researchers employed by the Spanish industrial sector work at pharmaceutical companies.

The above data demonstrate the **pharmaceutical industry's research leadership** and its strategic importance in shaping a new growth model in our country. Consequently, and to make progress on this goal, it would be desirable to develop policies that, without compromising savings goals or the need for austerity measures within the different government areas, would help to reconcile these aims with developing the industrial sectors needed to support and extend economic growth in our country over the last few years.

DOMESTIC MARKET

According to the figures published by the Ministry of Public Finance, in 2018 **hospital expenditure** registered an increase of **+7.3%.**

In turn, according to FARMAINDUSTRIA'S own estimations, **sales of medicines** at retail pharmacies in 2017, in net figures after the deductions set out in Royal Decree-Act 8/2010, increased by **+1.8%.**

As a result of the evolution of the two segments, **total sales** of medicinal products in 2018 would have increased by around **+4%** compared with 2017.

DOMESTIC MARKET FOR MEDICINAL PRODUCTS (MSP, million €)						
	Retail pharmacies (1)	Increase (%)	Hospitals (2)	Increase (%)	Total	Increase (%)
2015	8,957	+1.3 %	6,386	+26.4 %	15,343	+10.4 %
2016	9,361	+4.5 %	6,002	-6.0 %	15,603	+0.1 %
2017	9,579	+2.3 %	6,168	+2.8 %	15,747	+2.5 %
2018	9,756	+1.8 %	6,619	+7.3 %	16,375	+4.0 %

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

(2) Provisional data on public hospital spending for regions, civil service mutual insurers and prison institutions published by MINHAFP.

Source:

Retail pharmacies: FARMAINDUSTRIA from IQVIA data and own estimations.

Hospitals: MINHAFP hospital pharmaceutical spending. Updated March 2019.

Retail pharmacy market

In 2018 the total market via retail pharmacies recorded an **increase in sales of +1.7%,** thanks to a rise in the units sold of +1.4%, and an average price increase of +0.3%.

Nonetheless, as the following table shows, the sales corresponding to the **market open to reimbursement via the NHS**, which accounts for 88% of the total, grew by 2.8% as a consequence of a +2.5% increase in the number of units and a rise of +0.2% in the average price.

In November 2018 a new reference price order was published, creating 20 new groups and eliminating 11. As a result, the Reference Pricing System groups within the scope of retail pharmacies total 428, of which 147 have a composition without any generic medicine (3 of them with a biosimilar medicine). The new order took effect for expenditure purposes in January 2019.

MARKET STRUCTURE AT RETAIL PHARMACIES

	Units (million)	Share	Inc.	MSP Sales (million €)	Share	Inc.	Average MSP (€)	Inc.
Market subject to reimbursement	1,125	85.9 %	+2.5 %	8,835	87.8 %	+2.8 %	7.85	+0.2 %
Non-reimbursed market	185	14.1 %	-5.0 %	1,230	12.2 %	-5.2 %	6.64	-0.3 %
Total market (prior to deductions under Royal Decree-Act 8/2010)	**1,310**	**100 %**	**+1.4 %**	**10,066**	**100 %**	**+1.7 %**	**7.68**	**+0.3 %**

Source: FARMAINDUSTRIA from IQVIA data and own estimations.

During 2018 there were **283 new medicines** released into the domestic market by the retail pharmacy channel, registering total sales of 60 million euros.

Of these 283 products, **189 correspond to generic medicines, 20 are pharmacy medicines, 4 are medicines containing a new active substance**, and the remainder contain active substances or combinations of active substances that already existed in the marketplace.

By late 2018, 82.2% of the units sold on the retail pharmacy market were at the same price level as their corresponding generic.

Therapeutic groups

In 2018, based on IQVIA data, **total sales of medicines** via retail pharmacies by therapeutic group were distributed as shown in the following table.

TOTAL SALES OF MEDICINES VIA RETAIL PHARMACIES BY THERAPEUTIC GROUP (2018)

Therapeutic group	Units (thousands)	Share (%)	Inc. (%)	MSP values (thousands)	Share (%)	Inc. (%)	Average MSP (€)	Inc. (%)
N Nervous System	342,167	26.1 %	2.9 %	2,336,791	23.2 %	2.5 %	6.83	-0.4 %
A Alimentary tract and Metabolism	205,729	15.7 %	1.8 %	1,849,077	18.4 %	7.4 %	8.99	5.4 %
C Cardiovascular system	256,181	19.6 %	2.5 %	1,513,831	15.0 %	-0.9 %	5.91	-3.3 %
R Respiratory system	124,358	9.5 %	1.1 %	1,073,616	10.7 %	4.0 %	8.63	2.9 %
G Genito-urinary Products	53,896	4.1 %	0.5 %	677,671	6.7 %	-3.1 %	12.57	-3.6 %
B Blood and blood forming organs	67,206	5.1 %	0.7 %	664,729	6.6 %	10.4 %	9.89	9.6 %
M Musculoskeletal system	84,812	6.5 %	-1.0 %	455,606	4.5 %	-1.7 %	5.37	-0.7 %
J Anti-infectives for systemic use	47,003	3.6 %	-3.5 %	352,325	3.5 %	-15.9 %	7.50	-12.9 %
L Antineoplastic and immunomodulating agents	6,788	0.5 %	3.5 %	350,350	3.5 %	-2.3 %	51.61	-5.6 %
D Dermatologicals	49,021	3.7 %	-1.5 %	289,238	2.9 %	0.9 %	5.90	2.4 %
S Sensory organs	43,160	3.3 %	-2.3 %	227,396	2.3 %	-1.9 %	5.27	0.4 %
H Hormones	23,132	1.8 %	4.6 %	216,206	2.1 %	2.3 %	9.35	-2.2 %
V Various	1,506	0.1 %	5.4 %	44,411	0.4 %	0.0 %	29.49	-5.1 %
P Antiparasitics	1,735	0.1 %	3.2 %	9,793	0.1 %	-2.5 %	5.64	-5.6 %
K Hospital solutions	3,346	0.3 %	-13.3 %	4,114	0.0 %	1.5 %	1.23	17.0 %
TDiagnostic agents	18	0.0 %	3.9 %	305	0.0 %	6.8 %	17.15	2.8 %
TOTAL	**1,310,056**	**100.0 %**	**1.4 %**	**10,065,461**	**100.0 %**	**1.7 %**	**7.68**	**0.3 %**

The **Central Nervous System** group, which accounts for a quarter of the pharmaceutical market in terms of units and values, **grew by +2.5%** as a consequence of an increase of +2.9% in the units sold, owing to a rise in the consumption of painkillers, which are 47.2% of units in this group. As for the average price, following a slight increase in 2017 this once again dropped, as has been the case since 2010.

With regard to **Digestive Apparatus**, the average price of the medicines lying within this group **grew above the average**, both as a result of the release of therapeutic innovations, and because this is one of the groups with the greatest number of units still under patent.

As for **Cardiovascular Apparatus**, this group registered a further **drop in the average price of -3.3%,** affected by the lower price of certain medicines in this group within the dynamic of Homogeneous Groupings. Around 90% of the units in this group lie within the Homogeneous Groupings and/or Reference Prices System segment.

The set of medicines belonging to the **Respiratory Apparatus** group revealed **an increase in sales of +4%**. Within this group, only 60% of the units sold are open to funding, and the average price of this latter group registered an increase of +0.7%, following successive falls over recent years as a consequence of the impact of reference prices.

Hospital Market

In the hospital market, according to IQVIA data 67.5% of sales are concentrated in two therapeutic groups:

1. **Group L -** Antineoplastic agents and immunomodulatory agents, in which antineoplastic agents account for 69.3% and immunosuppressive agents for 29.5%.

2. **Group J -** General anti-infectives, a group in which systemic antivirals account for 75.8% of sales.

The new **reference price** order published on 28 November 2018 created **23 new groups** in the hospital area, bringing the total number of reference groups in this area to **217 at present** (106 of which correspond to clinical packaging formats), 41 of which were created without a generic medicine, with 6 based on a biosimilar medicine.

In 2018, 101 new medicines were added to the hospital market, of which 44 are generic medicines, 8 are biosimilar medicines, 20 are new active substances, and the rest are medicines with active substances or combinations of active substances already on the market.

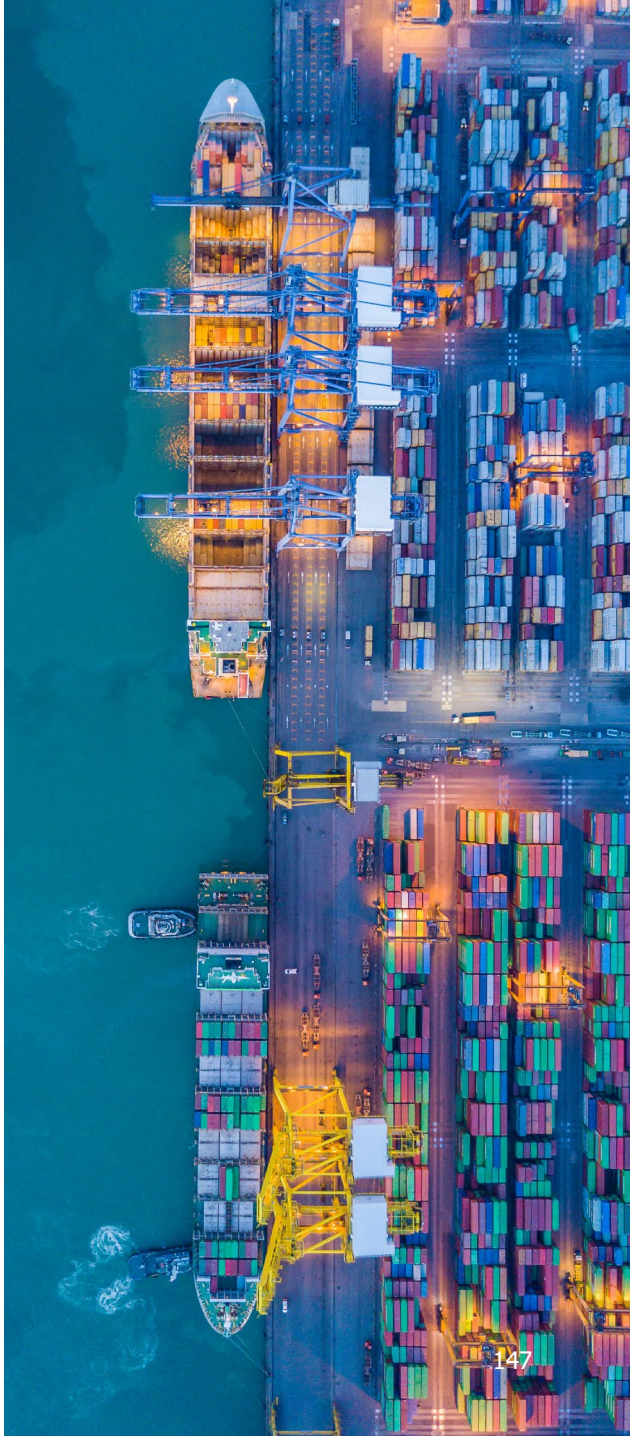
PHARMACEUTICAL FOREIGN TRADE[6]

The **production structure of the Spanish economy** has traditionally made the country an importing nation in net terms, as it spends more on foreign purchases than it produces for foreign markets, which means that the **trade deficit** is one of the traditional imbalances in the economy.

This trend is exacerbated in times of economic boom, in which internal demand strongly drives imports, slowing down at times of a deceleration in economic activity when foreign purchases are at a reduced pace and when companies based in our country are obliged to send their surplus production abroad with the resultant increase in exports.

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

[6] The data in this section are confined to foreign trade in pharmaceutical products. The 2018 data are provisional, subject to subsequent review, and should therefore be interpreted with caution.



Success was subsequently achieved in containing the traditional pattern of behaviour of Spain's trade balance during boom periods, since despite the **upturn seen in the Spanish economy** over the last five years (2014-2018), the trade deficit by late 2018 stood at 2.8% of GDP, in other words just 1.2 percentage points higher than the level in 2013, which remains Spain's best balance of trade figure since 1995.

Meanwhile, the cover ratio (the ratio of exports to imports) stood at 89% at the close of 2018, a very similar figure to the record maximums seen in 2013 and 2016 (93% in both cases).

Despite the reduction of 3 percentage points compared with 2017, these levels of coverage are much higher than those seen in the Spanish economy prior to the economic crisis, when the ratio stood at around 65%, demonstrating the paradigm shift and the evolution towards **a more export-focused productive model** in the country.

This strong growth trend was seen again last year, in which **Spanish exports** recorded an **increase of +2.9%** compared with 2017, although it is also true that imports grew at an even higher rate (+5.6%), which explains the slight worsening of the trade deficit from 2.1% of GDP in 2017 to 2.8% in 2018.

As regards overseas trade in the pharmaceutical sector, this followed a very similar track in 2018 to the overall balance of trade, registering a **higher level of growth in imports** (+7.8%) than exports (+1.1%), leading to a reduction in the pharmaceutical sector cover ratio, from 80.1% in 2017 to 74.1% in 2018.

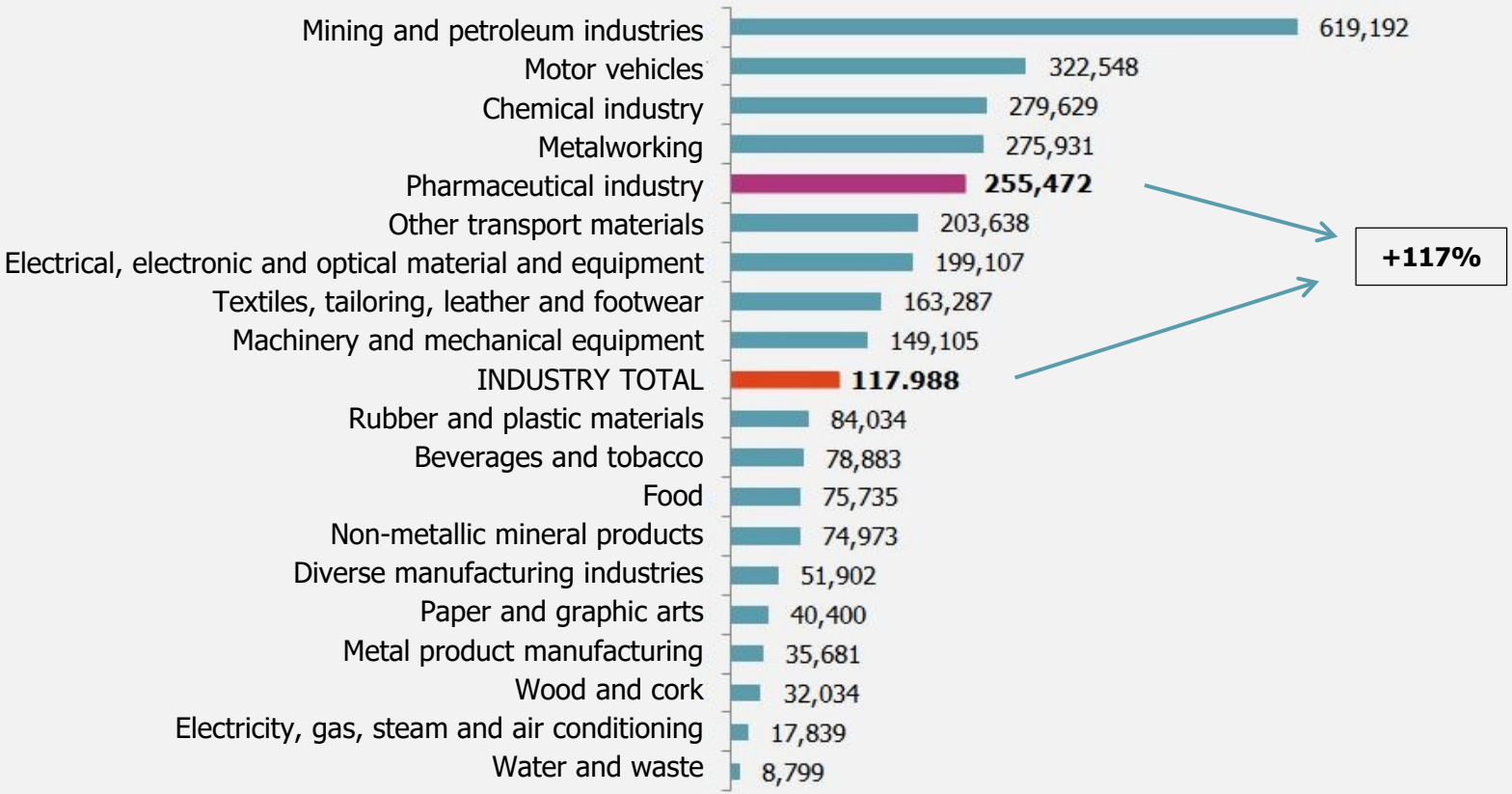
In 2018, the pharmaceutical export figure for the second time in its history broke the 11 billion euro barrier (this first occurred in 2015), accounting for **3.9% of total goods exports** from the country. These figures serve to consolidate the pharmaceutical industry's position as the sixth-largest export sector in the Spanish economy according to the tariff section classification.

The above figures highlight the significance of the pharmaceutical industry for Spanish overseas trade through an export contribution that is much higher than one would expect according to its size (0.7% of domestic GDP). However, the significance of the industry in the exports sector is not only quantitative but also qualitative, as demonstrated by the fact that, according to INE figures, **pharmaceutical exports represent 25% of all domestic exports of high-tech products**, making it the most important sector in this field, alongside the aerospace industry.

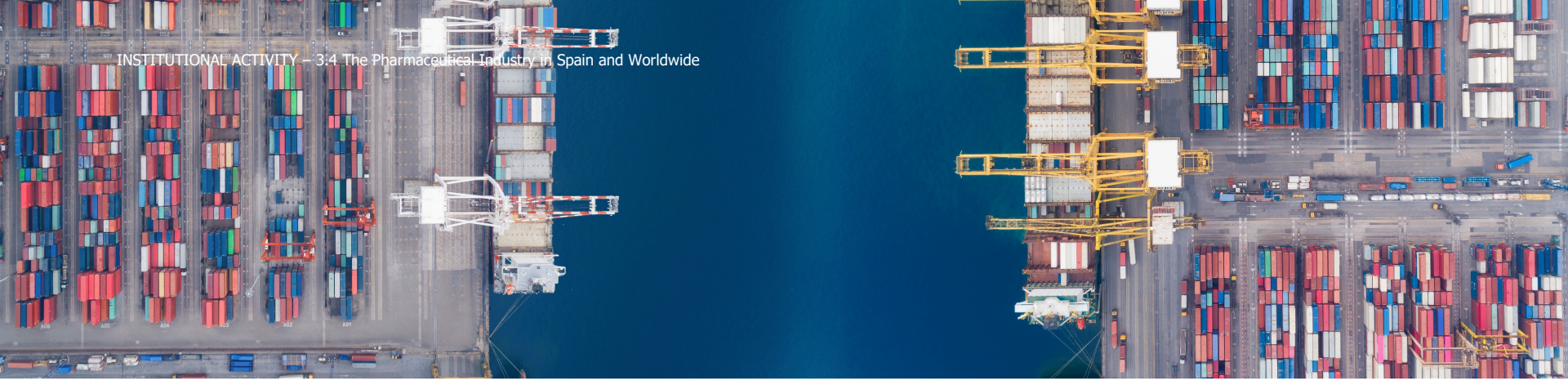
To round off the analysis of the contribution made by the pharmaceutical industry to the export sector in Spain, one must consider external competitiveness of the sector, allowing us to measure the relative indicators which highlight the volume of exports from a sector with regard to its turnover, number of employees, etc. An analysis of the indicator for exports over turnover, using the figure for 2017 (the most recent available) revealed that the pharmaceutical industry stands at double the average for industrial sectors as a whole (81% versus 41%).

Meanwhile, if one uses the indicator of exports over employment, the difference is even more significant, making the pharmaceutical sector the **fifth-ranked in the country in terms of overseas competitiveness**, with exports of more than 255,000 euros per employee in 2017, more than twice the average for Spanish industry, as shown in the following graph.

Main sectors of the national economy in exports per employee (2017)



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



With regard to the geographical distribution of pharmaceutical foreign trade, it should be noted that in 2018 **the EU continued to be Spain's main business partner.** 60% of Spanish imports of pharmaceutical products come from European partners and 49% of exports head to them.

Within the EU, **Germany remains the main destination** for pharmaceutical output (21.9% of all exports to the EU), followed by France, Italy and the Netherlands. Nonetheless, the destination registering the greatest growth is unquestionably Ireland, where Spain tripled its sales of pharmaceutical products in two years, from accounting for just 1.1% of exports in 2016 to a current level of 3.3%.

Mention should also be made this year of events with regard to the **UK**, the fifth most important global destination for Spanish pharmaceutical exports. Following a number of years when the share out of total exports had gradually fallen (in 2015, pharmaceutical exports to the UK accounted for 6.1% of all Spanish pharmaceutical exports, while in 2017 the figure was just 4.6%), in 2018 the proportion rose to 5.9% the Spanish pharmaceutical exports, registering **annual growth** of +30%, which could reveal a certain stockpiling effect given the existing uncertainty as to the possibility of a no deal Brexit.

As for non-EU markets, which now account for half of all Spanish pharmaceutical exports, the main destinations are Switzerland (19.4%), the USA (6.4%), Japan (3.5%) and China (2.4%). These four countries **represent 62.5% of all pharmaceutical exports** headed to countries outside the EU.

Economic Area	2017		2018 (p)	
	Export	Import	Export	Import
World Total	100.0 %	100.0 %	100.0 %	100.0 %
EU 28	50.8 %	61.3 %	49.2 %	60.2 %
Germany	11.4 %	15.4 %	10.8 %	16.6 %
Belgium	1.7 %	8.7 %	1.9 %	5.2 %
France	7.0 %	7.4 %	6.2 %	8.1 %
Netherlands	5.1 %	6.9 %	4.6 %	7.9 %
Ireland	2.2 %	4.0 %	3.3 %	4.3 %
Italy	5.6 %	4.4 %	5.0 %	5.2 %
United Kingdom	4.6 %	5.9 %	5.9 %	6.2 %
Rest of Europe	**19.4 %**	**9.0 %**	21.2 %	11.0 %
Switzerland	17.2 %	8.7 %	19.4 %	10.7 %
Rest of World	**29.8 %**	**29.6 %**	29.5 %	28.8 %
China	2.5 %	2.9 %	2.4 %	2.9 %
United States	7.1 %	18.9 %	6.4 %	16.9 %
India	0.3 %	1.0 %	0.4 %	1.1 %
Japan	3.1 %	0.5 %	3.5 %	0.5 %

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

Note: (p) provisional.

NHS SPENDING ON PRESCRIPTIONS DISPENSED IN PHARMACIES						
Year	**Spending** (Million € RRP VAT)	**Inc.** (%)	**No. of Prescriptions** (Millions)	**Inc.** (%)	**Spending per Prescription** (€)	**Inc.** (%)
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	-12.3 %	913.8	-6.1 %	10.7	-6.6 %
2013	9,183.2	-6.0 %	859.6	-5.9 %	10.7	-0.1 %
2014	9,360.5	+1.9 %	868.6	+1.1 %	10.8	+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 %	11.2	+1.8 %
2018	10,476.0	+3.0 %	924.0	+1.7 %	11.3	+1.3 %

Source: Medical Prescription Invoicing. MSCBS.

Public pharmaceutical expenditure on official NHS prescriptions

The figures from the Ministry of Health, Consumption and Social Well-being for 2018 as a whole revealed an **increase in public pharmaceutical expenditure via retail pharmacies of +3.0%,** standing at €10.476 billion. This change in the level of expenditure is the consequence of a +1.7% increase in the number of prescriptions and a +1.3% increase in the average cost per prescription.

Regional distribution of public pharmaceutical spending per capita

In 2018, public pharmaceutical expenditure through official NHS prescriptions stood at **224.2 euros per inhabitant**, equivalent to an increase of +2.7% compared with 2017.

At the regional level, those regions with the **highest pharmaceutical expenditure per capita are Extremadura, Asturias and Galicia**, while the lowest levels correspond to the Islas Baleares and Madrid.

Pharmaceutical expenditure per capita rose in all Spanish regions in 2018, with Andalucía (+4.0%) and Cantabria (+3.9%) registering the highest growth rates, and Murcia (+0.4%) and the País Vasco (+0.4%) the lowest.

PHARMACEUTICAL SPENDING PER CAPITA BY REGION (2018)

Region	Spending share (%)	€ per capita	Inc. (%)
Extremadura	3.1 %	298.1	2.2 %
Asturias	2.7 %	271.0	2.3 %
Galicia	6.8 %	262.8	2.2 %
Valencia	12.1 %	255.1	2.3 %
Castilla y León	5.8 %	252.9	3.5 %
Castilla la Mancha	4.9 %	252.1	3.5 %
Cantabria	1.4 %	251.9	3.9 %
Aragón	3.1 %	251.9	2.6 %
Murcia	3.3 %	235.0	0.4 %
Islas Canarias	4.7 %	231.6	3.6 %
La Rioja	0.7 %	231.1	2.5 %
Total Spain	**100.0 %**	**224.2**	**2.7 %**
País Vasco	4.7 %	221.5	0.4 %
Andalucía	17.5 %	218.6	4.0 %
Navarra	1.3 %	211.1	1.5 %
Cataluña	13.9 %	191.9	2.0 %
Madrid	11.8 %	188.5	3.4 %
Islas Baleares	2.0 %	182.7	1.8 %

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

4 Member services

4.1 Online Services

FARMAINDUSTRIA has, for more than 15 years now, been committed to **digitalization of their information systems**, enhancing their telematic systems.

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

To begin with, our general interest portals (Members' Internet, Public Portal and Self-regulatory System), along with our focused sites (Innovative Medicines Platform, Proprietary medicine Classification, Series and Tables, and the new Cybersecurity Vulnerabilities site) serve to filter and channel any quality information to be conveyed to our users.

We also maintain a number of internal tools to handle association processes, and also to administer regulatory procedures, such as the application of deductions derived from Royal Decree-Act 8/2010.

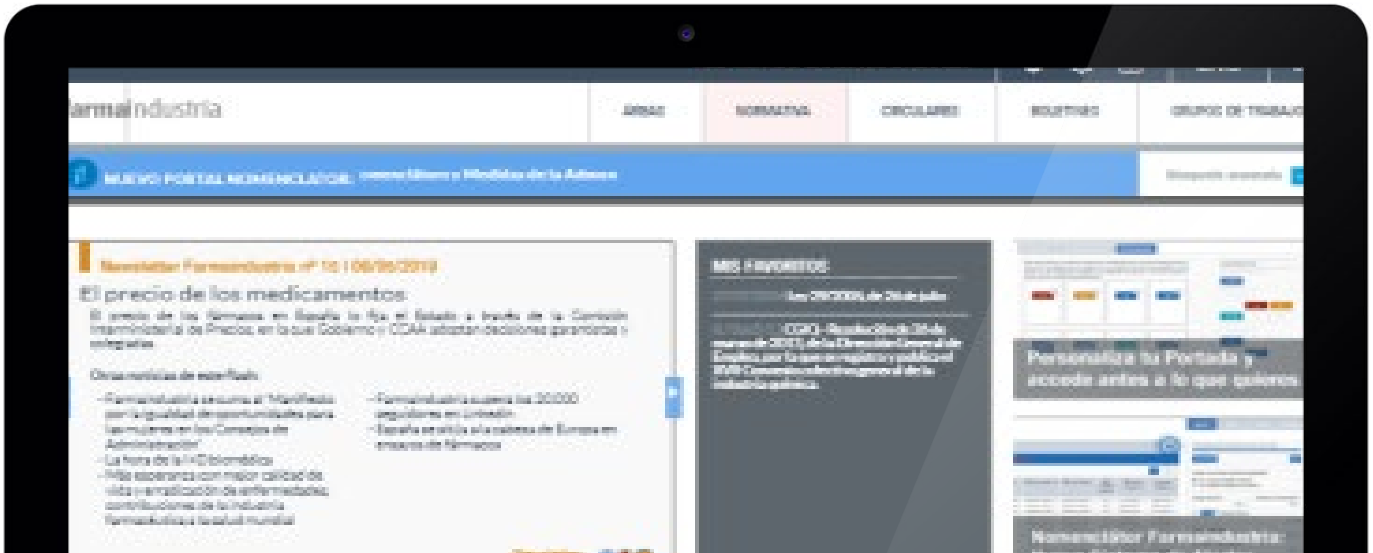
Corporate website. Intranet with the industry. Working groups.

For the exclusive use of member companies, this contains over **85,000 documents** grouped into over 50 categories, including circulars, publications, departmental areas, flashes, newsletters, regulations, etc.

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

It incorporates a comprehensive, powerful search engine that greatly reduces information access times and helps user move instantly through the data structure.

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



Public website

The FARMAINDUSTRIA public website is especially designed to **convey information** clearly, quickly and openly to anyone interested in the Spanish pharmaceutical industry. A weekly newsletter was recently added, with key information about the industry and medicinal products.

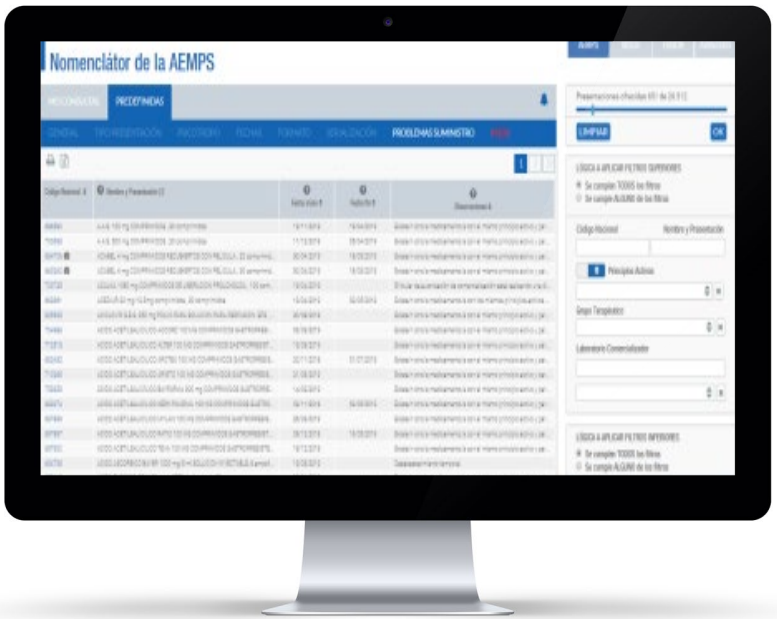
Websites are also developed and maintained for Innovative Medicines (https://www.medicamentos-innovadores.org) and Somos Pacientes (https://www.somospacientes.com), with information connected with technological platforms for medicinal product innovation and a collaborative environment for the community of patients' associations, respectively.

Self-regulatory System Website

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

Four Proprietary medicine Classification of micro-sites

The format in which the Ministry of Health and the Spanish Medicines and Healthcare Products Agency present their Classification of proprietary medicines raises complications for the industry when performing queries or accessing data. FARMAINDUSTRIA therefore developed four micro-sites providing users with in-depth knowledge of both databases and changes to them over time.



A number of improvements were made during 2018, including in particular:

1. **Alert generator**: users can now ask to receive an email every time new information is uploaded to eight areas of the site.

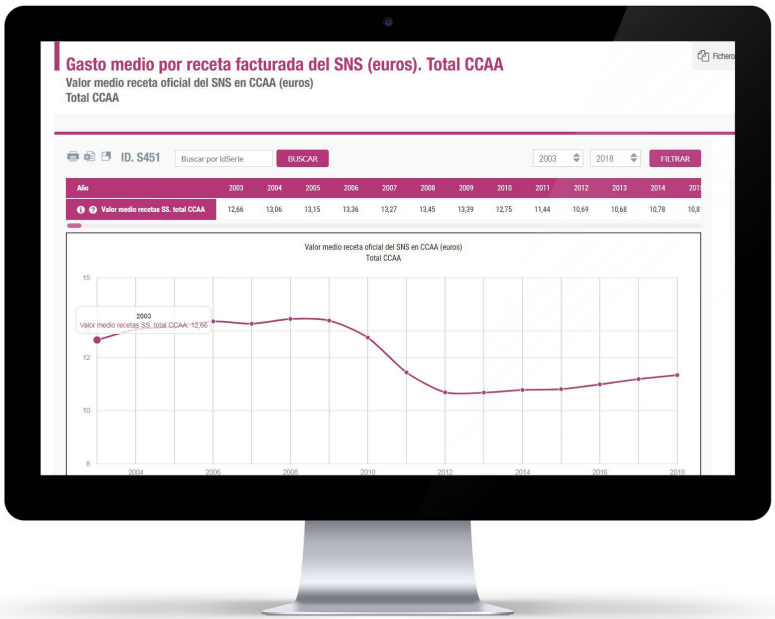
2. Fields connected with **serialisation** have been added:
   - If the medicine is serialised.
   - The expiry date of the last batch released without serialisation.
   - The GTIN and NTIN codes.

3. Fields have also been added in connection with **supply problems**: start and end date of the incident and a field for remarks.

4. Meanwhile, the **"Presentation Data Sheet"** has had photos of the packaging and pharmaceutical form added.

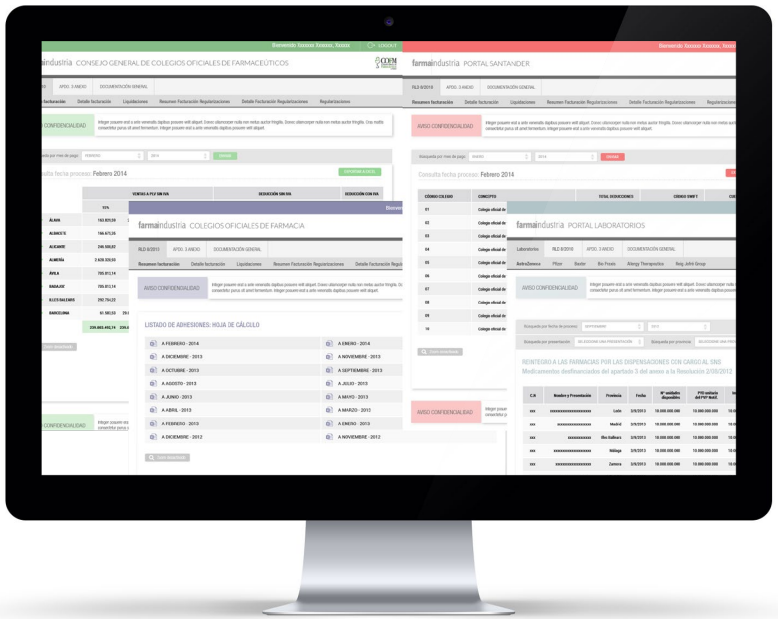
Series and Tables Portal

Back in 2017 we added online services to this portal, with more than 3,000 data series, but it was in 2018 that we redefined the regions area, allowing for comparisons and analyses.
Meanwhile, a new "Data Sheets" area has been added, with a selection of spreadsheets for direct usage.



Portals for administration of Royal Decree-Act 8/2010

In late 2017 the second generation of more agile and intuitive portals to administer Royal Decree-Act 8/2010 were launched, for pharmaceutical manufacturers, Official Associations of Pharmacists, the General Council of Official Associations of Pharmacists and the management bank, with these tools being consolidated in 2018.
The portals help the four main interlocutors to check, evaluate and deal with the regulated deductions.

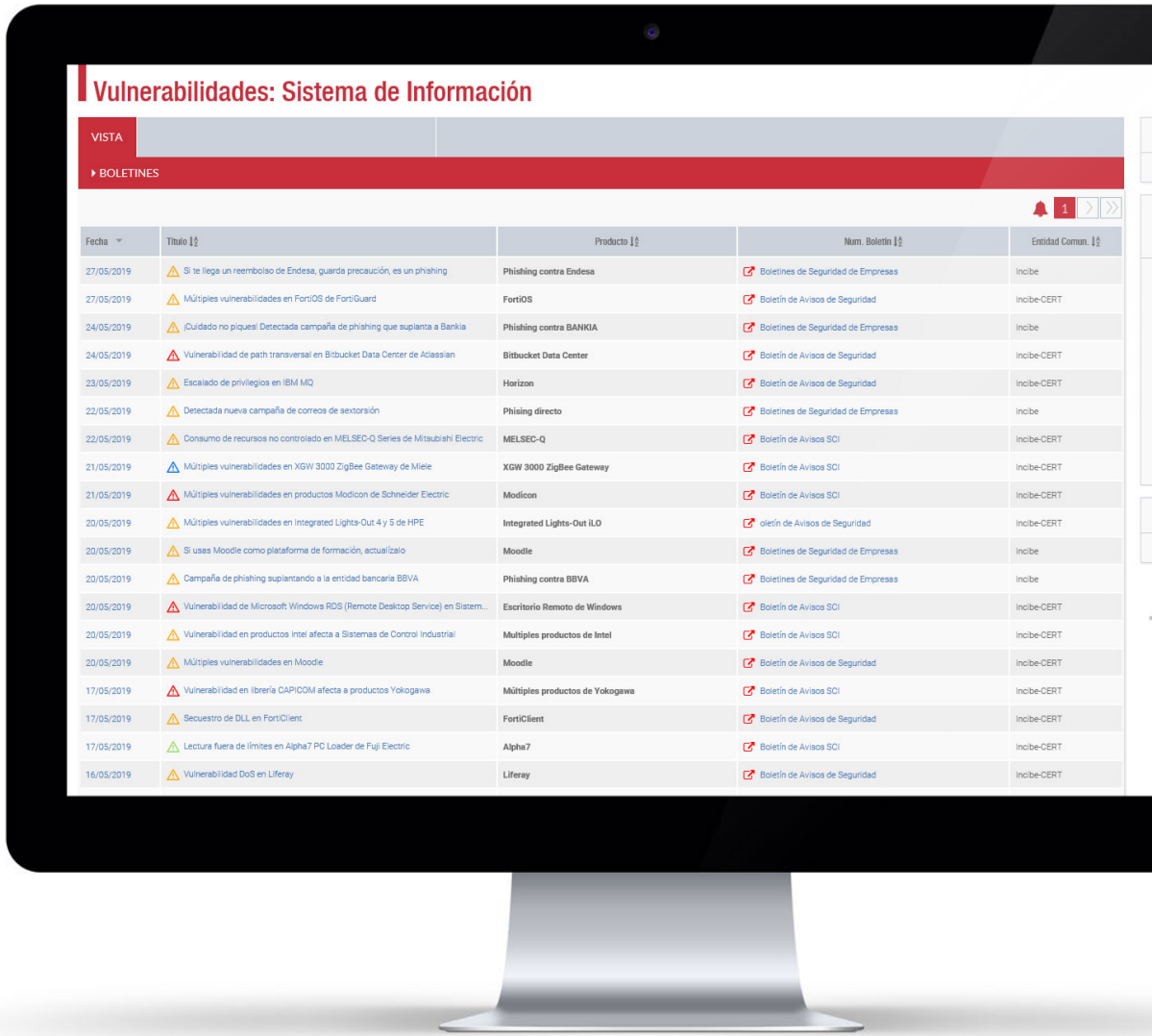


New portal for cybersecurity vulnerabilities

In 2018 a new Cybersecurity project was undertaken by FARMAINDUSTRIA, to support the creation of a working party and the launch of this new site.

The main aim of the project is to establish channels within the industry and with public authorities to help us be better prepared to combat cybercrime.

The new portal includes an alert system for vulnerabilities detected in hardware and software (commonly used at companies), and the procedure to be followed to correct these incidents.



4 Member services

4.2 Working Groups

The FARMAINDUSTRIA working groups set up by the governing bodies to provide members with up-to-date information about the subjects corresponding to each of them and coordinated by the different departments at FARMAINDUSTRIA are intended to foster active participation by the companies in the work of the Association, to explain legislative or regulatory initiatives by the various Public Authorities, to draw up sectoral arguments or pursue action plans to address key aspects for the sector, to be passed on by the Association to the authorities and corresponding interlocutors.

These parties are organised by matters of interest to the pharmaceutical industry and are governed by specific operational standards, the overarching principles being respect for competition regulations (the contents of which govern all meetings of the parties), personal data protection, compliance and confidentiality.

The current list of working groups is set out below:

1. Economic Regulation
2. *Health Technology Assessment (HTA)*
3. Hospital Debt
4. Hospital Market
5. Technical Regulation
6. Biotherapeutic Medicines
7. Manufacturing
8. Environment
9. Pharmacovigilance.
10. Vaccines
11. Pharma-Bio
12. Medical and Research Directors (BEST)
13. Clinical Research
14. Legal Services
15. Tax
16. Human Resources
17. Code of Practice
18. International
19. Relations with Regions
20. Trademark protection
21. Communication and Corporate Social Responsibility.
22. Patients

Meanwhile, a number of ad-hoc groups have been set up with a more limited level of participation to **explore a range of aspects in greater depth**, subsequently passing the results on to the full working group to which they are attached.

The activities of the various FARMAINDUSTRIA working groups over the course of 2018 are summarised below.

Economic Regulation Working Group

In 2018, among other aspects, this working group continued to analyse parliamentary initiatives and regulations connected with economic governance in the sphere of the pharmaceutical sector, and the key developments in this regard.

One of the most significant matters was the monitoring of the **Collaboration Agreement** with the Spanish Government, in force since 2015 and extended until the end of 2019, with the shared goal of contributing towards the sustainability of the NHS, and public access to innovations.

FARMAINDUSTRIA has progressively provided the party with information as to the development of the Agreement, in particular regarding the evolution of the main indicators for expenditure and access.

This working party received detailed information from the monitoring of access to innovations and the corresponding indicators drawn up by the Association, in particular monitoring the publication of the **IPTs (Therapeutic Positioning Reports)**, above all their inherent reasoning and the duration and singularities of the preparation procedure.

This working party's members have conducted detailed monitoring of the **processing of the regulatory project**, arguments and subsequent publication of Order SCB/1244/2018, of 23 November 2018, implementing the 2018 **update of the National Health System's Reference Price System.**

In turn, in coordination with the **Manufacturing Working Group**, the party closely monitored the work conducted by FARMAINDUSTRIA and SEVeM to comply with the provisions of the Falsified Medicines Directive and the Delegated Regulation, by the specified deadline of 9 February 2019.

This working party also receive detailed information on the progress of the projects to measure health outcomes and costs being promoted by the international ICHOM consortium, to which the health services and hospitals of a number of Spanish regions have signed up through the respective collaboration agreements.

Lastly, the members of the party received timely information on the developments occurring within the context of the **Health Technology Assessment (HTA) Working Group** in connection with the proposed Regulation on HTA published by the European Commission in early 2018, as referred to in the following section of this Annual Report (HTA Working Group).

Health Technology Assessment Working Group

This working group was set up by FARMAINDUSTRIA with the aim of developing technical documents referring to the main issues affecting the procedures for economic assessment of medicinal products.

Over the past year the party continued with its efforts to **foster the measurement of health outcomes** in order to contribute in the future to a transition towards a **more sustainable health system** based on value and improving relevant health outcomes for patients. This work was conducted at both the national and international levels by monitoring the various initiatives in progress, including the ICHOM health outcomes measurement project and the Do-It programme of the IMI initiative Big Data for Better Outcomes (BD4BO), in which FARMAINDUSTRIA was involved, as mentioned in other sections of this Annual Report.

The progress made on the proposed Regulation published by the European Commission in January 2018 with regard to the joint initial assessment of new medicines was likewise closely monitored, having been debated by the European Parliament at the first hearing, and being processed by the European Council at the time when this Annual Report was drawn up.

The party received timely information on the evolution of medicinal product efficacy assessments conducted by EUnetHTA at the European level, and undertaken within the context of Joint Action 3 (2016-2020), with implications for Spain.

At national level, monitoring of the various initiatives regarding the assessment of medicinal products at the national, regional and local levels continued.

Hospital Debt Working Group

Over the last 12 months this working party conducted monthly monitoring both of the evolution of the **debt through the supply of medicines to NHS hospitals** and also payment periods (Days Sales Outstanding, or DSO) of the various regional health services.

The party likewise continues to monitor **the impact of measures to combat late payment**, in particular with regard to the application of the measures brought in by Organic Act 9/2013, on the Control of Trade Debt in the Public Sector, and payments made via the FLA (Regional Liquidity Fund). These payments, together with those made via the increasingly significant ordinary treasury operations of the Autonomous Regions, served during 2018 to consolidate levels of debt and DSO at the NHS below 90 days, a feat achieved for the first time in the history of the sector in 2017.

During the past year, this working party closely followed the main developments in terms of late payment, such as work in progress for the reform of the regional financing system, the processing of the State General Budget and the modification of the calculation system for the average payment period published monthly by the different Public Authorities, without losing sight of the processing of the various ongoing regulatory proposals aimed at combating late payment in business operations.

The Hospital Debt Working Group has an ad-hoc Sub-party on Electronic Invoicing which has continued its close monitoring of electronic invoicing implementation by the regions and the General State Administration, since this was made compulsory in January 2015.

In this regard, over the course of 2018 FARMAINDUSTRIA continued to participate at the institutional level on various forums are connected with this issue:

1. MINHAFP electronic invoice forum.
2. CEOE Digital Society Commission.
3. FACe Working Group on electronic invoicing in the private sector.

The last of these is intended to **achieve progress in the implementation of electronic invoicing** in the private sphere, with its work culminating in June 2018 with the operational presentation of the **Business-to-Business Electronic Invoice Distribution Platform** (FACeB2B), capable of complying with the provisions of Additional Provision 32 of Public Sector Procurement Act 9/2017, of 8 November 2017, which has been a mandatory requirement since 30 June for Public Authority contractors and subcontractors.

Hospital Market Working Group

This working party focuses its operations on **monitoring and tracking the hospital market**, along with economic and legal analysis of the various initiatives conducted at the national and regional levels, such as regulations, centralised procurement, regional tenders with significant peculiarities, management agreements that could limit supply and access to innovative medicines or freedom of prescription, implementation of regional management models, etc.

In accordance with its purpose, this working group coordinates closely with the working groups on Hospital Debt, Biotherapeutic Medicines, Trademark Protection, Relations with Regions and Economic Regulation.

Technical Regulation Working Group

The main activities of this working party 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 commercial release 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 Act**.
This working party focuses on analysing matters with a substantial technical component, such as fees, labelling and information sheet, authorisation of applications modifications, recognition of authorisations, sunset clause, classification of medicines with no commercial interests, etc. Ad-hoc parties are also set up where necessary to address specific issues.

In 2018, the working group analysed, among other issues:

1. The future domestic regulations which will bring in certain aspects regarding the serialisation and verification of medicines and which will modify certain aspects of the procedure for the authorisation of industrially manufactured medicines for human use.
2. The implementation of safety features in medicinal packaging subject to Delegated Regulation 2016/161, of 2 October 2015.
3. The process of identification of medicines with no commercial interest conducted by FARMAINDUSTRIA, in order to identify those presentational formats, the absence of which could have a negative impact on healthcare in Spain.
4. The coordination procedure of the Pharmacy Standing Committee for access to and usage of medicines in special situations.
5. The changes to medicine registration that will be caused by Brexit.

At all its meetings, this working group discusses the technical aspects of eight subject areas:

- Therapeutic Positioning Reports
- Early access
- Product information
- Biological medicines
- National procedure and management
- Quality regulation
- Risk management plan
- European procedures

Biotherapeutic Medicines Working Group

This working group in particular monitors the **key aspects concerning biologic medicines** in terms of regulation, authorisation processes and access at national and international levels. The agenda of its meetings also always includes an analysis of the issue of orphan medicinal products.

Biological medicines have distinctive characteristics compared with chemical medicines, which has led them to be the focus of specific attention. From a regulatory point of view, the uniqueness of biotherapeutic medicines determines their prescription by trade name (trademark), with notification likewise by trademark and batch number.

Consideration is also given to medicines requiring special monitoring for the purposes of pharmacovigilance (in accordance with Article 3 of Royal Decree 1718/2010, on medical prescriptions, and Article 5 of Royal Decree 577/2013, on pharmacovigilance).

In addition, Royal Legislative Decree 1/2015, of 24 July 2015, approving the recast text of the Guarantees and Rational Use of Medicinal Healthcare Products Act, establishes in Article 89.4 that there are certain medicines that, because of their bioavailability characteristics and narrow therapeutic range, must comprise an exception to the general criteria for substitution by the pharmacist.

In this regard AEMPS updated the section of its website focusing on non-substitutable medicines in September 2018.

The interpretation given in this update is that the scope of Order 2874/2007 applies only to the dispensing of medicines by a pharmacist at a retail pharmacy, not a hospital pharmacy.

Nonetheless, at the request of FARMAINDUSTRIA the Director of the AEMPS clarified the interpretation of non-substitutable medicines and the role of hospital clinical committees, indicating that in the case of biological medicines, the AEMPS espouses the EMA recommendations in its Information Guide for Healthcare Professionals and its Information Guide for Patients on **Biosimilar Medicines**, which indicate that it would be advisable for any decision regarding the replacement of one medicine with another to take into account the national policies in place with regard to prescription in each country.

In this regard, and in terms of the role of clinical committees, the indication is that "they are collegiate bodies for participation and consultancy" which "establish policies for the use of medicines, with the participation of doctors, nurses and pharmacists, with doctors prescribing in accordance with these policies".

The Director of the AEMPS indicates that in the case of biotherpaeutic medicines **"both prescription and notification must be performed by trade name".**

Manufacturing Working Group

The preparations for the application of Commission Delegated Regulation (EU) 2016/161, laying down rules for the safety features of packaging (unique ID and anti-tampering device) define the agenda of this working group throughout the period prior to the effective application of the regulation on 9 February 2019. The new obligations with regard to verification and serialisation of medicines thus have an impact both on the scope of production and the systems to be applied by pharmaceutical companies at their packaging facilities, and also medicine registration and commercial release operations.

Although those matters that are the responsibility of the Member States were expected to be developed in Spain through the corresponding regulations, for the moment, following several frustrated initiatives, two provisions that will supplement the European civilisation regulations remain at an urgent procedural stage. On the one hand, the modification of Royal Decree 1345/2007, governing the registration of medicines and other more technical aspects, and furthermore a proposed Royal Decree to adapt the administration of NHS pharmaceutical provision in accordance with the regulatory framework for the verification and authentication of medicines, which would govern aspects connected with the verification of medicines dispensed at the expense of the NHS.

In any event, given the need to have regulations in place indicating specific aspects to conduct proper serialisation, this working group made contributions towards various AEMPS proposals. SEVeM was similarly involved in all the meetings of this working party, serving to provide updates on the progress made in implementing the verification system as each step was taken.

Lastly, the regular points addressed by this working group include the importance of guaranteeing the supply of medicines, an aspect which at the time when this Annual Report was drawn up was attracting considerable media attention.

Environment Working Group

During 2018, and in collaboration with SIGRE, this working party monitored important legislative regulations for the pharmaceutical industry regarding the environment, such as circular economy, waste, environmental responsibility, climate change and energy transition, potential soil contaminants or spills.

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

Pharmacovigilance Working Group

This working group **channels the main questions and clarifications derived from both national and European pharmacovigilance provisions**. In 2018 the development of the Royal Decree on pharmacovigilance and the instructions document of the Royal Decree on clinical trials were monitored. As for future regulations, particular mention should be made of the monitoring of the future Royal Decree governing observational studies with medicines and in the area of data protection, the guidelines to be covered by the future Code of Conduct in the area of pharmacovigilance following publication of Organic Act 3/2018, on Personal Data Protection and the Guarantee of Digital Rights.

This working group addresses six well-defined thematic areas at all its meetings

- Inspection and audits
- Risk management plans
- Master file
- Expedited reporting
- Periodic safety reports
- Pharmacovigilance and the internet

The working group also reviewed issues of both a technical and regulatory nature, emphasising such matters as:

- The processing of the proposed Royal Decree on observational studies with medicines.
- The possible non-continuity of certain types of **Patient Support Programme**, as future regulations suggest that only those undertaken within the context of an observational study with medicines could be performed in Spain.
- The possibility of the distribution of what are known as Safety Information Materials duly authorised by the AEMPS via scientific societies, as occurs at present with safety letters sent to healthcare professionals.

Vaccines Working Group

Among the main issues dealt with in 2018 by this working group was the need to collaborate with authorities and scientific societies on disseminating messages on the value of vaccines, as in this area there is a significant concern from the health authorities regarding the decrease in vaccination rates for some diseases due to the false sense of security for certain diseases that are erroneously considered to have been overcome nowadays, or the lack of confidence in vaccination generated by social beliefs or influences.

On 28 December the Official Journal of the EU published a Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases (2018/C 466/01), providing an institutional response to this concern.

The working group has been monitoring these tasks and has helped to publicise actions so as properly to disseminate this information. Lastly, this working group addressed technical issues regarding serialisation, adherence and supply problems likewise carry in the field of vaccines.

Pharma-Bio Working Group

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

Since 2011, when FARMAINDUSTRIA launched the Pharma-Bio cooperation programme, 17 interactive meetings have been held in the areas including central nervous system, oncology, respiratory apparatus, inflammation and autoimmune disease. These meetings have involved more than 115 public and private sector agents, analysing 519 R&D projects for new medicines, 133 of which have been presented to pharmaceutical companies, so far generating 43 new molecules which are currently at the development stage and under patent protection.

The key aspect of this initiative has been to build a bridge between researchers and small biotech enterprises working on promising projects, and the pharmaceutical companies that have the required resources and technology in order to be able to undertake clinical research and attempt to provide patients with new medicinal products. This is helping to spread the word about Spanish basic research at the decision-making centres for major biomedical R&D investments at the international level.

The Pharma-Bio Working Group also aims to promote public-private partnership instruments for R&D, with a number of meetings having been held with the CDTI (Centre for Technological and Industrial Development) and with the Ministry of Science, Innovation and Universities, to study new grants or modify some of those that already exist, in accordance with sector demands.

Meeting	Date	City	Location	Treatment area	Projects presented	Centres and hospitals	Biotech Companies	Pharmacy Companies
Day 1	2/11	Barcelona	PHARMA INDUSTRY	Nervous system	6	0	6	19
Day 2	4/11	Barcelona	PHARMA INDUSTRY	Oncology	8	0	8	13
Day 3	5/11	Madrid	PHARMA INDUSTRY	Oncology	7	1	6	14
Day 4	7/11	Madrid	PHARMA INDUSTRY	Various areas (1)	9	0	9	14
Day 5	3/12	Barcelona	PHARMA INDUSTRY	Various areas (2)	7	4	3	14
Day 6	6/12	Zaragoza	ARAGONESE SERVICE	Various areas (3)	5	3	2	6
Day 7	9/12	Bilbao	BIOSPAIN 6TH	Oncology	6	0	6	Open Day
Day 8	5/13	Madrid	PHARMA INDUSTRY	Various areas (4)	6	1	5	12
Day 9	7/13	Barcelona	PHARMA INDUSTRY	Nervous system	7	4	3	7
Day 10	11/13	Madrid	PHARMA INDUSTRY	Various areas (5)	7	5	2	10
Day 11	7/14	Madrid	PHARMA INDUSTRY	Various areas (6)	8	7	1	10
Day 12	9/14	Santiago de Compostela	BIOSPAIN 7TH	Various areas (7)	10	3	7	Open Day
Day 13	9/15	Barcelona	PHARMA INDUSTRY	Nervous system	8	3	5	15
Day 14	11/15	Madrid	PHARMA INDUSTRY	Various areas (8)	8	7	1	11
Day 15	11/16	Madrid	PHARMA INDUSTRY	Various areas (9)	8	6	2	12
Day 16	11/17	Madrid	PHARMA INDUSTRY	Various areas (10)	6	5	1	9
Day 17	11/18	Madrid	PHARMA INDUSTRY	Various areas (11)	9	3	6	16

Emphasis should lastly be placed on this working party's aim of stimulating participation by pharmaceutical companies in national and international R&D programmes, above all in the IMI (Innovative Medicines Initiative) and the actions of the PTEMI (Spanish Technological Platform for Innovative Medicines).

Medical Directors and Research Directors (BEST Project) Working Group

This working group, set up 13 years ago as a platform for excellence in clinical research, falls within the scope of the Spanish Technology Platform for Innovative Medicines (PTEMI) and is focused on **designing the strategy and promoting competitiveness in clinical research in Spain**, facilitating processes and improving activity indicators (time, recruitment, international comparison) to achieve the best environment for conducting clinical trials in this country, with particular emphasis on early phases. Spain has in fact managed to position itself at the forefront of European clinical research, with Spanish involvement in three out of every ten trials on the continent.


Innovación en los laboratorios

La industria farmacéutica convierte a España en una potencia en ensayos clínicos

La anticipación a la normativa europea es bien recibida por los laboratorios

La investigación con pacientes de la industria

Estudios clínicos en España Número de ensayos autorizados

Evolución del gasto en I+D Miles de millones de euros

The **BEST Project** currently involves 50 pharmaceutical companies, 4 scientific societies, Clínica Universitaria de Navarra, the Grupo Quirón Salud, 13 regions and 54 publicly and privately owned establishments.

According to the latest BEST Project data, the lead times for the launch of clinical trials, a decisive factor in achieving investment in this field, have on average been cut to 132 days, down -14% compared with 2015, the last year when the previous regulations are enforced.

		2004	2018	%	CAGR*
1	No. of BDMetrics trials	117	3,303	N/A	N/A
	No. of IF trials	473	754[3]	59 %	4 %
2	Expenditure on clinical research	299[1]	662[3]	121 %	7 %
	Expenditure on R&D	706[1]	1,147[3]	62 %	4 %
3	Start-up (days)	191	132	-30 %	-2 %
	Differential regarding 1st European patient	93	25	-73 %	-9 %
	Authorisation after the CEIC	37	14	-62 %	-7 %
	Processing of the contract	164	92	-44 %	-4 %
4	Efficiency in recruitment	92 %[2]	95 %	3 %	0.2 %
5	Trials in early phases	37 %	52 %	41 %	3 %
6	Trials at AP centres	14 %	7 %	-50 %	-5 %
7	Oncology trials	28 %	49 %	75 %	4 %
	Cardiovascular trials	15 %	4 %	-73 %	-9 %
	Neuroscience trials	9 %	6 %	-30 %	-3 %

***CAGR: Compound Average Growth Rate**

1 Data for 2005.

2 Data for 2005. Clinical trials concluded in the year. Average recruitment rates calculated by CREC.

3 Data for 2017. Sources: AEMPS and FARMAINDUSTRIA

During 2018, an Early Phases working sub-group was launched within the context of the **BEST Project**, made up of representatives from 11 companies who worked on a review of the **Standards Manual for Clinical Trials Units** in early phases, drawn up by the Health Quality Agency of Andalucía. Meanwhile, in early 2019 this sub-group began the review and design of the 4th update to the FARMAINDUSTRIA Early Phases Guide.

Another working sub-group was also set up in 2018 to concentrate on the **analysis of criteria of excellence** for the selection of centres staging clinical trials. These criteria focus on scientific aspects, management levels, facilities, human resources, recruitment, etc. The permanent dialogue that FARMAINDUSTRIA maintains with the centres and the heads of clinical research of the regions will serve to pass on the conclusions of the study, as following full application of the EU Regulation of clinical trials, competitiveness among countries and among centres will increase significantly.

During 2018, **workshops were held with a number of different patients' associations** in the fields of multiple sclerosis, rare diseases, oncology and haematology, to explain to them the process of R&D for a new medicine, the applicable legislation, the agents involved, etc. There have also been efforts to explain the new personal data protection regulations to patients, and their impact on clinical research.

Meanwhile, three workshops were held for secondary school students in 2018 in Malaga, Barcelona and Madrid, focused on **explaining what new medicine R&D is, how it takes place, the phases involved and what it means for society.** Likewise as part of the BEST Project, FARMAINDUSTRIA undertook a study in 2018 into the clinical research undertaken by the pharmaceutical industry at private centres. The data were presented jointly with the IDIS (Institute for the Development and Integration of Healthcare) at its annual seminar.

Clinical Research Working Group

Over the last year, this group carried out intense monitoring of **Spanish and European legislative initiatives regarding clinical research**, in particular Regulation 536/2014, of the European Parliament and of the Council of 16 April 2014, published in the EU Official Journal on 27 May 2014, and Royal Decree 1090/2015, of 4 December 2015, regulating clinical trials with medicinal products, medicinal product research ethics committees and the Spanish Clinical Studies Register. Both texts pursue greater transparency, simplification and harmonisation of processes, in order to make clinical research more competitive. Spain was the first country in the EU to implement the new European regulation on clinical trials. A European clinical trials regulations sub-group was set up during 2018, with the aim of sharing the initiatives being undertaken for the full application of EU Regulation 536/2014 in the year 2020.

In 2018, FARMAINDUSTRIA and the Spanish Society of Clinical Pharmacology finalised a template letter of thanks for patients after participation in a clinical trial. This template also takes into account the provisions set out in the current Spanish and European regulations with regard to the obligation on the promoter publicly to disclose the results of the clinical trial undertaken with a period of one month of conclusion of the study. European regulations have established that a summary written in a language understandable to a lay person should also be prepared, according to the content established in Annex V of EU Regulation 536/2014. This guide for the preparation of the letter of thanks following patient participation in a clinical trial was published on the **AEMPS** website in September 2018.

During 2018, FARMAINDUSTRIA continued its active efforts to ensure that the **Document of Supplementary Instructions to Royal Decree 1090/2015 of December 4**, responds to sectoral needs, and also worked with AEMPS and the Ethics Committees in Medicine Research (CEIm) so that the annexes to this document are adapted to the demands of the pharmaceutical industry and translated into English. All this information is available on the AEMPS website.

Meanwhile, over the course of 2018 FARMAINDUSTRIA worked with the CEIm Group in an attempt to reach **consensus as to an informed consent format** compliant with the new regulations and aligned with the recommendations established in the IMI Do-It project, in which FARMAINDUSTRIA was also involved, as referred to in section 4.3 of this Annual Report. The Association is also working on the new Code of Conduct as a mechanism for self-regulation and interpretation of the new Organic Act 3/2018, on Personal Data Protection and the Guarantee of Digital Rights. The aim of the code is to respond to the requirements established in the new regulations regarding data protection in the field of clinical research and pharmacovigilance. A working group was set up during 2018 with the task of updating the code, made up of the heads of the companies' legal, clinical research and pharmacovigilance departments, as 6 December 2019 is the deadline established in the data protection regulations (Second Transitional Provision) to adapt the content of Standard Codes already registered with the **AEPD** (Spanish Data Protection Agency) in accordance with the new regulations, and to apply for the Agency's approval. During 2018 the working party made up of representatives of the FARMAINDUSTRIA Patients, BEST and Clinical Research working parties, together with representatives of the patients sector (EUPATI and the Platform of Patients' Organisations) drew up a document of recommendations for the structuring of involvement by patients and patients' associations in the process of pharmaceutical R&D, the key conclusions of which are set out in the subsection corresponding to the Patients Working Group in this Annual Report.

Legal Working Group

The activities of this working group focused on all matters which are of interest to the members because of their legal connotations, as well as those of relevance to other departments at the companies that assist the legal departments.

The main aspects analysed were legislative developments that have been approved or are being processed at the European, national and regional levels (with detailed information regarding some of these changes in other subsections of this Annual Report), along with the most notable case-law impacting on the sector.

The following should be emphasised at the national level:

1. **Organic Act 3/2018**, of 5 December 2018, on the Protection of Personal Data and the Guarantee of Digital Rights, which FARMAINDUSTRIA monitored closely during its passage through parliament, sponsoring a number of amendments focused on the regulation of extensive consent, the re-use of data, and exceptions to certain rights being exercised within the context of research, in accordance with the report issued by the Spanish Data Protection Agency in March 2018, to ensure that the Act would not have a retrograde effect on biomedical research. Work is still ongoing to adapt the new Code of Conduct (as established in the Second Transitional Provision of the Act), which will serve to clarify those matters that could be open to interpretation in the new Organic Act.

2. **Act 1/2019,** of 20 February 2019, on Business Secrets, the transposition of Directive 2016/943 of the European Parliament and of the Council,

of 8 June 2016, on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. The Act establishes the conditions to be fulfilled in order for information to be considered a business secret, and includes among the cases of a violation of said secrecy, any breach of non-disclosure agreements. FARMAINDUSTRIA submitted its observations intended to protect the confidentiality of medicinal product prices as a business secret, against any publication that might be imposed by any regulations (such as public procurement or the Recast Text of the Guarantees and Rational Use of Medicinal and Healthcare Products Act), while also governing the limits on the right of access set out in the Transparency Act in the case of business secrets.

3 **Implementing Regulation for Acts 39/2015** on Administrative Proceedings and **40/2015** on the Legal Regime of the Public Sector, regarding which FARMAINDUSTRIA set out its observations in connection with electronic notifications.

4 **Implementing Regulation for Transparency Act 19/2013**, on which observations were submitted in order to maintain the priority granted to non-disclosure obligations by any other legislation, such as those regarding public procurement, business secrets and the Recast Text of the Guarantees Act.

5 It has to be highlighted that the **Call for Arguments** issued by the Directorate-General for the Basic Portfolio of National Health System and Pharmacy Services, in response to a request for access via the Transparency Portal to the CIPM minutes for the years from 2007 to 2017, to which arguments were submitted in response, emphasising the confidentiality of the information contained in said minutes in accordance with the Guarantees Act, and the existence of grounds for inadmissibility and limits on access to the information requested in accordance with the terms of the Transparency Act, the information published by the Ministry of Health on its website being sufficient for these purposes.

6 To round off this topic, mention should be made of the **Decision of the High Commissioner for Transparency of the Republic of Ireland in April 2018**, from which a number of significant arguments and conclusions are drawn, such as the declaration of the prevalence of a greater public interest in not providing access to certain information, specifically the price of financed medicinal products, if said publication could have a serious and adverse effect on the financial interests of the State.

In addition to all the above, it is also important to emphasise the prior public consultation process for the Draft Royal Decree governing the advertising of medicines; the Draft Royal Decree to modify the Royal Decree on Registrations; the Draft Royal Decree on Healthcare Products; the Draft Royal Decree on Serialisation; the 2019 Reference Prices Order, and the Decision by the National Markets and Competition Commission confirming the legality of the practice on the part of pharmaceutical manufacturers of setting a free market price which is adjusted to the regulated price if the distributor provides accreditation that the medicine was ultimately dispensed at the expense of the NHS, and validating the SEVeM (Spanish Medicines Verification System).

We should also emphasise the launch of the **Association's Compliance Programme**, and the start of internal training in this regard.

Tax Working Group

This working group's priorities focus on the analysis and monitoring of issues with tax implications for the pharmaceutical sector.

The traditional **Annual Tax Developments Seminar** was held in early 2018, open to all members and well attended throughout, analysing key matters of interest including in particular the **modification to Article 44 of the Personal Income Tax Regulation** to clarify that grants for the training of healthcare professionals (and other workers) do not constitute remuneration in kind for Personal Income Tax purposes, an analysis of the status of the VAT SII (Immediate Information Supply) system, modifications to the Implementing Regulations for the **General Tax Act and the Multilateral Agreements** for the exchange of country by country reports, alongside a review of significant legal principles and case-law for the sector.

The status, content and operational start-up on 1 January 2019 of the IGIC (Canary Islands Indirect Tax) bookkeeping system, based on the **SII (Immediate Information Supply)** system in the Islas Canarias, was another of the individual issues reported on by this working party over the course of the year.

The working group continued to receive information on case-law and legal theories published in connection with the tax treatment of grants for the training of healthcare professionals undertaken by pharmaceutical companies, as well as the legal regime governing the remuneration of executive directors.

Over the course of 2018 numerous regulations with a tax impact were published and circulated to the working group, including in particular:

1. **Order HFP/441/2018**, of 26 April 2018, approving the **Corporation Tax and Non-resident Tax return forms** for taxation periods beginning between 1 January and 31 December 2017, issuing instructions regarding the procedure for the tax return and deposit, and establishing the general conditions and procedure for electronic tax returns, and modifying form 222 "Corporation Tax. Tax Consolidation regime. Instalment payments" approved by Order HFP/227/2017, of 13 March 2017.
2. **Council Directive (EU) 2018/822**, of 25 May 2018, amending Directive 2011/16/EU as regards mandatory automatic exchange of information in the field of taxation in relation to reportable cross-border arrangements.
3. **Act 6/2018, of 3 July 2018, on the General State Budget** for 2018.
4. **Order HAC/941/2018, of 5 September 2018, amending Order HFP/227/2017**, of 13 March 2018, approving form 202 for interim instalment payments of corporation tax and non-resident tax, and form 222 for interim instalment payments of corporation tax under the Tax Consolidation Regime, and establishing general conditions of the procedure for electronic tax returns; Order HFP/441/2018, of 26 April 2018, approving the corporation tax and non-resident tax return forms for taxation periods beginning between 1 January and 31 December 2017, and Order HFP/1978/2016, of 28 December 2016, approving form 221 for the country by country information declaration.

5 **Order HAC/1147/2018**, of 9 October 2018, approving the implementing standards for the provisions of Articles 27, 101, 102 and 110 of the Special Taxes Regulation approved by Royal Decree 1165/1995, 7 July 1995.

6 **Order HAC/1148/2018**, of 18 October 2018, amending Order EHA/3434/2007, of 23 November 2018, Order EHA/3012/2008, of 20 October 2008, Order EHA/3786/2008, of 29 December 2008, and amending Annex XII Order EHA/1274/2007, of 26 April 2007.

7 **Act 8/2018**, of 5 November 2018, amending Act 19/1984, of 6 July 1994, amending the Economic and Taxation Regime of the Canary Islands.

8 **Act 11/2018**, of 28 December 2018, amending the Code of Commerce, the recast text of the Capital Companies Act, approved by Royal Legislative Decree 1/2010, of 2 July 2010, and Act 22/2015, of 20 July 2015, on Accounts Auditing, with regard to non-financial information and diversity.

9 **Order HAC/277/2019**, of 4 March, approving the personal income tax and wealth tax return for the financial year 2018, amending Order HAP/2194/2013, of 22 November, regulating the general procedures and conditions for the filing certain self-assessment tax returns and tax-related information declarations, tax register declarations, communications and requests for refunds.

Human Resources Working Group

In the meetings of this working group it was considered information as to the state of the discussions of the **Negotiating Committee for the 19th General Collective Agreement of the Chemical Industry,** comprising the FEIQUE (Spanish Chemical Industry Business Federation), along with the trade union organisations UGT-FICA and CCOO-Industria. Following signature of the Collective Agreement, the most notable circumstances affecting pharmaceutical manufacturers were analysed, and queries in this regard resolved.

The group also analysed the most recent reforms implemented by the Spanish Government in the field of employment through Royal Decrees-Acts, specifically **Royal Decree-Act 6/2019** of 1 March 2019, on equal opportunities for women and men, and Royal Decree-Act 8/2019, of 8 March 2019, on urgent measures for social protection and to combat precarious employment conditions in working hours.

The first of the above enumerated Royal Decrees-Acts, number 6/2019, makes changes to Equality Act 3/2007 and the Workers' Statute, including in particular the mandatory requirement for companies with more than 50 workers to have an equality plan in place, the creation of an equality plan register (pending regulatory implementation) and the obligation on companies to maintain a **register of mean salary values**, with a breakdown by gender and professional group. Meanwhile, Royal Decree-Act 8/2019 brings in a new obligation on companies to maintain a daily record of the start and end times of employees' working days, in force from May 2019 onwards.

The Party also analysed the changes included in the new **Organic Act on Personal Data Protection** and the Guarantee of Digital Rights, regarding the digital disconnection policy and the use of technological devices affecting companies and their workers.

Meanwhile, the working group continued throughout the year to receive full information about regulations that had been approved or were being processed, including above all:

1. **Royal Decree 1462/2018**, of 21 December 2018, setting the minimum wage for 2019, and approving an increase to 900 euros per month.
2. **Royal Decree-Act 28/2018,** of 28 December 2018, on the adjustment of public pensions and other urgent social, occupational and employment measures, which contains measures concerning Social Security, in particular the adjustment to pensions and other public social benefits, determination of the minimum and maximum levels for contributions, the establishment of new special Social Security agreements, and new regulations regarding the scope of coverage of the Special Regime for Self-employed Workers.
3. **The Decision of 8 April 2019** of the Department of Employment, publishing the Resolution of the Council of Ministers of 5 April 2019, approving the 2019-2021 three-year 'Reincorpora-t' Plan to prevent and reduce Long-Term Unemployment.
4. **The Royal Decree-Act on urgent measures to promote Spanish industry**, which has the aim of fostering the competitiveness of the industrial sector through initiatives such as improved occupational productivity, lower energy costs and increased industrial safety, and also governing partial retirement with the simultaneous arrangement of a relief contract for manufacturing industry.

In addition to all the above, the working group was also involved in the innovative pharmaceutical industry **employment survey**, the notable conclusions of which include the high level of employment stability at pharmaceutical companies (**94.2% on permanent contracts**), the high level of qualifications (**62.4% university graduates**), full-time employment (1.5% of employment is part-time), and a high proportion of female employment (52%, twice the overall industrial average).

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Code of Practice Working Group

The activities of this working group were mainly dictated by the publication for the first time in Spain of all **transfers of value to healthcare professionals and organisations on an individual basis**.

The key issues addressed by the party during the year and which are directly or indirectly connected with this matter are as follows:

- The entry into force of the new **General Data Protection Regulation** (25 May), and the position adopted by a number of scientific societies in this regard, made it necessary to clarify that its entry into force in no way affected the legal justification and basis of an "information model" rather than a "consent model", the legal basis indicated in Annex I to the Code.
- The approval of a new version of **Consultation 120 on Annex III to the Code**, including a guideline format allowing healthcare organisations to publish the collaboration received for their training support programmes, and an operational procedure in the event of a breach or failure to comply with the terms and conditions of the consultation itself.
- **Collaboration in conducting the survey on transfers of value** and in reviewing and updating the Communication and Contingency Plan documents, initiatives which although they have been undertaken since the first publication of data (in June 2016) became particularly significant in 2018 because of the fact that all transfers of value would be published individually.

The recent approval of entry into force of a **new version of the IFPMA Code**, together with the more than likely approval of a new version of the EFPIA Code, suggests that the process of updating and improving the Code of Practice will be a matter to be addressed shortly by this working group.

International Working Group

The International Working Group was set up with the aim of analysing the priorities of EFPIA and IFPMA and contributing to the design of the strategy and action plan of the pharmaceutical industry in Spain in defence of 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 UK's exit from the European Union.
2. International initiatives affecting the pharmaceutical innovation model, including the analysis of the European Commission on intellectual property incentives; the Ministerial Round Tables on Prices, access and sustainability; collaboration among European countries on prices and access, and the OECD Report on Sustainable Access to Innovative Therapies.
3. Proposal for a European Commission Regulation on Health Technology Assessment (HTA).
4. Monitoring of the meetings of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO Council) and the Competitiveness Council.

Relations with Regions Working Group

This working group has the following goals:

- **Monitor** the different initiatives in healthcare and pharmaceutical policy, particularly those of a regulatory nature or technical reports affecting the pharmaceutical provision and freedom of prescription in terms of equality in each region;
- **Strengthen dialogue** and collaboration with public authorities.

- **Promote balance** in the healthcare system to make NHS sustainability compatible with patient access to medicines and the development of industrial activity.

- **Consolidate alliances** with the different agents in the healthcare sector to achieve common goals, with a special focus on healthcare professionals.

- **Participate in forums** of a political, scientific or professional nature to help disseminate the value of the pharmaceutical industry and the contribution of medicines to improving the population's health.

- **Set up a regional early warning system** to detect and monitor regional prescription-dispensing policies.

The working group collaborates in the preparation of reports by the **Regions Observatory**, an information and consultation tool that is available to companies on the situation of the regions, including information on healthcare and pharmaceutical policy as well as in the field of R&D in each region.

Trademark Protection Working Group

A trademark is an attribute identifying any consumer product. In the case of medicines, the trademark may represent a strong link between the medicine and the patient, which in some cases contributes to **greater adherence** or facilitates pharmacovigilance, since the trademark is unequivocally associated with a particular presentational format.

This working group monitors the various actions that FARMAINDUSTRIA has been taking to protect trademarks. Although from the legal perspective **the preference to dispense a generic medicine rather than a trademarked version if the prescription is based on the active substance has been eliminated**, many sectors of society continue wrongly to believe that for any given active substance, the price of generic medicines is lower than trademarked medicines.

Communication and Corporate Social Responsibility Working Group

The meetings of this working group addressed those issues of greatest interest to the sector, and analysed initiatives in the field of communication, both external and internal, in order to help the industry to maintain a uniform public position regarding the key aspects of **innovative medicines.**

The party addressed the initiatives launched in fields such as the value of innovation, the sectoral agenda (**surveys into R&D, Employment, Production and Corporate Social Responsibility**) and the transparency of transfers of value by the industry to healthcare organisations and professionals, as well as Spanish involvement in the European initiative **#WeWontRest**. It likewise addressed the information aspect of the Sustainability, Access and Innovation Agreement, and other cyclical topics connected with the latest information.

Patients Working Group

The meetings of this working group during 2018 considered issues of interest for the sector along with preparations for the staging of the **Somos Pacientes** Seminar and the content of the surroundings of the Standing Dialogue Panel.

During 2018 a group made up of representatives of the FARMAINDUSTRIA Patients, BEST and Clinical Research working groups, together with representatives from the patients' sector (EUPATI and the Platform of Patients' Organisations), produced a document of recommendations for the structuring of involvement by patients and patients' associations in the process of pharmaceutical R&D.

The working team involved in this initiative concluded, among other aspects, that at least eight areas can be identified to structure participation and contribution by patients in the biomedical R&D process in an effective and valuable manner:

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. Dissemination of relevant aspects 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. Search for and publicising of clinical trials of interest for each pathology.
6. Participation in the preparation and authoring of executive summaries of clinical trials (lay summaries).
7. Collaboration in the recruitment of patients to take part in clinical trials.
8. Patient bodies with an interest in participating in industrial R&D activities.

BARCELONA DELEGATION

The FARMAINDUSTRIA Delegation in Barcelona provides support and consultancy covering a range of issues for pharmaceutical manufacturers based mainly in Cataluña, on a cross-disciplinary basis and in coordination with the different departmental areas that make up the Association. It provides both horizontal and subject-based functions for the other member companies, and collaborates in the coordination of the various working parties in place at FARMAINDUSTRIA. In turn, the Delegation provides a venue for meetings of the governing bodies of FARMAINDUSTRIA, the various Statutory Groups and other organisations in the healthcare sector.

Throughout 2018, the Barcelona Delegation continued to work closely with the FARMAINDUSTRIA **National Statutory Group,** taking on the role of technical secretary at its bimonthly meetings, coordinating the Group's own initiatives and managing information of interest for national companies that are members of the Association. It also continued to provide technical and logistical support for the other FARMAINDUSTRIA Statutory Groups.

The FARMAINDUSTRIA Delegation in Barcelona has continued to maintain **active interlocution** with the public health administration in Cataluña on issues of various kinds and in particular, in the field of electronic invoicing. In this regard, and in close coordination with the Hospital Debt Working Group and the Electronic Invoicing Sub-group, the Delegation has been comprehensively monitoring the level of implementation of electronic invoicing nationwide, serving as the direct interlocutor with the Department of Regional Policy and Public Administration, the General Inspectorates of the Spanish Regions, health services and healthcare centres, in order to rectify any incidents that might arise in this field, in accordance with electronic invoicing regulations.

It should lastly be noted that throughout 2018 the Delegation continued to maintain contact with academic institutions and entities related to the pharmaceutical industry in the region, likewise participating in the Delegated Joint Commission for Cataluña, Fedequim, and in the Social and Employment Commission of said Federation.

4 Member services

After running for over 12 years, the **Spanish Technology 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 the 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 activities undertaken by the PTEMI during 2018 include in particular the **BEST Project for Excellence in Clinical Research** (see the subsection on the BEST Working Party in this Annual Report), as well of the Pharma-Bio Cooperation Programme, which is discussed at length in the Pharma-Bio Working Group subsection of this Annual Report.

The PTEMI carries out much of its work in the area of disseminating and promoting actions aimed at all agents of the **science-technology-enterprise system**, to publicise the results of research activities or public and private actions of interest to the industry, in order to boost cooperation between agents.

The PTEMI communicates through its website (www.medicamentos-innovadores.org), which is a benchmark in national pharmaceutical biomedical research and is used as a meeting point to coordinate activities, information and communication among all participants.

A newsletter is issued monthly and sent to 3,000 people interested in PTEMI activities. 96 editions of this newsletter had been published by March 2019.

On 5 and 6 March 2019, the PTEMI coordinated and organised its **12th Annual Conference in Madrid**, together with the Spanish Platforms for Nanomedicine Technology, Healthcare and Biotech Market Technologies which under the title **"How to promote biomedical research in Spain"** brought together more than 250 researchers, health authorities and representatives of pharmaceutical, biotech and healthcare technology companies.

The various topics addressed included a presentation taking stock of the BEST Project, highlighting the average reduction of **-14% in lead times to launch clinical trials** since Royal Decree 1090/2015 took effect. The conference also confirmed the considerable drive being provided by the various stakeholders in order to position the country at the forefront of worldwide biomedical research, both in the field of clinical research and precision medicine and big data, attracting and coordinating a number of flagship projects in these areas. The presentations and videos are available at www.medicamentos-innovadores.org.

Meanwhile, the PTEMI has been working in collaboration with the **Spanish Clinical Pharmacology Society** on the preparation of a template letter thanking patients for participating clinical trials, which has received the approval of the **Clinical Trials Coordination Group** (AEMPS/CEIm), and has been published on the AEMPS website.

Work is also ongoing to **update the Code of Conduct for Data Protection in Clinical Research and Pharmacovigilance,** in accordance with the Organic Act on Personal Data Protection and the Guarantee of Digital Rights, published in the Official State Gazette on 6 December 2018, the Second Transitional Provision of which establishes a period of one year from its entry into force for the promoters of Standard Codes registered in the AEPD register to adapt their content in accordance with the terms of Article 40 of the GDPR.

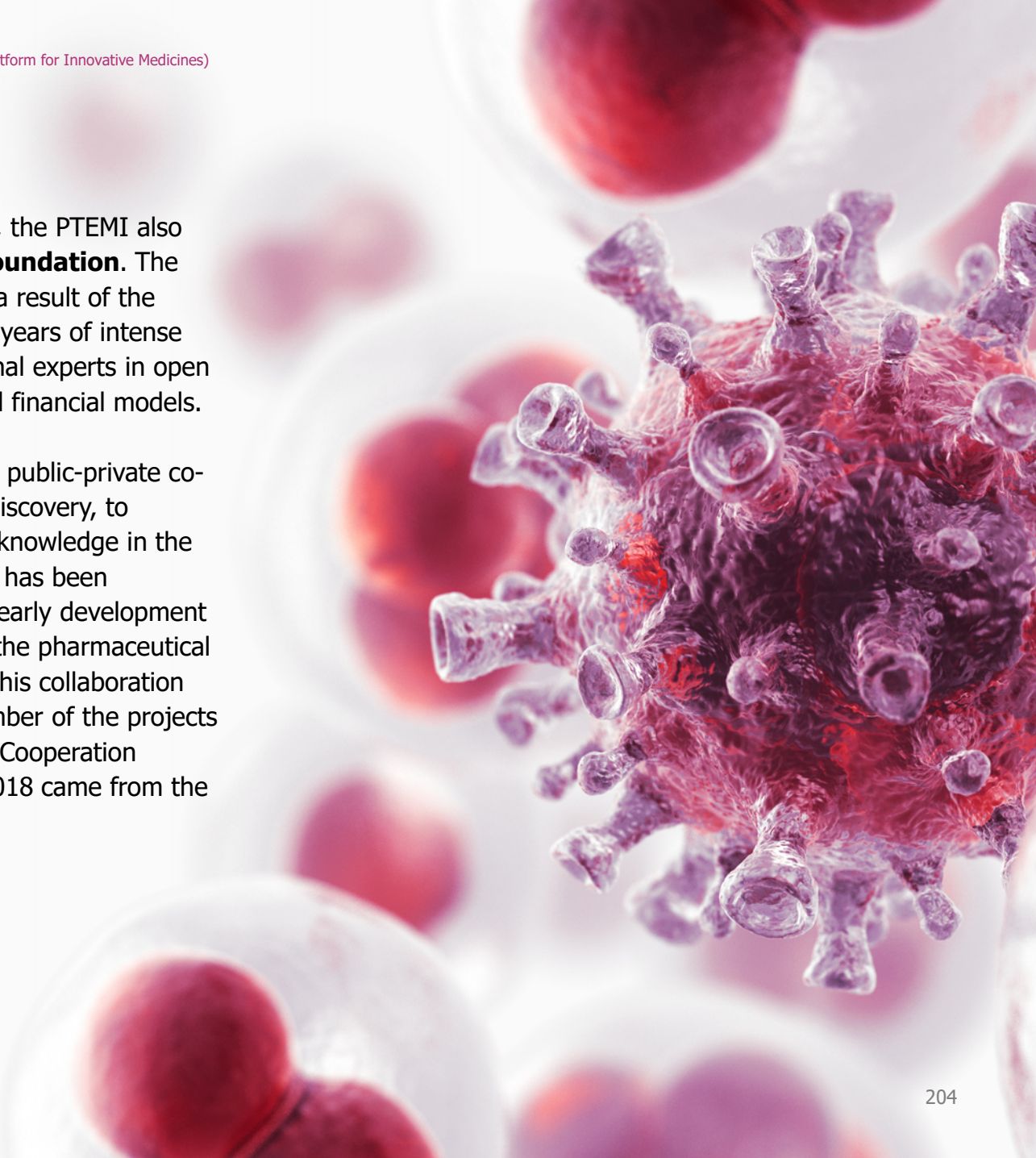
The new code will interpret the law in accordance with the GDPR with regard to:

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.

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

In the field of pre-clinical research, the PTEMI also collaborates with the **KÆRTOR Foundation**. The Foundation was set up in 2017 as a result of the conclusions reached following two years of intense work by a committee of international experts in open innovation, medicine discovery and financial models.

It aims for an open innovation and public-private co-development model for medicine discovery, to facilitate the reciprocal transfer of knowledge in the discovery of medicinal products. It has been developed as an incubator for the early development of medicines in collaboration with the pharmaceutical industry. One notable example of this collaboration may be seen in the fact that a number of the projects presented at the 17th Pharma-Bio Cooperation Gathering held on 28 November 2018 came from the **KÆRTOR** project portfolio.



In turn, the Platform has organised specific seminars and workshops addressing topics of interest for agents in the **science-technology-enterprise** system within the sector, such as those mentioned below:

Clinical research at private centres

Aware of the growing importance that research at private centres is taking on, and with the aim of increasing the number of private centres involved in clinical research, a specific seminar was staged to address this topic on 8 May 2018. These seminars take place yearly.

Research in early phases

Last year the number of **clinical trials** authorised by the AEMPS for early phases **increased by 50%**, confirming the trend which began some years ago as a result of a number of factors, including in particular both the quality, infrastructure and performance levels of the NHS to develop this type of clinical research at specific units, and also the increased investment by the pharmaceutical industry in Phase I and II clinical trials.

Within this context, the PTEMI took part at a seminar organised by the Instituto Fundación Teófilo Hernando on 14 June 2018 at the Hospital Central de Defensa Gómez Ulla on Phase I clinical trials. The PTEMI is also working on a review of the standards manual for early phase clinical trial units produced by the Healthcare Quality Agency of Andalucía, as well as the fourth update to the **Guide for Early Phase Clinical Trial Units**

Clinical research of rare diseases

The PTEMI was also involved in the **25th International Congress on Law and the Human Genome** held on 14-15 May in Bilbao, highlighting the substantial progress seen in recent years in clinical research into rare diseases in Spain, in particular in the **area of leukaemia and lymphoma**, as well as **auto-immune and metabolic pathologies**.

Digital transformation in biomedical innovation

In May 2018 a seminar was organised by IDIS, FARMAINDUSTRIA, Fenin and Asebio, at which the PTEMI was again involved in the sphere of biomedical innovation with regard to the new regulatory framework for data protection. The possibility of reusing clinical data for research purposes within the context of an extensive model of informed consent to take advantage of all the possibilities offered by new big data tools is the main key in guaranteeing the future development in Spain of what is known as precision medicine. The use of such data will in any event require appropriate guarantees for those participating in the field of biomedical research.

Clinical research and data protection

The PTEMI took part at the seminar on the impact of the new data protection regulations on biomedical research, organised by CEFI and held in Madrid on 26 June 2018, sharing a round table discussion with representatives of the Spanish Data Protection Agency, the Medicine Research Ethics Committees and the pharmaceutical industry.

Given the importance of the issue, the PTEMI also took part at the 13th AMIFE Congress to address the issue of application of the guide to the General Data Protection Regulation (GDPR) in Clinical Research, as well as the **Spanish Health IT Society Forum** held in Valladolid on 7 February 2019.

CLINICAL RESEARCH WITH PATIENTS' ASSOCIATIONS

In June 2018, the PTEMI took part at a seminar organised by the FECMA (Spanish Breast Cancer Federation) and Universidad Internacional Menéndez Pelayo, with the aim of discussing the present and future of oncology, with a particular emphasis on personalised care for patients with breast cancer. It was likewise involved in the 1st International Congress on an Amytrophic Lateral Sclerosis, or ALS (CincELA), organised by the Luzón Foundation in September 2018, at the **2nd Congress of Patients' Organisations** held in Madrid in October 2018, and the 6th Somos Pacientes Seminar also held in Madrid, on 11th December.

BIOSPAIN

The PTEMI similarly played an active role at the seventh edition of the **BIOSPAIN 2018 biotech trade fair,** the largest European event with a permanent venue in one country, which was held in Seville in September. A specific session was organised with two roundtable discussions addressing Pharma-Biotech cooperation

To illustrate and facilitate the debate, the PTEMI prepared a document on a number of the decisive obstacles limiting the capacity of the Spanish science and technology system to transfer efficient results to industry and ultimately to the marketplace.

10th Anniversary of IMI

The PTEMI was involved at the seminar to mark the **10th Anniversary of IMI**, held in Madrid in November 2018, to present Spain's results and participation in IMI 10 years after the launch of the programme.

Public-private partnership has proved essential in driving biomedical research, with key issues including the use of big data to develop medicines, predict toxicity and achieve greater patient engagement in R&D.

With regard to the 2019 working plan, provision has been made for the continuation of a number of lines begun in 2018:

- Implementation of European legislation and improvement of procedures.
- Guide to criteria of excellence for the selection of centres.
- Update to the early phases guide.
- Strengthening of paediatric trials.

- Application of personal data protection regulations.
- Recommendations for the structuring of participation by patients and patients' associations in the process of bio-pharmaceutical R&D.
- Promotion of Spanish participation at IMI.
- Active participation at forums, seminars and workshops to make Spain one of the leading nodes to attract international biomedical innovation projects.

IMI DO - IT

The IMI's **DO - IT** project, which was first launched in February 2017 and ended in February 2019, was established as a public-private consortium with the structure of a **CSA (Coordination and Support Action)** under the IMI 2 Programme 'Big Data for Better Outcomes' (BD4BO). **DO - IT** was made up of more than **35 members**, including FARMAINDUSTRIA. The aim of the **DO - IT** Project was to use the CSA to establish a platform that would allow an interrelationship with stakeholders so as to guarantee the consistency and coordination of specific projects in progress under the **BD4BO programme:**

- **Haematology tumours** (HARMONY Project).
- **Alzheimer's** (ROADMAP Project).
- **Cardiovascular** (BigDa-ta@Heart Project).
- **Prostate cancer** (PIONEER Project).

The aim was to exploit the synergies between projects, so that they would all make an aligned contribution to foster the usage of big data as a means to improve the efficiency of healthcare systems and patient health.

During 2018 **DO - IT** made considerable progress in efforts intended to reach a consensus as to a common, standardised informed consent model for the different countries, reconciling the existing diversity in terms of ethics, legislation and confidentiality in the processing of patient data in accordance with the new **General Data Protection Regulation**.

Nonetheless, given the existing disparity among national legislative systems, two different informed consent templates were published:

1. **"Conservative" informed consent** (with the legal basis for future uses under extensive consent): http://bd4bo.eu/wp-content/uploads/2019/03/DO-IT_WP4_D4.10_Level3_Clinical-ICF.docx.

2. **"Alternative" informed consent** (future use of data for future scientific research with a legal basis in other articles of the GDPR, such as Article 9(2)(j) and Article 6(1)(f) both referring to scientific research and legitimate interest, in the latter case establishing a series of guarantees for patients such as data pseudonymisation): http://bd4bo.eu/wp-content/uploads/2019/03/DO-IT_WP4_D4.13_Explantory_Information_withAnnex-1.pdf.

An FAQ document was also drawn up, intended above all for participants in the clinical trial using the consensus-based informed consent template, the purpose of which is to provide essential information about the processing of personal data in biomedical research: http://bd4bo.eu/wp-content/uploads/2019/03/DO-IT_WP4_D4.14_FAQ.docx.

4 Member services

CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

In June 2018 Spain became the first EFPIA member country to make use of its self-regulatory system in order individually to publish all transfers of value performed by pharmaceutical manufacturers to healthcare professionals.
Meanwhile, and although this was a separate matter from the transparency obligations, another particularly significant event was the clarification of the tax treatment of pharmaceutical industry collaborations with healthcare professionals for **attendance and participation at training activities** and scientific-professional meetings. Royal Decree 1074/2017 was issued in this regard on 30 December, amending Article 44 of the **Personal Income Tax Regulation**, and establishing that grants for the training of healthcare professionals (and other workers) do not constitute remuneration in kind for income tax purposes. The requirements imposed by the regulations for staff skills development or refresher study expenses not to be considered as remuneration in kind are:

1. The training must be required in order to perform the employee's activities or the characteristics of the job.

2. The studies must be provided and funded directly or indirectly by the employer to update, refresh or further develop the skills of its staff.

In order for it to be understood that the studies were **provided and funded** indirectly by the employer, two additional requirements must be met:

1. They must be funded by other companies or entities marketing products requiring workers to have appropriate training.

2. The employer must authorise their participation.

In turn, the Governing Board of FARMAINDUSTRIA gave its approval on 18 September 2018 for the **new text of Consultation 120** on Annex III of the Code, which covers **collaboration offered to healthcare organisations,** including a "guideline template to allow Healthcare Organisations to publish the collaboration received for their training support programmes" and an "operational procedure in the event of a breach or non-compliance of the terms and conditions of the consultation".

With regard to transparency, the measures adopted by a number of scientific societies required clarification for pharmaceutical manufacturers that the entry into force of the new **General Data Protection Regulation** did not affect or in any way modify the legal basis and justification set out in the report issued by the Spanish Data Protection Agency in April 2016 (Annex I to the Code) for the publication of transfers of value.

In June 2018 the **manufacturers published all transfers of value to healthcare professionals on an individual basis**. This publication serves to consolidate the existing collaboration model, based on principles of professionalism and responsibility. The way in which the vast majority of the media addressed this communication acknowledged the significance and value of the transparency initiative adopted by the pharmaceutical industry.

At the international level, both the IFPMA Code and the EFPIA Code have been subjected to a process of review and updating. In the case of the IFPMA Code, the main developments are:

1. The inclusion of operational ethical principles based on "trust".
2. A ban on the distribution of promotional gifts and gratuities.
3. Certain procedural technical improvements and the updating of guides.

This new version of the **IFPMA Code** took effect on 1 January 2019.

In the case of the **EFPIA Code** the review focuses on the approval of a new consolidated version covering the three codes currently in force. At the time when this Annual Report was finalised, the new version of the EFPIA Code was pending approval.

ETHICS SUPERVISION UNIT (USD) ACTIONS

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

- **Participation in the Code Working Group** to update, report and monitor issues connected with the transparency initiative and the individualised publication of transfers of value, and active monitoring of the self-regulatory system.
- **Collaboration and participation in other FARMAINDUSTRIA** working parties to analyse issues connected with the Code of Good Practice.
- **Meetings with pharmaceutical manufacturers** to monitor and support transparency projects.
- **Meetings with the Health Departments of the Autonomous Regions** to address issues connected with the transparency initiative and the self-regulatory system in general.
- **Meetings with scientific societies** for more in-depth analysis and resolution of queries regarding transparency matters, and to pursue and approve the basis for collaboration in the sphere of ongoing medical training.
- **Generation of information and communication materials** regarding the self-regulatory system and the transparency initiative.
- **Delivery of training sessions** specifically designed to meet needs and demands of pharmaceutical manufacturers (in-company training)
- **Joint work on delivering training sessions relating to the Code** within the framework of specialised courses, doctorates, masters, etc.
- **Participation at various seminars** organised by FARMAINDUSTRIA with the media and managerial staff from the Spanish Regions

- **Participation in the EFPIA working parties** responsible for overseeing the transposition and implementation of the approved standards within the applicable codes of each national association, along with the *Codes Committee* (Chair), *Strategic Committee, Ethics & Compliance Committee* (Vice-Chair) and *Validation Team* (e4ethics).
- **Participation in the process of consolidation of the EFPIA** *"Code Consolidation Group"*.
- **Continuous collaboration with IFPMA**: *Chair* of the IFPMA Code Appeal *Group*; participation in the working party for scientific meetings and congresses, and support in the process of updating the IFPMA Code of Good Practice.

With regard to relationships with patient organisations, the **USD** ensures that pharmaceutical companies comply with the commitment to provide updated information on the joint projects carried out during the year (available at www.codigofarmaindustria.es).

Consultancy and joint projects

The USD continued its collaboration and support tasks through:

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

During 2018, 5 circulars related to the Pharmaceutical Industry Code of Good Practice were published.

Monitoring and prevention

The total number of **preventive actions** undertaken during 2018 amounted to **1,513** (161 fewer than in 2017). In turn, a total of **three grievances were filed on the initiative of the Unit**, as a result of activities or practices in breach of the provisions of the Code regarding: "Information to be Provided" (Article 2), "Transparency of the Promotion" (Article 5), "Distribution of Promotional Material" (Article 7), "Digital Environment" (Article 8), "Guarantees of Independence" (Article 10) and "Services Provided by Healthcare Professionals or by Healthcare Organisations" (Article 16). The three grievances were resolved at the mediation phase or the Professional Ethics Committee.

In order to offer a more useful service to manufacturers with regard to the control, monitoring, rectification and classification of training activities and scientific-professional meetings organised by third parties, the decision was taken to **publish third-party events on the web platform** only in the case of those events with a greater reach and scope (attended by at least 200 healthcare professionals).

The adoption of this measure serves to **reduce the volume of scientific-professional meetings** analysed and verified each year, amounting to a total in 2018 of **3,894** (1,483 fewer than in 2017).

3,894

Scientific and professional meetings

96.2%

Level of compliance

262

Market research studies communicated

290

Projects communicated

This measure places a greater level of demand and responsibility on pharmaceutical manufacturers in their internal review and authorisation processes, allowing the USD to focus its efforts on ensuring that third-party organisers increasingly espouse the existing standards in connection with hospitality and meetings.

In this regard, the level of **meeting compliance** in 2018, was **96.2%** (compared with 94.6% in 2017). Meanwhile, the **number of market research studies** disclosed amounted to a figure of **262** (31 fewer than in 2017), while the **projects disclosed** totalled **290** (74 fewer than in 2017). Both activities reveal a percentage increase in the level of compliance, rising in the case of studies to 95% compliance (compared with 92.5% in 2017), and 93.1% compliance in the case of projects, as opposed to 88.2% in 2017.

EFPIA e4ethics platform

As active members of the EFPIA e4ethics *Validation Team*, during 2018 **204 scientific-professional meetings** were reviewed at the European international level. This review process continues to find that in the case of international meetings the inclusion of elements that would be in breach of most of the **self-regulatory systems** applicable at the European level, including the Spanish system, is relatively common.

It therefore remains common for these meetings to **include hospitality levels** exceeding the standards applicable in the codes and more specifically those in force in the countries selected by the organisers to host the events, and also the possible attendance of people other than healthcare professionals (companions).

		USD ACTIVITY (1 January to 31 December 2018)															
		2004 Apr. – Dec.	**2005**	**2006**	**2007**	**2008**	**2009** (a)	**2010**	**2011** (b)	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018** (c)	**Cumulative** Apr. 2004 – Dec, 2018
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**	**61,011**
	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	55,043
	% 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 %	90.22 %
STUDIES (a)	**ANALYSED**						**687**	**724**	**626**	**512**	**400**	**449**	**300**	**317**	**293**	**262**	**4,570**
	No incidents						397	546	565	416	332	368	251	280	271	249	3,675
	% Compliance						57.79 %	75.41 %	90.26 %	81.25 %	83.00 %	81.96 %	83.67 %	88.33 %	92.49 %	95.04 %	80.42 %
SERVICES (b)	**ANALYSED**								**357**	**330**	**306**	**350**	**368**	**363**	**364**	**290**	**2,728**
	No incidents								282	272	230	292	301	274	321	270	2,242
	% Compliance								78.99 %	82.42 %	75.16 %	83.43 %	81.79 %	75.48 %	88.19 %	93.10 %	82.18 %
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	31,394
USD COMPLAINTS		18	11	9	18	8	12	4	3	1	9	7	7	2	3	3	115

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

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

ACTIONS OF THE PROFESSIONAL ETHICS COMMISSION

The Pharmaceutical Industry **Code of Good Practice** establishes the functions of the Professional Ethics Commission in Article 25.3, including in particular mediation between the parties involved in grievances to ensure the reconciliation of disputes concerning matters covered by the Code, and referral to the Jury of any grievances received by the Secretariat of the Professional Ethics Committee, unless prior reconciliation has been achieved.

In this regard, **12 meetings of the Professional Ethics Committee** were held in 2018, discussing matters of interest connected with the scope of application of the Code, in addition to mediation processes.

As for mediation cases, in 2018 **6 grievances were filed with the Professional Ethics Committee**. These grievances were processed in compliance with the ordinary procedure referred to in Article 32.2 of the Pharmaceutical Industry Code of Good Practice.

50% of the grievances were presented by the USD (Professional Ethics Supervision Unit). One novelty in 2018 was a member manufacturer reporting itself to the USD, with the case being passed on to the Professional Ethics Committee.

The grievances dealt with by the Professional Ethics Committee in 2018 refer in the main to promotional activities, promotional materials or breaches of the Articles of the Code of Good Practice.

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

TOTAL	6
PROFESSIONAL ETHICS COMMISSION	**6**
Commission Mediation	4
Self-Regulation Jury	2
PLAINTIFFS	
USD	50 %
Member companies	50 %
DEFENDANTS	
Member companies	83.3 %
Adhering companies	16.7 %

Meanwhile, the Professional Ethics Commission played an active role in collaborating in all measures developed over the course of 2018 in the field of transparency, in particular the **publication of transfers of value**.

The Commission also discussed two binding consultations, specifically one connected with the **reproduction of scientific information** in connection with subsection 3.4 of the Code, and another concerning issues of interpretation of transfers of value.

With regard to the legislation evaluated at the Commission, particular emphasis should be placed on the draft Royal Decree governing the prescription, **use and authorisation for dispensation of medicines and healthcare products for human use on the part of nurses**, a debate having been conducted as to the training requirements that will be imposed on nursing professionals for the prescription, use and authorised dispensation of medicines and healthcare products.

The Royal Decree, which was passed and ultimately published in October 2018 establishes a new regulation which clarifies the definition of spheres of responsibility within which prescription, use and authorised dispensation of medicines on the part of such professionals must lie.

Meanwhile, the Professional Ethics Commission was informed of the amendment to Consultation 120 on the Code of Good Practice connected with the publication of transfers of value, and also the initiative by ANEFP (an association of which FARMAINDUSTRIA is a member) to establish a Professional Code of Ethics, along with the comments submitted to it by FARMAINDUSTRIA. This last initiative is suspended for the moment because of the positions adopted by a number of the associations affected, as well as the resolution passed by the Executive Self-control Board not to approve the new Code proposal, as a number of Self-control members do not agree with the terms as suggested.

Code of Conduct for Data Protection in Clinical Research and Pharmacovigilance

On 15 January 2019 a **meeting was held to set up the new Monitoring Committee** for the future Code of Conduct for Personal Data Protection in the field of Clinical Research and Pharmacovigilance, comprising Francisco Abad Santos, Doctor of Medicine and clinical pharmacologist at Hospital Universitario de la Princesa, whose position has been renewed; Alexis Rodríguez Gallego, Graduate in Medicine and Surgery and clinical pharmacologist at Hospital Universitario Vall de'Hebrón, and Ricard Martínez Martínez, Doctor of Law and Director of the Chair of Privacy and Digital Transformation, and Academic Delegate of the Rector for Data Protection at Universidad de Valencia, all of them **appointed by the Executive Board** of FARMAINDUSTRIA.

The **Monitoring Committee** will be the supervisory body for the new Code of Conduct, which will further **analyse membership requests** received from companies, and regulations impacting on the contents of the Code, both those being considered and those that have been approved. The Committee is currently collaborating on efforts to adapt the Code of Conduct to the new applicable regulations, since according to the Second Transitional Provision of the new Organic Act on Personal Data Protection and the Guarantee of Digital Rights, which took effect in December 2018, the promoters of Standard Codes registered with the Spanish Personal Data Protection Agency are granted a period of one year to perform this adaptation.

This adaptation work is being conducted by FARMAINDUSTRIA via two ad-hoc working parties which have been set up, comprising representatives of the clinical research, pharmacovigilance and legal service departments of the Companies.

The aim of the new code is not simply to **adapt to the new General Data Protection Regulation and the Organic Act on Personal Data Protection and the Guarantee of Digital Rights, but also to establish self-regulation,** and to provide a framework delivering guarantees in this field, potentially making it the appropriate tool to clarify issues subject to interpretation in the regulations, thereby serving as a reference document not only for the industry but for all agents involved in clinical research and pharmacovigilance operations: promoters, centres, monitors, researchers, healthcare professionals, etc.

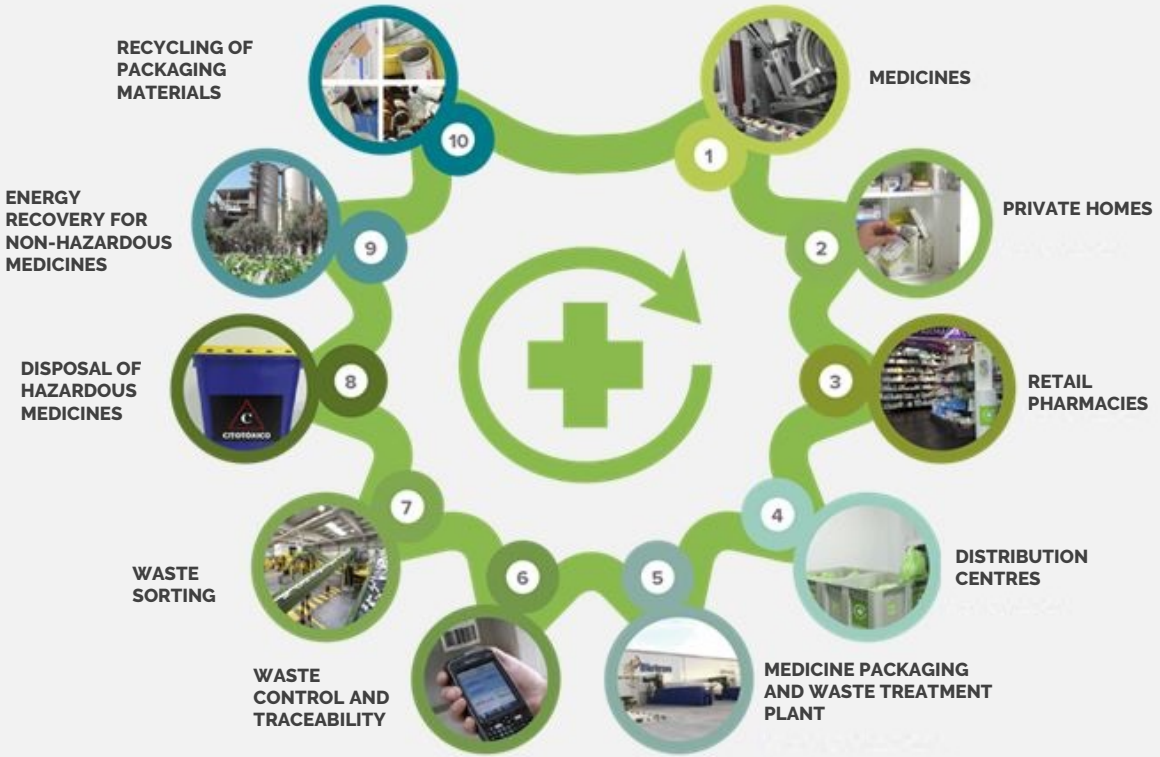
5 Annex I

SIGRE Medicine and Environment

A SUSTAINABLE AND SAFE SYSTEM

SIGRE Medicine and Environment is the non-profit entity set up by the pharmaceutical industry to guarantee the proper environmental management of packaging and waste medicines of domestic origin, a system which is convenient and safe for the general public, and effectively protects the environment.

SIGRE is made up of the main organisations representing the agents that comprise the medicinal product chain, as a sector committed to society and to improving quality of life, a commitment seen in the activities it performs.



Collaboration by all agents in the pharmaceutical sector (manufacturers, pharmacies and distributors) has proved decisive in the success of the SIGRE operational model, which has become the largest collaborative project undertaken by the sector.

It operates on the basis of a **reverse logistics system for waste collection** , which helps to avoid accidents, loss, illegal trading and falsification, furthermore encouraging the appropriate use of medicinal products and combating climate change.

The collection points for waste medicines and packaging are located at retail pharmacies because
of the **need to guarantee control of such waste for public health and safety reasons.**

COMMITMENT TO HEALTH AND THE ENVIRONMENT

SIGRE pursues a twofold objective:

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

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

In accordance with these objectives, **SIGRE has three operational fields** in order to fulfil the terms established in both environmental and health legislation:

- **Eco-design of packaging.**
- **Responsible waste management.**
- **Awareness-raising.**

(7) https://www.aenor.com/

COMMITMENT TO CONTINUOUS IMPROVEMENT AND QUALITY

Since it was first founded, SIGRE has been committed to **continuous improvements in the service** it provides to the pharmaceutical industry for prevention of packaging at source and the **proper environmental management** of waste medicinal products.

In 2018 the organisation updated its certificates issued by AENOR for its Quality Management (ISO 9001:2015), Environmental Management (ISO 14001:2015), Energy Management (ISO 50001:2011) and Health and Safety at Work Systems (OHSAS 18001:2007).[7]

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

CONTRIBUTION TO THE SUSTAINABLE DEVELOPMENT GOALS

With the aim of driving the transition towards a circular economy model in this country, SIGRE contributes to the achievement of the Sustainable Development Goals (SDG) which form part of the United Nations 2030 Agenda.[8]

It supports in particular the following SDGs:

- "Good health and well-being" (SDG 3)
- "Quality education" (SDG 4)
- "Clean water and sanitation" (SDG 6)
- "Industry, innovation and infrastructure" (SDG 9)
- "Sustainable cities and communities" (SDG 11)
- "Responsible consumption and production" (SDG 12)
- "Climate action" (SDG 13)
- "Partnerships for the goals" (SDG 17)

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

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

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

SIGRE was also one of the first organisations to sign up to the **Compact for a Circular Economy**[9], and as a member of the Executive Committee of the REPM (Spanish Network of the UN Global Compact) it helps raise awareness among society, companies and institutions as to the importance of combining efforts to achieve the 2030 Agenda goals and together to build a more sustainable planet.[10]

Proof of the efforts being made by the sector to progress towards a circular economy may be seen in the accolades received in 2018 by the REPM for the 2017 Sustainability Report and the 5th Catalogue of Eco-design Initiatives, as examples of good practice in the field of CSR and the SDG, respectively.

A NEW REGULATORY FRAMEWORK TOWARDS THE CIRCULAR ECONOMY

On 14 June 2018 the directives of the circular economy package were published, and will be required to take effect by 5 July 2020. These new directives include a series of measures intended to avoid waste and, where this is not possible, significantly to intensify recycling.

The new aspects that have been incorporated include the establishment of certain minimum functional requirements to be fulfilled by all organisations complying with obligations in the name of producers, known as PROs (Producer Responsibility Organisations).

In the case of SIGRE, as the PRO for packaging, in addition to the establishment of more ambitious recycling targets the most significant change is that all packaging, including commercial and industrial packaging, must be covered by **extended producer responsibility** by 31 December 2024.

TOWARDS A CIRCULAR ECONOMY THROUGH ECO-DESIGN

Eco-design is one of the cornerstones on which the **circular economic model** is based, being more competitive, innovative and sustainable than a linear "throwaway" economy.

In 2018, SIGRE published the 5th Catalogue of Pharmaceutical Sector Eco-design Packaging Initiatives,[11] a tool which supplements others previously developed to foster eco-design, such as the specific eco-design website,[12] and the Practical Guide to Eco-design of Pharmaceutical Packaging.[13]

This edition of the Catalogue contains a selection of the main measures applied by the pharmaceutical industry to bring about increasingly sustainable and easily recyclable packaging. It includes a total of 39 eco-design initiatives launched by 25 pharmaceutical manufacturers between 2013 and 2016. These measures have been applied to immediate, external, grouped or transportation packaging with the aim of **reducing the environmental impact** throughout the lifecycle. Each initiative has a factsheet describing the measure by and setting out the quantitative aspects achieved.

[11] https://www.sigre.es/wp-content/uploads/2018/04/ECODIS_2018.pdf

[12] http://www.sigre-ecodiseno.es/

[13] https://www.sigre.es/wp-content/uploads/2015/11/Guia-Practica-Ecodiseno.pdf

TRAINING FOR THE ANNUAL PACKAGING DECLARATION

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 2018, 125 representatives of pharmaceutical manufacturers attended.

This information, alongside data connected with the waste packaging collected and the environmental processing applied to the packaging, are all included in the **Annual Packaging Declaration** and the **Company Packaging Prevention Plan** that SIGRE is required to submit to the environmental authorities each year.

DIALOGUE WITH THE PHARMACEUTICAL INDUSTRY

In order to create a forum for information and debate with the pharmaceutical industry, SIGRE organises seminars each year in Madrid and Barcelona to address those topics of the greatest interest to pharmaceutical manufacturers, such the latest developments in the field of the **circular economy and eco-design** and the environmental implications of the **new anti-falsification devices** that must be fitted to packaging.

The Industry + SIGRE 2018 Meeting held in Madrid was attended by the Director-General for Environmental Sustainability of the Region of Madrid, Mr Luis del Olmo, while the Barcelona event was attended by the Director of the Waste Agency of Cataluña, Mr Josep María Tost, who both congratulated SIGRE and the pharmaceutical industry on their commitment to innovation in order to create more sustainable medicinal product packaging.

Over the course of the two gatherings, plaques and diplomas were handed out to pharmaceutical manufacturers that apply prevention and eco-design measures during the term of the 2015-2017 PEP, in recognition of their environmental efforts.

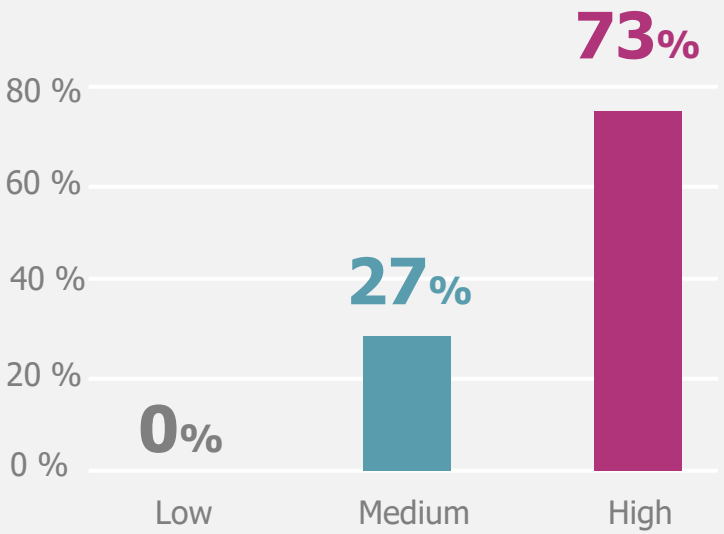
THE VALUE OF TRANSPARENCY

Every two years SIGRE conducts an 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 form part of the SIGRE sustainability strategy and help identify those aspects requiring attention in order to offer greater value to the pharmaceutical industry.

The key results from 2018 include in particular the fact that **73% Register a "high" level of satisfaction in terms of their relationship with SIGRE**, and 91% believe that SIGRE's operations help to present to the public the efforts made by the pharmaceutical industry to care for the environment.

General level of satisfaction of pharmaceutical laboratories in their relationship with SIGRE



PREVENTION OF PACKAGING AT SOURCE

SIGRE is the organisation responsible for producing and coordinating the PEPs (Company Waste Prevention Plans) for packaging in the pharmaceutical sector, the ultimate aim of which is to ensure that the containers and packaging used in conditioning pharmaceuticals are increasingly sustainable and environmentally friendly, promoting to this end the application of a circular economy model which will minimise environmental impact over the course of the entire lifecycle.

Following the positive results achieved with the 2015-17 PEP, which brought about an overall reduction in the weight of packaging of 6.86%, last year the environmental authorities were presented with the 7th PEP, which will be implemented over the three-year period 2018-2020, and sets a reduction target of 1%.

Despite the legal and technical difficulties that the inclusion of pharmaceutical packaging prevention measures entails, during the first year of the 7th PEP, a total of 49 manufacturers applied 101 measures, serving to reduce the weight of medicinal product packaging by 1.48%.

This is the first plan to be addressed entirely from **the circular economy perspective**, incorporating the latest advances in the field of eco-design to reduce the size and thickness of packaging, improve recyclability and minimise environmental impact.

RESPONSIBLE WASTE MANAGEMENT

SIGRE is the body responsible for presenting the environment authorities with the **Annual Packaging Declaration**, a document which sets out information about the medicines released to market (pharmaceutical presentation, weight and materials used), as well as the use made of the packaging and leftover medicines collected.

During 2018, the **21,800 SIGRE Points** collected an average of 103.1 grams per inhabitant of packaging that was empty or contained leftover medicines, successfully recycling 62.34% of materials from the recovered packaging.

To this end, the waste medicines deposited by the general public at SIGRE Points 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 having been designed exclusively for the appropriate environmental treatment of this type of waste.

A competitive tender was conducted in 2018 to award the collection, transport, storage, classification and final treatment service for SIGRE waste. Following consideration of the bids received, the Board of Directors of SIGRE awarded the contract to the company **BIOTRAN** to manage the waste for 5 years from 2020 onwards.

ENVIRONMENTAL AWARENESS-RAISING

Citizen engagement is essential in order to achieve the proper management of waste medicines. To get the public to cooperate, SIGRE launches **awareness-raising campaigns** every year to publicise the importance of properly recycling empty packaging and leftover medicines via the SIGRE Point at a pharmacy. In autumn 2018 SIGRE launched the **"Thanks for lending a hand"** campaign, continuing the communication strategy begun in 2016 with "Hand-in-hand for a better world", and extended in 2017 with "Your hand matters too".

The 2018 campaign highlights the contribution and effort made by agents in the sector, and surpassed the targets that had initially been set for reach and impact among the general public, through both conventional and digital media. The campaign was supported by the distribution of an information leaflet via pharmacies.

INFORMATION ABOUT MEDICINES

In 2018 SIGRE launched the **"Medicinal packaging, helping your health"** campaign, to inform the general public of the content and meaning of the symbols, abbreviations and texts most commonly found on pharmaceutical packaging.

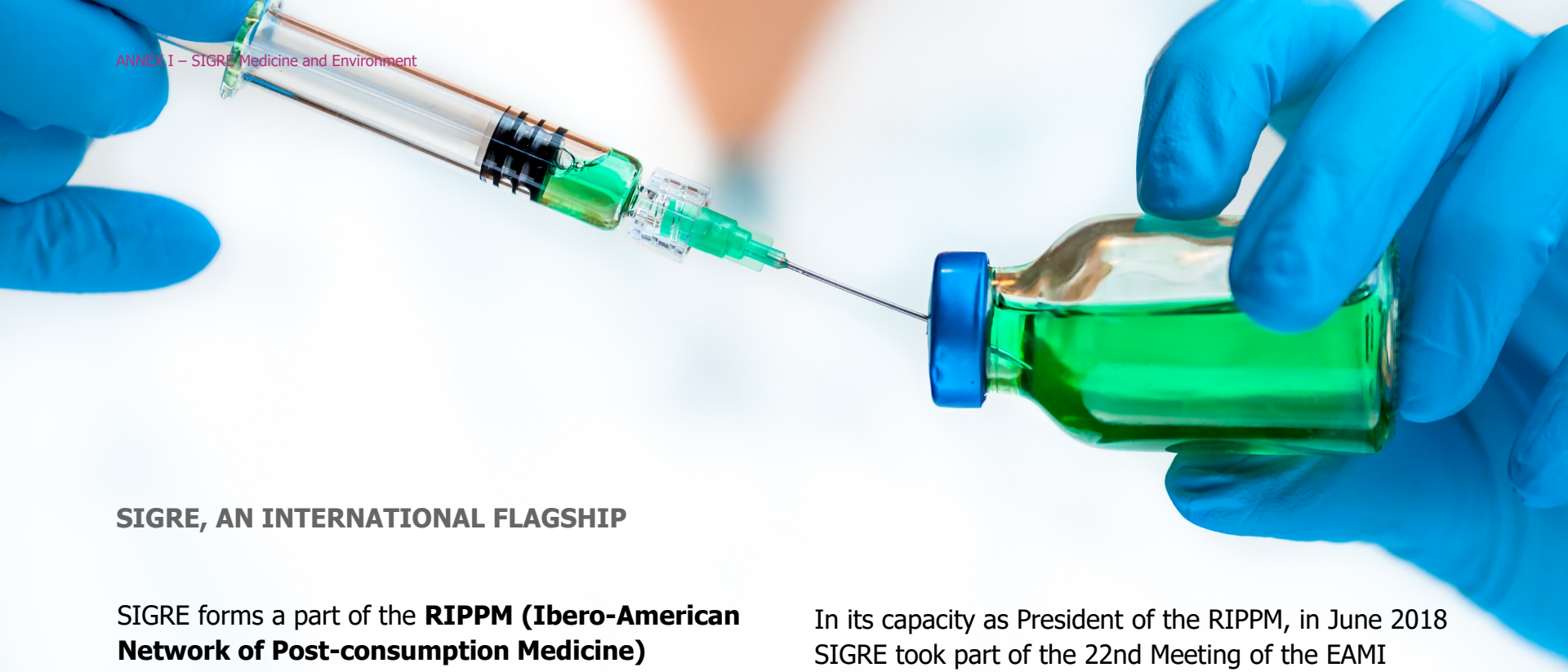
The aim of the campaign was to familiarise the general public with the information provided by both the packaging and the datasheet accompanying medicinal products.

DISSEMINATION AT ENVIRONMENTAL AND HEALTHCARE FORUMS

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

Over the course of 2018 we would highlight our participation at:

- 3rd Professional Seminar of Distribution Pharmacists.
- 38th Symposium of the Spanish Association of Industry Pharmacists.
- 14th International Congress on Energy and Mineral Resources.
- 6th In-person Pharmaceutical Cooperation Seminars.
- 21st National Pharmaceutical Congress.
- EMPACK 2018.
- 14th Edition of the National Environmental Congress.
- Seminar: "Sustainable waste management: towards a circular economy".



SIGRE, AN INTERNATIONAL FLAGSHIP

SIGRE forms a part of the **RIPPM (Ibero-American Network of Post-consumption Medicine) Programmes**[14], an organisation set up to facilitate the exchange of experiences serving to identify the pros and cons of the different post-consumption medicine programmes in operation in the countries of Iberia and Latin America, with the aim of establishing best practices for the design, organisation, structuring, execution and implementation of post-consumption medicine programmes.

In its capacity as President of the RIPPM, in June 2018 SIGRE took part of the 22nd Meeting of the EAMI (Network of Medicine Authorities of Ibero-America)[15], an organisation made up of the authorities responsible for medicines in the 22 countries of Iberia and Latin America. At the meeting, the environmental and healthcare benefits derived from the proper management of waste medicines and packaging were presented.

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

(15) https://www.redeami.net/web/homes/eami_conten_home.htm

6 Annex II

SEVEM (Spanish Medicines Verification System)

BACKGROUND

In 2008 the European Commission presented a legislative proposal amending Directive 2001/83/CREC, by incorporating measures intended to **prevent falsified medicines from entering** the legal medicine supply chain.

This initiative was in response to concern at the public health threat that could result from an **increase in falsified medicines** in terms of their identity, record and origin within the EU.

The Falsified Medicines Directive, Directive 2011/62, governs the **inclusion of 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 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.

To date, the medicines subject to medical prescription not required to carry security devices are:

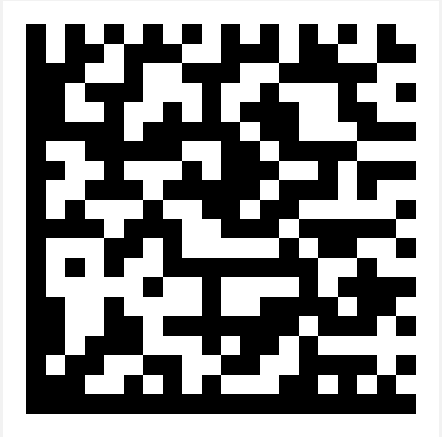
- Homeopathic medicines.
- Radionuclide generator.
- Equipment.
- Radionuclide precursors.
- Advanced therapy medicines comprising for containing cells or tissues.
- Medicinal gases.
- Parenteral nutrition solutions with an ATC code beginning B05BA (solution for infusion).
- Solutions affecting electrolytic balance with an ATC code beginning B05BB (solution for infusion).
- Solutions for osmotic diuresis with an ATC code beginning B05BC (solution for infusion).
- Additives for intravenous solutions with an ATC code beginning B05X.
- Solvents and diluents, including solutions for irrigation, with an ATC code beginning V07AB.
- Contrast mediums with an ATC code beginning V08.
- Allergy diagnosis tests with an ATC code beginning V04CL.
- Allergen extracts with an ATC code beginning V01AA.

Medicines without prescription are excluded from the scope of application of the Delegated Regulation, except for those included on the list in Annex 2 (omeprazole in hard gastro-resistant capsules of 20 mg and 40 mg). The competent national authorities may nonetheless notify the Commission of medicines not subject to medical prescription that they believe run the **risk of falsification**. In addition, the Member States may extend the scope of application of the unique ID, for the purposes of reimbursement for pharmacovigilance.

The detailed implementation of the provisions included in the **Falsified Medicines Directive** is delegated to the European Commission which, in accordance with this mandate issued Delegated Regulation (EU) 2016/161 in October 2015, applicable from 9 February 2019. The Delegated Regulation implements, among other aspects, the technical characteristics and specifications of the unique ID, the forms of verification of the safety devices and the creation and administration of the system of repositories containing information about the IDs.

Each agent in the legal medicine supply chain is assigned different obligations. Manufacturers are thus required to fit the outer packaging of each medicine with an anti-tampering device and two-dimensional code (**Datamatrix**), comprising a product code, a 20-character serial number generated by a randomisation algorithm, the batch number and expiry date.

Counter-manipulation device



Datamatrix

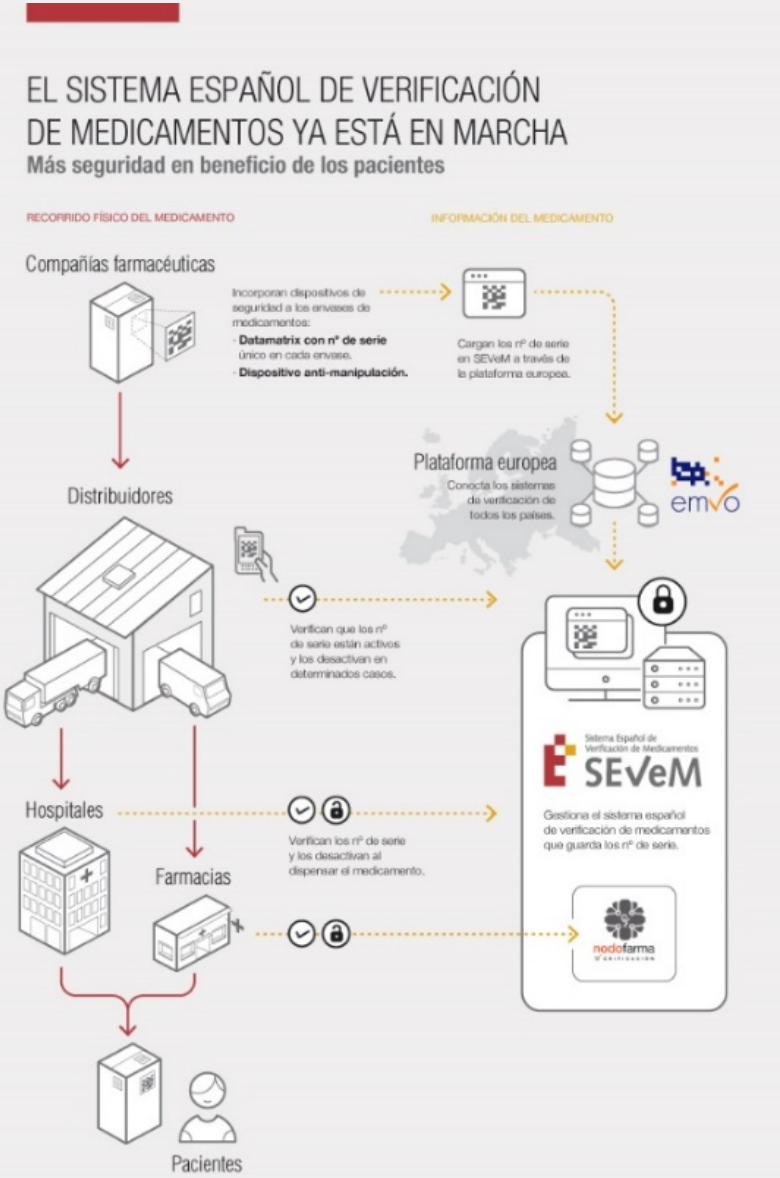
In addition, in the case of Spain and at the behest of the national authorities the **Datamatrix** also contains the national reimbursement number, either as part of the product code itself or in a fifth field. To allow packaging to be verified, the unique IDs must be **uploaded by the manufacturers** into the repository system.

Wholesalers are obliged to verify those medicines with the greatest risk of falsification, which means that if they were falsified they would not remain unnoticed for long, while retail pharmacies and pharmaceutical services or other agents authorised to dispense medicines will verify and deactivate the **unique ID of the packaging unit** to be dispensed to the patient.

It should be pointed out that since the Delegated Regulation was published, considerable progress has been made in order to make the European Medicines Verification System a reality, both at the European level overall, and specifically in each of the participating countries.

For example, the **EMVO (European Medicines Verification Organisation)** was set up to take responsibility for developing the European platform and coordinating the progress of the various European countries in **establishing the national repositories** in accordance with the technical specifications drawn up by the European body.

In Spain, the verification system was developed by the company Spanish Medicines Verification System (SEVeM), which has since it was founded worked to implement the Spanish part of the project.



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 Falsified Medicines Directive). The corporate purpose of SEVeM likewise includes ensuring that information about SEVeM-authenticated medicines will be used to calculate the reimbursement owed by retail pharmacies to pharmaceutical manufacturers and distribution organisations of those medicines dispensed outside the NHS.

SEVeM was set up by the main agents in the 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 Meeting** is made up of the shareholders of SEVeM (AESEG, FARMAINDUSTRIA, General Council of Official Associations of Pharmacists and FEDIFAR), while the governing body of SEVeM is the Board of Directors, made up in 2018 as follows:

PRESIDENT

- Mr Humberto Arnés Corellano

DIRECTORS

- Mr Jesús María Aguilar Santamaría
- Mr Luis Amaro Cendón
- Ms Amalia Gracia Avilés Uruñuela
- Mr Emili Esteve Sala
- Ms Lourdes Fraguas Gadea
- Mr Eladio González Miñor
- Ms Raquel Martínez García
- Mr Ángel Luis Rodríguez de la Cuerda
- Ms María Iciar Sanz de Madrid Ibrán
- Mr Javier Urzay Ramírez

NON-DIRECTORIAL SECRETARY

- Mr Pedro Yanes Yanes

NON-DIRECTORIAL VICE-SECRETARY

- Mr Miguel Valdés Garaizabal

In addition, and in accordance with the articles of association of **SEVeM**, the **Spanish Medicines and Healthcare Products Agency** is also invited whenever the Board of Directors addresses issues concerning the development and functioning of the Spanish repository.

DELEGATED BODIES

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

The Operations Committee comprises representatives of the four SEVeM services (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 2018 the Operations Commission met monthly to address topics connected with:

1. Regulatory provisions under preparation for the effective application in Spain of the provisions of the regulations within the context of falsified medicines.
2. Criteria for the management of system users.
3. Procedures required for the evaluation of SEVeM conducted by EMVO.
4. Working plan for the integration of the NHS Node.
5. Practical issues for the functioning of the system.
6. Project progress and monitoring of agents connected.
7. Management of alerts and advanced algorithm for the end user software.
8. System stabilisation period.
9. Voluntary aggregation of codes for hospitals.

The Audit Commission, which comprises representatives of the four shareholders as established in the **SEVeM** articles of association, met on three occasions during 2018 to **review the annual accounts and to supervise the generation of the company's income and expenditure budgets** to be presented to the Board of Directors.

COMMUNICATION

Ever since it was founded, **SEVeM** has had a website (www.sevem.es) to provide the general public and stakeholders with an insight into the activities performed by the organisation, ensuring that information connected with the project is available and kept up-to-date.

The executive team of **SEVeM** also plays an active role at numerous conferences, seminars and courses to explain its activities, and the progress and results achieved through the various phases of the project. The notable events attended in 2018 would include:

- Spanish Royal Academy of Doctors: The Spanish Medicines Verification System, held on 17 January 2018.
- INFARMA: Situation of the Spanish Medicines Verification System, held on 14 March 2018.
- AEFI: Current situation of the repositories system, held on 25 April 2018.
- 38th AEFI Symposium, held on 10 May 2018.
- Lifelong Learning Institute - IL3, held on 23 October 2018.
- Official Association of Pharmacists of Barcelona, held on 22 November 2018.
- 16th Seminar on Standards for proper manufacturing of medicines and active substances, held on 11 December 2018.

PROJECT PROGRESS

Since it was first established in July 2016, **SEVeM** has been required to mark various milestones:

1. The incorporation of its **technical team**.
2. The selection of the **technology provider** that developed the system.
3. The implementation of **infrastructure** across Spain.
4. The integration of the **NodoFarma Verification** node to link up 22,000 Spanish pharmacies in an extremely short time period.

Positive engagement by all meant that by 9 February 2019 **Spain was able to comply with the deadlines imposed by European legislation**. One week earlier, more than 11,400 pharmaceutical SKUs intended for the Spanish market had been uploaded to the system, with some 70% of medicine distribution warehouses located in the country being connected.

In just five days, more than 8,000 pharmacies received accreditation to access the system, and by the deadline practically all pharmacies had linked up to **SEVeM**. During the first month that the system was operational, more than **3.6 million deactivations** were clocked up.

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