farmaindustria

2017
ANNUAL REPORT

Letter
from the President

Jesús Acebillo

PRESIDENT OF FARMAINDUSTRIA

We live in an era of great challenges, but also of enormous opportunities, particularly in the field of biomedical research. Thanks to our growing understanding of the human genome and the development of the '-omic' sciences, we have already started the greatest revolution in the history of medicine, opening the door to a new way of understanding the approach to disease based on increasingly individualised and precise therapies, and with fewer side effects. This new model, together with the development of digitalisation, also encompasses a great potential to transform the healthcare system by incorporating efficiency elements in the use of public resources.

At the beginning of this exciting era of so-called precision medicine, the pharmaceutical industry is playing a leading role in the healthcare system, both as a generator of new biomedical knowledge through its intense R&D activity and by the discovery and development of new treatments that are already allowing to cure diseases that were previously incurable or to convert other diseases that were fatal until a few years ago into chronic diseases, and by achieving substantial improvements in patients' quality of life.

On the other hand, it should not be forgotten that the pharmaceutical industry is also an industrial sector that has a very significant and positive impact for the economy, since it combines three key levers of modern companies: industrial activity, innovation and internationalisation, together with highly qualified employment.

In Spain, this unique, diverse and active role of the pharmaceutical industry has been developed in recent years through multiple actions and initiatives that we could divide into five major areas which, in turn, make up our Strategic Plan: Innovation, Sustainability, Employment and Economic Development, Transparency, and Dialogue.

The firm commitment to research and development in Spain of new medicines is evidenced in the record R&D investment, already in the range of €1.1 billion per year, of which almost half are allocated to collaboration contracts with public and private hospitals and research centres. Today we can no longer understand R&D if it is not within the framework of international projects of open innovation, where public-private collaboration is an inescapable requirement if we want to achieve good results. All this effort, together with a favourable legal framework, collaboration with health authorities, the excellence of our healthcare professionals, the robustness and quality of the National Health System and the growing participation of patients, have made it possible to place Spain in the lead group of European countries with better conditions for conducting clinical research, which represents a clear benefit for patients and the healthcare system itself.

R&D INVESTMENT

50%

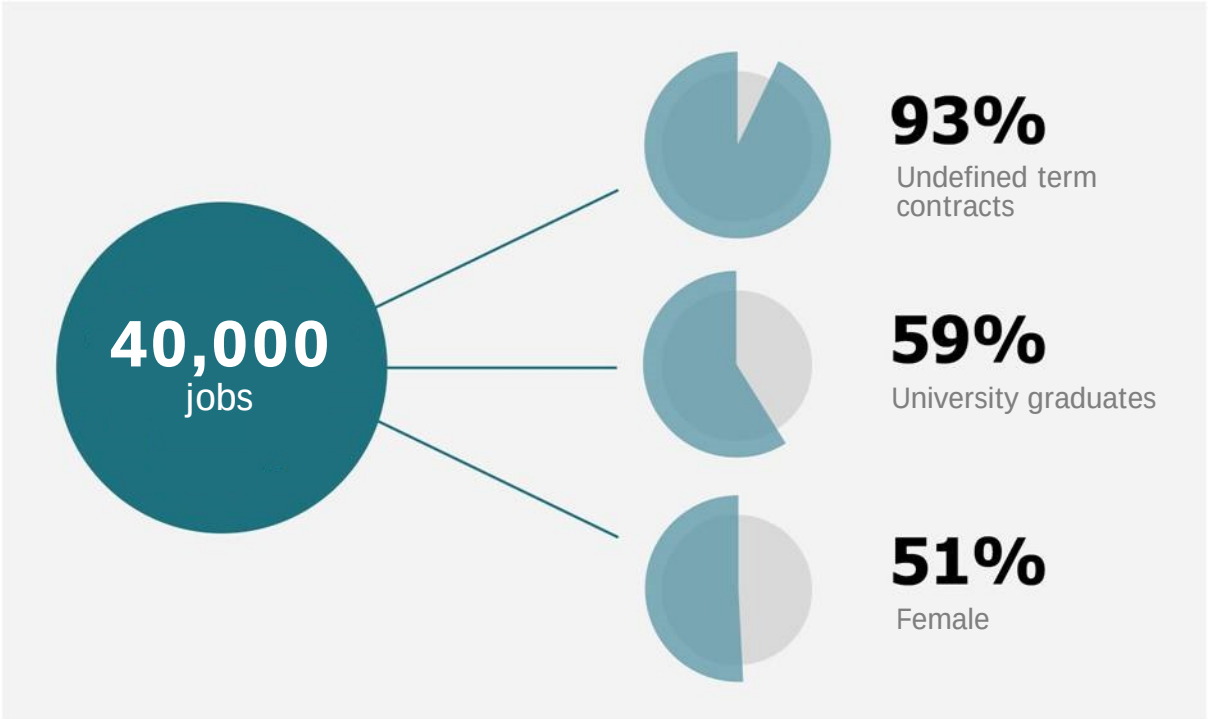
In collaboration contracts with hospitals and research centres

Another objective that has guided the actions of the pharmaceutical industry in 2017 was **maintaining the sustainability of the National Health System** (NHS), of which we are key part and therefore committed to the robustness of its finances. In this context, we should not forget the renewal, for one more year, of the Agreement for Sustainability, Access and Innovation signed with the Spanish government. This instrument, together with others such as new contracting formulas (spending ceilings, risk sharing agreements, etc.), allows us to have a **framework of stability and predictability** of great value for a sector operating in the long term, as this is required for innovation in medicines, but particularly leads us to solutions demanded by the NHS and society, while the Agreement is a means of budget control and, therefore, a guarantee for patients to access the medicines they need.

The budget control guarantee allows the NHS to address future challenges more confidently. In this regard, it is important, and the pharmaceutical industry has demonstrated this, to move forward decisively together with healthcare managers towards incorporation of the concepts of **“health outcomes”** and **“value for the patient”** of healthcare interventions. If we want to be able to combine innovation, access and sustainability in the medium and long term, we must know objectively and rigorously the impact of innovations (also medicines) in economic, health and social terms, and the associated costs. We have the means (big data and digital technologies) to measure each decision better. This will allow the healthcare system to be more effective–and thus improve patient quality–and to be more efficient. Last September, at the annual meeting of the pharmaceutical industry in the summer course of the Menéndez Pelayo International University in Santander, we committed to supporting pilot outcome measurement experiences, and we can say that dialogue with different regional health departments is about to culminate in the participation of Spanish hospitals in international initiatives. **It’s the way forward.**

That real experience will also help us in the necessary evolution of the NHS from a budget-based vision, which focuses on the **immediate cost of health care**, towards one that regards healthcare innovation as an investment which, beyond the health benefits for patients, translates into savings for the healthcare system and productivity for the whole economy.

Economic development is another of our basic commitments. The pharmaceutical industry–as noted above–is a **driving sector of the Spanish economy.** And the 2017 data support this reality. For employment, and beyond the 200,000 jobs generated by the pharmaceutical industry, **40,000 of them direct**, the survey conducted by FARMAINDUSTRIA shows very stable employment (**93% are undefined term contracts**), highly qualified (**59% are university graduates**), and with a high proportion of female staff, to the extent that **51% of jobs are held by women**, twice the average of the industrial sector. What's more, in the R&D area, female employment accounts for 65%, the largest figure of all productive framework in Spain.



We support innovation, consistent with the commitment and responsibility of the pharmaceutical industry to Spanish society

Jesús Acebillo

PRESIDENT OF FARMAINDUSTRIA

In addition, as compared to the high unemployment rates affecting young people in Spain, in our case it is precisely the group under 29 years of age which has experienced the greatest growth in recent years with **one in three new contracts being for a young person.**

Our sector plays a highly relevant role within the current Spanish industrial map and has great potential to continue improving its efficiency and competitiveness ratios, always clearly in line with public administrations. We are responsible for a **production figure of more than 15,000 million** Euros (only in Spain), 24% of the high-tech across the country, and **almost 11,000 million** Euros worth of **export products** (27% of high-tech exports), and all this without forgetting that one in five euros that are used in Spain for industrial R&D is from pharmaceutical companies, the leaders in this area.

In any case, this positive impact across the country through R&D investments, employment, productivity and savings would not be possible if our industry did not always work within a dynamic and cooperative ongoing dialogue with other key stakeholders in the healthcare field, such as healthcare administrations and managers, professionals and organizations representing them, the other sectors operating in the healthcare sector and, of course, patient associations, which are playing an increasingly decisive role.

PRODUCTION IN SPAIN

15,000

MILLION EUROS

EXPORTATION OF PRODUCTS

11,000

MILLION EUROS

INDUSTRIAL R&D INVESTMENT

20%

COMES FROM
PHARMACEUTICAL COMPANIES

The Collaboration Agreement, renewed for the second time in 2017, or the creation of the **Spanish System for Verification of Medicinal Products** (SEVeM), introduced by generic medicine manufacturers, distributors and pharmacies, and which has been consolidated over this past year, are examples of the commitment to dialogue by the companies that make up FARMAINDUSTRIA.

This is precisely how this framework of understanding and dialogue on how the collaborations between pharmaceutical companies and organizations and healthcare professionals can be best understood. We have no doubt about the value of the services that many professionals provide to the industry, whose clinical experience is essential for R&D and appropriate use of medicines, or the benefits for the professionals and for the healthcare system as well as patients being awarded grants from pharmaceutical companies thus continuing education, which in turn allows our physicians to participate in national and international scientific forums and be at the forefront of knowledge.

Hence, our commitment to **transparency**, by publishing all such collaborations, preventing potential conflicts of interest and showing society the need and value of such collaborations.

This transparency initiative was launched in June 2017 with the second data publication. It was a step further for this commitment that companies started many years ago when publishing, for example, resolutions and mediations under the Code of Good Practice of the Pharmaceutical Industry or collaborations with patient organisations.

It was also the precursor of a further step in the development of this measure, as all collaborations carried out in 2017 will be published (in 2018) on an individualised basis (versus the dual choice of individualised and aggregated data in the first two years), which is more responsive to the spirit of transparency.

This effort of the pharmaceutical industry in terms of transparency, unparalleled in other sectors, is being recognised by society, and it is satisfying and encouraging to know that with perseverance we will close the year and be distinguished in the **2nd Edition of the Award for Transparency, Integrity and Combating Corruption**, awarded by the General Council of Spanish Lawyers and Transparency International Spain, one of the most widely recognised entities worldwide in this area.

I do not want to omit mentioning two additional cross-cutting areas of action that also play a very important role in FARMAINDUSTRIA. I am referring, on one hand, to the necessary and increasingly strong **alignment** of our international practices and positioning with the federations which FARMAINDUSTRIA belongs to, both European (EFPIA) and international (IFPMA), with which we maintain very close collaboration in such relevant matters as health technology assessment (HTA), industrial property or the ethical code. And, on the other hand, to the effort in **Communication** made by our association so that we are known and well understood by society and our stakeholders, including what we do, how we do it, and why we do it.

In short, the changes in the pharmaceutical industry across these large areas show the industry's commitment to society and puts us on the right path to deal with the challenges ahead and, above all, to take advantage of the great opportunities that emerge. The fruits we are beginning to gather from our strong commitment to R&D in biomedicine in the past decades are not at all a problem, as some narrow views have sought to see, but a great opportunity for our society and, especially, for patients, which is what gives meaning to the task of everyone working in the field of health. Dialogue and commitment show that there are means and solutions to reconcile innovation and sustainability. Let's work together.

Jesús Acebillo
PRESIDENT OF FARMAINDUSTRIA

1

Member Companies

At the time of publishing this Annual Report, the number of FARMAINDUSTRIA'S member companies rose to **154**, whose geographical distribution is as follows:

PHARMACEUTICAL COMPANIES PER GROUP

National:		International:			
		American		European	
Total	**49**	**18**		**87**	
Large:	5			Germany	10
SMEs (Small and Medium sized):	44			France	10
				Mixed	37
				United Kingdom	19
				Switzerland	11

FARMAINDUSTRIA'S member companies account for 45% of marketing authorisation holders of medicinal products, or local representatives thereof for centrally authorised products, both with and without production activity in Spain. In terms of sales, they represent 73% **of the total prescription market** (retail pharmacies and hospitals).

2

Organisation

2.1 Governing Bodies

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

The Government of the Association is comprised of:

1. **The Executive Board,** made up of the President and 33 representatives of member companies (9 representatives from national capital companies and 24 from foreign capital companies, of which 15 are European/international companies and 9 are American companies).

2. **The Board of Governors,** made up by the President and 22 members, of which 10 are Vice-Presidents (3 from national companies, 3 from American companies and 4 from European/international companies), and 12 spokespersons designated by the Executive Board (3 from national companies, 3 from American companies and 6 from European/international companies).

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

At the General Assembly, held on 27 June 2017, **amendments were approved to Articles 1, 2, 8, 35, 42, 43 and 44** of the Articles of Association of FARMAINDUSTRIA to introduce remarks requested by the Public Office for Registration of Articles of Association.

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

BOARD OF GOVERNORS	
PRESIDENT	
Mr Jesús Acebillo Marín	
VICE-PRESIDENTS	
Mr Timmo Rousku Andersen	Ms Margarita López-Acosta
Mr Antoni Esteve Cruella	Mr Juan López-Belmonte Encina
Mr Ángel Fernández García	Mr Salvador Pons Ribas
Mr Jorge Gallardo Ballart	Mr David Solanes López
Ms Cristina Henríquez de Luna Basagoiti	Mr Martín Sellés Fort
Mr Roberto J. Urbez Plasencia	
SPOKESPERSONS	
Mr Juan Carlos Aguilera Rodríguez	Mr Eduardo Recoder de la Cuadra
Mr Antonio Buxadé Viñas	Mr Sergio Rodríguez Márquez
Ms Marieta Jiménez Urgal	Mr Eduardo Leyva Pinzón
Mr José Mª Martín Dueñas	Mr Mario Rovirosa Escosura
Mr Federico Plaza Piñol	Mr Enrique Trias Vidal de Llobatera
Mr Francisco Quintanilla Guerra	Pending appointment of a Spokeperson by the American Group

EXECUTIVE BOARD

PRESIDENT

Mr Jesús Acebillo Marín **NOVARTIS FARMACÉUTICA, S.A.**			

VICE-PRESIDENTS

Mr Jorge Gallardo Ballart **ALMIRALL, S.A.**	Mr David Solanes López **LABORATORIOS ERN, S.A.**	Mr Martín Sellés Fort **JANSSEN CILAG, S.A.**	Mr Juan López-Belmonte Encina **LABORATORIOS FCOS. ROVI, S.A.**
Mr Timmo Rousku Andersen **BOEHRINGER INGELHEIM ESPAÑA, S.A.**	Mr Antoni Esteve Cruella **ESTEVE**	Mr Salvador Pons Ribas **LABORATORIOS MENARINI, S.A.**	Ms Margarita López-Acosta **SANOFI-AVENTIS, S.A.**
Mr Roberto J. Urbez Plasencia **BRISTOL-MYERS SQUIBB, S.A.**	Ms Cristina Henríquez de Luna Basagoiti **GLAXOSMITHKLINE, S.A.**	Mr Ángel Fernández García **MERCK SHARP & DOHME DE ESPAÑA, S.A.**	

SPOKESPERSONS

Mr Eduardo Leyva Pinzón **ABBVIE SPAIN, S.L.U.**	Ms Katherine Stultz **CELGENE, S.L.**	Mr Joao Simoes **GRÜNENTHAL PHARMA, S.A.**	Mr Federico Plaza Piñol **ROCHE FARMA, S.A.**
Mr César Concepción **ALCON CUSI, S.A.**	Mr Francisco Quintanilla Guerra **FAES FARMA, S.A.**	Mr Nabil Daoud **LILLY, S.A.**	Mr Regis Fedrigo **LABORATORIOS SERVIER, S.L.**
Ms Fina Lladós Canela **AMGEN, S.A.**	Mr Javier Font Faus **FARDI, LBO. DE APLICACIONES FARMACODINAMICAS, S.A.**	Ms Marieta Jiménez Urgal **MERCK, S.L.**	Mr Jesús Sobrino García **UCB PHARMA, S.A.**
Mr José Mª Martín Dueñas **ASTELLAS PHARMA, S.A.**	Mr Tomás Olleros Izard **GRUPO FARMASIERRA, S.L.**	Mr Francisco Javier Alvarado García **MUNDIPHARMA PHARMACEUTICALS, S.L.**	Mr Enrique Trías Vidal de Llobatera **VIFOR PHARMA ESPAÑA, S.L.**
Mr Eduardo Recoder de la Cuadra **ASTRAZENECA FARMACÉUTICA SPAIN, S.A.**	Mr Mario Rovirosa Escosura **FERRER INTERNACIONAL, S.A.**	Mr Sergio Rodríguez Márquez **PFIZER, S.A.**	Mr Antonio Buxadé Viñas **LABORATORIOS VIÑAS, S.A.**
Mr Luis Ángel Cordero Puentes **LABORATORIO BETA, S.A.**	Mr Juan Carlos Aguilera Rodríguez **FERRING, S.A.U.**	Mr Ignasi Biosca Reig **LABORATORIO REIG JOFRE, S.A.**	

2

Organisation

2.1 Governing Bodies

2.2 Executive Organisation

THE FARMAINDUSTRIA Director General is the head of the executive organisation, structured into functional departments.

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

Humberto Arnés
Director General

Javier Urzay
Sub-Director General

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

Pedro Luis Sánchez
Director of Studies

Emili Esteve
Technical Director

Iciar Sanz de Madrid
Director of International Affairs

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

Francisco J. Fernández
Director of Communications

3

Institutional Activity

Following the formation of the Executive Committee at the end of 2016, the year 2017 was characterised by the lack of **publication of new regulations**, resulting from the parliamentary minority of the party in power, but at the same time, by a **high entry into force of regulations** that were previously approved.

In this framework, and of special relevance for the pharmaceutical industry, it should be noted that the Collaboration Agreement between the Spanish Central Administration (Ministry of Finance and Public Administration and Ministry of Health, Social Services and Equality) and FARMAINDUSTRIA, signed on 29 December 2016, has remained in force in 2017. This Agreement affected public spending on **"non-generic branded medicines"** during the 12-month period between 1 January and 31 December 2017, which was renewed for 2018 in December last year.

It is important to remember that the aim of the Agreement is to limit the growth of public pharmaceutical spending on non-generic branded medicines, by linking its growth in Spain to changes in the GDP, so that the access of Spanish patients to the best innovative medicines is compatible with pharmaceutical industrial development in Spain.

The text of the Agreement states that:

"[...] if the total spending of the National Health System in the non-generic branded medicines section should exceed the reference rate for Gross Domestic Product growth in the medium term [...], but did not reach the actual GDP growth rate of the Spanish economy, the Monitoring Committee will establish alternatives to those compensatory or corrective measures which, not assuming an increase in the monetary amounts can have some economic content and can be of interest to the Spanish economy or for the National Health System; [...] if that expense were to exceed the actual growth rate of the GDP of the Spanish economy, the above measures will be supplemented by a monetary compensation in relation to the excess of growth above the actual GDP in the section relative to the industry according to the criteria established by the Monitoring Committee [...]".

Specifically for 2017, the medium-term GDP growth reference rate of the Spanish economy was set at +2.1%. However, according to advance information published by the INE, the actual GDP growth rate in Spain was +3.1% in 2017.

Data published by the Ministry of Finance and Public Administraton yield a **total spending growth** (including generics and biosimilars) of +2.8% in 2017 (+2.5% in retail pharmacies and +3.3% in hospitals).

At the time this Annual Report was published, no final figures are available on the change in 2017 in pharmaceutical spending subject to the Collaboration Agreement (the total but excluding generics and biosimilars), as the meeting of **Monitoring Committee of the Collaboration Agreement** for closure of 2017 has not yet been held. However, in view of the change in total spending (+2.8%), no growth of spending under the Agreement is expected to exceed the actual GDP growth (+3.1%).

In another area of activity, it should be noted that since September 2016 the company managing the **Spanish System for Verification of Medicinal Products** (SEVeM), comprised of FARMAINDUSTRIA , the Spanish Association of Generic Medicinal Products (AESEG), the General Council of Official Pharmaceutical Associations (CGCOF) and the National Federation of Wholesale Distributor Associations of Proprietary Medicinal Products and Parapharmaceutical Products (FEDIFAR) have a Board of Directors composed of a president (the Director General of FARMAINDUSTRIA), three vice-presidents (the Director Generals or presidents of AESEG, CGCOF and FEDIFAR) and seven board members (directors of the above associations and boards). The AEMPS also takes part in the Board of Directors meetings, where it also has system oversight functions.

SEVeM has been highly active in 2017 since it is necessary to act quickly to comply with the effective date of application of the Commission Delegated Regulation (EU) 2016/161, which regulates packaging safety features (single identifier and anti-tampering device), which is expected to be on 9 February 2019. This Regulation involves very complex changes and adaptations in the area of manufacture and traceability of medicinal products.

Within the field of unpatented medicine regulation, the ministerial ruling updating the reference groups and prices was published in the BOE of 29 November 2017, and entered into force for spending purposes in January 2018. In addition and in the same month, the MSSSI started the procedure for the modification of the Royal Decree 177/2014, of 21 March, regulating the **reference prices system and homogeneous groupings of medicinal products** in the National Health System, referred to in the following section of this Annual Report.

The regulations that have come into force in the period of activity set out in this Annual Report must include the new Law 9/2017, of 8 November on Public Sector Contracts, whereby the European Directives on this matter are transposed into the Spanish legal system, which came into force on 9 March 2018 and which introduces important novelties in the modalities of procurement procedures, award criteria (quality-price), promotion of competition or deburocratisation, among others.

In terms of the European Regulation on **personal data protection**, effective as of 25 May 2018, FARMAINDUSTRIA has been very active in its relationship with stakeholders to indicate the need for Spanish regulations to adequately reflect the importance of scientific research.

It is also important to mention that in Europe, the publication by the European Commission in January 2018 of a legislative proposal of the European Parliament and Council on **health technology assessment** (HTA), would implement, in its current terms, a joint assessment of the relative efficacy of medicinal products at a European level, the adoption of which, after a transitional period, would be mandatory for all EU countries.

However, the legislative process on this matter has only just gotten underway.

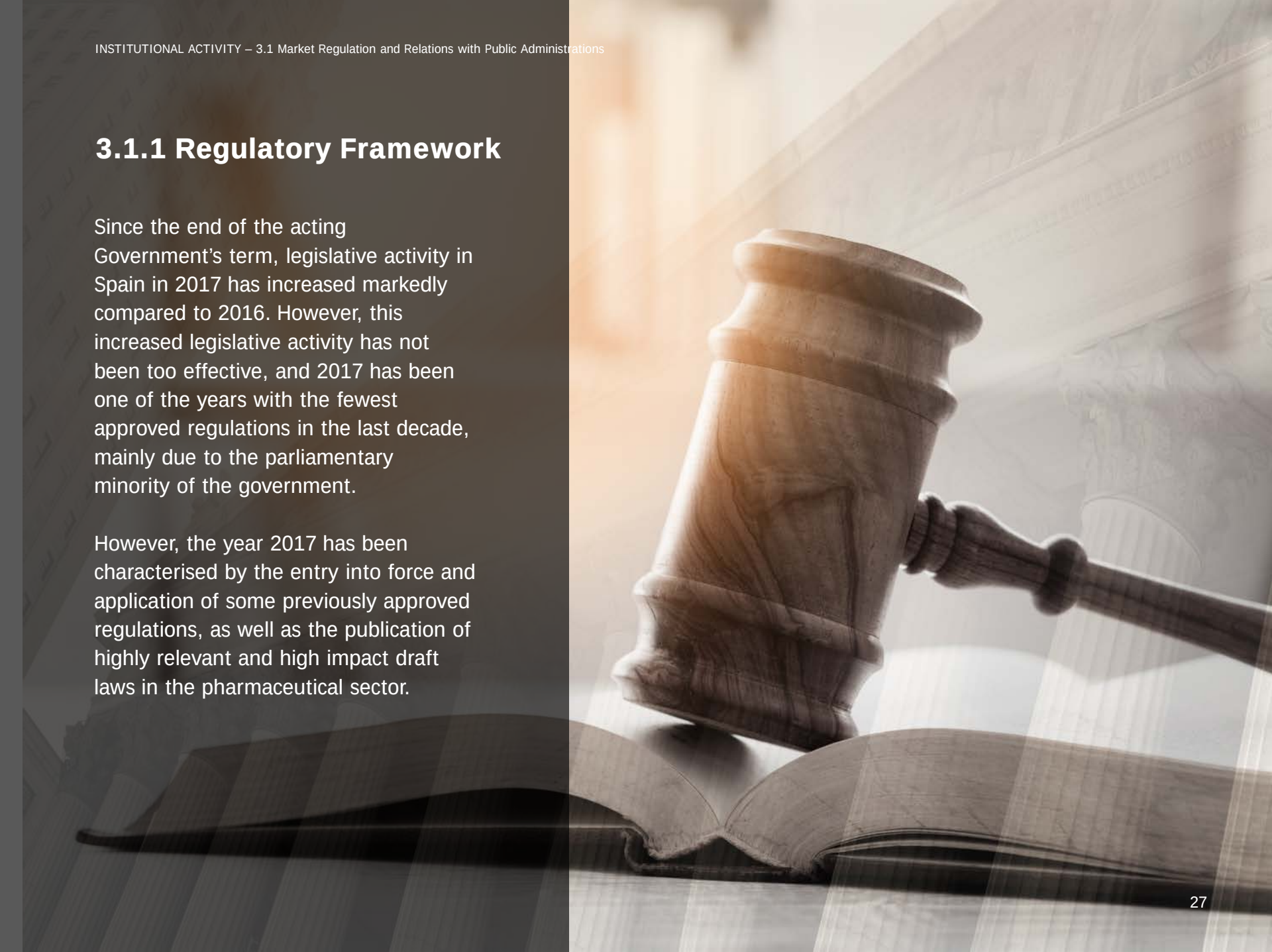
Finally, in hospitals it is important to note that the **Regional Liquidity Fund** (FLA) **payments**, as well as those performed through the ordinary cash flow of the autonomous regions, which are becoming increasingly important, in 2017 gave the **best financial year closure in the pharmaceutical industry** since records began in 1996, as the NHS's DSO (*Days Sales Outstanding*) was reduced to 81 days.

A detailed review of the main pieces of legislation and the elements of the most relevant regulation of the past year is given below.

3.1.1 Regulatory Framework

Since the end of the acting Government's term, legislative activity in Spain in 2017 has increased markedly compared to 2016. However, this increased legislative activity has not been too effective, and 2017 has been one of the years with the fewest approved regulations in the last decade, mainly due to the parliamentary minority of the government.

However, the year 2017 has been characterised by the entry into force and application of some previously approved regulations, as well as the publication of highly relevant and high impact draft laws in the pharmaceutical sector.



REFERENCE PRICE SYSTEM

On 29 November, Order SSI/1157/2017, of 28 November, was published in the Official State Gazette (BOE), leading to the **2017 Update of the Reference Price System for Medicines** in the National Health System, from which an error correction was subsequently published on 30 December (Order SSI/1312/2017, of 19 December), with no relevant changes except for calculations of some reference prices.

The aforementioned Order did not take into account the Supreme Court sentences, which upheld the contentious-administrative appeals filed by various companies against previous ministry orders (in 2014, 2015 and 2016) regarding the formation of reference groupings by the ATC5. In addition, the Order follows criteria that were not applied to previous Orders, such as the formation of groupings with parallel importation only, or groupings of a single medicine with two brands.

Since these changes could lead to a very negative precedent for the industry, an administrative appeal has been filed by FARMAINDUSTRIA against the Order, and its execution is pending.

With the above, in the month of January 2018 the Ministry of Health, Social Services and Equality (MSSSI) started the procedure for prior public consultation of the Draft Royal Decree amending Royal Decree 177/2014, of 21 March, regulating the reference price system and homogeneous groupings of medicinal products in the National Health System, and certain information systems in the field of **financing and prices of medicinal products and medical devices**. Some of the objectives of the regulation are consistent with proposals that FARMAINDUSTRIA has been transmitting to the MSSSI in recent years to resolve problems arising from the automatic application of the reference price formula, which does not take into account the specific cases of presentations that are useful for patients and for the NHS, but have no economic viability in the current situation.

As part of this public consultation, FARMAINDUSTRIA considers it important to acknowledge **incremental innovation in classical medicines** that are of interest to patients and the NHS, creating separate groupings or costs/treatment/day for medicines with the same active ingredient but different delivery device, pharmaceutical form, specific administration route or new significant indications. It has also been requested to clarify the definition of groupings, not including in the same grouping, different active substances that share the same ATC5 code or to create them when there is only a different brand from the same company that manufactures the same active substance or a parallel import.

In addition, two other considerations have been submitted to the MSSSI:

1. **To recognise investment required** to incorporate the new safety features of medicinal products (single identifier and anti-tampering device) and their impact, especially on low-price products, by changing the threshold of €1.60 that will also be applied to presentations that now have a lower price.

2. **To allow price changes to not involve changes** in the National Code on medicinal products dispensed at retail pharmacies, in order to facilitate work for administrations and supply chain agents. At the date of this Annual Report, the MSSSI is waiting to initiate the hearing process for the aforementioned regulation.

DATA PROTECTION

In the area of data protection, the imminent first application, as of 25 May 2018, of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the **protection of natural persons with regard to the processing of personal data** and the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

It is also important to mention the publication on 24 November of the project of the Draft Organic Law on personal data protection. The text submitted to the Congress, which will repeal Organic Law 15/1999, complements the regulations provided by Regulation (EU) 2016/679 in the exercise of the power granted therein to the Member States to qualify or restrict some aspects foreseen therein. FARMAINDUSTRIA , as it did in the hearing proceedings of the draft proposal, has indicated the importance of **ensuring**:

1. **Recognition of scientific and biomedical research** as an activity of public interest that legitimates data processing without consent, but with ethical, technical and organisational guarantees for patients.

2. **Regulation of second investigational uses** with the adoption of adequate guarantees to safeguard the rights of patients, so that Spain will not be under inferior conditions in this regard by more restrictive regulations than those adopted by other EU States.

With regard to the above, it should be noted that the Spanish Data Protection Agency (AEPD) has published a report on the impact that could occur in the field of biomedical research under the General Data Protection Regulation (RGPD), as well as the approval of the new Organic Law on Data Protection.

The Report confirms that the RGPD and the Draft Organic Law on Data Protection not only maintain unchanged the regime contained in Law 14/2007, of 3 July, on Biomedical Research and Royal Decree 1090/2015, of 4 December, **regulating clinical trials with medicinal products**, the Medicinal Product Research Ethics Committees and the Spanish Clinical Studies Registry, but allow for a more flexible interpretation of the scope that may be given to the consent given in accordance with these regulations.

It is important to highlight the intense activity carried out by FARMAINDUSTRIA both at the national and European level to ensure that the future Organic Law on Data Protection complies with the **needs of the industry.**

Finally, it is important to note that work has begun on **updating of the Standard Code on Personal Data Protection** in the area of clinical research and pharmacovigilance of FARMAINDUSTRIA, to adapt it to the new regulation (Code of Conduct).

PUBLIC CONTRACTING

On 9 March, Law 9/2017, of 8 November, on Public Sector Contracts entered into force, which transposes European Directives on this matter to Spanish legal regulations. The most important developments in the Law include:

1. Greater transparency.
2. Establishing new anti-corruption measures.
3. Further guidance on quality aspects such as awards based on the principle of best value for money.
4. Enhanced tender access by SMEs.
5. The introduction of new procedures: simplified open procedure and partnership for innovation.

Within the scope of the medicine supply contract, we can highlight the following news:

- Reduced **contract amount** to less than €15,000 per year and company, and quarterly publication is required, including the price.
- Modified **regulation of negotiated procedures**.
- Multiple award criteria focused on **better value for money**, with quantitative and qualitative criteria.
- It is established that the tendering party may designate the **confidential content** of its bid (commercial, technical secrets, etc.).
- A new simplified open procedure is introduced that replaces the negotiated procedure without public notice due to the amount.

The requirement for batch formation as a **“functional unit”** disappears and batch division is established as a general rule.

In this area, we should also mention the recent publication of Royal Decree 94/2018, of 2 March, creating the Interministerial Commission for the incorporation of social criteria into public procurement.

LATE PAYMENT PROVISIONS

Late payment of debts acquired by public administrations is a subject followed particularly closely at both national and European level, reflected in a wide variety of regulations.

First of all, mention should be made of Royal Decree 1040/2017, of 22 December, amending Royal Decree 635/2014, of 25 July, by which the **methodology for calculating the average payment period** to suppliers of the public administrations and the conditions and procedure for retaining resources of the financing arrangements, laid down in Organic Law 2/2012, of 27 April, on Budgetary Stability and Financial Sustainability, and secondly, the Resolution of 21 December 2017 of the General Secretariat of the Treasury and Financial Policy, publishing the legal interest rate on arrears applicable to trade operations during the first half of 2018.

In addition, Order PRA/360/2017, of 21 April, was published, publishing the Agreement of the Government Delegate Commission for Economic Affairs dated 2 March 2017 on additional conditions to be met by the autonomous regions that joined the Financing Fund for Regions, 2017 Regional Liquidity Fund compartment, as well as various resolutions of the Directorate General of Treasury related to the **Financing Fund for Regions**.

Finally, regarding **e-invoicing,** these include:

1. the Resolution of 24 August 2017 of the Undersecretariat, publishing the Resolution of 25 July 2017 of the Secretariat of State for Information Society and Digital Agenda, and of the Secretariats of State for Finance and Budgets and Expenditures, publishing a new version, 3.2.2, of the electronic invoice format **"e-invoice".**
2. Circular 1/2018, of 23 January, from the General Intervention Board of the State Administration, on the effects arising from the entry into force of Act 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations on the regulations laid down in Act 25/2013, of 27 December, on the promotion of the electronic invoice and the creation of the **accounting record of invoices in the public sector**, relating to the use of the electronic invoice in the public sector.

PATENTS AND BUSINESS SECRETS

Regarding industrial property, coinciding with the entry into force on 1 April of Law 24/2015, of 24 July, on Patents, Royal Decree 316/2017, of 31 March, approving the Regulation for the implementation of the aforementioned Law, was published. The Regulation contains the necessary development to achieve the objectives of this Law, in particular:

1. **To establish** a system for awarding strong patents.
2. **To generate** legal safety by bringing together, into two regulations, the previous legal dispersion on the subject.
3. **To improve** regulatory clarity.
4. **To make more flexible** and speed up procedures.
5. **To adapt** and modernise aspects such as professional representation before the Spanish Patents and Trademarks Office.
6. **To promote** innovation and support for SMEs and entrepreneurship.

Order ETU/320/2018, of 26 March, establishing the requirements and conditions for translating European patents and international patent applications, for which FARMAINDUSTRIA had the opportunity, in the process of public information, to transmit its observations so that these requirements do not involve any additional administrative costs or burdens for the companies. The requirements finally established in the aforementioned Order revolve around the language and technical knowledge to carry out this translation.

On the other hand, in February 2018, the Ministry of Justice initiated the procedure for public information of the Preliminary Draft of the Law on Business Secrets, which transposes into Spanish legal regulations Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016.

This **Preliminary Draft Law** defines business secrecy and regulates procedural aspects that allow business owners secrecy to be offered effective tools for the legal guardianship of their legal position. FARMAINDUSTRIA has submitted its allegations via the CEOE, in particular those relating to the **need to preserve confidentiality** that other regulations may give to any information concerning the company, not permitting its disclosure by virtue of the **Transparency Act**.

The General Council of the Judicial Power has stated in a recently issued report that the transposition of the Directive could take place without the need for a new Law (via the Civil Procedure Law, the Unfair Competition Law). It also considers that the definition of *secret business* is imprecise and that the criterion for determining when information should be considered secret business *"it should revolve around the existence of a legitimate interest* (of its owner) *to keep it confidential and a legitimate expectation that such confidentiality is maintained".* The report adds that such a legitimate interest, in line with the provisions of the Supreme Court when interpreting Article 13.1 of the Unfair Competition Law, should be based on the competitive value of the information, i.e. the advantage given to its owner over competitors.

In turn, the National Commission for Markets and Competition has also issued a report in this Preliminary Draft, again emphasizing the need for a **greater precision of the concept of secret business** and for a protective regulation of complainant's communications within the scope of the law, among other matters.

OBSERVATIONAL STUDIES

In September, the **prior public consultation of the Draft Royal Decree on Observational Studies** with Medicinal Products was initiated. This regulation seeks to update the previously published guidelines to incorporate and develop the new aspects of the new legislation (RD 577/2013, of 26 July, and Royal Decree 1090/2015, of 4 December), to resolve the problems detected due to the complexity of the current procedure, to define the scope of scientific advice on observational research with medicinal products and to establish the actions of the different parties involved during it, in order to promote the conduct of such studies, necessary to improve clinical practice.

As part of this prior public consultation, FARMAINDUSTRIA has submitted its proposals to:

- **Give validity to the prior opinion** of a CREC that is binding throughout the country.
- **Have a list** of accredited CRECs.
- **Establish a unified approval process** for autonomous regions, where one of them is the reference.

NURSING PRESCRIPTION

In February 2018, the hearing procedure of the Royal Decree was started, amending Royal Decree 954/2015, of 23 October, regulating the indication, use and authorisation of **dispensing of medicinal products and medical devices for human use by nurses**. According to the statement of reasons, the difficulties arising from the application of the aforementioned Royal Decree by the different interpretations regarding the competence areas of the professions concerned require consensus solutions between the medical profession and nurse representatives, who work collaboratively. Thus, the indication, use and authorization to dispense medicines subject to medical prescription by nurses will be conditioned on the terms established by each protocol and clinical and care practice guideline, both in the general care setting and in the area of specialized care, approved by the Standing Committee of Pharmacy of the Inter-Territorial Council of the NHS, validated by the Directorate General of Public Health, Quality and Innovation of the MSSSI.

SERIALISATION

In July 2017 the AEMPS posted the Information Note on the **Implementation of safety features in marketing authorisations for medicinal products for human use** on its website, establishing the recommendations of the Agency for the pharmaceutical companies to start serialisation of the medicinal products subject to Delegated Regulation 2016/161 of 2 October 2015. The Note has taken into account most requests from FARMAINDUSTRIA. It is worth noting the following:

1. **Fee payment exemption** for the incorporation of safety features (no other changes), which will be processed as notifications rather than as registration variations.

2. **Acceptance of pre-serialization** so that manufacturers can use cartons on which the single identifier has already been printed from an audited third party and with which a written contract describing the respective responsibilities is used.

3. **That medicines** that before 9 February 2019 (date of application of safety features according to the Delegated Regulation) are released for sale or distribution without safety features, can **be marketed**, distributed and dispensed until their expiration date. Regarding the continuation of the National Code, the Agency has decided to maintain it after checking it with the Directorate General of Basic Services and Pharmacy. The National Code will be printed at the upper right corner and must also be coded in the Datamatrix for automatic capture.

REGULATION OF PHARMACEUTICAL COMPANIES

In early 2018, the AEMPS published the prior public consultation for the Draft Royal Decree amending Royal Decree 824/2010, of 25 June, regulating pharmaceutical companies, manufacturers of active substances for pharmaceutical use, and foreign trade in medicines and investigational medicinal products. The regulation has two specific objectives, firstly **to update principles and guidelines** of good manufacturing practice of medicinal products for human use according to the wording included in Directive (EU) 2017/1572 and to modify the references to the manufacture of investigational medicinal products for human use where applicable, and secondly to incorporate into national regulations the specification of those aspects that the Delegated Regulation (EU) 2016/161, of 2 October 2015, leaves up to the Member States, among others:

1. Extension of the scope of safety features to other medicinal products not required to bring them into service for pharmacovigilance or safety purposes
2. Additional verifications of safety features by distribution entities.
3. Verifications of security features in the event of direct sale to healthcare professionals.
4. The national reporting procedure for tampering or suspected falsification.
5. The establishment of the repository in national territory and the obligations of the non-profit legal entity that creates and manages the national repository.
6. The form of contribution to the management of the national repository by national competent authorities.
7. Access to and supervision of the repository information by national competent authorities.

The most relevant for pharmaceutical companies is precisely this latter objective, which develops certain aspects of the verification system so that all involved agents can adequately comply with their obligations on 9 February 2019.

Through the Spanish System for Verification of Medicinal Products (SEVeM) and, in collaboration with the other supply chain agents, FARMAINDUSTRIA has transmitted to the MSSSI some regulatory proposals considered necessary **to provide legal safety and efficacy to the management entity of the SEVeM** and to the agents involved, including the procedures for implementing the provisions of Article 94.7 of the Consolidated Text of the Law on Guarantees.

REGULATORY COMPLIANCE AND COMPLIANCE PROGRAMME

During 2017 FARMAINDUSTRIA has been working on the development of a **Compliance Programme**.

In the framework of the Programme, the preparation of a **Code of Ethics** that is in its final phase of internal processing and subsequent approval by the governing bodies of the Association, and, on the other hand, the writing of a series of protocols collecting the measures and procedures already existing in FARMAINDUSTRIA, as well as the new measures and procedures that have been deemed necessary, in order **to prevent inappropriate behaviours** or the commission of offences that could generate criminal liability for the Association.

The Compliance Programme will consist of a manual with a general part and a special part, as well as an Ethics Code and the corresponding procedures and protocols, including the internal communication channel and the Compliance Committee Statute, which, after approval, will be disseminated and communicated to all its recipients.

3.1.2 The Regions

Throughout 2017 FARMAINDUSTRIA has continued institutional activity with the regional health authorities, scientific societies, professional organisations and institutions in order to reinforce the positioning of our sector as a strategic ally and collaborator in the healthcare system in improving the health levels of the population. The innovative pharmaceutical industry is committed to equitable patient access to pharmaceutical innovation within a sustainable public health system.

At the same time, with the collaboration of the working groups of the Regions and Hospital Market of the Association, close monitoring has continued of the different regional initiatives related to health policy and pharmaceutical service provision, informing companies of the most relevant aspects.

FARMAINDUSTRIA FORUMS-REGIONS

As we already mentioned in the 2016 Annual Report, on 31 March 2017, the **20TH FARMAINDUSTRIA Forum-Regions**, involving ten communities and the INGESA, was held in Melilla. This time the issues discussed were twofold: the **Spanish System for Verification of Medicinal Products** (SEVeM) and the chances of improvement offered by the **measurement of health outcomes**, for both economic efficiency and access to innovation.

At the time of writing this Annual Report, the 21st Forum has just been held in Murcia, attended by ten communities, and the INGESA. Three main topics were discussed on this occasion:

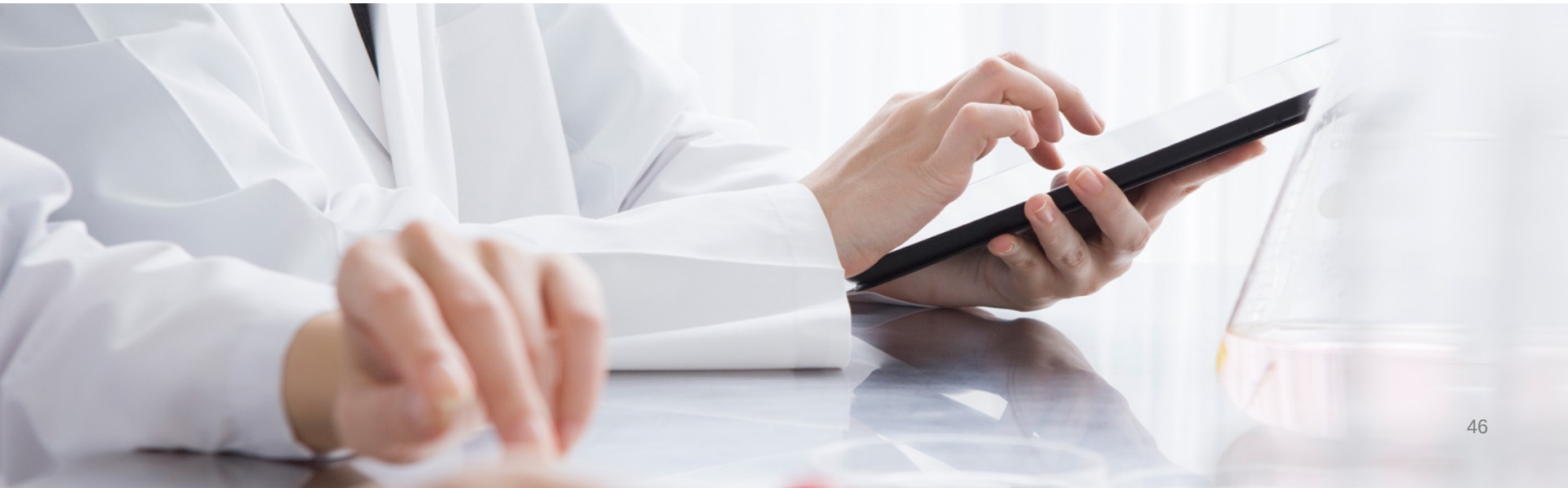
1. **The Draft Data Protection Law** and its implications in the healthcare and research setting.
2. **The Law on Public Sector Contracts** and the purchase of medicines for hospital dispensing.
3. **The Code of Good Practice** of the Pharmaceutical Industry and the transparency initiative.

REGULATORY INITIATIVES IN THE REGIONAL FIELD

Below is a review of the most relevant regional policies, regulations and initiatives of the last year with impact on the medicine and pharmaceutical service provision sector, as well as the actions undertaken by FARMAINDUSTRIA in the defence of the legitimate interests of its members.

E-health projects in the NHS: Electronic prescription and interoperable clinical records. Status in the Regions.

As indicated in previous annual reports, the **development of health information and communication systems** has enabled useful applications such as electronic prescription and medical records. However, these systems were diverging into different regional applications, limiting the operability of the National Health System. This unequal development led to the **need to move forward to interoperable systems across the NHS**.

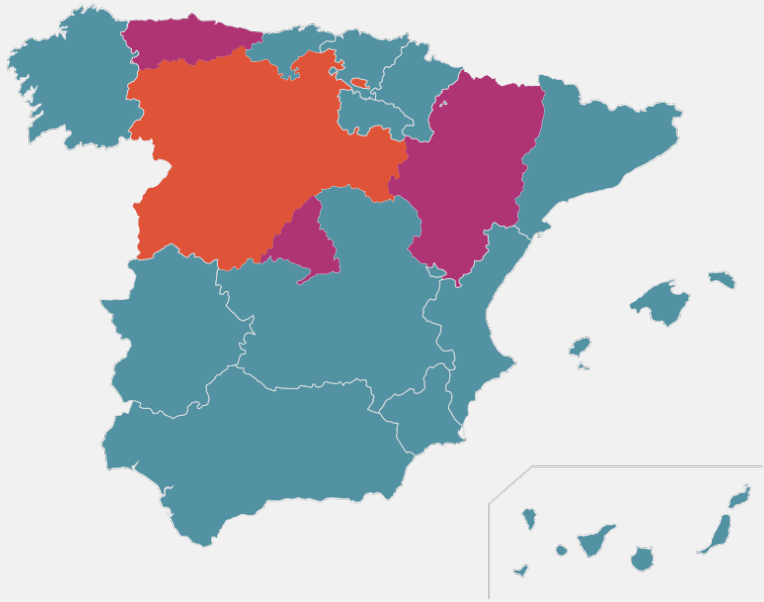


Electronic Prescription

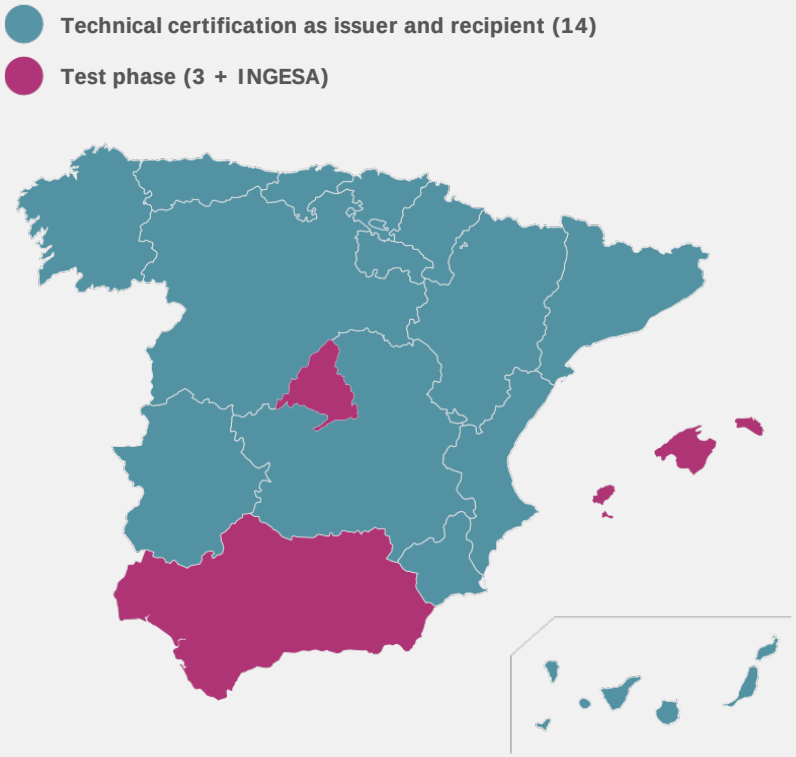
At the end of 2017, the electronic prescription was fully implemented in all care levels in all Regions, except in Madrid, Asturias, and Aragon, where it has not yet been implemented in hospitals, and in Castile-Leon, where implementation in hospitals is only partial. The percentage of prescriptions dispensed electronically in the NHS by the end of 2017 was over 90%.

STATUS OF ELECTRONIC PRESCRIPTION BY REGION

- EP implemented in all healthcare centres, clinics, hospitals and retail pharmacies.
- EP implemented in all healthcare centres, clinics, hospitals and retail pharmacies, but NOT in hospitals.
- EP implemented in all healthcare centres, clinics, hospitals and retail pharmacies. Partially implemented in HOSPITALS (7.14%)



STATUS OF INTEROPERABILITY PROJECT FOR ELECTRONIC PRESCRIPTION



Issuer: Generates electronic prescriptions that can be dispensed in another region.

Recipient: Receives and performs dispensing of electronic prescriptions generated to interoperate with another region.

The MSSSI, with the collaboration of the Regions, started the **electronic prescription interoperability project** and there are currently 14 Regions with technical certification by the MSSSI of both the issuer (issues electronic prescriptions, which can be dispensed in another region) and the receiver (receives and performs dispensing of electronic prescriptions generated in another region). The Regions of Andalusia, the Balearic Islands and Madrid, as well as the ENGESA that are currently in the testing phase, and Catalonia, which, though certified, is still inoperative, remain to be included in this system.

National Health System Digital Medical Records.

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

By the end of 2017, all regional health services, with the exception of Catalonia, have managed to become information issuers and recipients, covering almost 78% of the population holding an individual health card.

CatSalut Pharmacotherapeutic Harmonisation Program

In May 2017, Instruction 05/2017 **CatSalut Pharmacotherapeutics Harmonisation Programme** became effective, which simplifies the advisory boards and committees that made up the previous program and creates the Advisory Board for primary and community care and specialised care medicines (CAMAPCE). It also extends the harmonisation of medical prescriptions and recommendations for use to primary care and specialised care.

Within the framework of this programme, CatSalut has proposed to modify the categories of the new medicinal products being evaluated, replacing the names used to date, which were agreed by the Joint Evaluation Committee on New Medicinal Products.

The **proposal for new categories** was sent to FARMAINDUSTRIA by CatSalut for comments. After discussion by various working groups, the following comments were submitted to CatSalut for consideration:

1. To take into account the Therapeutic Positioning Report (IPT), of the medicine being evaluated and all available evidence on the medicine.
2. To consider the context in which the prescription is made and the clinical, social and personal circumstances of the patient.
3. The manufacturers holding the marketing authorisation of the medicinal product may submit the allegations they consider necessary during evaluation and request re-evaluations if new evidence becomes available.
4. The system responds flexibly to changes that may occur as a result of state regulations (review of reference prices; voluntary price decreases; approval of new indications, etc.).
5. To modify the name of Category D medicinal products “with no added therapeutic value”, or at least when public funding is indicated.

The response received from CatSalut states that the standard operating procedures of the Pharmacotherapeutic Harmonization Programme (PHF) for categorisation of medicines establishes that **the process evaluates all available evidence on the medicine**, the context in which the medicinal product is prescribed, and refer to, as a relevant and highly useful document to be considered, the IPT of the medicinal product evaluated, also highlighting their active participation in its preparation.

They also confirm the possibility that the marketing holder submits allegations during the evaluation or requests a re-evaluation, if new relevant clinical evidence becomes available.

Furthermore, they indicate that the PHF evaluates medicinal products included in the pharmaceutical service provision of the NHS and that the classification of medicinal products assigned does not involve limitations on their prescription and dispensing in the Catsalut area, or differences in terms of access conditions established by the MSSSI according to legal regulations.

Finally, they state that the new categories will apply to new products evaluated from April 2018 and that only the medicinal products included in the list of medicinal products with adequate therapeutic alternatives (MATMA) of the 2018 CatSalut Pharmaceutical Provision Quality Index (IQF) have been planned to be recategorised.

Tenders for medicines dispensed in retail pharmacies: Andalusia

On 26 May 2017, the Andalusian Health Service (SAS) announced the **11th tender for medicines in which tenders for 468 presentations were offered** (208 active ingredients), of which 181 presentations (78 active ingredients) were awarded by the Resolution of 18 July 2017.

At the time of publication of this Annual Report, the Resolution of 27 March 2018 has just been published, announcing the 12th tender for medicines. In this call, tenders were offered for 487 presentations corresponding to 212 active substances, of which 148 presentations were awarded in the eighth tender and 278 were included in the call for the eleventh tender but were not awarded. Also included are 61 new presentations of newly created homogeneous groupings.

Below is the list of calls, active substances tendered, and awards made in the different calls for the selection of medicines made by the Andalusian Government to date.

Medicine tenders. Calls for tenders and awards

	CALL			AWARD		
	Resolution Date	Active Ingredients Tendered	Bidding Companies	Date of Resolution	Active Substances Awarded	Companies 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	26.05.17	208	29	18/07/2017	78	26
12	27/03/2018	212	NA	NA	NA	NA

Draft Law on Guarantees and Sustainability of the Public Health System of Andalusia

This Draft Law was published on 3 January 2017 and was processed as a preliminary draft in the second half of 2015. The text sent to Parliament contains **negative provisions for the sector in terms of prescription by active substance**, auctions of medicines or the most efficient therapeutic alternatives, as well as the obligation of the laboratories to report the monetary or in-kind contributions (financially valued) made to hospitals, departments and professionals of the public health system of Andalusia their participation in clinical trials, training courses and research projects "under the terms and conditions established by the competent Health Department". Failure to comply with this information obligation would be considered a serious health breach.

At the time of writing this Annual Report, the processing of this law in the Parliament of Andalusia continues.

Preliminary Draft of the Pharmacy Law of the Community of Madrid

In July 2017, the Community of Madrid opened the procedure for prior public consultation for this initiative, which was submitted to public hearing and information on the transparency portal of this region in January 2018. The text, in addition to addressing different aspects related to pharmacies, regulates the **functions and competences of pharmacists** in primary care and hospital care, including the competence to review and reconcile medication prescribed by physicians.

In order to clarify the scope of these functions and, where applicable, adapt them to the provisions of Royal Legislative Decree 1/2015 approving the consolidated text of the Law on Guarantees, which gives these healthcare professionals a **coordination task** in pharmacotherapy, a proposal for amendment that was sent to the Department of Health by FARMAINDUSTRIA has been taken into consideration in the draft of the currently available Preliminary Draft of the Law.

Law 8/2018, of 20 April, amending Law 10/2014, of 29 December, of the Generalitat, on Health in the Valencia Region

In April 2018, this Law was approved, amending the Law 10/2014 on Health. Its main novelties are related to the **universality of healthcare**, guarantee of equity and non-discrimination, pharmacotherapeutic equity, mental health care, promotion of biomedical and health research, promotion of donation and transplantation, transparency and reporting of accounts, food safety, environmental health or occupational health.

During the processing of this initiative, FARMAINDUSTRIA submitted allegations to the projections on medicinal products contained in the draft, in order to reinforce its linkage to the Law on guarantees and rational use of medicinal products and medical devices.

Network for Rational Use of Medicinal Products and Medical Devices of Aragon

On 8 August 2017, the order of the Health Department of the Regional Government of Aragon was published, creating the **Network for Rational Use of Medicinal Products and Medical Devices** of this region, as an advisory body composed of structures of the Aragon health system, whose objective is to provide healthcare professionals with protocols, pharmacotherapeutic guidelines, consensus documents and, in general, tools to aid prescription.

A letter was sent to the Health Director by FARMAINDUSTRIA requesting confirmation that the actions of the Network did not limit access of the citizens of that region to the pharmaceutical provision of the NHS.

NATIONAL HEALTH SYSTEM PURCHASING PLATFORM

Based on Additional Provision 4 of Royal Decree-Law 16/2012, after agreement of the Inter-Territorial Council of the National Health System, the Health Management Institute (INGESA) has called eight centralized purchasing tenders, in which various regions are taking part. For exclusive medicinal products, the procedure adopted by INGESA was the **negotiated procedure without public notice** (Art. 170.d of the Consolidated Text of the Law on Public Sector Contracts), while in non-exclusive medicinal products, an open procedure by ordinary processing and subject to harmonised regulation was adopted (Articles 196 to 198 of the Consolidated Text of the Law on Public Sector Contracts).

The table below summarises the basic aspects of the centralised purchasing tenders for the NHS called by INGESA to date, as well as the regions and other administrative bodies that have joined these procedures.

MEDICINES OUT FOR TENDER	PROCEDURE	CONTRACTING ADMINISTRATIONS	CONTENT OF BATCHES	NO. OF BATCHES OUT FOR TENDER	NO.OF BATCHES AWARDED
CLOTTING FACTOR VIII	Negotiated without public notice (Art. 170.d of the Consolidated Text of Law on Public Sector Contracts)	10 Regions (Asturias, Balearic Islands, Cantabria, Castile-La Mancha, Castile-León, Extremadura, Galicia, Murcia, Navarre and La Rioja) and INGESA	Brand	4	4
EPOETINS	Negotiated without public notice (Art. 170.d of the Consolidated Text of Law on Public Sector Contracts)	5 Regions (Asturias, Cantabria, Castile-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 Law on Public Sector Contracts)	10 Regions (Aragón, Asturias, Cantabria, Castile-La Mancha, Castile-León, Extremadura, Madrid, Murcia, La Rioja and Valencia Region), 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 Law on Public Sector Contracts)	11 Regions (Aragón, Asturias, Balearic Islands, Castile-La Mancha, Cantabria, Extremadura, Galicia, Madrid, Murcia, Navarre and La Rioja), INGESA, Ministry of the Interior and Ministry of Defence	Active substance Includes two biosimilars, which share batch with reference biologic	20	20
CLOTTING FACTOR VIII	Negotiated without public notice (Art. 170.d of the Consolidated Text Act of Public Sector Contracts	9 Regions (Asturias, Balearic Islands, Cantabria, Castile-La Mancha, Castile-León, Extremadura, Murcia, Navarre, La Rioja) and INGESA	Brand	4	4
EPOETINS	Negotiated without public notice (Art. 170.d of the Consolidated Text of Law on Public Sector Contracts)	7 ACs (Asturias, Balearic Islands, Cantabria, Castile-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 Law on Public Sector Contracts)	11 Regions (Aragón, Asturias, Balearic Islands, Cantabria, Castile-La Mancha, Castile-León, Extremadura, Madrid, Murcia, La Rioja, Valencia Region), INGESA, Ministry of Defence and Prison Institutions	Active substance	9	9
ANTIRETROVIRALS	Negotiated without public notice (Art. 170.d of the Consolidated Text of Law on Public Sector Contracts)	10 Regions (Aragón, Asturias, Balearic Islands, Cantabria, Castile-La Mancha, Castile-León, Extremadura, Madrid, Murcia, La Rioja), INGESA, Ministry of Defence and Ministry of the Interior	Active substance	26	12

The 2016 Annual Report informed that INGESA was preparing a new **Framework Agreement on Exclusive Oncological Medicinal Products** and for macular degeneration, divided into batches by active substance and negotiated procedures without public notice.

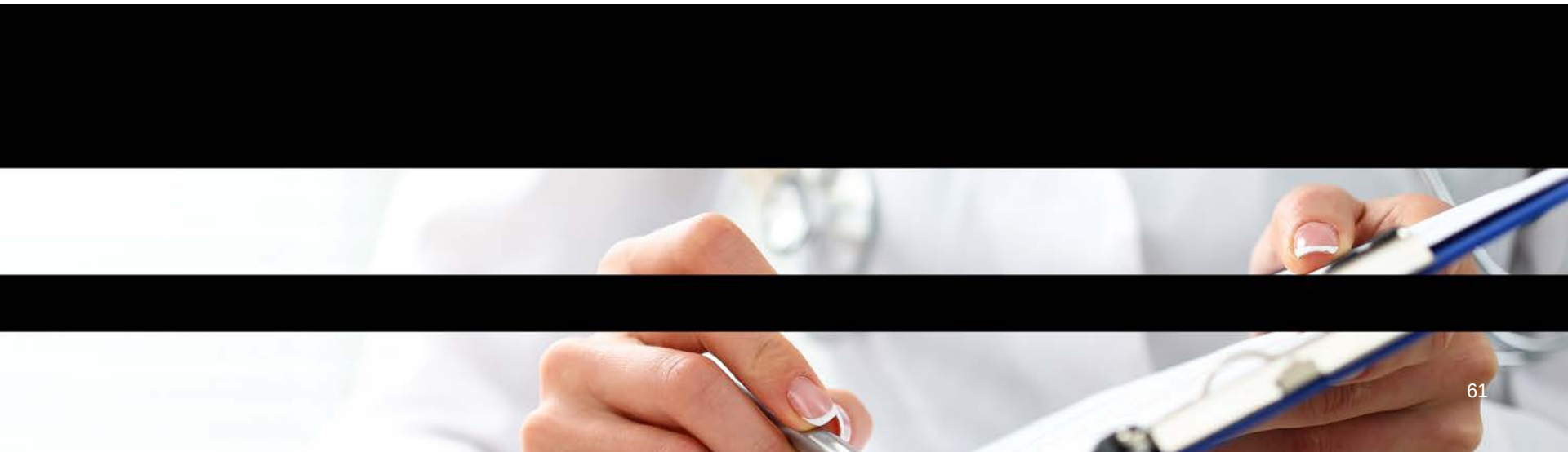
At the time of writing this Annual Report, INGESA continues to work on this new centralised tender, adapted to the new provisions contained in Law 9/2017, of 8 November, on Public Sector Contracts, by which European Parliament and Council Directives 2014/23/EU and 2014/24/EU, of 26 February 2014, are transposed into Spanish legal regulations. As discussed in other sections of this Annual Report, this Law came into force on 9 March 2018 and replaces the Consolidated Text of the Law on Public Sector Contracts and **introduces important novelties** in terms of purchasing procedure modalities, process transparency, batch splitting of contracts, award criteria (value for money), promotion of competition or deburocratisation, among others.

TREATMENT ADHERENCE PLAN (RESPONSIBLE USE OF MEDICINES)

After completion of the Treatment Adherence Plan, driven by FARMAINDUSTRIA and officially submitted in Barcelona in November 2016, the MSSSI still needs to raise this initiative to the Inter-Territorial Council of the National Health System for its analysis, consideration and, where applicable, implementation, with the modifications and improvements that may be agreed.

3.1.3 Advisory and Guidance Committees

Spanish legislation includes the existence of certain committees for the MSSSI to know the position of the different social and healthcare agents in a framework of **increased participation and transparency**. There are also other committees that have not required a legal provision for their establishment, but are convened regularly. FARMAINDUSTRIA is invited to participate in these Committees on behalf of the pharmaceutical industry, the most relevant being those mentioned below.



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

Presided by the Secretary General of Health and Consumer Affairs, this Committee is composed of **representatives of the different administrations** (general, regional and local), trade unions and business organisations, including FARMAINDUSTRIA, which holds the vice-presidency for business organisations.

The Committee held a meeting in May 2017 and discussed topics of special interest for the functioning of the NHS, some of which had direct impact on the area of medicines.

The update of the Strategic Plan for the Management of Hepatitis C in the NHS, focusing on five areas, should be noted:

1. To extend treatment, always based on medical judgement, to all fibrosis grades from F0 to F4.
2. To incorporate new funded medicines.
3. To update treatment recommendations.
4. To add a new annex to the Plan on the paediatric population.
5. To extend the Plan for three more years, until 2020.

Another issue related to medicinal products was the submission to the Committee of the annual report on the current Antimicrobial Resistance Plan (2014-2018). This Plan focuses on six lines of work: surveillance, control, prevention, research, education and communication and information.

The importance of finding incentives to promote R&D of new antibiotics was transmitted by FARMAINDUSTRIA to the Committee, as the current system does not promote their entry.

AEMPS COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE

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

The main mission of the CMH is **to ensure the efficiency and transparency of medicinal product authorisation procedures**, to provide necessary but non-binding information on the procedures for authorisation, substantial amendment, suspension or revocation of medicinal products for human use and, also, at the request of the Director of the Agency, to issue reports on the procedures related to medicinal products for human use.

The Committee has 11 ordinary meetings per year, in which the assessment reports on medicinal products processed through a centralised procedure are presented and discussed, in which Spain is a 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 in the Committee's agenda. The Committee is also informed of the Therapeutic Positioning Reports and assessment reports submitted by external experts to the Agency.

3.1.4 Collective Bargaining Agreement

With regard to the **18th Collective Bargaining Agreement for the Chemical Industry** (current agreement), no salary review was conducted for the year 2017, as certified in the Minutes of the Negotiating Committee of the Agreement of 23 January 2018.

On 14 December 2017 within the **Business-Trade Union Discussion Forum of the Spanish Chemical Industry,** the Negotiating Commission of the 19th Collective Bargaining Agreement for the Chemical Industry was established.

Negotiation is structured into **four blocks** which has been developed during the first quarter of 2018, specifically the following:

Block 1: Positive Action, Equality and Licenses
Block 2: Occupational Health, the Environment and Union Rights
Block 3: Training, Employment, Professional Classification, Functional and Geographical Mobility
Block 4: Working hours and Salaries

They are scheduled for upcoming plenary meetings and are expected to be approved during the 2018 fiscal year.

3

Institutional Activity

SOCIAL COMMUNICATION

During 2017 FARMAINDUSTRIA continued to work on the development of the Communication Plan approved the previous year, which has as a priority objective the **dissemination of information content** on the value that innovative medicines bring to society, both in terms of health and in terms of the sustainability of the healthcare system and the quality of care, all without forgetting the socioeconomic dimension of the pharmaceutical industry as the main driver of industrial R&D in Spain.

In accordance with this overall objective, both the volume of published contents, seeking the highest quality in the information, and the types of support used for its dissemination were markedly increased, making a special effort in the digital area and social networks, where profiles were opened in new networks and significant advances were achieved in others where the presence of FARMAINDUSTRIA was already established.

The information published throughout the year showed its firm commitment to biomedical R&D, its commitment to society through the generation of quality qualified employment, its status as an economic driver for the production system of the country, its transparency system development or its commitment to the sustainability of the National Health System.

THE MEDIA AND EVENTS

In the area of media in 2017, FARMAINDUSTRIA turned its efforts to the **generation of new content**, both its own and in collaboration with different media, in order to deliver the key industry messages to society. In this regard, the main objective was to foster the dissemination of media reports emphasizing the **real importance of innovator medicines**, both for the health of individuals and the quality of healthcare delivery and for the sustainability of the National Health System. To do so, FARMAINDUSTRIA has worked with all types of media (paper and digital press, television and radio), scopes (national, regional, local) and specialties (general, economic, healthcare and sectoral).

FARMAINDUSTRIA disseminated a total of 131 news releases in 2017, of which 33 were official press releases and 98 website news items (also collected by the media in the vast majority of cases), which represents a significant increase in activity from the previous year, when 50 news releases were made public (34 press releases and 16 website news items). The information notes have made it possible to raise awareness of the positioning of the pharmaceutical industry on various issues, to account for the participation of the Association in different forums and to disseminate information content linked to the value of innovative medicines for society, among other aspects.

At the same time, FARMAINDUSTRIA launched a new line of opening information windows on the websites of different media in order to **provide users interested in issues related to health and medicines** access to the information spaces on the Association's website itself, and new experiences of collaboration with social networking media were started.

Likewise, part of the communication work consisted of promoting the presence of HEADS OF FARMAINDUSTRIA in the media to explain industry positioning. In this regard, different media (both national and regional, general or specialized) published **10 editorials or opinion articles** from different Farmaindustria spokespersons. Interviews by representatives of the Association were also conducted and arranged in a variety of media, including several television channels. Furthermore, representatives of the Association, including its president and its Director General, participated in debates and discussions between different entities in the healthcare, economic and social fields throughout the year.

On the other hand, in 2017 the advertising creativity firm that has been used in recent years was replaced by a new one, using infographics and with clearly informative content, which includes the main data of the sector and reflects the reality of the pharmaceutical industry located in Spain.

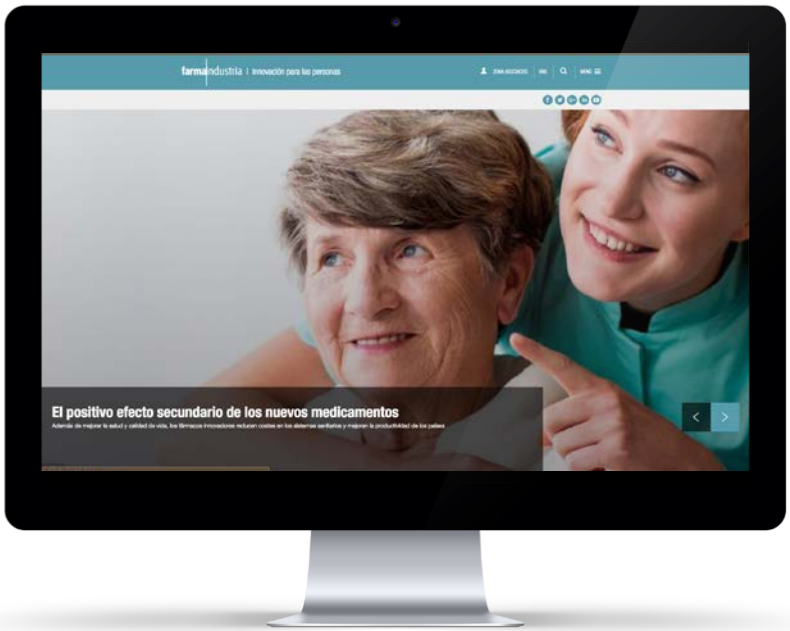
INTERNET AND SOCIAL NETWORKS

One of the most relevant lines of work in communication activities related to FARMAINDUSTRIA in 2017 was the **dissemination of information through social networks,** with the aim of achieving fluid and direct communication with the social network users and offering society a complete and updated information space on the **pharmaceutical industry and medicines.**

In this sense, FARMAINDUSTRIA maintained increasing activity that translated into intense dissemination of its own messages through these channels with clearly positive results, both in terms of profile development and audience development.

Specifically, FARMAINDUSTRIA'S **Twitter profile, which at the end of 2017 had more than 26,000 followers**, gained almost 3,000 over the year (+141% more than in the previous year), and its tweets were subject to 1.1 million views (an additional +269%), becoming the reference social network of the Association. In addition, the presence of FARMAINDUSTRIA in **Facebook and LinkedIn,** and a specific channel was activated on **YouTube**, containing half a hundred videos at the end of the year.

As part of this commitment to encouraging content generation in the digital environment. FARMAINDUSTRIA renewed its website, **www.farmaindustria.es** to strengthen its role in communicating with society and the healthcare sector and to enhance the dissemination of the different aspects related to the value of the innovative medicines in a very easy to navigate **multi-device web environment**.



The **new design** ensures that a contents search on the Association's website is optimum on each device, whether this be personal computers or mobile devices, in which internet use has shown an increasing trend in recent years.

All these spaces also provide direct access to content on the FARMAINDUSTRIA website, such as **dynamic infographics** in *parallax scrolling* format included in ***The value of medicines*** series, which in turn formed one of the main types of content disseminated by the Association.

In terms of the existing ones, *The value of medicines* and *The value of vaccines*, new documents were added in 2017: *The value of medicines in oncology, The value of medicines in diabetes* and *The value of medicines in cardiovascular disease.*

EVENTS WITH MEDIA IMPACT

In addition, last year FARMAINDUSTRIA held a dozen of its own forums or in collaboration with other entities that had a relevant impact on the media and/or social networks:

- 1st Session on “Transparency in the Pharmaceutical Sector”.
- 10th Annual Conference on Biomedical Research Technology Platforms: Innovative Medicines, Nanomedicine, Healthcare Technology and Biotech Markets.
- 20th Forum FARMAINDUSTRIA - Autonomous Regions in Melilla.
- Session on “Innovation in private centres with a view to 2018”.
- Meeting on the future of clinical research in Spain.
- 17th Meeting of the Spanish Pharmaceutical Industry.
- Presentation of the Guide to Clinical Research Units in Paediatrics.
- Meeting with the managers of the European System for Verification of Medicinal Products.
- 14th Workshop on “The Pharmaceutical Industry and the Media”.
- 5th Session and 3rd edition of “Somos Pacientes” Awards.
- Session on ”Bringing science into schools”.
- Signing event for renewal of the Collaboration Agreement for sustainability and access to medicines.

2017 NEWS MILESTONES

As in the previous year, 2017 came to a close with the news in December of the **Ministries of Finance and Public Function, and of Health, Social Services and Equality** signing the renewal of the Collaboration Agreement between the General Administration of the State and FARMAINDUSTRIA, for sustainability, innovation and access.

At a packed media event, and with prior authorisation from the Assembly of FARMAINDUSTRIA, the President of the Association, Mr. Jesús Acebillo, signed the Agreement with the Ministers Mr Cristóbal Montoro and Ms Dolors Montserrat. FARMAINDUSTRIA sent a press release to the media explaining the details of the **Collaboration Agreement** and posted on its website the document signed by the parties. This milestone had a great media impact.

The 5th Session of “Somos Pacientes” was also held in Madrid in December, organized by the Foundation. FARMAINDUSTRIA, which focused on the participation

of patients in public life in Spain. During the session, parliamentary spokespersons from the main political forces, healthcare professionals and representatives from patient associations and organisations agreed to defend the need to improve and enhance the participatory mechanisms of this group, not only in the healthcare system but also in political life and in society in general. The session ended with the delivery of the **3rd "Somos Pacientes" Awards** at an event presided by the General Secretary for Health, Mr José Javier Castrodeza.

The session was broadcast via streaming and had a wide impact on social networks, where the hashtag **#SomosPacientes17** became a national trending topic for much of the morning. Likewise, the information on the day and the awards had a significant echo in the media, particularly in specialized press.

On the other hand, in December FARMAINDUSTRIA received one of the distinctions from the **2nd Award for Transparency, Integrity and Combating Corruption**, an award granted by the Spanish General Council of Lawyers and Transparency International Spain. The distinction, which was collected by FARMAINDUSTRIA'S Director General, gave recognition to the firm commitment of the pharmaceutical industry established in Spain to transparency and good practice.

In November, the Royal Academy of Medicine (RANM) and FARMAINDUSTRIA signed a collaboration agreement with the first objective of achieving a better understanding of medicine in general and medicine in particular in the Spanish society. The agreement, signed by the Presidents of the RANM, Mr Joaquín Poch, and FARMAINDUSTRIA, Mr Jesús Acebillo, will allow the organisation, at the RANM headquarters and through 2018, to give conferences, scientific sessions, meetings and debates addressing issues related to medicine and health, particularly in the field of **pharmacotherapeutic** innovation.

In October, the **14th Workshop on "The Pharmaceutical Industry and The Media"** was held in Sigüenza (Guadalajara), a FARMAINDUSTRIA initiative focused on current pharmaceutical industry analysis. This Workshop became one of the main meeting points between the press and the heads of the Association, reaching in 2017 the greatest attendance in recent years, with the participation of 31 journalists, representatives from a similar number of general and specialised health and economic information media. The meeting had a significant impact on the media (176 press reports) and social networks.

The new infographics also began to be used in October for information purposes, which reflects, through the main data on the activity of the sector, the reality of the pharmaceutical industry based in Spain. The page was published by different media and was also disseminated by the social networks of FARMAINDUSTRIA.

Another of the most important news milestones of the year took place in September: **the presentation of the results of the Survey of Pharmaceutical Industry R&D in 2016**, which showed a +8% growth in R&D investment to €1,085 million, the largest increase since 2008. Numerous media echoed the contents of the press release launched by FARMAINDUSTRIA, which was the subject of 158 media reports.

In terms of social networks, the impact on Twitter was particularly relevant, where more than 400 posts with mentions to the Farmaindustria press release were generated. These actions were accompanied by a brief video in which FARMAINDUSTRIA'S Director General discusses key survey results.

In mid-September, the **17th Meeting of the Spanish Pharmaceutical Industry** took place in Santander, within the framework of the summer courses of the Menéndez Pelayo International University. More than one hundred healthcare and pharmaceutical industry representatives attended.

The meeting was also attended by 10 media and news agency representatives and had a significant impact on the media, with 121 printed and digital news items. Retransmitted via streaming, it also had a broad impact on Twitter, where 401 posts were issued.

In July, FARMAINDUSTRIA completed several agreements with entities, such as the agreement signed with the **Spanish Society of Healthcare Managers** (SEDISA), whose aim is to promote research, dissemination and transfer of knowledge in the field of medicines and the management of healthcare and healthcare services from a professional and independent perspective, based on the strictest ethical principles and codes of professional conduct. The agreement was the subject of a joint press release published by virtually all specialised media, as well as numerous general media and social networks.

An agreement with the **Spanish Society of Paediatric Rheumatology** to establish a general framework to facilitate cooperation between both entities, especially in the area of transparency. This agreement falls within the commitment of the pharmaceutical industry to foster transparency and is aimed at **reinforcing confidence** of society in the pharmaceutical industry and the healthcare system as a whole. FARMAINDUSTRIA also issued a press release on the matter, which had a wide dissemination in healthcare media and was reported in social networks.

Similar agreements were signed in the previous months with entities such as the Spanish Association of Urology, the Spanish Society of Neurology, or the Spanish Society of Paediatric Cardiology. All these agreements were disclosed through press releases and reflected in the media and social networks.

On 29 June 2017, the second annual publication of pharmaceutical industry collaborations with organisations and professionals took place (in this case those corresponding to 2016). For this reason, FARMAINDUSTRIA published a press release including the different items and explained that the publication of this information is the result of the European transparency initiative adopted by the companies adhered to **Code of Good Practice of the Pharmaceutical Industry** in Spain.

The press release was widely disseminated in the specialised and general press and particularly in the economic press, where the main headlines gave important spaces, both in their printed and digital versions, to disseminate the news. Dissemination of the information generated about 70 **news reports focused on transparency**, which had a potential audience of more than 13 million people. In general, the pharmaceutical industry's commitment to transparency was received as a positive initiative in both the media and networks.

Two days earlier, the Ordinary General Assembly of FARMAINDUSTRIA was held in Madrid, which approved the budget for the year 2017 and the Annual Activity Report for 2016. For this reason, FARMAINDUSTRIA issued an additional press release reporting the holding of the assembly and the content of the speech by the President of the Association, Mr. Jesús Acebillo, who highlighted that commitment to transparency, contribution to the sustainability of the healthcare system, and investment in research and development are the three pillars underlying the social commitment of the innovative pharmaceutical industry in Spain. The press release was widely reproduced in the healthcare and general media and was also disseminated through social networks.

In May, information activity dealt with, to a large extent, the controversy on the tax treatment of transfers of value. This was dispelled by the statement of the **Ministry of Finance and Public Function** in which it expressed the intention of the government to modify the Regulations on Personal Income Tax to clarify in the regulations that training courses for healthcare personnel, financed by companies, are not subject to taxation in personal income tax. The provision finally became effective on 30 December 2017.

FARMAINDUSTRIA issued a press release expressing its satisfaction with the Executive statement in which the Association reiterated its conviction that the current formulation of continuing training is a model that benefits all agents involved (public administrations, pharmaceutical companies, healthcare professionals and particularly patients).

On 20 April, the Minister of Health, Social Services and Equality, Ms. Dolors Montserrat, held an institutional meeting with the Executive Board of FARMAINDUSTRIA, headed by President and Director General.

The meeting, to which the Minister came with the General Secretary of Health and Consumer Affairs, Mr Javier Castrodeza, was conducted within the framework of dialogue and collaboration maintained by the Government and FARMAINDUSTRIA. For this reason, an informative note was published on the website and social networks that was collected by specialized and general media.

Also in April, FARMAINDUSTRIA participated in a colloquium organised by the National Commission of Markets and Competition (CNMC) with the collaboration of the Spanish Compliance Association under the title ***"transparency as value"*** in which the Director General of FARMAINDUSTRIA reaffirmed the clear commitment of the innovative pharmaceutical industry to transparency. The Association published a press release on this matter, which was reported by many social media and networks.

In the month of March, the **10th Annual Conference on Biomedical Research Technology Platforms**: **Innovative Medicines, Nanomedicine, Healthcare Technology and Biotech Markets, was held in Madrid.** Organised by FARMAINDUSTRIA, Asebio, Fenin and Ibec, the conference was attended by nearly 300 people among researchers, authorities, representatives of public administrations, pharmaceutical, biotech and health technology companies, among others. FARMAINDUSTRIA convened a press conference, which was offered by the managers of the four platforms and issued a press release.

The Conference was attended by 28 media and agency representatives, generating over one hundred news reports, with a potential audience of over 13 million people. In social networks, the hashtag **#IDbiomedica17** was used in 249 posts.

Another news milestone for the year was the holding of the **First Session on Transparency in the Pharmaceutical Sector** on the 24th of January, organized by FARMAINDUSTRIA and Transparency International Spain. The session had more than 200 attendees and had extensive media coverage. During the session, representatives of entities such as the Board of Transparency and Good Government, the Spanish Data Protection Agency, the National Commission of Markets and Competition and the Supreme Court, among others, addressed the main challenges faced by the pharmaceutical industry in this area. Representatives of physicians were also involved through the Federation of Spanish Scientific-Medical Associations (Facme) and the health authorities, with the presence of the Department of Health of Catalonia.

The day was retransmitted in real time via streaming and social networks under hashtag **#transparencyfarma**, with a wide impact on Twitter. In addition, a video-summary and several video interviews were made and a press release was distributed among the media reflecting the position of the pharmaceutical industry in the area of transparency, and this was reported by numerous media.

PARTICIPATION IN THE #WEWONTREST INITIATIVE

From the beginning in June, FARMAINDUSTRIA took part in the news initiative **#WeWontRest**, promoted by the **European Federation of Pharmaceutical Industries and Associations** (EFPIA), with the aim of showing how research on medicines has transformed health care and life expectancy and emphasising the firm commitment of the innovative pharmaceutical industry to patients, as the fundamental reason for the work carried out by pharmaceutical companies.

FARMAINDUSTRIA was informed of the initiative in Spain at its launch in June through the dissemination of a video and different information materials. Subsequently, in September, the testimonials of different professionals from companies with activity in Spain began to be published, who, in first person, express specific commitments to patients under the motto “Our vocation”. The commitments and all other materials can be found in a specific section on the website of FARMAINDUSTRIA.

Since the start of the campaign in June, Spain positioned itself, together with other countries such as Belgium or France, as one of the most active in the dissemination of contents in networks, and especially on Twitter, where it promoted, depending on the week, between 20 and 30% of posts on **#WeWontRest** in the above-mentioned social network.

RELATIONSHIPS WITH PATIENT ASSOCIATIONS

In 2017 FARMAINDUSTRIA maintained its relationship and **collaboration with patients** and the associations representing them. FARMAINDUSTRIA considers patients, family members, disabled people and carers, through their organizations, as key voices in the healthcare sector and seeks to maintain the best possible relationship with these entities and to establish areas of cooperation in areas where common or shared interests are defined. With that goal, action in this area focuses on two distinct lines:

1. Dialogue with associations, both directly and through Farmaindustria's **Permanent Dialogue Round Table** with Patient Organizations.

2. Management and enhancement of the **Somos Pacientes** online community of associations.

Collaboration with patient associations

In 2017, FARMAINDUSTRIA participated in numerous meetings, sessions, conferences, talks, seminars and diverse activities with **patient organisations** to share experiences with them and support their work.

Among the many invitations, projects and activities organised by patient associations in which FARMAINDUSTRIA took part in 2016, we should mention the course organised annually by the Spanish Federation of Breast Cancer (FECMA) at the Menéndez Pelayo International University,

the **1st Congress of the Platform of Patient Organizations** and the radio programme **"Rare Diseases".** In addition, FARMAINDUSTRIA was in direct contact with organisations such as GEPAC, FEDER, Parkinson Spain, Alcer, ASEM Federation or FEDE, among others.

In July, FARMAINDUSTRIA signed a collaboration agreement with the Spanish Patient Forum which, similar to the one signed in the previous year with the Platform of Patient Organisations, will **promote activities** encouraging patient empowerment, strengthening the association's movement and transparency of relationships between these entities and the pharmaceutical companies.

Permanent Dialogue Round Table

Farmaindustria's Permanent Dialogue Round Table with **Patient Organisations** maintained in 2017 its activity as a forum for information and discussion with a representative group of more than 20 federations and confederations of patient associations to address current and common interest issues with the ultimate goal of establishing a relationship of mutual confidence and thus improve knowledge of the needs and concerns of this group.

The Board held two meetings in 2017 in which, among other issues, the **Treatment Adherence Plan** or measurement of health outcomes and their relevance to patients.

Somos pacientes

At the end of 2016, the online patient association community Somos Pacientes **www.somospacientes.com**, set up by FARMAINDUSTRIA in 2012, brought together more than 1,700 organisations that are registered and compiled on the **National Map of Patient Organisations**.

Somos Pacientes offers a shared space for information, participation, training, services and joint work for all patient and disabled associations in Spain, as well as for family members, carers and professionals.

Among its tools, the most frequently used by associations are virtual conferences (webinars), online meetings, or the live video and audio online streaming channel. Using this tool, **Somos Pacientes** offered a range of activities from several member entities in 2017, plus the full 5th Somos Pacientes conference held in December, featuring the **third edition of the Somos Pacientes Awards.**

In this edition of the Somos Pacientes Awards, more than one hundred valid applications were received for its six categories and sections. A jury of 15 members with extensive knowledge of this area was formed in parallel that chose the winning applicants in the different categories and sections of the awards.

The awards were the high point of the 5th Somos Pacientes conference. One of the awards, the website users' favourite initiative, had nearly 67,000 registered votes online.

The **5th Somos Pacientes conference**, held in early December, consolidates its position as a meeting point to exchange ideas, needs and projects among the representatives of patient associations, the innovative pharmaceutical industry, the health authorities and health and research professionals. The programme for this edition focused on the need to improve and enhance the mechanisms of involvement of patients, not only in the healthcare system, but also in political life and society in general.

The **three round table meetings** featured representatives from patient associations, healthcare professionals, government spokespersons and members of the pharmaceutical industry.

The event was a success with over **170 attendees** participating. The conference could be followed via the Somos Pacientes streaming channel and the event generated more than **2 million hits** and that morning was a trending topic nationwide.

In this area, we highlight the activity of the Somos Pacientes portal, the online patient association community promoted by the FARMAINDUSTRIA Foundations, which maintains its strong vocation for the presence and dissemination of its activity and contents on the Internet and social networks. Somos Pacientes has a prominent presence on both Twitter and Facebook.

5th **Somos Pacientes** Conference

In the first case, the **Twitter** profile of Somos Pacientes had over **17,500 followers** at the end of 2017. Through this channel, the platform disseminates all its new content and maintains an open dialogue with the more than 1400 associations that are followed through this social network.

On **Facebook**, Somos Pacientes has a page by which they disseminate their contents which had more than **3,300 followers** at the end of 2017. In addition, the community has a YouTube channel in which it posts all reports and video interviews published on the platform.

The **Somos Pacientes newsletter**, which distributes weekly a summary of the main content published on the platform, had more than **3,100 subscribers** at the end of 2017.

EUPATI. European Patients Academy

This European Commission initiative, in which FARMAINDUSTRIA participated, was ended in February 2017 when it met its goal in 2016 to develop training courses and prepare educational materials, in addition to organising a public online library to train patient 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 kept the **National EUPATI Platform** active in Spain and entered into an agreement with the Spanish Agency for Medicinal Products and Medical Devices. This agreement enabled the conduct in 2017 of several training activities for representatives of patient groups. FARMAINDUSTRIA, although it has not formally been part of the Platform since February 2017, has maintained its support and backing of the Platform by offering advice and providing spaces and tools for its meetings.

3

Institutional Activity

FARMAINDUSTRIA'S international activity revolves around **three key aspects**:

1. **Developing** stable relationships with international associations and federations in the pharmaceutical industry.

2. **Positioning** FARMAINDUSTRIA and the pharmaceutical industry based in Spain as a model to international institutions and agencies in the defence of industry interests.

3. **Maximizing** the presence of Spanish companies in third party markets, mainly in emerging countries.

The Association's alignment with global pharmaceutical industry positioning and practice remains a cross-cutting element to the different actions of Farmaindustria's **Strategic Plan** and its objective is to compile the experience and information accumulated by the Association both in its interaction and participation in the two major international federations: the **European Federation of Pharmaceutical Industries and Associations** (EFPIA) and the **International Federation of Pharmaceutical Manufacturers & Associations** (IFPMA), as in numerous bilateral and multilateral meetings that FARMAINDUSTRIA holds with other national associations from the pharmaceutical industry.

In this context, FARMAINDUSTRIA established a new working group in 2017: the International Working Group to address EFPIA and IFPMA priorities and to help design the pharmaceutical industry strategy and action plan in Spain.

3.3.1 European Context

ACTIVITIES WITHIN THE EFPIA FRAMEWORK

FARMAINDUSTRIA'S ACTIVITIES IN Europe are mainly channelled through its participation in EFPIA, an organization that represents 33 national associations from the pharmaceutical industry and 41 companies in Europe, consolidating Farmaindustria's active participation in most of the strategic working groups and committees in the European Federation.

EFPIA General Assembly and Annual Conference

On 14 June 2017, the **EFPIA Annual Meeting and Conference** took place in Brussels, focusing this year on disruptive innovation that can transform healthcare and patient quality of life, the critical role of information technology and big data, and the importance of industrial property as a key tool to drive pharmaceutical innovation.

In the **EFPIA General Assembly**, the attendees analysed the progress made in the different issues addressed by the Federation's strategic committees:

Patients and Access, Innovation, International Markets and Finances. The General Assembly also approved the lines of action for the period 2017-19, prioritising among other aspects:

- **Financing models** that can make sustainability of healthcare systems compatible with patient access to innovations.
- **Consolidation of an environment to protect** industrial property rights in both European and third party markets.
- **Promotion of effective and flexible regulatory environments** that promote R&D for new medicines.

In addition, meetings of the **EFPIA Governing Bodies** were also held, ratifying the appointment of Mr Stefan Oschmann (Merck KGaA) as the new president of EFPIA, replacing Mr Joseph Jiménez (Novartis) in this position.

EFPIA Board

In 2017, the EFPIA Board addressed a number of priority topics, in coordination with its Strategic Committees, including:

1. The European Commission analysis on industrial property incentives and waiver of the Supplementary Patent Protection Certificate (SPC).
2. The various joint initiatives between Member States on medicine prices and health technology assessment.
3. Measurement and analysis of health outcome data.
4. Brexit.
5. EU trade policy with third party countries.

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

Meetings of EFPIA's European Markets Committee (EMC)

During 2017, and under the presidency of Sanofi and the vice-presidency of FARMAINDUSTRIA, meetings with the **European Markets Committee** (EMC) continued , made up of **European Directors** from pharmaceutical companies and Director Generals from national associations. The primary objective of this Committee is to monitor correct national implementation of the decisions made by the EFPIA Board 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 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 party markets.
- Impact of UK Brexit from the EU
- Incremental innovation.

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 Associations Meetings (G1 and G2 Groups)

During 2017, **five meetings** were held among the national associations for the main European markets, including both the so-called “G1”group (Germany, United Kingdom, France, Italy, Spain and Switzerland) and the “G2” group (Belgium, Netherlands, Denmark and Sweden).

These meetings looked in-depth at the major new developments in pharmaceutical policy affecting each country, stating their common concern to make **access to innovations** compatible with the sustainability of healthcare systems. In addition, different sections of the meetings were dedicated to in-depth look at the measurement of health outcomes, assessment of the relative efficacy of medicines at the European level (EU-REA), or actions to reduce the economic impact of serialising medicine packaging on European SMEs.

MAIN AREAS OF FARMAINDUSTRIA ACTION IN EUROPE

Brexit

Brexit is the term coined to refer to the **departure of the United Kingdom from the European Union**.This will occur as a result of the outcome of the referendum in this country in June 2016.

After the United Kingdom formally notifying the European Council of its intention to leave the EU, Article 50 of the Treaty on Lisbon was activated, starting a period of two years, after which the exit of the United Kingdom from the EU will take effect.

The terms of the exit of the United Kingdom from the EU will be set in two consecutive phases:

Phase 1

Negotiation to agree on **distribution of the so-called Brexit bill,** the conditions of residence and work and border management (Northern Ireland and Gibraltar).

Phase 2

Negotiation to agree on the **terms of the future economic and trade relationship** between the EU and the UK.

Phase 1 will define the negotiation and implementation period of Phase 2, in which all economic sectors must adapt to the new scenario. In this context of uncertainty, and due to the uniqueness of the health sector, the innovative pharmaceutical industry considers it necessary:

- **To maintain cooperation** and regulatory alignment and to prevent any change in the trade relations between the EU and the United Kingdom from adversely affecting R&D, manufacturing and supply of medicinal products to patients.
- **To define a transitional period** for pharmaceutical companies to make the relevant changes, preventing delays in access to medicinal products and possible disruptions in the supply chain.

FARMAINDUSTRIA has opened up specific lines of dialogue with the AEMPS and the competent Spanish authorities requesting their support for the demands of the sector focused on various key areas: regulation, R&D, industrial property, labour mobility, trade and medicine supply.

The pharmaceutical R&D model and the defence of industrial property rights

2017 has been a year of intense debate focusing 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 incentives on industrial property in access to innovations and sustainability of healthcare systems.

To determine this, several studies are currently ongoing:

- Economic impact of incentives on industrial property.
- Evaluation of the Regulation on Supplementary Protection Certificates (SPCs).
- Public consultation to optimise the legal framework for industrial property rights.
- Review of the Regulation on orphan medicinal products.
- Report on the 10 years of implementation of the Regulation on paediatric medicines.

In light of these studies, the **European Council of Employment, Social Policy, Health and Consumers** (EPSCO) will determine whether it is appropriate to review the incentive system for industrial property and, if so, to what extent.

To minimise the risk of a review that limits the current industrial property incentive system, EFPIA has developed an action plan and strategy based on:

- **Providing evidence,** with practical examples, as to the importance of industrial property rights for therapeutic progress.
- **Defending** the pharmaceutical industry R&D model.
- **Communicating** the value of the medicine and its contribution to the EU economy (action aligned with the **#WeWontRest** campaign which is discussed in other sections of this Annual Report).

In addition, and within the framework of the overall analysis of incentives on industrial property, the European Commission is analysing in parallel the opportunity to modify the current legislation on SPCs, establishing a waiver of these certificates so that other operators can manufacture products still under patent in force for export purposes to third party markets (the so-called *manufacturing waiver*).

The industry most affected by this change is the industry that develops and produces innovative medicines, as it finds in these SPCs a way of ensuring an effective period of **patent protection** to recover the cost of the resources it invested in research.

If such a change is decided, the negative impact in terms of foreign trade, **production and employment** in Spain could be significant. In fact, the export of innovative products produced in Spain, which makes up the largest part of the nearly €11,000 million per year of Spanish pharmaceutical exports, could be affected, as the production of these innovative medicines has a global or even worldwide scope, the loss of sales of these products caused by a rapid "**genericisation"** in third party markets will cause a fall in the value of Spanish exports of innovative products.

In any case, the main negative impact of this potential modification of the current status quo on industrial property is none other than the weakening of these rights granted by the EU as an incentive to innovation. The **negative impact** that such modification may have on European, and therefore Spanish, biomedical R&D may be very high, not just for the **reduction in research efforts** that would result from decreased resources, but also strategically, because of the negative impact on R&D investment decisions in Europe. A weakening of industrial property rights would convey a confusing signal about the European commitment to research that would undoubtedly be taken advantage of by other markets.

Furthermore, the effect of this measure in terms of savings for European health systems is zero, as exemption from these certificates is only for the purpose of **export to third party markets**, and therefore does not affect the internal marketing conditions.

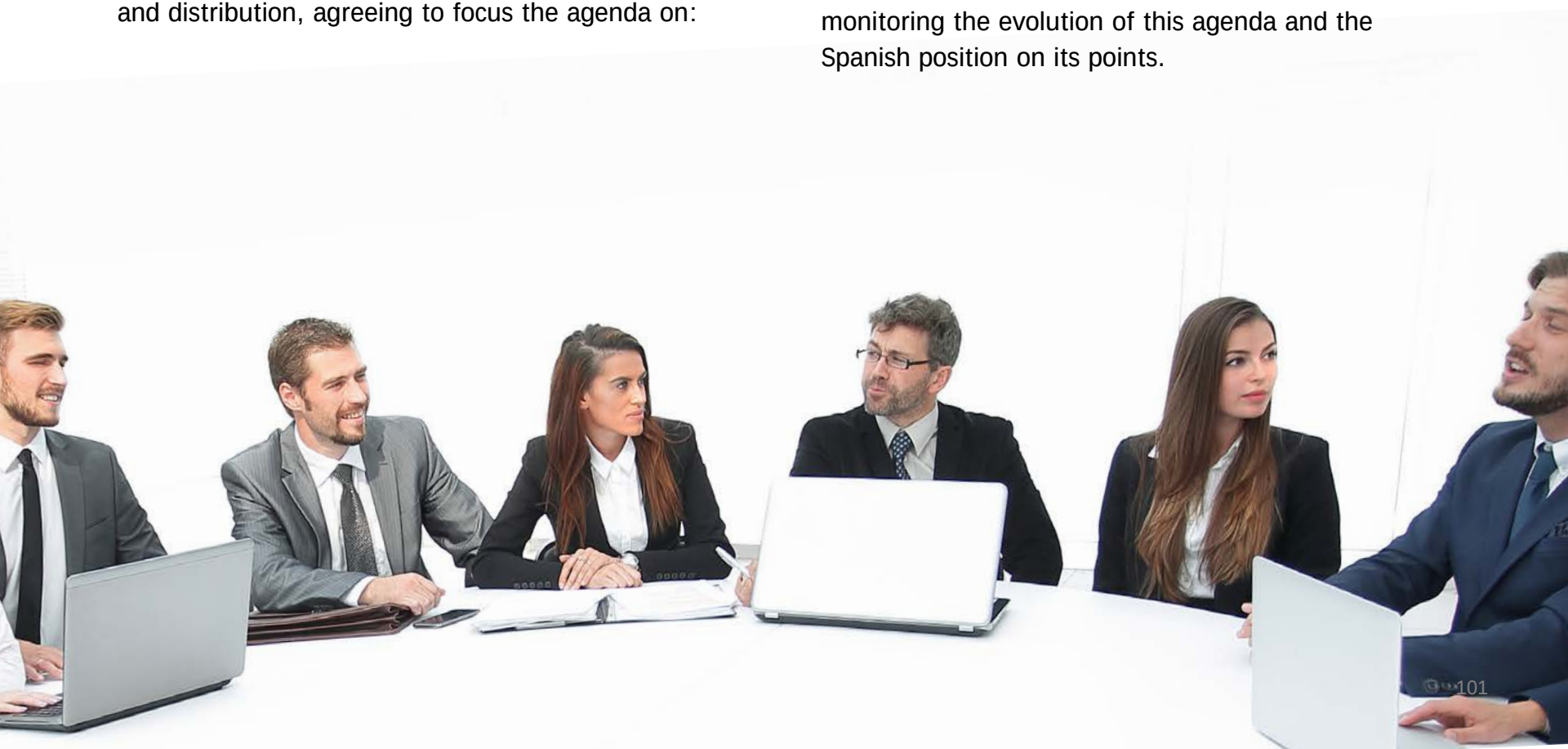
In October 2017, the European Commission issued a public consultation on the possibility of an SPC waiver. At the end of the year, FARMAINDUSTRIA sent its response to the consultation, aligned with EFPIA, sending in parallel letters to various authorities: Minister for Health, Social Services and Equality, Secretary of State for **R&D&i**, or Director of the Spanish Patents and Trademarks Office, among others, informing them about the repercussions for the industry and requesting their support to prevent changes in current European legislation.

Ministerial round tables on prices, access and sustainability

As part of this initiative, the first meeting of its **High Level Group** was held to prepare a work agenda. **Fifteen countries** (including Spain) took part in the meeting, together with representatives of the industry and distribution, agreeing to focus the agenda on:

- Alternative funding models for disruptive innovations.
- Increased access to generics and biosimilars.
- Promotion of competition.
- Equality in access to medicines between countries.

FARMAINDUSTRIA, aligned with **EFPIA**, is closely monitoring the evolution of this agenda and the Spanish position on its points.



Collaboration initiatives between European countries on pricing and access to innovations

Pricing and access to medicines is a **policy priority** in all European countries. In fact, several voluntary collaboration initiatives between 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 in different developmental phases and their approach is still to be defined in many cases. The most prominent initiatives include:

1. **Declaration of La Valletta**, made up of Cyprus, Spain, Greece, Italy, Malta, Portugal, Slovakia, Ireland 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 adds, in the case of Spain, the Spain-Portugal bilateral agreement, aimed at making common public purchases and the exchange of price information.

2. **BeneluxA cooperation**, of which Belgium, the Netherlands, Luxembourg and Austria are a part. Of great interest to the pharmaceutical industry and subject to monitoring due to the potential impact of one of its lines of work, the so-called *Horizon Scanning for Pharmaceuticals*, to which Switzerland has also joined.

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

All these ongoing projects and initiatives raise concerns for the pharmaceutical industry as the industry defends better access of all countries to innovations based on **price policies** and acquisitions of individual medicines for each country, according to the different economic and social and health situations.

Following the actions proposed by EFPIA, Farmaindustria is closely monitoring the **initiatives** in which Spain participates.

European Parliament Report on Alternatives to Improve Access to Pharmaceutical Innovations (INI Report)

Following its mandatory legislative processing in various Committees, the European Parliament adopted the **"Report on EU options to improve access to medicines"** in February 2017, the rapporteur of which was the Spanish MEP, Ms. Soledad Cabezón, and which has proposals to improve traceability of R&D expenditure and public funding of medicinal products.

After intensive institutional activity by EFPIA and FARMAINDUSTRIA, the final text was more balanced than the initial proposal of June 2016, due to the introduction of numerous amendments, including the rejection of a **European fee** implementation on pharmaceutical sales, or the amendment in which the Commission is encouraged to make legislative proposals that harmonise transparent criteria for the **efficacy assessment** relating to new medicines, and recognition of the value of incremental pharmaceutical innovation.

Antimicrobial Resistance

On 29 June 2017, the European Commission adopted the European **“One Health”** action plan to fight antimicrobial resistance and position the EU as a leading region in this issue. The action plan consists of three pillars:

1. **Positioning** the EU as a best practice region.
2. **Boosting** research, development and innovation.
3. **Shaping** and giving content to the global agenda. In addition, specific objectives are included for the development of new economic and incentive models for combating antimicrobial resistance.

In this context, EFPIA is undertaking several activities for the European Parliament, through the **ENVI and ITRE** committees, to acknowledge the importance of incentives for the development of **new antibiotics** and the commitment of the pharmaceutical industry to eradicate antimicrobial resistance.

In parallel, in May 2017, IFPMA in collaboration with EFPIA launched the intersectorial initiative **"Antimicrobial Resistance Industry Alliance,"** with the aim of measuring the progress of the pharmaceutical industry in this area, ensuring that it complies with the objective signed in the **"Declaration of the Industry on Antimicrobial Resistance"** (World Davos Economic Forum, January 2016) and the **"Industry Road Map for Combating Antimicrobial Resistance"** (United Nations General Assembly, September 2016); specifically:

1. **Reducing** the environmental impact of antibiotic production.
2. **Contributing** to the rational use of antibiotics.
3. **Improving** access to available antibiotics and future treatments.
4. **Exploring** collaborative opportunities between industry and public entities from a multisectorial perspective, including bodies such as the World Health Organization or United Nations.

In 2017, the Alliance organised three meetings in which the **governance bases** were established and the progress report was compiled, showing the advances made by the industry in its fight against antimicrobial resistance.

Vaccines

After renewal of its mission and strategic direction, **Vaccines Europe** has multiplied its efforts, both in terms of institutional actions and PR campaigns and in raising public awareness on the importance of vaccines.

In this regard, publication of the report **"The Vaccine Industry in Figures"** should be noted, which is accompanied by a number of infographics and other PR material, praising the European Union as a global strategic centre for R&D in vaccines, and highlighting this sector's contribution to patient health, but also to economic growth and job creation in the EU.

Specific reports on the role of vaccinations in the fight against antimicrobial resistance have also been published globally, as well as its contribution to reducing mortality and improving quality of life in the world.

Finally, in January 2017, coinciding with the **World Economic Forum in Davos**, a global alliance was announced to prevent pandemics, with the support of IFPMA and several governments around the world.

Biotechnology

In March 2017, EFPIA, EBE (*European Biopharmaceutical Enterprises*) and IFPMA issued a joint position paper entitled **“Considerations for Healthcare Professionals on Switching Decisions regarding Biosimilars”.**

Furthermore, in May 2017, the European Medicines Agency, in collaboration with the European Commission, published an information document on questions and answers for healthcare professionals on biosimilar medicines.

The goal of the guidance is to provide healthcare professionals with continuing education on the state of knowledge and regulation in the use of biosimilar medicines.

Pharmaceutical products in the environment

On 21 November 2017, the European Commission (ENVI Committee) launched a public consultation on **“Strategic Options for Pharmaceutical Products in the Environment”,** in order to collect the observations of the different interest groups and incorporate them into the finalisation of the draft European Strategy for Pharmaceutical Products in the Environment, which will foreseeably be made public in 2018.

EFPIA, in collaboration with Medicines for Europe and AESGP have participated in the public consultation and are conducting, together with the national associations, activities to approach and inform members of the European Parliament and convey to them the firm commitment of the pharmaceutical industry on this subject.

LEGISLATIVE INITIATIVES IN EUROPE

Regulation on Health Technology Assessment (HTA)

In January 2018, the European Commission published a legislative proposal of the Parliament and the European Council on **health technology assessment** (HTA). The proposal includes, as a key element of the operative text, a joint assessment of the relative efficacy of medicinal products whose adoption, after a transitional period, would be mandatory in all EU countries, with the aim of **ensuring compliance with internal market objectives** and address the inefficient fragmentation and duplication of assessments occurring in the different Member States.

FARMAINDUSTRIA in line with EFPIA and in order to accelerate access and avoid barriers and repetitive assessments, support a future European HTA regulatory proposal based on a clinical assessment at the European level, within the limits of subsidiarity and proportionality, whereby the **Member States** maintain the competence to incorporate, after such clinical assessment, any non-clinical (mainly economic) consideration necessary in national pricing and reimbursement decision procedures for new medicines.

Directive 2011/62/EU (Falsified Medicinal Products) Delegated Regulation (EU) 2016/16. Setting up SEVeM in Spain

After publication in the EU's Official Journal on 9 February 2016 of the Commission Delegated Regulation (EU) 2016/161, of 2 October 2015, which establishes specific rules on the inclusion of mandatory safety features in the **medicine packaging** (single 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.

In this period, the national verification systems that will be managed by the repositories that will store the information on these safety features must be established in the Member States to be fully operational at the date of implementation of the Regulation (9 February 2019).

Owing to the high economic impact this measure will have on SMEs due to the need to adapt their production lines, at a cost close to **€200 million** for the whole industry in Spain, measures such as the possibility of packaging medicines with pre-serialised containers are being studied.

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 System for Verification of Medicinal Products (SEVeM) was set up, comprised of FARMAINDUSTRIA, the Spanish Association of Generic Medicinal Products (AESEG), the General Council of Official Pharmaceutical Associations (CGCOF) and the National Federation of Wholesale Distributor Associations of Medicinal Products and Parapharmaceutical Products (FEDIFAR).

SEVeM was officially launched in September 2016 with the forming of its **Board of Directors**. The AEMPS also participates in its meetings and additionally has system oversight functions.

Legislative package on personal data protection

The new European legislation on the protection of personal data consisting of a General Data Protection Regulation, which repeals Directive 95/46/EC, and a Data Protection Directive on the compliance and observation of the laws on this matter, is effective as of April 2016 and fully applicable as of 25 May 2018.

The Regulation is aimed at **increasing the level of personal data protection** of European citizens when they are subject to any type of treatment, but while simultaneously generating new opportunities in the digital single market, particularly through the reduction of administrative barriers.

After its publication, the Member States have two years to regulate some aspects that need to be harmonised at the European level in order to guarantee the legal security of all international biomedical research projects that are already ongoing or will be conducted in the future.

In fact, a restrictive interpretation of data protection regulations would adversely affect the ability of European health systems and investigators to advance in biomedical research and take advantage of the full potential offered by big data to health authorities, investigators and patients.

3.3.2 International Context

ACTIVITIES WITHIN THE EFPIA FRAMEWORK

FARMAINDUSTRIA channels much of its activities in the international context through its participation in the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), an organization composed of 49 associations (47 national and 2 regional) and 36 pharmaceutical companies.

FARMAINDUSTRIA is represented in the meetings of the governing bodies of IFPMA (General Council and Assembly) as well as the Committee of Managing Directors of National Associations (*Heads of Associations*).

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

Reform of IFPMA statutes and governing bodies

During 2017, IFPMA implemented its **new statutes and governance system** (both approved by their governing bodies in 2016), in order to enhance the alignment of the pharmaceutical industry's actions globally and to strengthen its work agenda in the areas of sustainable access and incentives to innovation. Within this context of governance, FARMAINDUSTRIA has established its position as a permanent member in **IFPMA governing bodies.**

In addition to the General Assembly and Council, a new governing body was set up in 2017: the ***"CEO Steering Committee"***, including but not limited to EFPIA Presidents of EFPIA, the Japanese Association (JPMA) and the American Association (PhRMA).

Finally, and as a result of the organizational changes made by IFPMA, Mr Thomas B. Cueni was confirmed as the new Managing Director.

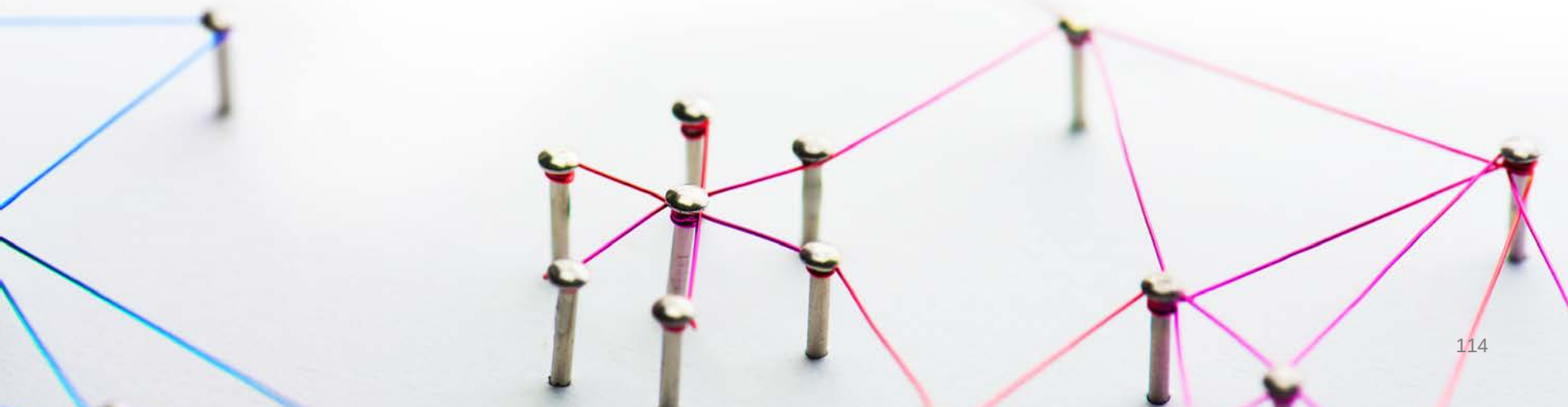
Meetings of the IFPMA governing bodies

FARMAINDUSTRIA participated in the meetings of the **IFPMA Council and Assembly** held in 2017, in which the **2018-2020 Strategic Plan** was adopted, revolving around three strategic lines:

1. **Providing incentives** for the development of an environment favourable to biopharmaceutical innovation.
2. **Promoting** a system of sustainable access to medicines and vaccines.
3. **Tackling** global challenges for the healthcare system, all within a framework of business ethics and integrity.

Industrial property

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



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 their inconsistency with other OECD guidelines on innovation, access and sustainability.

IFPMA organised and participated in meetings and events with the OECD member states to try to ensure that the final report does not include messages that would reduce industry innovative activity and patient access to new medicines. As a result of the IFPMA activity, the final draft (published in late 2017) is much more balanced. The final report is expected to be approved with minor changes in 2018.

WHO Fair Pricing Forum

The **World Health Organization** organised a medicine pricing forum in May 2017, the ***Fair Pricing Forum*** to discuss the concept of a “fair price” for medicines, through expert panels, discussions, and group sessions. The forum was very critical with the innovative industry, largely due to the poor understanding of the concept ***Value-based pricing***.

Given the current international framework that challenges the business model and is characterised by a lack of understanding of how the pharmaceutical industry works and how medicines are developed, IFPMA has developed a set of key messages with the goal of emphasizing and disseminating the value that the pharmaceutical industry brings to society.

COMPETITIVENESS AND INTERNATIONALISATION

FARMAINDUSTRIA it taking action on two different levels on this subject. On the one hand, in **foreign trade**, in coordination with EFPIA and IFPMA, through specialised working groups; and, on the other hand, through the **Competitiveness and Internationalisation Working Group** of FARMAINDUSTRIA. The ultimate goal is to improve the presence of associated 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 party countries or regions.

EU-US Mutual Recognition Agreement on Medicinal Product Inspection

On 1 November 2017, the Mutual Recognition Agreement on the Inspection of Medicinal Products signed between the EU and the USA became effective in January of the same year. This Agreement **allows automatic recognition of inspections** conducted at production plants for human medicines in the EU and the USA, avoiding duplication of inspections and **facilitating access to medicines**. Spain is one of the eight EU Member States (together with Austria, Croatia, France, Greece, Italy, Sweden and the United Kingdom) who were audited by the U.S. Regulatory Agency (FDA) and may therefore benefit from the advantages of this Agreement. All other EU Member States must wait until July 2019 to obtain this recognition.

EU-Canada Free Trade Agreement (CETA)

After signing and final adoption on 30 October 2016, the EU-Canada Free Trade Agreement entered into force on 21 September 2017. As this is a **mixed agreement**, it must be ratified by the national Parliaments of all EU Member States in order to enter fully into force. 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 to Canadian legal regulations the **main provisions** of the CETA on pharmaceutical industrial property:

- Right to appeal for innovative laboratories.
- 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. The agreement is essentially intended to remove trade barriers.

Once the legal review of the Agreement is completed, it will be submitted for **approval by the European Parliament** (planned in November 2018) and the EU Member States with the goal of entering into force before the current European Commission mandate is ended in 2019.

EU-Mercosur Association Agreement

In 2015, the EU and Mercosur (consisting of Argentina, Brazil, Paraguay and Uruguay) relaunched the negotiations of the Association Agreement, initiated in 1999 and suspended in 2004. During 2017 the negotiation rounds have intensified and a final wording of the Agreement is expected in mid-2018.

3

Institutional Activity

3.4.1 The pharmaceutical industry in Europe

The analysis of the progress of a business sector in a given period should be put into the context of **general economic changes over this period,** although it is true that not all business sectors are affected in the same way.

In 2017, with a **growth of +2.4%,** the growth started by the European economy in 2014 (+1.6%) and continued in 2015 and 2016, has accelerated with average growths of +2.0%. The growth of +2.4% in 2017 is the best growth figure recorded by the European economy over the past ten years.

This acceleration of activity has resulted in **greater job generation,** as reflected by the decrease in the unemployment rate in the EU-28, from 8.2% of the active population in 2016, to 7.3% at the close of 2017, thus recovering the pre-crisis levels (2007) in which this ratio was around 7.0% of the active population.

In addition, austerity measures continued in 2017 by **reducing the deficit for all Public Administrations** in the EU-28 was reduced for the eighth year in a row, going from 6.9% of GDP in 2009 to 1.0% in 2017, six tenths below the 2016 level.

Future forecasts point towards a consolidation of growth rates recorded in 2017. So, the European Commission, in its ***European Economic Forecast - Spring 2018***, calculates the forecast growth rate of real GDP growth for the EU-28 as +2.3% in 2018.

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

Although the above factors will limit the growth of the European pharmaceutical market in the coming years, there are other elements that will drive sales upwards, such as the ageing population, the chronicity of certain diseases, or the appearance of disruptive innovations and highly innovative therapies in high impact therapy areas, among others.

For example, the forecast from the IQVIA consultancy[1] put the average annual growth rate for the five major European markets in the 2018-2022 five-year period in the (+1% / +4%) band, significantly below the growth forecasts for the sector worldwide (+3% to +6%), as well as growth forecast for the USA (+4% / +7%) and emerging markets, such as Brazil, India and Russia, which will see average annual growth in the (+6% / +9%) band.

[1] IMS Market Prognosis, October 2017. The data correspond to the total pharmaceutical market in each country (Out-patients + Hospital).

As in the previous five-year period (2013-2017), out of the five major European markets, **France** (+0% / +3%) and **Spain** (+1% / +4%) will be the countries with the **lowest annual average growth** in the 2018-2022 period, while Germany, Italy and the United Kingdom will have average growth rates of between +2% and +5% per year.

Finally, and regardless of growth, it is important to emphasize the **relevance of our country** 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 (2015)						
Country	**Number of Pharmaceutical companies** (1)	**Production** (million €) (2)	**Employment:**	**Domestic sales** (MSP) (million €) (3)	**Foreign trade** (MSP) (€ million) (4)	
					Import	Export
Germany	304	29,536	114,069	30,038	42,282	68,706
Austria	116	2,864	14,140	3,550	8,002	8,472
Belgium	123	11,232	34,617	4,708	34,694	41,003
Denmark	33	13,080	26,963	23,066	3,592	11,537
Spain	**183**	**15,213**	**38,677***	**15,625**	**13,826**	**10,934**
Finland	45	1,598	5,476	2,246	2,011	852
France	255	20,554	98,690	27,645	23,659	27,857
Greece	65	929	26,000	4,058	2,790	1,018
Netherlands	43	6,180	12,000	4,821	19,168	27,434
Ireland	46	19,305	26,373	1,818	5,752	30,231
Italy	186	29,326	63,500	22,703	21,372	19,052
Portugal	118	1,490	7,500	2,933	2,360	920
United Kingdom	52	19,313	61,500	22,375	30,503	33,343
Sweden	90	7,809	11,012	3,809	3,577	7,600
Total EU-15	**1,659**	**178,429**	**540,517**	**169,395**	**213,588**	**288,959**

(*) Year 2014

Note: Luxembourg is not included due to poor representativeness.

(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

R&D&i

Research, development and innovation activities (R&D&i) is a central part of a sustainable, competitive, high-quality growth model and is key to creating employment and improving the productivity and competitiveness of an economy.

Regarding R&D, the Government itself highlights its *"essential role in long-term growth, job creation and improved productivity and competitiveness of the Spanish economy".*[2]

To promote these activities, the **Government drew up the Spanish Strategy for Science and Technology and Innovation 2013-2020**, which, together with the Strategy Europe 2020, makes up the backbone of R&D policy.

[2] Passage taken from the Spanish National Reform Programme 2017 (page 29). Available at: http://www.mineco.gob.es/stfls/mineco/comun/pdf/170503_np_reformas.pdf.

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 summarized in the following table:[3]

INDICATORS OF THE SPANISH SCIENCE, TECHNOLOGY AND INNOVATION STRATEGY			
Effort Indicators	**2010**	**2016**	**2020**
R&D spending in relation to Gross Domestic Product (%) Source: INE	1.39%	1.48%	2.00%
Private sector R&D spending in relation to Gross Domestic Product (%) Source: INE	0.60%	0.73%	1.20%
Ratio between private and public funding of R&D spending Source: INE	0.86	1.06	1.70
% of foreign funding for R&D spending Source: INE	5.7%	9.6%	15.0%

However, the latest data recorded, corresponding to 2016, show how **the actual change in R&D spending has been far from those objectives**, seriously compromising achievement of the objectives proposed for 2020. Thus, the weighting of R&D spending over national GDP changed from 1.39% in 2010 to 1.19% in 2016, far from the 1.48% targeted for that date.

In terms of R&D expenditure funded by the private sector, far from increasing its weighting in GDP, it has fallen from 0.60% in 2010 to 0.55% in 2016 so its weighting should be doubled in the period 2017-2020 to achieve

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

the target committed to Brussels (1.2% of GDP), a rather difficult task.

With regards to the 2017-2020 period, in December 2017 the Government approved the State Plan for Scientific and Technical Research and Innovation 2017-2020, establishing the framework for action in the coming years for achieving the objectives of the Spanish Strategy for Science and Technology and Innovation 2013-2020 and of Strategy Europe 2020. This Plan contains a specific programme to promote R&D carried out by the private sector, since as is literally cited in the Plan:[4]

"Business investment in R&D&i in Spain, representing 0.64% of GDP in 2016,[5] 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."

[4]Page 58 of the Plan. Available at: http://www.idi.mineco.gob.es/stfls/MICINN/Prensa/FICHEROS/2018/PlanEstatalIDI.pdf

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

The State Plan endorses the **2013-2020 Strategy objectives** by adapting the 2017-2020 annual path to the real data observed until 2016. Despite this, the Government has already been warned by some of its leading advisory bodies that transferring the responsibility for duplicating the R&D investment percentage to the private sector in such a short period would require a wide range of measures that would establish a much more favourable framework for private sector investments in this area.[6]

In this regard, it is essential to boost and promote the participation of the pharmaceutical industry in its role as the leading industrial sector in research, as demonstrated by the data of the INE, which can be summarised as follows:

[6]CES. Report 02/2015: The situation of R&D&i in Spain and how it affects competitiveness and employment. Available at: http://www.ces.es/documents/10180/2471861/Inf0215.pdf

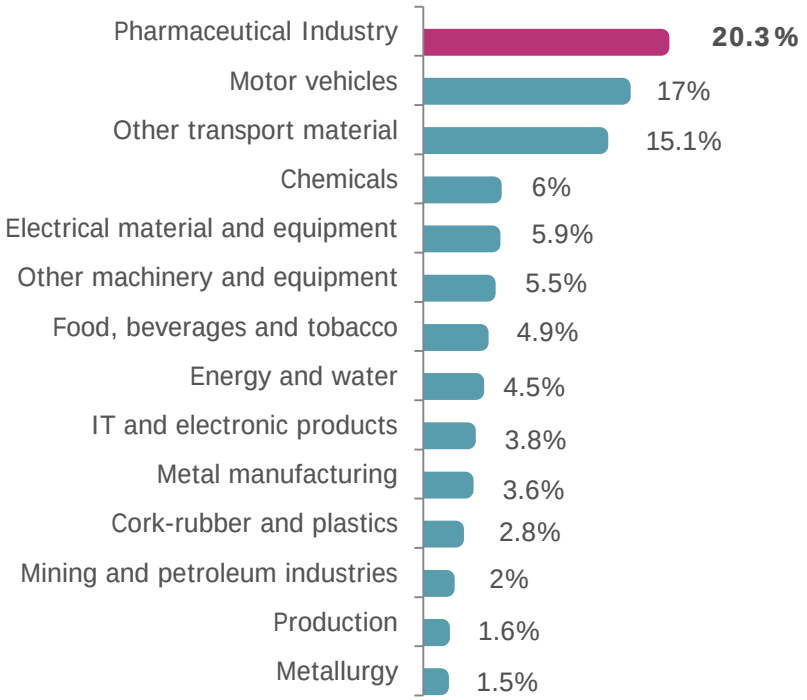
1

The pharmaceutical industry invested €966 million in research and development in 2016, 20.3% of the total R&D investment in the Spanish industry, which makes it, by far, the leading industrial sector by volume of spending on research. It is also a particularly relevant percentage when considering that the turnover from pharmaceutical companies only represented 2.4% of the industrial total.

2

When analysing how R&D spending breaks down into phases, the pharmaceutical industry once again leads the industrial ranking for volume of resources intended for basic or fundamental research, where it accounts for half of the total spending of the industrial sector in Spain and for applied research (31% of the total).

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



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

3

Furthermore, 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 Spanish industry.

4

The pharmaceutical industry's leadership is not only limited 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 are working in 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 the savings goals or the need for austerity measures within the different government areas, would help to conciliate these aims with developing industrial sectors required to support and extend economic growth in our country over the last few years.

HOME MARKET

In 2017, and according to data published by the Ministry of Finance and Public Function (MINHAFP), public hospital **pharmaceutical spending** grew by **+3.3%.**

In turn, and according to Farmaindustria's own estimations, **sales of medicines** in retail pharmacies in 2017, in net figures after the deductions considered in Royal Decree-Law 8/2010, increased by **+2.3%.**

As a result of the evolution of both segments,**total sales** of medicines in 2017 increased by **+2.7%** from 2016.

HOME MARKET OF MEDICINAL PRODUCTS (MSP, million €)

	Retail pharmacies (1)	Increase (%)	Hospitals (2)	Increase (%)	Total	Increase (%)
2014	8,842	+0.7%	5,254	-	14,096	-
2015	8,957	+1.3%	6,641	+26.4%	15,598	+10.6%
2016	9,361	+4.5%	6,242	-6.0%	15,603	+0.0%
2017	9,580	+2.3%	6,448	+3.3%	16,028	2.7%

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

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

Source:

Retail pharmacies: FARMAINDUSTRIA from IQVIA data and own estimations.
Hospitals: MINHAFP hospital pharmaceutical spending. Updated March 2018.

Retail pharmacy market

The total market through retail pharmacies recorded a **+2.3% increase in sales** in 2017, primarily as a consequence of the increase in average price, with no significant change in the number of units compared to 2016.

However, as shown in the table below, when only considering the units from the market segment subject to reimbursement by the NHS, representing 85% of the total, the number of units grew by +0.6% and their average price by +1.7%.

At the end of November 2017, the fourth reference price order came into effect based on the criteria set out in Royal Decree 177/2014, of 21 May, in which 20 new groupings were created and 11 were removed. There are currently 427 Reference Price System groups in retail pharmacies, of which 179 do not included a generic medicine and 2 are with a biosimilar. The new order had no impact on the spending in 2017 because it took effect for these purposes in January 2018.

MARKET STRUCTURE IN RETAIL PHARMACIES

	Units (million)	Share	Inc.	MSP Sales (million €)	Share	Inc.	Average MSP (€)	Inc.
Market subject to reimbursement	1,099	85%	+0.6%	8,284	86.9%	+2.3%	7.5	+1.7%
Non-reimbursed market	193	15%	-3.5%	1,296	13.5%	+2.3%	6.7	+6.0%
Total market	**1,292**	**100.0%**	**0.0%**	**9,580**	**100.0%**	**+2.3%**	**7.4**	**+2.4%**

Source: FARMAINDUSTRIA from IQVIA data and own estimations.

Updating of homogeneous groupings, along with the creation of new reference groups has led to the situation at the end of 2017 that 81.4% of units sold in the retail pharmacies market are sold at the same price level as their corresponding generic medicine.

Therapeutic groups

In 2017, and based on IQVIA data, **sales of medicines** through retail pharmacies by therapeutic groups were distributed as shown in the following table.

TOTAL SALES OF MEDICINES THROUGH RETAIL PHARMACIES BY THERAPEUTIC GROUPS (2017)

Therapeutic group	Units (thousands)	Share (%)	Inc. (%)	MSP values (thousands)	Share (%)	Inc. (%)	Average MSP (€)	Inc. (%)
N Nervous System	332,736.3	25.8%	+1.6%	2,281,775.4	23.1%	+2.4%	6.86	+0.8%
A Alimentary tract andmetabolism	202,001.9	15.6%	-1.4%	1,722,206.6	17.4%	+4.2%	8.53	+5.7%
C Cardiovascular system	250,608.6	19.4%	+1%	1,532,094.1	15.5%	-1.3%	6.11	-2.3%
R Respiratory system	123,058.9	9.5%	-0.9%	1,032,792.4	10.4%	-1.4%	8.39	-0.5%
G Genito-urinary system	53,629.6	4.2%	+0.6%	699,461.8	7.1%	+2.3%	13.04	+1.7%
B Blood and blood forming organs	66,732.4	5.2%	+1.2%	602,886.7	6.1%	+11%	9.03	+9.7%
M Musculoskeletal system	85,440.5	6.6%	-4.3%	462,164.4	4.7%	-1.9%	5.41	+2.5%
J Anti-infectives for systemic use	48,710.4	3.8%	-3.1%	419,140.3	4.2%	+2.7%	8.60	+6%
L Antineoplastic and immunomodulating agents	6,558.0	0.5%	+1.2%	358,635.2	3.6%	+3.8%	54.69	+2.6%
D Dermatologicals	49,767.7	3.9%	+0.7%	286,683.4	2.9%	+3.8%	5.76	+3.1%
S Sensory organs	43,642.2	3.4%	-3.5%	227,821.9	2.3%	-0.8%	5.22	+2.8%
H Hormones	22,112.1	1.7%	+4.9%	211,373.9	2.1%	+5.5%	9.56	+0.6%
V Various	1,428.6	0.1%	+1.9%	44,400.2	0.4%	+2.7%	31.08	+0.8%
P Antiparasitics	1,680.5	0.1%	+5.4%	10,049.2	0.1%	+14%	5.98	+8.1%
K Hospital solutions	3,857.2	0.3%	+7.8%	4,054.0	0.0%	+8.4%	1.05	+0.5%
TDiagnostic agents	17.2	0.0%	-17.2%	286.0	0.0%	-14%	16.66	+3.8%
TOTAL	**1,291,982.1**	**100%**	**0.0%**	**9,895,825.4**	**100%**	**+2.1%**	**7.66**	**+2.1%**

The **Central Nervous System** group, representing a quarter of the pharmaceutical market in units, grew +2.4% as a result of an increase in units of +1.6% and an increase of +0.8% in the average price. The increase in units is influenced by the increase in consumption of painkillers, which represents 47% of the units in this group. Regarding the average price, there was an increase for the first time since 2010, though in the part of the market subject to reimbursement the average price fell by -0.2%.

As for the **Digestive System** group, the -1.4% fall in the units was the consequence of the decrease in the consumption of anti-ulcer medicines, which represent 35.6% of units in this group, which fell by -4.8%.

With reference to the **Cardiovascular System**, after the average price increase last year, a drop of -2.3% was again recorded, influenced by the price decrease of some medicines in this group, within the dynamics of the homogeneous groupings.

The **Respiratory System** group had a decrease in units of -0.9% and -0.5% in average price. In this group, only 60% of the units sold are subject to reimbursement and their average price recorded again a fall of -4.1% as a result of the impact of reference prices.

New launches

In 2017, a total of 271 new medicines were launched in the retail pharmacies channel, with total sales of €67.3 million over the year. Of these, 198 are generic medicines, 20 are OTC medicines, 3 are medicines containing a new active ingredient, and the remainder are medicines with active ingredients or combinations of active ingredients already on the market.

Hospital Market

In the hospital market, and according to IQVIA data, 66.6% of sales are concentrated in two therapeutic groups:

1. **Group L.** Antineoplastic agents and immunomodulatory agents, in which antineoplastic agents account for 56% and immunosuppressive agents for 38.7%.

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

Through the new reference price order published on 28 November, 14 new groups have been created in the hospital setting so that the current number of reference groups amounts to 211 (113 of them correspond to clinical packs) of which 41 were created without a generic medicine and 5 are based on a biosimilar.

In 2017, 102 new medicines have been introduced into the hospital market, of which 47 are generic medicines, 2 are biosimilar medicines, 22 are new active substances, and the rest are medicines with active substances or combinations of active ingredients already on the market.

PHARMACEUTICAL FOREIGN TRADE[7]

The **production structure of the Spanish economy** has traditionally made our 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 our economy.

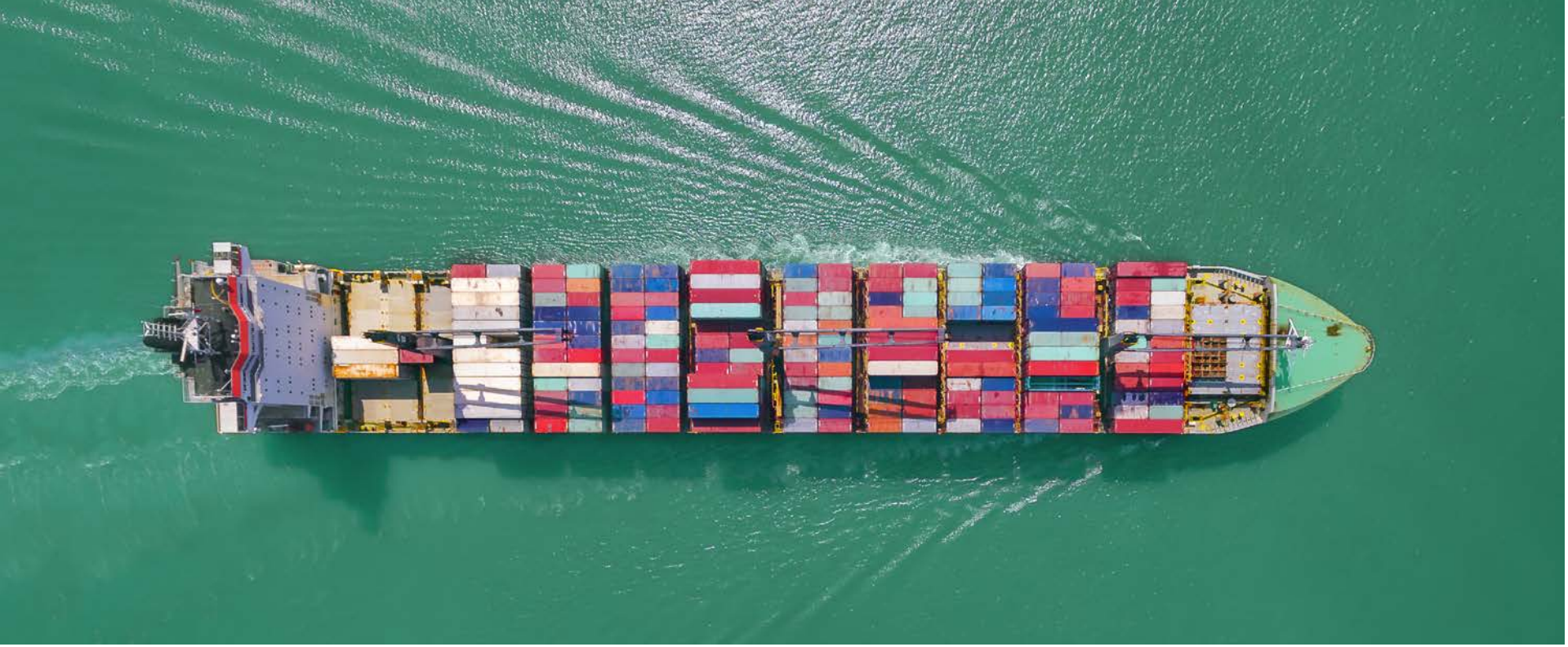
This trend is exacerbated in times of economic boom, in which our internal demand strongly drives imports, slowing down at times of economic activity deceleration, when foreign purchases to the reduce their pace and when furthermore companies based in our country are obliged to send their surplus production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

The described behaviour, together with the increased competitiveness of the Spanish economy seen in recent years, explains how the trade deficit in our 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).

[7] The data in this section are restricted to foreign trade of pharmaceutical products. The 2017 data are provisional, subject to subsequent review, and should therefore be interpreted with caution.

The traditional behaviour of our trade balance was later moderated during times of economic prosperity, since, despite the **economy upswing** experienced in the past four years (2014-2017), the **trade deficit** at the end of 2017 was 2.1% of the GDP, i.e., only five tenths above the 2013 figure, which remains the best result of our trade balance since 1995. The trade coverage rate (ratio of imports and exports) was 92% at the end of 2017, very close to the historical maximums recorded in 2013 and 2016 (93%). These coverage levels are far above those recorded by our economy before the crisis, when this ratio was 65%, which shows the paradigm shift experienced by our foreign sector.

This strong growth trend was seen again last year, in which Spanish exports recorded an increase of +8.9% as compared to 2016, though it is true that imports grew at an even higher rate (+10.5%), which explains the slight worsening of our trade deficit that went from 1.6% of the national GDP in 2016 to 2.1% in 2017.



Regarding foreign trade in pharmaceutical products, the trend was the reverse in 2017, with exports growing well above imports (+2.4% vs. -0.6%), which has allowed for the **reduction of the pharmaceutical trade deficit by -10.8%** in 2017, increasing the coverage rate for the pharmaceutical sector for the second consecutive year to over 80% (80.1%).

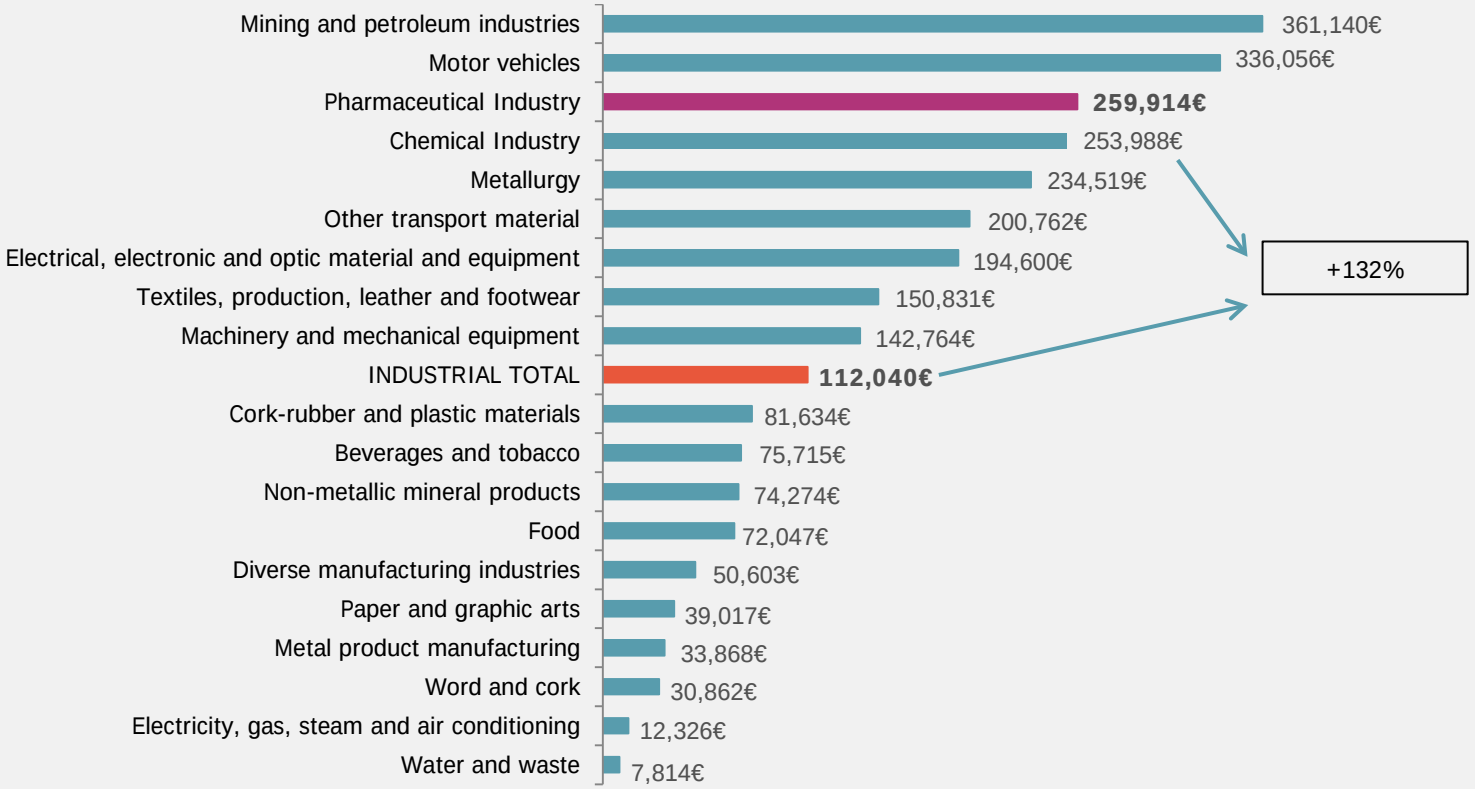
The buoyant export sector of the industry enabled the industry to close the 2017financial year with foreign sales of €10,898 million, which is the second largest record in the industry's history. These figures allowed the pharmaceutical industry to consolidate its position as the sixth most exporting sector of our economy in the classification by tariff chapters, reaching a share of 3.93% of total national exports.

However, the relevance of the pharmaceutical industry and its weight in our foreign trade sector is not only quantitative but also qualitative as shown by the fact that, according to the data of the INE, **pharmaceutical exports account for 27 % of total national exports** of high-tech products, making it the most important national economy sector in this area.

Furthermore, an analysis of the contribution of the pharmaceutical industry to the external sector of our country would not be complete if foreign competitiveness is not assessed. For this purpose, the relative indicators that assess the amount of exports of a sector in relation to its turnover, number of employees, etc. are highly illustrative. If the exports/turnover figure is analysed, the latest available data (year 2016) show how the pharmaceutical industry almost doubles the average of the industrial sectors altogether (78% vs. 41%).

On the other hand, if the export/employment indicator is used, the difference is even greater and places the pharmaceutical industry as the **third-ranking sector of the country in foreign competitiveness**, with exports of almost €260,000 per employee, which is more than twice the average of the Spanish industry, as shown in the chart below.

Main sectors of the national economy in exports per employee (2016)



With regard to the geographical distribution of pharmaceutical foreign trade, it should be noted that in 2017 the European Union continues to be our main business partner: **61% of Spanish imports of pharmaceutical products come from our European partners and** 51% of our exports go out to them.

Within the EU, Germany remains the main destination of our pharmaceutical production (23% of total exports to the EU), followed by France, Italy and the Netherlands. With regard to the United Kingdom, although it continues to be the fifth destination in the EU concerning importance by volume of exports, its share has dropped in recent years from 6.1% of Spanish pharmaceutical exports in 2015 to 4.6% in 2017.

It should also be noted that exports to the Irish market have doubled in 2017 and already account for 2.2% of our total exports of medicines.

For non-Community markets, which now account for half of the total Spanish pharmaceutical exports, the main destinations are Switzerland, the United States, Japan and China (in this order), which **account for 60 % of total pharmaceutical exports to** countries outside the European Union.

Economic Area	2016		2017 (p)	
	Export	Import	Export	Import
World Total	100.0%	100.0%	100.0%	100.0%
EU 28	51.9%	57.9%	50.9%	61.1%
Germany	12.2%	15.4%	11.4%	15.3%
Belgium	1.3%	6.2%	1.7%	8.7%
France	7.4%	6.3%	7.0%	7.3%
Netherlands	5.4%	6.4%	5.1%	6.9%
Ireland	1.1%	4.6%	2.2%	4.0%
Italy	6.9%	3.9%	5.6%	4.5%
United Kingdom	5.1%	6.3%	4.6%	5.9%
Rest of Europe	**17.7 %**	**10.1 %**	**19.3 %**	**9.0 %**
Switzerland	15.6%	9.8%	17.1%	8.7%
Rest of the world	**30.5 %**	**32.0 %**	**29.8 %**	**29.9 %**
China	2.4%	3.1%	2.45%	3.0%
United States	7.3%	21.2%	7.1%	19.2%
India	0.3%	0.8%	0.3%	1.0%
Japan	3.4%	0.8%	3.1%	0.5%

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

Note: (p) provisional.

NHS SPENDING FOR 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%	12.75	-4.8%
2011	11,135.4	-8.8%	973.2	+1.6%	11.44	-10.2%
2012	9,770.9	-12.3%	913.8	-6.1%	10.69	-6.6%
2013	9,183.2	-6.0%	859.6	-5.9%	10.68	-0.1%
2014	9,360.5	+1.9%	868.6	+1.1%	10.78	+0.9%
2015	9,535.1	+1.9%	882.1	+1.6%	10.81	-0.3%
2016	9,912.8	+4.0%	901.6	+2.2%	10.99	+1.7%
2017	10,170.8	+2.6%	908.5	+0.8%	11.19	+1.8%

Source: Medical Prescription Invoicing. MSSSI.

PUBLIC PHARMACEUTICAL EXPENDITURE ON OFFICIAL NHS PRESCRIPTIONS

According to the MSSSI data, in 2017 public pharmaceutical spending in retail pharmacies on official **NHS** prescriptions **grew by +2.6%, to stand at €10,170.8 million**, as a consequence of a +0.8% increase in the number of prescriptions and a +1.8% increase in average spending per prescription.

REGIONAL DISTRIBUTION OF PUBLIC PHARMACEUTICAL SPENDING PER CAPITA

Public pharmaceutical spending on official NHS prescriptions was on **€218.40 per inhabitant in 2017,** an increase of +2.6% versus 2016.

At a regional level, the regions with the greatest pharmaceutical spending per capita are **Extremadura, Asturias and Galicia**, while those with lowest spending are the Balearic Islands and Madrid.

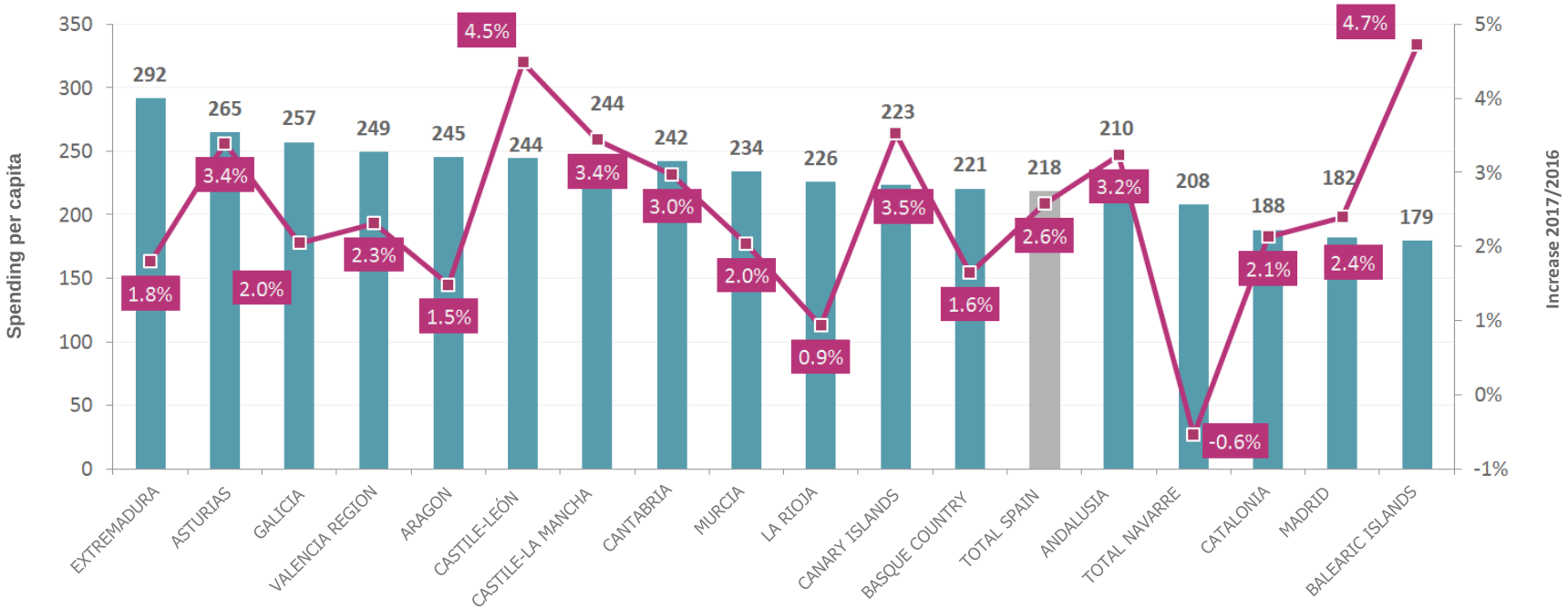
Regarding the changes in pharmaceutical spending per capita, **Navarre is the only region where this scale declined in 2017** (-0.6%). All other regions recorded increases.

PHARMACEUTICAL SPENDING PER CAPITA PER REGION (2017)

Region	Spending share(%)	€ per capita	Inc. (%)
Extremadura	3.1%	291.6	1.8%
Asturias	2.7%	264.9	3.4%
Galicia	6.9%	257.2	2.0%
Valencia Region	12.1%	249.3	2.3%
Aragon	3.2%	245.4	1.5%
Castile-León	5.8%	244.4	4.5%
Castile-La Mancha	4.9%	243.5	3.4%
Cantabria	1.4%	242.4	3.0%
Murcia	3.4%	234.1	2.0%
La Rioja	0.7%	225.6	0.9%
Canary Islands	4.6%	223.4	3.5%
Basque Country	4.8%	220.6	1.6%
Total Spain	**100.0%**	**218.4**	**2.6%**
Andalusia	17.4%	210.2	3.2%
Navarre	1.3%	208.1	-0.6%
Catalonia	14.0%	188.1	2.1%
Madrid	11.7%	182.4	2.4%
Balearic Islands	2.0%	179.5	4.7%

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

PHARMACEUTICAL SPENDING PER CAPITA ON OFFICIAL NHS PRESCRIPTIONS PER REGION 2017



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

4 Member Services

4.1 Online services

As part of the continuous process of modernising the services provided to member pharmaceutical companies, FARMAINDUSTRIA continued to incorporate intranet improvements with the industry (https://www.farmaindustria.org) and on the public website http://www.farmaindustria.es/ Significant improvements have also been made to the merger of the Gazetters (https://nomenclator.farmaindustria.org) developed from the AEMPS and MSSSI databases.

On the other hand, five websites for managing Royal Decree-Laws 8 and 10/2010 have been developed, one internal for implementation of the procedure and four external for pharmaceutical companies, provincial pharmacist associations, the managing bank and General Council of Official Pharmaceutical Associations.

Finally, we incorporated a new website to online services of the Association by opening the new Series and Tables website to the industry (https://series.farmaindustria.org), with over 3,000 data series related to the pharmaceutical industry and its socioeconomic environment.

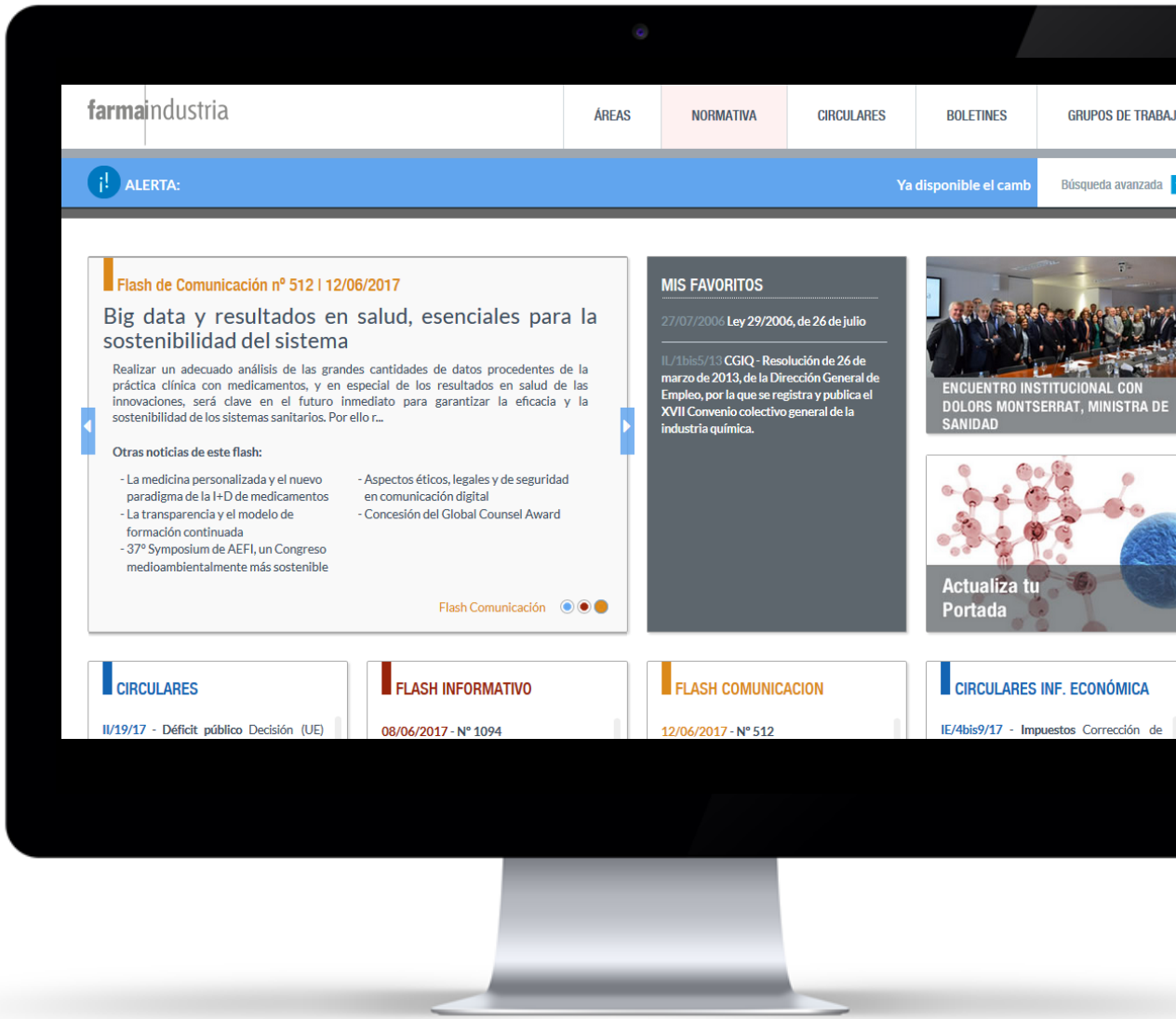
CORPORATE WEBSITE. INTRANET WITH THE INDUSTRY

For the exclusive use of member companies, it contains over 80,000 documents, in over 50 categories, including circulars, publications, departmental areas, flashes, newsletters, regulations, etc.

It has a personalised home page for each of the 2000 registered users in the industry, allowing them to choose what should be summarised on their home page and what they can access with a just a click.

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

Each FARMAINDUSTRIA working group has a private space, structuring its fast, secure access for over 800 members. It also includes documentation for the Association's Statutory Groups.



PUBLIC WEBSITE

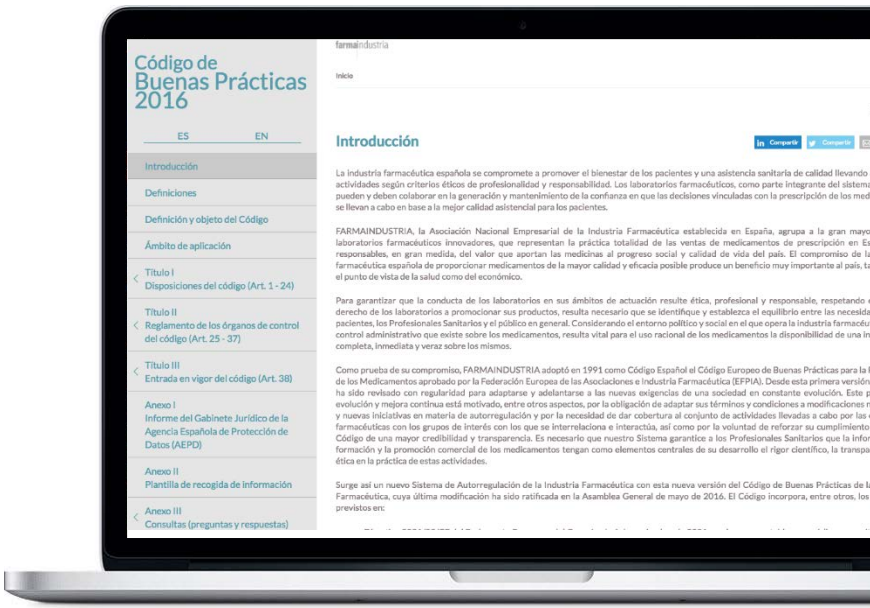
The FARMAINDUSTRIA public website is especially designed to **put across information** clearly, quickly and openly to anyone interested in the Spanish pharmaceutical industry.

In turn, the websites for Innovative Medicines and Somos Pacientes are developed and maintained, which provide information on medicine innovation and technological platforms and the collaborative environment for the community of patient associations, respectively.

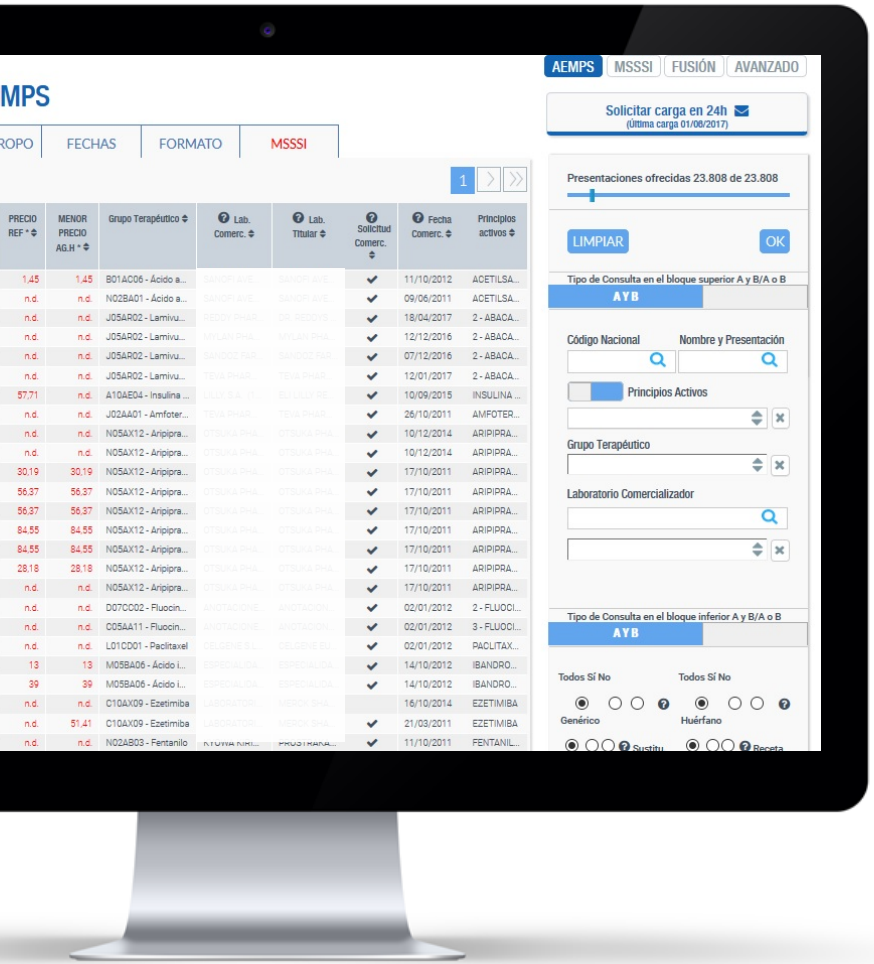
SELF-REGULATION SYSTEM WEBSITE

In 2017, the **Self-Regulation System** website and its micro-site **Code of Practice** were improved.

From this website, not only is it possible to access to the Code of Practice or the Practical Case Test, but all the information on transparency, control bodies, regulatory framework, list of training activities, in addition to incorporating an area reserved for the management and reporting of events and scientific meetings.



FOUR GAZETTER MICRO-SITES



The format that the MSSSI and the AEMPS use to publish the information of their gazetters is complex for the industry when making queries or accessing their data. Therefore, FARMAINDUSTRIA has developed four micro-sites which allow the user to make all types of queries, analysis and to export this information.

Some additions were made in 2017 and included the following:

- **AEMPS Site**: A configurable and customizable view generator for each user, who can define his own permanent selection of fields to be displayed.
- **Merger Site**: New views of several classifications.
- **Advanced Site**: Filters in change control for new additions and presentations deleted for each load or interval.

NEW WEBSITE OF SERIES AND TABLES

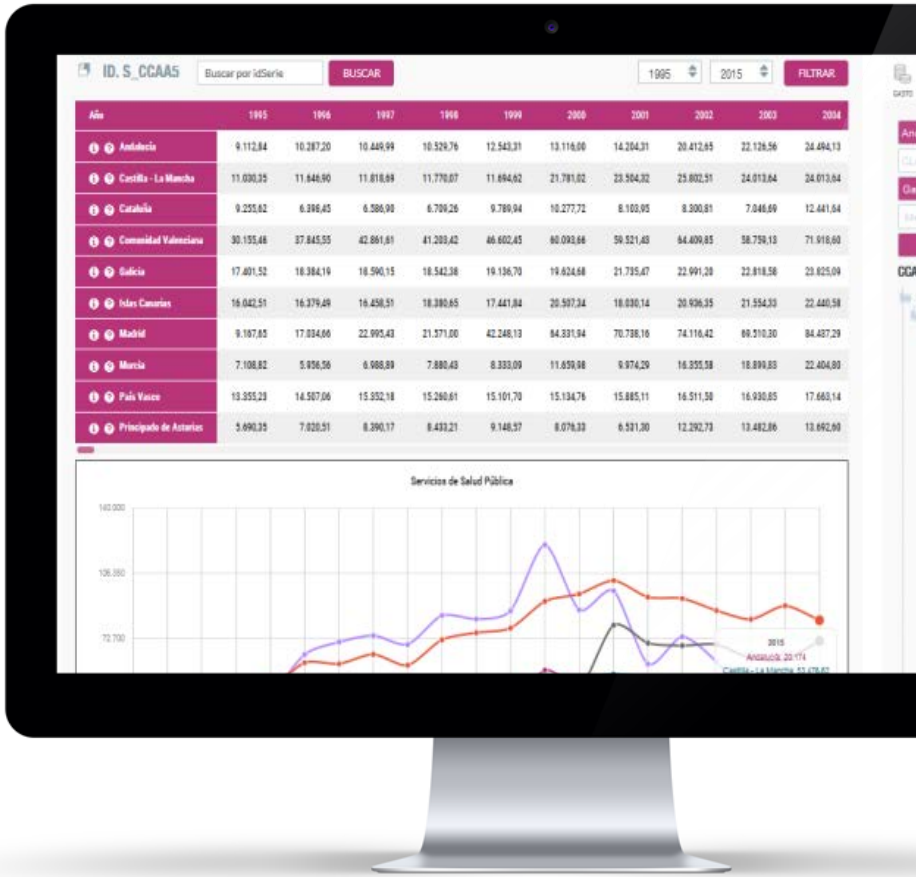
In 2017, the Association's online services included a website that grouped more than **3000 data sets**, categorised into five sections: Spending, HR, GDP, Demography and Regions.

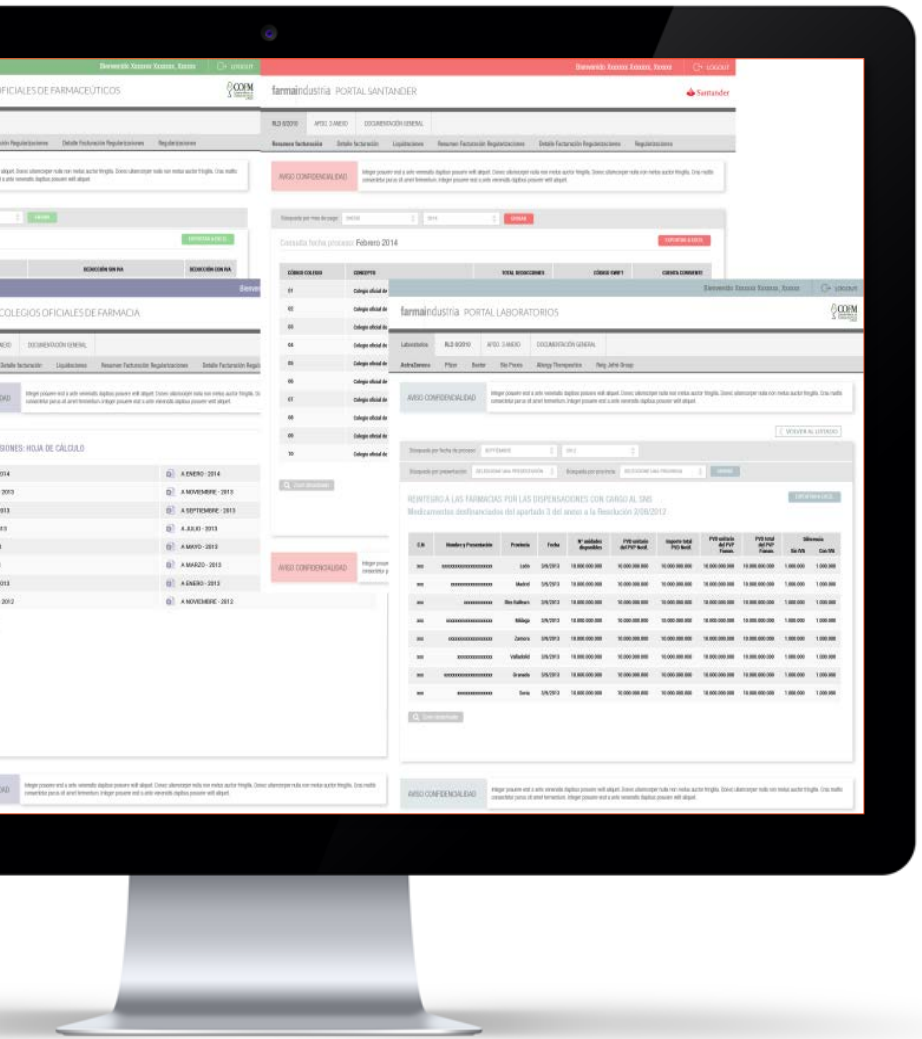
Among other functions, the tool allows **to delimit the working period** and export it to Excel, print it or generate charts.

A table generator has also been designed whereby it is possible to compare, in the same table and in the same graph, up to ten series chosen from among the more than 3,000 available.

Each series includes information on how it was generated, whether data from different sources (and what they are) needed to be pooled, the date of its updated, and an explanation of its evolution and content.

This tool will be refined during the year 2018 and the final aim is to make it available to the general public.





WEBSITES FOR MANAGEMENT OF ROYAL DECREE-LAWS 8/2010 AND 10/2010

In 2017 and 2018, **four management websites** of Royal Decree-Laws 8 and 10/2010 will go into production (for pharmaceutical companies, provincial pharmacist associations, the management bank, and General Council of Official Pharmaceutical Associations), migrating the service to a modern environment, integrated with the languages and designs from the other websites.

The operating mode will be more intuitive and less dependent on the each user's profile in terms of updates to operating systems and other tools of the different personal teams.

These new websites provide all stakeholders with a **powerful and agile tool** for this exchange of information necessary for the management of payments derived from Royal Decree-Laws 8/2010 and 10/2010, in addition to also managing the procedure regulating definanced medicinal products in Section 3 of the Annex to Resolution 2/08/2012, on notified/financed prices.

4

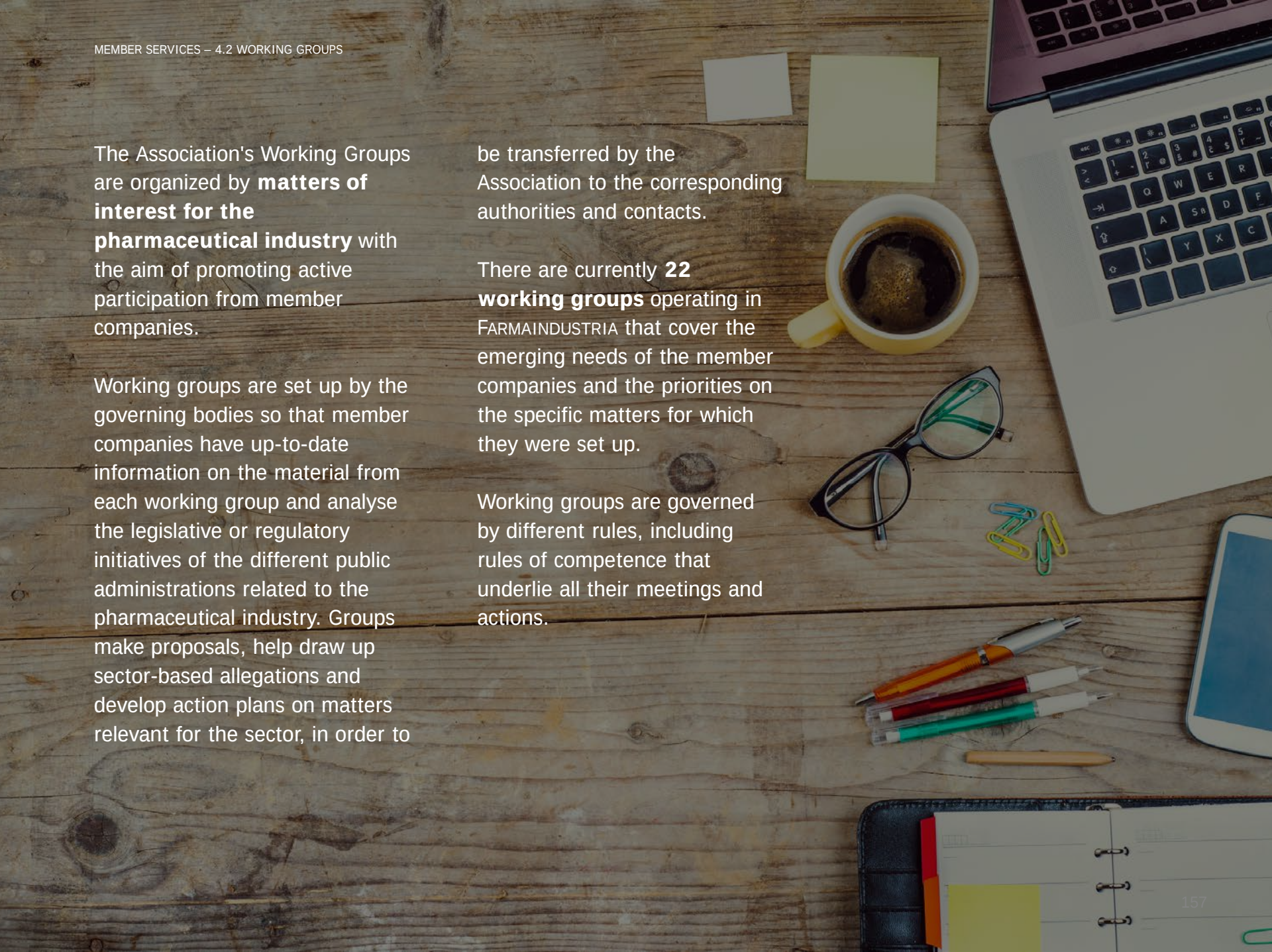
Member Services

The Association's Working Groups are organized by **matters of interest for the pharmaceutical industry** with the aim of promoting active participation from member companies.

Working groups are set up by the governing bodies so that member companies have up-to-date information on the material from each working group and analyse the legislative or regulatory initiatives of the different public administrations related to the pharmaceutical industry. Groups make proposals, help draw up sector-based allegations and develop action plans on matters relevant for the sector, in order to be transferred by the Association to the corresponding authorities and contacts.

There are currently **22 working groups** operating in FARMAINDUSTRIA that cover the emerging needs of the member companies and the priorities on the specific matters for which they were set up.

Working groups are governed by different rules, including rules of competence that underlie all their meetings and actions.



The current list of working groups is given below:

1. Sustainability and Economic Regulation.
2. *Health Technology Assessment (HTA).*
3. Hospital Debt.
4. Hospital Market.
5. Technical Regulation of Medicines.
6. Biological Medicines.
7. Manufacturing and Traceability.
8. Environment.
9. Pharmacovigilance.
10. Vaccines.
11. Farma-Biotech.
12. Medical and Research Directors (BEST).
13. Clinical Research.
14. Legal Services.
15. Taxation.
16. Human Resources.
17. Code of Practice.
18. Competitiveness and Internationalisation.
19. International Working Group.
20. Relationships with Regions.
21. Communication and Corporate Social Responsibility.
22. Patients.
23. Barcelona Delegation.

In addition, depending on the issues and with a lower level of participation, there are a few ad hoc groups, set up with the aim of going into greater depth different aspects and finally transferring the results to the corresponding plenary working group.

A summary is presented below of Farmaindustria working groups' activities over 2017.

1

Sustainability and Economic Regulation Working Group

The regulations related to economic regulation in the pharmaceutical sector and the most significant news in this area have been the focus of activity of this working group over the last year.

One of the priority issues included in the agenda of the meetings of this working group has been the Collaboration Agreement with the Spanish government, effective since 2015 in order to guarantee the sustainability of the National Health System and the access of citizens to innovations. This Agreement was renewed for the financial year 2018. The group receives timely information on the development of the Agreement, particularly on the changes in the economy and public pharmaceutical spending and access indicators, as well as possible scenarios for 2018.

Another issue that has focused the interest of the working group is the possible reactivation of the Draft Royal Decree on Price and Financing, on which the MSSSI continues to work and about which FARMAINDUSTRIA has communicated the industry's priorities.

On the other hand, in each of its meetings the working group receives detailed information on **monitoring of access to innovations** and indicators relating to innovations performed by the Association, with special monitoring of the publication of **Therapeutic Positioning Reports** (IPT) and implementation of their conclusions.

Furthermore, the detailed analysis performed on Order SSI/1157/2017, of 28 November, by which the reference price system for medicinal products in the National Health System is updated in 2017 in order to prepare the pertinent allegations.

Periodically and in coordination with the **Manufacturing and Traceability Working Group**, the Sustainability and Economic Regulation Working Group monitors the work being undertaken by FARMAINDUSTRIA and the Spanish System for Verification of Medicinal Products (SEVeM) to comply with the provisions of both the Falsified Medicines Directive and its Delegated Regulation, and article 94.7 of Royal Legislative Decree 1/2015, of 24 July, approving the Consolidated Text of the Law on guarantees and rational use of medicinal products and medical devices, on notified prices in retail pharmacies.

Over the past year, the group has closely followed the Public Consultation prior to the **Draft Amendment** of Royal Decree 177/2014 on reference prices that the Ministry is working on in order to resolve some practical aspects in the application of reference prices.

Finally, the members of this working group are informed timely of the developments discussed within the Health Technology Assessment (HTA) Working Group related to the proposal of the Regulation on Health Technology Assessment, published by the European Commission in early 2018, with the aim of improving the functioning of the single market in terms of the availability of innovations for all European patients, in turn providing a framework of greater predictability to pharmaceutical companies.

2

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 group has continued working to promote the measurement of health outcomes that in the future will contribute to the transition of more sustainable health systems based on value and patient outcomes. These studies have been conducted both nationally and internationally by monitoring the different ongoing initiatives (e.g. ICHOM), with special attention paid to Coordination and Support Action (Do-It Programme) of the IMI Big Data for Better Outcomes (BD4BO) initiative that started in February 2017 and in which FARMAINDUSTRIA participated, and which is discussed in other sections of this Annual Report.

It has also closely followed progress towards the proposal of the European Commission on the regulation of health technology assessment published in January 2018, as well as joint assessments of the relative efficacy of medicines at the European level (EU REA) developed within the Joint Action 3 of EUnetHTA (2016-2020) and which have implications for Spain.

In the national setting, this working group has continued to monitor the degree of follow-up in practice of the recommendations of the Therapeutic Positioning Reports (IPT) prepared by the AEMPS, while analysing the various practices and initiatives for the assessment of medicinal products at both the national and regional or local levels.

3

Working Group on Hospital Debt

Over the last twelve months, this Group has carried out monthly monitoring of the debt incurred by supplying medicines to NHS hospitals, as well as the average payment periods (DSO) for the different regional health services.

This group continues to monitor the **impact of late-payment measures**, particularly in terms of payments made through the Regional Liquidity Fund (FLA). These payments, together with those made through the ordinary cash flows of the autonomous regions, which are becoming increasingly important, have given the best closure of financial year in the pharmaceutical industry in 2017 since historical series are available (1996), as the NHS's DSO was reduced to 81 days.

During the past year, this working group has 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 or modification of the calculation system for the average payment period published monthly by the different Public Administrations, without losing the processing of the various ongoing regulatory proposals aimed at combating late payment in business operations.

The Working Group on Hospital Debt has an ad hoc Subgroup on Electronic Invoicing (SG FAC), which has continued its close monitoring of electronic invoicing implementation by the regions and the General State Administration, compulsory since January 2015.

4

During 2017, FARMAINDUSTRIA has continued to participate at the institutional level in the various forums related to the electronic invoice:

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

This last working group requires special mention as it includes the MINHAFP initiative which aims to move forward in the **drive for the electronic administration** and implementing electronic invoicing between companies in the private sector (B2B electronic invoicing project). After reviewing the measures of success of the public sector electronic invoicing model, this working group is focusing its work on promoting those necessary and viable invoicing relations between private sector companies, having transmitted to FARMAINDUSTRIA its position on those aspects considered relevant by the innovative pharmaceutical industry for B2B electronic invoicing.

Hospital Market Working Group

This Working Group focuses its work on monitoring the hospital market and analysis (economic, legal and market access) of any national and regional initiatives, particularly regarding regulation, management agreements that might limit supply and access to innovative medicines, as well as freedom of prescription, implementation of regional management models and prompt payment guarantees.

Due to its objective, this Group is working closely with the Hospital Debt, Biological Medicinal Products, Regions and Economic Working Groups. The Group consists of **representatives of 48 pharmaceutical companies** and it met on three times in 2017.

Technical Regulation of Medicines Working Group

The main activities of this working group focus on analysing regulations from European institutions and those published by the MSSSI and the AEMPS referring to the procedures for the authorisation, registration and marketing of medicinal products, particularly the regulations for developing **Royal Legislative Decree 1/2015 approving the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices**. This working group focuses on analysing subjects with a major technical aspect, such as fees, labelling and package leaflet, authorisation applications and modifications, authorisation validation, Sunset clause, classification of medicines without commercial interest, etc.

In 2017, the working group analysed, among other issues:

1. The future implementation of safety features in medicine packaging subject to Delegated Regulation 2016/161, of 2 October 2015.
2. The process for the identification of medicinal products with no commercial interest being carried out by FARMAINDUSTRIA in order to identify among the medicinal products marketed in Spain the presentations whose lack could have a negative healthcare impact.
3. Significant changes in medicine registrations as a result of Brexit.

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

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

Finally, at one of its meetings in 2017, this working group received a visit from the AEMPS Head of Area of Licensing and Standardisation of Medicines, who provided information about

the benefits of dividing the summary of product characteristics and package leaflet of centralised medicinal products; the (voluntary) inclusion of photos of the packaging material/pharmaceutical form in RAEFAR; the update of the ISO IDMP/SPOR project, and the way in which safety features are submitted to comply with the Delegated Regulation on serialisation.

6

Biological Medicines Working Group

Biological medicines are becoming increasingly more important therapeutically and economically, as they represent a major advance for certain serious diseases. In addition, these medicines have differential characteristics compared to chemical medicines, which has led to special attention being paid to them.

From a regulatory point of view, the uniqueness of biological medicines determines their prescription by trade name (brand name) and their notification by brand and batch number. They are also considered medicines with special monitoring for pharmacovigilance purposes.

For all the above, this working group particularly monitors key aspects related to biological medicines in the area of regulation, authorisation processes and access.

The international area is also making especially relevant decisions on the use of biological medicines once they have lost market exclusivity. At all its meetings, this working group looks into new issues that affect these medicines in other countries.

7

Manufacturing and Traceability Working Group

The publication of Commission Delegated Regulation (EU) 2016/161, which regulates packaging safety features (single identifier and anti-tampering device) and which will be applicable on 9 February 2019, has led to considerable changes and adaptations in the area of manufacturing and traceability which are subject to timely monitoring by this working group.

The new obligations for verification and serialization of medicinal products has a significant impact on the industry, including changes in production and systems to be applied by pharmaceutical companies in packaging lines, which involve substantial investments over a short and limited time period. Medicine registration and marketing activities will also be affected.

This new scenario has raised many questions that have been channelled to different areas of the Association. Those referring to the **manufacturing area** have been discussed in this working group, helping to better understand the provisions published by both the European Commission and the AEMPS. In particular, this working group must consider the requests made by the **Directorate General for Basic Services and Pharmacy Portfolio**, to facilitate hospital verification and unit identification of medicinal products on primary packaging.

Furthermore, as the aforementioned Delegated Regulation provides that national authorities may regulate matters of their competence, the MSSSI is expected to promote a Royal Decree in 2018 covering all aspects related to the verification of medicinal products in Spain.

Finally, the usual points of this working group include the importance of guaranteeing medicine supply or inspections conducted by non-Community authorities.

8

Environment Working Group

During 2017, and in collaboration with SIGRE, this working group monitored important legislative regulations for the pharmaceutical industry regarding the environment, such as a circular economy, waste, environmental responsibility, climate change and energy transition, potential soil contaminants or spills.

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

Pharmacovigilance Working Party

This working group **channels the main questions and clarifications** derived from both national and European pharmacovigilance provisions. In 2017, a follow-up was performed of the development of the Royal Decree on post-authorisation studies and data protection issues, and the guidelines to be considered in the future Code of Conduct on the processing of personal data in pharmacovigilance.

The Group holds regular meetings and they cover seven well-defined topic areas:

1. Inspection and audits.
2. Risk management plans.
3. Master File.
4. Expedited reporting.
5. Periodic safety reports.
6. Pharmacovigilance and the Internet.
7. EFPIA Pharmacovigilance Group.

9

Finally, the Heads of the Division of Pharmacoepidemiology and Pharmacovigilance of the AEMPSin participated in one of the group meetings, and presented the current situation and challenges for 2018 in terms of pharmacovigilance (GVPs, spontaneous reporting and signals, periodic safety reports, post-authorisation studies and risk minimisation measures and their impact) and news on signal management in the EU.

Vaccines Working Group

Among the main issues dealt with in 2017 by this working group is 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 sensation of security for certain diseases that are erroneously considered to have been nowadays overcome, or the lack of confidence in vaccination generated by social beliefs or influences. Various European institutions and Vaccines Europe are working together on this with the goal of placing vaccines back in international health recommendations, especially in the case of adult vaccination.

One of the meetings of the group was attended by the Head of the AEMPS Vaccines Area to discuss the **main challenges in vaccine evaluation and control** at the European level and the role that Spain plays in this area.

Finally, this working group addressed technical issues relating to serialisation, adherence, or supply problems related to this type of product whose marketing is also unique.

11

Farma-Biotech Working Group

This group, made up of **37 companies**, works on goals such as **promoting cooperation** between the industry, small biotechnology companies and public research centres, highlighting the differential, complementary aspect that FARMAINDUSTRIA CAN CONTRIBUTE.

In 2011, FARMAINDUSTRIA launched the Farma-Biotech cooperation programme and since then 16 interactive meetings have been held between the two sectors, mainly in the areas of the central nervous system, oncology, respiratory system, inflammation and autoimmune diseases. Forty-one companies and 29 research centres and hospitals participated in these meetings, presenting the advanced research projects selected for their potential for innovation. At the different meetings, there have been more than 40 pharmaceutical companies interested in the projects presented.

This working group also seeks **to promote public-private cooperation instruments** in R&D and therefore has held various meetings with the Centre for Technological and Industrial Development (CDTI) and with the Ministry of Economy, Industry and Competitiveness, in order to **study new aids** or modify some existing ones according to industry demands.

This working group also seeks to stimulate the participation of companies in national and international pharmaceutical R&D programs, especially the Innovative Medicines Initiative (IMI) and the actions of the Spanish Technology Platform for Innovative Medicines (PTEMI).

12

Medical Directors and Research Directors (BEST Project) Working Group

This working group, set up twelve 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 the processes and improving performance indicators (time, recruitment, international comparison) to achieve the best environment for conducting clinical trials in our country, with particular emphasis on early phases.

Spain is currently a particularly attractive country for clinical research, highlighting:

1. Greater involvement from all stakeholders (hospitals, investigators, scientific societies, patients, CREC, etc.
2. All stakeholders value clinical research.
3. Spain has become more competitive internationally.
4. Dialogue flows easily between strategic agents (industry, research sites and regions).

The BEST Project is currently made up of 45 pharmaceutical companies, 3 scientific societies, the University of Navarra Clinic (CUN), 13 regions and 60 centres.

During 2017, within the framework of the BEST Project, the **Guide to Clinical Research Units in Paediatrics in Spain** was drawn up (available in Spanish and English at www.medicamentos-innovadores.org) in collaboration with 30 Research Units in Paediatrics. This guide was presented publicly at a conference organised at Hospital Niño Jesús in Madrid on 20 September 2017 and is structured around two main sections. The first section provides an overview of the clinical research units in paediatrics and the second section presents in detail the characteristics and capabilities of each unit.

As of July 2017, FARMAINDUSTRIA in collaboration with the AEMPS and Vall d'Hebron Institute of Oncology (VHIO), organized a work session on **adaptive designs for clinical research in oncology**, whose objective was to share - with the regulatory authorities that must approve these trials -, the new scientific paradigms that support this type of research, in order to facilitate its conduct in Spain, with all guarantees for patients.

During 2017, workshops were held with different patient associations in the areas of oncology and hematology to explain what the R&D process is for a new medicine, the applicable legislation, what agents are involved, etc.

In 2017, three workshops were held in the cities of Málaga, Barcelona and Madrid for secondary students focused on disseminating what R&D of new medicines involves, what are its phases and what it means for society.

Representatives from FARMAINDUSTRIA and speakers from different medicine R&D fields, such as investigators, AEMPS, ethics committees, etc.

Similarly, and within the BEST Project, in 2017 FARMAINDUSTRIA ran a study on the clinical research conducted by the pharmaceutical industry in private centres. Data were presented jointly with the Institute for Healthcare Development and Integration (IDIS) during the Session entitled "Innovation in private centres with a view to 2018", held in Madrid on 27 April. This event involved more than 100 agents involved in pharmaceutical R&D.

13

Clinical Research Working Group

Over the last year, this group has carried out intense **monitoring of Spanish and European legislative initiatives** regarding clinical research, particularly Regulation 536/2014, of the European Parliament and of the Council of 16 April 2014, published in the Official State Journal on 27 May 2014, and of the new Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, medicinal product research ethics committees and the Spanish Clinical Studies Registry, which entered into force on 13 January 2016. Both texts seek greater transparency, simplification and harmonization of processes,in order to make clinical research more competitive. Spain was first country in the EU to implement the new European regulation on clinical trials.

To achieve the objectives of simplifying and harmonising the processes established by the new Royal Decree and for Spain to be prepared for the application of the new European Regulation on clinical trials in 2019, FARMAINDUSTRIA is working closely not only with the AEMPS but with research managers from the regions, public and private hospitals, investigators, ethics committees, patients and other agents involved, by holding a significant number of meetings with all of them in 2017.

In 2017, FARMAINDUSTRIA, together with the Spanish Society of Clinical Pharmacology, drew up a model thank you letter for the patient after participation in a clinical trial. In addition, this model took into account the provisions of current Spanish and European regulations regarding the sponsor's obligation to publicly report the results of the clinical trial conducted within one year of its completion. European regulations have established that a summary written in a language understandable to a lay person (someone without specialised knowledge) should also be prepared, according to the content established in Annex V of EU Regulation 536/2014.

During 2017, FARMAINDUSTRIA has worked intensely so that the **Supplemental Instructions Document** of Royal Decree 1090/2015, of 4 December, responds to the sector's needs and has also worked with the AEMPS and mpRECs so that the annexes to this document are also adapted to the demands of the pharmaceutical industry and translated into the English language. All this information is available on the AEMPS website.

As of 25 May 2018 the new General Data Protection Regulation EU 2016/679 will be fully applicable, FARMAINDUSTRIA is working with the Ethics Committee Group to try to **agree on an informed consent form** adapted to the new regulation. The Association is also working on updating the Standard Code on Personal Data Protection in the field of clinical research and pharmacovigilance of 2009 to the new European and national regulations on data protection.

In the last half of 2017, a working group consisting of representatives from the Farmaindustria Patients Working group, BEST and clinical research groups, together with representatives from the patient groups (EUPATI and the Platform of Patient Organizations), was created in order to develop a guideline of recommendations on the relations between pharmaceutical companies and patient associations in the field of R&D of innovative medicines.

The action plan includes, but is not limited to:

1. Patient participation in future review of the lay summary (summary for laypersons of the results of each clinical trial).
2. Review of the informed consent form (published by the AEMPS) to make it more accessible to patients and in accordance with the new General Data Protection Regulation.
3. Review of the design and content of the Spanish Clinical Studies Registry to simplify and optimize its use.
4. An international benchmarking study on practical cases involving patient associations in medicine R&D activities.

14

Legal Working Group

In the year covered by this Annual Report, this working group's actions have focused on monitoring all matters that might be of interest to group members in its field due to their legal implications, as well as for other departments of the companies to which the legal managers provide support.

These issues include new legislation approved or being processed at the European, national or regional level, which is reported in detail in other sections of this Annual Report, as well as the most relevant jurisprudence affecting the sector. However, this section highlights some regulations of interest that have also been addressed by this working group.

With regard to the General Data Protection Regulation (RGPD), the different actions carried out by FARMAINDUSTRIA, both internationally and nationally, in matters such as the recognition of scientific/biomedical research as an activity of public interest, the definition of public interest or pseudonymisation, have been reported.

These issues have subsequently been transferred to the Draft Law on Personal Data Protection that continues its processing. In parallel to this processing, work has started on updating the Standard Code on Personal Data Protection in Clinical Research and Pharmacovigilance, and meetings have been called with the representatives of Farmaindustria's Clinical Research, Pharmacovigilance and Legal Services Working Groups.

At **national level**, several regulations have been subject to analysis in this working group, in addition to those referred to in the regulatory framework section of this Annual Report:

1. General State Budget Law for 2017 in which FARMAINDUSTRIA promoted different amendments relating to taxation of educational grants for healthcare professionals and the reference price system.

2. Royal Decree amending the Personal Income Tax Regulation, among other taxes, clarifying that educational grants for healthcare professionals (and other workers) are not remuneration in kind for the purposes of personal income tax.

At **regional level**, the following regulations have been followed, among others:

1. Draft Law on Guarantees and Sustainability (Andalusia), currently going through Parliament.

2. Order creating the network for rational use of medicinal products and medical devices (Aragón), set up as an advisory body to provide healthcare professionals with tools to aid prescription.

3. Draft Law to amend Health Law 10/2014 submitted to the Courts of Valencia, recently approved by the Valencian Courts and pending publication.

Regarding jurisprudence, in addition to the Constitutional Court Decisions of 2017 on the auctions of Andalusia, which confirm that the selection of the medicine to be dispensed for a prescription of an active ingredient falls to the **Andalusian Health Service,** the EU General Court Decisions of February 2018 on access to EMA documents submitted for the marketing authorisation application for a medicinal product should also be noted. In the latter decision, the Court validates the position of the EMA favourable to access the information due to a overriding public interest in its disclosure, while respecting the commercial information that is confidential.

Of great relevance to the sector was the Supreme Court Decision of 29 January 2018 regarding the Framework Agreement of the Andalusian Health Service, which recognises that **batch formation must be by active substance and interchangeability**, not by indication, even if the same ATC classification is shared. The Chamber also shares the Decision of the Central Administrative Court for Contract Appeals of 27 March 2013, which discussed the composition of batches by active substances rather than therapeutic indications and which reminds that article 86.3 TRLCSP permits the fractionation of the purpose of the contract, provided the functional unit is respected. In this regard, it states that the only groupings of medicinal products set down in the Law (and, therefore, functional units of medicinal products) are those indicated in Article 93.2 of Law 29/2006 of 26 July, LGURMPS: the groups for presentations of medicinal products having the same active ingredient and the same administration route; and in additional provision 14.2: Homogeneous grouping of medicinal products, with the same active ingredient and interchangeability.

This important decision confirms the interpretation Farmaindustria and member companies have been defending regarding the need to take into account the particularities of pharmaceutical legislation in administrative contracting, as well as in other cases where general legislation applies.

Finally, the Higher Court of Justice of Cantabria, by Decision of 27 July 2017, has ruled that the administrative appeal lodged by FARMAINDUSTRIA against Order SAN/31/2016 establishing the Corporate Pharmacy Committee within the scope of the Cantabria Health Service, annulling the above-mentioned order as it was considered a provision affecting the rights of third parties (health professionals), from the time this Committee took on functions such as the preparation of a form for medicinal products and evaluation of proposals for the inclusion of new medicinal products, so the mandatory hearing proceedings should have been done for the adoption of such a provision.

This decision was the subject of an appeal for judicial review by the Cantabria regional administration, an appeal that was dismissed by the Supreme Court by means of the order of 9 March 2018 as no argument has been made as to the interest for review of the matter or on the sufficient relevance of the general provision annulled.

The members of this working group have been informed, in addition to other relevant issues, such as those relating to the Collaboration Agreement between FARMAINDUSTRIA and the General State Administration, which was extended for the year 2018, of the actions carried out in relation to the Code of Practice or the negotiation status of the 19th Collective Bargaining Agreement of the Chemical Industry, among others.

At the meetings of this working group, several presentations have been given on regulations or issues of interest, in addition to presentations by high-level guests, such as Mr David Mellado, Ex-Technical General Secretary of the Ministry of Finance and Public Administrations Public and Ms Nuria Díaz Abad, member of the Standing Committee of the General Council of the Judiciary.

15

Tax Working Group

This working group focuses on the analysis and monitoring of all issues with tax implications for the pharmaceutical industry and held several sessions during the year to address relevant topic for member companies.

At the beginning of 2017, the traditional **Annual Taxation Seminar** was held (open to all member companies), attended by fifty managers in charge of tax and finances from pharmaceutical companies. This seminar was used to analyse - among other aspects that will be presented further on -, relevant aspects of Royal Decree-Law 2/2016, of 30 September, introducing tax measures aimed at reducing the public deficit, the most relevant issues of Royal Decree-Law 3/2016, of 2 December, on tax measures aimed at consolidating public finances, and all new developments related to the BEPS project, in addition to relevant jurisprudence and doctrine for the industry.

The status of the tax treatment of **educational grants for healthcare professionals** made by pharmaceutical companies has been one of the priority issues for this working group, monitoring the doctrine and pronouncements of the Central Economic-Administrative Court (TEAC) and Spanish Tax Agency (AEAT) on this matter and subsequent processing of the regulatory modification of Article 44 of the Income Tax Regulation, which has culminated with the approval of Royal Decree 1074/2017, of 29 December. With the publication of this regulation, the Government has definitively clarified that, under the terms set out in Article 44, educational grants for healthcare professionals and other workers do not constitute retribution in kind for the purposes of personal income tax.

On another front , the working group worked intensely to fully identify the **sector features that could have an impact on the operation of the VAT Immediate Supply of Information System (SII)**, effective 1 July 2017, all of which have been clarified in a timely manner by the AEAT. Furthermore, all the existing regulations and doctrine on the SII have been transferred in a timely manner to the working group for their information, including Order HFP/417/2017, of 12 May, regulating the regulatory and technical specifications for implementing the carrying of the VAT Registration Books via the AEAT electronic site; Royal Decree 529/2017, of 26 May, amending the VAT Regulation, Order HFP/187/2018, of 22 February, amending Order HFP/417/2017, and other tax regulations.

It should also be highlighted that, throughout 2017, numerous **regulations with tax implications** have been published, which have been circulated to the working group, including the following:

1. Order HFP/399/2017, of 5 May, approving the corporate income tax and non-residence income tax forms for the tax periods between 1 January and 31 December 2016.
2. Law 3/2017, of 27 June, on the General State Budget for 2017.
3. Order HFP/816/2017, of 28 August, approving the informative tax return form 232 on related-party transactions and transactions and scenarios relating to countries or territories classified as tax havens.
4. Resolution of 25 August 2017, amending the Resolution of 11 July 2014, containing the instructions for completion of the SAD.
5. Order HFP/1271/2017, of 21 December, amending Order EHA/3316/2010, of 17 December, approving the models of self-assessment form 210. 211 and 213 of the non-resident income tax.

6. Royal Decree 1070/2017, of 29 December, amending the General Regulation on the actions and procedures for tax management and inspection and the development of common regulations for tax application procedures.
7. Royal Decree 1071/2017, of 29 December, amending the General Tax Collection Regulation.
8. Royal Decree 1072/2017, of 29 December, amending the General Regulation of tax-related sanctions.
9. Royal Decree 1073/2017, of 29 December, amending the general enacting Regulation of the General Tax Law 58/2003, of 17 December, concerning administrative reviews.
10. Royal Decree 1075/2017, of 29 December, amending various Tax Regulations (VAT, Tax on Property Transfers and Certified Legal Documents, Special Taxes, Tax on Fluoride Gases of Greenhouse Effect), and the Regulation regulating invoicing obligations.
11. Order HFP/1307/2017, of 29 December, amending Order EHA/1274/2007, of 26 April, approving forms 036 and 037 of tax register declaration, Order EHA/3434/2007, of 23 November, approving forms 322 and 353 of monthly self-assessment tax returns, and Order EHA/3786/2008, of 29 December, approving VAT self-assessment form 303.
11. Resolution of 8 January 2018, of the Directorate General of the State Tax Agency, approving the general guidelines of the 2018 Annual Tax and Customs Control Plan.
12. Order HFP/231/2018, of 6 March, approving the personal income tax and wealth tax return for financial year 2017, amending Order HAP/2194/2013, of 22 November, regulating the general procedures and conditions for the filing specific self-assessment tax returns and tax-related information declarations, tax register declarations, communications and requests for returns.

On the other hand, this working group has been informed, in a timely manner, of the **OECD Guidelines** on transfer prices and the BEPS project, having approved the

16

government the agreement to acknowledge the OECD Multilateral Agreement for the exchange of tax information from country to country, signed in Paris on 27 January 2016. Regarding this, Spain, together with other signatory countries, has committed to exchange country-by-country reports as of 2018.

It should also be noted that the working group monitors jurisprudential pronouncements related to **special and other taxes**, for example, the recent Supreme Court decision of 26 February 2018 on the legal regime for company directors' remuneration.

Human Resources Working Group

During the year, this working group was informed of relevant regulations, including the Regulation on health protection against risks derived from exposure to ionizing radiation, as well as the **Government's strategic plans**, such as the Spanish Social Economy Strategy 2017-2020; the Annual Employment Policy Plan for 2018; the Strategic Plan for Labour and Social Security Inspection 2018-2020 (which includes an assessment of the Plan for Combating Fraud), or the Draft Strategic Plan for Equality of Opportunities 2018-2021.

In addition, during the year, the corresponding Labour Market Reports analysing the figures registered for unemployment, new jobs and number of people registered with the Social Security according to the data of each month of 2017, prepared by the CEOE Labour Relations Department, have been submitted to the working group.

With regard to the **18th Collective Bargaining Agreement for the Chemical Industry** (current agreement), no salary review was conducted for the year 2017, as certified in the Minutes of the Negotiating Committee of the Agreement of 23 January 2018.

Furthermore, with regards to the 19th Collective Bargaining Agreement of the Chemical Industry, meetings intended only to inform of the status of its negotiations have been held. Approval of the Collective Agreement is expected over 2018.

17

Code of Practice Working Group

After intense work in this working group, the General Assembly of FARMAINDUSTRIA approved in October 2016, a new version of the Code of Practice. This new version, in addition to reinforcing the general principle imposed by the obligation to publish the information on transfers of value individually (endorsed by the report issued by the Spanish Data Protection Agency - Annex I of the Code), incorporates a new consultation (no. 120) and adapts several existing ones regarding data individualisation.

Although the activity of this working group was marked in the last year by the change in individual publication of transfers of value from a **"consent model"** to an **"information model"**, issues such as updating the tax treatment of sponsorships of the pharmaceutical industry of healthcare professionals for training activities and scientific and professional meetings, and the necessary and legitimate collaboration with the main interest groups which pharmaceutical companies interact with (especially scientific societies), were particularly relevant in the work of this working group in 2017.

18

Competitiveness and Internationalisation Working Group

This working group, which aims **to make member pharmaceutical companies more competitive and promote internationalisation**, has maintained its activity in 2017 concerning both specific private internationalisation initiatives for member companies and interaction with public and private bodies aimed at promoting the internationalisation of the companies or the actions with embassies/consulates and local institutions to promote internationalisation.

19

International Working Group

In 2017, this new working group was set up to address the **EFPIA and IFPMA priorities** and contribute to the design of the strategy and action plan of the pharmaceutical industry in Spain for defending these priorities. The topics covered by this working group include:

1. **Brexit.**
2. **International initiatives** affecting the pharmaceutical innovation model, including the analysis of the European Commission on Industrial Property Incentives; the Ministerial Round Tables on Prices, Access and Sustainability; the Declaration of la Valletta agreement for collaboration between European countries on prices and access, or the OECD Report on Sustainable Access to Innovative Therapies.
3. The proposal of the European Commission Regulation on **Health Technology Assessment** (HTA).

20

Relations with Regions Working Group

This working group has the following goals:

1. **Monitor** the different initiatives in healthcare and pharmaceutical policy, particularly those of a regulatory nature or technical reports affecting the offer of medicines and freedom of prescription in terms of equality in each region.
2. **Strengthen dialogue** and collaboration with the administrations.
3. **Promote balance** in the healthcare system that makes NHS sustainability compatible with patient access to medicines and the development of industrial activity.
4. **Consolidate alliances** with the different agents in the healthcare sector to achieve common goals, with special attention to healthcare professionals.
5. **Participate in forums** that might be political, scientific or professional that help to disseminate the value of the pharmaceutical industry and the contribution of medicines to improving the population's health.
6. **Set up a regional early warning system** to detect and monitor regional prescription-dispensing policies.

The working group is made up of 62 pharmaceutical companies and has held five work meetings in 2017.

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 from each region.

21

Communications and Corporate Social Responsibility Working Group

This working group held quarterly meetings that were well attended by representatives from the pharmaceutical companies. These meetings addressed the issues of most interest for the industry and analysed communication initiatives.

22

Patients Working Group

In the field of its work related to patient associations, FARMAINDUSTRIA keeps the Patients Working Group operational and highly active, using it to share initiatives and projects with its member companies.

This working group held four meetings in 2017 addressing issues of interest for the sector and preparing the Somos Pacientes Conference and the content for sessions of the Permanent Dialogue Round Table.

23

Barcelona Delegation

The Farmaindustria Delegation in Barcelona offers various types of **support and advice** to member pharmaceutical companies mainly located in Catalonia, in collaboration with the different departmental areas of the Association.

In addition, and for material reasons, it provides cross-discipline functions for the remaining member companies and supports the coordination of different Working Groups operating in FARMAINDUSTRIA.

The Delegation is also a **meeting point** for meetings of the FARMAINDUSTRIA, Governing Bodies, Statutory Groups and other healthcare organisations.

Throughout 2017, the Barcelona Delegation has continued working closely with the Farmaindustria National Statutory Group, taking on the role of technical secretary at its bimonthly meetings, coordinating the Group's own initiatives and managing interesting information for national companies that are members of the Association. It has also provided technical and logistic support to other statutory groups of FARMAINDUSTRIA.

Furthermore, the Delegation **has maintained an active dialogue with the Catalan public health administration** on different topics, and particularly in the field of the electronic invoice.

For these purposes, and in close coordination with the Hospital Debt Working Group and the Electronic Invoicing Subgroup, the Farmaindustria Delegation has continued to closely monitor the extent to which electronic invoicing has been implemented in the different regions, taking on direct liaison tasks with the MINHAFP, General Interventions of the Regions, health services and health centres, in order to deal with the incidents in this field to defend the interests of pharmaceutical companies. It has also continued to closely monitor the different regional and state regulations published on this matter.

Finally, it should be noted that, throughout 2017, the Delegation has continued maintaining contacts with academic institutions and entities related to the pharmaceutical industry in the region, also participating in the **Delegated Joint Commission for Catalonia**, Fedequim, and in the Social and Labour Commission of this 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 from the EFPIA and European Commission **to promote research on 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.

Activities developed by the PTEMI in 2017 include the following: **BEST Clinical Research Excellence Project**, which has been a key tool for making Spain one of the best European countries for conducting clinical trials (see section on BEST Working Group of this Annual Report) and also the Farma-Biotech Cooperation Programme, launched in February 2011 to facilitate collaboration between the pharmaceutical industry and the Spanish biotechnology sector.

Between 2011 and 2017 there have been 16 interactive meetings, mainly in the areas of the central nervous system, oncology, respiratory system, inflammation and autoimmune diseases.

503
Project applications

103
Presented to biopharmaceutical companies

16
Interactive meetings

In this period, it has received 503 project applications from which 103 projects have been selected and presented to biopharmaceutical companies. The Farma-Biotech Cooperation Program is discussed in greater detail in the Farma-Biotech Working Group section 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-business system, to make known the results from research activities or interesting public and private actions for the industry, **in order to boost cooperation between agents.**

On 5 and 6 March 2018, the PTEMI coordinated and organized its 11th Annual Conference in Barcelona, together with the Spanish Technological Platforms for Nanomedicine, Healthcare Technologies and Biotechnology Markets, in which different advances were presented in the field of disruptive biomedical innovation in the approach to different diseases. During those days and with more than **50 speakers and 280 public and private sector attendees**, the activities carried out by the Biomedical Research Technological Platforms in the last year were presented.

There were several presentations on different topics such as:

- The new regulation on the protection of personal data for use in biomedical research.
- The new clinical trial designs.
- The use of the big data in healthcare management.
- The application of nanotechnology to advanced therapies.
- Artificial intelligence developments in the field of genomics.
- The use of CAR-T cells to design personalised immunotherapies.

Specific examples of **public-private biomedical R&D collaboration**; the results of the State Plan for Scientific and Technical Research and Innovation and national and international funding in the field of biomedicine were also presented. The presentations are available at www.medicamentos-innovadores.org

Also, within the collaboration agreement with SEDISA in the area of clinical research, a work meeting was held in July 2017 on: **"The Future of Clinical Research in Spain and its Status in the Madrid Region,"** to analyse the most relevant aspects of clinical research in Spain in terms of healthcare management, for example, the regulatory framework derived from Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, medicinal product research ethics committees and the Spanish Clinical Studies Register, and the BEST Project on Clinical Research Excellence. This meeting involved members of the SEDISA Board of Directors and managers of public and private hospitals in the Madrid Region.

In the field of dissemination and training of different stakeholders, the Platform participated, in collaboration with investigators, health organisations and representatives of patient associations, in various **Medicine R&D Sessions** with more than 400 high school students.

The Programme of Workshops with Patient Associations has also been relevant to explain what R&D of a new medicine entails, applicable legislation, what agents are involved, etc.

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 over 2,500 people interested in PTEMI activities. The website is available in Spanish and English and is updated weekly.

During 2017, the PTEMI carried out activities aimed at **promoting international collaboration**. It participated in the IMI Forum, organised every six months by the Centre for Industrial Technological Development (CDTI) and on the Committee of Experts that met with the Director of the AEMPS as the assessor of this initiative. It has also intensely monitored the calls for the IMI-2 initiative, as part of the EU Framework Programme for Research and Innovation, Horizon 2020.

It is also important to note that since 1 February 2017, FARMAINDUSTRIA has been participating in a new IMI consortium. This time, it is a *Coordination & Support Action*, specifically the IMI 2 Big Data for Better Outcomes, Policy Innovation and Healthcare Systems Transformation (DO-IT), which has a dual purpose:

1. **Maximising the potential** that is offered by the large amounts of information generated in the healthcare sector (methodologies and data).

2. Encouraging changes in the health systems, working towards **models based on value and measuring outcomes**. Four specific diseases have been included (initially) in this programme: Alzheimer's disease, hematological malignancies, prostate cancer, and cardiovascular disease.

Public information on the project can be found on its website: http://bd4bo.eu/.

FARMAINDUSTRIA participates in two of the four lines of work in the **DO → IT Consortium**, specifically those related to communication, dissemination of results and coordination with stakeholders, and the line relating to ethical and legal issues on privacy and data protection, in accordance with the new European legislation on the matter and the need for harmonized models in this field.

FARMAINDUSTRIA was present at the initial project meeting (Basel, 9 and 10 February 2017), where the master lines of the project were drawn up, and at the Annual General Assembly (Berlin, 9 and 10 October 2017) in which the consortium progress was reported.

Additionally: FARMAINDUSTRIA has participated in various work meetings in the aforementioned areas, one of which took place at the Madrid Association's headquarters on 5 and 6 April 2018.

The presence of FARMAINDUSTRIA in this IMI Consortium will make it easier for the results of these projects in the area of big data and outcome measurement to be transferred to the Spanish administrations and to the other participants in the NHS.

The **DO → IT Project** has a duration of 2 years, a budget of €7.2 million, and is carried out through a Consortium made up of 36 partners from the public and private sector, specifically:

- London School of Economics and Political Science (Project Coordinator).
- Novartis (Project Leader).
- National Institute for Health and Care Excellence (NICE).
- Swedish Dental and Pharmaceutical Benefits Agency.
- European Cancer Patient Coalition.
- European Multiple Sclerosis Platform.
- Semmelweis University.
- Imperial College London.
- Swedish Institute for Health Economics.
- Centre for Research in Healthcare Management at Università Bocconi.
- Norwegian Institute of Public Health.
- Association of the British Pharmaceutical Industry (ABPI).
- Amgen.

- Bayer.
- Boehringer Ingelheim.
- Celgene.
- European Federation of Pharmaceutical Industries and Associations (EFPIA).
- FARMAINDUSTRIA.
- GlaxoSmithKline.
- Health iQ.
- InterSystems.
- Janssen Pharmaceutica.
- Eli Lilly and Company.
- Merck Group.
- MSD.
- Novo Nordisk.
- Pfizer.
- Roche.
- Sanofi.
- Servier.
- UCB.
- German Association of Research-Based Pharmaceutical Companies (VfA).
- Norwegian Medicines Agency.
- Technology Methods and Infrastructure for Networked Medical Research (TMF).
- Inserm Toulouse.

4

Member Services

The report issued by the legal department of the Spanish Data Protection Agency (AEPD) in April 2016 required the amendment and review of Article 18 of the **Transparency Code of the Pharmaceutical Industry's Relationships**. In this regard, the Farmaindustria General Assembly approved a first version in May 2016, including the aforementioned report as Annex I, and a second version in October 2016 (currently in force) to reinforce compliance with the general principle of individual publication.

It is appropriate to briefly remember these events because the transfers of value published in 2017 considered the two possible modalities to date:

- Publication in **individual** form.
- Publication in **aggregated** form (in those cases where the pharmaceutical company did not have prior consent).

However, by virtue of the aforementioned AEPD report, as of 1 January 2017, all transfers of value made by the laboratories must be published individually. In this regard, it should be noted that in June 2018 Spain will be the first country in the European Union that, under its Self-Regulation System, will individually publish all transfers of value made by pharmaceutical companies to healthcare professionals in 2017.

On the other hand, although this was a tangential and independent issue to the transparency obligations undertaken by pharmaceutical companies, the **tax treatment of pharmaceutical industry collaborations** with healthcare professionals for their attendance and participation in training activities and scientific and professional meetings took on special relevance during 2017. Further details and information on this matter are provided in the Taxation Working Group section of this Annual Report.

In June 2017, and for the second consecutive year, pharmaceutical companies published transfers of value made in 2016 to healthcare professionals and organisations for donations, training activities and scientific and professional meetings, service provision and R&D. Notwithstanding that this information is available with unrestricted access, the information was published by the pharmaceutical companies adopting the requirements of the AEPD, thus preventing its potential indexing through search engines, and including a legal warning indicating its purpose and preventing its possible use for other purposes. The transparency initiative consolidates and strengthens the commitment and responsibility of the pharmaceutical industry to society and the main stakeholders they interact with.

In addition, FARMAINDUSTRIA, as a member of the Association for **Self-Regulation of Commercial Communication** (Autocontrol), adhered to the European Advertising Standards Alliance, has received **Annual Corporate Social Responsibility Certificate**, whereby it takes on the ethical commitment to responsibly exercise the freedom of commercial communication, helping to strengthen advertising self-regulation. FARMAINDUSTRIA still has a position on the Board of Directors of Autocontrol.


AUTO
CON
TROL
CERTIFICADO
RESPONSABILIDAD SOCIAL CORPORATIVA
A LOS EFECTOS DE CONCESIÓN DEL DISTINTIVO
"IGUALDAD EN LA EMPRESA"
A los efectos que procedan y, en particular, en relación a las exigencias previstas por el artículo 6.1.b) del Real Decreto 1615/2009, de 26 de octubre – que ha sido modificado por el Real Decreto 850/2015, de 28 de septiembre - por el que se regula la concesión y utilización del distintivo «Igualdad en la Empresa», desarrollando el artículo 50 de la Ley Orgánica 3/2007, de 22 de marzo, para la igualdad efectiva de mujeres y hombres.
El citado precepto dispone:
"Documentación. 1. Las candidaturas [de concesión del distintivo "Igualdad en la Empresa"] además de la documentación acreditativa de los extremos citados en el artículo 4, deberán ir acompañadas de la siguiente documentación: (…) b) El balance o informe sobre las medidas o planes de igualdad implantados en la empresa conforme al artículo 4.2.g). En aquellas entidades con la obligación legal o convencional de tener aprobado un plan de igualdad abordará aspectos relacionados con las condiciones de trabajo, el modelo organizativo, la responsabilidad social de la empresa o la difusión y publicidad de los productos y servicios ofrecidos por la misma".

ETHICS COMMISSION ACTIONS

The Ethics Commission's main mission is **to mediate between the parties involved in complaints in an attempt to achieve conciliation**. It held 10 meetings in 2017, playing a mediating role in all of them and also dealt with a range of subjects, on which the Ethics Commission has advised the companies and how to interpret specific subjects and the Pharmaceutical Industry Code of Practice. In particular, the Ethics Commission has worked actively on all the measures that have been developed by FARMAINDUSTRIA throughout 2017 and continuing in 2018, in accordance with the provisions of the Code.

In 2017, 9 complaints were submitted to the Ethics Commission. These complaints were processed in compliance with the ordinary procedure referred to in Article 32.2 of the Pharmaceutical Industry Code of Practice.

A third of the complaints were submitted by the Ethics Supervision Unit, one of which was resolved with a voluntary contribution from the infringing company for rational use of medicines. On the other hand, the Self-Regulation Jury resolved 4 complaints on which an agreement was not reached in the mediation phase imposing sanctions in all cases.

The following schematic summarises the complaints, grouped according to classification criteria.

TOTAL	9
ETHICS COMMISSION	**9**
Commission Mediation	5
Self-Regulation Jury	4
PLAINTIFFS	
USD	33%
Members companies	67%
DEFENDANTS	
Members companies	89%
Adhered companies	11%

ETHICS SUPERVISION UNIT (USD) ACTIONS

Self-regulatory system dissemination

- **Participation in the Code Working Group** to inform about implementation of the Code in Spain.
- **Participation in different working groups** within FARMAINDUSTRIA to analyse the scope of the Code.
- **Meetings with pharmaceutical companies** to monitor and support transparency projects.
- **Meetings with Health Departments** from the different Regions to bring them the main aspects and new issues related to the transparency initiative.
- **Meetings with scientific societies** to go into greater depth and answer queries on transparency topics, and to search for mechanisms to collaborate on training.
- **Preparation of information and communication materials** on the self-regulatory system and transparency initiative.
- **Giving training sessions** specifically designed to meet needs and demands of pharmaceutical companies (in-company training).
- **Joint work on training sessions** relating to the Code within the framework of specialised courses, doctorates, masters.
- **Participation in EFPIA working groups** responsible for ensuring transposition and implementation of the approved standards to the applicable codes in each national association.
- **Active member** of the Codes Committee (Chair) and the Strategic Committee, the Ethics & Compliance Committee (Vice-Chair) and Validation Team EFPIA (e4ethics).
- **Continuous collaborations with IFPMA**: Chair of the Appeals Court for the complaints procedure for the IFPMA Code (Appeal Group), participation in the working group of scientific meetings and congresses and in meetings of the Ethics and Business Integrity Committee (eBIC).

With regards to relationships with **Patient Organisations,** ensure that pharmaceutical companies comply with the commitment to provide updated information on the joint projects carried out during the year (available at www.codigofarmaindustria.es).

Consultancy and joint projects

The USD has increased its joint project and assistance work through:

- Review, adaptation and improvement of the internal procedures implemented by pharmaceutical companies to ensure **compliance with the Code and regulations** in force on the promotion of medicinal products.
- **Continuous support to pharmaceutical companies** 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 2017, three circulars related to the Pharmaceutical Industry Code of Practice have been published.

Monitoring and prevention

The number of **preventive actions** carried out in 2017 was 1,674 (an increase of 191 compared to 2016). The total number of complaints lodged at the initiative of the USD was three, two of which were due to non-compliance related to professional and scientific activities and meetings, and the other to donations and grants. Two of these complaints were resolved by a mediation agreement before the Ethics Commission and the other before the Self-Regulation Jury.

The volume of scientific and professional meetings analysed and verified annually has been maintained, with a total of 5,377 in 2017; therefore, **the average number of reviews remains at more than 5,000 annual events.** In percentage terms, the compliance level of the meetings remains at 95%.

On the other hand, the number of market research studies communicated was 293 (24 less than 2016), and the number of projects communicated was 364, practically the same as in 2016. A **relative increase in the compliance percentage** of both activities was seen, with 92.5% for studies vs 88.3% in 2016 and 88.2% for projects vs 75.5% in 2016.

5,377

Scientific and professional meetings

95%

Compliance

293

Market research studies communicated

364

Projects communicated

EFPIA e4ethics platform

As active members of the Validation Team of the EFPIA e4ethics platform, 252 European international scientific and professional meetings were reviewed during 2017. It was detected that in the case of international meetings, the inclusion of elements that are contrary to most of the self-regulation systems applicable at the European level, including Spain, is still quite common.

Thus, **it 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 organizers to host the events, and also the possible attendance of people other than healthcare professionals.

For further information:
www.codigofarmaindustria.org

		USD ACTIVITY (1 January to 31 December 2017)														
		2004 Apr-Dec	2005	2006	2007	2008	2009 (a)	2010	2011 (b)	2012	2013	2014	2015	2016	2017	Cumulative Apr.'04 – Dec.'17
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	57,117
	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	51,296
	% 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%	88.29%
STUDIES (a)	ANALYSED						687	724	626	512	400	449	300	317	293	4,308
	No incidents						397	546	565	416	332	368	251	260	271	3,426
	% compliance						57.79%	75.41%	90.26%	81.25%	83.00%	81.96%	83.67%	88.33%	92.49%	81.57%
SERVICES (b)	ANALYSED								357	330	306	350	368	361	364	2,438
	No incidents								282	272	230	292	301	279	321	1,972
	% compliance								78.99%	82.42%	75.16%	83.43%	81.79%	77.29%	88.19%	80.78%
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	29,881
USD COMPLAINTS		18	11	9	18	8	12	4	3	1	9	7	7	2	3	112
INSPECTIONS		21	67	75	77	45	70	81	32	58	36	27	25	8	42	664

(a) System for Communicating Studies approved in the 2008 Code
(b) System for Communicating Services approved in the 2010 Code

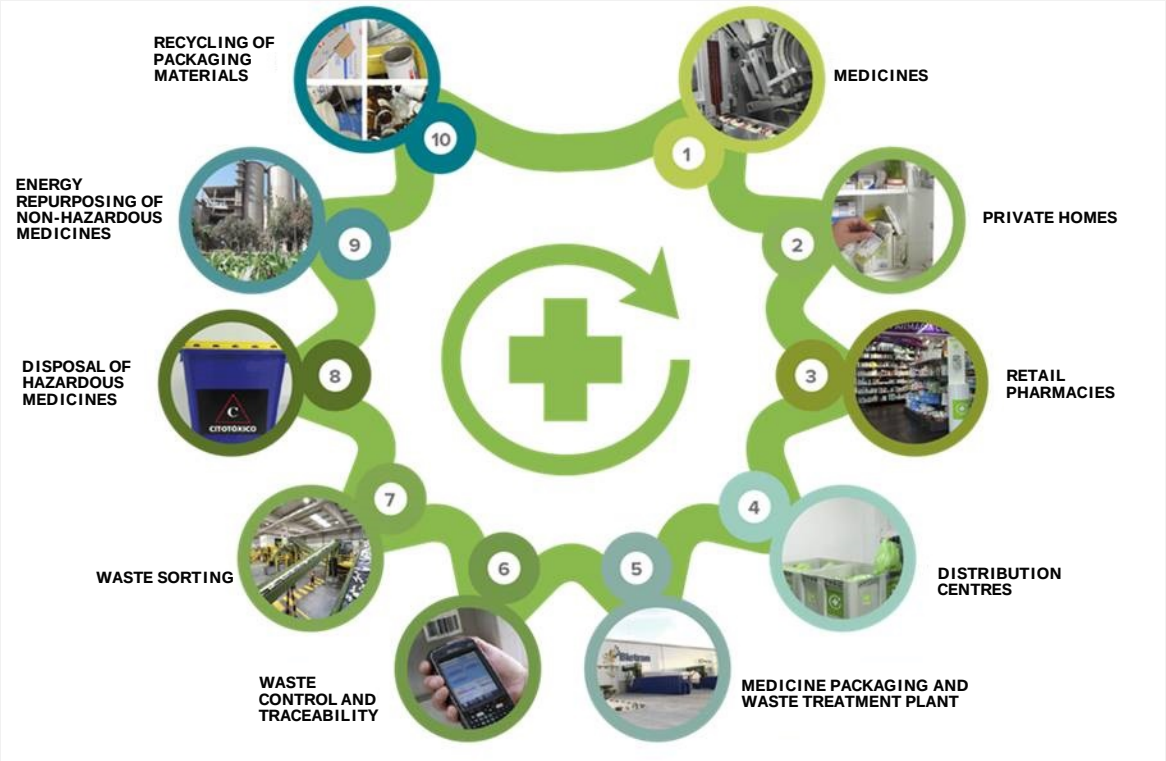
7 Cases resolved in the Courts
6 Clear resolutions by the Self-Regulation Jury in favour of the USD
85 Resolved by mediation before the Ethics Commission, acknowledging the infraction and accepting corrective measures
12 Archived at the request of the USD
2 Not upheld by the Self-Regulation Jury
0 Under evaluation by the Ethics Commission

Anexo

Sigre Medicines and the Environment

SIGRE: A SUSTAINABLE MANAGEMENT MODEL

The pharmaceutical industry is primarily a sector committed to society and to **improving people's quality of life**. This commitment is reflected in all activities. SIGRE Medicines and the Environment (SIGRE) is a clear example of this. At the time of defining its mission, the industry materialised these values by creating a management system for the waste of medicinal products and their packaging which, with the collaboration of distribution and retail pharmacies, is very convenient and safe for citizens and effective for the conservation of our environment.



SIGRE began operating in 2001 with a two-fold objective:

1. Environmental, minimising the environmental impact of empty packaging or leftover medicines of household origin.
2. Public health, removing expired medicines from private homes, in poor conditions or which are no longer needed and thus prevent accidents resulting from their inappropriate use.

The collaboration and co-responsibility of all pharmaceutical sector agents (pharmaceutical companies, pharmacies and distribution companies) has been a determining factor for the success of SIGRE, which has become the **largest joint project undertaken by this sector**. This has set an example for the implementation of similar initiatives within and outside our country.

Prevention at source

Responsible waste management

Raising awareness

TOWARDS A SUSTAINABLE CIRCULAR ECONOMY

The slogan **“For Nature’s Health**” reflects the spirit in which SIGRE was established and which is none other than the environmental commitment and awareness of the entire pharmaceutical sector to help ensure the future of the planet and preserve our natural resources.

To achieve these goals, it is essential to make the transition from the current linear economic model (extraction, manufacture, use and disposal) towards another circular model which pursues the **efficient use of resources** and is more environmentally-friendly.

The pharmaceutical industry and SIGRE, aware of the benefits of a circular future, were the first agents to adhere to the Pact for a Circular Economy, sponsored by the Ministries of Agriculture and Fisheries, Food and the Environment, and by the Ministries of Economy, Industry and Competitiveness.

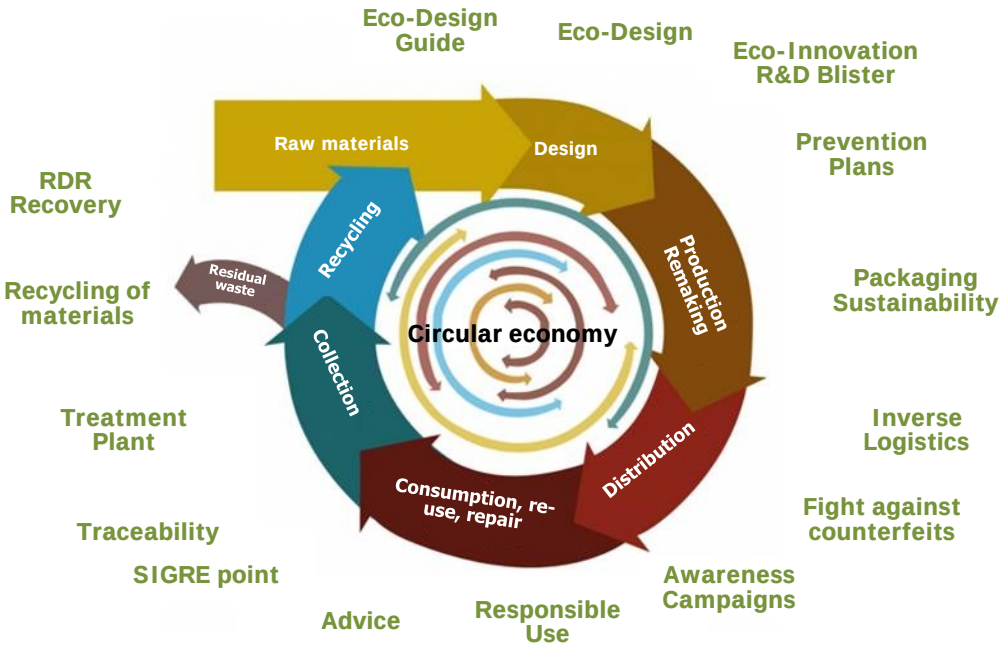


Fig. Circular economy actions undertaken by SIGRE

In addition, as a member of the Executive Committee of the Spanish Network of the World Pact, SIGRE is committed to contribute to the UN Sustainable Development Goals to end poverty, fight inequality and unfairness, and combat climate change.

Fig. The 17 United Nations SDGs, approved in the 2015 Sustainable Development Summit. Highlighted with a green box are those most linked to SIGRE's activity.

AN INTERNATIONAL MODEL

During 2017, the Ibero-American Network of Medicine Post-Consumption Programmes, chaired by SIGRE, initiated preliminary contacts with health and environmental authorities in Latin American countries in which systems have not yet been implemented to ensure the correct treatment of waste from medicines and their packaging, while continuing to support and advise on existing programs.

Of particular note within this area is the meeting of its General Assembly in Mexico City, which had a public session in which the healthcare authorities and entities from the sector had the opportunity to find out about the models that are currently available for the management of medicine waste and the mechanisms for collaboration offered by the Network to help countries in Europe to adequately manage this waste.

Additionally, through its website and its participation in social networks, SIGRE has supported the #Medsdisposal campaign, an initiative launched in 2016 by the main pharmaceutical and health associations in Europe to inform citizens about the different medicine waste management systems available in Europe.

AWARDS AND ACKNOWLEDGEMENTS

In the over 16 years since it was established, SIGRE has received numerous awards and distinctions for its environmental work. During 2017, it received the following recognitions:

- The Ibero-Americana Network of **Medicine Post-Consumption Programmes** was recognised in the Green Latin America Awards as one of the best social and environmental projects in this region, with the greatest contribution to the United Nations Sustainable Development Goals (SDGs).

- The initiative **"Caring for your health and nature",** presented by SIGRE to the initiative "Sustaining Care in City", was selected by Forética as one of the best practices in social responsibility, linked to urban sustainability.

- The first specific website on **pharmaceutical packaging eco-design** prepared by SIGRE was distinguished by the UN Global Compact Network Spain as an example of good practices for achieving the SDGs in the framework of the "SDGs ,Year 2. Analysis, trends and business leadership in Spain".

- The **SIGRE 2016 Sustainability Report** was published by the Ministry of Employment and Social Security on its website, recognising the work on transparency. It was also distinguished with the "Advanced" level, the highest rating given by the United Nations to assess the implementation of organizational principles, transparency and information.

- The campaign **"Pass a breath to the planet",** launched between the Spanish Society of Pneumology and Chest Surgery and SIGRE to promote adequate recycling of inhalers, has been distinguished as one of the Best Initiatives of 2017 in the Awards organized annually by the publication Correo Farmacéutico.

2017 RESULTS

Within the aims set by the pharmaceutical industry, **there are three fields of action for SIGRE** to be able to meet both environmental and healthcare legislation: eco-design of packaging, responsible waste management and awareness-raising.

Eco-design of packaging

Responsible waste management

Awareness-raising

All of SIGRE's activities are made possible by the funding provided by the **314 member pharmaceutical companies**, which pay a quota per medicine dispensed at pharmacies for consumption in private homes.

As a guarantee that the waste will receive the correct environmental treatment, all medicines marketed in Spain for household consumption include the SIGRE symbol on their outer packaging and include an informative legend in the package leaflets on how to dispose of these waste correctly through the pharmacy SIGRE Point so that they do not damage the environment or people's health.

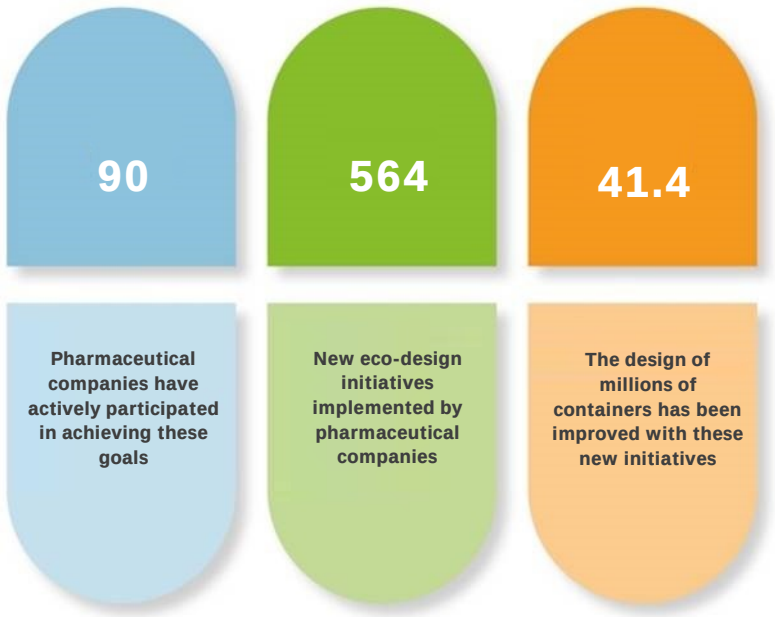
ECO-DESIGN OF PACKAGING

The best waste is that which is not produced. Under this premise, SIGRE has developed three-yearly Pharmaceutical Industry Company Prevention Plans (PEPs) since 2000, which include measures to be implemented by pharmaceutical companies to reduce the environmental impact of medicine packaging and set global reduction targets for this sector.

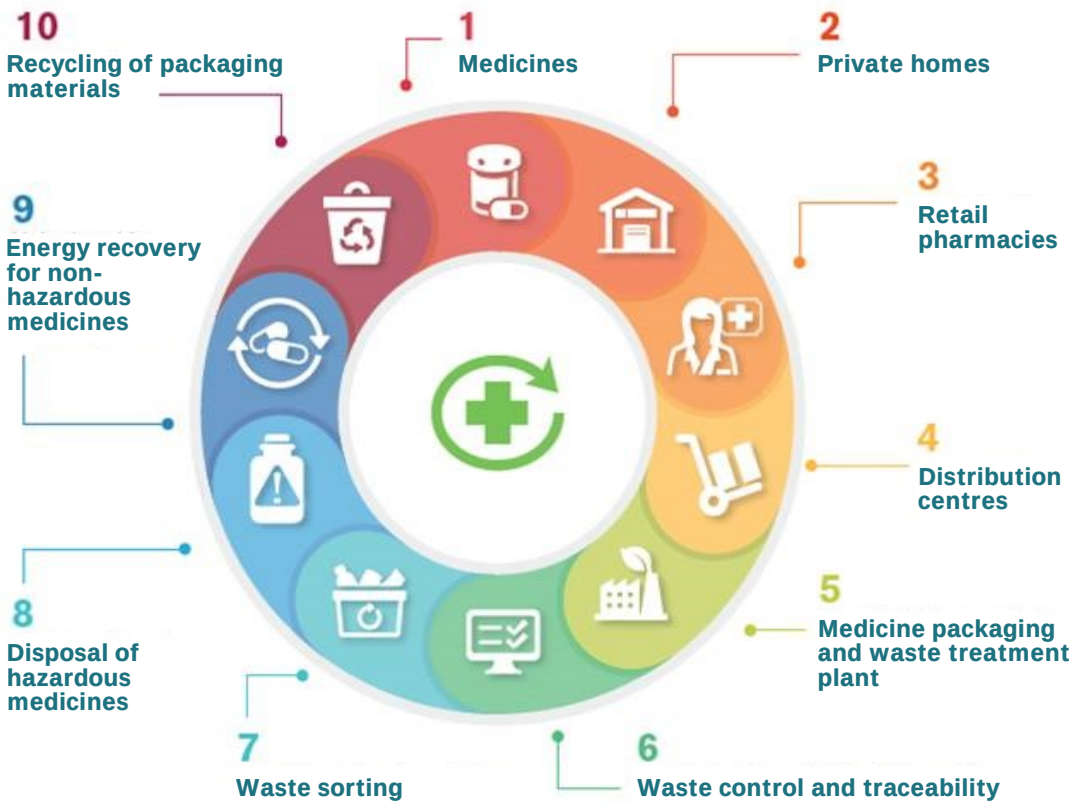
In March 2018, the Third PEP Follow-up Report 2015-2017 was submitted to the environmental authorities, which closed this three-year plan.

The goals initially planned for this Company Prevention Plan (PEP), the sixth carried out by the pharmaceutical industry with the support and coordination of SIGRE, have been widely surpassed, with an overall reduction in the weight of packaging of -6.86%.

This was made possible by the work of manufacturers adhered to SIGRE and the innovative eco-design initiatives that are being implemented in pharmaceutical packaging. The chart below shows the most representative figures achieved in this period.



These results support the commitment of SIGRE and the pharmaceutical industry to the circular economy and eco-design, one of its key pillars, which is materialised in a range of innovative initiatives such as the implementation of the **first website on eco-design in pharmaceutical packaging**, the Practical and Technical Guides of Eco-design of the pharmaceutical industry, or the edition of the **5th Catalogue of Design Initiatives in Pharmaceutical Sector Packaging**, which will be edited in 2018.



RESPONSIBLE WASTE MANAGEMENT

The inverse logistics system implemented by SIGRE for the collection of waste helps prevent accidents, theft, illicit sale and counterfeits, while also fostering the responsible use of medicines and the fight against climate change.

The fact that the collection points for waste from medicines and their packaging are located in pharmacies, both in Spain and in other European countries, is due to the need to guarantee the control of these waste for safety and public health reasons.

In the last year, through 21,727 SIGRE Points located at Spanish pharmacies, an average of 91.92 grams of packaging (empty or containing leftover medicines) were collected per inhabitant, a similar figure to 2016.

In this regard, the high percentage of completely empty containers deposited by citizens was maintained, reflecting a more rational use of the medicine and a greater social awareness of the recycling of this waste.

MEDICINE PACKAGING AND WASTE TREATMENT PLANT

Empty packaging or packaging with leftover medicines deposited by citizens at SIGRE Points throughout Spain are sent to the Medicine Packaging and Waste Treatment Plant, located at Tudela de Duero (Valladolid). This facility, which began operating in 2012, is a pioneering facility worldwide as it was designed exclusively for the **appropriate environmental treatment** of this type of waste.

Thanks to the technology incorporated and the innovative industrial processes to which waste is subjected in this plant, the **recycling rate** for medicine packaging (paper, cardboard, plastic, glass, metals, etc.) **has practically doubled from the previously obtained amount.**

At this facility, leftover medicines, along with the packaging materials that cannot be separated for recycling, are subject to an **energy recovery process** by transformation into a refuse-derived fuel used in cement plants.

AWARENESS-RAISING

Communication campaign

In terms of activities related to awareness, in 2017 the **“Hand in hand for a better world” campaign** was continued, exceeding the coverage and impact objectives initially planned among citizens. The campaign in conventional advertising media was complemented by the distribution through pharmacies of a new information leaflet which, under the slogan **“Your hand also counts”**, seeks to continue raising awareness in society of the importance of properly recycling medicine waste and its packaging.

This campaign also served to highlight the contribution that industry agents make to increasingly implement medicine recycling in Spanish homes.

SIGRE has joined the campaigns for **responsible antibiotic use,** as antimicrobial resistance has become part of the international agenda as a major threat to public health and sustainable development.

Industry + SIGRE Meeting 2017

In June 2017, Madrid and Barcelona hosted the **Industry + SIGRE Meeting 2017,** once again it was well attended by pharmaceutical companies and had strong institutional support.

In Madrid, the Meeting was closed by Mr Diego Sanjuanbenito, Director General of the Environment of the Community of Madrid; and in Barcelona, by Mr Xavier Reinaldos, Deputy Director of the Catalan Waste Agency. Both governments publicly recognised the contribution of SIGRE to the protection of the environment and the effort of the pharmaceutical industry in packaging prevention pharmacist.

In these meetings, diplomas were awarded by SIGRE to the pharmaceutical companies that applied the best eco-design measures in the previous year.

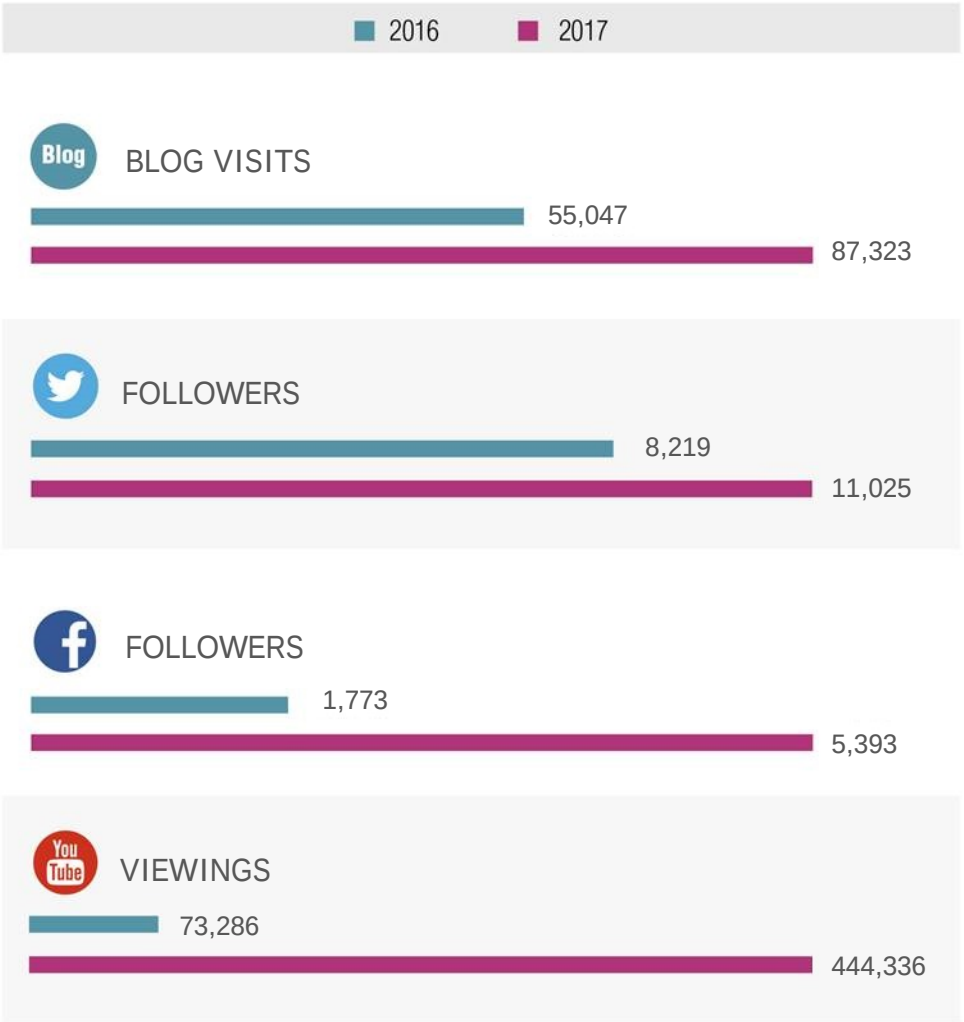
SIGRELAB 2017 Training Sessions

SIGRE has an online software application called SIGRELAB 5.0, **to facilitate submission by pharmaceutical companies of their Annual Business Statement,** which is then submitted by SIGRE to the environmental authorities.

Last year, representatives of more than **118 pharmaceutical companies** attended the conferences organised in Madrid and Barcelona to find out about its new functionalities.

Social networks

People are becoming increasingly aware of medicine recycling, as indicated by the increase recorded in 2017 in the number of visits and interactions in the different social networks (Facebook, Twitter and YouTube) and in the SIGRE Blog shown in the figure below.



Forums and congresses

During 2017, SIGRE collaborated in different events focused on the environment and the pharmaceutical industry, particularly on issues related to the circular economy and climate change, two aspects highly related to its activity.

The most important events participated in included the **37th Symposium of the Spanish Association of Industry Pharmacists (AEFI)**, the Workshop organised by the SERES Foundation on SDGs, the 10th Pharmaceutical Congress of Castile-Leon, the 50th Congress of the Spanish Society of Pneumology and Chest Surgery, the **12nd National Congress on Environmental Journalism**, the Conference of the Madrid Association of Lawyers on the extended responsibility of the producer and the Conference on the Spanish Strategy for a Circular Economy, organised by the Ministry of Agriculture and Fisheries, Food and Environment.

farmaindustria