
Annual
REPORT
2016
farmaindustria

Letter
from the President

Jesús Acebillo

PRESIDENT OF FARMAINDUSTRIA

Medicines are one of the most important assets of our society. Thanks to them our **life expectancy and standard of living** have largely been increased over the last few decades.

Fortunately, medicines are not usually scarce or hard to access in developed and modern societies and despite their complex research and development process, drugs are available for us exactly when we need them.

The industry **strives to research and develop medicines**, but this is a joint effort, involving the health system and its professionals, universities and research centres and patients. Without this collaboration, there would not be any medicines and the work carried out would be pointless should access to those who need them not be guaranteed.

Consequently, the pharmaceutical industry's commitment goes way beyond putting valuable new medicines on the market; it is a profound medical, economic and social commitment.

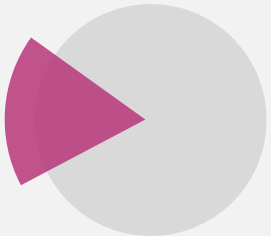
This commitment revolves around **five major elements:** backing innovation; commitment to sustainability of the public health system; a desire to create wealth and generate good quality employment; trust in dialogue to spur us on to work with the world around us and guarantees of transparency and good practice as our work continues to develop.

Innovation is our trademark. The pharmaceutical industry invests more than a billion Euros in R&D work, making it the leading sector in this field in both absolute and relative terms year after year.

LEADERS IN R&D

20%

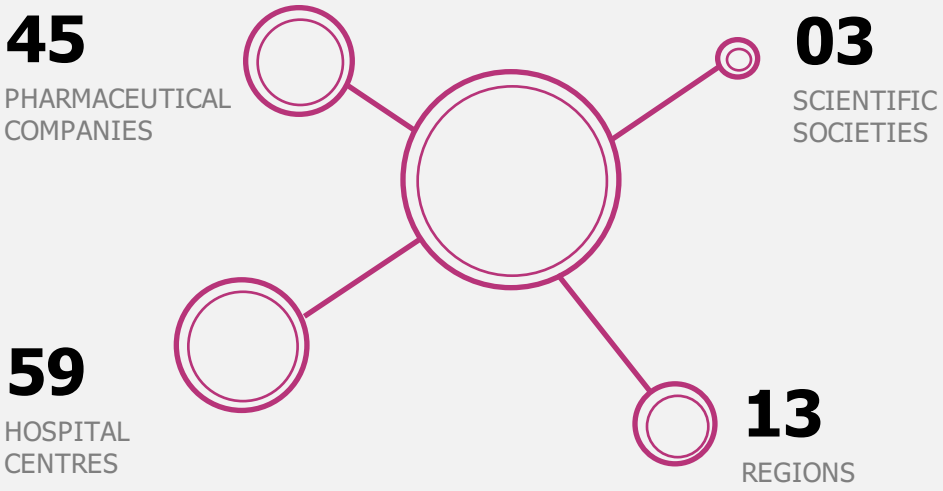
of all Spanish industry



It represents 20% of the total invested in R&D by all Spanish industrial sectors put together. This intense innovative work means that more than 12% of the 38,000 people employed directly by the innovative pharmaceutical industry (over 4,500) are working in R&D, a figure that represents almost half of all employment in these roles from the high-tech sectors.

In addition, this commitment is particularly special as it involves **working with the public sector.** Around 40% of the billion Euros that the pharmaceutical industry invests in R&D goes to contracts with research centres, universities and hospitals to develop projects with high scientific and health-related interest, requiring public-private tenders. This makes the pharmaceutical industry a driving force behind public research in Spain, keeping our country at the forefront of science.

We are consequently promoting this joint work and affine example of this would be the **BEST project** for excellence in clinical research into medicines in Spain, promoted by FARMAINDUSTRIA for the last decade. Year after year, BEST promotes our country's participation in clinical research projects, with involvement from 45 pharmaceutical companies, 59 hospitals, 13 Regions and three independent clinical research groups.



This method of backing **innovation** is harmonious with the pharmaceutical industry's commitment and assumed responsibility towards Spanish society, particularly noticeable over the last few years in our contribution to sustaining the public health system.

The pharmaceutical sector has clearly demonstrated its **loyalty towards Public Administration**, withstanding a third of all cuts in public health spending between 2009 and 2014, during the hardest years of the terrible recent economic recession.

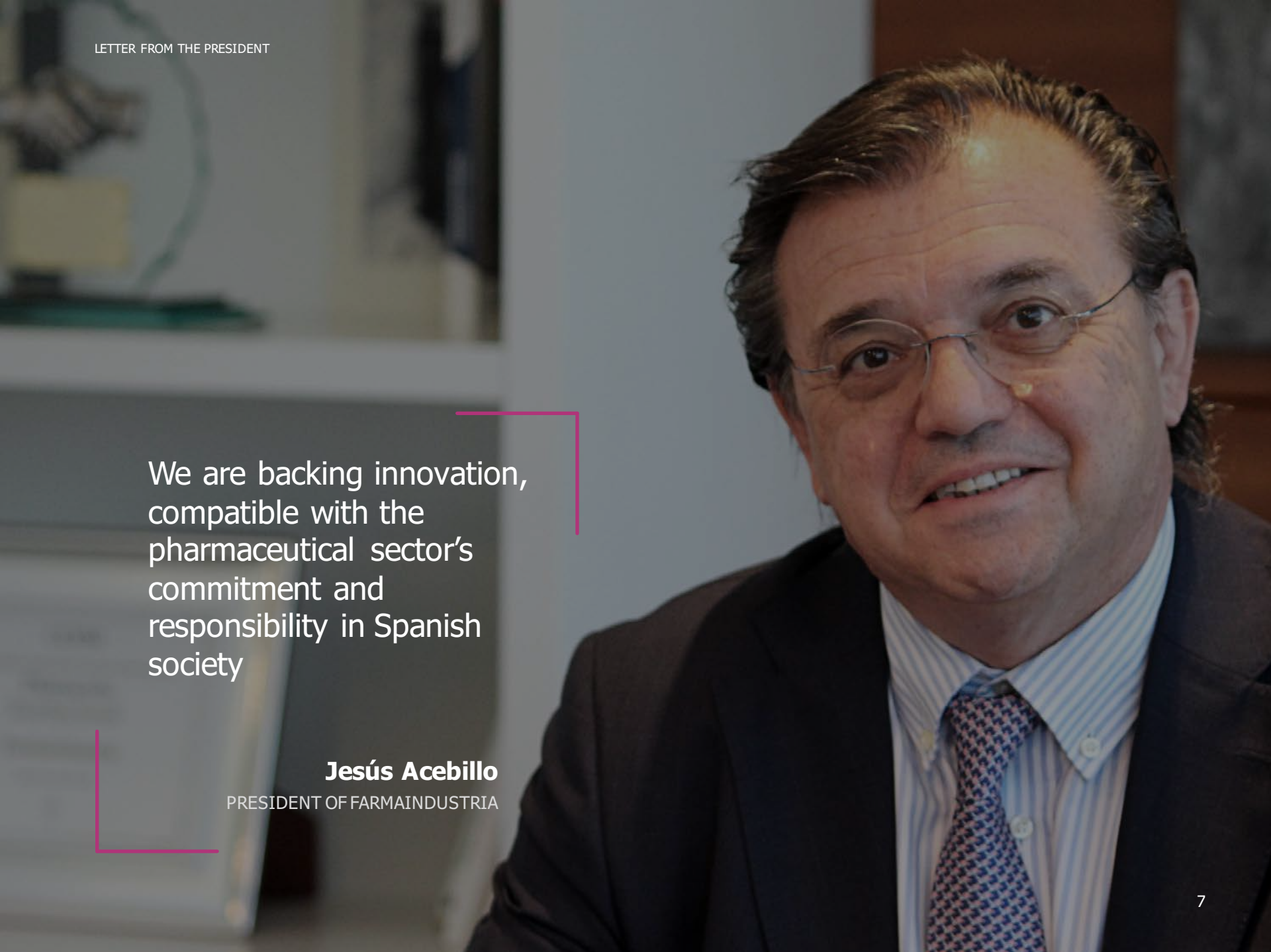
The effects of the severe adjustment made by the pharmaceutical industry may be hard to adjust to but, despite it all, we have faith in our strengths to continue fulfilling our role whilst also meeting society's expectations by providing new **therapy opportunities** and solutions that reach the patients. In particular, we can take into account that we are at the dawn of a new era of great progress in medicine-related therapy: new biomedical technologies are increasing the current therapeutic arsenal - even more so over the next few years - with radical innovations that are going to take a great leap in health terms, even changing how diseases are treated.

In these circumstances, imaginative models must be found to allow for access and sustainability, and one clear example is the Collaboration Agreement, renewed last December between the General State Administration and FARMAINDUSTRIA in an attempt to guarantee that pharmaceutical spending grows in line with our country's GDP.

This agreement is a further demonstration of the **pharmaceutical industry's strong commitment** towards the sustainability of the public health system.

In the same way, along with guarantees of access, there is a universal responsibility to promote rational and responsible use of medicine because, as the World Health Organisation demonstrated, non-compliance with therapy is one of the most serious public health problems and a source of inefficiency that affects and threatens all health systems in developed countries.

Consequently, progress in adherence has led to a drop in health spending and an important improvement in patients' quality of life. Along this line, in 2016 FARMAINDUSTRIA promoted consistent work alongside scientific societies and patient organisations, specified in the so-called *Treatment Adherence Plan*, a solid, practical, cross-discipline proposal to the Administration to tackle this considerable challenge.



We are backing innovation, compatible with the pharmaceutical sector's commitment and responsibility in Spanish society

Jesús Acebillo

PRESIDENT OF FARMAINDUSTRIA

It is undeniable that our business and economic commitment **to boost a new economic model in Spain** is more advanced, more sustainable and more prosperous in the medium and long term. The Spanish pharmaceutical industry is the most productive sector in our country per worker (double the average for industry), a leader in terms of exports (over 10,600 million Euros per year) and boasts the most stable, skilled and diverse employment (over 95% have a permanent contract, 50% have been to university and 50% are women).

We should develop all innovative, industrial and commercial work in our companies, as well as all our relations with other collectives in the social-health environment (patients, professionals, institutions), in accordance with the highest ethical and transparency standards. Consequently, since 2002, the innovative Spanish pharmaceutical industry has been governed by a self-regulated system, reflected in our Code of Practice, modified almost annually to adapt to new demands from a modern and demanding society.

This chapter should put special emphasis on our transparency initiative. The publication of our transfer of value to the health system and its professionals in 2016 was a significant milestone. This represents a further step forwards, putting us in a new dimension in terms of social commitment and it is a step, as I mentioned, in as much as it is part of a process, involving a constantly changing dynamic.

EXPORT LEADERS

10,600

MILLION EUROS

MORE STABLE EMPLOYMENT

95%

PERMANENT WORKERS

SKILLED EMPLOYMENT

50%

UNIVERSITY GRADUATES

In 2016 we also decided, and added to our **Code of Practice**, that our joint work with health professionals should be published individually from 2018 onwards.

Transparency is one way for us to prevent potential conflicts of interest and help us showing to society the need for, and value, of our joint projects with the health system, based on accuracy and independence, explaining why we back individualisation. All changes are complicated, more so if they run deep. However, backing from institutions such as the Transparency and Good Government Council, the National Commission for Markets and Competition, and International Transparency, among other social agents and media ensure that we are on the right track and encourage us to keep plowing forward.

The innovative pharmaceutical industry's undeniable commitment to Spain thereby clearly revolves around these five bases: innovation, employment and economic development, sustainability, dialogue and transparency.

These five characteristics perfectly define the work in our sector in 2016, a year that has seen initial steps taken in new lines of work that will lead us much further in the future.

One is the creation and implementation of the Spanish Medicines Verification System (SEVeM) emerging from joint work between industry, distribution and pharmacies with the objective, defined throughout Europe, to provide further safety guarantees to the 'medicine supply chain' and therefore, to patients.

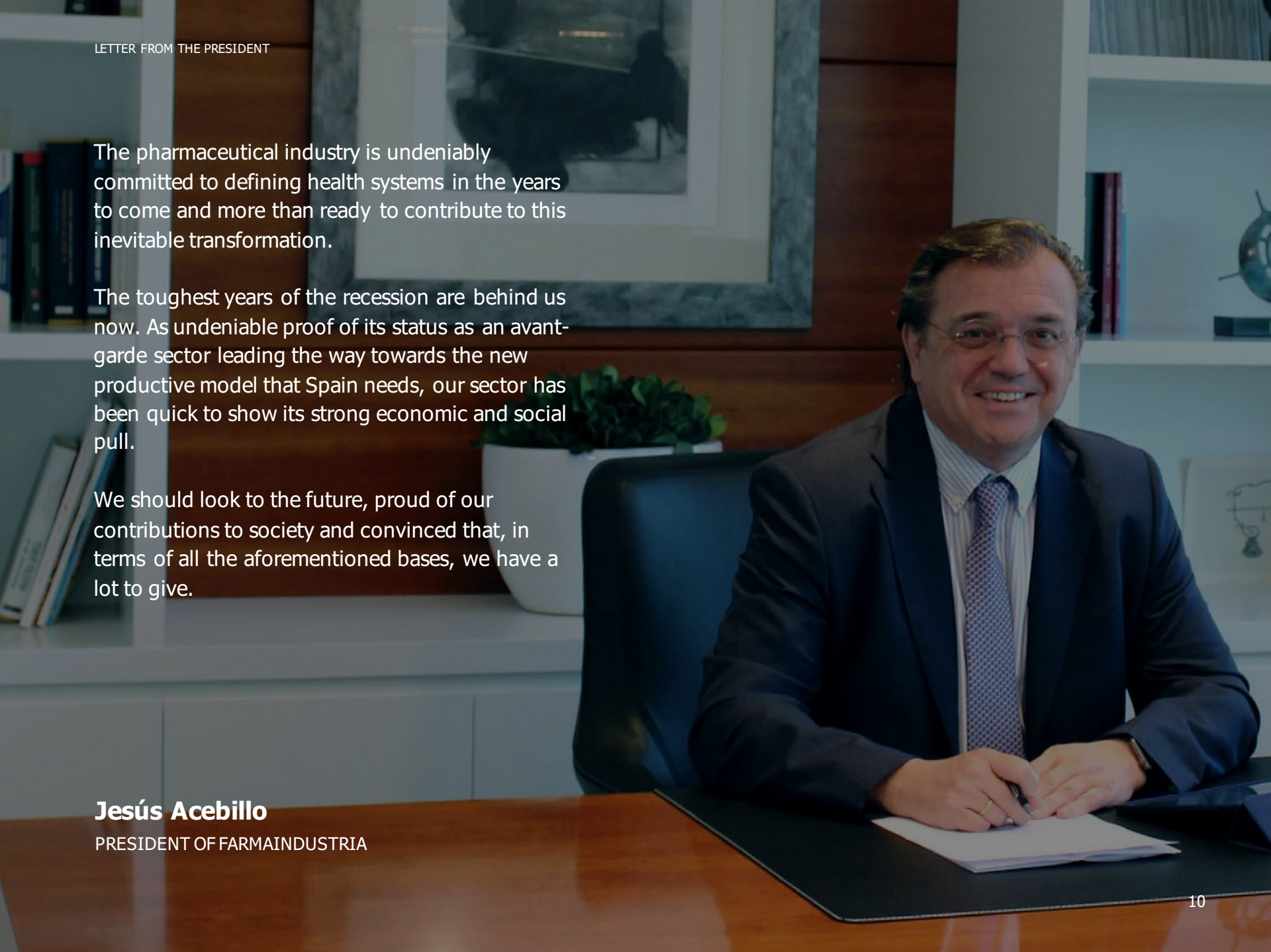
The other, less specific as it lies in the field of ideas, is the industry's clear backing of measuring health results as a basis for transforming the health system and within it, pharmaceutical service provision.

The need to conciliate sustainability and access to innovation should involve efficiency, ideally as a consequence of using information technologies to analyse clinical evidence and health results.

The pharmaceutical industry is undeniably committed to defining health systems in the years to come and more than ready to contribute to this inevitable transformation.

The toughest years of the recession are behind us now. As undeniable proof of its status as an avant-garde sector leading the way towards the new productive model that Spain needs, our sector has been quick to show its strong economic and social pull.

We should look to the future, proud of our contributions to society and convinced that, in terms of all the aforementioned bases, we have a lot to give.



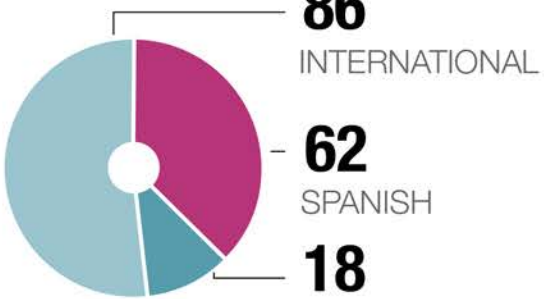
Jesús Acebillo

PRESIDENT OF FARMAINDUSTRIA

2016 REPORT
THE SECTOR IN FIGURES

FARMAINDUSTRIA IS MADE UP OF

166
COMPANIES

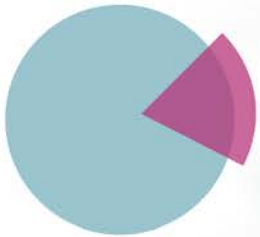


86
INTERNATIONAL

62
SPANISH

18
AMERICAN

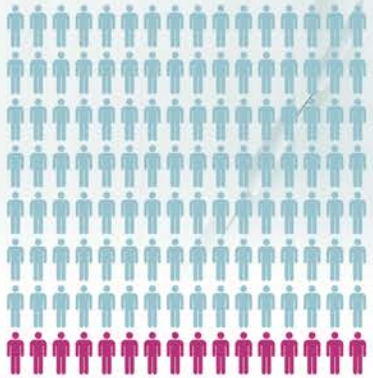
LEADERS IN R&D INVESTMENT



20%
of the total R&D for Spanish industry

EMPLOYMENT IN SPAIN

38,677
PEOPLE
work in the pharmaceutical industry



4,859
in R&D

Over
160,000
INDIRECT JOBS

PRODUCTION
15,213
MILLION EURO

SALES
15,595
MILLION EURO

EXPORTS
10,645
MILLION EURO

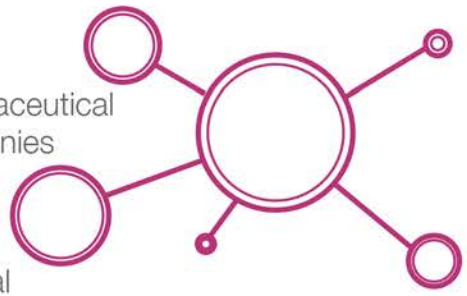
30 NEW INNOVATIVE MEDICINES IN 2016

BEST PROJECT

Clinical tests promoted by the pharmaceutical industry

45 pharmaceutical companies

59 hospital centres



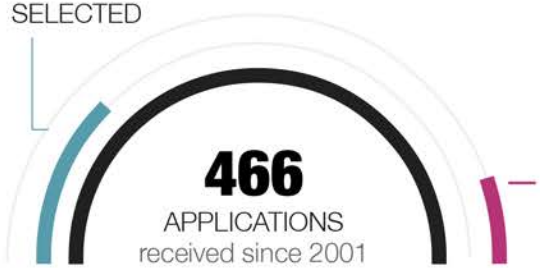
04 independent research groups

13 Regions

FARMA-BIOTECH PROGRAMME

Public-private entities working together on the development of medicines

110 SELECTED



42 NEW MOLECULES
Mainly in the preclinical research phase, although some are already on the market

CODE OF PRACTICE SURVEILLANCE UNIT (USD)

5,382
SCIENTIFIC-PROFESSIONAL MEETINGS
have been analysed and verified by the USD

45 MORE THAN IN 2015

94.95%
ADEQUACY FINDING

1 Member Companies

At the time of publishing this Report, FARMAINDUSTRIA member companies comprise of **166 pharmaceutical companies**, with the following geographic distribution:

PHARMACEUTICAL COMPANIES PER GROUPS

National:		International:			
		American		European	
Total	**62**	**18**		**86**	
Large:	5			Germany	12
SMEs (Small and Medium sized):	57			France	13
				Mixe	34
				United Kingdom	16
				Switzerland	11

In terms of numbers, FARMAINDUSTRIA members represent 45% of licensed product vendors, or their local representatives in the case of vendors authorised by the centralised procedure, regardless of whether they are involved in manufacturing in Spain. In terms of sales, they represent 72% **of the total prescription market** (dispensing pharmacies and hospitals).

2

Organisation

2.1 Governing Bodies

2.2 Executive Organisation

2.1 Governing Bodies

The General Assembly, made up of all the Association's members, is the supreme governing body for FARMAINDUSTRIA, expressing the pharmaceutical companies' collective wishes and intentions.

The Association's Governance comprises of:

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

2. **The Board of Governors,** made up of 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 Board of Directors from among its members (3 from national companies, 3 from American companies and 6 from European/international companies)

There is an additional Vice-President who is the out-going President.

At the Extraordinary General Assembly meeting, held on October 20th 2016, some **changes were made to the Statutes** for FARMAINDUSTRIA, specifically articles 18, 30, 35, 36, 37 and 38, mainly in relation to the structure of the Governing Bodies; increasing the number of members. The Executive Board increased its members from 31 to 33 and the Board of Governors from 20 to 22. A Vice-President was also added for the European/International group and the out-going President became an additional Vice-president. On the other hand, in terms of distribution of positions, the American Group increased its number of members (now holding 9 positions on the Executive Board and 6 on the Board of Governors) likewise the European/International Group (15 positions on the Executive Board and 10 on the Board of Governors) whilst the number of members in the National Group decreased (9 positions in the Executive Board and 6 on the Board of Governors).

On the same date, **elections were held to renew the Associations Governing Bodies**. In compliance with the statute imposing Presidency rotation every two years, Mr Jesús Acebillo Marín, from Novartis Farmacéutica, S.A., company in the European/International Group, specifically from the Swiss Group, was designated President of FARMAINDUSTRIA replacing Mr Antoni Esteve i Cruella.

The structure of FARMAINDUSTRIA'S Governing Bodies on the date this report was published is as follows:

BOARD OF GOVERNORS	
PRESIDENT	
Mr. Jesús Acebillo Marín	
VICE-PRESIDENTS	
Mr. Javier Ellena Aramburu	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. Jordi Ramentol Massana
Ms. Cristina Henríquez de Luna Basagoiti	Mr. Martín Sellés Fort
Mr. Rainer Krause	
SPOKESPERSONS	
Mr. Juan Carlos Aquilera Rodríguez	Mr. Eduardo Recoder de la Cuadra
Mr. Antonio Buxadé Viñas	Mr. Sergio Rodríguez Márquez
Mr. Jordi Martí Pi i Figueras	Mr. David Solanes López
Mr. José Mª. Martín Dueñas	Mr. Christoph Stolle
Mr. Federico Plaza Piñol	Mr. Enrique Trias Vidal de Llobatera
Mr. Francisco Quintanilla Guerra	Mr. Roberto J. Urbez Plasencia

EXECUTIVE BOARDRES

PRESIDENT

D. Jesús Acebillo Marín **NOVARTIS FARMACEUTICA, S.A.**			

VICE-PRESIDENTS

Mr. Jorge Gallardo Ballart **ALMIRALL, S.A.**	Mr. Jordi Ramentol Massana **FERRER INTERNACIONAL, S.A.**	Mr. Javier Ellena Aramburu **LILLY, S.A.**	Mr. Juan López-Belmonte Encina **LABORATORIOS FCOS. ROVI, S.A.**
Mr. Rainer Krause **BAYER HISPANIA, S.L.**	Ms. Cristina Henríquez de Luna Basagoiti **GLAXOSMITHKLINE, S.A.**	Mr. Salvador Pons Ribas **LABORATORIOS MENARINI, S.A.**	Ms. Margarita López-Acosta **SANOFI-AVENTIS, S.A.**
Mr. Antoni Esteve Cruella **ESTEVE**	Mr. Martín Sellés Fort **JANSSEN CILAG, S.A.**	Mr. Ángel Fernández García **MERCK SHARP & DOHME DE ESPAÑA, S.A.**	

SPOKESPERSONS

Mr. Eduardo Leyva Pinzón **ABBVIE SPAIN, S.L.U.**	Mr. Timmo Rousku Andersen **BOEHRINGER INGELHEIM ESPAÑA, S.A.**	Mr. Tomás Olleros Izard **GRUPO FARMASIERRA, S.L.**	Mr. Federico Plaza Piñol **ROCHE FARMA, S.A.**
Dª. Ana Isabel Gómez Ferrer **ALCON CUSI, S.A.**	Mr. Roberto J. Urbez Plasencia **BRISTOL-MYERS SQUIBB, S.A.**	Mr. Juan Carlos Aguilera Rodríguez **FERRING, S.A.U.**	Mr. Regis Fedrigo **LABORATORIOS SERVIER, S.L.**
Mr. Roman Stampfli **AMGEN, S.A.**	Mr. Jordi Martí Pi i Figueras **CELGENE, S.L.**	Mr. Christoph Stolle **GRÜNENTHAL PHARMA, S.A.**	Mr. Jesús Sobrino García **UCB PHARMA, S.A.**
Mr. José Mª. Martín Dueñas **ASTELLAS PHARMA, S.A.**	Mr. David Solanes López **LABORATORIOS ERN, S.A.**	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 FARMACEUTICA SPAIN, S.A.**	Mr. Francisco Quintanilla Guerra **FAES FARMA, 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. Javier Font Faus **LBO. DE APLICACIONES FARMACODINAMICAS, S.A. FARDI**	Mr. Ignasi Biosca Reig **LABORATORIO REIG JOFRE, S.A.**	

2

Organisation

2.1 Governing Bodies

2.2 Executive Organisation

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

The Association headquarters are in Madrid plus a satellite office in Barcelona. The FARMAINDUSTRIA functional organisation chart is as follows on the date of publication:

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 Regions

Francisco J. Fernández
Director of Communications

3 Institutional Activity

In the political field, after the general election in December 2015, 2016 was marked by **three fundamental milestones:**

- The Spanish Parliament did not vote in the government presidential candidate from the Partido Socialista Obrero Español (Spanish Socialist Party), Mr Pedro Sánchez, on March 4th and so Parliament was dissolved on May 3rd.
- A new general election was held on June 26th.
- A new government was formed by the Partido Popular (Popular Party), swearing in Mr Mariano Rajoy as president of the government on October 29th after 315 days with an acting government.

Throughout the acting government period, very little legislation was passed which affected health and pharmaceutical standards.

However, within this framework of relatively little regulatory activity, the Protocol of Collaboration was actually valid between the Spanish Central Administration (Ministry of Finance and Public Administration and Ministry of Health, Social Services and Equality) and FARMAINDUSTRIA, signed on November 4th 2015.
The Protocol affects how public spending evolved for "non-generic branded medicines" during the 12-month period between December 1st 2015 (first day of the month after the Protocol was signed) and November 30th 2016.

The Protocol aimed to limit the growth of public pharmaceutical spending on non-generic branded medicines, by linking its growth in Spain to changes in GDP, thereby bringing Spanish patients' access to the best innovative drugs into line with the pharmaceutical industry’s development in our country.

Literally, the protocol test 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 expenses 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 […]"

Once the information regarding the protocol validity period, had been compiled, on April 19th2017 a **meeting of the Monitoring Committee was held with representatives from the Spanish Central Administration** (Ministries of Finance and Public Administration and of Health, Social Services and Equality), FARMAINDUSTRIA and the 10 Regions that joined the Protocol. In this meeting it was stated that the pharmaceutical spending subject to the Protocol has been reduced by -0.5% in 2016, with a variation that was way below the limits set in the Protocol test that were:

1. The GDP growth rate for the Spanish economy in the medium term, set at +2.1%.
2. The real GDP growth rate for the Spanish economy that was +3.2% in 2016, according to the latest INE estimations.

In light of this information, the proposal approved by the Protocol Monitoring Committee was to not determine compensatory or corrective measures in favour of the NHS.

On the other hand, on December 29th 2016, a new Collaboration Agreement was signed between the Spanish Central Administration (Ministries of Finance and Public Administration and of Health, Social Services and Equality), and FARMAINDUSTRIA replicating the same terms as the Collaboration Protocol and extending its effects to all of 2017.

In the new Collaboration Agreement, the reference GDP growth rate for the Spanish economy in the medium term in 2017 is set at +1.8% whilst the latest forecasts (in May 2017) put real GDP growth for the Spanish economy at +2.8% in 2017.

Setting these thresholds is a clear demonstration of the **Spanish pharmaceutical industry's commitment** to balancing public accounts, whilst achieving greater stability and predictability for the pharmaceutical sector, by introducing an element of certainty in its economic regulation, and avoiding introducing temporary and improvised spending containment measures that have a negative effect on the principles of good regulation.

At the time of publishing this Annual Report, the first Monitoring Committee for the Collaboration Agreement is about to be held, although periodic contact is maintained with the Ministry of Health, Social Services and Equality involving regular monitoring of how pharmaceutical spending is evolving in both hospitals and dispensing pharmacies.

As with the Protocol, the new Agreement also includes a series of provisions that are related to effective access to innovative medicines in Spain, by carrying out

> "[…] periodic monitoring of patients' access to innovation through the use of common indicators, seeking, wherever the sustainability of the system allows it, the reduction of timelines for resolving public funding and, if it is the case, for setting prices for the new medicines financed by the NHS, and also the effective access of all patients in all the Regions in conditions of equality […]"

In another line of work, it is important to highlight that, as part of developing the Counterfeit Medicines Directive, the European Commission published a delegated regulation on February 9th 2016 which included clauses regarding **labelling of individual packaging** that will become compulsory three years after publication. In turn, the Guarantees Act states that information for refunds in the case of medicines dispensed outside the NHS will be obtained through a system that complies with the Directive, making it possible to design the Spanish system of medicine verification to help fight counterfeiting and the application of notified prices for dispensing pharmacies.

In this way, and after many meetings and intense work with all the *stakeholders*, in July 2016 the administrative company was set up for the Spanish Medicines Verification System (SEVeM), made up of FARMAINDUSTRIA, the Spanish Generic Medicines Association (AESEG), the General Board of the Official Pharmaceuticals Colleges (CGCOF) and the National Federation of Wholesale Distribution Associations Specialising in Pharmaceuticals and Parapharmaceutical Products (FEDIFAR).

In the same way, on September 6th 2016, the **SEVeM Board of Directors** was set up with a President (Director General of FARMAINDUSTRIA), 3 vice-presidents (the Director Generals or Presidents of AESEG, CGCOF and FEDIFAR) and seven board members (executive managers from former associations and boards). The AEMPS will also take part in the Board of Directors meetings and will play a system supervision role.

Within the field of unpatented medicine regulation, the ministerial ruling that updates the **reference groups and prices** was published in the BOE on August 2nd 2016, coming into force in October for spending purposes.

In addition, at the time of publishing this Annual Report, the AEMPS has published 125 **Therapeutic Positioning Reports** (IPTs), of which 57 were published in 2016. However, the AEMPS has yet to publish the standardised working procedure for IPT preparation that will give greater details of the deadlines, procedures and evaluation methods that will be used to write these reports.

In hospitals, it is important to highlight that after the extraordinary payment from the Region Cash Fund (FLA) / Financial Facility Fund (FFF) in December 2016, **public hospital debt** was paid just 95 days late (DSO), representing the best historical result since debt statistics have been collected in our country.

A detailed review of the main **legislation** and the most relevant **regulations** from the past year is given below.

3.1.1 The regulatory framework

Legislation in Spain during 2016 was highly conditioned by the political impasse in Parliament, after the results of the General Election on December 20th2015 and the repeated elections on June 26th 2016 that left the country with an acting Government for almost 10 months. In accordance with Law 50/1997, an acting Government has very limited management power for ordinary public affairs.

However, despite this situation, some **previously approved standards** were brought into force, affecting the pharmaceutical sector.

ENFORCEMENT OF THE ADMINISTRATIVE REFORM

Laws 39/2015, on Public Administrations common administrative procedure (LPAC) and 40/2015, on the legal regime in the public sector, approved on October 1st 2015, came into force on October 2nd 2016. They shape a **new regulatory framework** for the Public Administrations' legal regime and for administrative procedure, revoking much of the previous legislation.

One of the new main issues introduced by these laws is the **boost for electronic Administration**; the LPAC establishes full digitalisation of the administrative procedure and relations between the Administration and citizens, revolving around a series of technological tools.

1. Backing en entirely interconnected electronic Public Administration, using zero paper.
2. It makes electronic relations easier for citizens and companies with the Administration as well as electronic communications between Administrations.
3. It increases transparency by creating new administrative public registers.
4. It rationalises the administrative structure and, for the first time, establishes a regime of supervision, assessment and extinction of public entities.

ENDORSEMENT OF LEGISLATIVE REFORM ON INDUSTRIAL PROPERTY

After approving Law 24/2015, on July 24th, on Patents, in February 2016, the Spanish Patents and Brands Office (OEPM) began processing the Regulation to Execute the Law.
As when processing the law, FARMAINDUSTRIA has kept a close eye on the different texts being drawn up, taking part in the audience processing initiated by the OEPM both directly through the CEOE and before the State Council, on aspects affecting the request (and extension) procedure for the Complementary Protection Certificates (for medicines) and the translation of the European Patent, among others.

In relation to this initiative, the following have issued rulings and reports:

1. The National Markets and Competition Commission (Report IPN/CNMC/019/16 dated November 24th).
2. The State Council (Ruling 174/2017 of dated March 16th).
3. The General Council of Judicial Power (Report dated October 27th2016).

Royal Decree 316/2017, dated March 31st, approving the regulation to executive Law 24/2015, dated July 24th, on Patents was published in BOE no. 78, dated April 1st 2017 and came into force on the same day, coinciding with the enforcement of Law 24/2015, dated July 24th, on Patents.

This completes the procedure to review the patent protection procedure in Spain, highlighting the following characteristics:

1. A single patent award procedure with prior examination of the new aspect and the actual invention, thereby awarding strong patents.

2. A new Bolar clause (art. 61.1 b) and c) of the Law), that distinguishes between "acts for experimental purposes" and "studies and trials to obtain authorisation to sell all the medicines."

3. The obligation to provide information on the geographic origin or the source of the biological material referred to in the invention.

4. The particular possibility of patenting substances or compositions that are already known for use as a medicine or for new therapeutic applications.

5. The regulation of Complementary Protection Certificates for medicines.

The new legislation will benefit the Spanish innovation sector, by offering Spanish businesses, individual entrepreneurs and public and private institutions a fast and effective procedure to protect their innovations.

REFERENCE PRICE SYSTEM

Processing the **Reference Price Order for 2016** began halfway through the year and the final test of Order SSI/1305/2016, of July 27th, leading to the update in 2016 of the reference price system for medicines in the National Health System was published in the BOE on August 2nd.

The text removes references to the Additional Second Clause of Royal Decree 177/2014 (obligation for pharmaceutical companies to provide information about presentations that are sold more cheaply in any EU country, for medicines to which the weighted or threshold price are applied) as it was cancelled by the Supreme Court sentence on October 28th 2015.

DATA PROTECTION

In terms of data protection, three important new issues for companies should be highlighted, particularly for the pharmaceutical sector.

Firstly, adoption, mid 2016, by the European Commission and the Government of the United States of the **new framework agreement for transatlantic exchanges of personal data for commercial purposes:** the Privacy Shield that is mentioned in other sections of this Annual Report.

Secondly, the **approval** of Regulation (EU) 2016/679 by the European Parliament and Council, dated April 27th 2016, relating to the **protection of physical persons regarding processing their personal data and the free circulation of this data**, revoking Directive 95/46/CE (General data protection regulation), in an attempt to establish common rules in the European Union adapted to the digital world, reinforce citizens' rights in terms of processing their personal data and guarantee high standards of

protection, trust and legal security. This clause will be fully applicable from May 25th 2018.

However, it is important to highlight that number eight of its considerations states the possibility that the Member States include elements of the Ruling in national law, as well as the provisions that leave aspects to be developed by the Member States. These aspects include article 89, relating to processing data for the purposes of scientific research, and it should be highlighted that the States can set exceptions to the rights considered in articles 15, 16, 18 and 21 (access, rectification, limitation of processing and opposition).

This should emphasise the importance of data protection regulation to scientific research, fundamental to develop the pharmaceutical industry, containing provisions for a regime in favour of using personal data in this context for purposes other than initially envisaged.

Additionally, it is interesting to highlight the following new issues:

1. **Citizen's rights** are reinforced by applying the transparency principle, imposing obligations for additional information on the data owner and guaranteeing the right to be informed if the data has been hacked.
2. It includes what is referred to as the **right to be forgotten (privacy by default)** (the Supreme Court had already ruled on this issue in sentences dated October 15th 2015, March 14th 2016 and April 5th 2016).
3. It regulates the **collaboration framework** between the supervisor and the person in charge of processing the data.
4. The figure of **Data Protection Delegate** is created.

Last but by no means least, the Report by the Legal Office (number 2016-0172 REF 143318/2016 dated April 22nd) of the Spanish Data Protection Agency (AEPD) is a milestone for the sector and for new transparency obligations in the Pharmaceutical

Industry's Code of Practice (modifications of which will be analysed more widely in this Report's section on the Self-regulation System), in response to an enquiry formulated by FARMAINDUSTRIA on how to implement the goal of **100% individual publications of transfers of value to health professionals**, adopted by the Association's Extraordinary Executive Council meeting in February 2016.

The AEPD considers that individual publication of transfers of value to health professionals is covered by the rule to balance rights and interests in article 7 f) of Directive 95/46/CE, stating that this publication does not require consent from the interested parties. This means that the AEPD, the independent public authority in charge of looking out for citizen privacy and data protection, considers the pharmaceutical industry's interest in publishing individualised data to be legitimate.

Additionally, the AEPD considers it advisable to incorporate measures to guarantee **privacy for professionals** in order to avoid subsequent data processing that exceeds the purpose that justifies its publication.

REGULATORY COMPLIANCE AND THE 'COMPLIANCE PROGRAMMES'

The lack of a clear design for these Programmes in the Criminal Code brought about the publication of Memo 1/2016 on January 22nd from the General State Public Prosecutor, on legal persons' criminal liability. This Memo, along with two Sentences from the Plenary Meeting of the Supreme Court Penal Room: 154/2016 dated February 29th and 221/2016 dated March 16th, give their characteristics.

The obligation for companies to implement a *Compliance Programme* is separate from other regulatory compliance programmes already adapted to Self-Regulation Codes, in particular in the case of our sector, the Code of Practice for the Pharmaceutical Industry. In addition, attention should be drawn to the distinction to be made in companies between the figures of **Internal Supervisor** (art. 12.11 of the Code of Practice) and the **Criminal Compliance Officer** (or simply Compliance Officer) in order to avoid confusion between their functions and responsibilities.

ADMINISTRATIVE PROCUREMENT PROVISIONS

In this area, we should highlight the Resolution dated April 6th 2016 from the General State Patrimony Board, publishing the Recommendation from the Administrative Contracting Advisory Board on **the use of the Single European Contracting Document envisaged in the new Directive on Public Contracting.** By virtue of this Resolution, from April 18th 2016 onwards, contracting bodies should accept bids subject to harmonised regulations, as preliminary proof of compliance with requirements prior to access to the call for bids, a responsible declaration that Directive 2014/24/UE calls "Single European Contracting Document" or DEUC.

It is also important to mention the Resolution dated December 19th 2016 from the General State Patrimony Board, publishing the Agreement from the Council of Ministers dated December 16th 2016 **instructing state public sector entities to publicise certain contracts not subject to harmonised regulation**.

In this Resolution, and to meet the objectives set within Europe, a series of binding instructions is established for all Spanish Central Administration and its organisations that define the lines and strategic aims so that good management of public purchasing is a contributing factor to correcting public deficit. Control mechanisms are thereby adopted a priori to implement improvements in the public contracting sector such as the obligation to publicise certain contracts that are not subject to harmonised regulation and virtualise their main governors, such as the transparency principle and free competition.

In addition, a mention should be given to Royal Decree 55/2017, dated February 3rd, developing Law 2/2015 dated March 30th, on de-indexation of the Spanish economy. Its purpose is to establish conditions to create a **price system** that shows market information faithfully, avoiding inflationary bias. This standard provides both economic operators and contracting

bodies with a series of tools to tackle the problem issue of price reviews on public contracts with the due legal guarantees, always safeguarding the principle of economic balance for bids by means of review mechanisms that are designed ad-hoc to reflect the conditions for each call.

Finally, as this Annual Report went to the press, the **Public Sector Contracts Bill** is still in the processing phase.

PROVISIONS IN CASE OF LATE PAYMENTS

Late payments of debts arising from Public Administration contracts is a subject followed particularly closely by both the European Union and the national government, reflected in a wide variety of standards.

In this respect, this section should highlight the publication of Organic Law 1/2016, dated October 31st, amending Organic Law 2/2012, dated April 27th, on Budgetary Stability and Financial Sustainability.

Alternately, a mention should be given to Order PRE/710/2016, dated May 12th, publishing the Agreement from the Government Delegate Commission for Economic Affairs dated March 31st 2016 on additional conditions to be met by the **Regions that joined the Financing Fund for Regions**, Autonomous Cash Fund 2016 compartment.

Additionally, the Resolution of December 27th 2016 from the General Secretariat of Treasury and Financial Policy was published, which established the legal interest rate on arrears applicable to trade operations during the first half of 2017 (set at 8%).

Finally, with regards to electronic invoicing, a joint Memo was published on June 22th 2016 by the Public Defender's Office-State Legal Service Board and the General Intervention Board of the State Administration regarding **processing electronic invoicing** and its effects relating to providing credit in the field of state public sector contracting.

3.1.2 The Regions

During 2016, FARMAINDUSTRIA has continued its important institutional activity, working with the regional healthcare administrations, scientific companies, professional organisations and institutions in an attempt to boost a framework of understanding and trust, benefiting the health system and its sustainability, pharmaceutical innovation, access and rational and responsible use of it and, in short, improving the population's health.

At the same time, close monitoring has continued on **regional initiatives** related to health policy and pharmaceutical service provision, informing companies, from time to time, of the most relevant aspects.

Continuing with renewal of regional governments, on September 25th 2016 elections were held in Galicia and the Basque Country, the only two Regions that had not held elections in 2015.

FARMAINDUSTRIA FORUMS - REGIONS

FARMAINDUSTRIA'S annual forums held every year are a meeting place for the innovative pharmaceutical industry and heads of health departments from central and Regional Governments, where common interest issues are analysed and shared, seeking agreements within a framework of understanding and loyal collaboration.

In April 2016, the 19th Forum was held in León, focusing on the **Treatment Adherence Plan**. In addition to this Plan, mentioned in greater detail at the end of this section of the Annual Report, the 19th Forum presents an update on the information available on **the pharmaceutical industry's commitments to transparency**, echoing the Pharmaceutical Industry's Code of Practice.

The Forum was opened by the General Health Secretariat, Mr. Javier Castrodeza, and the Director General of Health from the Castilla y León Regional Healthcare Service Board, Mr. José Jolín, with participation from ten Regions and INGESA.

At the time of writing this Annual Report, the 20th Forum has just been held in Melilla, following a dual theme: The Spanish Medicines Verification System (SEVeM) and the chances of improvement provided by measuring health results, both from the point of view of economic efficiency and access to innovation.

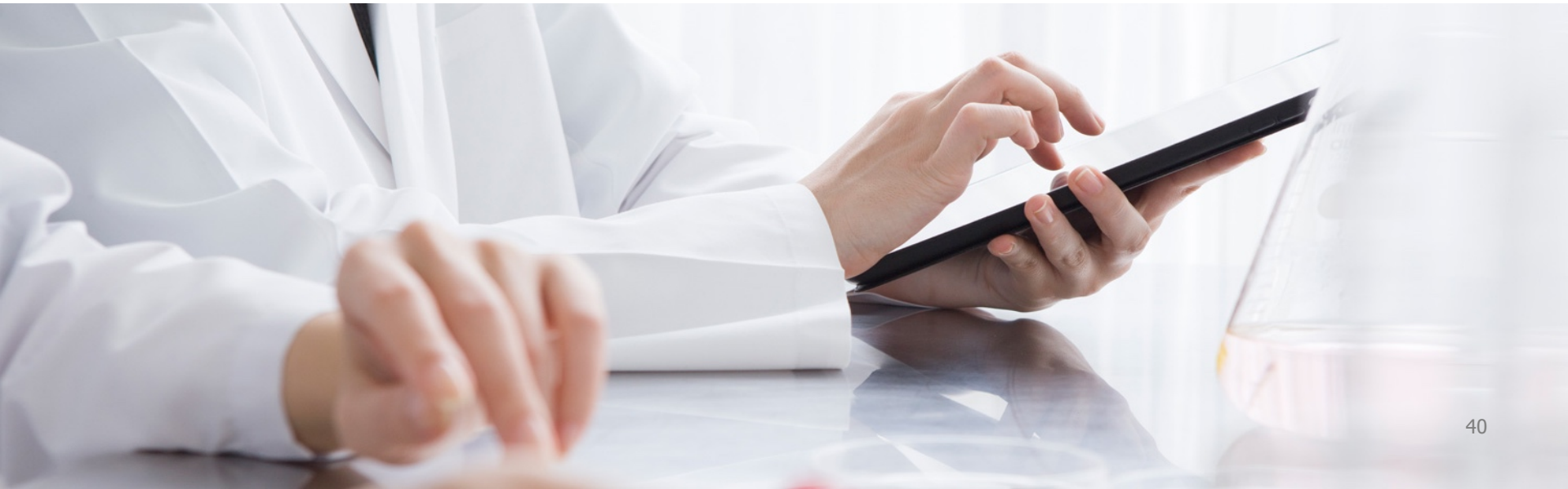
REGULATION INITIATIVES IN THE REGIONAL FIELD

The review below looks at the most relevant **regional policies, regulations and initiatives** from the last year, plus some of the actions run by FARMAINDUSTRIA in this regard, defending their member companies' legitimate interests.

e-health projects in the NHS: Electronic prescriptions and interoperable clinical records. Situation in the Regions

The introduction of information and communication technologies in health, specifically **electronic prescriptions and interoperable electronic clinical records,** represents significant progress to improve the quality of patient care, as well as providing the National Health System (NHS) with cohesion and efficiency.

Electronic prescriptions are a digital service method supporting healthcare. This method allows physicians to issue and send prescriptions electronically that are subsequently dispensed.



The Regions have been progressively developing **electronic prescription models**, using different applications of their own that limited their operability nationwide, making it practically impossible for anyone to obtain their medication from a dispensing pharmacy in a different Region to where the electronic prescription was made out.

To improve electronic prescription interoperability, the Ministry of Health, Social Services and Equality (MSSSI), working with the Regions, has implemented a project that revolves around a central node and which, once certain technological requirements have been met, can be **joined by the Regions as electronic prescription issuers**, recipients-dispensers or both. As a prior requirement, electronic prescriptions must have been implemented in the corresponding Region.

Electronic prescriptions were introduced in Castilla y León in 2016, leading to implementation in all health centres and dispensing pharmacies in the NHS.

In addition, except for the Regions of Aragon, Asturias, Castilla y León and Madrid, this electronic prescription system is also completely operative in specialised care. **Over 88% of prescriptions were dispensed electronically in the NHS by the end of 2016.**

Regarding the electronic prescription interoperability project within the NHS, during 2016 the Canary Islands, Extremadura and Navarra obtained MSSSI certification to issue and dispense prescriptions from other Regions in any of their dispensing pharmacies whilst Castilla La Mancha obtained the technical issuing certification. On the other hand, except for the Balearics, still in the development phase, the remaining Regions were all testing the system by the end of 2016.

On the date of writing this Annual Report, the Regions of Valencia and Galicia have joined the NHS interoperable electronic prescription system, featuring electronic prescriptions that can be dispensed in another region (issuer), plus electronic prescriptions made out in another community can be received and the corresponding medicines dispensed (recipient), as long as that Region is part of the interoperability project, of course.

On the other hand, the National Health System Digital Clinical Records project, led by the MSSSI, aims to guarantee citizens and health professionals, access to the most relevant clinical documentation for each patient's healthcare.

This includes documentation that is electronically available anywhere in the NHS, assuring citizens that their information will only be consulted by people authorised to do so.

At the end of 2016, all regional health services, with the exception of Catalonia, have managed to become information issuers and recipients, covering almost 78% of the population holding a Health Card.

Exclusion of branded medicines from the electronic prescription database: Castilla La Mancha

The 2015 Annual Report stated that the Castilla La Mancha Superior Court of Justice, by means of sentences on February 1st and 29th 2016, had calculated the appeal resources lodged by FARMAINDUSTRIA against the sentences from the Contentious-Administrative Court no.1 in Toledo of July 10th 2014 and November 24th 2014, declaring them null.

These sentences confirm that the instructions from the Castilla La Mancha Health System, informing doctors that a variety of medicines had been deactivated in the electronic prescription system, only allowing prescription of the active ingredient or generic medicine (March 2010 and February 2011) were null.

As a result, the situation has been progressively normalised and the medicines excluded from the Turriano prescription base have been gradually

included, allowing normal electronic prescription. However, residually, three medicines still cannot be prescribed with the electronic prescription, although they are available on a computerised prescription. FARMAINDUSTRIA has raised this situation with the MSSSI to analyse and correct it, as although this does not prevent the prescription of these medicines, it does make electronic prescription interoperability difficult.

Medicine tenders for dispensing pharmacies: Andalusia

On December 15th 2016, the Constitutional Court passed sentence 210/2016 dismissing the appeal for anti-constitutionalism lodged by the Spanish Government against Decree Law 3/2011 that regulates the tenders.

In the same way, on January 19th 2017 this same legal body, by means of sentence 7/2017, dismissed the positive conflict of powers promoted by the Spanish Government in relation to the resolution from the Andalusian Health Service Board, on January 25th 2012, announcing the call for bids to select medicines to be sold by dispensing pharmacies in Andalusia, when in the medical prescriptions and official dispensing orders from the National Health System, they are prescribed or recommended by active ingredient.

In turn, and as we mentioned in the 2015 Annual Report, we have been made aware of the ruling given by the Court for Competition Issues of the National Markets and Competition Commission (CNMC) which orders that no disciplinary process is to be started and the lawsuit must be discontinued, in relation to the statement of complaint filed on September 24th 2014 by the General Manager of the Andalusian Health Service (SAS) against the MSSSI, FARMAINDUSTRIA, AESEG, CEOFA and a large number of pharmaceutical companies, individually, for an alleged infringement of the rules of competition regarding the Ruling of January 25th 2012 (1st auction).

Find below a list of the tenders offered, the active ingredients put out to tender and the awards in the different tenders to select medicines called by the Andalusian Board to date.

Medicine tenders. Calls for tenders and awards

	TENDER			AWARDING		
	Date of Ruling	Active Ingredients put out to Tender	Bidding Laboratories	Date of Ruling	Awarded Active Ingredients	Selected Laboratories
1	25.01.12	18	13	19.03.12	5	4
2	20.12.12	330	17	01.02.13	68	11
3	20.06.13	288	14	21.11.13	52	12
4	31.03.14	251	17	24.07.14	43	13
5	02.10.14	214	13	17.11.14	17	10
6	09.12.14	243	17	06.02.15	69	15
7	12.05.15	249	18	16.07.15	74	16
8	29.04.16	210	21	21.06.16	71	19
9	21.07.16	156	16	30.09.16	58	14
10	28.10.06	178	23	15.12.16	70	21

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

As we revealed in the 2015 Annual Report, in the second half of 2015, Andalusia began the formality of publicly issuing the Draft Bill on Guarantees and Sustainability of the Public Health System of Andalusia which dedicated article 15 to the rational use of medicine and includes provisions that might have an adverse effect on the pharmaceutical industry (compulsory protocols and Pharmacotherapy guides; promoting INN; therapeutically equivalent alternative ATEs; auctions of medicines for dispensing pharmacies) and article 16 which would limit the inclusion of new technologies.

During the phase informing the public about this legislative project, FARMAINDUSTRIA has submitted appeals against this draft bill, insisting that the guides and protocols should just be guidelines respecting the scope of competences regarding actions, therapeutically equivalent alternatives, portfolio of services and inclusion of innovations, among other issues.

The following rulings have been issued on this draft bill:

1. The Andalusia Economic and Social Council (September 26th 2016) emphasising that the Regions can expand the catalogue of NHS service provisions but never restrict them.

2. The Andalusia Advisory Council (November 15th 2016) that highlights the project's dense programme content, with articles requiring specification and its lack of contribution to the standard in force. In turn, a specific vote has been compiled in relation to the actions, opposing the basic legislation.

Once this consultation and public information phase was complete, the Andalusian Government approved sending the project back to Parliament (December 5th 2016). In the text sent to the Andalusian Parliament, negative stipulations are maintained for the sector in terms of prescription by active ingredient, auctions or more therapeutically efficient alternatives, and a new provision has been added, that did not appear in the previous version of the appeal phase, making it compulsory for **pharmaceutical companies to report monetary or cash contributions** (economic value) that are made to centres, services and professionals in the public health system in Andalusia, for their participation in clinical trials, training courses and research projects "in the terms and conditions that are determined by the competent health ministry." Not providing this compulsory information would be considered a serious offence.

In the light of this new clause and the sector's commitment to transparency in transferring value, a request has been made to the Regional Health Ministry that, in the case of pharmaceutical companies that are part of the FARMAINDUSTRIA self-regulation system, the obligation in this clause can be met by providing the health authority with information published on the pharmaceutical company websites, as envisaged in the self-regulation system.

At the time of writing this Annual Report, we are awaiting the expert opinion phase, bringing the sectors before the Andalusian Parliament commission and opening the amendment phase and the subsequent debate. FARMAINDUSTRIA expects that the text will be improved during this phase, making it more legally secure for the sector, as well as for patients and healthcare professionals.

Medicines used in hospital diagnosis to be dispensed in hospital pharmacy services / inclusion of medicines in the hospital domain

In line with former rulings from the High Court of Justice of La Rioja, Cantabria and Andalusia, the Supreme Court, by means of a ruling on March 2nd 2016, declared null the Resolution from the Andalusian Health Service, SDC 0403/10 dated December 22th 2010 that transferred **dispensing certain medicines** used in hospital diagnosis from the dispensing pharmacy to the hospital pharmacy services for out-patients.

The Supreme Court **thereby dismissed the appeal lodged by the SAS** against the rulings of March 17th and May 12th 2014 from the Andalusia High Court of Justice, that considered the contentious-administrative appeals lodged by FARMAINDUSTRIA and by the Andalusia Confederation of Dispensing Pharmacy Owners (CEOFA) against this Resolution.

The High Court ruling confirms that legislation on pharmaceutical products is the **exclusive competence of the State** that, among other aspects, includes establishing and, when appropriate, modifying the dispensing conditions or the singular reserves for prescription or dispensing pharmaceutical products. The Supreme Court understands that the aforementioned Resolution exceeds the regional competence to execute state legislation as it would alter the dispensing regime for medicines.

On July 1st 2016, the SAS Management ruled on Resolution SA 0217/16, revoking Resolution SDC 0403/10 dated December 22nd 2010 and informing that the affected medicines will have to be prescribed by an official medical prescription from the Andalusian public health service and dispensed in the dispensing pharmacies when they are given to out-patients.

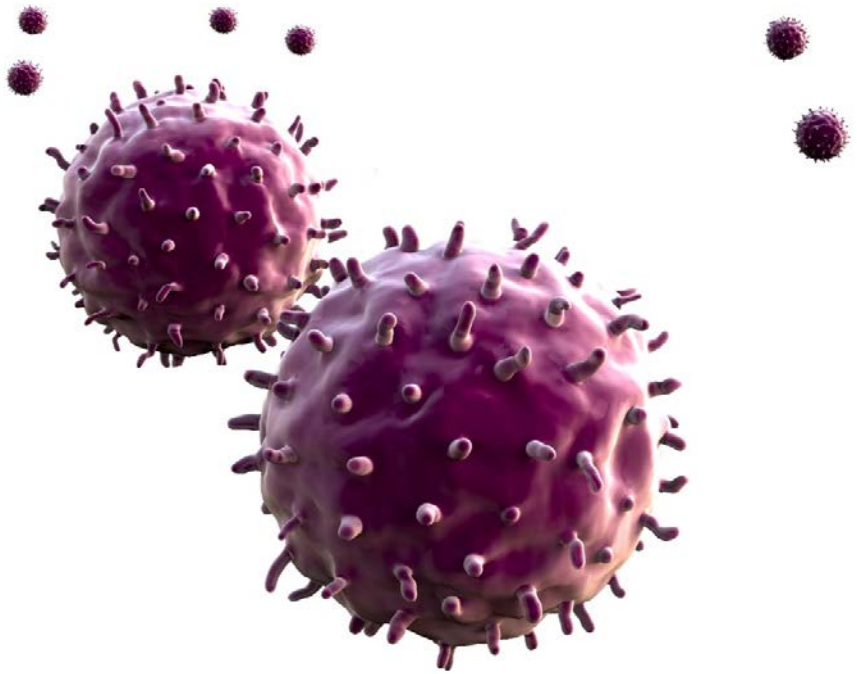
NATIONAL HEALTH SYSTEM MEDICINE PURCHASING PLATFORM

Royal Decree-Law 16/2012 states in its Fourth Additional Provision that the inter-territorial Council of the NHS will run joint actions with Region health services to **acquire any product** which, due to its characteristics, can be purchased using a **joint centralised purchasing mechanism.**

As a means of developing this provision, up until December 2016, there were eight centralised purchasing calls for tender. The first three (recombinant clotting factor VIII, epoetins and immunosuppressants), called between October and December 2013, were called using the former aggregated purchasing model as they were exclusive medicines, using the Framework Agreement for negotiated procedures without public notice, in accordance with article 170.d) of the Consolidated Text of the Law on Contracting with the Public Sector (TRLCSP). These Framework agreements were in force until December 31st 2015.

The fourth call included medicines with generic authorisation. It was authorised in October 2014, is valid until December 2016 and can be extended for a further year. The Framework Agreement for Open Procedure was chosen, processed ordinarily and subject to harmonised regulation.

In September 2015, as validity of the first three Framework agreements (recombinant clotting factor VIII, epoetins and immunosuppressants) was nearing expiry, they were subject to a new call for tender, including a **new tender for supplying antiretroviral drugs.** These four tenders were called in accordance with the 28th additional provision of the TRLCSP, using the standard adoption procedure, provided in Order SSI/1075/2014, dated June 16th, which declared medicines to be eligible items for centralised purchasing. The tender was awarded again using negotiated procedure without public notice, as the items for supply under the contract (exclusive medicines) are included in the case provided in article 170.d) of the TRLCSP.



At the time of writing this Annual Report, INGESA is preparing a **new, exclusive Framework Agreement for oncology and macular degeneration medicines**, divided into 18 batches per active ingredient, and negotiated procedure without public notice with each company.

The basic aspects of the centralised purchasing tenders for the NHS (Framework Agreements) called to date by INGESA for the Regions that are part of these procedures are shown below.

MEDICINES OUT FOR TENDER	PROCEDURE	CONTRACTING ADMINISTRATIONS	CONTENT OF BATCHES	Nº OF BATCHES OUT FOR TENDER	Nº OF AWARDED BATCHES
CLOTTING FACTOR VIII	Negotiated without public notice (art. 170.d Consolidated Text of the Law on Contracting with the Public Sector)	10 Regions (Asturias, Baleares, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Galicia, Murcia, Navarra and La Rioja) and INGESA	Brand	4	4
EPOETINS	Negotiated without public notice (art. 170.d Consolidated Text of the Law on Contracting with the Public Sector)	5 Regions (Asturias, Cantabria, Castilla la Mancha, Extremadura and Murcia), INGESA and the Ministry of Defence	Active Ingredient	5	4
IMMUNOSUPPRESSANTS	Negotiated without public notice (art. 170.d Consolidated Text of the Law on Contracting with the Public Sector)	10 Regions (Aragón, Asturias, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja and Valencia Region), INGESA, Home Office and Ministry of Defence	Active Ingredient	9	6
GENERIC AUTHORISATION MEDICINES	Open procedure by means of ordinary processing and subject to harmonised regulation (articles 196 to 198 of the Consolidated Text of the Law on Contracting with the Public Sector)	11 Regions (Aragón, Asturias, Baleares, Castilla la Mancha, Cantabria, Extremadura, Galicia, Madrid, Murcia, Navarra and La Rioja), INGESA, Home Office and Ministry of Defence	Main ingredient includes two biosimilars that share a batch with the reference biotherapeutic product	20	20
CLOTTING FACTOR VIII	Negotiated without public notice (art. 170.d Consolidated Text of the Law on Contracting with the Public Sector)	9 Regions (Asturias, Baleares, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja) and INGESA	Brand	4	4
EPOETINS	Negotiated without public notice (art. 170.d Consolidated Text of the Law on Contracting with the Public Sector)	7 Regions (Asturias, Balearics, Cantabria, Castilla la Mancha, Extremadura, Madrid and Murcia), INGESA and the Ministry of Defence	Active Ingredient	5	4
IMMUNOSUPPRESSANTS	Negotiated without public notice (art. 170.d Consolidated Text of the Law on Contracting with the Public Sector)	11 Regions (Aragón, Asturias, Baleares, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja, Valencia Region), INGESA, Ministry of Defence and Prison Institutions	Active Ingredient	9	9
ANTIRETROVIRALS	Negotiated without public notice (art. 170.d Consolidated Text of the Law on Contracting with the Public Sector)	10 Regions (Aragón, Asturias, Balearics, Cantabria, Castilla la Mancha, Castilla y León, Extremadura, Madrid, Murcia, La Rioja), INGESA, Ministry of Defence and Home Office	Active Ingredient	26	12

TREATMENT ADHERENCE PLAN (RESPONSIBLE USE OF MEDICINES)

The Treatment Adherence Plan (ATP) is a proposal brought about by FARMAINDUSTRIA, associating the **industry's commitment to rational and responsible use of medicine to sustainability of the NHS**, drawn up with support from 15 scientific societies, patient and expert associations, making up a Promoters' Committee for the project.

The ATP is a strictly scientific initiative, endorsed by a wide number of organisations and experts, prepared to work with health authorities to tackle a problem that affects all health systems, patients, the quality of care and health results whilst bringing about inefficiency, and wasting economic resources. This is an unprecedented project in integral and integrating terms, cross discipline, ambitious and with wide-reaching intentions for applicability and continuity.

The ATP structured how strategies and actions can be identified and organised to improve adherence and can:

1. Boost implementation of projects and initiatives promoted by the different institutions.
2. Strengthen integration of the different projects in common strategies that are long-lasting.
3. Help to evaluate project results and costs.
4. Facilitate the need for collaboration between professionals, institutions and organisations for professionals and patients.

The ATP proposes a complete work strategy made up of six pillars, carrying out 18 initiatives that in turn are divided into 26 actions.

The initiative also includes developing a model that analyses the economic and health impact of non adherence, that has already been applied to highly prevalent pathologies such as EPOC, type II diabetes, cardiovascular disease and severe depression, and that brings in convincing data on potential improvements that could be made in terms of health and savings thanks to improving therapeutic adherence in these pathologies.

In terms of the financing for actions included in the ATP, following a suggestion by FARMAINDUSTRIA, backed by the MSSSI, the National Health System Advisory Body agreed on April 6th 2016 to allocate it part of the revenue provided by the pharmaceutical industry from sales of its medicines to the NHS that are managed by the actual MSSSI (sixth additional provision of the Law of Guarantees). This proposal was made and received positively at the Inter-territorial Council meeting on April 13th 2016.

Once the written work was complete, the ATP **was presented in Barcelona on November 23rd 2016**, at a scientific session with wide ranging participation from scientific societies, experts, patient associations, representatives from the health administrations and industry. It was inaugurated by the Catalonia Health Minister, Mr. Antoni Comín and the General Secretariat of Health and Consumption, Mr. José Javier Castrodeza whose speech expressed the Government's intention to take this initiative to the National Health System Inter-territorial Council for analysis, consideration and, when appropriate, implementation, with any due modifications and improvements.

At the time of writing this Annual Report, the next meeting of the Inter-territorial Council is due to be scheduled shortly.

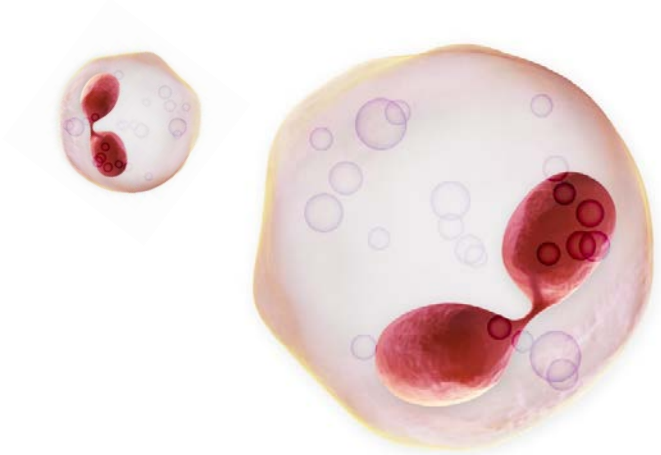
3.1.3 Advisory and Guidance Committees

Spanish legislation anticipates the existence of certain committees in order to inform the MSSSI of the opinion of the different **social workers and health practitioners** within a framework of **greater participation and transparency**. Other committees meet regularly although they do not exist in any other legal provision. FARMAINDUSTRIA is invited to participate in these Committees as a representative of the pharmaceutical industry, the most relevant of which are mentioned below.

ADVISORY BOARD OF THE NATIONAL HEALTH SYSTEM INTER-TERRITORIAL COUNCIL

Chaired by the General Secretariat for Health and Consumption, this committee is composed of members of the various administrations (local, regional and general), unions and business organisations, among them FARMAINDUSTRIA that holds the vice-chair of the business organisations.

The Committee only held one meeting last year (April 2016) dealing with issues of particular interest concerning how the NHS operates, some of which directly affect **medicines**. The Committee reviewed, for ratification and information, the draft of the order to update the system of reference prices for medicines in the National Health System and the draft of the Royal Decree regulating the authorization procedure to run promotion and publicity for donating cells and human tissues.



In addition to the draft legislation, various **strategies** were presented (Strategy on neurodegenerative diseases, mental health, promoting health and prevention), along with national plans (common vaccination calendar, preparation and response to diseases transmitted by vectors) and information on **distribution of funds to the Regions** for strategies on rare diseases and other health strategies and, in particular, information on managing funds from the 6th Additional Provision of the Royal Decree Legislation 1/2015.

As mentioned previously, this Advisory Committee backed the proposal to assign part of the funds from this Additional Provision to the Treatment Adherence Plan promoted by FARMAINDUSTRIA.

AEMPS COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE

The Committee for Medicines for Human Use (CMH), partially renewed last year, has 22 members, 10 holding office as members and 12 appointed by the AEMPS Governing Board, one of them designated by FARMAINDUSTRIA.

CMH's main mission is to ensure efficiency and transparency in procedures for **authorising medicines**, provide necessary but non-binding information on authorisation procedures, any relevant modification, suspension or cancellation of medicines for human use and also, at the request of the Agency Director, issue reports on procedures related to medicines for human use.

Last year, this Committee held **11 meetings** in which they discussed the situation of evaluating the medicines authorised under processes using the centralised procedure in which Spain was a speaker or a co-speaker. The Committee is also informed about Therapeutic Positioning Reports and the assessment reports sent by external experts to the AEMPS.

3 Institutional Activity

The communication strategy from FARMAINDUSTRIA in 2016 reflected a year of both boosting and strengthening changes. A new Communication Plan has thereby been drawn up, focusing on **strengthening and amplifying the Association's role** as a source and channel of information in it, particularly through its website, its social media profiles and new digital tools such as infographics, online videos, and broadcasts via streaming or parallax scrolling formats.

Communication work at FARMAINDUSTRIA revolves around putting across a more appropriate **image of the sector to reflect the pharmaceutical industry's real work and its contribution** both to Spanish people's health and standard of living and to our country's social and economic welfare.

Communication work was also not limited to merely drawing up and broadcasting information on FARMAINDUSTRIA'S activities but it aims to help the Association generate **educational contents of social interest.**

THE MEDIA AND EVENTS

Engagement with the **media** was once again a large part of FARMAINDUSTRIA'S communication activities, including all media types (written press, TV, radio and digital), fields (national, regional, local) and specialities (general, economic, health-related, etc.).

In the past year, FARMAINDUSTRIA has issued **34 press releases**, five more than in the previous year, providing information on the pharmaceutical industry's positioning on different issues, reporting on FARMAINDUSTRIA'S participation in activities or events and providing data and reports of particular interest for the sector.

In the same way, using the "Other news" section, the Association has provided 16 other pieces of information of interest on its website.

Over the last year FARMAINDUSTRIA held ten events that were either own events or held in conjunction with other organisations:

01 Session on "Biomedical Innovation on the 2020 frontier"

02 Marcathlon

03 9th Annual Conference for Technical Biomedical Research Platforms

04 Presentation of the Treatment Adherence Plan

05 16th Meeting of the Pharmaceutical Industry in the UIMP

06 Session on "Strengthening R&D+i collaboration"

07 Session on R&D on Rare Diseases

08 8th Journalists Seminar

09 Session on "Bringing science into schools"

10 Session on "Medicines in cancer: from their discovery to use on patients"

11 4th Session and 2nd edition of the "Somos Pacientes" Awards

12 Two media events on the new Code of Practice

13 Signing event for the Collaboration Agreement with the Ministries of Finance and Public Functions, Health, Social Services and Equality

14 Four press conferences

In the press, different newspapers (national and regional, general and specialist) published **10 editorials** or opinion articles from different FARMAINDUSTRIA spokespersons.


DINERO LA VANGUARDIA

PAÍS: España
PÁGINAS: 6-7
TARIFA: 13500 €
ÁREA: 332 CM² - 30%
FRECUENCIA: Semanal
O.J.D.: 150739
E.G.M.: 657000
SECCIÓN: DINERO

6 Marzo, 2016

El farmacéutico, un sector comprometido

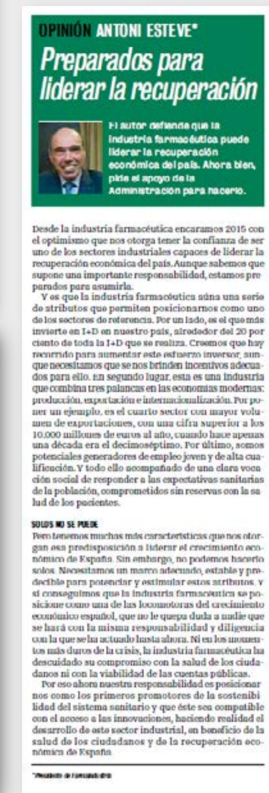
ANTONI ESTEVE
PRESIDENTE DE FARMAINDUSTRIA

"Un 50% del aumento de la esperanza de vida registrada en los últimos años se debe a la incorporación de nuevos medicamentos"


MEDIR LA EFICIENCIA DEL SISTEMA SANITARIO

Pedro Luis Sánchez

Urge mantener la vigilancia del gasto, pero sin descuidar los resultados que obtiene el paciente


OPINIÓN ANTONI ESTEVE*

Preparados para liderar la recuperación

El autor defiende que la industria farmacéutica puede liderar la recuperación económica del país. Ahora bien, pide el apoyo de la Administración para hacerlo.


Opinión **Resolver paradojas**

Uno de los bienes más apreciados por la sociedad es el medicamento. Nadie lo duda, y menos quienes viven condicionados por la enfermedad. Este valor no se extiende tanto a quien lo hace posible: la industria farmacéutica. Y quizá sea porque el sector no ha sabido transmitir a la sociedad qué hace y cómo lo hace.

Es innegable que la industria es la responsable de las novedades farmacológicas, y lo es gracias a la estrecha colaboración con las organizaciones y los profesionales sanitarios. La I+D de nuevos medicamentos y su uso adecuado no serían posibles en los términos actuales sin la interacción entre los laboratorios y el sistema sanitario. Genera un círculo virtuoso que redunda en el bienestar de la sociedad, pues actualiza y mejora los conocimientos de los profesionales sobre los medicamentos y permite a la industria hacer el mejor uso de su experiencia clínica y científica, clave para el desarrollo de la investigación.

Es una paradoja que esta relación pueda interpretarse en ocasiones como negativa, sobre la idea de que podría condicionar la independencia de los profesionales. Por eso en la industria tenemos tan claro que la decisión de transparentar esas relaciones a través de la publicación de las transferencias de valor entre laboratorios, organizaciones y profesionales sanitarios solo puede ser positiva.

Es un paso más en las medidas de transparencia que en los últimos años viene tomando la industria farmacéutica, por ejemplo, con la publicación de las relaciones con las asociaciones de pacientes, de resultados de ensayos clínicos o las resoluciones de Autocontrol y los Acuerdos de Mediación tras denuncias ante la Comisión Deontológica. Y es una iniciativa que, aunque tenga su primer hito con la publicación de datos en junio, responde a un compromiso de mejora que se consolidará y optimizará en los próximos años.

Da respuesta a las crecientes expectativas de transparencia de la sociedad. Pero, sobre todo contribuirá a mostrar el rigor y la independencia con la que se produce la colaboración entre sistema sanitario e industria farmacéutica y, seguro, a resolver paradojas al proporcionar más confianza.

José Zamarriego
Director de la Unidad Deontológica de Farmaindustria

On the other hand, the Association took active part in **13 reports** on some of the main subjects of interest for the sector that appeared in all the supports.

Four interviews were also given and organised with representatives from FARMAINDUSTRIA in different media formats. They all tackled the **situation of innovating industry** in Spain, putting particular emphasis on leadership in the **R&D** sector or on the outlook for access to innovations, as well as other questions relating to healthcare and pharmaceutical policy.

Representatives from the Association also took part in many **debates and discussions** held by the media and the President of FARMAINDUSTRIA spoke at around ten sessions and conferences, widely broadcast in the media.

In terms of news, 2016 came to a close with the signing of the **Collaboration Agreement** in December, guaranteeing NHS sustainability and access to innovation, with the Ministries of Finance and Public Function, and of Health, Social Services and Equality.

At a packed media event, the President of the Association, Mr Jesús Acebillo, signed the Agreement with Ministers Mr Cristóbal Montoro and Ms Dolors Montserrat. FARMAINDUSTRIA issued a press release to the media explaining the details of the Collaboration Agreement, and also put the full document, signed by the parties, on their website. This milestone was widely broadcast in the media, both in the written press and on radio and TV.

Firma del Convenio de Colaboración

A few weeks earlier, in November 2016, FARMAINDUSTRIA held a presentation session in Barcelona for the **Treatment Adherence Plan**, widely attended by representatives from professional colleges, scientific societies and other healthcare organisations plus participation from the General Secretariat for Health, Mr. José Javier Castrodeza, the Generalitat de Catalunya Health Minister, Mr. Antoni Comín, the Secretary of the Patient Organisations Platform, Ms Esther Sabando and the President of the Spanish Society of Clinical Pharmacology, Ms Cristina Avendaño.

In October, FARMAINDUSTRIA reported on its Extraordinary Assembly Meeting where **Mr. Jesús Acebillo replaced Mr. Antoni Esteve** as president of the Association.

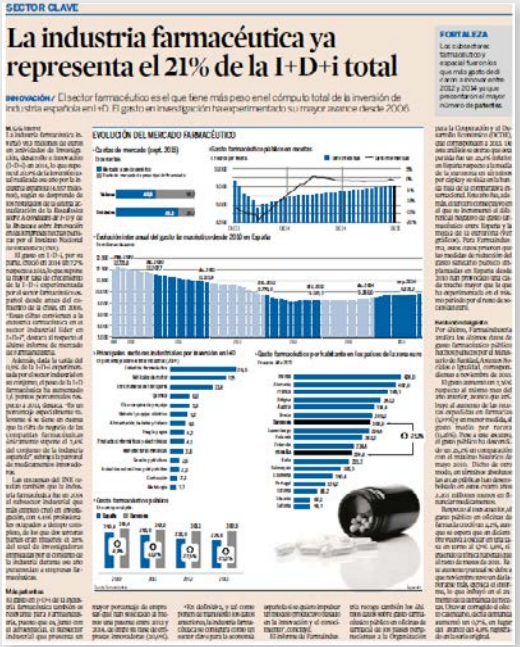
In June, FARMAINDUSTRIA issued a press release to all media announcing the general data for joint projects between the pharmaceutical industry and **healthcare professionals and organisations** during 2015, within the pharmaceutical industry's transparency initiative in Europe. The press release highlighted that most of the interactions revolved around scientific-professional activities and R&D. The vast majority of the media, both national and regional, also specialist media on health and economics, and digital media, reported on this information that was one of the new issues of the latest update to the **Pharmaceutical Industry Code of Practice.**

The "icing on the cake" this year was an **audience with His Majesty King Felipe VI** on July 12th where FARMAINDUSTRIA'S Executive Board confirmed their **commitment to sustainability and access to pharmaceutical innovation in Spain** to the monarch.

The press release issued by the Association, accompanied by several photographs of the event was widely reported in the media.

In another field of activity, FARMAINDUSTRIA worked intensely on its **institutional approach** to a variety of media and opinion leaders, in order to give them first hand information on the pharmaceutical industry's situation in Spain and provide society with more in-depth knowledge of this sector.

The publication in the Expansión economic newspaper of the Medicine Market Conjuncture Bulletin drawn up by FARMAINDUSTRIA is yet another important **media action from the Association**, giving society a more detailed analysis of different aspects relating to the Spanish pharmaceutical market.



SECTOR CLAVE

La industria farmacéutica ya representa el 21% de la I+D+i total

FORTALEZA

INNOVACIÓN/ El sector farmacéutico es el que tiene más peso en el cómputo total de la inversión de industria española en I+D. El gasto en investigación ha experimentado su mayor avance desde 2006

EVOLUCIÓN DEL MERCADO FARMACÉUTICO

Los medicamentos en España son ya de los más baratos de la eurozona

COPAGO

INFORME DE FARMAINDUSTRIA/ España se ha convertido en uno de los países con menor precio medio por receta: un 16% por debajo de la media, sólo por encima de Portugal, Eslovaquia y las repúblicas bálticas

EL GASTO FARMACÉUTICO SE ESTABILIZA EN ESPAÑA

El gasto farmacéutico ha caído un 25,1% respecto al máximo histórico de 2010

Los españoles gastan una media de tres euros menos por receta desde 2009, un 15,3% menos

MERCADO FARMACÉUTICO

Españoles e italianos, los europeos que menos fármacos consumen

ESTADÍSTICA

FARMAINDUSTRIA/ España es, sólo por detrás de Italia, el país de la zona euro con menor consumo de medicamentos expedidos con receta en farmacias y está un 11% por debajo de la media europea.

EL GASTO FARMACÉUTICO SE ESTABILIZA EN ESPAÑA

El impacto de los medicamentos en España será un 16% por debajo de la media de la eurozona

Desde 2010 el gasto farmacéutico ha caído un 24,2%, según los últimos datos de abril

The Menéndez Pelayo International University hosted the traditional Pharmaceutical Industry Meeting in September, sponsored by FARMAINDUSTRIA. Its **16th edition** revolved around **adherence to medicinal** treatments. This meeting was attended by the Cantabria Health Minister, Ms María Luisa Real, the Director General of the NHS Basic Services Portfolio and Pharmacy, Mr. Agustín Rivero, and the presidents of the Collegiate Medical Organisation, Mr. Juan José Rodríguez Sendín, and the General Nursing Board, Mr. Máximo González Jurado, and the General Board of the Official Colleges of Pharmacists, Mr Jesús Aguilar, among others.

Likewise, in November FARMAINDUSTRIA held the **13th edition of the Pharmaceutical Industry and Media Seminar,** which brought together 25 journalists from different media.

The meeting was attended by the President of the National Health Informers Association (ANIS), Mr Emilio de Benito, and reviewed the current status of the sector in an attempt to anticipate its major challenges. In turn, this meeting was the perfect occasion for the new president of FARMAINDUSTRIA, Mr. Jesús Acebillo, to speak to the media for the first time.

COMMUNICATION 2.0

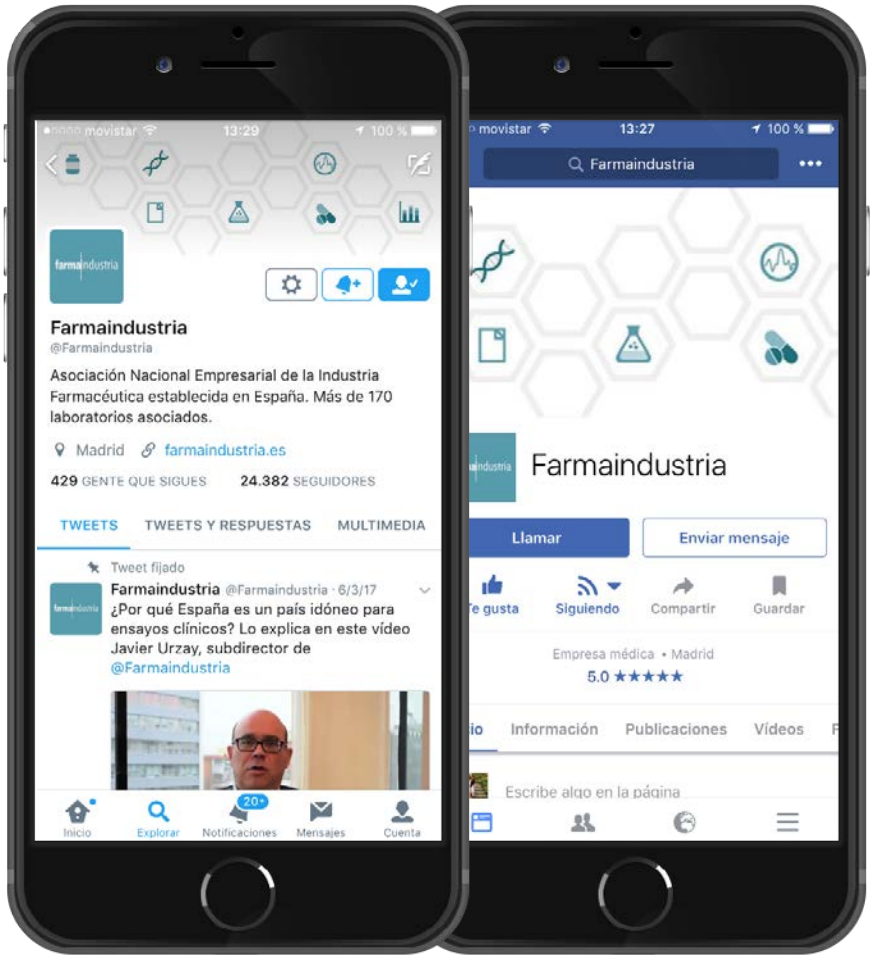
As a continuation of its digital strategy, first started in 2014 with a new website, FARMAINDUSTRIA has continued to generate its **own audiovisual content** in an attempt to help it reach society directly, to demonstrate the sector's peculiarities first hand.

Consequently, an educational video was published called "Working together for patients" explaining why the pharmaceutical industry and health professionals work together, giving details of how patients and the health system benefit from this alliance. Infographics were also produced on adherence to treatment.

FARMAINDUSTRIA'S presence on social media has **grown considerably in 2016**. Now in its fifth year, the FARMAINDUSTRIA **Twitter** account boasted more than **23,000 followers** by December and, according to different indicators, remains one of the most relevant health sector agents in this social medium.

FARMAINDUSTRIA'S activity on Twitter focuses on spreading the work about the Association's own work as well as providing information or relevant and interesting content for the Spanish pharmaceutical sector. In addition, in 2016, a variety of hashtags were developed concerning adherence to treatment or transparency in the industry.

FARMAINDUSTRIA'S presence on **Facebook** has focused on the Association's page on this site, also providing **contents of its own and from others** that are both interesting and relevant for the industry.



On the other hand, Somos Pacientes (We are Patients), an online community of patient associations promoted by FARMAINDUSTRIA, works hard on its internet presence, spreading the word about its activity and contents on the web 2.0.

In addition to giving all its users and readers the chance to share the platform's contents on different social media, Somos Pacientes boasts outstanding participation on both **Twitter** and Facebook. In regard to the former, the Somos Pacientes profile on Twitter had over **15,000 followers** by the end of 2016. The platform broadcasts all its new contents and maintains an open dialogue through this channel with over 1,300 associations that it follows on this social medium.

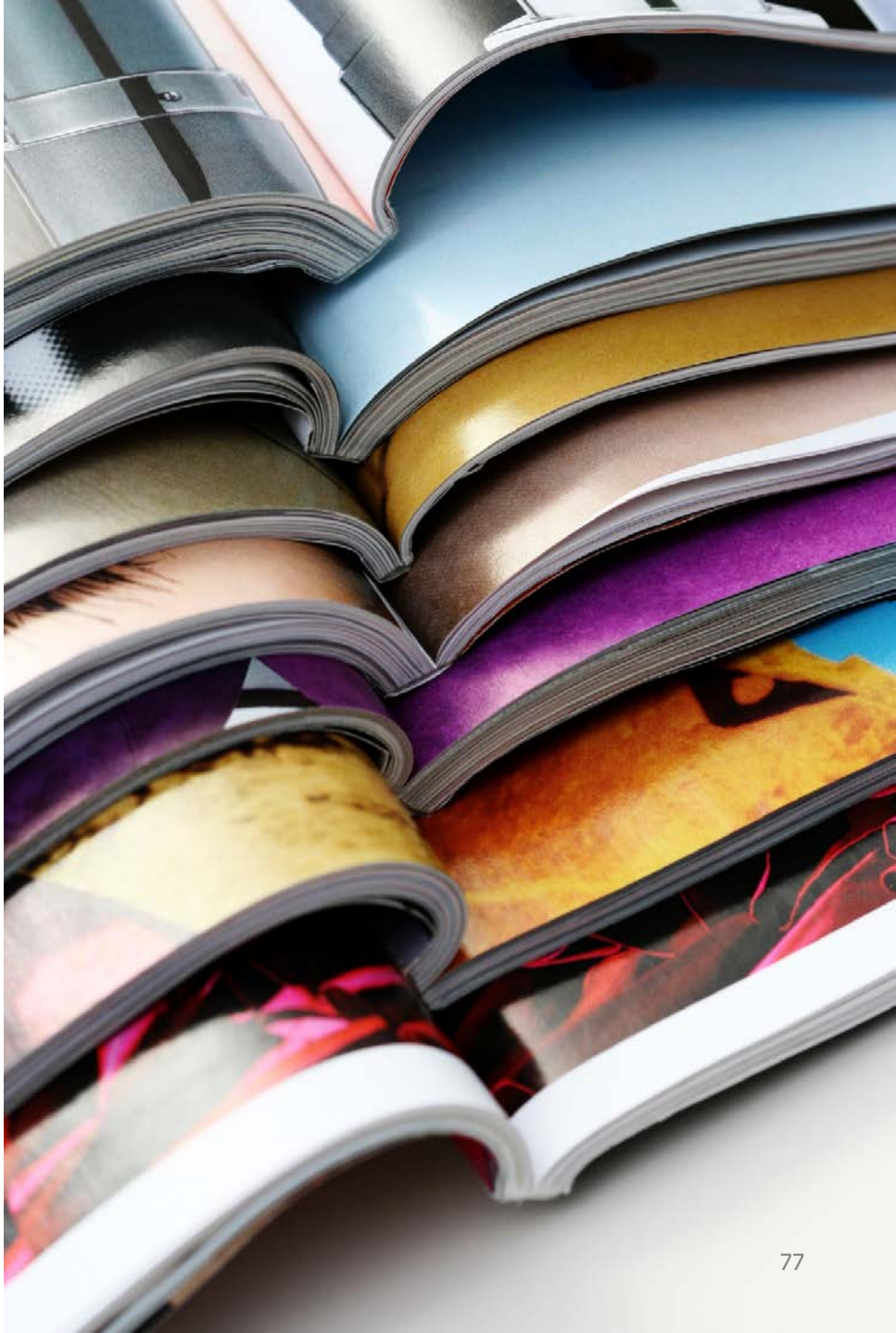
On **Facebook,** Somos Pacientes has a page that it uses to broadcast its contents. At the end of 2016, this page had over **3,000 followers**. In addition, the community has a YouTube channel showing all the reports and video interviews that it publishes on the platform.

Finally, we should highlight that FARMAINDUSTRIA streamed the Presentation of the Treatment Adherence Plan, and the Somos Pacientes Conference and Awards.

IN-HOUSE COMMUNICATION

In-house communication still represents an important work area for FARMAINDUSTRIA. The Communication Working group held quarterly meetings, well-attended by pharmaceutical company representatives. These meetings tackled the sector's burning issues and they drew up **joint strategies and positioning.** In this field, we should highlight the information coordination for the first publication of data from the transparency initiative in June that contributed to its success.

In addition, member companies receive the Weekly News Flash every Monday. This ran 41 issues in 2016, providing clear information on FARMAINDUSTRIA'S communication work.



RELATIONSHIPS WITH PATIENT ASSOCIATIONS

In 2016, FARMAINDUSTRIA consolidated its relationship and joint work with the **patient collective and the associations representing them.** FARMAINDUSTRIA considers patients, family members, disabled and carers, through their organisations, as key voices in the health sector and intends to build the best possible relationship with these associations and establish an environment of cooperation in areas where a common or shared interest might be identified. With this aim in mind, action in this area focuses on two clear lines:

1. Dialogue with associations, both directly and through FARMAINDUSTRIA'S Permanent Dialogue Round Table with Patient Organisations.
2. Management and enhancement of the Somos Pacientes online community of associations that offers information, training, services and joint work tools to patient organisations, family members, the disabled and carers as well as society as a whole.

Working with patient associations

In 2016, FARMAINDUSTRIA took part in many encounters, meetings, sessions, seminars and a wide range of activities with patient organisations to share experiences 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 every year by the Spanish Breast Cancer Association (FECMA) at the Menéndez Pelayo International University, the LinkEM Session, from Multiple Sclerosis Spain, or the radio programme on "Rare Diseases". In addition, FARMAINDUSTRIA was in direct contact with organisations such as the Platform for Patient Organisations, the Spanish Patients Forum, FEDER, Parkinson Spain, Alcer, AEM Federation, AMES or FEDE among others.

It is also important to mention that FARMAINDUSTRIA signed an agreement in March to **work with the Patient Organisation Platform** to promote activities encouraging patient empowerment, thereby strengthening the association movement and transparency of relationships between these entities and the pharmaceutical companies.

Permanent Dialogue Round Table

The FARMAINDUSTRIA Permanent Dialogue Round Table with the Patient Organisations held an information and debate forum in 2016 involving over 20 federations and confederations of patient associations to tackle news and common interest issues, with the ultimate aim of building a relationship of mutual trust and thereby improving knowledge of this collective's needs and concerns.

The Round Table does not meet with a set frequency but is scheduled whenever suggested by any of the parties. It held two meetings in 2016 where, among other matters, they tackled the new aspects of the Royal Decree on Clinical Trials, the pharmaceutical industry's transparency initiative, European collaboration on medicine assessment or the importance of measuring health results.

Somos Pacientes

At the end of 2016, the online community of patient associations "Somos Pacientes" (www.somospacientes.com), set up by FARMAINDUSTRIA en 2012, brought together over 1,600 entities and organisations that are registered and compiled on the National Map of Patient Organisations.

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

Among its tools, the most frequently used by associations are webinars, online meetings or the video and audio live streaming channel. Using this tool, Somos Pacientes offered a range of activities from several member entities in 2016, plus the entire fourth edition of the 'Somos Pacientes' conference held in December, featuring the second edition of the 'Somos Pacientes' awards.

This second event received **120 valid applications** to its five categories and sections. A Jury of 13 members 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 4th 'Somos Pacientes' conference and it is important to highlight that one of the winners, the website users' favourite initiative, received almost 18,000 registered votes online.

The 4th 'Somos Pacientes' conference, held at the beginning of December, consolidating its position as a meeting point to exchange ideas, needs and projects among the representatives from patient associations, the innovative pharmaceutical industry, the Health Authorities and healthcare and research professionals. The programme for this edition, attended by over one hundred people, focused on the role that the patient can and should place in a medicine's life cycle; from the start when decisions must be made on what to investigate and how to do it to develop new drugs, until the end, working with other health agents so that the drugs are used suitably.

The three round table sessions featured representatives from patient associations, researchers, healthcare professionals, spokespersons from public administration and members of the pharmaceutical industry. Over 170 people attended the event.

The Conference could be followed on the Somos Pacientes streaming channel and the event generated more than 1.5 million hits and was a trending topic that morning both in Madrid and nationwide.

EUPATI. European Patients Academy

This European Commission initiative, in which FARMAINDUSTRIA participates, met its goal in 2016 to **develop training courses and draw up educational materials**, in addition to organising a public internet library to train patient representatives and the general public on all processes involved in developing medicines.

With the initiative already boasting full and satisfactory results, FARMAINDUSTRIA took part in several work meetings with members of the consortium in 2016. It also coordinated the National EUPATI Platform in Spain **that met on several occasions** over the year and represented this project in material and content dissemination activities held in Oviedo, León, Malaga, Madrid and Valencia.

Other Activities

The FARMAINDUSTRIA Patients Working Group held four meetings in 2016 tackling **matters of interest for the sector** and preparing both the running of the Somos Pacientes Conference and the contents of the calls for the Permanent Dialogue Round Table.

Within this Working group, an ad hoc group was appointed to be in charge of drawing up a document of proposals to review the standard on self-regulation in the relationships between pharmaceutical companies and patient associations. The result of this group's work was subsequently agreed on and approved by the plenary meeting of the Patients Working Group and, finally, reviewed and agreed on with the Ethics Supervision Unit of FARMAINDUSTRIA, in charge of assuming its ultimate content and incorporating it into the Pharmaceutical Industry Code of Practice in its next review.

3 Institutional Activity

3.1 Market Regulation and Relations with Public Administrations

3.2 Social Communication

3.3 International relations

3.4 The pharmaceutical industry in Spain and worldwide

FARMAINDUSTRIA's international activity revolves around three fundamental axes:

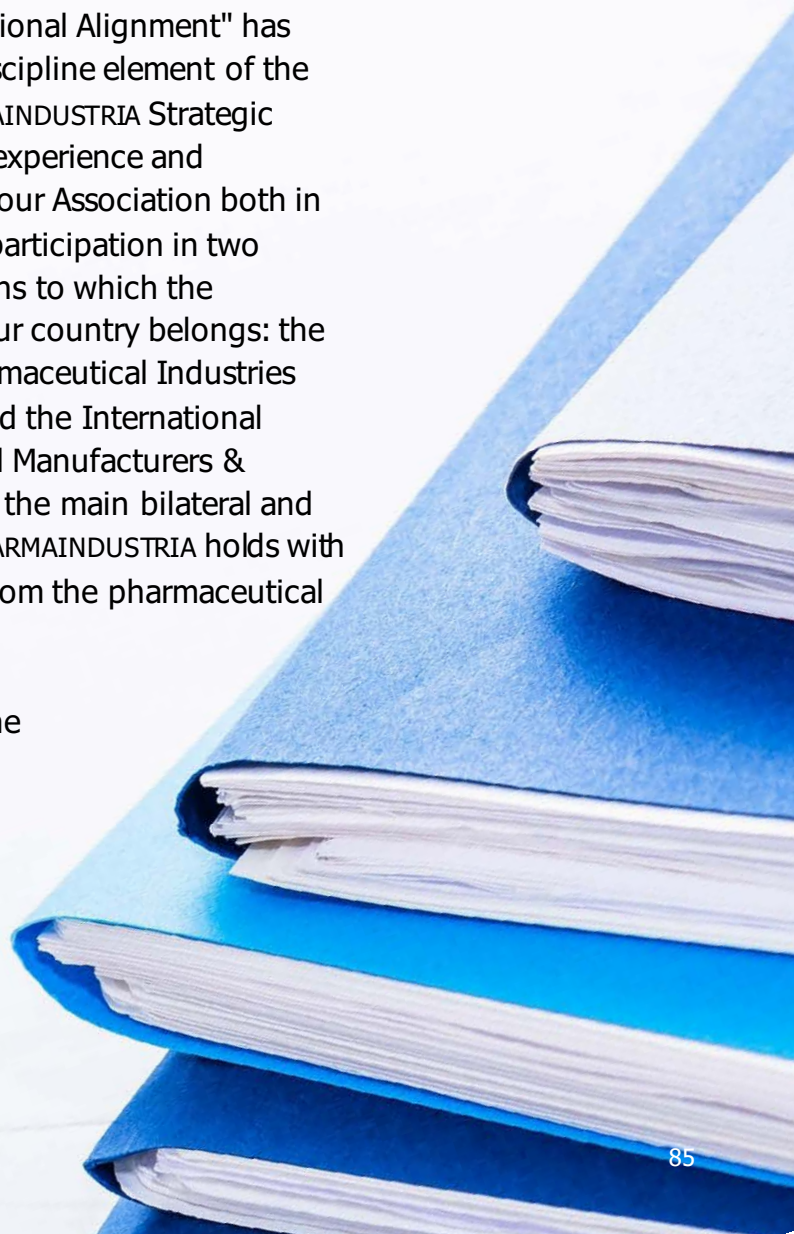
1. Developing **stable relationships** with international associations and federations in the pharmaceutical industry.

2. Positioning FARMAINDUSTRIA and the pharmaceutical industry in Spain as a **role model and reliable partner** before the international institutions and organisations that defend the sector's interests.

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

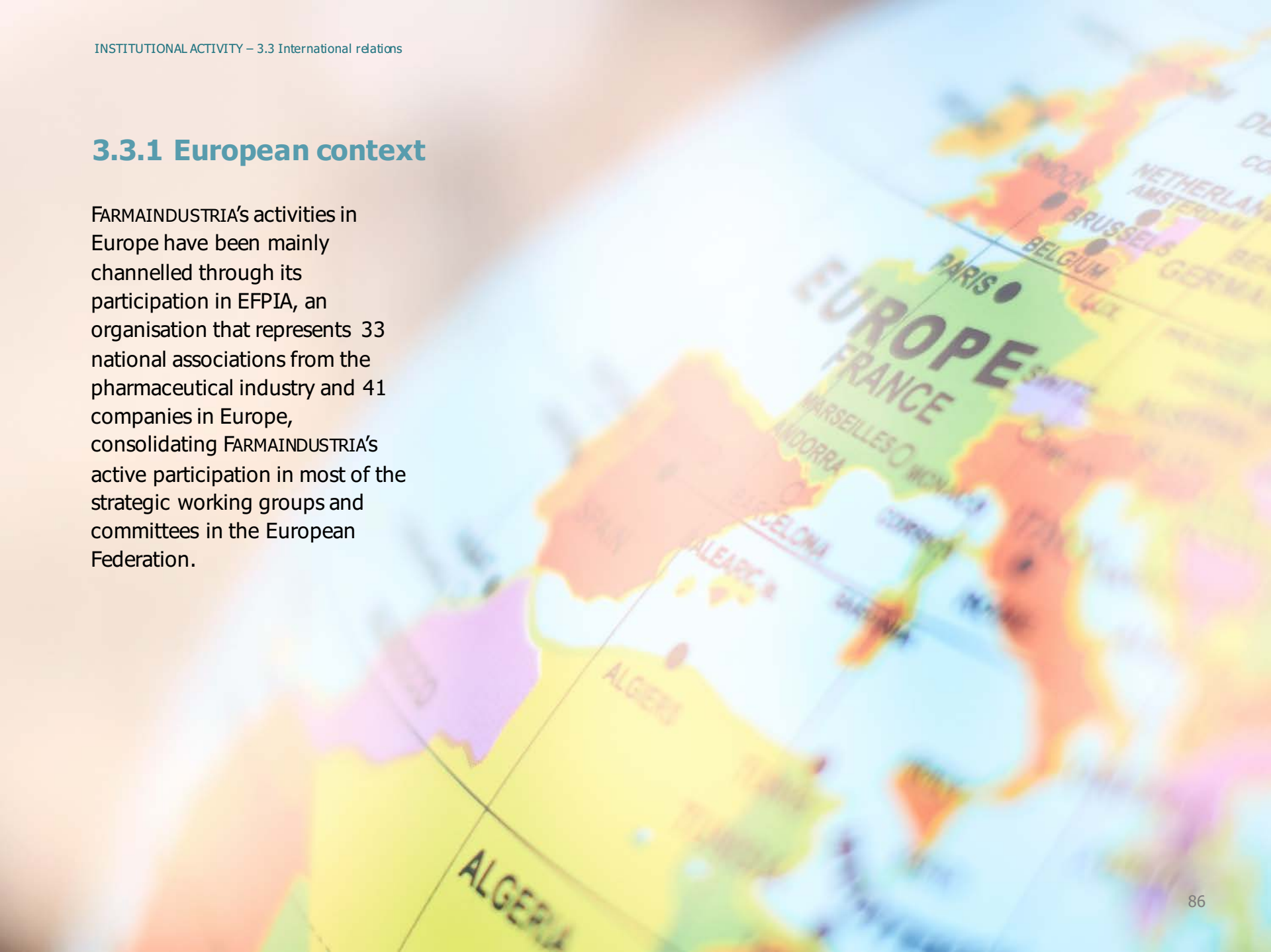
On the other hand, "International Alignment" has been identified as a cross-discipline element of the different actions in the FARMAINDUSTRIA Strategic Plan, thereby compiling the experience and information accumulated by our Association both in its interaction and constant participation in two major international federations to which the pharmaceutical industry in our country belongs: the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and in the main bilateral and multi-lateral meetings that FARMAINDUSTRIA holds with other national associations from the pharmaceutical industry.

This all helps to guarantee the necessary alignment of FARMAINDUSTRIA's action with international positioning and practices.



3.3.1 European context

FARMAINDUSTRIA's activities in Europe have been mainly channelled through its participation in EFPIA, an organisation 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.



GENERAL ASSEMBLY MEETINGS AND NEW DIRECTOR GENERAL OF EFPIA

The Annual General Assembly Meeting of EFPIA was held in Brussels on June 15th 2016, analysing the progress made in different **issues dealt with by the Federation's strategic committees** (Patients and Access, Innovation, International Markets and Finances). The Assembly also approved the priority lines of action for 2016-17 that include, among other topics, tackling new financing models that can make public health system sustainability compatible with patient access to innovations, consolidation of an environment to protect industrial property rights in third party markets or encouraging effective and flexible regulatory environments that promote R&D for new medicines.

As usual, the Assembly was also a time to hold **meetings for the EFPIA Governing Bodies**, ratifying the terms of office for Mr. Joseph Jiménez (Novartis) as President and Mr. Stefan Oschmann (Merck) and Mr. Marc De Garidel (IPSEN) as Vice-presidents for 2016-17.
During the General Assembly, several conferences and workshops were held that were open to the public:

- Analysis of new health challenges in the EU.
- Identification of solutions through innovation.
- Sustainable healthcare systems based on results.

EFPIA BOARD

The **representation of the national associations** in this EFPIA governing body continued in the hands of FARMAINDUSTRIA (Italy) and LEEM (France).

In 2016, the Board tackled priority topics, in coordination with its Strategic Committees, concerning a variety of joint initiatives between Member State public institutions on matters of medicine prices and HTA, compiling and measuring health results data, EU trade policy with third party countries or the General Regulation for Data Protection.

MEETINGS OF EFPIA's EUROPEAN MARKETS COMMITTEE

During 2016, meetings continued with the European Markets Committee (EMC), made up of European Directors from pharmaceutical companies and Director Generals from national associations, aiming for correct implementation and national monitoring of decisions adopted by the EFPIA Board strategic committees, as well as early detection of risks and threats for the industry in the Member States.

The EMC monitored the main national developments on pharmaceutical policy very closely, paying particular attention to the Relative Efficacy Assessment (REA), the national developments of the Counterfeit Medicines Directive, the possible review by European institutions of the incentives in terms of industrial property, plus implementation of the General Regulation for Data Protection in different countries.

In parallel, the EMC has analysed best practices for health results in different countries, including FARMAINDUSTRIA's projects in this field boosted by the Outcomes Strategic Committee in our national association.

Another topic regularly covered by the EMC is transfers of value to healthcare professionals and organisations, particularly national implementation of specific recommendations carried out by the EFPIA Board over their publication period (June 23rd to 30th 2016), plus the need to intensify interaction with healthcare professionals and coordinate reinforced communication plans.

NATIONAL ASSOCIATIONS MEETINGS (GROUPS G1 AND G2)

During 2016, **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) as well as the "G2" group (Belgium, Netherlands, Denmark and Sweden). As a cross-discipline decision, the participants agreed to permanently include global topics in the meeting agenda in coordination with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) after reforming its governing structure, particularly in terms of prices, access and industrial property.

Among other topics, the national associations held in-depth debates on the main new issues in **pharmaceutical policy that affect each country**, stating their common concern to make access to innovation compatible with public healthcare system sustainability, paying particularly close attention to the Collaboration Protocol between the General State Administration and FARMAINDUSTRIA, signed on November 2015, mentioned in detail in other sections of the Annual report.

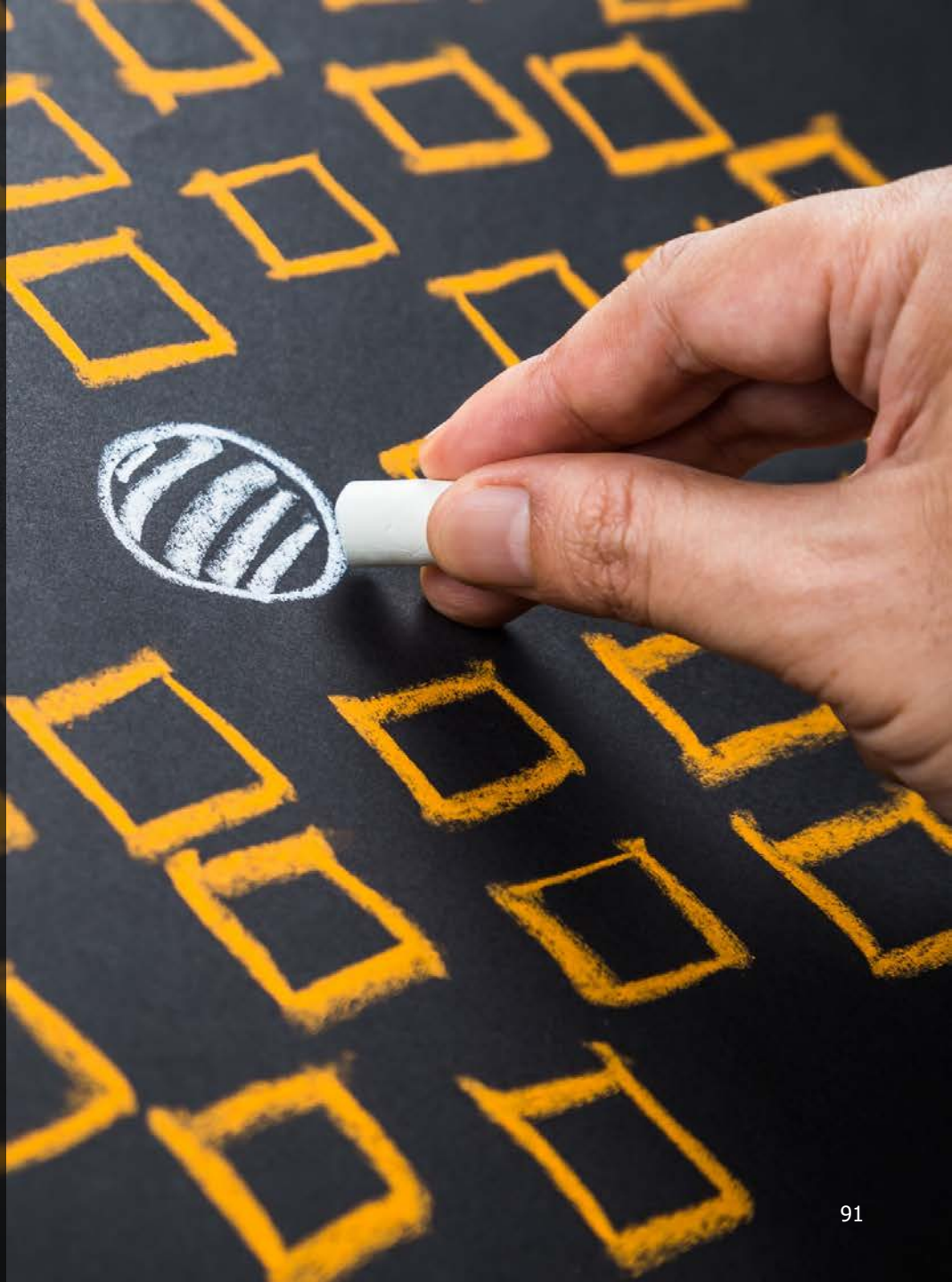
Additionally, different sections of the meetings were given over to an in-depth look at health results, price strategies for combined therapies, assessment of the relative efficacy of medicines on a European level (EU-REA) or actions to reduce the economic impact of serialising medicine packaging on European SMEs.

MULTILATERAL MEETINGS

As usual, a variety of meetings were held with national associations from other countries where, as well as sharing initiatives regarding pharmaceutical policy and development of their respective markets, an opportunity was provided to explain the scope of the **Collaboration Protocol** signed between FARMAINDUSTRIA and the Spanish Government. In this respect, the workshop organised by FARMAINDUSTRIA in February 2017 deserves a mention, involving several companies and representatives from the American, PhRMA, management in the Middle East and Africa, plus AFIDRO (association of innovative pharmaceutical companies in Colombia) that had expressed an interest in understanding the details of the Protocol. The meeting was also attended by a representative from the Secretary of State for Finance who highlighted the benefits of the Protocol for both parties and the positive climate of trust and working together that it brought about.

BREXIT.
POSITION OF THE PHARMACEUTICAL INDUSTRY IN EUROPE

Following the referendum held in the United Kingdom that will lead to its departure from the EU within the next two years, EFPIA, known to be against this situation, has set up a working group to assess the consequences of BREXIT on the European pharmaceutical industry and lead this process management as effectively as possible in several areas: R&D, regulation, manufacturing and supply of medicines, and access to the market. The EFPIA Council will monitor this process continuously, working on public relations and institutional actions with all the relevant stakeholders in the short and medium term.



EUROPEAN INSTITUTIONS

European Council conclusions on EU pharmaceutical policy

The latest meeting of the European Council of Employment, Social Policy, Health and Consumers (EPSCO) was held in June 2016 under the Dutch presidency.

The conclusions acknowledged the pharmaceutical industry's contribution to healthcare system sustainability in the EU, although it did also identify some **potential challenges** for these systems if their management is not optimised. These conclusions invited the European Commission, in close collaboration with the Member States and fully respecting their competences, to **analyse the legislative instruments in force in terms of incentives for developing and marketing new medicines**, particularly mentioning the Supplementary Protection Certificates (SPC) in terms of industrial property and regulations on R&D for paediatric and orphan medicines.

The European Commission has expressed its willingness **to work with the Member States** on this process, always emphasising the need to consider coherence with other EU policies and their position in international forums, plus support for employment and investment from the pharmaceutical industry based in Europe.

EFPIA, on the other hand, issued a press release offering to work with the European Commission on this initiative, highlighting the importance of **developing ways for the pharmaceutical industry and the European governments to work together innovatively** (payment per results, REA), to meet challenges facing the healthcare systems.

European Parliament report on alternatives to improve access to pharmaceutical innovation

After its mandatory legislative process in different Committees since publication, in February 2017, the European Parliament adopted the "Report on EU options for improving access to medicines" presented by the Spanish MEP, Ms Soledad Cabezón, that includes proposals for improving **traceability of R&D spending and public financing for medicines**.

EFPIA and FARMAINDUSTRIA worked intensely with institutions to produce a final text that was more balanced than the initial proposal from June 2016, thanks to many amendments such as rejecting setting up a European body that influences national decisions on price and reimbursement and implementing a European rate on pharmaceutical sales. Another amendment urged the Commission to make legislative proposals that harmonise transparent criteria to assess the relative efficacy of new medicines and recognise the value of incremental pharmaceutical innovation.

European Union Institutions Transparency Register

In June 2015, FARMAINDUSTRIA signed up to the **"Transparency Register"** for organisations and self-employed persons who participate in making and applying EU policies," an instrument set up by the European Parliament and the European Commission to enforce transparency in work by the interest groups that attempt to influence formulation of European policies.

In March 2016, the European Commission launched a public consultation to compile points of view from all stakeholders on **how the Register was working** up to that point, intending to propose the necessary improvements to evolve towards a compulsory register mechanism that includes the European Parliament, the European Council and the European Commission, as announced in the policy guidelines by the president of the Commission Mr Jean-Claude Juncker.

EFPIA sent an official response to this consultation and published an open letter in which its member companies and associations publicly declared their **support for making this Register compulsory** in all three institutions, highlighting the importance of transparency as an essential tool to develop correct relations between EFPIA and the European institutions, intending to set up and maintain a suitable ecosystem for research and development of medicines in Europe, as well as optimising the use of innovative medicines and the sustainability of EU healthcare systems.

LEGISLATIVE INITIATIVES IN EUROPE

Directive 2011/62/EU (counterfeit medicines). Delegated Regulation (EU) 2016/16. Setting up SEVeM in Spain

After the Delegated Regulation (EU) 2016/161 by the Commission dated October 2nd 2015 was published in the DOUE in February 2016, setting specific rules on inclusion of compulsory **security measures** on **medicine packaging** (single ID and anti-tampering device), the three-year deadline envisaged for full compliance was officially set (February 2019), meaning that all prescription medicines (with only a few exceptions) must have security and anti-tampering devices to prove that they are authentic.

Over this period (until February 2019), national verification systems should be set up in the Member States that will manage the directories storing information from these security devices.

Due to this measure's expense for national SMEs, as production lines must be adapted (costing around **€200 million** for the industry as a whole in Spain), FARMAINDUSTRIA has worked intensely with institutions, both nationally and internationally, to achieve a sector-based exemption for companies that sell their products exclusively in Spain, although in the end this was turned down. Consequently, alternative measures are currently being examines plus the possibility of packing medicines in pre-serialised packaging.

Alternately, after meetings and intense work with the stakeholders, the Spanish Medicines Verification System (SEVeM) administration company was set up in July 2016, made up of FARMAINDUSTRIA, the Spanish Association of Generic Medicines (AESEG), the General Board of the Official Pharmaceutical Colleges (CGCOF), and the National Federation of Wholesale Distribution Associations Specialising in Pharmaceuticals and Parapharmaceutical Products (FEDIFAR).

SEVeM officially kicked off in September 2016 by putting together its Board of Directors (AEMPS will also participate in these meetings) that also supervises the system.

Due to its international relevance, it should be highlighted that the National Markets and Competition Commission (CNMC) published a resolution in February 2017 confirming that the so-called "free price" contracts established by a pharmaceutical company with distribution companies are not prohibited by Article 1 of the Anti-trust Law or Article 101 of the Treaty on the Functioning of the European Union.

On the other hand, the resolution acknowledges significant changes in Spanish legislation on medicine prices, confirming that Spanish legislation "has a decisive influence" on this type of contract so it is "not possible to blame the company for a situation that is derived from the legal order and that is imposed by the Administration."

Adoption of the Legislative Package on Personal Data Protection

The European Parliament approved the Legislative Package on **personal data protection** in its Plenary Session in April 2016. This Legislative Package is made up of a new General Personal Data Protection Regulation (that will replace Directive 95/46/EC) and a Data Protection Directive relating to compliance with, and observation of the laws in this field that will replace the decision adopted by the European Institutions in 2008.

The regulation fundamentally aims to increase the level of **data protection** for European citizens whose data is being processed, at the same time generating new opportunities in the single digital market, particularly in terms of reducing administrative barriers.

Following its publication in the DOUE last May, the Member States have two years to regulate aspects that, according to EFPIA and FARMAINDUSTRIA, require harmonisation at a European level in an attempt to guarantee legal security for all on-going and future international biomedical research projects.

In fact, the sector considers that restrictive interpretation of data protection laws would be detrimental to progress for the European healthcare systems and researchers in biomedical research, and would not make the most of Big Data's potential for healthcare authorities, researchers and of course, patients.

Consequently, EFPIA has set up an ad hoc working group that, while constantly coordinating with the national associations, works to meet these objectives, particularly focusing on five key elements affecting the biomedical sector:

1. Making personal data anonymous.
2. Broad consent from the subject and reuse of the data.
3. Data ownership.
4. Genetic data.
5. Subjects' rights.

European Parliament Adoption of the EU-U.S. Privacy Shield

The European Parliament voted as a majority to adopt the framework agreement on what is known as the "Privacy Shield" in December 2016. This agreement, signed between the United States and the European Union in June, created a framework for transatlantic personal data flows in line with requirements set by the EU Court of Justice that declared the former mechanism, known as "Safe Harbour", to be invalid in 2015.

The Privacy Shield fundamentally aims to encourage protection of European and US citizens by coordinating the fight against organised crime and terrorism, whilst guaranteeing their fundamental rights in terms of personal data protection. The framework agreement will come into force when both territories have completed their internal adoption processes. In the case of the EU, this processing will be completed when the European Council decision is approved, envisaged for 2017.

European Commission legislative package on privacy in electronic communications and personal data protection for EU institutions

The European Commission has been working on a legislative package aiming to update the legislation in force in accordance with **requirements in Regulation** (EU) 2016/679 on EU data protection, and broaden its field of application to all electronic communications service providers. In the same way, the Commission aims to standardise personal data protection by EU organisations in all Member States and establish a strategic focus in terms of international transfer of personal data.

Among other measures, the package includes **information regarding international transfers of personal data** that aims to encourage commercial exchanges and international police cooperation.

The Commission has requested that the European Parliament and European Council work quickly to thereby guarantee that these measures are adopted before May 25th 2018, when the general regulation on data protection will become applicable.

Sentence of the CJEU on late payment interest in supplier payment plans

The final sentence from the CJEU (Court of Justice of the EU) was published on February 14th 2017 regarding Matter C-555/14, on the request for a preliminary ruling lodged by Contentious-Administrative Court no. 6 in Murcia, regarding the compatibility with the community standard of renouncing late payment interests required to participate in Supplier Payment Plans promoted by the Spanish Government in 2012-14. In line with the Conclusions already issued by the Attorney General, Ms Eleanor Sharpston, in May the previous year, the CJEU declared that:

"Taking into account all previous considerations, to answer the first and second preliminary ruling that Directive 2011/7, particularly in Article 7, sections 2 and 3, should be interpreted in the sense that it does not oppose a national rule, such as the rule contested in the main dispute, that allows the creditor to renounce demanding late payment interest and compensation for the charging costs balanced by the immediate payment of the majority of the credit due, as long as this renouncement is freely consented, as proven by a national judge."

REACH regulations and inclusion of aprotic solvents in Annex XIV

The REACH Regulation on Register, Evaluation, Authorisation and Restriction of Chemical substances came into force in 2007. Ever since, certain substances used for manufacturing active ingredients and medicines were excluded from the regulation although, more recently, some substances used in manufacturing active ingredients such as some solvents began to be included in the "Authorisation" processes (lists in Annex XIV).

So, when a substance is included in these Authorisation lists, the pharmaceutical companies that use them have to request authorisation from the European Chemicals Agency (ECHA) to continue using them, until a suitable alternative can be found.

EFPIA and FARMAINDUSTRIA have been explaining the sector's concerns to all relevant agents at home and in Europe, claiming sector-based exclusion for the pharmaceutical industry in relation to the use of these substances, arguing that they are already evaluated by the EMA in the authorisation process.

Nagoya Protocol. Draft of Royal Decree relating to access to the genetic resources coming from wild taxons and to controlling their use

FARMAINDUSTRIA, in coordination with EFPIA and IFPMA, continues to work with institutions to guarantee a legal security framework for the pharmaceutical industry in processes derived from effective application of Regulation 511/2014, relating to user compliance measures from the **Nagoya Protocol on access to genetic resources and fair and equal participation in the benefits derived from their use in the EU**.

The potential limitations and obstacles to use and share pathogens are particularly important, with a direct impact on the industry's fast and effective response to threats such as the Zika virus. IFPMA, on the other hand, published a statement in January 2017 recalling the importance of considering the implications for public health of any legislation that is adopted on this matter, and in particular the appropriate use of genetic resources.

BIOTECHNOLOGY

Work by FARMAINDUSTRIA in this field is run with both EFPIA and EBE (*European Biopharmaceutical Enterprises*).

Joint statement from EFPIA, EBE and IFPMA on the interchangeability of biotherapeutic medicines by healthcare professionals

In March 2017, EFPIA, EBE and IFPMA published a position document and a press release under the title: "Considerations for physicians on switching decisions regarding biosimilars".

The three associations emphasise that progressive introduction of biosimilars increases the risk of making decisions regarding **switching treatment with biotherapeutic medicines based only on economic reasons**, without considering the unique characteristics of these products. In this respect, they argue that physicians should be free to designate which biotherapeutic medicine should be prescribed and/or dispensed in each case, fundamentally using clinical criteria, also emphasising that patients should be consulted on any decision regarding switching treatments with biotherapeutic or biosimilar medicines and given appropriate clinical monitoring.

Q&A document on biosimilar medicines

In December, the European Commission published an update of its Q&A document on biosimilar medicines (first published in 2013), specifically focusing on European patients.

This guide forms part of a consensual information document known as "What I need to know about biosimilar medicines" in an attempt to give **patients information on these treatments**, helping them understand key concepts on biotherapeutic and biosimilar medicines by explaining them in layman's terms.

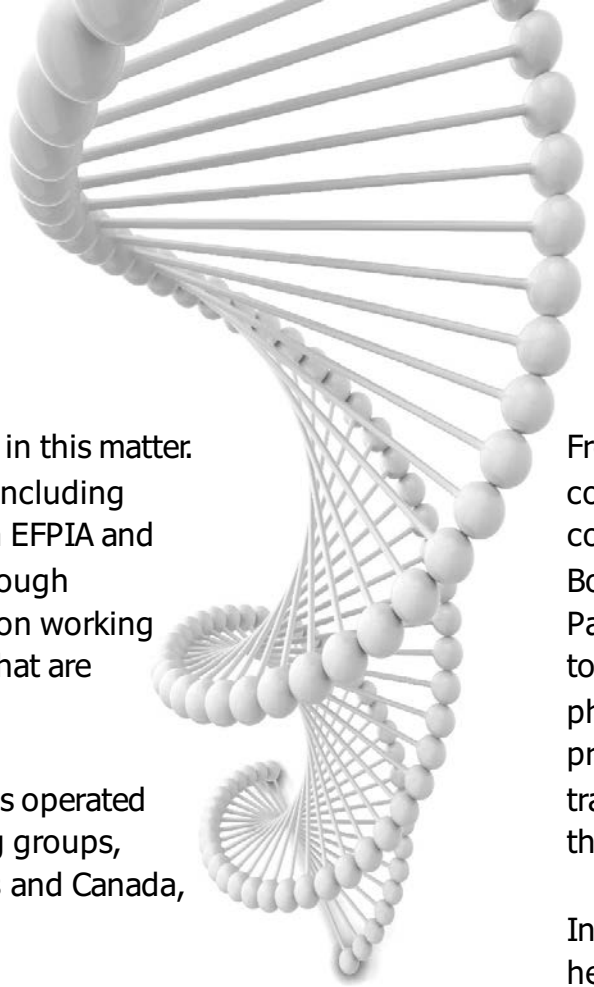
VACCINES

After refreshing its mission and focus direction, the *Vaccines Europe* association has increased its work with institutions, PR campaigns and public awareness-raising.

In this respect, an annual report was published in 2016 entitled "The vaccine industry in figures", accompanied by a variety of info-graphics and other PR material, praising the European Union as a worldwide strategic centre for R&D into vaccines, highlighting this sector's contribution not only to patient health, but also to the economy and creating jobs in the EU.

Specific reports have also been published **on the role of vaccination** in the global fight against anti-microbial resistance and its contribution as an effective public health tool to reduce mortality and improve standards of living throughout the world.

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



COMPETITION AND INTERNATIONALISATION

FARMAINDUSTRIA acts on two fronts in this matter. On the one hand, internationally, including foreign trade, in coordination with EFPIA and IFPMA and on the other hand, through Competition and Internationalisation working groups, with national companies that are members of FARMAINDUSTRIA.

Internationally, FARMAINDUSTRIA has operated through specialised EFPIA working groups, particularly from the United States and Canada, and from emerging markets.

EFPIA decided to consider Japan and the conclusion of the Free Trade Agreement with the EU as priority actions in 2017 and 2018 and a new group has also been set up for strategic foreign trade with Latin America, presided over by FARMAINDUSTRIA.

From our Association, and in coordination with EFPIA, work has continued at all levels (General Trade Board in Spain, Embassies, European Parliament and European Commission), to guarantee that the innovative pharmaceutical industry's interests and priorities appear in all trade agreements between the EU and third party countries.

In this respect, meetings have been held with national authorities to tackle these foreign trade priorities and other geopolitical aspects that affect trade, such as the new American presidency or BREXIT.

TTIP: Transatlantic Trade and Investment Partnership between European Union and the United States

Although TTIP negotiations have been put on hold until after the new President of the United States has taken office, the European Commission has confirmed that the agreement has been updated to mutually acknowledge production plant inspections and good manufacturing practices between **Europe and the United States**, as negotiated within this Partnership.

This mutual acknowledgement will lead to as much as **40% reductions** in terms of duplicating the number of inspections either side of the Atlantic, not to mention saving over 30 million Euros, in accordance with estimations made by EFPIA and the US association, PhRMA. The agreement is particularly relevant for Spain as it appears on the list of eight Member States that have already been audited (along with the United Kingdom, France, Italy, Sweden, Croatia, Greece and Austria), where measures will be applied directly from November onwards.

Canada. "Comprehensive Economic and Trade Agreement" (CETA)

Although it was firmly adopted in 2016, because this is a mixed agreement, it must be confirmed by the national Parliaments of all Member States before it can be fully applied. FARMAINDUSTRIA is monitoring this process in Spain, although our country is in favour of its ratification.

On the other hand, and in coordination with EFPIA, Law B-30 is being monitored exhaustively. It will transpose the main provisions of the CETA in terms of pharmaceutical industrial property to the legal Canadian ruling:

1. Right to appeal for innovative pharmaceutical companies.
2. Patent protection compensation periods.
3. Extension of the data protection period.

Japan. Free trade agreement

This is expected to be **signed mid 2017**. Both EFPIA and FARMAINDUSTRIA are in constant contact with national and European authorities in an attempt to guarantee that the sector's priorities are included appropriately in the final text.

Turkey and Russia

FARMAINDUSTRIA, EFPIA and PhRMA actively monitor **protective measures and non customs barriers to trade that are in force in these countries.** In both cases, the governments prioritise local production, obliging the companies to send authorities any plans for their implementation on national soil that, if not accepted, become discriminatory practices for foreign companies (such as exclusion from public purchasing processes).

Mexico, Colombia and Chile

FARMAINDUSTRIA leads the EFPIA working group that is in charge of **monitoring negotiations on the free trade agreement between Mexico and the European Union.** This Agreement was given a strong boost with the announcement of two new rounds of negotiations in April and June 2017, strengthening relations with the Mexican Association for the innovative pharmaceutical industry (AMIIF), in an attempt to align the sector's main demands, specifically relating to harmonisation of industrial property protection, data protection and transparency and fairness in market access.

On the other hand, **legislative developments in Colombia and Chile** are being monitored exhaustively as they focus on allowing compulsory licences for patent-protected medicines for reasons of public health.

3.3.2 International Context

FARMAINDUSTRIA channels its activities in this field through the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), represented in meetings of its Governing Bodies (Council and General Assembly), and its Board of Directors.

IFPMA's activity revolves around a variety of Committees of which FARMAINDUSTRIA is a member, and in which it participates actively and regularly.

Reform of IFPMA statutes and Governing Bodies
New Director General

In December, the IFPMA Governing Bodies approved a reform of the statutes and the system of governing the Federation in an attempt to coordinate the overall actions of the pharmaceutical industry in terms of access to medicines and industrial property. In addition to the General Assembly and the Council, it was agreed to set up a new governing body, the "CEO Steering Committee", made up of the presidents of PhRMA, EFPIA and JPMA among others.

Finally, appointments were confirmed that have become effective over 2017, including Mr. Ian C. Read (Pfizer) as President of IFPMA, and designating Mr. Thomas Cueni (Interpharma) as the new Director General.

Meetings of the IFPMA Governing Bodies

On another note, FARMAINDUSTRIA, as usual took part in the IFPMA Council and Assembly meetings, held in July and November 2016. Among other matters, the Strategic Plan for 2017-2018 was adopted, revolving around four strategic lines:

1. Provide incentives for developing a favourable environment for **biopharmaceutical innovation.**
2. Design a **communication plan** in an attempt to promote sustainable access to medicines and vaccines.
3. Provide **leadership in terms of ethics and transparency**
4. Tackle global **challenges for health systems**. The Council also unanimously approved the IFPMA's Code of Practice reform.

Other matters included the World Health Organisation's policy on essential medicines plus new regulations in Brazil, India and China. In addition, the Alliance to Fight Cancer, set up by IFPMA with the WHO's Regional Committee in Africa, was publicly presented and a variety of suggestions were analysed to encourage the pharmaceutical industry to take part in initiatives to reduce antimicrobial resistance on a global scale.

INNOVATION, INTELECTUAL PROPERTY AND TRADE

Modification of World Trade Organisation (WTO) rules on intellectual property (ADPIC/TRIPS)

An amendment to the **Intellectual Property Agreement** (ADPIC/TRIPS) came into force in January 2017 in an attempt to furnish developing countries with an appropriate legal framework to access affordable medicines following WTO rules.

The modification made in paragraph 6 of the Doha Declaration on ADPIC and Public Health agreements, from this moment on, allows export of medicines manufactured under the compulsory licence for less developed third party countries that are lacking their own production, as long as conditions set previously by the WTO have been met.

GLOBAL HEALTH

IFPMA report on essential medicines in the world

Working with IMS/Quintiles, IFPMA published a report in November 2016 entitled "Ensuring essential medicines satisfy priority healthcare needs of populations." The report analyses different parts of healthcare systems that have a potential impact on management, use and availability for financing and use of these treatments, and best practices are pinpointed to bring out the maximum potential from these essential medicines in health systems. The countries being studied include Brazil, China, India, Indonesia, Kenya, Mexico and South Africa, looking at the use of essential medicines in different high-prevalence therapeutic areas: autoimmune diseases, cardiovascular illnesses, diabetes, HIV, malaria, mental health, oncology and TB.

COUNTERFEIT MEDICINES

In this field, it should be highlighted that WHO Member States adopted a single definition of "counterfeit and substandard quality medicines" in January 2017, highlighting the **disassociation with any consideration on industrial property**, in line with what is established by the IFPMA that considers counterfeiting medicines as a priority public health problem.

On the other hand, the **"AIM report"** has been published on counterfeit medicine incidents on a global scale, brought out jointly with several companies and associations that are members of IFPMA, coordinated by the Pharmaceutical Security Institute (PSI), set up in 2002 by several pharmaceutical companies to protect public health, with the specific aim of compiling, analysing and diffusing information on counterfeit medicines and their risks, as well as promoting coordinated measures and strategies with the competent authorities to **fight counterfeiting.** The AIM Project analyses illegal activities associated with medicines, working with and receiving information from pharmaceutical companies, authorities and sector-based associations from all over the world. In Spain, most counterfeits are medicines for treating erectile dysfunction, oncology and steroids.

NON-COMMUNICABLE DISEASES

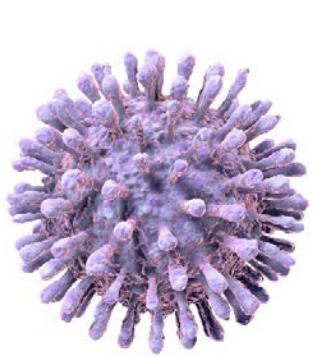
Coinciding with the World Economic Forum in Davos, several innovative pharmaceutical companies presented the global initiative entitled *"Access Accelerated Initiative"*, aimed at promoting **prevention and treatment of non-communicable diseases in less developed countries.**

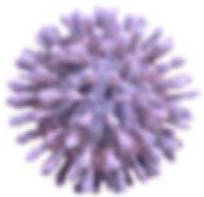
In addition to individual company involvement, the initiative is backed by the World Bank, both in terms of financing and service provision and breaking down regulatory barriers, taking charge of developing pilot projects in selected countries.

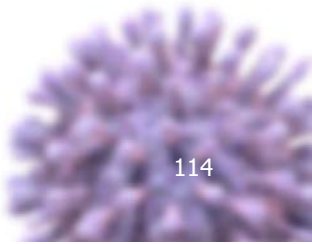
ANTIMICROBIAL RESISTANCE

In September 2016, several EFPIA and IFPMA member-companies presented a **"Route map for the pharmaceutical industry to fight antimicrobial resistance"** coinciding with the United Nations General Assembly, representing continual commitment from the sector at the Davos Economic Forum in January of the same year. In this respect, the signatory companies are committing to measures such as:

1. Reducing the environmental impact of producing antibiotics.
2. Contributing to rational use of antibiotics.
3. Improving access to antibiotics that are already available and to future treatments (also vaccines and diagnoses).
4. Exploring opportunities to work together openly between the industry and public administration, from a multi-sector perspective, including organisations such as the WHO and the United Nations.







OECD HEALTH MINISTRY MEETING

The Organisation for Economic Cooperation and Development (OECD) held another meeting of its member countries' Health Ministers in January 2017, under the general title of "The next generation of health reforms," looked at the possibilities of **reducing ineffective healthcare spending** and adapting healthcare systems to new technologies. To mark this this meeting, the OECD published the report "New Health Technologies: Managing Access, Value and Sustainability" that, among other measures, recommends guaranteeing balance in negotiating processes between authorities and the pharmaceutical industry through initiatives such as regular information exchange, centralised purchasing or prices differentiated by indication. EFPIA and IFPMA have published a joint statement demonstrating the importance of the pharmaceutical industry as the administrations' key ally to identify solutions that guarantee development of scientific innovation in sustainable and efficient health systems.

UNITED NATIONS REPORT ON ACCESS TO MEDICINES

In early 2016, the Secretary General of the United Nations promoted setting up a "High-Level Panel on Access to Medicines", with the aim of "analysing and evaluating proposals and recommendations that coherently balance out the justifiable rights of the inventors, international legislation on human rights, rules on trade and public health in access to healthcare technologies and medicines." Finally, the United Nations published a report of conclusions last September to which the IFPMA answered with a statement expressing its concern as it considers this a missed opportunity to find **real solutions that help to improve global health.** The statement also highlights the pharmaceutical industry's crucial R&D role and its relevance when discovering and developing effective treatments for pathologies such as HIV or Hepatitis C, reiterating the commitment from IFPMA and its members to provide access to health services and its intention to forge alliances guaranteeing universal healthcare cover throughout the world.

3 Institutional Activity

3.1 Market Regulation and Relations with Public Administrations

3.2 Social Communication

3.3 International relations

3.4 The pharmaceutical industry in Spain and worldwide

3.4.1 The pharmaceutical industry in Europe

Analysis of the progress of a business sector in a certain 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 this respect, with real **growth of +1.9% of GDP** in 2016, this has consolidated the growth rate that the European economy began in 2014 (with growth of +1.6%) that intensified in 2015 (+2.2%), after holding steady for a few years.

This consolidation has led to **more jobs**, bringing the EU-28 unemployment rate down from 9.0% in 2015 to 8.2% in 2016, although it has yet to recover pre-recession levels (2007) when this rate stood at around 7% of the active population.

In addition, austerity measures continued in 2016 by **reducing**, the **deficit for all Public Administrations** in the EU-28 for the seventh year in a row, going from 6.9% of GDP in 2009 to 1.7% in 2016.

Future forecasts point towards a consolidation of the **growth rates recorded in the 2014-2016 period**. So, the European Commission, in its European *Economic Forecast- Spring* 2017, calculates the forecast growth rate of real GDP for the EU-28 as +1.9% in 2017 and 2018.

On the other hand, we should remember that although there has been great progress, austerity measures have not been lifted in some European countries, so the public budget for these countries (including healthcare spending) is still tightly controlled as seen in containment measures on healthcare spending and public pharmacies. It is logical to assume that this will have an effect on the evolution of a market such as the pharmaceutical sector that is strongly regulated and that depends on public budgets. In addition, these measures can often be seen in terms of restricted access to certain products and growing pressure on medicine prices.

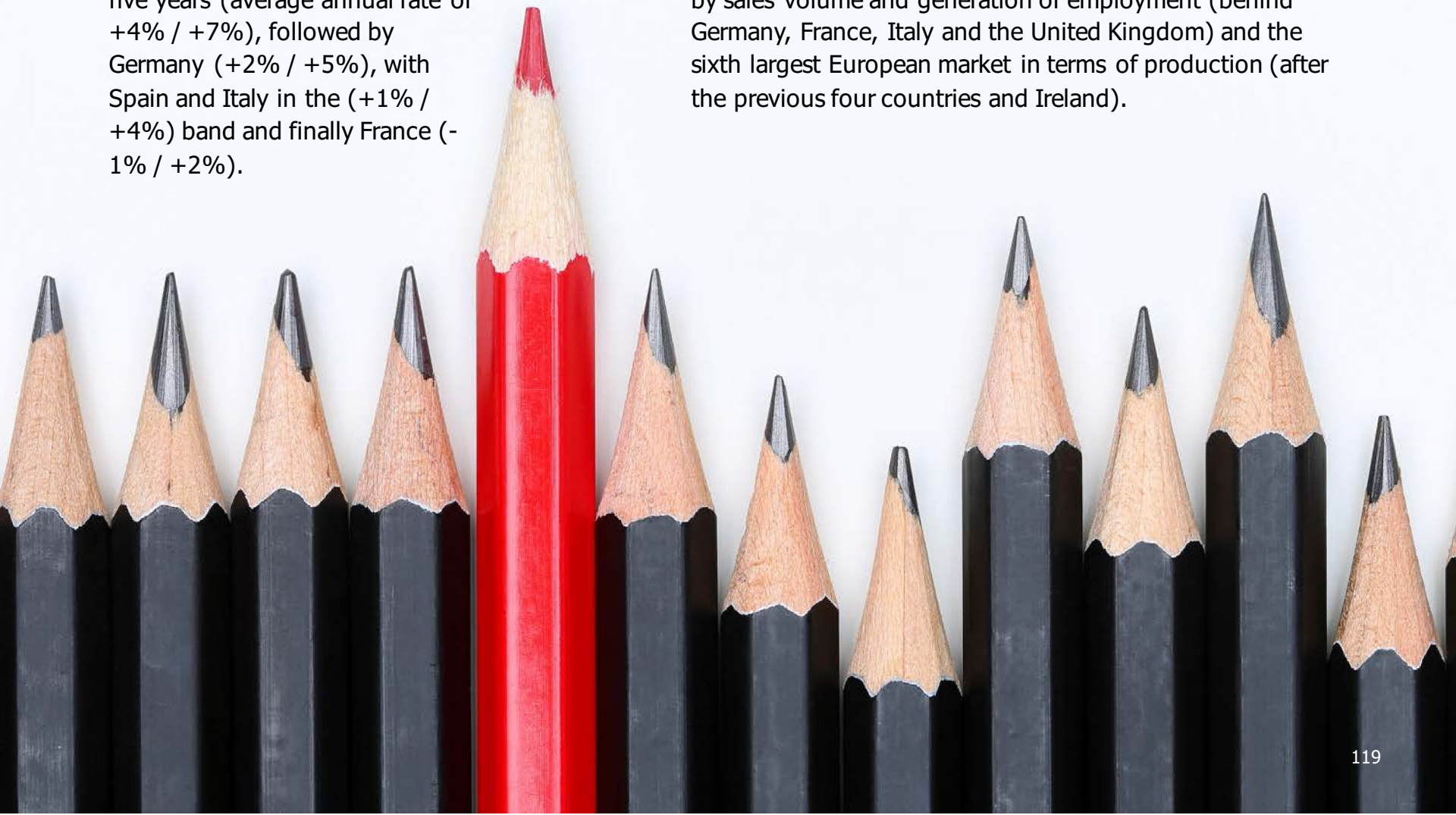
Although the aforementioned measures will limit the growth of the European pharmaceutical market, there are other factors that will boost it, such as the ageing population and innovation in high impact therapy areas. This was the case for **new treatments for hepatitis C** introduced in 2015 or new oncology therapies and the new biotherapeutic treatments for certain autoimmune diseases, such as psoriasis or rheumatoid arthritis in 2016.

Taking these factors into account, the forecast from the IMS Health[1] consultancy put the average rate of annual growth for the five main European markets in the 2016-2021 period in the (+1% / +4%) band, slightly below the growth forecast for the sector worldwide (+4% / +7%) and the growth forecast for the United States and emerging markets such as Brazil, India and Russia that will see average annual growth in the (+6% / +9%) band.

[1] IMS Market Prognosis, October 2016. The data corresponds to the total pharmaceutical market for each country (Out-patients + Hospital).

Out of the five major European markets, the **United Kingdom will grow the most** in the next five years (average annual rate of +4% / +7%), followed by Germany (+2% / +5%), with Spain and Italy in the (+1% / +4%) band and finally France (-1% / +2%).

Spain is a highly relevant country in the European pharmaceutical context. As shown in the following table, Spain is the fifth largest pharmaceutical market in Europe by sales volume and generation of employment (behind Germany, France, Italy and the United Kingdom) and the sixth largest 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 laboratories** (1)	**Production** (millon €) (2)	**Employment**	**Domestic sales** (PVL) (millon €) (3)	**Foreign trade** (PVL) (millon €) (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
U.K	52	19,313	61,500	22,375	30,503	33,343
Sweden	90	7,809	11,012	3,809	3,577	7,600
Total UE-15	**1,659**	**178,429**	**540,517**	**169,395**	**213,588**	**288,959**

(*) 2014

NB: Luxemburg is not included as it is barely representative.

(1) Pharmaceutical companies that are members of the EFPIA associations.

(2) The data refers to activities producing pharmaceutical specialities and raw materials for human and veterinary use, except in Germany, Spain and Ireland, where they only refer to activity intended for human use.

(3) It includes sales through dispensing pharmacies, hospitals and other distribution channels.

(4) Pharmaceutical foreign trade (SITC 54). Includes veterinary products.

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

3.4.2 The Pharmaceutical Industry in Spain

R&D+i

Research, development and innovation (R&D+i) is a central part of a competitive, high quality model with sustainable growth and it is essential to create jobs and improve productivity and economic competition, as recognised by the Government of Spain in its Annual Reforms Programme sent to Brussels[2].

The Government thereby highlights the importance of these activities and the starring role they are called on to play in economic recovery so that, within the Europe 2020 Strategy, an objective has been set for R&D spending in our country to reach 2% of GDP by 2020.

To meet this goal, the **Government drew up the Spanish Strategy for Science, Technology and Innovation 2013-2020**, making up the backbone of the R&D policy for the next few years and establishing strengthening business leadership in R&D+i as one of its 4 main goals.

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

Based on the above, the aforementioned document sets a series of objectives to be achieved over the next few years in terms of R&D spending in relation to GDP and how R&D spending is divided between the public and private sector. These objectives are summarised in the following table: [3]

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

In summary, the objective set by the Government for 2020 involves **doubling research work in the Spanish business sector in relation to GDP and maintaining the percentage represented by the public sector within our economy as a whole.** As shown in the table, this would represent going from a situation as in 2010, where for each Euro invested in R&D by the public sector, €0.86 was invested by the private sector, to a situation in 2020 where for each public Euro invested in research, €1.70 would be invested by the private sector.

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

The latest data available (2015) shows how the weighting of R&D spending over national GDP has been dropping over the last few years, going from 1.39% in 2010 to 1.22% in 2015.

Analysis of R&D funding in our country shows that private initiatives have prevented the R&D from losing its weighting in our economy even further. Specifically, in the 2010-2015 period, the R&D spending financed by public funds dropped -19.3%, going from representing 0.55% of GDP in 2015, whilst the figures from private initiatives dropped much less (-3.4%), meaning that it now represents 0.57% of GDP, although it is still far from the 0.73% that it must reach in 2016 and a long way off the 1.20% set for 2020.

Although the Government has made its claim in these goals, soon to be endorsed by the imminent approval of the State Plan for Scientific and Technical Research and Innovation 2017-2020, it has already been warned by some of its main advisory bodies that transferring the responsibility of 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 investments in this field[4].

In this respect, it is of the utmost importance to boost and promote participation from the pharmaceutical industry in its role of leader of the industrial sector in research, as demonstrated by the INE data summarised below:

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

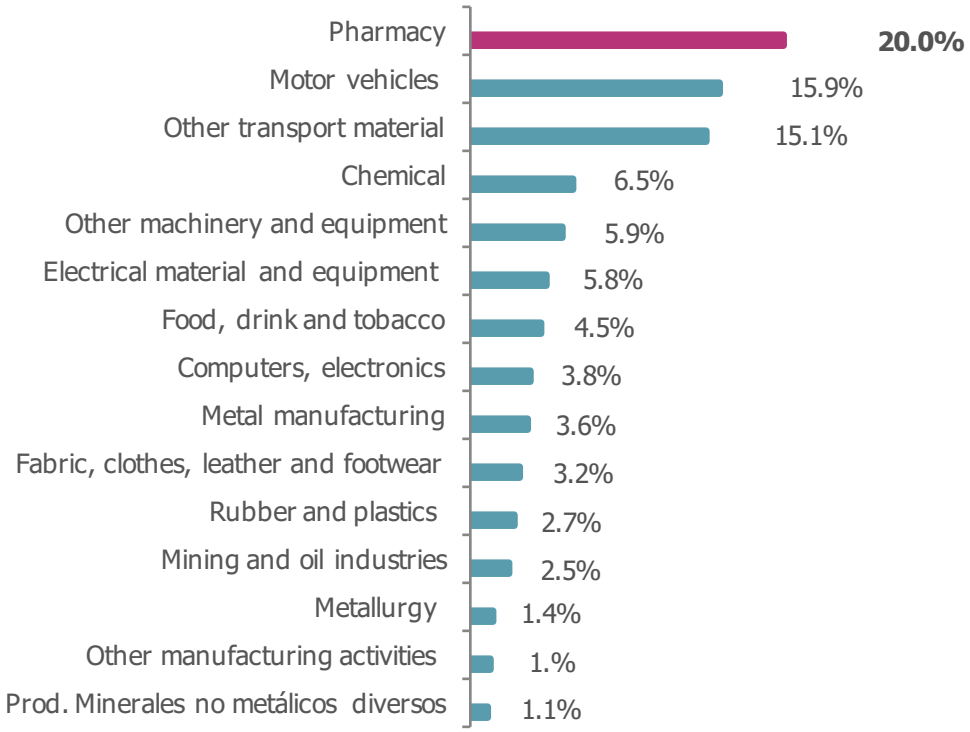
1

In 2015, the pharmaceutical industry invested over 900 million € in R&D, representing 20% of the Spanish industry total and made it, by far, the leading industrial sector by volume of spending on R&D, as shown in the following graph. Representing 20% of all industrial R&D is 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 sector once again leads the industrial ranking for volume of resources intended both for basic resources and applied research.

R&D investment from each sector in Spanish industry as a whole
(as a % of the industrial total) (2015)



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

3

However, the pharmaceutical industry's leadership is not only limited to resources invested in R&D activities; this sector also generates the most employment in R&D with 4,859 professionals working on these tasks full time. In addition, two thirds of these positions are taken on by women, meaning that currently, 29% all female researchers employed in the Spanish industrial sector are working in pharmaceutical companies.

The aforementioned data demonstrates the pharmaceutical industry's leadership in research and its strategic importance in shaping a new growth model in our country. Consequently, and to make progress on this goal, it would be a good idea to develop policies that, without compromising savings goals or the need for austerity measures within different Administration fields, 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 2016, and according to data published by the Ministry of Public Finance and Administration (MINHAFP), public hospital pharmaceutical spending **fell -6.1%** on 2015.

In turn, and according FARMAINDUSTRIA's own estimations, the total sales of medicines in dispensing pharmacies, in net figures after the deductions considered in Royal Decree-Law 8/2010 would have increased +4.5%.

As a consequence of the evolution of both segments, the total sales for medicines in 2016 in Spain would have remained the same as in 2015.

HOME MARKET FOR MEDICINES (manufacturers' sale prices, million €)

	Dispensing 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%	6,234	-6.1%	15,595	-0.0%

(1) Sales of medicines in dispensing pharmacies, after deductions (RDL 8/2010).

(2) Provisional data for public hospital spending corresponding to regions, civil servant mutual benefit societies and prison institutions published by the MINHAP.

Source:

Dispensing pharmacies: FARMAINDUSTRIA working from IMS data and own estimations.
Hospitals: MINHAP hospital pharmaceutical spending Updated in February 2017.

Dispensing pharmacies market

The total market through dispensing pharmacies in 2016 saw an **increase in sales of +4.5%**, as a consequence of a +2.8% increase in the average price and a +1.5% increase in the number of units.

However, when only considering the market segment likely to be reimbursed by the NHS, the sales increase stands at +3.9%, where units that most contribute to growth have risen +2.8% whilst the average price increased +1%.

In October 2016, the **third price reference order** came into force for spending purposes based on the criteria set in Royal Decree 177/2014 dated 21st May, allowing the groups to be set up without a generic medicine. This order created 16 new groups and removed 12. There are currently 424 Reference Price System groups in the field of dispensing pharmacies 157 of do not include a generic medicine.

MARKET STRUCTURE IN DISPENSING PHARMACIES

	Units (mill.)	Quota	Inc.	Manufacturers' sale prices – sales (mill. €)	Quota	Inc.	Manufacturers' sale prices – sales (€)	Inc.
Market subject to reimbursement	1,092	84.5%	+2.8%	8,430	86.9%	+3.9%	7.7	+1.0%
Non reimbursed product market	200	15.5%	-5.0%	1,267	13.1%	+8.0%	6.3	+13.7%
Total market	**1,292**	**100.0%**	**1.5%**	**9,697**	**100.0%**	**+4.4%**	**7.5**	**+2.8%**

Source: FARMAINDUSTRIA working from IMS data.

According to FARMAINDUSTRIA's estimations, the **year on year impact of this order for companies would have risen to €85 million** at manufacturers' sale prices, after deductions corresponding to Royal Decree-Law 8/2010. This impact comes alongside the impact derived from updating homogeneous groups when a new generic medicine or competitor enters the market. During 2016, this represented an impact of €40 million at manufacturers' sale prices for the industry as a whole, also post-deductions from the Royal Decree-Law 8/2010.

Updating the homogeneous groups, along with creating new reference groups has led to a situation at the end of 2016 where 79.7% of the units sold in the dispensing pharmacies market are sold at the same price as their corresponding generic medicine.

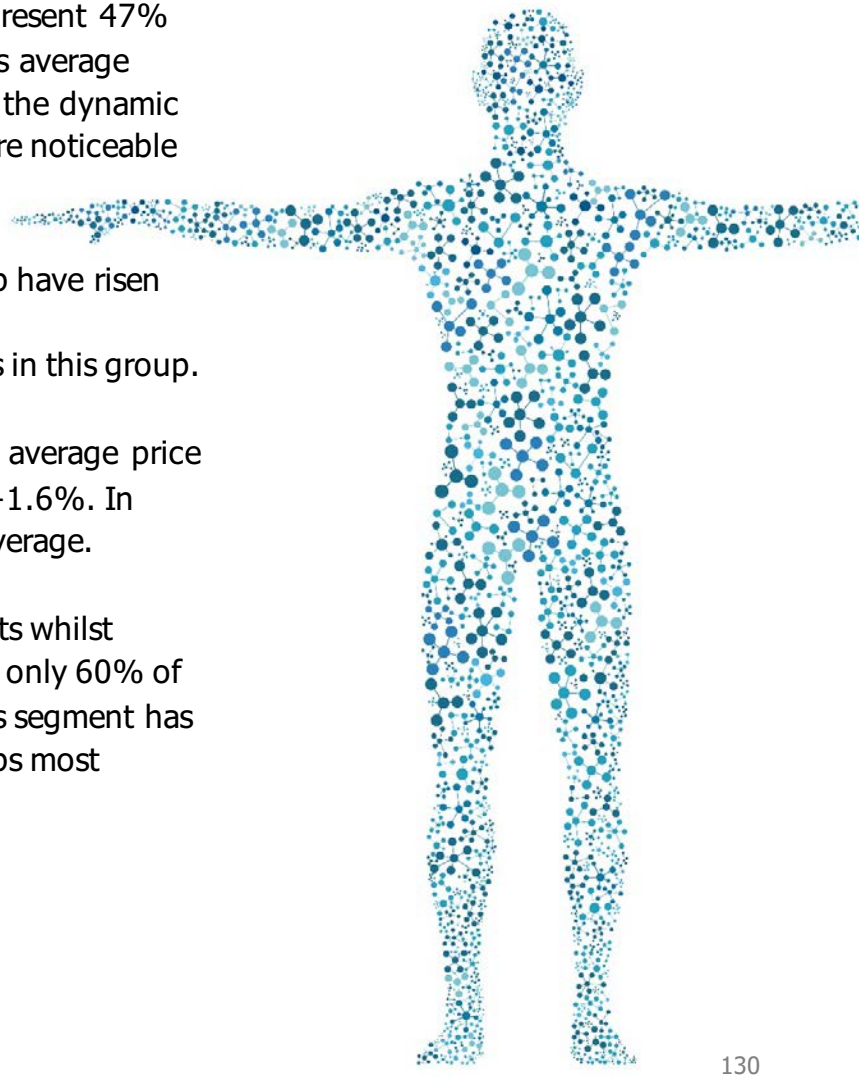
Treatment group

In 2016, according to IMS data, **sales of medicines** through dispensing pharmacies by treatment groups were divided up as shown in this table.

TOTAL SALES OF MEDICINES THROUGH DISPENSING PHARMACIES BY TREATMENT (2016)

Treatment group	Units (thousands)	Quota (%)	Inc. (%)	Manufacturers' sale prices values (thousands)	Quota (%)	Inc. (%)	Average manufacture	Inc. (%)
N Nervous System	327,498	25.3%	+3.6%	2,228,652	23.0%	+3.2%	6.81	-0.4%
A Digest. system and Metabol.	204,810	15.8%	+1.2%	1,652,560	17.0%	+7.3%	8.07	+6.1%
C Cardiovascular system	248,022	19.2%	+1.6%	1,551,600	16.0%	+3.3%	6.26	+1.6%
R Respiratory system	124,158	9.6%	-2.8%	1,047,352	10.8%	-2.5%	8.44	+0.3%
G Genital-urinary system	53,334	4.1%	+1.7%	683,678	7.1%	+3.0%	12.82	+1.3%
B Blood and Hemato. organs	65,935	5.1%	+2.8%	543,263	5.6%	+11.6%	8.24	+8.6%
M Locomotive system	89,271	6.9%	+1.3%	471,230	4.9%	+3.6%	5.28	+2.3%
J Infectious diseases via General	50,283	3.9%	+0.2%	408,238	4.2%	+27.9%	8.12	+27.6%
L Antineoplastic and Immun. Agents	6,662	0.5%	+5.0%	347,889	3.6%	+2.4%	52.22	-2.5%
D Dermatological	49,448	3.8%	+0.6%	276,347	2.8%	+2.5%	5.59	+2.0%
S Sensory Organs	45,236	3.5%	-0.6%	229,638	2.4%	-0.1%	5.08	+0.5%
H Hormones	21,080	1.6%	+2.2%	200,231	2.1%	+3.3%	9.50	+1.0%
V Misc.	1,402	0.1%	-0.4%	43,213	0.4%	+0.9%	30.83	+1.3%
P Antiparasite	1,595	0.1%	+9.4%	8,825	0.1%	+12.6%	5.53	+3.0%
K Hospital Solutions	3,578	0.3%	+6.8%	3,741	0.0%	+6.7%	1.05	-0.2%
T Diagnostic Agents	21	0.0%	-9.3%	333	0.0%	-20.1%	16.05	-11.9%
TOTAL	**1,292,330**	**100%**	**+1.5%**	**9,696,798**	**100%**	**+4.4%**	**7.50**	**+2.8%**

The **Central Nervous System gro**up that represents a quarter of the pharmaceutical market in units is **growing over average figures in units**, largely due to the increase in consumption of pain killers that represent 47% of units in this group, recording an +4.5% increase. Regarding its average price, and after -5.4% price drops last year, as a consequence of the dynamic of homogeneous groups, this year it has fallen again slightly, more noticeable in the reimbursable market (-1.1%).



As far as the **Digestive System** is concerned, units in this group have risen below market average, whilst average prices have increased +6.1%, influenced by the introduction of therapeutic innovations in this group.

With reference to the **Cardiovascular System**, after successive average price drops over the last few years, in 2016 there was an increase of +1.6%. In turn, the units of this treatment group rose around the market average.

The **Respiratory System** group has shown a -2.3% drop in units whilst average prices held steady. In this group, it should be noted that only 60% of units sold would enter the market that is likely to be funded. This segment has recorded an average price drop of -4.6% as it is one of the groups most affected by the reference prices.

New launches

During 2016, 221 new medicines have been launched on the market in the dispensing pharmacies channels, with total sales of €94 million in 2016. Out of the 221 new medicines being sold, 116 are generic medicines, 7 are new active ingredients and the rest are medicines with active ingredients or combinations of active ingredients that already existed on the market.

Hospital Market

In the hospital market, according to IMS data, 71% of sales are concentrated in two therapy groups:

1. General anti-infective medicines. Within this group, systemic antivirals represent 79% of sales.

2. Antineoplastics and immunological agents, whose two main sub-groups (anti-neoplasics and immunosuppressants) account for practically 90% of total sales in this treatment group.

The hospital market was also affected by the new **price reference order** which led to the creation of 14 new groups, 4 of which involve clinical packaging. With this new order, 19% of hospital sales would be affected by the Price Reference System.

During 2016, **97 new medicines** have been launched on this market of which 40 are generic medicines, 2 biosimilar medicines, 30 correspond to new active ingredients and the rest are medicines with active ingredients or combinations that already exist on the market.

PHARMACEUTICAL FOREIGN TRADE[5]

In 2016, exports of medicines dropped by -4.3% in Spain. However, the fact that pharmaceutical imports dropped a further half point (-4.8%) has improved the pharmaceutical sector cover rate (exports over imports) from 77.4% in 2015 to 77.8% in 2016.

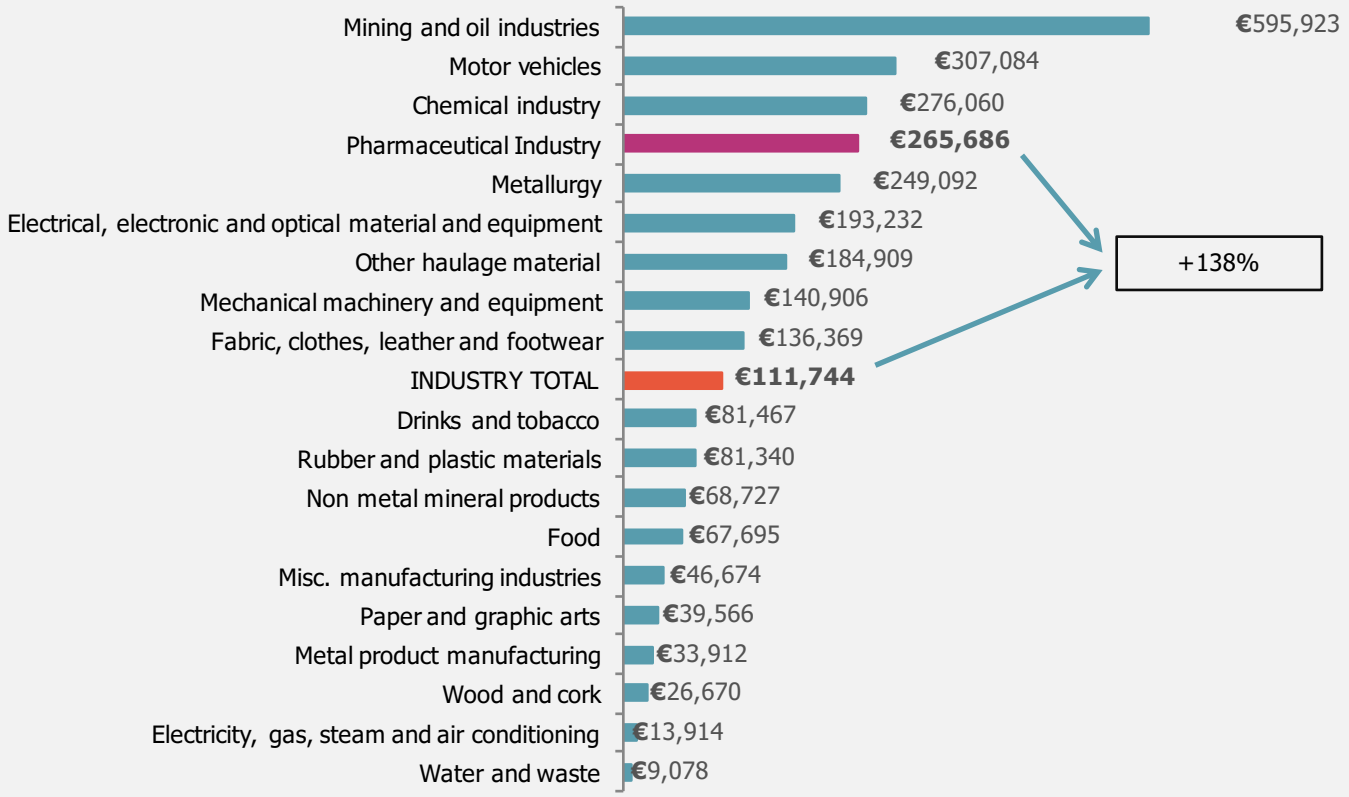
Nevertheless, in 2016 pharmaceutical exports, with €10,645.5 million **have exceeded €10,600 million for the third time in their history**, and the pharmaceutical industry has consolidated its position as one of the main export sectors in Spain.

This data demonstrates the relevance of the pharmaceutical sector for our country's foreign trade. Furthermore, far from being merely situational, this contribution has been maintained over the last few years, not only quantitatively but also qualitatively. So, for example, the pharmaceutical industry represents 26.5% of national exports of high technology products, making it the most important sector of the Spanish economy in this area.

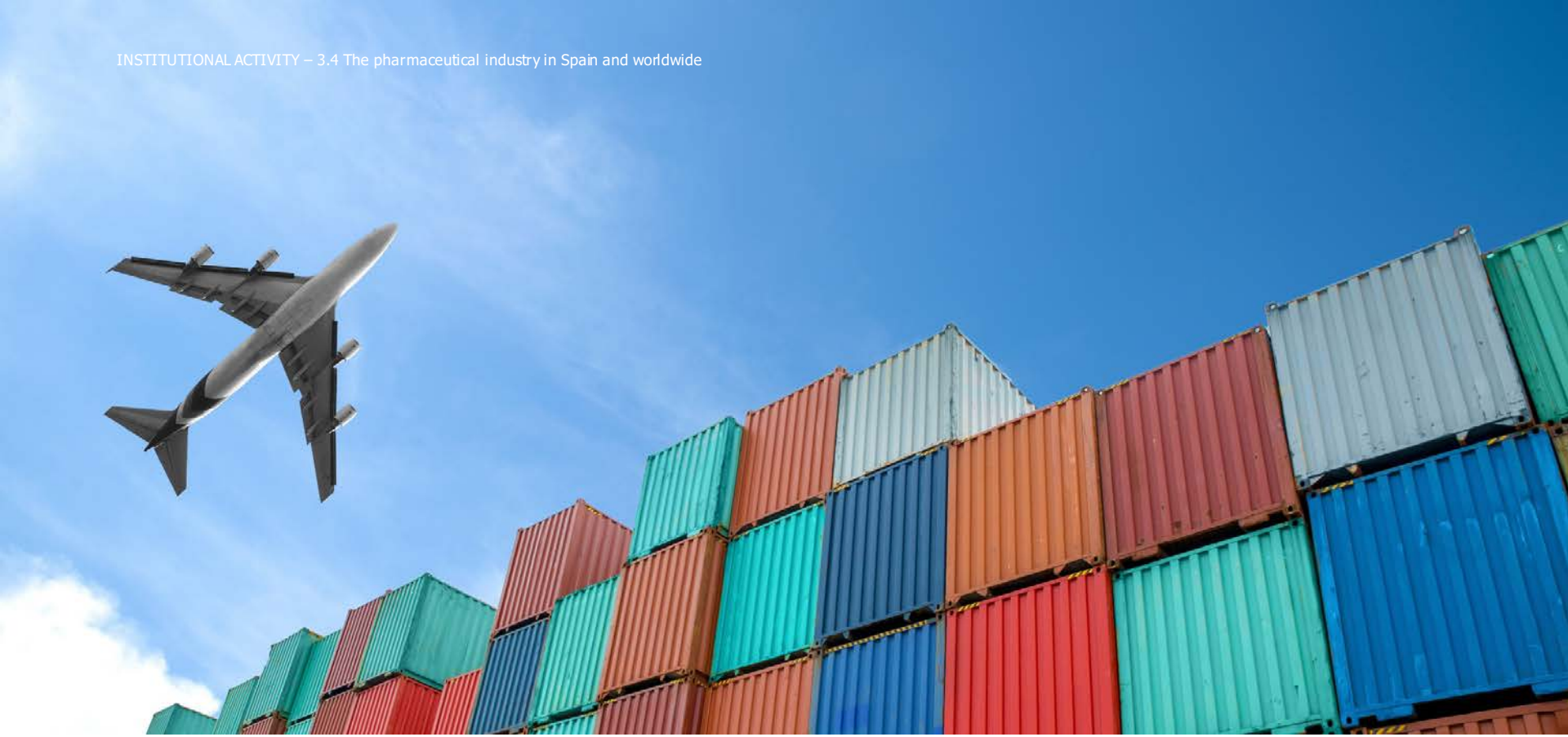
In addition, in terms of exports as a percentage of turnovers, the latest available data (2014) shows how the pharmaceutical industry, with 75%, doubles the average of the industrial sectors altogether (38%). On the other hand, if the export/employment indicator is used, the difference is even greater and puts the pharmaceutical industry in fourth place in the Spanish economy with over €265,000 of exports per employee.

[5] The data in this section refers to foreign trade in general goods and pharmaceutical products in particular. In both cases, data for 2016 is provisional, and likely to be reviewed at a later date, so it should be interpreted with caution.

Main sectors of the national economy in exports per employee (2014)



Source: FARMAINDUSTRIA using data from the Secretary of State for Trade INE



As far as the geographic distribution of pharmaceutical foreign trade in 2016 is concerned, it should be highlighted that the **EU-28 continues to be, by far, our main trade partner.** 58% of Spanish imports of pharmaceutical products come from our European partners and 52% of exports go out to them.

A special mention should be given to the United Kingdom with whom trade exchanges fell considerably in 2016, particularly exports, that dropped -21% on 2015. However, the UK remains the seventh most important destination for Spanish pharmaceutical exports although its share as a percentage of the total has dropped from 6.1% in 2015 to 5.1% in 2016.

Regarding markets outside the EU, that already represent half of the total Spanish pharmaceutical exports, the main destinations are Switzerland, the United States, Japan and China, in that order. These four countries represent 60% of pharmaceutical exports to countries outside the EU-28.

Economic Area	2015		2016 (p)	
	Export	Import	Export	Import
World Total	100.0%	100.0%	100.0%	100.0%
EU 28	51.0%	57.9%	52.0%	57.8%
Germany	10.5%	13.7%	12.1%	15.4%
Belgium	0.9%	6.7%	1.3%	6.2%
France	7.7%	6.7%	7.4%	6.3%
Netherlands	5.9%	5.9%	5.4%	6.5%
Ireland	0.9%	6.5%	1.3%	4.7%
Italy	7.2%	4.0%	6.9%	3.9%
United Kingdom	6.1%	6.4%	5.1%	6.3%
Rest of Europe	**15.7%**	**8.5%**	**17.7%**	**10.2%**
Switzerland	13.1%	8.2%	15.7%	9.9%
Rest of the World	**33.3%**	**33.6%**	**30.3%**	**32.0%**
China	2.3%	2.9%	2.4%	3.1%
United States	8.2%	24.0%	7.1%	21.3%
India	0.3%	0.8%	0.3%	0.8%
Japan	4.5%	0.7%	3.4%	0.8%

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

NHS SPENDING FOR PRESCRIPTIONS DISPENSED IN PHARMACIES						
Year	**Spending** (Millon € RRP VAT)	**Inc.** (%)	**Nº of Prescriptions** (Millons)	**Inc.** (%)	**Spending per Prescriptions** (€)	**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%

Source: Medical Prescription Invoicing. MSSSI

PUBLIC PHARMACEUTICAL SPENDING ON OFFICIAL NHS PRESCRIPTIONS

According to MSSSI data, in 2016 public spending in dispensing pharmacies on official **NHS** prescriptions **grew by +4.0%, to stand at € 9,912.8 million**, as the consequence of a +2.2% increase in the number of prescriptions and a +1.7% increase in average spending per prescription.

REGIONAL DISTRIBUTION OF PUBLIC PHARMACEUTICAL SPENDING PER CAPITA

Public pharmaceutical spending on official NHS prescriptions stood at **€212.90 per inhabitant in 2016**, registering an increase of +4.1% on 2015.

At a regional level, the regions with the greatest pharmaceutical spending per capita are Extremadura (€286.40), Asturias (€256.30) and Galicia (€252), whilst the lowest spending takes place in the Balearic Islands (€171.40) and Madrid (€178.10).

All the regions have increased public spending per capita, with Aragon and the Valencia region recording the greatest increases (+7.3% and +7.1%, respectively) while Catalonia along with Galicia increased their public spending per capita the least in 2016 (+1.9% and +2.1% respectively).

PHARMACEUTICAL SPENDING PER CAPITA PER REGION (2016)

Community	Spending share (%)	€ per capita	Inc. (%)
Extremadura	3.1%	286.4	+4.2%
Asturias	2.7%	256.3	+4.6%
Galicia	6.9%	252.0	+2.1%
Valencia Region	12.2%	243.7	+7.1%
Aragón	3.2%	241.8	+7.3%
Castilla-La Mancha	4.8%	235.5	+6.5%
Cantabria	1.4%	235.4	+5.1%
Castilla y León	5.8%	234.0	+4.7%
Murcia	3.4%	229.5	+4.7%
La Rioja	0.7%	223.5	+3.4%
Basque Country	4.8%	217.1	+2.8%
Canaries	4.6%	215.8	+4.6%
Spain Total	**100%**	**212.9**	**+4.1%**
Navarre	1.4%	209.3	+3.7%
Andalusia	17.2%	203.6	+3.5%
Catalonia	14.0%	184.2	+1.9%
Madrid	11.6%	178.1	+4.3%
Baleares	1.9%	171.4	+3.6%

Source: Medical prescription invoicing (MSSSI) and Municipal Electoral Roll figures (INE).

4 Member Services

Over the last few years, FARMAINDUSTRIA has been working hard to **broaden and improve the services** that it provides to pharmaceutical companies, as well as the Association's own institutional activity, run from its foundation. In 2013, it was necessary to modify how this service provision was expressed, due to changes in article 20, One, 12 of the Value Added Tax Law (VAT).

The aforementioned modification, coming into force on January 1st 2013, declared quotas paid to the Association in return for the institutional work to run its association activity as free from VAT, with no possibility of appeal. However, the obligation was maintained to charge the corresponding VAT on quantities paid in return for services rendered to member companies or to other third parties.

In this respect, although FARMAINDUSTRIA has been providing different services from its association activity, both to its member companies and to third parties, until now, it had not been necessary to differentiate between the revenue from one concept or another, given that both are subject to and not exempt from VAT.

This legal change has meant that the association or institutional services are, in all cases, free from VAT, implying that both revenues, from January 1st 2013, were taxed differently, making it necessary to distinguish the two types of services provided: FARMAINDUSTRIA's industrial services and other services.

4.1 Online Services

Within the continuous process of modernising the services provided to associate pharmaceutical companies, in addition to important improvements to the intranet with the industry (www.farmaindustria.org) and on the public website (www.farmaindustria.es), this year a new Presentation Catalogue website (nomenclator.farmaindustria.org), has been included, four websites have been redesigned on Management of deductions from Royal Decree-Law 8/2010 and the Self-regulation Systems website has gone into production along with its Interactive Code.

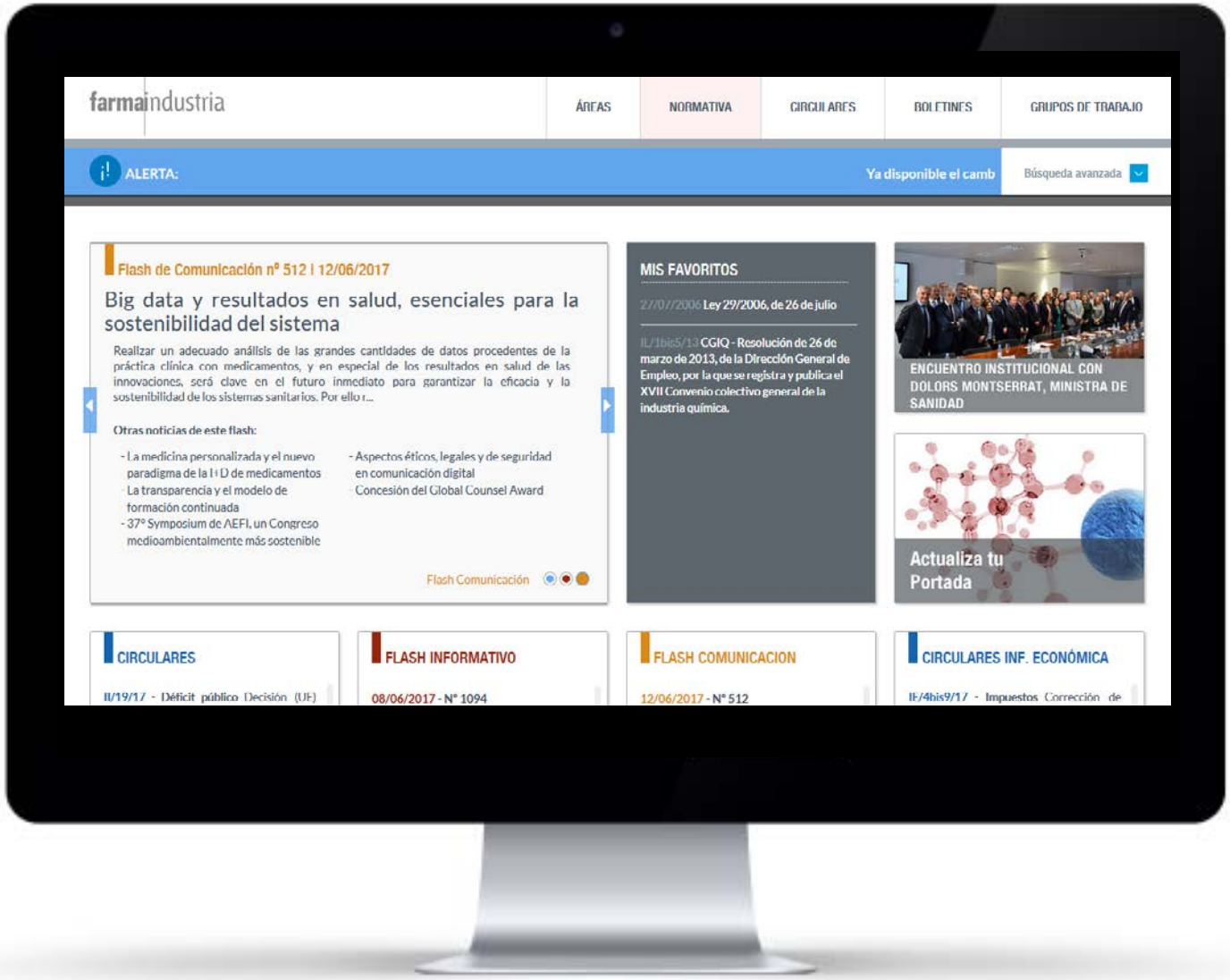
CORPORATE WEBSITE. INTRANET WITH THE INDUSTRY

This Website already contains more than **80,000 docu**ments with over 50 categories including memos, publications, departmental sections, news flashes and newsletters and a Regulations section.

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

It includes a complete, powerful **search tool** that drastically reduces information access times and help users move instantly through the data structure.

Each FARMAINDUSTRIA working group has a **private space**, structuring its fast, secure access to more than 800 members. It also includes documentation for the Association's Statutory Groups.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Búsqueda avanzada
Flash de Comunicación nº 512 | 12/06/2017
Big data y resultados en salud, esenciales para la sostenibilidad del sistema
Realizar un adecuado análisis de las grandes cantidades de datos procedentes de la práctica clínica con medicamentos, y en especial de los resultados en salud de las innovaciones, será clave en el futuro inmediato para garantizar la eficacia y la sostenibilidad de los sistemas sanitarios. Por ello r...
Otras noticias de este flash:
- La medicina personalizada y el nuevo paradigma de la I+D de medicamentos
- La transparencia y el modelo de formación continuada
- 37º Symposium de AEFI, un Congreso medioambientalmente más sostenible
- Aspectos éticos, legales y de seguridad en comunicación digital
- Concesión del Global Counsel Award
Flash Comunicación
MIS FAVORITOS
27/07/2006 Ley 29/2006, de 26 de julio
IL/1bis5/13 CGIQ - Resolución de 26 de marzo de 2013, de la Dirección General de Empleo, por la que se registra y publica el XVII Convenio colectivo general de la industria química.
ENCUENTRO INSTITUCIONAL CON DOLORS MONTSERRAT, MINISTRA DE SANIDAD
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II/19/17 - Déficit público Decisión (UE)
FLASH INFORMATIVO
08/06/2017 - Nº 1094
FLASH COMUNICACION
12/06/2017 - Nº 512
CIRCULARES INF. ECONÓMICA
IE/4bis9/17 - Impuestos Corrección de

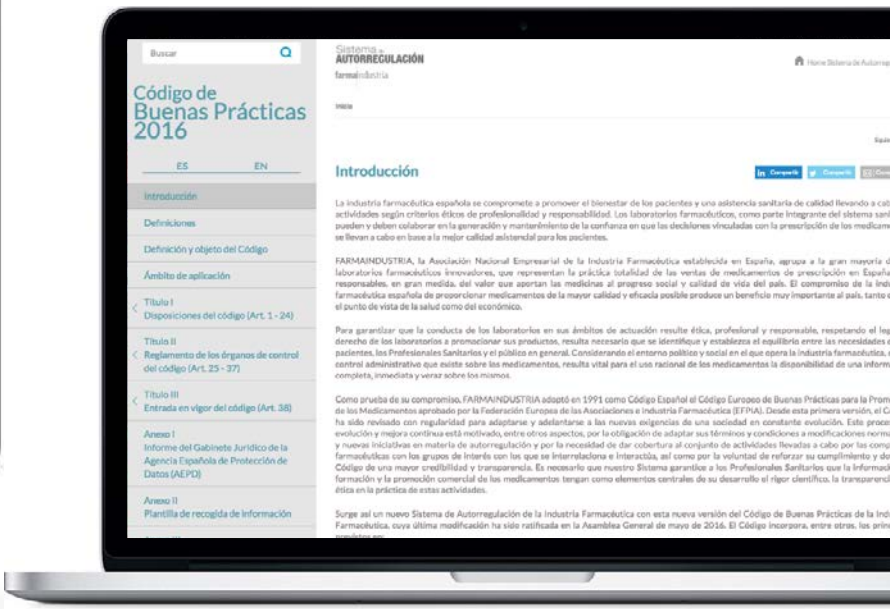
PUBLIC WEBSITE

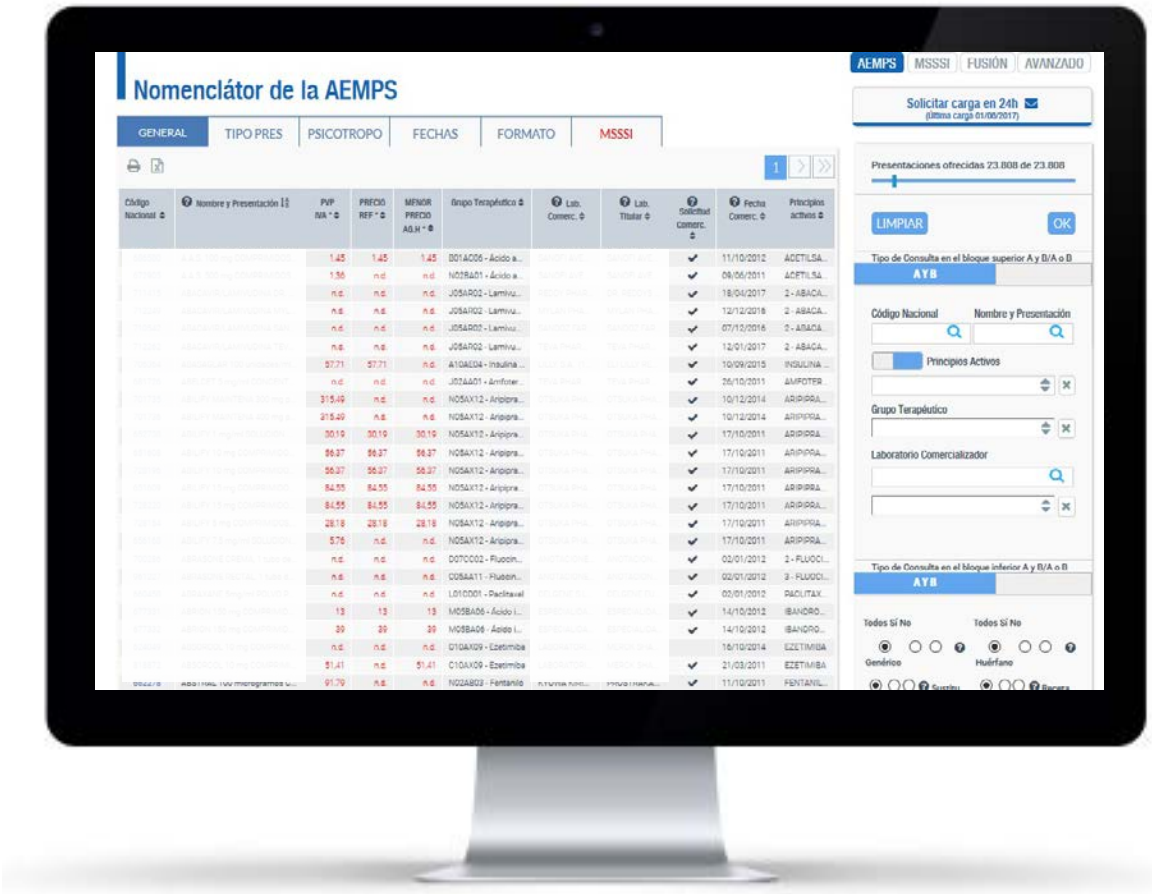
The FARMAINDUSTRIA public website is especially designed to **put across information clearly, quickly and openly** to anyone interested in the Spanish pharmaceutical industry. In turn, websites have been maintained for:

1. *Medicamentos Innovadores* (Innovative medicines).
2. *Somos Pacientes*, that provide information on the medicine innovation technological platforms and the collaborative environment for the community of patients' associations, respectively.

NEW SELF-REGULATION SYSTEM WEBSITE

From this website, not only is it possible to access the Code of Practice or the Practical Case Test but all the information on Transparency, Control Bodies, Standard Framework, List of training activities and it includes a private zone to manage and communicate events and scientific meetings.





NEW GAZETTEER FUSION WEBSITE

A new website has been developed that offers updated information on each presentation in the AEMPS or MSSSI gazetteers.

The formats that both institutions use to publish their information are not very practical to access the data and, at FARMAINDUSTRIA, a pilot has been started up on the information available in both gazetteers that will soon become accessible for all member companies.

WEBSITES TO MANAGE ROYAL DECREE-LAW 8/2010

During 2016, all the websites have been **redesigned and completely migrated to a modern and streamlined environment**, integrated with languages and designs from the other websites. The operating mode will now be more intuitive and less dependent on each user's profile. It will go into production during 2017, thereby giving all users a powerful and streamlined tool to exchange all the information required to manage the RDL 8 and 10/2010.

Due to the type of information that they contain, these websites ensure maximum confidentiality and security standards for access control.

4 Member Services

The Association's Working Groups promote active participation from member companies within FARMAINDUSTRIA.

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

In October 2016, when renewing the FARMAINDUSTRIA Governing Bodies, the working groups were updated for a further period of two years.

By virtue of the same, there are currently **22 working groups** operating in FARMAINDUSTRIA, that cover the emerging needs from the member companies. They are governed by different operating standards, including competition standards that underlie all their meetings and actions.

The current list of working groups is given in detail below:

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

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

A summary is presented below of the FARMAINDUSTRIA working groups' activities over 2016.

Working Group on Sustainability and Economic Regulation

Over 2016, this Working Group has continued to monitor all rules related to economic regulation in the pharmaceutical sector field and any new issues in this field.

The Group has produced a detailed analysis of Ruling SSI/1305/2016, dated July 27th, updating the reference price system for medicines in the National Health System in 2016, with a view to preparing the relevant appeals.

In turn, the situation and development of the Collaboration Protocol signed in 2015 with the Spanish Government was also included in the Group meetings agenda.

For these purposes, it should be highlighted that this Protocol was renewed on December 29th 2016 by means of signing a new Agreement with the Government for 2017, with the common goal of guaranteeing National Health System sustainability and citizen access to innovations.

The Group occasionally receives information on **developments in the Agreement**, particularly regarding changes in the economy and public pharmaceutical spending and access indicators, as well as possible scenarios for 2017.

The Group has continued to monitor access to innovation, plus occasionally monitoring Therapeutic Positioning Report publications by the AEMPS.

In turn, the Group has monitored jobs completed by the Association, in coordination with the FARMAINDUSTRIA Manufacturing and Traceability Working Group to develop the Spanish Medicines Verification System (SEVeM), formally set up on July 21st 2016 to comply with the Directive on Counterfeit Medicines and its delegated Regulation and art.94.7 of the Legislative Royal Decree 1/2015, dated July 24th, approving the reworked Text of the Law on guarantees and rational use of medicines and healthcare products, regarding notified prices in dispensing pharmacies.

The Group's agenda also includes a point on the hospital market, to analyse how debt is evolving using medicine supplies to public hospitals and the State's measures and instruments to guarantee that companies receive payment for them, aspects that are monitored by the FARMAINDUSTRIA Hospital Debt Working Group.

Finally, members of this Working Group have been informed from time to time about the Association's work related to the Treatment Adherence Plan was presented publicly on November 23rd 2016.

2

'Health Technology Assessment' Working Group

This working group was set up in FARMAINDUSTRIA with the aim of **developing technical documents** referring to the main questions that affect procedures for economic assessment of medicines.

Over the last year, the Group has continued work to promote measuring health results that will contribute to the future transition towards more sustainable health systems based on value and results for patients.

In addition, progress has been closely followed on joint assessment of medicines' relative efficacy within Europe (EU REA), within the framework of Joint Action 3 of EUnetHTA (2016-2020), plus its main implications for Spain. Additionally, the sector's position has been coordinated in relation to this matter with a view to international cooperation post-2020.

Nationally, the Group has continued monitoring compliance with recommendations from the Therapeutic Positioning Reports (IPT), drawn up by the AEMPS, whilst analysing regional initiatives to evaluate medicines.

Over the next year, the Group will continue working on these and other technical issues to **show how the pharmaceutical industry is tackling** medicine assessment procedures.

3

Hospital Debt Working Group

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

In addition, it continues to monitor the **impact of late payment measures** on the pharmaceutical industry, particularly referring to payments made through the Regional Liquidity Fund (FLA).

These payments, along with any made through the Regions' ordinary treasury, have given the best close of financial year in 2016 since records have been kept (1996) as the NHS's DSO was reduced to just 95 days.

Despite the buoyant situation, two infringement cases are being brought against Spain by the European Commission due to insufficient compliance with the Late Payment Directive. The group is monitoring this situation from time to time alongside modifications to standards that might be derived from it.

Finally, they continued analysing the main macro-economic aspects of the Regions (debt, deficit, growth, etc.), particularly referring to the evolution of resources received by the Regions within the framework of their participation in the State's revenue due to its potential influence on future payments.

In addition, it should be highlighted that the ad hoc subgroup for Electronic Invoicing (SG FAC), set up within the Hospital Debt Group, has continued its close monitoring of **electronic invoicing implantation**, compulsory since January 15th 2015, and from time to time has monitored Memos from the State Administration General Intervention in addition to the State and Regional regulations on this subject, transferring the relevant appeals to the regulations being processed.

Institutionally, the Association has kept up its **active participation in different forums** related to e-invoicing:

1. MINHAFP electronic invoice forum.
2. The CEOE Digital Society Commission.
3. The MINETUR National Multilateral Forum on electronic invoicing.
4. The recently set-up MINHAFP Working Group on electronic invoicing in the private sector.

This Group has also focused on the MINHAFP initiative, suggested by some business sectors, to move forwards in the drive for e-Administration and implanting electronic invoicing between companies in the private sector, defending the aspects that the innovative pharmaceutical sector considers relevant in the field of B2B electronic invoicing.

4

Hospital Market Working Group

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

Due to its objective, this Group is working closely with the Hospital Debt, Biotherapeutic Medicines, Regions and Economic Working Groups. The Group is made up of **representatives from 48 pharmaceutical companie**s and it met three times in 2016.

Working Group on Technical Regulation of Medicine

The main activities of this working group focus on **analysing regulations** from the community rules and regulations published by the MSSSI and the AEMPS referring to procedures for authorisation, registering and marketing medicines, particularly regulations for developing Legislative Royal Decree 1/2015 approving the reworked text of the Law of guarantees and rational use of medicines and healthcare products. The Group focuses on analysing subjects with an important technical aspect such as rates, labelling and prospecting, applications and authorisation modifications, validation of authorisations, Sunset clause, classification of medicines without commercial interest, etc.

In 2016, the Group also analysed the delegated Regulation for the Counterfeit Medicines Directive, specifically future **incorporation of safety devices into medicine packaging** and commented on the technical document concerning dangerous medicines drawn up by the National Institute for Occupational Health and Safety published in September 2016.

5

In all its meetings, this Group tackles eight specific topic areas:

1. Therapeutic Positioning Reports.
2. Early access.
3. Product information.
4. Biotherapeutic Medicines.
5. National and management procedure
6. Regulation in the quality field.
7. Risk management plan
8. European procedures.

In 2016, the Group received a visit from the Deputy Head of the Medicines for Human Use Department of the AEMPS, providing information on ISO IDMP regulations.

Biothereutic Medicines Working group

The therapeutic and economic importance of biotherapeutic medicines and how they differ from chemical medicines has means that these products are the focus of many fields.

From a regulatory point of view, the singularity of **biotherapeutic medicines** determines their prescription by commercial name (brand) and also their notification by brand and batch number. They are also considered to be medicines requiring special monitoring for the purposes of pharmacovigilance.

In the case of **biosimilar** medicines, there is no substitution with the original biotherapeutic medicine (only the doctor can decide on the prescription and consequent dispensing).

The Group particularly monitors regional actions, position documents from different institutions, legal sentences, and other provisions in this field, proposing actions when appropriate.

The international field is also making decisions on the use of biotherapeutic medicines and in all its meetings. This working group looks into new issues that affect these medicines in other countries.

Finally, it should be highlighted that the agenda for this working group always features a point on **orphan medicines**. Each meeting monitors initiatives in our country in this field and the most relevant aspects that affect the EU.

Working Group on Manufacturing and Traceability

This working group has maintained an intense pace of meetings over the last year, derived from the **consequences of the Delegated Regulation (EU) 2016/161** published by the Commission that regulates packaging security devices (single identifier and anti-tampering device).

Although the aforementioned Regulation will be applied directly in all member states in February 2019, the European Commission has drawn up a Q&A document to clarify a few matters until this date. All in all, elements are merely nationals, requiring specific instructions from the AEMPS so that authorised medicines can start to be serialised in our country. This Group is helping to shape them, considering the AEMPS's intention to reduce the trauma of applying the aforementioned Regulation for the sector. Applications from the group such as the possibility of using previously serialised packaging, not charging fees for incorporating security devices,
or flexibility in choosing the product code, have been dealt with by the AEMPS.

Another regular point in this working group refers to the importance of **guaranteeing medicine supplies.** In this respect, and with a view to drawing up the "Plan to guarantee medicine supply," the AEMPS asked FARMAINDUSTRIA for comments that have been debated within this working group, particularly referring to supply problems in terms of technical issues, monitoring suppliers, existence of alternative suppliers, monitoring stock or reporting low levels of a product.

Finally, this Group covers other, more specific, issues such as the problem issue of controlled temperature transport, air transport for medicines or flows of medicines for humanitarian donations.

Working Group on the Environment

During 2016 and working with SIGRE, this working group monitored important **legislative standards** for the pharmaceutical industry in environmental terms such as: circular economy, waste, environmental responsibility, activities that might contaminate the soil, energy efficiency, climate change or tipping.

On the other hand, FARMAINDUSTRIA still sits on Environmental Commissions within different business organisations (CEOE and FEIQUE).

Pharmacovigilance Working Group

This working group **channels the main questions and clarifications** derived from national and European pharmacovigilance provisions. In 2016, development of the Royal Decree on Pharmacovigilance has been monitored, along with the future modification of the EPA Order and the Pharmacovigilance Best Practices for the pharmaceutical industry.

In addition, during 2016, the group analysed **the Instructions from the Royal Decree on clinical trials** document, in an attempt to clarify how to report both the annual safety reports (DSUR) and the Severe and Unexpected Adverse Reactions (RAGI/SUSAR).

The Group holds bimonthly meetings and they all cover six well-defined topic areas:

1. Inspection and audits.
2. Risk management plans.
3. Master File.
4. Efficient notification.
5. Periodic safety reports.
6. Pharmacovigilance and Internet.

This structure helps to review the most relevant new issues in each work session and suggests proposals and measures to the Group to pass on to the Administrations or to improve how the actual pharmaceutical company units' work.

Finally, the working group also received a visit from the AEMPS Division Head of Pharmaco-epidemiology and Pharmacovigilance who presented the current situation and forecasts for 2017 in terms of pharmacovigilance (SCOPE project, GVP, PRAC, reporting suspicions of adverse reactions, risk management plans, periodic safety reports, post-authorisation studies and communications on medicine safety).

10

Vaccines Working Group

The importance and the singularity of vaccines, due to their preventive nature and their role in healthcare, justify the existence of this working group.

The main issues dealt with by the Group over this year include **monitoring actions intended to promote the value of vaccines**, that demonstrate their specific aspects compared to other medicines as well as the benefits they bring to society. One of the group meetings was attended by the Director General of *Vaccines Europe* in an attempt to identify synergies with this EFPIA-dependent institution.

Finally, the Group tackled technical topics relating to serialising, adherence or supply problems, referring to this type of medicine that is also marketed differently.

11

Farma-Biotech Working Group

This Group, made up of **36 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 between 2011 and 2016, **fifteen interactive meetings** have been held between these two sectors, mainly in the fields of the central nervous system, oncology, respiratory system, inflammation and autoimmune diseases.

These meetings were attended by a total of 109 direct agents (40 pharmaceutical companies and 69 representatives from the biotechnology sector).

Within the framework of this Programme, a session was held in September 2016 on best practices in cooperation with Farma-Biotech, demonstrating this Programme's role as a fundamental bridge in the biopharmaceutical ecosystem to facilitate flow among agents. In turn, a Session was held at FARMAINDUSTRIA headquarters in Madrid on November 15th regarding different pathologies. All the presentations are available on the website: www.medicamentos-innovadores.org.

In addition, to strengthen joint public-private work on excellence-based research, on July 20th 2016 the Ministry of the Economy, Innovation and Competition held a session on collaboration and searching for new opportunities in the field of R+D+i attended by representatives from the 23 Severo Ochoa Centres of Excellence and the María de Maeztu Excellence Units, with outstanding members from several pharmaceutical companies interested in exploring joint projects with these public research institutions.

The Farma-Biotech Working Group also aims to **promote public-private cooperation instruments** for R&D and so it held a variety of meetings with the Centre for Technological and Industrial Development (CDTI) and with the Minister of the Economy, in order to study different funding options. Specifically, the workshop held on September 26th 2016 was particularly interesting for companies, with a sneak peek of the main funding features and up-coming calls planned by the CDTI.

These workshops are a good opportunity for Administration representatives to listen to the sector's demands and so adapt the funding.

In addition, this Group also hopes to **stimulate industry participation in national and international programmes** for pharmaceutical R&D, particularly in the *Innovative Medicines Initiative* (IMI) and in actions by the Spanish Technology Platform for Innovative Medicines (PTEMI).

12

Working Group on Medical Directors and Research (BEST project)

This working group, set up ten years ago as a platform for excellence in clinical research, is framed within 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 the performance indicators (time, recruitment, international comparison) to conjure up the best environment for clinical tests 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 the stakeholders (hospitals, researchers, scientific societies, patients, CEIC, etc.)
2. All stakeholders value clinical research.
3. Spain has become more competitive internationally.
4. Dialogue flows easily between strategic agents (industry, research centres 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 59 centres.

45 pharmaceutical companies

13 regions

BEST PROJECT
Clinical Research into Medicine

3 scientific societies and the CUN

GEICAM investigación en cáncer de mama

Spanish Breast Cancer Research Group (GEICAM)

TTD

Spanish Group to Treat Digestive Tumours

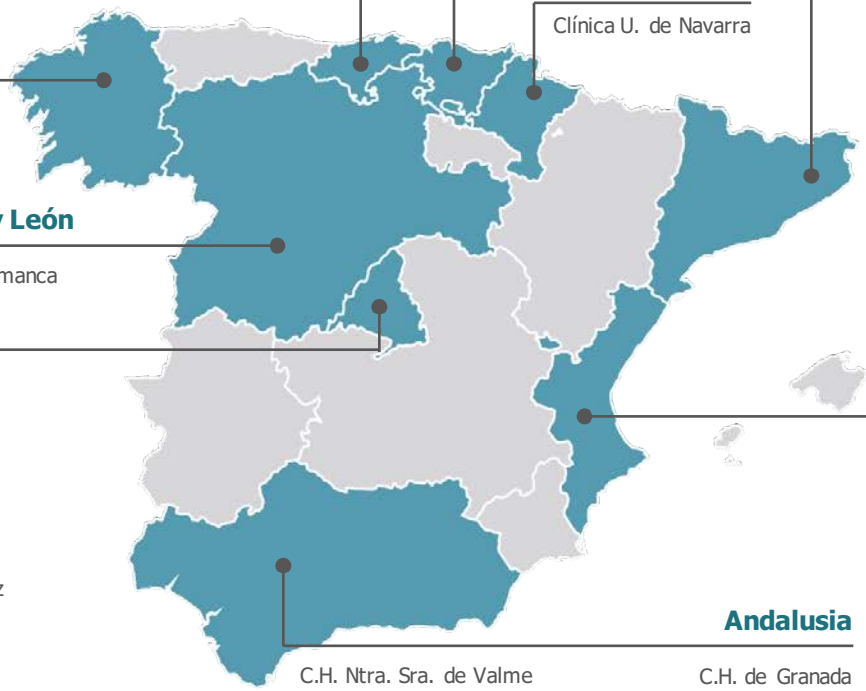
SOLTI

Academic Group for Reference Breast Cancer Research

Clínica Universidad de Navarra

Clínica Universidad de Navarra (CUN)

59 member centres



Basque Country
H.U. de Araba
H.U. de Cruces
H. De Basurto
H.U. Donostia
H. Onkologikoa

Santander
Hospital Marqués de Valdecilla

Navarra
Clínica U. de Navarra

Catalonia
H. Sant Joan de Deu
Hospital Clinic
Hospital Parc Taulí
Hospital Vall D'Hebron
Hospital Bellvitge
H. de la Santa Creu i Sant Pau
Instituto Oncológico Catalán
Hospital del Mar
Hospital Granollers
Hospital Quirón Barcelona
Hospital U.Quirón Dexeus

Galicia
C.H. de A Coruña
C.H.U. de Santiago
C.H. de Vigo

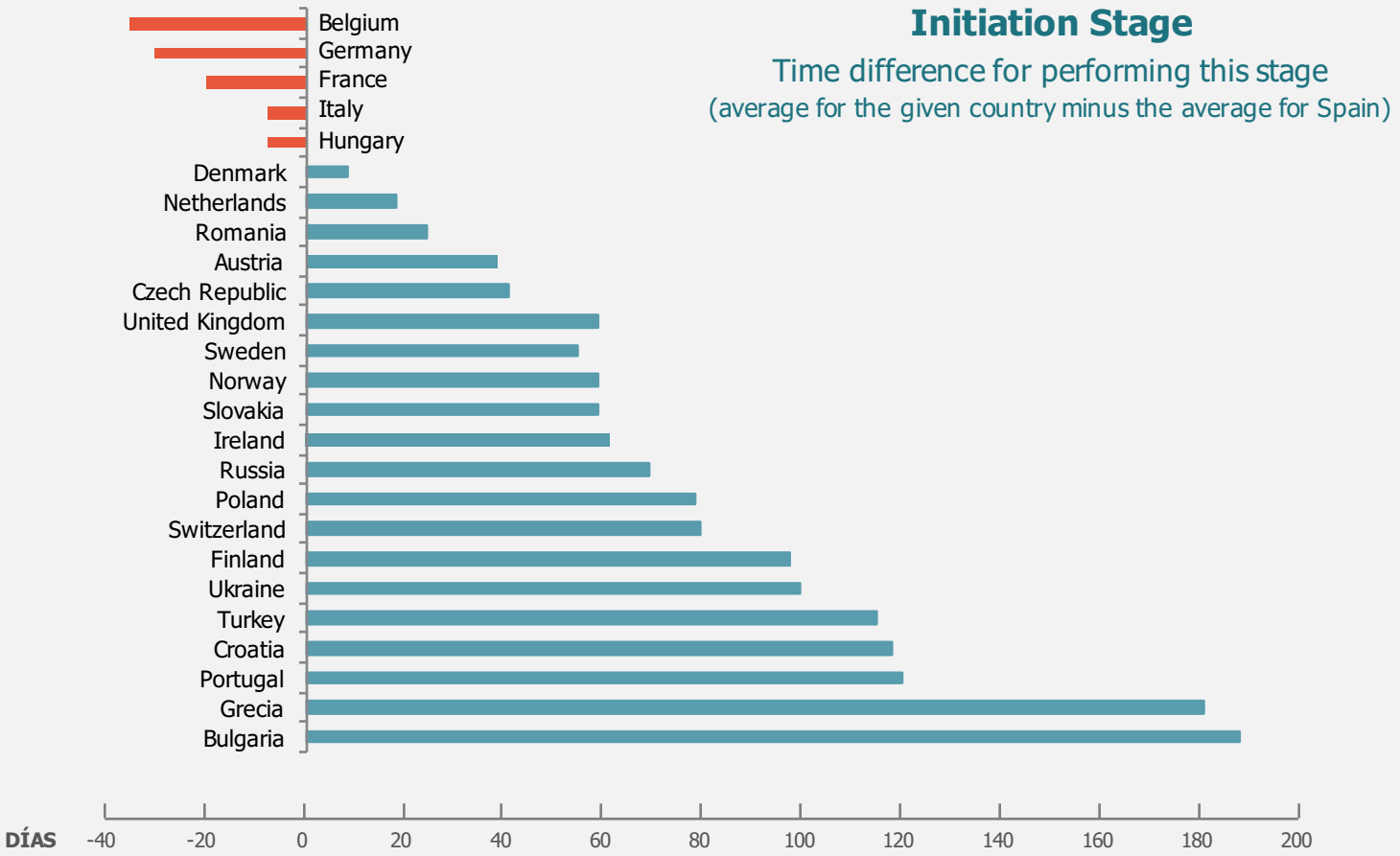
Castilla y León
H.U. de Salamanca

Madrid
H.U. de Getafe
H. Clínico San Carlos
Fundación H. de Madrid
H.U. de la Princesa
H.U. La Paz
H.U. Puerta de Hierro
H.U. Ramón y Cajal
H. Fundación Jiménez Díaz
H. Gregorio Marañón
H. Rey Juan Carlos
H.U. Infanta Elena
H.U. 12 de Octubre
H.U. Quirón Salud
H.U. Torrejón
H. Sanitas CIMA
H.U. de la Zarzuela
H.U. Niño Jesús

Valencia Region
H. General U. de Valencia
H. Clínico U. de Valencia
H. Malvarrosa
H.U. La Fe
H.G.U. de Elche
H.G.U. Dr.Peset
H. Arnau de Vilanova-Llíria
H.G.U. de Alicante

Andalusia
C.H. Ntra. Sra. de Valme
C.H. de Huelva
C.H. de Cádiz
Hospital Costa del Sol
C.H. Torrecárdenas
Área Sanitaria Jerez Norte
C.H. de Granada
C.H. de Jaén
C.H. Reina Sofía
C.H. Virgen de la Victoria
C.H. de Málaga-Carlos Haya
C.H. Virgen del Rocío
C.H. Virgen de la Macarena

The BEST Project has been very important during 2016 to measure the implementation of the Royal Decree 1090/2015 on Clinical Trials that came into force on January 13th 2016 and which after just one year of monitoring has maintained the reduction in time for implementing a clinical trial in our country by over a month.



During 2016, highly interesting workshops were run with different patient associations to explain what R&D really entails for a new medicine, the applicable legislation, which agents are involved and which roles they play, etc. and workshops were run in the areas of oncology and rare diseases.

In the second half of 2016, pilot workshops were run with secondary students focused on talking about what R&D entails, concerning new medicines, how it is performed, its phases and what it represents for society. These workshops were given by representatives from FARMAINDUSTRIA and speakers from different medicine R&D fields such as researchers, AEMPS, ethics committees, etc.

In the same way, and within the BEST Project, in 2016 FARMAINDUSTRIA ran a study on the clinical research carried out by the pharmaceutical industry in private centres. The data was presented jointly with the Institute for Healthcare Development and Integration (IDIS) during the Session entitled "Biomedical innovation with a view to 2020". This event was attended by over 100 agents from pharmaceutical R&D.

In 2016, work began on drawing up a **Guide for Clinical Research Units in Paediatrics** working jointly with AMIFE and RECLIP. Questionnaires have recently been received from 27 centres in 8 different Regions that meet the triple classification of:

- Centres with specific paediatric clinical units.
- Centres that do not have a specific unit for paediatrics but do have a central unit for clinical trials that can support the department.
- Paediatric departments that run clinical trials in different areas.

13

Clinical Research Working Group

Over the last year, this Group has carried out intense **monitoring of the Spanish and European legislative initiatives** concerning clinical research, particularly Regulation 536/2014, passed by the European Parliament and Council on April 16th 2014, published in the DOUE on May 27th 2014 and new Royal Decree 1090/2015, dated December 4th, regulating the clinical tests with medicines, the research ethics committees with medicines and the Spanish Register of Clinical Studies that came into force on January 13th 2016.

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

Meetings have been held with the AEMPS to pass on the **industry's position supporting the legislative initiative** to simplify assessment and authorisation procedures, reduce bureaucracy, strengthen cooperation between member states and improve the consistency of procedures used in research and transparency to ensure maximum guarantees in terms of protecting anyone participating in the research.

To meet simplification and harmonisation goals for processes mentioned in the new Royal Decree and with a view to preparing Spain to apply the new European Regulation on clinical trials in 2018, FARMAINDUSTRIA is working closely not only with the AEMPS but also with the research managers from the Regions, public and private hospitals, researchers, ethics committees, patients and other agents involved, by holding a significant number of meetings with them in 2016.

During 2016, FARMAINDUSTRIA has worked hard to help the Document of Complementary Instructions to the Royal Decree 1090/2015 dated December 4th meet the sector's needs. It has also worked hand in hand with the AEMPS and the CEIM so that the appendices to that Document, particularly referring to insurance certificates and the guide to correctly drawing up patient information sheets and informed consent also fit the demands of the pharmaceutical industry. It is currently working on additional information regarding biological samples that will be added to the patient information sheet, already been approved by the Ethics Committee Group.

14

Legal Services Working Group

Another year on, this working group's actions have focused on monitoring all matters that might interest Group members in its field due to the legal implications.

These matters include **new legislation that has been approved or that is on-going** in Europe, nationally or regionally, plus the most relevant jurisprudence affecting the sector.

At a European level, approval has been monitored regarding the (EU) Regulation 2016/679 by the European Parliament and Council, dated April 27th 2016, relating to the **protection of physical persons** regarding processing personal data and the free circulation of this data, revoking Directive 95/46/CE (General data protection regulation) and the new framework for international transfer of personal data between the European Union and the United States (*Privacy Shield*).

The Regulation will represent a decisive step in unifying the criteria and requirements that have been required for processing personal data in the different Member States, and which should adopt national regulations to develop some issues that are delegated to the Member States. This implies a complex transitory period in terms of protecting data that not only affects people obliged by it, but also the Spanish legislator and the Spanish Data Protection Agency (AEPD), working to adapt Organic Law 15/1999 dated December 13th, on Personal Data Protection (LOPD), to new requirements in the European Regulation on Data Protection.

Nationally, there have been several **standards**, that, without affecting the more detailed examination of them in the section devoted to the legal framework of this Annual Report, have been **analysed** within this Working Group, both whilst being processed and once approved:

1. Royal Decree 316/2017, dated March 31st, approving the regulation for executing Law 24/2015, dated July 24th, on Patents.

2. Order SSI/1305/2016, dated July 27th, to update the medicines reference price system in 2016 in the national Health System, plus Order SSI/1480/2016, dated September 7th, on correcting errors.

3. Order ETU/296/2017, dated March 31st, establishing maximum deadlines for resolving regulated procedures in Law 24/2015, dated July 24th, on patents.

4. Draft of Law to transpose (EU) Directive 2015/2436 from the European Parliament and Council dated December 16th 2015, relating to approximation of legislation from Member States regarding Brands.

5. Draft of the Public Sector Contracts Law currently going through Congress.

6. Green papers from different Parliamentary Groups that affect the sector aimed at: promoting centralised purchasing of medicines; completing development and implementation of electronic healthcare; and considering value transfer as tax-free when it concerns training NHS professionals, among others.

7. Draft Order modifying Royal Decree 1345/2007, dated October 11th, regulating the procedure for authorisation, registering and dispensing conditions for medicines for human use that are manufactured industrially.

Regionally, among others, the following projects have been monitored:

1. Draft of the law on Guarantees and Sustainability of the Public Health Service of Andalusia, currently going through Parliament.

2. Draft Decree constituting the Network for assessment, selection and therapeutic positioning of medicines for rational and harmonised use, defined in the Valencia Region Pharmaco-therapeutic Guide.

3. Draft Order creating and regulating the Network for rational use of medicines and healthcare products in Aragon.

In terms of jurisprudence, it is interesting to mention the Supreme Court sentence on February 22nd 2016 that, although dismissing the contentious-administrative appeal lodged by FARMAINDUSTRIA against Royal Decree 81/2014, dated February 7th, establishing rules to guarantee cross-border healthcare assistance, and that modifies Royal Decree 1718/2010 dated December 17th on medical

prescriptions and dispensing orders, confirms the full validity of prescription by brand.

The Constitutional Court has also handed down several sentences, on December 15th 2016, January 19th and February 2nd 2017 respectively, dismissing the appeal of unconstitutional and the positive competitive conflicts promoted by the Spanish Government against auctions in Andalusia, on understanding that public selection of medicines falls within the framework of the Regional Pharmacy Law and complies with Law 29/2006 dated July 26th on guarantees and rational use of medicines and healthcare products.

Following the line of jurisprudence, regionally, the following **announcements** in the sector deserve a mention:

1. Supreme Court of Justice sentence in the Balearic Islands on September 21st 2016, favourable to the contentious-administrative appeal lodged by FARMAINDUSTRIA against Decree 86/2015, dated October 23rd, creating the Pharmaco-therapeutic Commission, thereby cancelling certain precepts of the Decree, given that they give this Commission the power to exclude medicines included in the NHS catalogue from the pharmaceutical service provision, infringing citizens' rights to access pharmaceutical services in equal conditions all over the country.

2. Supreme Court of Justice sentences from Castilla La Mancha dated February 1st and 29th 2016 favourable to the contentious-administrative appealed lodged by FARMAINDUSTRIA, cancelling instructions issued by SESCAM in 2010 and 2011, aimed at the medical collective, deactivating or limiting the prescription of certain brand medicines in the electronic prescription system in Castilla la Mancha (Turriano). The Supreme Court of Justice of Castilla la Mancha declares that they are not internal instructions because they concern third parties (doctors, patients and pharmaceutical companies), as they modify these prescription systems and condition dispensing of these medicines to a large extent, stating that it is not possible to exclude medicines from the prescription programmes that are included in the NHS pharmaceutical service provision.

3. Sentence by the Supreme Court dated May 18th 2016 relating to Resolution SC/0403/10 by the Managing Director of the SAS, dated December 22nd 2010 to include certain medicines in hospital dispensing for out-patients treatments (DH-DH) and confirms the State's exclusive authority to modify conditions for dispensing medicines.

This Working Group has also concentrated on monitoring different matters treated in other Groups (Hospital Debt, Hospital Market, Regions, Human Resources, Code of Practice, etc.).

15

Taxation Working Group

This Group has been carrying out exhaustive monitoring of **matters with tax implications** for the sector, celebrating a variety of forums during 2016 to tackle relevant topics for pharmaceutical companies in this field.

For these purposes, at the beginning of the year, a new edition of the Annual Taxation Seminar was held (open to all member companies) and joined by many managers in charge of tax and finances from the pharmaceutical companies. This seminar was used to analyse the main points of the General Taxation Law reform, new aspects of Business Tax and Income Tax plus the General State Budget Law for 2016. Among the selection of relevant jurisprudence and doctrine for the industry analysed during the Seminar, we should highlight the response from the General Tax Board (DGT) to the binding consultation formulated by the General Board of the Official College of Pharmacists (V4142-15) due to the change in rules brought about by the new Law 27/2014, dated November 27th, of Business Tax, and its possible application to pharmacies (art.7.1.a).

It should be highlighted that, throughout 2016, **different rules with taxation implications** have been published, including the following:

1. Order HAP/296/2016, dated March 2nd, approving model 282, Informative annual declaration of funding received within the framework of the Economic and Taxation Regime for the Canary Islands and other state funding.
2. Order HAP/365/2016, dated March 17th, approving, among other aspects, the Income Tax and Patrimony Tax declaration models for 2015.
3. Order HAP/841/2016, dated May 30th, approving models 364 and 365 for VAT.
4. Order HAP/871/2016, dated June 6th, proving the Business Tax and Non Resident Income Tax declaration models for the taxation periods started between January 1st and December 31st 2015.
5. The Order dated July 29th 2016 removing the obligation to present the DUA for the declaration of import taxes due on low value deliveries.
6. Royal Decree-Law 2/2016, dated September 30th, introducing taxation measures aiming to reduce public deficit.
7. Order HAP/1552/2016, dated September 30th, modifying Order EHA/1721/2011, dated June 16th and Order HAP/2055/2012, dated September 28th, relating to payments in instalments.
8. Royal Decree-Law 3/2016, dated December 2nd, adopting measures in the taxation field aimed at consolidating public finances and other urgent social measures.
9. Royal Decree 596/2016, dated December 2nd, for modernisation, improvement and promotion of the use of electronic methods in VAT management.
10. Order HAP/1978/2016, dated December 28th, approving model 231 on Declaration of information country by country.
11. Order HAP/227/2017, dated March 13th, approving model 202 and model 222 on payments in instalments.

On the other hand, in Europe, monitoring has been performed on the new **European Union Customs Code** coming into force on May 1st 2016 and the following issues:

1. The European Commission Action Plan that compiles measures to revitalise the current VAT system in the EU in order to fight taxation fraud, support companies and help the digital economy and e-commerce.

2. Implications of the United Kingdom leaving the EU in direct taxation terms.

3. ECOFIN agreements.

4. Directive (EU) 2016/1065 from the Council, dated June 27th 2016, modifying Directive 2006/112/CE regarding processing bonds.

5. The European Commission Plan for Business Tax measures announced in October 2016.

6. Approval by over one hundred States of the so-called "Multilateral Instrument" to modify existing bilateral agreements to avoid double taxation.

In other matters, the **taxation of transferring value from the industry for medical training** has been another focus topic monitored by the Group, particularly the approval by the Healthcare Commission in Congress of the Green Paper urging the Government to continue considering transfers of value devoted to training professional in the National Health System as free from taxation.

We should also highlight monitoring carried out by the Community jurisprudence group from the European Union Court of Justice as well as resolutions from the Taxation Administration and doctrine from the Central Economic-Administrative Court (TEAC) relating to matters of tax interest for the industry, particularly quoting the Resolution from April 4th 2016 by the DGT relating to the deductibility of interest from late tax payments when applying Law 27/2014, dated November 27th, on Business Tax.

Additionally, and jointly with the Clinical Research Working Group, and with participation from the Centre for Technological Industrial Development Centre (CDTI), another edition was held of the annual workshop on finance instruments for the whole R&D+i cycle of a new medicine.

16

Human Resources Working Group

Made up of Human Resources Department managers from pharmaceutical companies, its mission **is to provide service for the pharmaceutical companies** in all matters related to **labour legislation** and take part in Trade Union agreement negotiations through FARMAINDUSTRIA representatives in the Negotiating Commission for the Agreement.

During 2016, the Group has closely followed the main new aspects of the labour reform and the jurisprudence that has been dictated both by the national courts and by the European Union Court of Justice.

On the other hand, FARMAINDUSTRIA has continued taking part in the monthly meetings of the Mixed Commission for Interpreting the Trade Union Agreement, Socio-Labour Commission within FEIQUE, and CEOE, plus any joint committees created within the Agreement, all of which the Group has been informed about from time to time.

17

Working Group on Code of Practice

Implantation and compliance with the Code of Practice is one of the main goals of FARMAINDUSTRIA. In this respect, the Governing Bodies of the Association approved setting up a specific High Level Group (HLG), made up of the top managers from 15-16 pharmaceutical companies representing all Statutory groups, with the task of proposing modifications and improvements to the Code that would be necessary to meet goals, particularly relating to achieving the greatest possible transparency.

Publication in April 2016 of the report by the Legal Dept. of the Spanish Data Protection Agency (AEPD) establishing that *"there is legitimate interest from the companies subject to the Code, so that consent is not required to individually publish the Transfers of Value to Health Professionals"* (current Annex I of the Code) demonstrated that aforementioned High-level Group needed to focus on adapting and modifying article 18 "Transparency of Inter-relations within the Pharmaceutical Industry" and Consultations from Annex II related to this precept, incorporating new questions.

This process concluded with the approval, in the FARMAINDUSTRIA General Assembly meeting held on May 26th 2016, of a new version of the Code, where article 18 compiles the companies' obligation to publish information from transfers of value individually, whenever legally possible, and this information can be provided accurately and consistently.

During 2016, this Group's work has been marked by the change that, in relation to the individual publication of the transfers of value, represents **going from a "*consent model*" to an "*information model*"**. In any case, this modification is endorsed by the aforementioned report issued by the AEPD.

18

Working Group on Competitiveness and Internationalisation

This working group, in an attempt to **make associated pharmaceutical companies more competitive and promote internationalisation**, has intensified its work in 2016, concerning both specific internationalisation initiatives for member companies and interaction with public and private organisations aiming to promote the internationalisation of the companies or actions with Embassies and local institutions promoting internationalisation.

19

Working Group for Relations with the Regions

This Group has the following goals:

1. **Monitor the Regions' pharmaceutical policy**, particularly standard-based developments and regional initiatives affecting the offer of medicines and freedom of prescription, putting access equality and market unity at risk.

2. Strengthening **dialogue and collaboration** with the Administrations.

3. Seeking scenarios that make NHS **sustainability compatible** with patient access to medicines and with balanced development of the market and industrial activity.

4. **Consolidate strategic alliances** with different agents from the healthcare field and look for areas of understanding that might help achieve common goals.

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

6. **Participate in forums** that might be political, scientific or professional that help broadcast the value of the pharmaceutical industry and the medicines' contribution to improving the population's health and that strengthen FARMAINDUSTRIA's position as a benchmark in this field.

This Group held five work meetings in 2016, and it is working on reports from the Regions Observatory, an information and consultation tool that is available to companies, on the situation of the different Regions, including key synthetic information on regional healthcare and pharmaceutical policy as well as the field of R&D+i from each Region.

20

Working Group on Communication and Corporate Social Responsibility

The Communication Working Group held quarterly meetings, well-attended by representatives from the different companies, where they tackled the **most interesting issues for the sector** and drew up joint strategies and positioning.

21

Patient Working Group

In the field of its work relating to patient associations, FARMAINDUSTRIA keeps the Patient Working Group Operative, and highly active, using it to **share initiatives and projects** with its member companies.

The FARMAINDUSTRIA Patients Working Group held four meetings in 2016 tackling matters of interest for the sector and preparing contents for the Somos Pacientes Conference and the different calls for the Permanent Dialogue Round Table.

BARCELONA DELEGATION

The FARMAINDUSTRIA Delegation in Barcelona offers **support and consultancy** of all types to associated pharmaceutical companies mainly located in Catalonia, working with the different departmental areas within the Association.

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

Alternately, the Barcelona headquarters are a meeting point for the FARMAINDUSTRIA Governing Bodies, Statutory Groups and other organisations in the healthcare sector (COASHIQ, ANEFP or SIGRE, among others).

During 2016, Delegation has continued working actively with the FARMAINDUSTRIA National Statutory Group, taking the role of Technical Secretary at its bimonthly meetings, coordinating the Group's own initiatives and managing interesting information for national companies.

On the other hand, the Delegation has maintained its active dialogue with the Catalan public healthcare administration on different topics, relevant to the innovative pharmaceutical industry.

Additionally, and in close coordination with the Hospital Debt Working Group and the Electronic Invoicing Subgroup, the FARMAINDUSTRIA Delegation has continued its exhaustive monitoring of how far e-invoicing has been implemented in Regions, taking on direct liaison tasks with the MINHAFP, General Interventions from the Regions, health services and health centres, in order to deal with emerging incidents in this field to defend our sector's interests and transfer opportune pleas regarding regulations being processed.

Finally, it should be noted that during 2016, the Delegation **has maintained contact with academic institutions and entities related** to the pharmaceutical sector in the regional field, also participating in the Delegated Mixed Commission for Catalonia, Fedequim, in order to interpret the text of the Chemical Industry Trade Union Agreement, and in the Social-Labour Commission for this Federation.

4 Member Services

After running for over eleven years, the Spanish Technological Platform for Innovative Medicines (PTEMI) has been consolidated as an initiative promoted by the pharmaceutical industry working with academic institutions, researchers and public administrations to **promote R&D in innovative medicines** in Spain.

The PTEMI is the Spanish reference point for the *Innovative Medicines Initiative* (IMI), an initiative from EFPIA and the European Commission to **promote research into new medicines**, aiming 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.

PTEMI activities in 2016 include the **Farma-Biotech Cooperation Programme**, set up in February 2011 to help the pharmaceutical industry and the Spanish biotechnology sector work together.

Between 2011 and 2016, fifteen interactive encounters have been held, mainly in the areas of the central nervous system, oncology, the respiratory system, inflammation and autoimmune diseases.

In this period, it has received 466 applicants for projects from which 110 projects were selected and presented to biopharmaceutical companies and a total of 42 new molecules, mainly in the preclinical research phase.

466
Project applicants

110
Presented to biopharmaceutical companies

42
New molecules, mainly in the pre-clinical research phase

The Farma-Biotech Cooperation Programme is mentioned in greater detail in the Farma-Biotech Working Group section of this Annual Report.

The PTEMI carries out a lot of its work in the area of broadcasting and promoting actions aimed at all agents in the science-technology-business system, to broadcast results from research activities or interesting public and private actions for the sector, in order to boost cooperation among agents.

On March 7th and 8th 2017, the PTEMI coordinated and organised its 10th Annual Conference in Barcelona, along with the Spanish Technological Platforms for Nanomedicine, Healthcare Technologies and the Biotechnology Markets.

Using the slogan "Innovation in the NHS" and speaking in front of over 300 participants, they analysed how the NHS has been transformed to meet the demands of a society that is intent on living longer and better, meaning that **innovation is the way forward in all fields of the health system**, seeking out joint public-private projects to benefit citizens and obtain real health results.

In addition, there was a chance to debate on the current financing instruments in the field of ***Open Innovation*** that in Spain also has relevant international programmes.

The PTEMI communicates through its website / portal (www.medicamentos-innovadores.org) that 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 brought out every month and sent to more than 2,400 people who are interested in the PTEMI's activities. The website is available in Spanish and English and is updated on a weekly basis.

During 2016, the PTEMI has carried out activities in an attempt to **promote international collaboration.**

It thereby participated in the IMI Forum, organised every six months by the Centre for Industrial Technology Development (CDTI) and on the Committee of Experts that met with the Director of the AEMPS as the assessor of this Initiative. In addition, calls from the IMI-2 initiative have been monitored intensely, within the European Union New Framework Programme for Research and Innovation envisaged for 2014-2020 (*Horizonte 2020*).

In order to promote participation from Spanish entities in IMI-2, on January 12th 2016 a specific IMI Workshop was organised for the oncology area working with the ISCIII, CNIO and CDTI, also involving representatives from FARMAINDUSTRIA, the IMI Executive Office and the consortiums already up and running.

FARMAINDUSTRIA is participating directly in an IMI consortium for the Third Call, known as the ***European Patients Academy on Therapeutic Innovation*** (EUPATI) that will provide objective, complete and scientific information on pharmaceutical R&D.

This project is made up of 29 organisations led by the European Patients Forum that combines pan-European patient organisations, academic and non-profit making institutions, experts on patient and public participation, as well as companies and associations that are members of EFPIA.

In addition, from February 1st 2017, FARMAINDUSTRIA has been participating in a new IMI consortium. This time, it is a *Coordination & Support Action*, specifically in the IMI 2 programme *Big Data for Better Outcomes, Policy Innovation and Healthcare Systems Transformation* (DO → IT), with a dual proposal:

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

2. Encouraging changes in the health systems, working towards **models based on value and measuring results**. This Programme (initially) included four specific pathologies: Alzheimer, hematologic neoplasia, prostate cancer and cardiovascular diseases.

FARMAINDUSTRIA takes part in two of the four lines of work in this Consortium, specifically concerning communication and coordination with stakeholders and the line relating to ethical and legal matters of privacy and data protection.

The Association's presence will make it easier to transfer results from these projects, in the area of big data and measuring results, to Spanish administrations and to the remaining participants in the NHS.

The DO → IT project initially lasts 2 years and it is made up of **36 partners** from the public and private sector:

- 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.
- National Quality Registries at the Swedish Association of Local Authorities and Regions.
- 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

Over 2016, joint work with pharmaceutical companies through different working groups and subgroups allowed FARMAINDUSTRIA to detect potential areas to improve the Code, particularly relating to new **transparency commitments** adopted by the pharmaceutical industry.

During the first semester, with advice from an external company that is an expert in communication issues, informative materials were designed to explain the initiative on transparency, legitimacy and the pharmaceutical industry's need to interact with healthcare professionals and organisations, the origin, destination and scope of the transfers of value derived from these exchanges and how this benefits patients in terms of **developing new treatments**, providing better care and positive for society as a whole.

This is an international initiative, adopted by most of European countries through different models (legislative, self-regulation or co-regulation) where the different studies promoted by EFPIA, comparing the different models (advantages and disadvantages, points in common, possible measures to be adopted to achieve certain harmonisation, etc.), allow areas of improvement to be detected in the Spanish model, such as the **consent level** for individual publication, nature and volume of exchanges with professionals and healthcare organisations.

Knowledge of this information led FARMAINDUSTRIA Governing Bodies to approve setting up a High-Level Group (HLG), made up of CEOs from companies in the Governing Bodies, entrusted with two fundamental aims for the Association:

1. **Modification of the Code of Practice** for the Pharmaceutical Industry in terms of transparency.

2. A **wider review of the Code** including changes, modifications and improvements that guarantee the strictest ethical principles of professionalism and responsibility for pharmaceutical companies' activities and practices.

The HLG designated a technical support working group to develop these goals.

Publication on April 22nd 2016, of the Legal Dept. Report number 2016-0172 (REF 143318/2016), by the Spanish Data Protection Agency (AEPD), made the modification and review of the Code focus exclusively on aspects related to transparency (Art. 18).

According to this AEPD report, there is a legitimate interest from companies subject to the Code, acknowledged by the actual Agency, **so consent is not necessary for individual publication of the transfers of value to healthcare professionals.**

In any case, pharmaceutical companies should inform health professionals, by virtue of Organic Law 15/1999, dated December 13th, on Personal Data Protection, that their data will be published according to the Code. This report is an integral part of the Code (Annex I).

On May 26th 2016, the General Assembly of FARMAINDUSTRIA approved a new version of the Code which came into force the following day, including these main new issues:

1. Individual publication of all transfers of value (except any related to R&D).

2. Including the AEPD Report in the Code (Annex I).

3. Adaptation of questions related to Article 18 on transparency from Annex III "Consultations (Q&A).

4. A Transitory Provision (Art. 38), establishing the possibility of transfers of value from 2016 being published in 2017 in accordance with rules on consent included in the version of the Code in force until May 26th 2016.

In any case, all transfers of value made from January 1st 2017 onwards should be published individually (except any related to R&D).

This new model referring to information over consent led to a new Consultation (no.120) and adaptation of existing articles on data individualisation. In short, measures focusing on guaranteeing meeting the general principle compiled in section 18.1 of the Code:

> "As far as legally possible and whenever it can be provided accurately and consistently, pharmaceutical companies should publish this information individually, identifying the Physician (instead of the Healthcare Organisation)."

Due to its relevance, the FARMAINDUSTRIA Extraordinary General Assembly held in October 2016 approved a **new edition of the Code of Practice.**

Without affecting activities to disseminate the main new aspects of the Code, explained in detail below, it is necessary to highlight the joint work from the pharmaceutical companies through the Strategic Committee for Pillar IV, and from the different working groups set up in 2016. More detailed information is provided on the aims and functions of each of these groups in the section of this Annual Report outlining the working groups.

In this way, for the first time and in line with the pharmaceutical industry's commitment, in June 2016, the pharmaceutical companies subject to the Code of Practice published the transfers of value made during 2015 to professionals and health organisations as donations, training activities and scientific-professional meetings, service provision and R&D.

The cover that the media has given these publications mainly focused on the quantities provided by the industry to health organisations and professionals and with the destination of these transfers. The publications have compiled figures and messages with a **generally positive tone** (pioneering initiative, framed within a strategy of transparency for the sector in the European field and a process that will continue making progress, necessary relationships, benchmark for other sectors, etc.) so the general feel after the first publication of data has been positive.

ACTIONS FROM THE ETHICS COMMISSION

The Ethics Commission held 11 meetings in 2016. Its main task is to mediate between the parties involved in complaints in an attempt to achieve conciliation. It played a mediating role in all of them and also dealt with a range of subjects, on which the Ethics Committee has advised the companies and has clarified how to interpret what has been stated on specific subjects. In particular, the Ethics Committee has worked actively on all the measures that have been developed by FARMAINDUSTRIA throughout 2016 regarding transparency, that will continue in 2017, in accordance with what appears in the Pharmaceutical Industry Code of Practice.

In 2016, **7 complaints** were taken before the Ethics Committee. These complaints were processed in compliance with the ordinary procedure contemplated in art.32.2 of the Pharmaceutical Industry Code of Practice. 28.5% of the complaints were presented by the Ethics Supervision Unit, and were resolved by a voluntary contribution from the offending company, for rational use of medicines. It should be highlighted that during 2016, all complaints were resolved by agreement, and none were transferred to the Self-Regulation Jury.

The complaints fundamentally refer to matters of hospitality and meetings and, to a lesser extent, to other promotion activities such as distribution of promotional material or promotion to the public. The following table summarises the complaints, grouped according to classification criteria.

TOTAL	7
ETHICS COMMISSION	**7**
Commission Mediation	7
Self-Regulation Jury	0
PLAINTIFFS	
USD	28.5%
Associated labs	71.5%
DEFENDANTS	
Associated labs	86%
Member labs	14%

CODE OF PRACTICE SURVEILLANCE UNIT (USD)

Regarding information provided on the self-regulation system, the following should be highlighted:

- Participation in the **Code Working Group** to explain how the Code is implemented in Spain.
- **Participation in different working groups** within FARMAINDUSTRIA to analyse the scope of the Code.
- **Meetings with the pharmaceutical companies** to monitor and support transparency projects.
- **Meeting with the Health Ministries** from the different Regions to pass on 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.
- Participation in the creation, design, launch and development of the **new version of the website** specific to the Self-Regulation System (www.codigofarmaindustria.org).
- **Update and review the test for Code case studies** and update the interactive version of the Code.
- **Drawing up specific information and communication materials** relating to both the self-regulation system and the transparency initiative.
- Giving **training sessions** specifically designed to meet the needs and demands of the pharmaceutical companies (in-company training).
- Joint work on **training sessions on the Code** within the framework of specialised courses, doctorates, master's courses.
- Participation in the *Action Team Disclosure* set up by the EFPIA *European Markets Committee*, in order to approve strategies and initiatives bringing about a continuous improvement process for the transparency initiative in all fields.

- Collaboration with EFPIA working groups in charge of watching over transposition and implementation of approved standards into the applicable codes in each national association.
- Active member of the Codes Committee (chair) and the Strategic Committee, the Ethics & Compliance Committee and the Validation Team (e4ethics) in EFPIA
- Continuous collaborations with IFPMA: chairman of the Appeals Court for the complaints procedure for the IFPMA Code (Appeal Group), participation in the meetings for the Code Compliance Network, etc.

In terms of reciprocal relations with patient organisations, make sure that pharmaceutical companies meet the commitment to provide updated information relating to their joint work projects.

Consultancy and joint projects

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

- Review, adaptation and improvement of internal procedures implemented by pharmaceutical companies to guarantee **compliance with both the Code and the regulations** in force regarding medicine promotion.
- **Continuous support to pharmaceutical companies** and third party agents involved, mainly scientific companies, technical secretaries and service providers in general.
- Active participation in **meetings and forums** organised by FARMAINDUSTRIA, EFPIA and IFPMA.

During 2016, 11 memos have been published related to the Pharmaceutical Industry Code of Practice.

Control and prevention

The number of preventive actions carried out in 2016 was 1,483 (compared to 2,138 the previous year). The total number of complaints by the USD was 2, both due to non compliance related to scientific and professional meetings (article 11), and they were resolved by means of a mediation agreement before the Ethics Commission.

During 2016, **a total of 5,382 scientific-professional meetings** have been analysed and verified (45 more than in 2015); the average number of reviews remains at 5,000 annual events and in percentage terms, the adequacy finding has increased (it was 94.9% in 2016 in comparison with 91.2% achieved in 2015).

Finally, the number of market research studies reported stood at 317 (17 more than in 2015), and the number of projects reported was 361, seven less than in the previous year. In percentage terms, the adequacy finding of both activities (studies and services) is high, both above 77%.

5,382
Scientific-professional meetings

95%
Adequacy finding

317
Market research studies sent

361
Projects reported

'E4ETHICS' PLATFORM FROM EFPIA

Since its launch in 2011, the EFPIA platform e4ethics, managed by FARMAINDUSTRIA, has been the reference tool for the pharmaceutical industry when participating or sponsoring scientific-professional meetings.

The collaboration agreement signed between EFPIA and FARMAINDUSTRIA included both the technical support required to design, operate and maintain the platform, and the provision of services relating to evaluation, analysis and consultancy required to assess the adequacy of the events reported on this platform against Article 10 of the EFPIA Code.

After almost 5 years of FARMAINDUSTRIA management, the decision was taken in 2015 to fully transfer the platform to EFPIA so that it might take over its management and operation directly from January 1st 2016 onwards. Consequently, without preventing FARMAINDUSTRIA from continuing to participate actively in review and classification of the events analysed under this platform, EFPIA will now provide information on the e4ethics statistics (number of events analysed, contacts with scientific societies, etc.).

For more information: www.codigofarmaindustria.org

		USD ACTIVITY (January 1st to December 31st 2016)													
		2004 Apr.- Dec.	**2005**	**2006**	**2007**	**2008**	**2009** (a)	**2010**	**2011** (b)	**2012**	**2013**	**2014**	**2015**	**2016**	**Accumulated** Apr.'04 - Dec.'16
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**	**51,740**
	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	46,212
	% Adequacy	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%	87.81%
STUDIES (a)	**ANALYSED**						**687**	**724**	**626**	**512**	**400**	**449**	**300**	**317**	**4,015**
	No incidents						397	546	565	416	332	368	251	260	3,155
	% Adequacy						57.79%	75.41%	90.26%	81.25%	83.00%	81.96%	83.67%	88.33%	80.21%
SERVICES (b)	**ANALYSED**								**357**	**330**	**306**	**350**	**368**	**361**	**2,072**
	No incidents								282	272	230	292	301	279	1,656
	% Adequacy								78.99%	82.42%	75.16%	83.43%	81.79%	77.29%	79.85%
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	28,207
USD COMPLAINTS		18	11	9	18	8	12	4	3	1	9	7	7	2	109

(a) Study Communication System approved in the Code 2008
(b) Services Communication System approved in the Code 2010
NB. The table attached summarises data from the Unit (annual and accumulated) from the start of work to 31/12/2016.

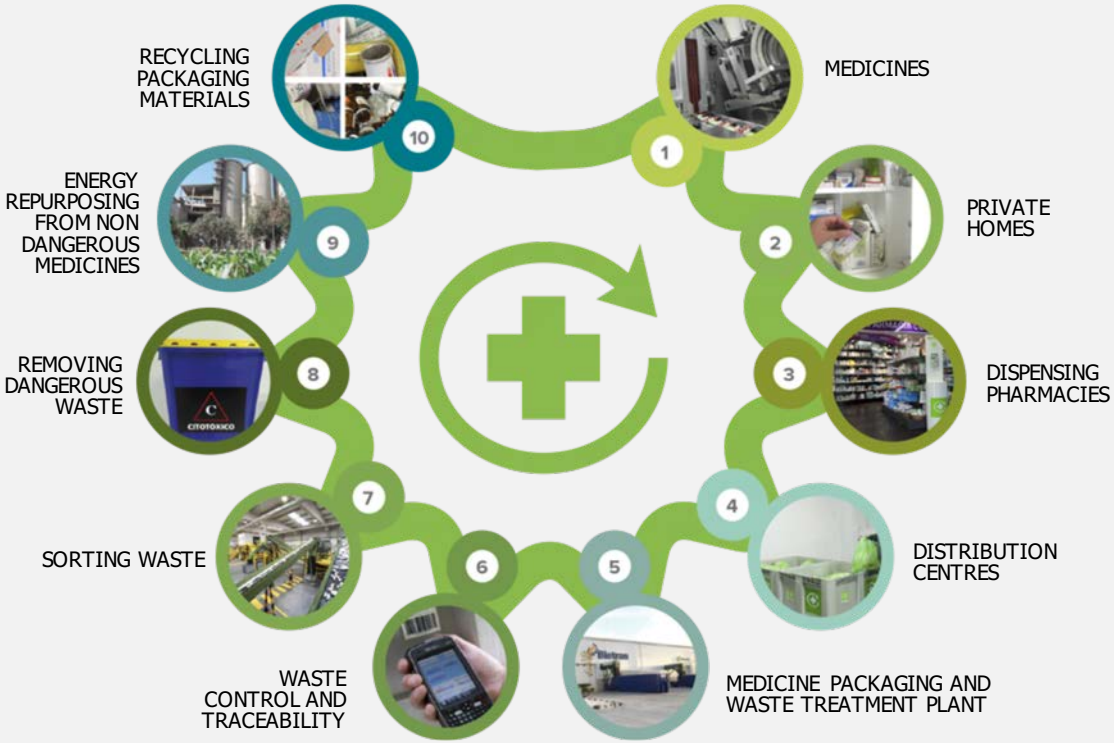
Annex

SIGRE Medicines and Environment

SIGRE Medicines and Environment is the **non profit making organisation set up by the pharmaceutical industry**, working jointly with the distribution and dispensing pharmacies to guarantee correct environmental management of packaging and leftover domestic medicines.

Inspired by principles of shared responsibility, the whole pharmaceutical sector participates actively in the SIGRE System.

By means of a closed reverse logistics process where the waste is collected by the actual agents in charge of medicine distribution and dispensing, control is guaranteed even during this last phase of their life cycle, constantly under professional surveillance and supervision from the pharmaceutical sector and avoiding any public health risks (illicit sales, counterfeiting, thefts, etc.).



Within the environmental and social-healthcare aims set by the pharmaceutical industry, **there are three fields of action for SIGRE** to be able to meet both environmental and healthcare legislation:

1. Prevention at origin.
2. Responsible waste management.
3. Awareness-raising.

Prevention at origin

Responsible waste management

Awareness-raising

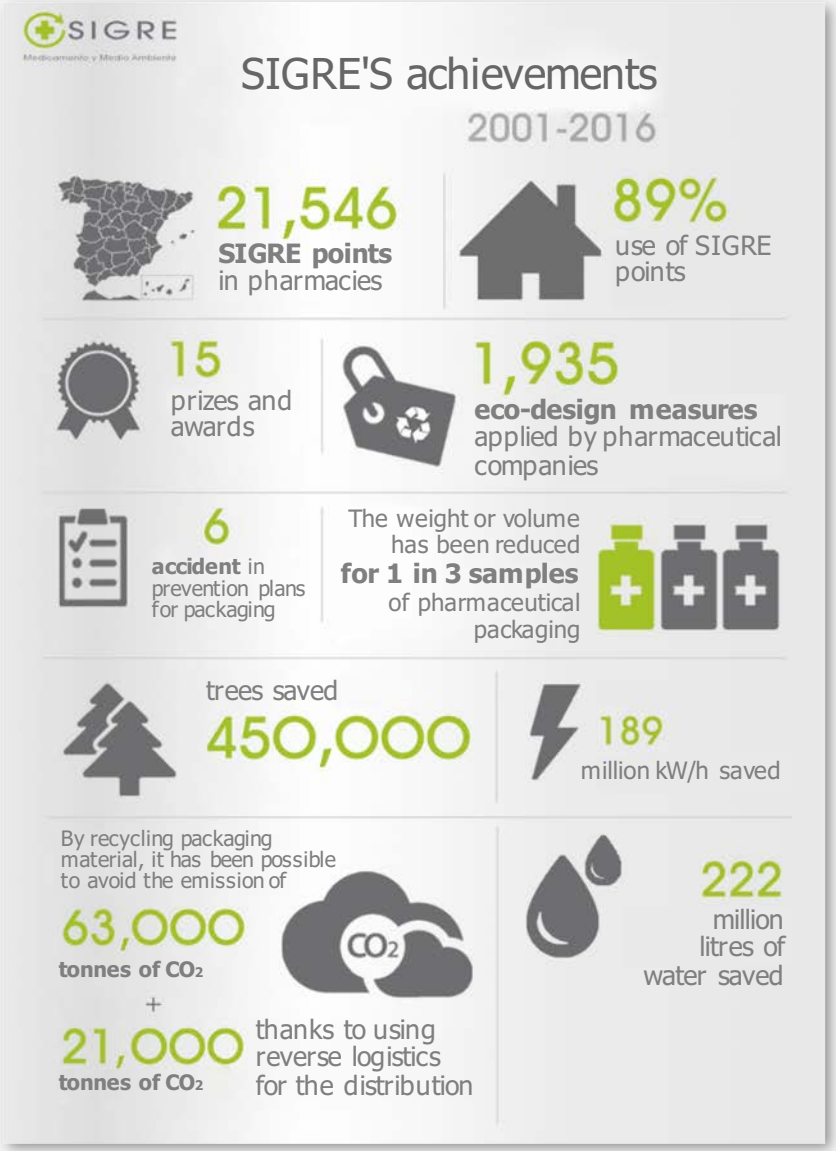
SIGRE's work is made possible by funding provided by the 313 member pharmaceutical companies that pay a quota per medicine dispensed in the dispensing pharmacies for consumption in private homes.

As a guarantee that the waste will receive the correct environmental treatment, all medicines sold for domestic consumption in Spain have the SIGRE symbol on their outer packaging and include an informative guide in the brochures on how to dispose of them so that they do not damage the environment or affect anyone's health.

15th ANNIVERSARY

2016 marked the 15th Anniversary of implementing the SIGRE System, an environmental and healthcare initiative that has become the largest joint project carried out by the pharmaceutical sector.

Thanks to the joint effort from all pharmaceutical sector agents, invaluable collaboration from citizens and continuous support from public administrations, the correct management of empty packaging or the remaining medicines has been consolidated in our country as a recycling habit that has spread to most Spanish homes.



To celebrate these fifteen years, a series of events and awards were organised to acknowledge the commitment from all agents involved in SIGRE's work. These encounters included the event held in the Ministry of Agriculture and Fishing, Food and the Environment, that was presided over by the then Secretary of State for the Environment, Mr Pablo Saavedra.

Picture of the main event held in November 2016 to commemorate 15 years of SIGRE.

During this event, the 15th anniversary insignias and plaques were awarded by the SIGRE Board of Directors to the people and institutions who have most contributed during this period to meeting environmental and social-healthcare goals.

This central event for the 15th anniversary was also used as the stage to present the 2nd SIGRE Medicines and Environment Awards to the pharmaceutical sector and the 2nd "Por la Salud de la Naturaleza" Awards to journalists.

ANNUAL PACKAGING DECLARATION 2016

SIGRE has presented the Regions' Environment Ministries with the Annual Packaging Declaration 2016, a document that compiles the main environmental results from this year.

This report states that last year, through 21,601 SIGRE Points located in Spanish pharmacies, 91.3 grams of packaging (empty or containing leftover medicines) were collected per inhabitant, representing 3% more citizen collaboration. In addition, there was a 4.7% increase in the units put on the market by pharmaceutical companies that are members of SIGRE.

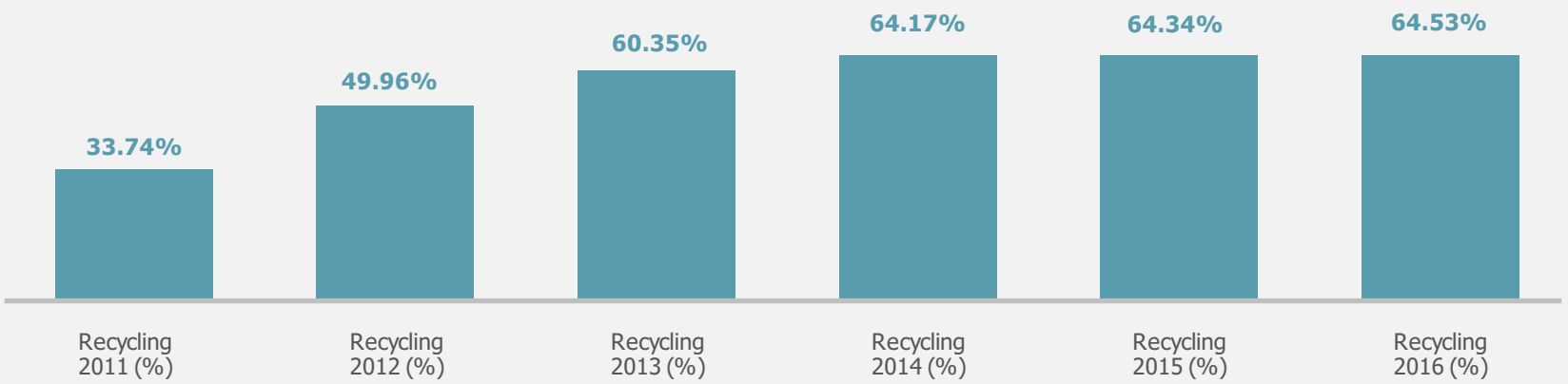
Regarding the current sixth Business Plan for Packaging Prevention from the pharmaceutical industry, it should be noted that the pharmaceutical industry applied 237 new environmental measures to its packaging last year that, along with the 172 measures applied in 2015, mean that over the first two years of this Plan, the goals set by the environmental authorities for 2015-2017 have been largely exceeded.

MEDICINE PACKAGING AND WASTE TREATMENT PLANT

The plant for processing medicine packaging and waste in Tudela de Duero (Valladolid) is a pioneering facility and a worldwide benchmark. Built specifically for ecological processing of empty packaging or packaging containing leftover medicines, it began operating in 2012 and uses innovative processes, particularly designed to separate and classify this type of waste.

This technological development has led to a 64.5% recycling rate for the medicine packaging materials collected, representing a new improvement in environmental treatment applied to this was

Rate of recycling medicine packaging materials



Throughout 2016, a variety of institutions and entities have visited these facilities to take a closer look at the different processes carried out there to provide the best environmental treatment for the waste left by citizens at the SIGRE Points in the over 21,600 collaborating pharmacies.

INDUSTRY + SIGRE MEETING 2016

In June 2016, the first Industry+SIGRE Meetings were held in Madrid and Barcelona, substituting the previous Pharmaceutical Companies Information Days that SIGRE has been organising with the environmental managers from member pharmaceutical companies for the last 15 years.

Once again, this event received strong institutional support with the presence in Barcelona of Mr. Xavier Reinaldos, Deputy Manager of the Catalonia Waste Agency and in Madrid, from Mr. Jaime González Taboada, Minister for the Environment, Local Administration and Territorial Ordinance who classified SIGRE's path as an "environmental example".

The Industry+SIGRE Meeting 2016 provided a place for participation, learning and debate. It tackled topics related to SIGRE's work (eco-design, waste management, climate change, standard changes, etc.) that arouse the greatest interest among pharmaceutical companies. On this occasion, SIGRE Diplomas were awarded to the best prevention measures applied by pharmaceutical companies to make medicines packaging even more ecological.

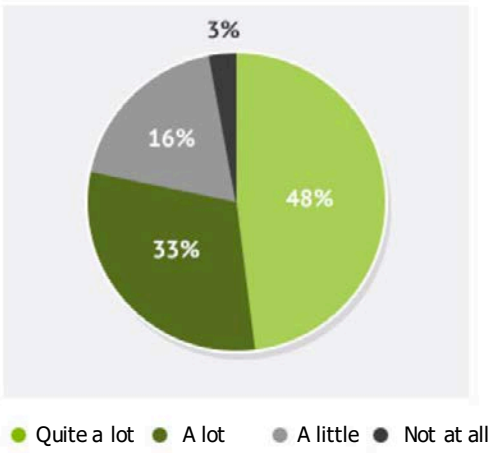
Jaime González Taboada, Minister of the Environment, Local Administration and Territorial Ordinance in the Madrid Region; Humberto Arnés, President of SIGRE; and Juan Carlos Mampaso, Director General of SIGRE, along with representatives from member pharmaceutical companies who received acknowledgement in Madrid for the preventive measures they have applied.

OPINION POLL AMONG PHARMACEUTICAL COMPANIES

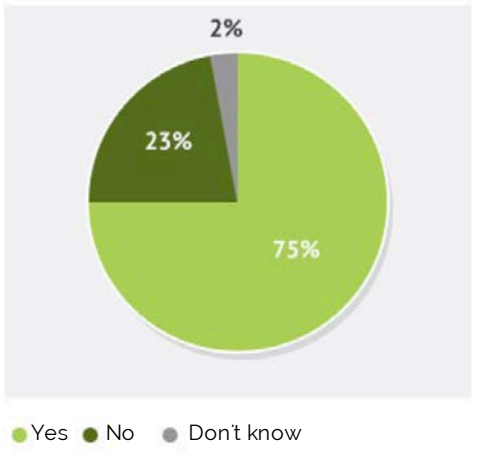
In order to find out about the expectations and demands of the pharmaceutical industry and assess the degree of satisfaction with the service they receive, SIGRE carries out a biannual opinion poll among the pharmaceutical company environment managers.

In 2016, the results from this study, involving participation from 59 professionals from different pharmaceutical companies and groups, reveal that in 3 out of every 4 cases, the pharmaceutical companies' level of satisfaction regarding their relationship with SIGRE is "high". In addition, they give a high score to the support provided to meet their legal requirements in terms of packaging prevention.

Do you think that putting medicines in the bin or down the drain might damage the environment?



Did you know that there are containers in pharmacies, known as SIGRE points, where you can leave medicines you are no longer using or that are out-of-date?



The results gathered will help identify new opportunities to improve SIGRE's service and continue offering to the pharmaceutical companies useful, effective and tailored-made solutions to suit their needs.

Lend a Hand

FOR A BETTER WORLD

SIGRE AWARENESS-RAISING CAMPAIGN

Working with the environmental and healthcare authorities, a new public relations campaign was launched last year with the slogan "Lend a hand for a better world". This new campaign aims to raise awareness among society on the importance for the environment and people's health of correct recycling of empty packaging or containing remains of medicines, expired or that are no longer needed, through the SIGRE Point in their pharmacy.

COMMUNICATION 2.0

In 2016, SIGRE has continued backing innovation by putting out information, consolidating and exploring new opportunities in this field.

Good proof of this is SIGRE's active presence in the social media or the intense communication developed through the different 2.0 channels, maintaining connectivity with users and making information available in real time.

The SIGRE corporate blog has been increasing its relevance progressively along with its visits and it has become an environmental and social-healthcare reference space on the Internet.

Thanks to technology and the social media, all SIGRE's news can be followed on its profiles on Facebook, Twitter, Goggle+ and YouTube, where the entity provides information on its work, broadcasts environmental and social-healthcare news and interacts with users.

SUSTAINABILITY REPORT

Every year, SIGRE publishes its results through the Sustainability Report that, in addition to compiling the activities carried out during the year, can highlight the pharmaceutical sector's environmental commitment.

In the Sustainability Report, drawn up following guidelines from the *Global Reporting Initiative* international standard, SIGRE explains its goals, measures its performance and manages change in an attempt to make its operations increasingly more sustainable.

The latest Sustainability Report from SIGRE was acknowledged by the Ministry of Employment and Social Security, through the General Board of Self-Employment, Social Economy and Corporate Social Responsibility, by means of publication on its website, thereby acknowledging the entity0s transparency work.

The Sustainability Report is, at the same time, the SIGRE "Progress Report" on applying the 10 Principles from the United Nations Global Compact. For the sixth year running, this Report has been given an "Advanced" level, the maximum score awarded by the United Nations to evaluate implantation of the principles, transparency and degree of information from the organisations. In 2016, only 35 Spanish companies and institutions achieved this distinction.

LATIN AMERICAN NETWORK OF POST-CONSUMPTION MEDICINE PROGRAMMES

SIGRE is currently presiding over the Latin American Network of Post-Consumption Medicine Programmes, an organisation that groups together the systems in charge of managing medicine waste and its packaging in these countries.

The main aim of this Network is to share experience from existing management systems to get specific and effective responses in each country to thereby guarantee collection and correct environmental treatment of medicine waste, helping to protect the environment and citizens' health.

The different initiatives developed during 2016 include the launch of its corporate website (www.redippm.org), setting up three Working Groups (financial, legal and technical) and holding its Assembly and Board of Directors meeting within the framework of the National Environment Congress 2016, the main environmental forum held in our country.

GLOBAL COMPACT NETWORK SPAIN

The UN Global Compact operates in Spain through the Spanish Network that currently has more than 2,500 member entities in this corporate social responsibility initiative. Since it was set up, the Global Compact Network Spain has been one of the top national platforms for the Global Compact and the local network with the largest number of signatories.

Since 2009, the year when SIGRE approved the 10 Universal Principles from the United Nations Global Compact in terms of human rights, work, environment and anti-corruption, it has been working actively in the Spanish Network, forming part of its Executive Board since 2012 and taking on the role of treasurer since 2016.

UN GLOBAL COMPACT

Pacto Mundial
Red Española

CONFERENCES AND SESSIONS 2016

SIGRE takes an active part in many environmental and healthcare forums to raise awareness on its results on managing medicine waste and to highlight the pharmaceutical sector's contribution to a more sustainable society.

During 2016, it was notably present at the National Environmental Conference CONAMA 2016, at the Symposium of the Spanish Association of Industry Pharmacists (AEFI) in the 20th National Pharmaceutical Congress and at the workshop on "The contribution from private companies to a universal agenda for Sustainable Development", organised by the United Nations Fund for Sustainable Development Goals.

SIGRE AND THE CIRCULAR ECONOMY

The transition from the linear economic model to a circular model, backing sustainability and more respectful of the environment, is inescapable to ensure the future of the planet and conserve natural resources.

SIGRE is already implicated in the circular economy and, among other matters, works on prevention, eco-design, recycling, energy repurposing, minimising waste removal or reduction of emissions.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