2014

ANNUAL REPORT

farmaindustria

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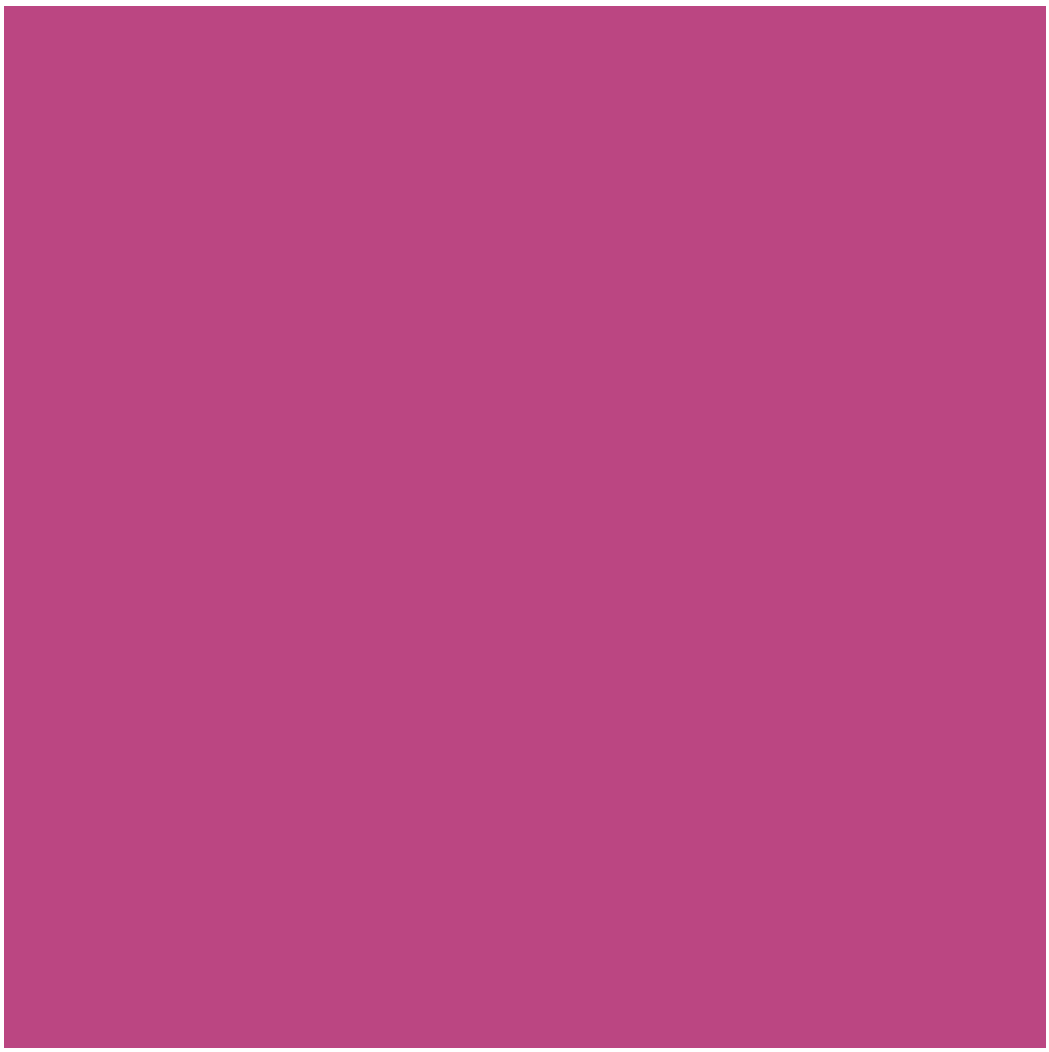

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MESSAGE FROM THE PRESIDENT

Antoni Esteve Cruella, President of FARMAINDUSTRIA

Those who know me will know that, by nature, I tend to be an optimist. Since I assumed the presidency of FARMAINDUSTRIA in October 2014, I have faced my second stint in this role full of hope and motivated by the work of, and for, a sector in which I have spent my whole career. Now that I can look back on what we have achieved in 2014, I am convinced that my optimism is better founded than ever.

The pharmaceutical sector has suffered hugely in recent years from the effects of the economic recession and health spending containment measures. These have had a great impact on our companies and, worse still, on employment, innovation capacity, the industry as a whole and internationalization. We have to believe we have hit rock bottom now, that the worst has passed and there is significant margin for improvement. Economic data for the sector, corresponding to 2014, indicates as much. After four successive years of big drops in business volume, in 2014 pharmaceutical company revenues for sales of medicines in pharmacy stores increased by 0.7% and the hospital market grew by 1.2%, resulting in overall market growth of 0.9%.

The incipient economic recovery we are starting to see should also have a effect on the activity of the innovative pharmaceutical industry established in Spain. We sincerely trust that the Public Administrations and society in general are able to recognize the effort we have undertaken as a sector and that they support our activity as being a key pillar in the structuring of the new productive model our country so needs.

In this context, we are ready to assume the role of protagonists in the system and a paradigm change in Spain's economic activity. The pharmaceutical industry is a strong industrial sector which brings together all the necessary characteristics to contribute to leading this change, since it has always successfully and intensively combined the three main factors for wealth generation: production, internationalization and innovation, three attributes to which can be added that of first-class human capital.

This is why our companies in recent years have neither abandoned their commitment to the health of the population, nor their commitment to becoming knowledge generators. They want to contribute anything that can help progress in a modern society: ideas, products and wellbeing. Indeed, the pharmaceutical sector we represent has shown, and continues to show, solidarity with society, its administrators, its health systems, all kinds of professionals and, of course, patients.

We still, however, have some barriers from the past to overcome. In the health field in general, and pharmacological treatments specifically, we are faced with the challenge of substituting once and for all the concept of price for one of value, and of expenditure for one of investment. We also need to measure all the effort we put in to achieve the benefits a certain therapy generates for people's health and the medium- and long-term savings this can lead to, both from an economic and a social perspective.

Our main commitment to society is for the patient to receive the right medicine she or he needs. One of our responsibilities is to promote the rational and responsible use of therapeutic innovations. Everyone should be able to access the best treatments available in accordance with their health and medical recommendations, but not a single medicine should be misused on a person who does not need it, and this is a challenge on which our sector is firmly committed to working with authorities, health professionals and patients.

As such, we maintain the ideal of being a loyal ally of authorities and Public Administrations, with whom we share a double objective: to guarantee patient access to the best and newest treatments, and to consolidate economic sustainability of a public health system that is both universal and of the highest quality. We must make this objective compatible with the development of an industry that generates value and hope for society.

In fact, the pharmaceutical industry as a whole has responsibly accepted all the adjustments it has had to suffer over the past four years, in the interests of achieving a sustainable health system, where the pharmaceutical budget is subject to great pressures, which on occasions has pushed our sector to the limit in order to continue guaranteeing the accessibility, quality and reliability of its services. Nevertheless, we have responded responsibly in all of this, with great solidarity, and confidence in the future. We are, however, subject to a regulatory framework that has little respect for our work and this situation needs to be reviewed immediately if our activity is to be deservedly recognized.

The double objective mentioned above is undoubtedly influenced by our Collaboration Protocol with the Spanish Government, on which we have been working for months, both with the Ministry of Health, Social Services and Equality, and the Ministry of the Treasury and Public Administrations, in order to ensure control of the public deficit as far as pharmaceutical expenditure is concerned, compatibility with the development of the pharmaceutical industry and the fair and efficient incorporation of therapeutic innovation.

A magnificent opportunity thus now arises to establish with the Government the stable and predictable framework we need to meet our business challenges with more confidence and optimism, and, in this way, achieve our goal of actively participating in Spain's economic recovery.

The future Royal Decree on Prices and Financing will be important, as will the Bill to reform the Guarantees Law and each Order of Reference Prices update.

Neither should we forget that we are entering a new and hopeful era in healthcare, with the breakthrough of a new generation of medicines, many of them of biological origin, which will see an authentic revolution in the treatment of many diseases most affecting us and this will facilitate a much more individualized approach to each pathology. These new drugs will not arrive by chance, but are the fruit of a considerable investment effort in R&D by our pharmaceutical industry, and are evidence of a deeper economic and health care revolution in our midst. As this new therapeutic era begins, situations of budgetary tension could occur in the short term, especially in treatments susceptible to being used for a high number of patients (as we have already seen with cases such as Hepatitis C). For this reason, it will now be particularly necessary to take into account the incalculable savings and benefits in the medium and long term derived from the use of these products, which will be much greater than their cost, and imply radical progress for hope and quality of life.

New drugs do not arrive by chance, but are the fruit of a considerable investment effort in R&D by our pharmaceutical industry, and are evidence of a deeper economic and health care revolution in our midst

Confronted by this new paradigm, the sector must fulfill its social vocation to respond to the healthcare expectations of society and, alongside the Public Administrations, be able to put forward new policies and formulas for financing, which should be as creative as necessary, to enable patients to have access to the best treatments and so that the demands of people for health care are in line with our level of economic and social development in Spain.

Other challenges include the need to end with the inequalities that exist in pharmaceutical services in different autonomous regions, both in the outpatient and hospital domains. The lack of cohesion and fairness here has provoked a situation in recent years where patients in Spain have different access to new medicines depending on which region they live in. Sometimes, it even depends on which city or district and this generates serious problems in relation to territorial inequity. This fact undoubtedly demonstrates the need to come up with and support solid structural mechanisms and sufficient regional financing to permit the regions to fund health cafe services adequately and fairly.

For FARMAINDUSTRIA, the building of collaborative and understanding environments does not end with the Administrations, but also extends to the rest of the agents in the system. We maintain a solid relationship with health professionals and patients' associations, with whom we also share challenges and concerns; they are unquestionably faithful allies in the defence of principles such as accessibility, fairness and cohesion. In this regard, we would like to highlight the effort the Association undertook in 2014, and will continue to carry out in 2015, to introduce the new measures stipulated in the Pharmaceutical Industry Code of Best Practices, particularly where it refers to transparency concerning transfers of value between companies and healthcare professionals and organizations. Once again, this is a great opportunity for us to generate closer ties with our environment, acquire commitments and actively participate as a reliable and committed partner in the progress of our healthcare system.

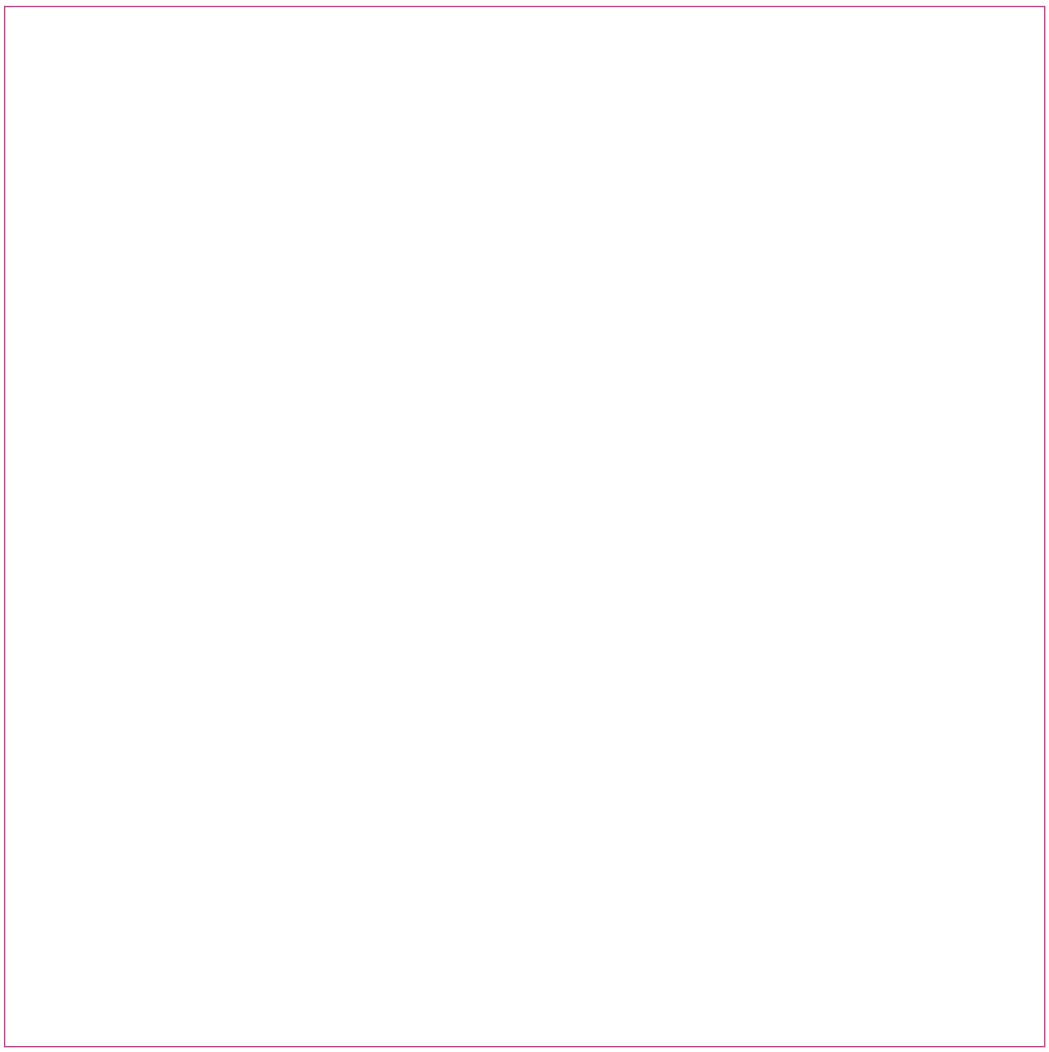
The Pharmaceutical Industry Code of Best Practices introduces measures on transparency of transfers of value between companies and health professionals and organizations

As you can see, the work performed by FARMAINDUSTRIA is great in quantity and quality, while in strict keeping with our Strategic Plan adopted several years ago. We are revising and updating the Plan this year in order to be coherent, persistent and efficient in our actions, lending them sufficient continuity and evolving as necessary. Our challenge is to analyze, identify and anticipate our response to the events around us.

A good part of the optimism my words exude is, logically, based on the serious and responsible positioning of the companies that make up FARMAINDUSTRIA. Special thanks goes to those who participate in our governance bodies and working groups. Their constant support and capacity to unify our efforts in favour of common objectives is of irreplaceable value. However, without the team of highly committed and talented professionals we are fortunate to have in FARMAINDUSTRIA, who tackle the challenges of our employers as if they were personal ones, it would be difficult for us to aspire to the objectives we set ourselves and, precisely because of that, not only do I call on them to continue in this vein, but also remind them they have our sincerest appreciation.

Last but not least, my sincerest thanks also to everyone who forms part of FARMAINDUSTRIA, for your support, wisdom and, indeed, commitment to making ours a sector that is well considered in Spanish society.

Antoni Esteve
Presidente



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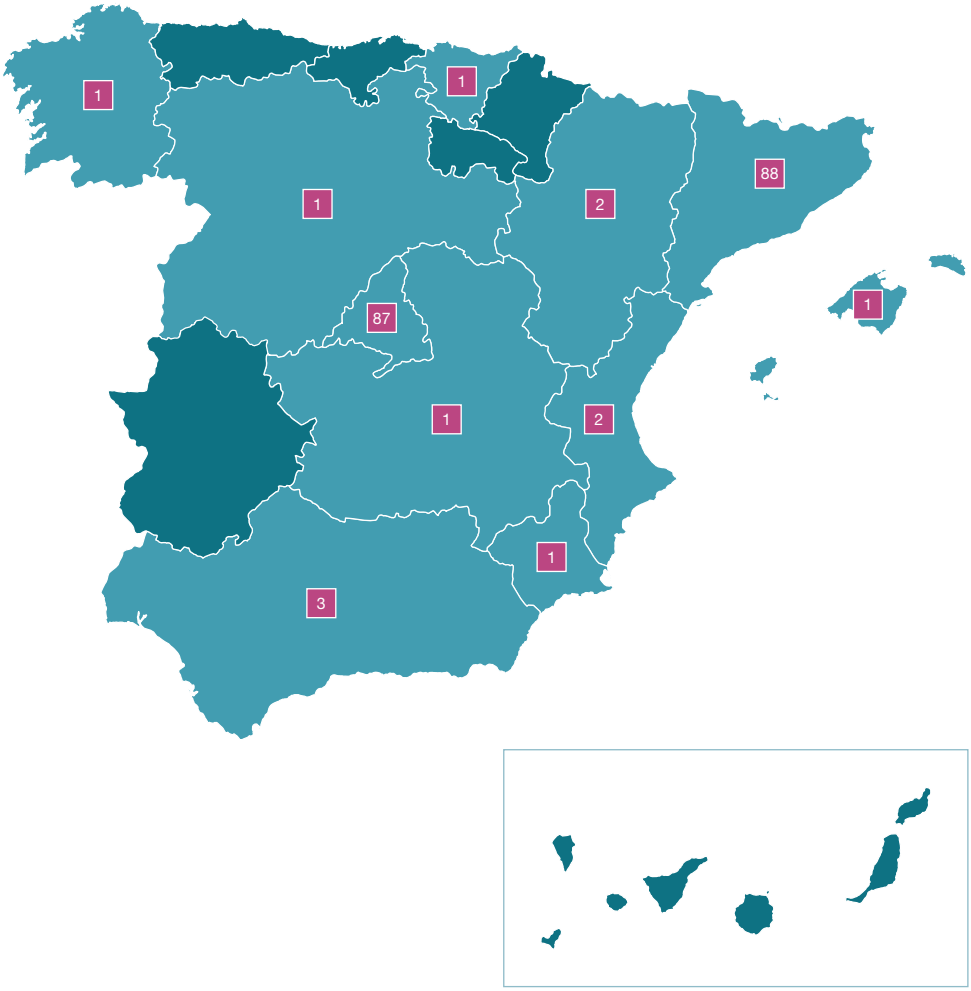
MEMBER COMPANIES

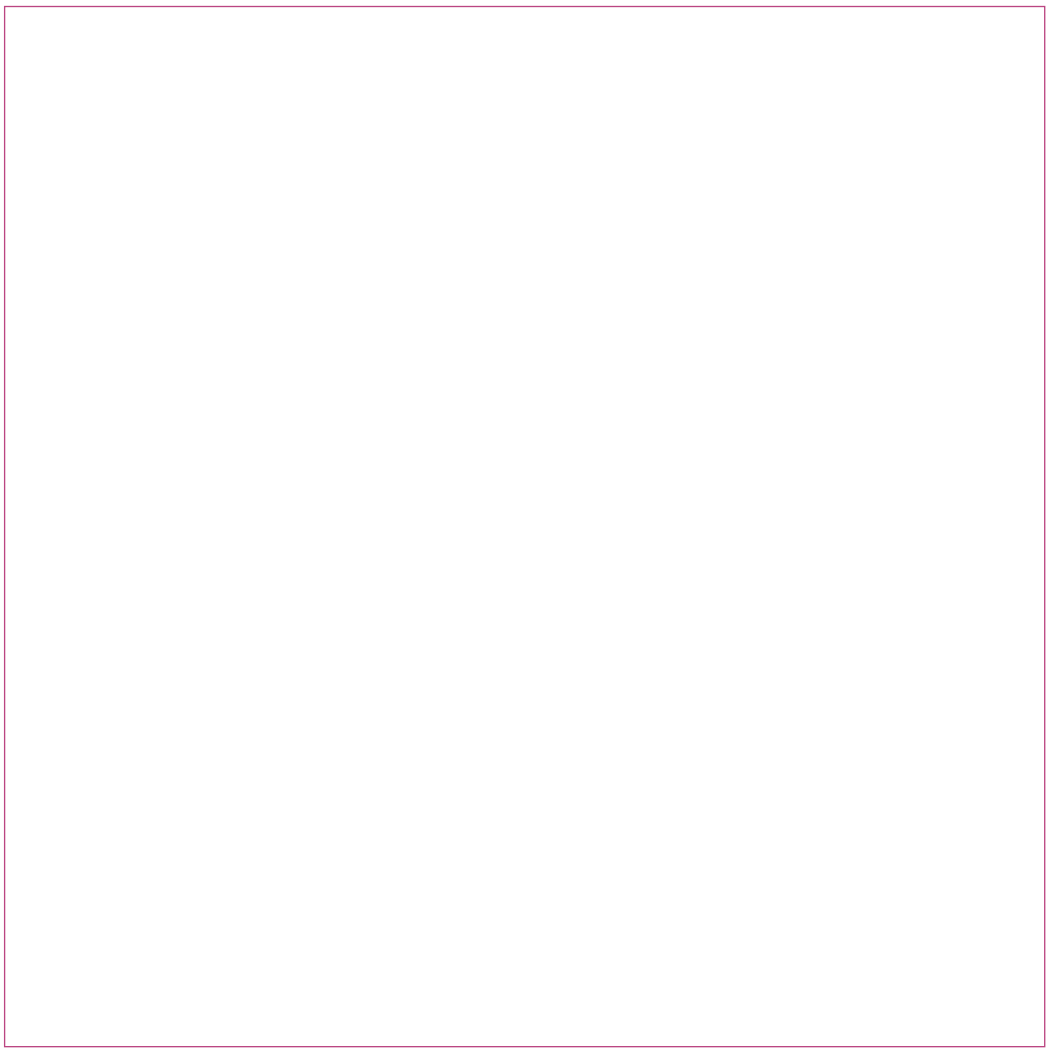
At 31 December 2014, some 188 companies were members of FARMAINDUSTRIA. Their geographic distribution is as follows:



The members of FARMAINDUSTRIA represent, by their number, 48% of licensed pharmaceutical product vendors or their local representatives in the case of those authorized by the centralized procedure, regardless of whether or not they are engaged in productive activity in Spain. In terms of sales, they represent 81% of the total prescription market.

LABORATORIES BY GROUPS

NATIONAL		INTERNATIONAL		
		AMERICAN	EUROPEAN	
Large	6		Germany	17
Medium	5		France	14
Small	61		Mixed	27
			United	24
			Switzerland	13
	72	21		95



2 ORGANIZATION

2.1 GOVERNANCE BODIES

The General Assembly is made up of the Association's member companies; it is the supreme governance body of Farmaindustria, through which the collective will of the member companies is expressed.

Governance of the Association resides in: i) the Steering Committee, which is made up of the President and 31 representatives of member companies (11 Spanish-capital and 20 foreign-capital companies. Twelve of the latter are European-capital businesses and eight are USA-capital concerns), and; ii) the Board of Governors, which is made up of the President and 20 member companies, nine of which are Vice-Presidents (three Spanish-capital, three USA-capital and three European-capital companies) and 11 board members designated by the Steering Committee from among its members (four Spanish-capital, two USA-capital and five European-capital companies).

Elections were held in October 2014 to renew the Association's Governance Bodies. In compliance with the statutory provision that establishes rotation of the Presidency every two years, the President was chosen, Mr Antoni Esteve I Cruella, from a company in the National Group, replacing Ms Elvira Sanz Urgoiti, who presided over the Association until that date as a representative of the American Group.

The Extraordinary General Assembly held in October, introduced a series of amendments to the Bylaws, reiterating among others the need for confidentiality as regards debates in the Governance Bodies.

The composition of the Governance Bodies of Farmaindustria at the time of this report closing was as follows:

BOARD OF GOVERNORS

PRESIDENT	
Mr Antoni Esteve Cruella ESTEVE	
VICE-PRESIDENTS	
Mr Jesús Acebillo Marín NOVARTIS FARMACÉUTICA, S.A.	Mr Juan López-Belmonte Encina LABORATORIOS FCOS. ROVI, S.A.
Mr Javier Ellena Aramburu LILLY, S.A.	Mr Jordi Ramentol Massana FERRER INTERNACIONAL, S.A.
Mr Jorge Gallardo Ballart ALMIRALL, S.A.	Ms Elvira Sanz Urgoiti PFIZER, S.A.
Mr Ludovic Helfgott ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	Mr Martín Sellés Fort JANSSEN CILAG, S.A.
Mr Rainer Krause BAYER HISPANIA, S.L.	
MEMBERS	
Mr Andreas Patrick Abt ROCHE FARMA, S.A.	Mr Jordi Marti Pi i Figueras CELGENE, S.L.
Mr Rogelio Ambrosi Herrera MERCK, S.L.	Mr Gustavo Pesquin SANOFI-AVENTIS, S.A.
Mr Ángel Fernández García MERCK SHARP & DOHME DE ESPAÑA, S.A.	Mr Salvador Pons Ribas LABORATORIOS MENARINI, S.A.
Mr Javier Font Salgado LBO. DE APLICACIONES FARMACODINAMICAS, S.A. “FARDI”	Mr Francisco Quintanilla Guerra FAES FARMA, S.A.
Ms Cristina Henríquez de Luna Basagoiti GLAXOSMITHKLINE, S.A.	Mr David Solanes López LABORATORIOS ERN, S.A.
Ms Inés Juste Bellosillo JUSTE, S.A. QCO. FCA.	

STEERING COMMITTEE

PRESIDENT	
ESTEVE Mr Antoni Esteve Cruella	
VICE-PRESIDENTS	
ALMIRALL, S.A. Mr Jorge Gallardo Ballart	LILLY, S.A. Mr Javier Ellena Aramburu
ASTRAZENECA FARMACÉUTICA SPAIN, S.A. Mr Ludovic Helfgott	NOVARTIS FARMACÉUTICA, S.A. Mr Jesús Acebillo Marín
BAYER HISPANIA, S.L. Mr Rainer Krause	PFIZER, S.A. Ms Elvira Sanz Urgoiti
FERRER INTERNACIONAL, S.A. Mr Jordi Ramentol Massana	LABORATORIOS FCOS. ROVI, S.A. Mr Juan López-Belmonte Encina
JANSSEN CILAG, S.A. Mr Martín Sellés Fort	
MEMBERS	
ABBVIE SPAIN, S.L.U. Mr Felipe Pastrana Molina	GLAXOSMITHKLINE, S.A. Ms Cristina Henríquez de Luna Basagoiti
ALCON CUSI, S.A. Ms Ana Isabel Gómez Ferrer	JUSTE, S.A. QCO. FCA. Ms Inés Juste Bellosillo
AMGEN, S.A.. Mr Roman Stampfli	LABORATORIOS LETI, S.L. UNIPERSONAL Mr Jaime Grego Sabaté
BAXTER, S.L. Mr Luigi Antoniazzi	LABORATORIOS MENARINI, S.A. Mr Salvador Pons Ribas
BOEHRINGER INGELHEIM ESPAÑA, S.A. Mr Thorsen Poehl	MERCK, S.L. Mr Rogelio Ambrosi Herrera
CELGENE, S.L. Mr Jordi Marti Pi i Figueras	MERCK SHARP & DOHME DE ESPAÑA, S.A. Mr Ángel Fernández García
LABORATORIOS ERN, S.A Mr David Solanes López	LABORATORIO REIG JOFRE S.A. Mr Ignasi Biosca Reig
FAES FARMA, S.A. Mr Francisco Quintanilla Guerra	ROCHE FARMA, S.A. Mr Andreas Patrick Abt
LBO. DE APLICACIONES FARMACODINÁMICAS, S.A. "FARDI" Mr Javier Font Salgado	SANOFI-AVENTIS, S.A. Mr Gustavo Pesquin
GRUPO FARMASIERRA, S.L. Mr Tomás Olleros Izard	LABORATORIOS SERVIER, S.L. Mr Olivier Vilaginés
FERRING, S.A.U. Mr Juan Carlos Aguilera Rodríguez	LABORATORIOS VIÑAS, S.A. Mr Antonio Buxadé Viñas

2.2 EXECUTIVE ORGANIZATION

FARMAINDUSTRIA has a Director-General who heads the Executive Committee, which is structured in functional departments. The Association has its headquarters in Madrid and maintains an office in Barcelona.

The functional organigram is as follows:

DIRECTOR-GENERAL

Humberto Arnés

DEPUTY DIRECTOR-GENERAL

Javier Urzay

GENERAL COUNSEL, LEGAL AFFAIRS AND HUMAN RESOURCES

Lourdes Fraguas

DIRECTOR OF STUDIES

Pedro Luis Sánchez

DIRECTOR OF COMMUNICATIONS

Beatriz Lozano

TECHNICAL DIRECTOR

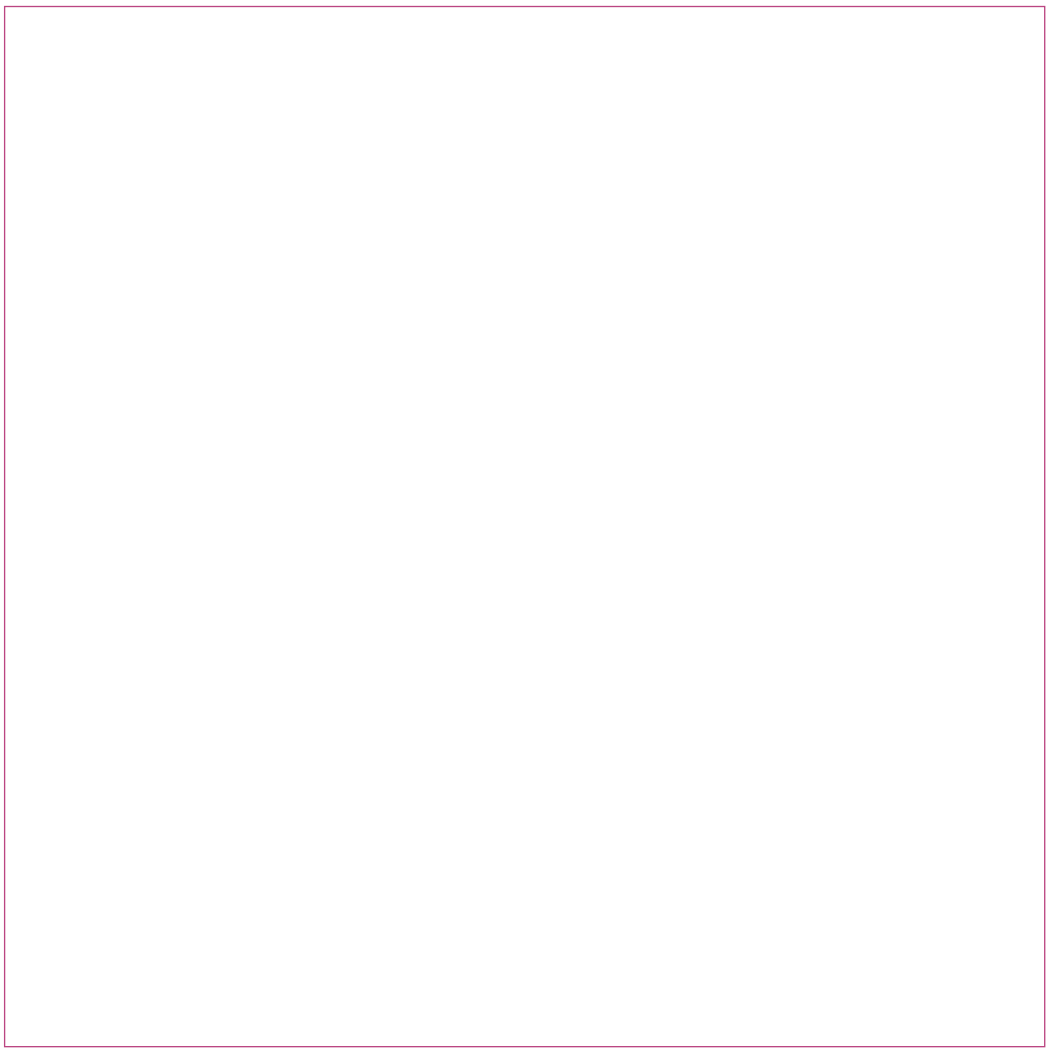
Emili Esteve

DIRECTOR OF RELATIONS WITH REGIONAL GOVERNMENTS

José Ramón Luis-Yagüe

INTERNATIONAL DIRECTOR

Icíar Sanz de Madrid



3 INSTITUTIONAL ACTIVITY

3.1 MARKET REGULATION AND RELATIONS WITH PUBLIC ADMINISTRATIONS

The last 12 months have seen a busy legislative period on the part of the Public Administrations, with some regulatory items which have already joined the body of pharmaceutical sector legislation and others which, although still in the redrafting process as this Annual Report was closing, will clearly have a notable impact on the Spanish pharmaceutical sector in the medium and long term.

As far as public pharmaceutical spending is concerned, slight growth in 2014 (1.9%) ended four years of consecutive decline in the pharmacy store market, during which expenditure fallen 25% overall, from some 13 billion euros per year in mid-2010 to the present value of barely nine billion euros per year.

The large part of this reduced expenditure is due to regulatory measures introduced in the Spanish pharmaceutical sector in previous years, especially Royal Decree-Laws 4/2010 and 8/2010, 9/2011 and 16/2012, which implemented important and effective regulatory elements to reduce public pharmaceutical spending, such as: i) discounts for sales to the SNS of medicines outside the Reference Price System, of 4%, 7.5% and 15% depending on medicine type; ii) the introduction of a new pharmaceutical copayment scheme as a function of earnings and not a person's work status, and; iii) the elimination of financing for medicines treating lesser symptoms.

2014 was the first year the pharmacy store market grew, albeit slightly, following four consecutive years of decline

In the area of market regulation for medicines that have run out of patent, following the publication of Royal Decree 177/2014, of 27 March 2014, Order SSI/1225/2014 was published in July updating series and references prices, and came into force to affect public spending on 1 September 2014. The impact of this Ministerial Order in terms of savings to the public budget is over 100 million euros a year, according to Farmaindustria estimates. At the time of writing, a new Ministerial Order on reference prices is in the pipeline and is foreseen to come into force in the second half of 2015. Its potential impact is over 150 million euros per year, although the final quantity could vary as a function of the exact wording of the Order once it has been approved.

Last year also saw Therapeutic Positioning Reports (IPTs) consolidated as a key element determining access for innovative medicines to the Spanish market. In 2014, 10 medicine IPTs were published, and in the first four months of 2015 another 24 were approved. The Spanish Medicines and Healthcare Products Agency (AEMPS) is to publish a normalized working procedure for the preparation of IPTs in which the deadlines, procedures and evaluation methodologies will be established in more detail.

IPTs presently constitute an increasingly important component in the pricing and public reimbursement procedure for new medicines. Although we are still awaiting the draft Royal Decree on the development of financing and pricing procedures established by Law 29/2006 on Guarantees and Rational Use of Medicines and Healthcare Products, last year Farmaindustria did have the opportunity to get to know the main points in the future Royal Decree on public pricing and financing of medicines and entered preliminary discussions with the team at the

Ministry of Health, Social Services and Equality (MSSSI), We submitted a series of proposals for improving the text. These proposals are being studies by the MSSSI with the aim of preparing a text that enjoys the largest possible consensus, although there is plenty of uncertainty around the date by which this regulation could be approved.

As this Annual Report went to press, the draft Royal Legislative Decree rewriting the Law on Guarantees and Rational Use of Medicines and Healthcare Products was also awaiting approval. This regulation does not suppose any legislative innovations; its objective is to consolidate, in a single text, amendments incorporated in Law 29/2006 since its introduction.

The draft Royal Decree for the development of financing and pricing procedures, as established by Law 29/2006, is still pending

Another regulatory element that came to attention during the year concerned the continuing activity of the medicines purchasing centre, which in 2014 added a call for tender for competent generic medicines to its 2013 calls for recombinant coagulation Factor VIII, epoetins and immunosuppressants. The first three calls were extended to 31 December 2015 and at the time of finishing this report a fourth centralized purchasing call was awaiting decision.

As explained elsewhere in this Report, the autonomous regions continued to introduce pharmaceutical policies of a diverse nature in 2014, although in some cases they exceeded their areas of competence. The most conflictive measures in this respect can be grouped into: i) exclusion of medicines from financing procedures; ii) establishment of dispensing protocols and algorithms, and; iii) calls for tender for “therapeutic equivalents”.

Finally, it is important to mention that, over the past 12 months, there has been a process of dialogue between FARMAINDUSTRIA and the Ministries of Treasury and Public Administration (MINHAP) and Health, Social Services and Equality (MSSSI) in order to agree on permission for linking public pharmaceutical spending in Spain with economic growth.

This process of dialogue began in July 2014 when the Fiscal and Financial Policy Council, in the framework of the consolidation process expressed in Organic Law 2/2012 on Budgetary and Financial Stability, discussed a series of containment measures for public pharmaceutical spending, the contents of which are extraordinarily damaging for the pharmaceutical sector. FARMAINDUSTRIA warned MINHAP and MSSSI about the seriousness of these measures and work on a sustainability agreement began to establish: i) a spending objective linked to GDP; ii) compensation in the event this is exceeded; iii) introduction of pharmaceutical policy measures respecting innovation, and iv) indicators for monitoring patient access to innovative medicines.

A dialogue process thus began in this regard and culminated in the approval, by an extraordinary FARMAINDUSTRIA General Assembly on 30 April 2015, of the idea of signing a collaboration protocol between FARMAINDUSTRIA, MINHAP and MSSSI concerning sustainability and innovation in the SNS.

With this protocol, the industry would commit itself to collaborating in the sustainability area on growth objectives for public pharmaceutical spending in 2015 that are linked to Spain's medium-term GDP growth rate, for which quarterly expenditure monitoring systems would be set up with a view to adopting, if necessary, compensatory or corrective measures in order to remain below the set levels. Additionally, the protocol would incorporate a section on patient access to innovation, where deadlines for fixing prices and financing for new medicines would be shortened and equal access assured in all autonomous regions. Other stipulations would recognize the importance of industrial value creation, highlighting the pharmaceutical industry's contributions in terms of R&D, exports, productive activity and qualified employment.

The protocol aims in this way to help Spain make good on the public health spending commitments it has with the European Commission, while developing the innovative pharmaceutical industry in Spain in line with economic growth. All this is aimed at providing adequate and fair access to therapeutic innovations for patients. The protocol should be signed before the end of the first half of 2015, although at the time of writing this Is still pending.

A detailed review of the most relevant main legislation and regulations over the past year now follows.

FARMAINDUSTRIA approved on 30 April 2015 the idea of signing a collaboration protocol with MINHAP and MSSSI on the sustainability and innovation of the National Health System (SNS)

3.1.1 LEGISLATIVE FRAMEWORK

Important regulations, further developing legislation in the pharmaceutical field, were approved during the last year. FARMAINDUSTRIA took part in drafting processes both at hearing stages and before the Council of State. A summary of the most relevant legislative developments approved during the year follows.

CROSS-BORDER HEALTHCARE

For the transposition of EC Directive 2011/24, on the application of the rights of patients to cross-border healthcare, Royal Decree 81/2014, of 7 February, was passed establishing standards for guaranteeing cross-border healthcare and also modifying Royal Decree 1718/2010, of 17 December, on medical prescriptions and dispensing orders, changing the prescription system in Spain in amending the prescription form.

The objective of Royal Decree 81/2014 is to guarantee access to safe, high-quality cross-border healthcare

The aim of Royal Decree 81/2014 is to ensure access to safe, high-quality cross-border healthcare, guaranteeing the mobility of patients and favouring health cooperation between Spain and the rest of the European Union. The Council of State issued its Ruling in this respect on 23 January 2014 (No. 1436/2013).

REFERENCE PRICE SYSTEM

Royal Decree 17/2014, of 21 March, was published in the Official State Bulletin (BOE) of 25 March 2014. This regulates the Reference Price System and Homogenous Groups for Medicines in the National Health System, and certain information systems on financing and prices of medicines and healthcare products.

For the first time, the basis characteristics of the Reference Price System are regulated via legislation that has Royal Decree status, as foreseen by the Council of State in its Ruling 167/2014 of 27 February 2014. As the title indicates, it also regulates homogenous groups and information systems for the financing and prices of medicines.

Meanwhile, on 10 July Order SSI/1225/2014 was approved developing this Royal Decree. This is the first Order where a commercial presentation of the generic or a biosimilar medicine is not essential for the formation of series. It is sufficient that the medicine or its principal active ingredient has been authorized in an EU Member State at least ten days beforehand.

With the modifications introduced to the Reference Price System by Royal Decree-Law 16/2012, of 20 April, and later amendments by Law 10/2013, of 24 July, we are almost at the limit for those medicines affected by the system, and this has generated a number of lawsuits with respect to the composition of series in the absence of generic or biosimilar medicines. The system has also been criticized for the obligation it has created to continue producing certain versions of medicines in spite of heavy price cuts implied by the system or by the fact that the biological medicine is treated under the same terms as the chemical medicine.

Nevertheless, the cycle for the new Reference Prices continues unchanged with the publication of the Nomenclature in April of each year.

PROVISIONS IN THE AREA OF CORPORATE CRIMINAL RESPONSIBILITY. LEGISLATIVE COMPLIANCE AND COMPLIANCE PROGRAMMES

Following the reform of the Penal Code by Organic Law 5/2010, of 22 June, the criminal responsibility of legal persons was established for the first time in Spain's legislative body.

Thus, in March this year, a new process of reform of the Penal Code concluded with Organic Law 1/2015, of 30 March, amending Organic Law 10/1995 on the Penal Code, of 23 November, and published in the Official State Bulletin, BOE, on 31 March 2015.

The new text represents a substantial change in the way in which criminal responsibility is expressed in legal persons. Companies, especially, will remain exempt from criminal responsibility if they have an organizational model and management system that includes supervisory and control measures designed to prevent crimes or to reduce significantly the risk of them taking place, i.e. if they incorporate what is known as a *Compliance Programme* or *Legislative Compliance*.

The new version of the Penal Code includes the criminal responsibility of legal persons for the first time

For such a *Compliance Programme* to serve as a defence, however, this needs to be accompanied by other measures specified in the legislation such as the nomination of a *Compliance Officer* or *Compliance Official*; that the crime was committed by avoiding the *Compliance Programmes*, and; that the manager concerned had not omitted or failed to exercise safeguards or the supervisory and control system in place.

It must be remembered that this obligation for a company to have a *Compliance Programme* is independent of other programmes already adopted under the framework of Self-Regulation Codes, in particular the Pharmaceutical Industry Code of Best Practices mentioned in section 4.4 of this Report.

ADMINISTRATIVE CONTRACTING PROVISIONS

In this section, the Order HAP/536/2014, of 3 April, modifying Order EHA/1049/2008, of 10 April, on the declaration of centrally contracted goods and services, should be mentioned first. This regulation concerns the recommendations of the Public Administrations Reform Committee (CORA) in the area of centralization of contracts for services and supplies. In this respect, the General State Administration can declare the centralized contracting of supplies, works and services contracted generally and similarly by different institutions and departments. With this modification, the target areas for centralized contracting are broadened through categories of contracts for supplies and services that could be centralized, excluding those considered to be of lesser importance.

Meanwhile, Law 13/2014, of 14 July, was published in the BOE on 15 July 2014, modifying the fund for paying suppliers. Its final first provision amends article 216.4 of Legislative Royal Decree 3/2011, of 14 November, approving the Consolidated Text of the Public Sector Contracts Law with the aim of giving a better guarantee to contractors, preventing abuse when agreeing payment periods.

Royal Decree Law 11/2014, of 5 September, on urgent measures in the competition area, was published, modifying Competition Law 22/2003, of 9 July, amending some of the precepts for public contracting in order to ensure continuity of the activity to which the contract refers to the benefit of the entities awarded tenders, third parties who perform institutional contracts, and the Public Administration concerned.

Spain and Europe work together to avoid arrears in the payment of invoices accumulated by Public Administrations

Elsewhere, on 31 October 2014 the Council of Ministers authorized the approval of collaboration agreements between the Ministry of the Treasury and Public Administrations and the Autonomous Regions of Aragon and Madrid and the autonomous city of Ceuta, the aim of which is to coordinate in the area of public contracts and specifically to avoid administrative duplications. The agreements, which follow those already made with Cantabria and Extremadura, are explained in CORA's Annual Report.

Finally, the European Commission, following consultations through the European Multi Stakeholder Platform on ICT Standardisation, and in view of the Treaty on the Functioning of the European Union and EU Regulation 1025/2012 on European standards and other standardization deliverables, adopted on 31 October 2014 a Decision designating as a referable standard version 2.1 of the Universal Business Language for use in public contracting.

PROVISIONS ON ARREARS

Late payment of invoices accumulated by Public Administrations is the object of special attention at both national and European level. In this regard, several relevant provisions published during the last year should be highlighted.

First, on 6 May 2014, EU Directive 2014/55 of the European Parliament, on electronic invoicing for public contracts, was published in the EU's Official Journal. The Member States will have to transpose this directive before 28 November 2018.

Indeed, detailed legislation in connection with electronic invoicing has been published, including Order HAP/1074/2014, of 24 June, regulating the technical and operational conditions to be met at the general Entry Point for the submitting of invoices; the Resolution of 25 June 2014, by the Secretary of State for Public Administrations, establishing the conditions of use of the FACe platform, and; the Resolution of 10 October 2014, by the Secretary of State for Public Administrations and the Secretary of State for Budgets and Expenditures, establishing the standardized technical conditions at the general entry point for the submitting of electronic invoices. Circular 1/2015 of 19 January was also published, concerning general interventions by the State Administration on the obligation to invoice electronically as of 15 January 2015.

Royal Decree 635/2014, of 25 July, developing the methodology for calculating the average payment delay to suppliers of Public Administrations and the conditions and procedure for retaining financing regime resources, as foreseen by Organic Law 2/2012, of 27 April, on Budgetary Stability and Financial Sustainability, should also be highlighted. This establishes the rules for the calculation of average payment delays to Public Administration suppliers and outlines the procedure by which the Central Administration can retain financial resources pertaining to those autonomous regions and local corporations late in paying commercial debts. Public Administrations must make these debts public according to transparency principles.

On the same date, the Royal Decree 636/2014, of 25 July, was published, creating an Economic and Financial Information Centre for Public Administrations and regulating the sending of information by the Bank of Spain and financial entities to the Ministry of the Treasury and Public Administrations.

Meanwhile, in connection with liquidity funds for autonomous regions and local bodies, the Royal Decree Law 12/1204, of 12 September, providing for the concession of supplementary and extraordinary credits in the budgets of the Ministries of Foreign Affairs and Cooperation, of Education, Culture and Sport, of Development, and of Agriculture, Food and Environment, should be mentioned. The text introduces an additional provision and two final provisions that explain the liquidity funds for autonomous regions and local bodies. Secondly, Royal Decree-Law 17/2014, of 26 December, on financial sustainability measures for the autonomous regions and local and other economic bodies, was published. Additionally, the Resolution of 20 January 2015 by the Spanish Parliament was published governing the validation agreement of Royal Decree-Law 17/2014, of 26 December, on financial sustainability measures for the autonomous regions and local and other economic bodies.

Several resolutions were adopted on arrears in 2014, concerning: interest rates legal for late payments, financial prudence applied to debt transactions, etc.

Finally, the publication should be mentioned of various Resolutions in the area of arrears: i) the Resolution of 30 December 2014 by the Secretary General for the Treasury and Financial Policy, publishing the legal interest rate for application to late payments in commercial transactions during the first half of 2015; ii) the Resolution of 5 February 2015 by the Secretary General for the Treasury and Financial Policy, defining the principle of financial prudence to be applied to debt transactions by local bodies, and autonomous regions using the Regional Financing Fund, and iii) the Resolution of 5 March 2015, by the Secretary General for the Treasury and Financial Policy, updating Annex 1 of the Resolution of 5 February 2015.

CLINICAL TRIALS

In July 2012, the European Commission took the initiative to substitute the directive regulating clinical trials for a Regulation: EU Regulation 536/2014 of the European Parliament and Council, of 16 April 2014, on clinical trials on medicinal products for human use, abolishing Directive 2001/20/EC. The change in the type of legislation is justified by the differences between

Member States that have appeared following the transposition, which has complicated, in the opinion of the Commission, the performance of clinical trials in the EU. The Commission also recognized the need for a legislative change, since: i) the number of clinical trials in the EU fell by 25% between 2007and 2011, and ii) compared to data before the 2001 Directive was applied, the cost of carrying out clinical trials had doubled and the time to conduct them increased by 90%. This Regulation is also explained in section 3.3 of this Report, on International Relations.

The new system requires a fully functioning Portal to be hosted by the European Medicines Agency (EMA). Although already published, the Regulation does not come into force until May 2016, or perhaps later if the Portal mentioned is not operating by then.

A change in the law governing clinical trials was needed, since their number fell by 25% in Europe between 2007 and 2011

In Spain, the preparation of a Royal Decree on clinical trials is being finalized in line with the Regulation and which will facilitate its introduction.

OTHER INFORMATION ON REGULATION OF MEDICINES FOR HUMAN USE. SPANISH AGENCY FOR MEDICINES AND HEALTHCARE PRODUCTS (AEMPS)

As is becoming customary, the AEMPS made rulings or proposals in the area of its competence through a number of means (Informative Notes, Circulars and Instructions) affecting the regulation of medicines for human use.

To summarize, in the area of authorization, registration and conditions for authorization of medicines: i) considerations were published on medicines for professional use; ii) criteria was indicated for the rebate of unused but paid taxes; iii) the obligation to communicate results of clinical trials to the European Union Clinical Trials Register was detailed; iv) a new application was created to manage technical files and prospectuses electronically, and v) the process to adapt the formats of the anti-infective drugs in J01 and J02 therapeutic groups was concluded. Meanwhile, in the area of pharmacovigilance, an Informative Note was published on the updating of the single evaluation of periodic safety reports for nationally authorized medicines. Finally, in the area of pharmaceutical control, the publication of the register of manufacturers, importers and distributors of active ingredients in Spain should be mentioned.

It is also necessary to highlight two important Ministerial Orders developed by the AEMPS: i) Order SSI/23/2015, of 15 January, approving the fifth edition of the Royal Spanish Pharmacopoeia and the second edition of the National Formulary, and iii) Order SSI/23785/2014, of 11 December, modifying Order SPI/2136/2011, of 19 July, fixing the procedures for border inspections of pharmaceutical products and regulating the External Healthcare Pharmaceutical Inspection Information System. The AEMPS later published Circular 1/2015, of 26 January, on foreign trade in medicines, which complements the latter Order and simplifies certain import and export activities.

IMPORTANT LEGAL TEXTS AFFECTING THE SECTOR IN PREPARATION AS THIS ANNUAL REPORT WENT TO PRESS

As this Annual Report closed for publication, several legal texts of importance for companies in general and the pharmaceutical sector in particular were being debated and voted upon in the Parliament.

First, the Patents Bill, whose amendments were published in the BOCG on 13 April 2015 and which abolishes current Law 11/1986. The new text strengthens the legal protection Spanish patents give, pulling together the commitments assumed by Spain at international level. The following bodies also published Rulings and Reports in 2014: the National Markets and Competition Commission (7 March); the Economic and Social Council (28 May); the General Legal Council (24 July), and; the Council of State (16 October).

Elsewhere, as this Report closed for publication, the Parliament was also debating the Consolidated Text of the Law on Guarantees and Rational Use of Medicines and Healthcare Products, which does not represent any legislative novelty but responds to the authorization stipulated in the 4th final provision of Law 10/2013 of 24 July, incorporating Spain's adoption of EU Directives 2010/84, of the European Parliament and Council of 15 December, on pharmacovigilance, and 2011/62, of the European Parliament and Council of 8 June, preventing the entry of counterfeit medicines into the legal supply chain, amending Law 29/2006 of 26 July on Guarantees and Rational Use of Medicines and Healthcare Products, which indicates that "with the effect of consolidating, in a single text, the amendments incorporated since the entry into force of Law 29/2006 of 26 July on Guarantees and Rational Use of Medicines and Healthcare Products, authorizes the Government to prepare and approve, within two years from the entry into force of this Law, a consolidated text of the Law on Guarantees and Rational Use of Medicines and Healthcare Products."

FARMAINDUSTRIA keeps up intensive institutional activities with health authorities, scientific associations and professional organizations

Meanwhile, the Ministry of Treasury and Public Administration also began, at the start of 2015, to receive public comments on the Bills promoting the reform of the functioning of the administrations, i.e. the Bill on the common administrative procedure for Public Administrations, and the Bill to adopt a legal regime for the public sector.

3.1.2 THE AUTONOMOUS REGIONS (ARS)

FARMAINDUSTRIA continued to carry out intensive institutional activities to maintain relations with the regional healthcare authorities, scientific associations, professional organizations and institutions. The aim is to continue to promote a framework of understanding and trust that allows faithful and transparent cooperation to be developed to the benefit of the public health sector, pharmaceutical innovation and the health of the population in general.

Meanwhile, it has also continued to monitor closely the different regional initiatives in healthcare policy and pharmaceutical services, and regularly informs members about the most important developments.

INSTITUTIONAL CONTACTS

Throughout 2014, FARMAINDUSTRIA maintained its channels of communication and dialogue with regional health authorities and scientific associations begun in previous years. We maintained institutional contacts with the directors of Health and heads of Pharmacy and Research in the different ARs, and the situation and priorities of the sector were communicated to them. In all these meetings, information was shared and the strong impact of the measures to contain expenditure could be observed. The evolution of the main indicators of pharmaceutical spending was analyzed and special emphasis was placed on the importance of brand for pharmaceutical companies.

The institutional meetings held during the year in relation to the management, monitoring and evaluation of the +i Programme for Cooperation in Translational Clinical Research should also be mentioned. These are described in a separate section of this Annual Report.

Bilbao hosted the 18th FARMAINDUSTRIA-Autonomous Regions Forum where the new scenario around the counterfeit medicines directive was debated

FARMAINDUSTRIA-AUTONOMOUS REGION FORUMS

These Forums constitute a meeting point with healthcare managers in central and regional authorities, at which subjects of common interest are analyzed and shared in order to improve the sustainability of the National Health System (SNS), access to innovation and, generally, the quality of care offered to patients.

In 2014, the 17th edition of the Forum was celebrated in Toledo, dedicated to analyzing the situation in the sector, as well as SNS pharmaceutical provision. The Forum was inaugurated by the Director of Health and Social Affairs for Castile-La Mancha and the President of FARMAINDUSTRIA, and attended by representatives from 13 ARs and INGESA.

Then, in April 2015 in Bilbao, the 18th Forum was held at which the new scenario created by the European directive on counterfeit medicines was reviewed. The Deputy Director of Health of the Basque Government and the Director-General of FARMAINDUSTRIA opened the Forum. Participants included representatives of 11 ARs, AEMPS, and INGESA, Spain's National Health Management Institute.

REGULATORY INITIATIVES IN THE AUTONOMOUS REGIONS

There now follows a summary of the most significant regional policies, regulations and initiatives to have taken place over the last year, as well as some of the activities carried out by FARMAINDUSTRIA in this respect.

Electronic prescriptions and medical records

During 2014, the different ARs continued to introduce the electronic prescription, while progress was made in the project to make it interoperable. The introduction of digital medical records proceeded in a similar vein.

The prescription system has thus been fully or mainly implemented in primary and specialized care, and pharmacies, in six ARs: Galicia, 100%; Andalusia, the Community of Valencia and Balearic Isles, 95%; the Basque Country, 88%, and; Extremadura, 84%.

Other ARs, such as Aragon, Asturias, the Canary Islands, Cantabria, Castile-La Mancha, Catalonia, La Rioja, Madrid and Navarre, have introduced the system in primary care and pharmacies, but still have some way to go in specialized care. The rest of the ARs face greater delays in this process.

As this Report closed for publication, around 75% of SNS prescriptions were made via electronic means.

As for the interoperability project for electronic prescriptions, the first quarter of 2015 saw the conclusion of a first pilot project involving Extremadura, the Canary Islands and the Balearic Isles, and the launch of a new phase in which trials were also carried out in Castile-La Mancha and Cantabria.

The interoperability of electronic prescriptions was trialed in Extremadura and the Canary and Balearic Isles

The collaboration agreement for this initiative comes under the activities contained in the Digital Agenda for Spain plan, the main aim of which is to use electronic administration and digital solutions to provide efficient public services. As for electronic prescription, the agreement aims to facilitate its interoperability throughout Spain so that doctors can prescribe and citizens acquire medicines in any autonomous region irrespective of the medicine's origin.

Meanwhile, the SNS Digital Medical Record (HCDSNS) system aims to guarantee citizens and health professionals access to the most relevant medical documents for the treatment of each patient. This includes documentation available electronically in any department of the SNS and ensures that patient data can only be consulted by those authorized to do so.

The HCDSNS project has been led by the MSSSI under its Health Online programme in cooperation with the public company red.es, 17 ARs and INGESA. Sixteen ARs and INGESA are currently connected to this system.

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

Legal actions undertaken by Farmaindustria against measures excluding certain branded medicines from electronic prescription systems, which began in 2010 in Castile-La Mancha region, have pursued their course and are awaiting resolution as of writing. Nevertheless, during 2014, problems incorporating certain MSSSI-approved medicines, available on the SNS, in the Castile-La Mancha Health Service electronic prescription database have once more been detected and Farmaindustria has asked for this anomaly to be corrected.

Auctions for medicines to be dispensed in pharmacies: Andalusia

Through Decree-law 3/2011, of 13 December, on urgent measures concerning Andalusia Public Health Service pharmaceutical provision, Law 22/2007, of 18 December, on Andalusia Pharmacy, was modified, introducing among others Article 60 bis establishing selection

procedures for medicines (known as "auctions") that must be dispensed in this region in the cases where a doctor makes out a prescription by active ingredient.

This provision also contains the legal Resolutions of 25 January 2012 (1st auction); 20 December 2012 (2nd auction); 20 June 2013 (3rd auction), 31 March 2014 (4th auction), 9 October 2014 (5th auction) and 9 December 2014 (6th auction) of the Andalusia Health Service (SAS) Management Executive for the selection of these medicines.

This initiative has resulted in the Spanish Government lodging a conflict-of-powers complaint before the Constitutional Court in relation to the first two calls claiming they invade competences that correspond exclusively to the State (Appeal of unconstitutionality vis-à-vis Decree-law 3/2011 on Pharmaceutical Service). Likewise, it has lodged contentious administrative appeals against the resolutions awarding the second and third calls.

Andalusia continued issuing calls for tender to select medicines – these are known as "auctions"

For its part, FARMAINDUSTRIA has also presented appeals against the SAS call-for-tender resolutions and awards through the administrative and contentious administrative channels. The contentious administrative appeals are currently paralyzed until the Constitutional Court resolves the fundamental question.

FARMAINDUSTRIA also maintains that the auctions as foreseen by the Andalusia authority have broken the unity of the national market, implying a serious distortion in competition, generating an imbalance in SNS pharmaceutical provision and representing inequality for Andalusian patients.

The table below shows the calls realized, the active ingredients requested and awarded, and the indications of the medicines subject to award.

MEDICINE AUCTIONS

	CALL			AWARD		
	DATE OF DECISION	ACTIVE INGREDIENTS OFFERED	LABORATORIES PRESENTING	DATE OF DECISION	ACTIVE INGREDIENTS OFFERED	LABORATORIES PRESENTING
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

	MEDICINES SOUGHT IN THE AUCTIONS
1	Stomach protectors, statins and platelet aggregation inhibitors.
2	Antihypertensives, oral antidiabetics, antidepressants, antieplileptics, osteoporosis treatments, antidementia drugs, antiinflammatories, pain relievers, antipsychotics, antihistamines, treatments for benign hypertrophy of prostate and cholesterol, peptic antiulcerants, stomach protectors and platelet antiaggregants.
3	Antihypertensives, pain relievers, anxiolytics, anti-inflammatories, antithrombotics, hypnotics and sedatives, opioids, antihistamines, antibiotics, hypoglycemic, peptic antiulcerants and stomach protectors, antidepressants and cholesterol treatments.
4	Antihypertensives, oral antidiabetics, antidepressants, cholesterol treatments, antiinflammatories, pain relievers, anxiolytics, antihistamines, osteoporosis treatments, antipsychotics, treatments for benign hyperplasia of prostate, antidementia drugs, peptic antiulcerants and platelet antiaggregants.
5	Antiulcerants, cholesterol treatments, antihypertensives and antiinflammatories.
6	Antihypertensives, oral antidiabetics, cholesterol treatments, antiinflammatories, pain relievers, anxiolytics, antihistamines, antiulcerants, platelet antiaggregants and vertigo treatments.

Substitution of medicines: Basque Country

The Supreme Court, in its decision of 17 February 2015, rejected FARMAINDUSTRIA's appeal for annulment of the decision of the Basque High Court confirming the legality of the first measure of substitution of medicines adopted by Osakidetza in 2010, by which four drugs (atorvastatin, clopidogrel, risedronate weekly and losartan hydrochlorothiazide) were replaced in the Basque Health Service electronic prescription system by corresponding generics.

The Court considers the measure to be an internal instruction and under no circumstances can be understood as a "one-off barrier" to the prescription and dispensation of medicines. It should be pointed out that the Court rejected FARMAINDUSTRIA's appeal on the basis of the old version of article 85 of Law 29/2006: "The health administrations will promote the prescription of medicines identified by their active ingredient in the medical prescription. In those cases in which the prescriber indicates in the prescription solely the active ingredient, the pharmacist will dispense the medicine that has the lowest price and, where the price is the same, the generic one, if he has it." When this instruction was approved, homogenous groups did not exist and brands and generics had different prices.

Likewise, the Spanish High Court ruling of 5 May 2014, on a complaint by the General Council of the Official Colleges of Physicians, should be mentioned. The Court ordered inspections of, and the consideration of sanctions against, the Basque Health Service (Osakidetza) and the Cantabrian Health Service (SCS) for possible wrongful access to medical records and modification of prescriptions without doctors' consent, allegations still under investigation.

Prioritized medicines catalogue: Galicia

On 18 December 2014, the Constitutional Court ruled on the unconstitutionality appeal lodged by the Spanish Government against Galicia AR's Law 12/2010, of 22 December, rationalizing pharmaceutical spending. This law created a catalogue of priority medicines determining that only lower priced drugs, containing the active ingredients specified by the regional, the Xunta, in the catalogue would be financed by the region from public funds.

The decision reiterated the doctrine of the Constitutional Court in that judgments given in unconstitutionality appeals must contrast the regional legislation being challenged with state legislation in force at the moment the judgment is made, and not in force at the time the autonomous region acted.

So, although the judgment indicated that, at the time the Galician law was passed, the Galician catalogue could be said to represent a restriction in this region on general catalogue of pharmaceuticals, needing to decide on the basis of the legislation now in force (modified by Royal Decree-law 16/2012), the Galician system must have the same effect as state law, such that it is not considered at present to have impacted upon the competences of the State and the appeal was thus rejected.

It is important to point out the particulars of the vote. Two of the magistrates, indicated their "radical disagreement" with the majority decision, since they believed the catalogue did indeed invade state competences by stipulating fewer medicines for Galicia than in the rest of the ARs.

They lamented that a judgment was not passed which clearly delineated the competences of the State and the ARs in this area, also taking into account art. 88 of Law 29/2006, introduced by Law 10/2013 and not only art. 85 as amended by Royal Decree-law 16/2012.

Therapeutic alternatives: Castile-La Mancha and Andalusia

In previous Annual Reports, we reported on the lodging of legal actions by Farmaindustria due to the 2012 incorporation of a new computer application in the Turriano prescription system, Castile-La Mancha Health Service, which introduced substitution by "therapeutic equivalents". In spite of the time that has passed, we are still awaiting a decision on our contentious administrative appeal.

Similarly, in the 2013 Farmaindustria Annual Report, we reported that in July 2013, Andalusia Health Service had published a Framework Agreement (FA) for the homologation of the selection of active ingredients for certain indications, destined to cover the needs of SAS health centres, against which Farmaindustria lodged a special appeal in the area of contracting with a request for precautionary measures consistent with the suspension of the Framework Agreement public tender award procedure. This procedure was indeed suspended preventively by the Andalusia Government Contractual Appeals Administrative Court (TARCJA).

On 12 March 2014, TARCJA found partially in favour of Farmaindustria in this appeal against the award procedure and specifications drawn up by the managers of the FA, which brought about its annulment by the body that made the award in July 2013. In May 2014, the SAS issued a new FA incorporating the observations of the TARCJA Resolution of 12 March. In this second FA, the same lots were maintained as in the first agreement. Farmaindustria made another contentious administrative appeal against this new FA.

Finally, in December 2014, we detected that the SAS hospitals, Virgen Macarena and Virgen del Rocío, had approached the laboratories holding the patents for bevacizumab, cetuximab and panitumumab, asking them to improve their economic offers so that one of them could be chosen for first-line treatment of metastatic colon cancer. This request followed the declaration that the three medicines are to be regarded as "therapeutic equivalents" by the two hospitals' joint pharmacy committee.

Farmaindustria wrote to the SAS Managing Director urging him to suspend this initiative, given that: i) the request for economic offers in these medicines violated the TARCJA suspension; ii) these medicines are not interchangeable, and iii) the determination of therapeutic equivalence has to be made by the SNS as a whole and in agreement with the conclusions of AEMPS, as well as on the basis of scientific studies accrediting such equivalence (3rd AD, Law 10/2013). The initiative now appears to have been suspended.

Meanwhile, among different actions carried out by Farmaindustria, the seminar organized by Joly Group in Seville on 1 July, should be mentioned. Farmaindustria participated in the event along with patients' representatives, medical professionals and lawyers. All the participants

agreed that "alternative therapeutic equivalents" diminished the value of innovation, resulted in inequality of treatment and restricted freedom of prescription.

In this sense, on 3 July, the Ombudsman, dealing with a complaint formulated by the Spanish Association for Medical Oncology (SEOM) against the second FA, asked the Health Department to modify or suspend the agreement, given that the effect of the initiative is to exclude MSSSI-authorized medicines from public financing in Andalusia, impacting on equality of treatment and the freedom of doctors to prescribe.

AEMPS, for its part, replying to a letter from FARMAINDUSTRIA in which the association asked the Agency to clarify the criteria relating to the status of "alternative therapeutic equivalents" and the competence to declare such equivalence between different active ingredients, showed it had not formally established this status beyond its agreement with that stated in the Third Additional Provision of Law 10/2013, i.e. in the context of the Therapeutic Positioning Reports, and that interchangeable medicines can only refer to those included in Homogenous Groups.

So-called "alternative therapeutic equivalents" diminish the value of innovation, produce inequality in treatment and restrict doctors' freedom to prescribe

To summarize, during 2014 FARMAINDUSTRIA repeatedly communicated, to the health authorities, its strong opposition to the drafting of purchasing protocols and procedures based on so-called "therapeutic equivalents" and "alternative therapeutic equivalents", given the harmful consequences this can have on innovation and the obvious prejudices it inflicts upon patients, health professionals and the industry. These initiatives represent a secret attempt to exclude the affected medicines from public financing, infringing the established legislative framework and diminishing the value of innovation.

Algorithms for therapeutic decision-making: Community of Valencia

The Official Journal of the Community of Valencia of 5 March 2013 published Decree-law 2/2013, on Urgent Management Actions and Efficiency in Pharmaceutical and Orthoprotesic Services.

This legislation includes a series of measures affecting the selection, prescription and dispensing services for medicines and healthcare products and introduces so-called "corporate therapeutic decision algorithms" that the Valencia Health Agency will elaborate for certain pathologies.

In relation to this Decree-law, FARMAINDUSTRIA has maintained various contacts with the regional health authorities, communicating its concern for this initiative and its doubts over the constitutionality of this legislation, requesting that the algorithms should only be used as a guide and that the freedom of the doctor to prescribe is to be respected.

Given the constitutionality problems for some aspects of this Decree-law, in May 2013 the Valencian Government (Generalitat), at the instance of the Spanish Government, agreed to constitute a Bilateral State-Generalitat Committee for General Administration Cooperation. The Committee, at its meeting of 19 November 2013, adopted an agreement by which the Generalitat committed itself to amend the Decree-law in order to adapt it to the state legislature.

Thus, with Law 5/2013, of 23 December, on Fiscal Measures, Administrative and Financial Management and Organization of the Generalitat, the amendments agreed upon in the Bilateral Commission were introduced. Specifically, and among other aspects, article 1 of the Decree-law was amended in the sense that the prescription algorithm system will apply on the terms foreseen in the state legislation.

Under this legislation, up to the publication of this report, six algorithms have been approved, for: i) hypolipidemics; ii) antiulcerants (prevention of gastropathy by non-steroidal anti-inflammatory drugs), gastroesophageal reflux disease, eradication of Helicobacter pylori, dyspepsia, peptic ulcers, and Zollinger-Ellison syndrome; iii) treatment of arthritis; iv) pregabalin; v) antipsychotics (clozapine, asenapine, quetiapine, risperidone, paliperidone), and; vi) antidepressants.

In relation to these algorithms, Farmaindustria has repeatedly communicated to the Valencia health authority that: i) they are for guidance and not to make the work of the doctor more difficult; ii) they must respect the freedom to prescribe; ii) they must not imply any restrictions or one-off barriers to prescription, and iv) they must not apply to continued treatment of stabilized patients.

The algorithms must only be for guidance, respect the doctor's freedom to prescribe and must not imply any restrictions or one-off barriers to prescription

Otherwise, within this Decree-law, the Valencia Directorate-General for Pharmacy introduced instructions for the prescription, preparation, transport, receipt and administration of pre-charged syringes of subcutaneous methotrexate, which has been appealed by Farmaindustria via the contentious administrative channel, since we believe it violates the legislative framework. The case is presently entering the conclusions phase.

Medicine Suppliers Round Table: Catalonia

In the framework of the relations Farmaindustria maintains with the Catalonian administration, in the meeting between the Taula Generalitat ('Catalonian Government Table') and the Pharmaceutical Industry held on 5 September 2012, it was agreed a Medicine Suppliers Round Table would be constituted, formed by representatives of CatSalut, experts in the management of public pharmaceutical provision and six representatives of Farmaindustria, three of them Vice-Presidents of the Association.

This Round Table also has a technical group to which Farmaindustria communicates the positions of the sector in various areas.

A meeting of the Taula Generalitat and the Pharmaceutical Industry was held on 5 February 2014, attended by three Ministers of the Catalonian Generalitat (of Health, Economy and Knowledge, and Business and Employment) and members of the Farmaindustria Steering Committee belonging to companies installed in Catalonia.The meeting analyzed different aspects related to the pharmaceutical industry and the regulation of the sector in Catalonia, and the participants agreed to continue deepening their knowledge in these areas in the Medicine Suppliers Round Table.

Invoicing by pharmacology/patient/month tariff: Catalonia

In March 2014, CatSalut agreed to modify the payment procedure for medicines dispensed in the XHUP (Xarxa Hospitalària d'Utilització Pública) network of public hospitals, changing to a pharmacology/patient/month tariff on 1 June 2014, later postponed to 1 July. The new payment system affects: i) growth hormones; ii) immunosuppressants selected for treatment of rheumatology, digestive disorders and dermatology, and iii) Aids.

To challenge this initiative, FARMAINDUSTRIA launched a series of actions that resulted in CatSalut willing to find formulas, within the legal framework, allowing progress in efficiency and control of healthcare management and the necessary guarantees, and that, at the same time, do not affect the legitimate interests of the pharmaceutical industry. It was thus agreed to work together on a new system of tariffs, to be calculated per disease, taking into account all the costs of the healthcare process and, as far as possible, the results of this health care. The system is designed to replace that of the pharmacological tariffs.

To progress in this model, a CatSalut technical committee was set up, in which FARMAINDUSTRIA participates. The committee held its first meeting in July 2014. The next one was being planned as this Report went to press.

CatSalut is working on a system of charging, by disease, that includes all the costs of the healthcare process, and takes into account healthcare results – this replaces the pharmacological tariff model

Guide to economic evaluation of medicines and analysis of the impact on budgets: Catalonia

CatSalut began a public consultation in March 2014 on the draft of a Guide aimed at standardizing the presentation and performance of economic evaluations and an analysis of the budgetary impact of medicines in its field of operations. During the process, FARMINDUSTRIA asked that the scope, objective and field of application of the Guide be clarified and insisted that the evaluations be done without extending the period of assessment of medicines entering the market.

The submissions presented by FARMAINDUSTRIA were mostly accepted and incorporated into the text.

Medicines related to hospital diagnoses exclusively dispensed in hospital pharmacy services/inclusion of medicines in the hospital domain

In 2010, a large number of ARs decided that certain medicines related to hospital diagnoses (DH) would be dispensed exclusively by hospital pharmacy services.

In this respect, the Directorate-General for the Basic Portfolio of Services of the SNS and Pharmacy published Resolutions in March 2012 and September 2013 in relation to medicines transferred to be dispensed by hospital pharmacy services, and which therefore lacked the corresponding certified coupon.

It should be remembered that there are three judgments of importance in this regard: one from La Rioja Supreme Court (TSJ), of 4 May 2011, and two from Cantabria TSJ, on 21 and 26 September 2011 respectively, which insist that this decision comes under the competence of the Ministry of Health, Social Services and Equality.

Similarly, Andalusia TSJ recently accepted, in its judgment of 12 May 2014, the contentious administrative appeal lodged by FARMAINDUSTRIA against Resolution SC 0403/10, of 22 December, of the SAS Management Executive, that certain medicines for treatment outside hospitals and being dispensed by hospital pharmacy services require, in the judgment of SAS, special care, supervision and control, thus annulling the said Resolution.

The judgment confirms that the Resolution mentioned does not represent a simple internal instruction and that the competence for establishing and modifying the conditions for dispensing pharmaceutical products where special vigilance, supervision and control is required, belongs to the State. The Andalusian authority presented an appeal to reverse this decision and this is presently pending.

SNS Purchasing Platform

As reported upon in previous Annual Reports, the agreements of the Interterritorial Council of the SNS of 18 March 2010 and 18 April 2012 foresee, among other initiatives, the establishment of an aggregated purchasing procedure for the whole of the SNS, to which ARs can adhere voluntarily.

The State has sole competence to set and alter conditions for dispensing medicines requiring special vigilance, supervision and control

In this regard, Royal Decree-law 16/2012 establishes in its Fourth Additional Provision that the Interterritorial Council of the SNS will develop joint actions with Autonomous Region Health Services to acquire any product, which, by its characteristics, can be done so via a joint centralized purchasing mechanism.

The Government expressed its clear wish to use centralized public purchasing to achieve savings in exclusive hospital products. In this respect, and in a framework of faithful collaboration towards the sustainability of the SNS, FARMAINDUSTRIA communicated to the Ministry of Health, Social Services and Equality some aspects which should be considered in the centralized purchasing procedures for exclusive products in the hospital area, with respect for the free decision of each company to participate and which can be resumed as follows: i) lots should be made up of active ingredients or brands (in the case of exclusivity); ii) procedures should be negotiated without advertising (for exclusive medicines protected by industrial property rights); iii) second rounds in the ARs should be avoided; iv) centralized early-payment procedures should be established; v) these should not apply to recently authorized medicines; vi) a minimum purchasing volume should be guaranteed; vii) regional bidding alongside the centralized procedure should be avoided, and; viii) there should be no pre-established prices.

As of writing, four centralized purchasing lots have been put out to tender via the Framework Agreement: i) recombinant coagulation Factor VIII; ii) epoetins; iii) immunosuppressants, and iv) medicines with generic competition. The procedure chosen for the first three, given they are exclusive drugs, was negotiated without advertisement under Article 170.d) of the Consolidated Text of the Public Sector Contracts Law. The fourth call (medicines with generic competition) used an ordinary open procedure subject to harmonized regulation (articles 196 to 198 of the Consolidated Text of the Public Sector Contracts Law).

The basic aspects of the four Framework Agreements called for tender are summarized below.

MEDICINES SOUGHT	PROCEDURE	CONTRACTING ADMINISTRATIONS	LOT CONSTITUTED BY	NO. OF LOTS OFFERED	NO. OF LOTS AWARDED
Coagulation Factor VIII	Negotiated without advertising (art. 170 of the Consolidated Text of the Public Sector Contracts Law)	10 ARs (Asturias, Balearic Isles, Castile-La Mancha, Castile & Leon, Cantabria, Extremadura, Galicia, Murcia, Navarre and La Rioja) and INGESA	Brand	4	4
Epoetins	Negotiated without advertising (art. 170 of the Consolidated Text of the Public Sector Contracts Law)	5 ARs (Asturias, Castile-La Mancha, Cantabria, Extremadura and Murcia), INGESA and the Ministry of Defence	Active Ingredient	5	4
Immunosuppressants	Negotiated without advertising (art. 170 of the Consolidated Text of the Public Sector Contracts Law)	10 ARs (Aragon, Asturias, Castile-La Mancha, Castile & Leon, Cantabria, Extremadura, Madrid, Murcia, La Rioja and the Community of Valencia), INGESA, the Interior Ministry and the Ministry of Defence	Active Ingredient	9	6
Medicines with generic competition	Ordinary open procedure subject to harmonized regulation (articles 196 to 198 of the Consolidated Text of the Public Sector Contracts Law)	11 ARs (Aragon, Asturias, Balearic Isles, Castile-La Mancha, Cantabria, Extremadura, Galicia, La Rioja, Madrid, Murcia and Navarre), INGESA, the Interior Ministry and the Ministry of Defence	Active Ingredient Includes two biosimilars, which share a lot with the biological of reference	20	Awaiting resolution (at May 2015)

The first three calls were extended to 31 December 2015. At the time of writing this Annual Report, the fourth purchasing tender is awaiting resolution.

Cooperation Programme with Autonomous Regions in Translational Clinical Research. +i Programme

During 2014, all the +i Programme projects in the Cooperation Programme with Autonomous Regions in Translational Clinical Research were concluded according to the agreements established between FARMAINDUSTRIA and the ARs.

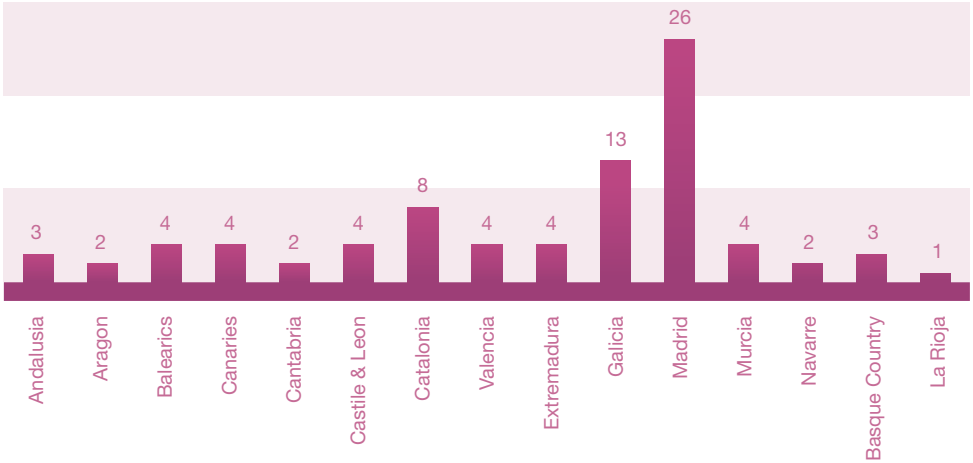
This innovative and unique project, which began in December 2009 in coordination with MSSSI and the Carlos III Health Institute to develop public-private cooperation platforms between health authorities and the pharmaceutical industry, in order to promote local research capacities in the biomedical field, has thus come to an end.

Under the +I Programme, 15 Cooperation Agreements were signed between the different ARs and FARMAINDUSTRIA and a total of 84 projects were cofinanced.

By number of projects, the Community of Madrid stands out (26), along with Galicia (13) and Catalonia (8). These three regions accounted for over 50% of the total number of projects undertaken.

All the +i Programme projects were completed during 2014

NUMBER OF PROJECTS



TYPE OF PROJECTS

DESCRIPTION	TYPE OF PROJECTS
Programmes/structures to support performance of clinical trials.	36
Programmes/structures to support clinical research in Primary Care.	9
Regional biobank programmes.	19
Investments and improvements in hospital centres for their accreditation as Health Research Institutes.	20
TOTAL	84

In order to ensure the coordination, development, monitoring and evaluation of the +I Programme and according to the provisions of the respective agreements, the ARs sent half-yearly execution reports for the different projects to FARMAINDUSTRIA, which were analyzed by a Technical Secretariat, called the Project Support Office (Deloitte), and submitted to the respective +i Programme Monitoring Committees.

At the time of writing this Annual Report, the Project Support Office (Deloitte) is analyzing the latest reports corresponding to the second half of 2014 and 2014 as a whole, as well as the audit reports relating to FARMAINDUSTRIA's contribution to the budget, which have to be submitted to the corresponding Monitoring Committees if no incidents have been detected that need to be reviewed. The approval of these reports will bring the programme to a close.

3.1.3 CONSULTATIVE AND ADVISORY COMMITTEES

FARMAINDUSTRIA participates in various consultative and advisory committees of the Ministry of Health, Social Services and Equality, which allow it to communicate to the health authority the position of the sector in a framework of greater involvement and transparency. FARMAINDUSTRIA is represented on the following Committees.

CONSULTATIVE COMMITTEE OF THE SNS INTER-TERRITORIAL COUNCIL

Chaired by the Secretary General for Health, this Committee is made up of representatives from the various administrations (local, regional and general), trade unions and business organizations, among them FARMAINDUSTRIA, which is occupying the vice-chairmanship corresponding to business organizations.

The Committee held four meetings last year in which it informed in areas that are of special interest concerning the functioning of the SNS and, as is mandatory for the passage of certain provisions, informed on the draft of the Legislative Royal Decree to approve the Consolidate Text of Law 29/2006; the draft of the Royal Decree to regulate the indication, use and authorization of the dispensing by nurses of medicines and healthcare products for human use, and; various drafts of Orders, such as that relating to the updating of the reference price system and the National Registry of Rare Diseases.

Likewise, the Committee debated items of interest to the sector, such as the AEMPS report on reverse distribution of pharmaceuticals, the Strategic Plan and Action Plan to reduce the risk of selection and dissemination of resistance to antibiotics, the Strategic Plan to tackle Hepatitis C, strategies against rare diseases and other healthcare concerns, including the treatment of confirmed cases of sickness caused by the Ebola virus.

MEDICINES FOR HUMAN USE COMMITTEE OF THE SPANISH AGENCY FOR MEDICINES AND HEALTHCARE PRODUCTS

The Medicines for Human Use Committee (CMH) is formed by 22 members, 10 as a function of their posts, and 12 named by the Agency's Governing Council. One seat on the Committee is allocated to Farmaindustria.

The main mission of the CMH is to supervise efficiency and transparency in medicine authorization procedures, inform on authorization procedures — non-bindingly, but in respect of its obligations — about important modifications, suspensions and revocations of medicines for human use, and also, when requested by the Director of the Agency, to issue reports on procedures related to medicines for human use.

Over the past year, the Committee held 11 meetings in which the situation concerning the evaluation of centrally processed medicines, in which Spain is deponent or co-deponent, was explained. The Committee was also informed on the Therapeutic Positioning reports and evaluation reports produced by AEMPS external experts.

3.1.4 COLLECTIVE BARGAINING AGREEMENT

The 17th Chemical Industry General Bargaining Agreement (CGIQ), which expired on 31 December 2014, establishes in its article 4 a three-month renegotiation period prior to expiry, i.e. as of 1 October.

As such, on 17 November 2014, following the Spanish Chemical Industry's Employer-Trade Union Forum, the 18th CGIQ Negotiating Committee was formed and held its first meeting on 11 December. At the time of writing, the Negotiating Committee meetings continue to make progress towards a consensus between the parties.

Meanwhile, this is the second year in which the salary review clause has been applied using the new formula introduced in the 17th CGIQ. This is in line with the 2nd Employment Agreement and the 2012, 2013 and 2014 Collective Bargaining Agreements, which resulted in no salary revision in 2014.

LABOUR REFORM

Last year continued to see important reforms in the area of employment and social security.

Royal Decree-law 8/2014, of 4 July, approving urgent measures for growth, competitiveness and efficiency has as its main axis the fostering of employability and occupation, with an emphasis on the following measures: i) specific incentives for contracting beneficiaries of the national system for youth guarantees, and their inclusion among the groups protected by

other rules for the promotion of employment; ii) incentives for offering workplace experience to students, and; iii) modification of the legal regime of temporary work companies.

Elsewhere, the Council of Ministers adopted an agreement on 5 September 2014 by which the Annual Employment Policy Plan was approved for 2014, in line with that established in article 4, of Law 56/2003, of 16 December, on Employment. Likewise, several regulations were approved, among them Royal Decree 418/2014, of 6 June, modifying the procedure by which the State hears reclamations concerning compensation in dismissal tribunals, and Royal Decree 751/2014, of 5 September, approving the 2014-2016 National Employment Activation Strategy.

The impact fiscal reform has had on earnings, through Law 26/2014, of 27 November, also needs to be mentioned. This Law introduced important amendments to Law 35/2006, of 28 November, concerning personal income tax, in the following areas: i) compensation for dismissal; ii) the gift of shares to employees; iii) use of homes owned by companies; iv) gifts or loans of vehicles to employees for own use; v) irregular earnings; vi) deductible costs; vii) reductions for other earnings, and; viii) the scale for the retention of earnings at source.

As this Report went to press, other rules were made in 2015 in the employment domain, such as Royal Decree-law 1/2015, of 27 February, on “second opportunity” mechanisms, the reduction of financial burden, and other social measures designed to promote job creation; and Royal Decree-law 4/2015, of 22 March, for the urgent reform of the professional training system for employment in the workplace.

3.2 SOCIAL COMMUNICATION

One of FARMAINDUSTRIA's main objectives during the past year has been to give society a better and deeper understanding of the contribution of the pharmaceutical industry in the area of social and economic wellbeing.

The appearance of new channels and supports for communication access has meant that traditional media no longer represent the only source of information for society and for this reason FARMAINDUSTRIA began, in 2014, a new communication strategy focused on grouping together all the important elements in the area of information: content generation, message broadcasting and its own channel. In this way, FARMAINDUSTRIA has in itself become both an information source and an information channel.

Thus, in 2014, we created a website adapted to this new digital environment, with a difference: we are no long just a repository of traditional content (press releases, media conferences, etc.), but a channel with specific digital content (videos, infographics, etc.). In this way, and adding this to its profiles in the social networks, FARMAINDUSTRRIA not only maintains its status as an information source for communication media, but it also undertakes this role for society in general.

FARMAINDUSTRIA built a website in 2014 adapted to the new digital environment, with specific digital contents

Meanwhile, FARMAINDUSTRIA continued with its work serving patients' associations, a collective whose activity and public importance grows year on year.

Finally, we should also highlight the internal communications between members, an area in which FARMINDUSTRIA has been particularly active.

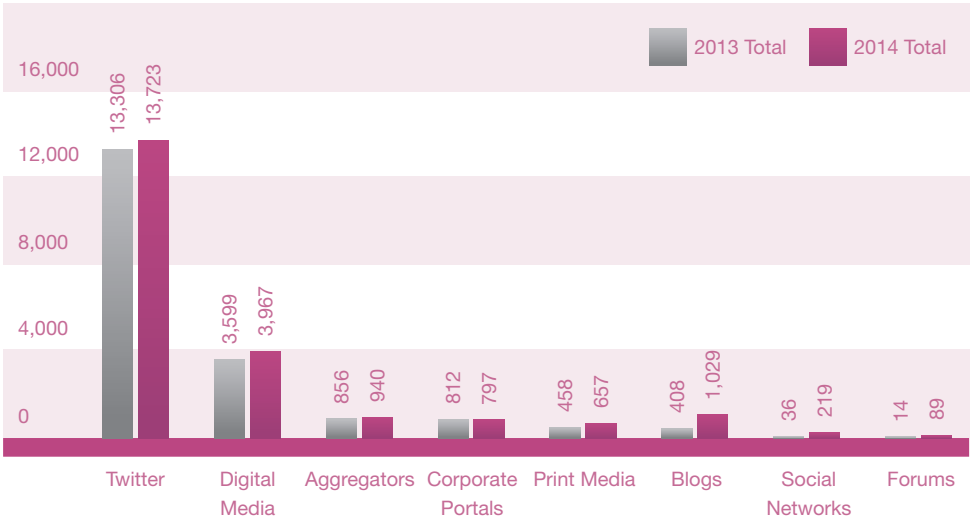
3.2.1 COMMUNICATION MEDIA

Throughout 2014, FARMAINDUSTRIA continued its prominent activities with communication media of all types and specializations: national, regional, economic, health and digital.

The specific activities with these communication media were channeled through 43 press releases in which we informed about the position of the sector on very different issues. We also communicated the participation of the Association at different events and disseminated data and reports of special relevance to the sector.

Diverse press conferences were held and leaders and opinion articles by representatives of FARMAINDUSTRIA were published, tackling diverse subjects: biological medicines, regional inequalities in access to drugs, the evolution of pharmaceutical spending, and pharmaceutical R&D, among others.

DISTRIBUTION BY CHANNEL



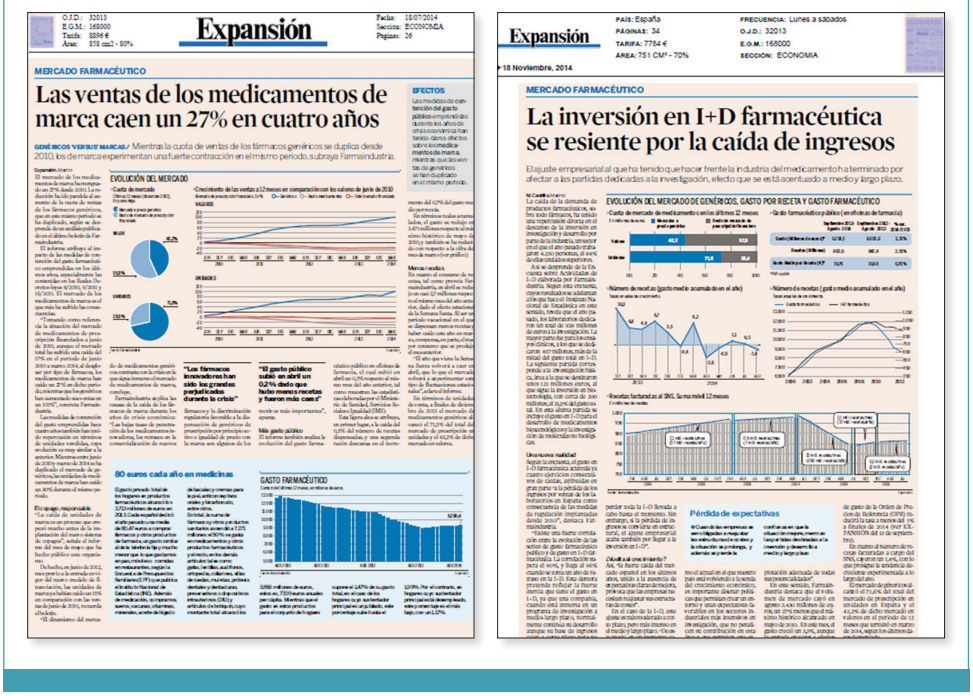
2014 was also significant for the change of presidency in FARMAINDUSTRIA, which occurred in October, an event that generated strong coverage in the communication media.

Another event that had a big impact in the media was the signing in March 2014 of a Collaboration Protocol between FARMAINDUSTRIA and the Ministry of Health, Social Services and Equality on the Sustainability of the SNS and the Quality of Pharmaceutical Provision.

Signing of the Agreement on the Sustainability of the SNS and the Quality of Pharmaceutical Provision

FARMAINDUSTRIA was also present in the communication media through interviews and reports in which the situation of innovative industry in Spain and the most important questions in the areas of health and pharmaceutical policy were discussed. Elsewhere in 2014, FARMAINDUSTRIA carried out intensive institutional lobbying work targeting several communication media and different opinion leaders with the aim of communicating to them firsthand the situation of the pharmaceutical industry in Spain and contributing thus to a greater and better understanding of this sector by society.

The publication, by the daily newspaper, *Expansión*, of the bulletin, Medicines Market Outlook, which FARMAINDUSTRIA prepares monthly, continues to constitute an important media action by the Association and provides society with a deeper analysis of relevant issues relating for the Spanish pharmaceutical market.



In July 2014, in the context of a new call by the Andalusia Government under the Therapeutic Equivalents Framework Agreement, FARMAINDUSTRIA organized, in collaboration with the Joly media group, a seminar in Seville on such barriers to accessing innovation. The main conclusions of the day were published over a double page in all the titles of the Joly group, the most important regional media entity in Andalusia.

Also, once again, the Pelayo Menéndez International University (UIMP) hosted the 14th Pharmaceutical Industry Meeting, sponsored by FARMAINDUSTRIA, which focused on the therapeutic and economic revolution represented by biological medicines.

The 14th Pharmaceutical Industry Meeting, held at UIMP

In the area of giving training to information professionals, the Association once more held its 11th annual Pharmaceutical Industry and Media Seminar, at which some 25 journalists from various media outlets gathered. The contents tackled during the seminar generated a great deal of coverage.

11th Pharmaceutical Industry and Media Seminar

Finally, FARMAINDUSTRIA conducted several advertising campaigns to communicate the value of scientific research, the work of the pharmaceutical industry and the importance of branded medicines.

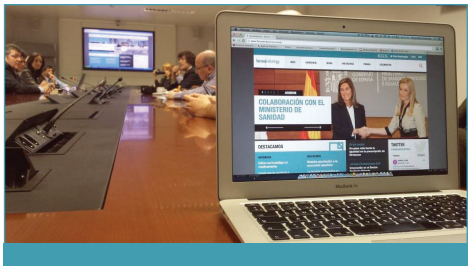
3.2.2 2.0 COMMUNICATION

As mentioned above, FARMAINDUSTRIA began 2014 with a new communications strategy to reach society directly, to enable people to get to know at firsthand all the attributes of the sector. This new strategy was channeled via a complete remodeling of the Association's website (www.farmaindustria.es), presented in March to a large and enthusiastic group of journalists.

The new FARMAINDUSTRIA website is a multimedia channel with traditional content and new audiovisual content bringing us closer to society

The remodeled FARMAINDUSTRIA website was conceived as a multimedia channel containing the traditional content the Association generates and new audiovisual content such as videos, infographics, presentations, etc., which bring us closer to society. Continuity and constant updating of the site represent the new tool by which we will express our views over the years to come, through pages focused on diverse issues of special relevance for the sector.

New content generated over the past year includes infographics on: i) the contribution of the pharmaceutical industry to society; ii) how a medicine is researched; iii) the commitment of the pharmaceutical industry to fighting neglected tropical diseases; iv) counterfeit medicines, and; v) brand value. A video was also produced to explain the new commitments of the pharmaceutical industry in the area of transparency.

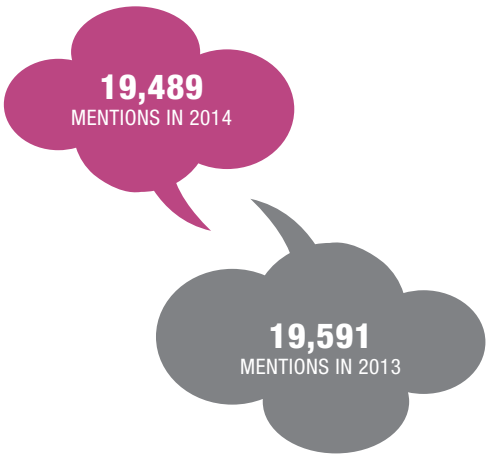


FARMAINDUSTRIA consolidated its presence in the social networks, which grew notably during 2014. Its Twitter channel, launched four years ago, had over 15,000 followers by December, and ended the year with a Klout influence score of 60 (four points more than at the end of 2013), making it one of the most reputed health organizations on Twitter.

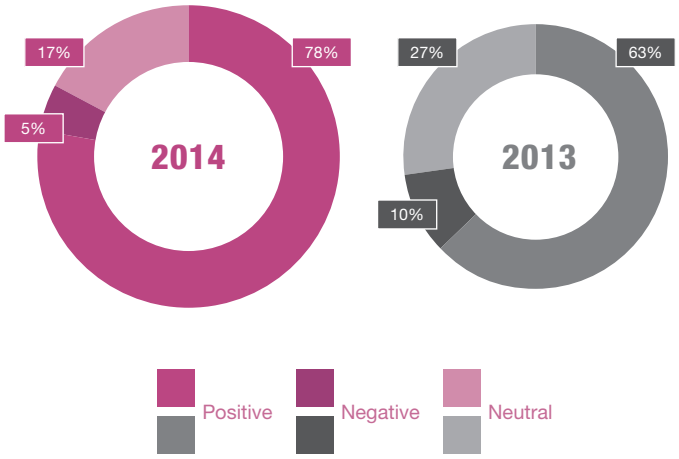
FARMAINDUSTRIA's Twitter activity is centered on disseminating information about the Association's own activities, as well as important information and content of interest to the Spanish pharmaceutical sector. On Facebook, it has concentrated its full presence via a page that offers both own and third party content relevant to the industry.

The annual report monitoring the presence and activity of FARMAINDUSTRIA and the pharmaceutical sector in the communication media and social networks reveals that in 2014 more than 19,000 articles and commentaries were published mentioning the Association, a similar figure to 2013 but with a 15 percentage points higher positive perception (78%, compared to 63% in 2013). Activity related to FARMAINDUSTRIA on Twitter alone generated around 15 million impacts in 2014, an average of over 11,200 impacts per published item on the network.

VOLUME OF ACTIVITY



SENTIMENT



TWITTER IMPACTS

2014
14,713,860

2013
14,836,616

Somos Pacientes ('We Are Patients'), the online community of patient associations promoted by FARMAINDUSTRIA, and which is explained in more detail in section 3.2.4 below, is clearly committed to being present and disseminating its activity and content on Web 2.0. Thus, as well as making available the possibility of *communicating the platform's content via different social networks to all its users and readers, Somos* Pacientes attracts a high level of participation on both Twitter and Facebook. The *Somos Pacientes* profile on Twitter had over 10,000 followers at the end of 2014. Through this channel, the platform broadcast its new content and kept an open dialogue with more than 1,000 associations that follow it via Twitter.

In Facebook, *Somos Pacientes* has a page through which it disseminates content and, at the end of 2014, had more than 1,500 followers. The community also has a YouTube channel in which it posts all the reports and interviews in videos.

This community had accumulated a Klout influence score of 63 by the end of 2014.

3.2.3 INTERNAL COMMUNICATION

Internal communication is another of the cornerstones of the Association's communications activities. The Communication Working Group holds quarterly meetings, in which the items of greatest interest to the sector are brought up and strategies and joint positions prepared.

'Somos Pacientes' attracts a high level of participation on both Twitter and Facebook

Internally, the weekly communication Flash continues to be distributed among Member Companies. Forty-three Flash were disseminated in 2014, giving up-to-date information on FARMAINDUSTRIA's communication activities.

In addition, every month, a report on the pharmaceutical industry and health sector presence in the media and social networks is made available to the members, as well as a weekly and annual comparison of the evolution of these activities.

3.2.4 RELATIONS WITH PATIENTS' ASSOCIATIONS

In 2014, FARMAINDUSTRIA intensified its relations and collaboration with patients and the associations that represent them. FARMAINDUSTRIA seeks to establish areas of cooperation with these organizations on subjects of common interest.

With this objective, our action in this area is characterized in two ways: i) dialogue with associations, both directly and via the FARMAINDUSTRIA Permanent Roundtable for Dialogue with Patient Organizations, and; ii) management and encouragement of the online community of associations, Somos Pacientes, which offers information, training, services and tools for working collaboratively with patients' organizations, families, people with disabilities and carers, as well as society as a whole.

FARMAINDUSTRIA also operates the very busy Patients' Working Group in which it shares the work it performs in this area with the companies that make up the group.

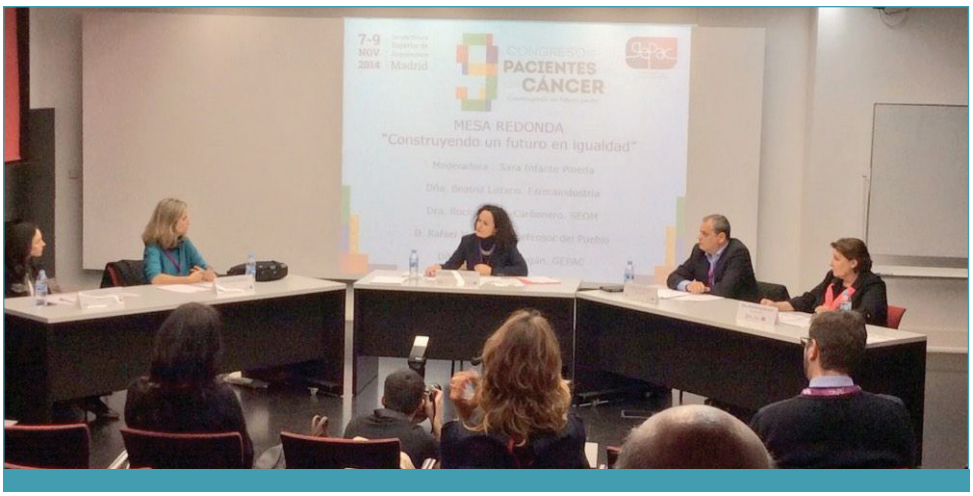
FARMAINDUSTRIA took part in various events with patients' organizations in 2014

COLLABORATION WITH PATIENTS' ORGANIZATIONS

FARMAINDUSTRIA took part in numerous events, meetings, days, seminars, debates and diverse activities with patients' organizations in 2014, to share experiences with them and support their work. Among them, we can mention: i) the study EsCrónicos, on the perception of the quality of healthcare received by chronic patients in Spain; ii) the course annually organized by the Spanish Breast Cancer Federation (FECMA) at UIPM; iii) the AECC seminar for World Cancer Day; iv) the 9th Cancer Patients Congress, and; v) FNETH's Hepatitis C Day. The Association also maintained direct contacts with organizations such as, FEDHEMO, EME, Alcer, FEP, the ASEM Federation and FEDE, among others.

PERMANENT DIALOGUE ROUNDTABLE

The FARMAINDUSTRIA Permanent Dialogue Roundtable with Patients' Organizations strengthened its activity in 2014 as a forum for information and debate with a representative group of over 20 federations and confederations of patients' associations to tackle important issues of common



The 9th Cancer Patients Congress

interest, with the ultimate aim of consolidating a relationship of mutual trust and thus improving knowledge of the needs and concerns of this collective.

The Roundtable, which meets at the proposal of any of the parties, held five meetings in 2014 at which, among other matters, it tackled the difficulties and delays that can occur in Spain in relation to the access to innovative treatments, inequalities in pharmaceutical provision in the different ARs, and changes in the prescription form and prescription of medicines caused by legislative changes.

SOMOS PACIENTES

The online community of patient associations Somos Pacientes ('We Are Patients', www.somospacientes.com), launched by FARMAINDUSTRIA in 2012, gave a voice by the end of 2014 to more than 1,400 registered bodies and organizations also listed in the National Patient Organizational Map.

Somos Pacientes offers a shared space for information, participation, education, services and collaborative work aimed at all associations of patients and people with disabilities in our country, as well as families, carers and professionals.

The tools most used by the associations are the virtual conferences (webinars), online meetings and the video and audio streaming rebroadcast channel. Through the latter, in 2014 *Somos Pacientes* offered press conferences and activities by different member bodies of the community, as well as the non-stop broadcast of the second edition of the *Somos Pacientes* Day held in December.

Among the main activities carried out in the context of *Somos Pacientes* during 2014 included our taking part in the production of the television programme, *Todos somos raros, todos somos únicos* ('We are all rare, we are all unique'), presented by the journalist Isabel Gemio and broadcast on RTVE's La 2 channel. The series was aimed at raising awareness among and informing the population on rare diseases and the situation of the more than three million people affected by this kind of disease in Spain. It included a weekly section devoted to *Somos Pacientes*, as part of the activities of the special Rare Diseases Year, in which the main characteristics, services and possibilities the organization offers were explained.

Elsewhere, the 2nd *Somos Pacientes* Day held at the beginning of December, reinforced its role as a meeting point for the exchange of ideas, needs and projects between representatives of patients' associations, the innovative pharmaceutical industry, health authorities, professionals and researchers. The programme in this edition, attended by over 100 people, focused on access of patients to therapeutic and technological innovation. The Day could again be followed on the *Somos Pacientes* streaming channel and the event had more than 1,600 Twitter mentions and generated over three million impacts in the network.

Also under the umbrella of *Somos Pacientes*, FARMAINDUSTRIA signed collaboration agreements in 2014 with Torrejón University Hospital and La Rioja International University with the double objective of facilitating the access of patients' organizations to online resources, and enriching the content of its training programmes.

EUPATI, EUROPEAN PATIENTS ACADEMY

This European Commission project, of which FARMAINDUSTRIA is part, is developing educational courses and material, and creating a public library on the Internet to train patients' representatives and the general public in all the processes involved in the development of medicines.

With the initiative still in the development phase, FARMAINDUSTRIA took part in several working meetings held in Brussels and Dublin. It also coordinated the Spanish National Liaison Team (NLT), which met on many occasions during the year, organized an event in November to present the initiative in Spain and led the launch in December of the National EUPATI Platform in Spain.

Event to present EUPATI in Spain

3.3 INTERNATIONAL RELATIONS

3.3.1 EUROPEAN CONTEXT

Once again, the activities of FARMAINDUSTRIA at the European level have been channeled mainly via the European Federation of Pharmaceutical Industries and Associations (EFPIA), which in Europe represents the voice of 33 National Associations and 40 pharmaceutical companies. FARMAINDUSTRIA participates not only in most of EFPIA's 29 committees and working groups, but also in all the meetings of its governing bodies: the Board, Heads of Association Committee and Executive Committee. In this latter, FARMAINDUSTRIA holds one of the vice-chairs, as representative of the National Associations.

The activities of FARMAINDUSTRIA at the European level are channeled mainly through its participation in the Federation EFPIA

MEETINGS OF THE EFPIA GOVERNING BODIES

On 4, 5 and 6 June 2014, the EFPIA General Assembly took place in Lyon, in which it was decided to center the strategies of the Federation along the framework of the *Health & Growth* project, which defines the main action lines for the pharmaceutical sector in Europe.

The EFPIA governing bodies held meetings ratifying the specific priorities for the 2014-2015 period: i) patient access to innovation (WAIT indicator, international price references and biological medicines); ii) scientific and regulatory environment (transparency in clinical trials and IMI-2), and; iii) international trade (industrial property rights and emerging markets).

EFPIA governing bodies also approved the renewal of FARMAINDUSTRIA as a member of the Board and vice-chair of the Executive Committee, as representative of the National Associations, along with Germany.

Finally, the Assembly approved the consolidated versions of the EFPIA Code of Practice, and of Transparency, concluding with a conference open to the public on the fight against counterfeit medicines in which the Secretary General of Interpol took part.

Otherwise, the EFPIA Board approved, in December 2014, the nomination of Joe Jimenez (Novartis) as President of the Federation, extending his mandate until June 2017, and Vice-Presidents Stefan Oschmann (Merck KGaA) and Marc de Garidel (Ipsen) for the same period.

Also, during 2014, regular meetings continued between the Executive Committee of EFPIA, made up of the directors of companies at European level (Heads of Europe) and directors-general of the main national associations.

The *Health & Growth* project formed part of the agenda in all the meetings of the Executive Committee and FARMAINDUSTRIA has been regularly publishing updated information on this project, and the project's presence in Spain, on its website.

As usual, the Executive Committee followed very closely the main national developments in the area of pharmaceutical policy, focusing on the five main European markets, although it also held sessions dedicated solely to countries of special interest such as Greece, Romania and Turkey.

During the last year, the Executive Committee paid special attention to initiatives such as: i) the establishment of ceilings for expenditure and rebate mechanisms on the part of the industry; ii) new public financing models aimed at promoting access to new treatments in a sustainable way, and iii) the development of efficient markets for out-of-patent biological medicines.

In parallel, regular meetings of the five High-Level Committees created in 2013 were held. These committees are charged with leading the coordination of strategies and actions of EFPIA in the following priority areas: i) scientific and regulatory; ii) communication and partnerships; iii) finances and planning; iv) growth in international markets, and; v) access to innovative therapies in Europe.

As for the EFPIA Board, during the first half of 2014 this governing body tackled the restructuring of EFPIA, reorganizing the different Committees and Working Groups while redefining the mission and objectives of the grouping of European Biopharmaceutical Enterprises (EBE) to demarcate its activities and avoid overlaps.

One of the main agreements of the EFPIA Board was to foster the proactivity of the pharmaceutical industry concerning the European institutions and Member States, with a global approach that pursues a balance between sustainability of health systems and access to innovation, recognizing the social and economic contribution of the industry.

EFPIA undertook a process of restructuring and reorganization of its different committees and working groups in 2014

Other subjects that were the object of analysis by the Board were as follows: i) analysis of the new EMA policy on transparency in the publication of data on clinical trials; ii) the use of medicines beyond their indications, and; iii) advances in the development of the European Medicines Verification System (EMVS) in the context of the Directive on counterfeit medicines.

In another activity area, the past year saw two meetings of the Heads of Association Committee, which, apart from the analysis of policies and measures applied in the different markets, tackled a number of priority issues: i) national implementation of the EFPIA Code of transparency in economic relations between the pharmaceutical industry and health professionals; ii) best practices in relation to policies of international reference prices applied in the different Member States, and iii) the role of the national associations of the pharmaceutical industry in EFPIA's *Health & Growth* agenda.

Also, during 2014, three meetings of the G1 Group were held. This Group is made up of the national associations of the main European markets (Germany, Spain, France, Italy, the United Kingdom and Switzerland). The meetings debated the role of the associations in the national development of pharmaceutical policy measures.

NEW EUROPEAN PARLIAMENT AND COMMISSION, 2014-2019. PROPOSALS FROM THE INNOVATIVE PHARMACEUTICAL INDUSTRY

Elections for the European Parliament were held in May 2014, beginning the process of renewing all the European institutions for the 2014-2019 legislature. The new Parliament in October approved the proposal for the new configuration of the European Commission and

College of Commissioners, presented by its President, Jean-Claude Juncker; they formally assumed their functions on 1 November 2014 for a period of five years.

As far as the pharmaceutical industry is concerned, the units responsible for medicines, medical devices, healthcare technology and cosmetics will continue under the responsibility of the Directorate-General for Health and Food Safety and the legislative initiatives in these areas will be shared by the Commissioner for Health and Food Safety (Vytenis Andriukaitis) and the Vice-President for the Internal Market, Industry, Entrepreneurship and SMEs (Elzbieta Bienkowska).

The document by the Commission President, *A new start for Europe: My agenda for Jobs, Growth, Fairness and Democratic Change*, makes explicit reference to the innovative pharmaceutical industry as a strategic sector for retaining European industrial leadership in the world.

The European Commission regards the pharmaceutical industry as a strategic sector for European industrial leadership

Commissioner Andriukaitis also referred on many occasions, during his investiture speech, to health as a motor of growth in Europe, and the European Parliament, in a document that reflects its priorities for the new legislature, demanded the inclusion of health policy indicators in the European Union's strategic programmes, with the aim of promoting health so that it is perceived as a factor of economic growth.

EFPIA MANIFESTO FOR INTEGRATED LIFE SCIENCE IN EUROPE

EFPIA published a Manifesto in May 2014 in which it urged the new European institutions to create multisectoral alliances and collective initiatives to overcome the challenges of the European Union in the areas of healthcare and competitiveness, showing its complete disposition towards working jointly with political leaders, regulators and healthcare actors to define an integrated strategy for life science in Europe, combining economic, healthcare, social assistance, scientific and industrial policy aspects, based on three distinct but interdependent pillars: i) improving healthcare results and eliminating inequalities, to the benefit of the patient: ii) contributing to the development of sustainable and predictable healthcare systems, permitting the speeding up of access to new treatments for patients, and; iii) promoting the development of a prosperous and innovative life science sector to foster European competitiveness.

The main demands of the sector were brought together in a Commission document, *Pharmaceutical Industry: an asset of the European Economy*, published in August 2014.

FARMAINDUSTRIA-DG ECFIN MEETING AND BILATERAL RELATIONS

FARMAINDUSTRIA sent a letter in November 2014 to the European Commissioner for Economic and Financial Affairs, Taxation and Customs, Pierre Moscovici, concerning the written response of the European Commission to a Spanish MEP on the specific recommendations made by the ECFIN Directorate-General to Spain in the healthcare area. Among other questions, the letter sent by FARMINDUSTRIA documented the strong impact that economic policy measures implemented by the Spanish Government over recent years have had on the Spanish pharmaceutical market, emphasizing the drastic reduction experienced in public pharmaceutical spending. The letter was accompanied by a complete up-to-date set of indicators for the Spanish public pharmaceutical market.

As a result of this letter, in March 2015 FARMAINDUSTRIA had a bilateral meeting in Brussels with DG ECFIN of the European Commission, with the aim of sharing the most recent data on the evolution of the Spanish pharmaceutical market. In this meeting, the parties went into detail about the contribution of innovative industry in achieving national deficit objectives. The representatives of the Commission welcomed the updated market and expenditure indicators with interest, as well as the rest of the information facilitated, agreeing to open a line of communication that will permit a regular monitoring of such indicators and the pharmaceutical policy measures that impact upon them.

EU LEGISLATIVE INITIATIVES

Progress in the development of the different European legislative initiatives in 2014 was affected by the priorities defined by the Greek and Italian presidencies.

EU Directive 2011/62 on counterfeit medicines

As documented in previous editions of this Annual Report, EU Directive 2011/62 (counterfeit medicines) establishes the obligation to identify the packaging of a medicine individually and verify its authenticity.

The European Commission, through a Delegated Act, has established a systematic verification model that must be fully operational by the end of 2018. The publication of this Delegated Act is foreseen for the end of 2015.

The European Medicines Verification Organization (EMVO) came into being in February 2015

Faced with this obligation, EFPIA, in collaboration with European agents in the medicines supply chain, worked on the model for the European Medicines Verification System (EMVS), which has to satisfy the demands of European legislation. This system is based upon: i) the use of unique, random serial numbers (Datamatrix); ii) an architecture with an inter-operative European hub and distinct national hubs, and iii) a governance system run by the supply chain agents.

The European hub ended its tests in the first quarter of 2015 and all the supply chain agents have endorsed the creation of a governance system, the European Medicines Verification Organization (EMVO), which came into being officially on 13 February 2015. This entity, established as a non-profit organization, will be responsible for the governance of the EMVS under the supervision of the European regulatory authorities and is made up of the European-level supply chain agent representatives: i) the pharmaceutical industry (EFPIA and EGA); ii) pharmacists (PGEU); iii) distributors (GIRP), and iv) parallel distributors (EAEPC). Its main undertaking at this early stage is to manage the European hub, which will serve as the link between the national medicines verification systems in Europe as well as the entry point for information on medicines marketed in the EU.

As for Spain, the AEMPS has communicated to FARMAINDUSTRIA its support for this European platform as well as its wish to promote its rapid incorporation in Spain, urging FARMAINDUSTRIA to lead with the rest of the national agents (CGCOF, AESEG, FEDIFAR and hospital pharmacy) a national platform (a Spanish EMVO) to comply with the legal requirements in this area.

FARMAINDUSTRIA has already contacted CGCOF, AESEG and FEDIFAR and potential technological providers on this matter.

Unitary Patent

After the adoption of the legislative packet in this domain (two regulations and the linguistic regime) by the European Parliament and Council, all the Member States, except Spain, Poland and Bulgaria, in February 2013 signed the Intergovernmental Agreement to set up, at the European Court, a single tribunal for patents on chemical and pharmaceutical products with its seat in London.

A specialist European court (the Unified Patent Court) will have special competence in European lawsuits in this area

The European Commission later published its proposal for the amendment of EU Regulation 1215/2012, relating to judicial competence and the recognition and implementation of legal resolutions in the civil and commercial areas, completing thus the legal framework for the protection of patents at European level through the updating of EU regulations on the powers of courts and the recognition of the legal resolutions (Brussels I Regulation). These changes establish the basis for a specialist European court (which will be called officially the Unified Patent Court), facilitating protection of companies' and inventors' patents through special powers in disputes in this area, thus avoiding multiple lawsuits in up to 28 different national jurisdictional bodies.

The European Council and Parliament ratified in March and April 2014, respectively, the Compromise Agreement reached on this proposal, which represented the two final legislative steps for the effective constitution of the Unified Patent Court. The Agreement has to be ratified by all the Member States, although this process had not been completed as this Annual Report went to press.

Personal data protection

During 2013 and 2014, EFPIA and FARMAINDUSTRIA coordinated a joint action with various stakeholders to develop and communicate their common position guaranteeing the adoption of a pragmatic approach in the area of personal data protection, ensuring that the data used in biomedical research kept a special consideration in the European legislation, avoiding bureaucratic barriers and duplication in the evaluation and restriction on its use.

However, the European Parliament adopted an amended text in October 2014 that included very negative aspects relating to the process and use of data in the healthcare sector, including some limitations set out in the draft proposal for article 81:

- With respect to limiting consent to a single investigation or similar specific investigations (art. 81 (b)), the sector considers that it must be taken into account that, when data is gathered, it is not always possible to describe the full future use that will be made of it, including the reuse of historical clinical data or epidemiological records relating to diseases that are highly useful presently, given the potential the phenomenon of Big Data in healthcare represents for all public and private stakeholders.

- On the other hand, the pharmaceutical industry considers that impeding or limiting the investigation due to the impossibility of contacting again the patients who have already given a consent (art. 81 – 2a), generates inequalities and a lack of harmonization that diminishes the benefits of a coordinated action at European level in this field, since it expressly establishes that "the legislation of the Member States can establish exceptions to the requirement of consent for the investigation mentioned in section 2, where the investigation is exceptionally important to the public interest, if the said investigation cannot be carried out in another way".

Proposal for a Regulation of the European Parliament and Council on Clinical Trials of Medicines for Human Use.

With the aim of simplifying European legislation in the area of clinical trials and promoting in this way clinical research in Europe, in July 2012 the European Commission published a proposal for a Regulation that both EFPIA and Farmaindustria welcomed very favourably, stressing the importance of taking advantage of this unique opportunity for the European Union to recover the place it lost as the location of preference for performing clinical trials.

During the legislative process, the European Council reached agreement in December 2013 on the proposal for a Regulation, annulling EC Directive 2001/20, which is still in force. The main new elements of the approved text include: i) the creation of a single entry point in the EU for the sending of authorizations, as well as a pan-European database for all the trials performed in the EU; ii) specific requirements to carry out low-intensity trials, as well as stricter requirements in the area of obtaining the informed consent of patients; iii) transparency in the publication of results, with the text finally respecting information considered commercially confidential.

The European database on clinical trials will be accessible by the public except in cases where information is considered to be confidential in specific situations

The final text establishes that the European database on clinical trials will be accessible to the public, except in the cases where the information contained in it could be considered confidential in four situations, where it concerns: i) personal data protection; ii) protection of commercially confidential information, especially taking into account the stage of the authorization procedure for the commercialization of a medicament, as long as public interest motives exist to justify this; iii) protection of confidential communications between Member States in relation to the preparation of evaluation reports, and; iv) guaranteeing effective supervision of the performance of a clinical trial by any Member State.

Regulation 536/2014 was approved by the European Parliament at the start of 2014, as a prior step to its final adoption and entry into force on 16 June 2014, although the Member States understand that its effective application will not be possible until the pan-European database, on which work is ongoing, is launched.

In Spain, the draft Royal Decree on Clinical Trials is still to be passed, since it is awaiting the definitive adoption of the European Regulation, so that the Spanish legislation can be aligned with the provisions in the European Regulation.

Transparency in the publication of clinical trial data

The European Medicines Agency (EMA) has acted in two senses in this field. First, after analyzing the results of the public consultation launched in July 2013, it published its own position on the publication of these data, advocating the proactive publication of clinical trial reports included as a part of the marketing authorization applications received concerning medicines for human use. This policy thus exceeded the requirements of Regulation 536/2014 in the sense that, for instance, clinical trials performed outside the European Union would be published if they were included in a marketing authorization application sent to the EMA.

Secondly, referring solely to the requirements of the Regulation, the EMA decided to launch a new public consultation with the aim of receiving proposals relating to the effective application of the transparency requirements in the context of a pan-European database. In this sense, the EMA has assured that it is pursuing the objective of obtaining a balance between a patient's, and the general public's, right to information and the need of the innovative pharmaceutical industry to obtain a legitimate return on its investments.

For its part, EFPIA launched a portal in January 2014 that offers direct links to the websites of several companies from which the results of various clinical trials carried out by these companies can be accessed. This is an initiative within the context of the *Principles for Responsible Clinical Trial Data Sharing*, adopted in 2013 by EFPIA and PhRMA. In the same way, EFPIA has inaugurated an online space dedicated exclusively to what is known as *Responsible Transparency* in the publication of data on clinical trials: http://transparency.efpia.eu/clinical-trials.

In January 2014, EFPIA launched a portal with direct links to the websites of companies where results of clinical trials carried out by these companies can be accessed

BIOTECHNOLOGY

In November 2013, the Board of the European Biopharmaceutical Enterprises (EBE) decided to redefine its mission and objectives to align itself with a new strategy that permits it to strengthen its unique position in the ecosystem formed by EFPIA/EBE/VE (Vaccines Europe). This also responds to new market characteristics, evolution in the process of developing biological medicines, and new needs of the EBE members. In this process, the areas of orphan drugs and rare diseases are now under EPFIA responsibility.

VACCINES

Vaccines Europe has renewed its mission and strategic direction, defining its principal objective as to encourage initiatives which promote better access to immunization policies, ensuring better community and individual health protection through existing vaccines and those still under development.

During 2014, several institutional actions were carried out, including the document, *Call to action: vaccines at the heart of public health policy*, which through a series of texts calls on public sector leaders in Europe to implement the European vaccination strategy, the aim of which is to get Member States to adopt effective national immunization plans.

EXTERNAL TRADE: ACTIONS IN THIRD COUNTRIES

EFPIA operates in the international context via its External Trade Policy Committee, in which FARMAINDUSTRIA participates actively. Its actions have meant that the interests of the pharmaceutical industry are taken into account in all commercial relations with third parties, both industrialized countries and emerging countries, communicating the concern of national and European authorities over the appearance of new barriers to trade, both purely tariff-based and or another kind, for example, preference for medicines produced domestically, discount demands and medicines of external origin, etc.

EU-US Transatlantic Trade And Investment Partnership (TTIP)

Seven rounds of negotiations have already been held, including important debates on the interests of the innovative pharmaceutical industry, which advocates an ambitious process of mutual recognition in the regulatory area (good manufacturing practices, inspections, industrial property rights protection, exchange of scientific knowledge, registers, etc.), and for the existence of a special chapter (annex) dedicated to the pharmaceutical industry. There are at least three more rounds of negotiations expected during 2015.

FARMAINDUSTRIA maintains regular contacts both with the Secretary of State for Trade in Spain and the Spanish Permanent Representation in Brussels, and has organized various informative meetings on the position of the innovative pharmaceutical industry in relations to the TTIP, both for multinational and Spanish companies who wish to undertake business in the United States.

EFPIA opera en el contexto comercial internacional a través de su Comité de Comercio Exterior

FARMAINDUSTRIA took part in an event in November 2014 organized by the European Commission's Office in Spain, in which the Trade and Investment Directorate-General of the Spanish Ministry of Economics and Competitiveness reiterated its firm commitment to the achievement of a bilateral agreement beneficial to Spain.

There was also the publication of a new document, by *Business Europe*, which is available on the FARMAINDUSTRIA website, in relation to the specific opportunities TTIP represents for SMEs.

EU-Canada Comprehensive Economic And Trade Agreement (CETA)

Although the complete text, including the principal demands of the innovative pharmaceutical industry, was presented at the EU-Canada summit in September, its approval is not planned till 2015. This will follow a debate in the European Parliament and approval by the national parliaments in the Member States.

In this sense, EFPIA and FARMAINDUSTRIA are collaborating closely with the Canadian pharmaceutical industry association with the aim of deploying a coordinated strategy of institutional actions to obtain rapid approval by the European Parliament.

EU-Japan Free Trade Agreement

After a first assessment of the progress made one year on from their launch, the European Commission expressed its firm intention to continue with the negotiations in line with the position maintained by EFPIA.

As with other trade agreements, EFPIA advocates for the regulatory homogenization, high levels of protection for industrial property rights and transparency guarantees from the Japanese government with regard to pricing and rebate processes, as well as the reflection of these questions in a specific annex of the Agreement.

EFPIA created a joint working group with the Japanese innovative pharmaceutical industry association (JPMA) in order to coordinate the institutional actions of both. FARMAINDUSTRIA also participates in the sectoral group created and coordinated by CEOE in Spain.

EU-India Free Trade Agreement

The debate on a possible EU-India free trade agreement is the object of strong discussions in the area of industrial property rights and mandatory licences.

EFPIA and PhRMA are highly active alongside the European Commission to ensure that India is included as a priority in the Market Access Advisory Committee, once it its list of trade barriers has been officially updated, and regarding the existing conflicts in the area of protection of industrial property rights.

China

An EPFIA delegation, led by the Director General and various Board members, visited China in September with the aim of consolidating the advances made in the regulatory area and healthcare policy reform in China. A China-EU summit focusing on the regulatory area was held shortly after this visit, in November, and EFPIA, EGA and the Chinese medicines agency participated.

The EFPIA Board is to visit China again in 2015, while relations with representatives at the Chinese Embassy to the European institutions are being strengthened.

Turkey

The Turkish government announced several protectionist measures aimed at promoting local pharmaceutical R&D and production. Although we have no specific details, some of them appear to represent discriminatory practices in relation to imported medicines.

EFPIA is working closely with the Turkish pharmaceutical industry association (AIFD) and PhRMA, as well as the European authorities, to guarantee than none of the measures adopted by the Turkish government contravene international law, while it is also opening a constructive dialogue with the Turkish authorities to develop a local environment favourable to foreign investment by the pharmaceutical industry.

Russia

Although some progress has been made in some areas, such as the requirement that clinical trials are carried out at local level, Russia continues to be a market that applies protectionist measures. EFPIA continues to work with the Russian innovative pharmaceutical industry association (AIPM), exploring the possibilities of initiating a bilateral dialogue with the Russian

authorities in the area of promoting investment, if they can guarantee an environment that respects innovation and industrial property rights.

3.3.2 INTERNATIONAL CONTEXT

FARMAINDUSTRIA channels its activities in this respect through the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA/FIIM), and is represented on its governing bodies (Council and General Assembly) and Steering Committee.

The activity of IFPMA centers on various Committees (Working Groups), of which FARMAINDUSTRIA is a member and in which it actively and regularly participates: i) the Global Health, Innovation, Industrial Property and Trade Committee; ii) the Socioeconomic Research Network, and; iii) the Communication and the IFPMA Code of Best Practices Committee. It also takes part in specific subgroups in the areas of mental health and neurological illnesses, universal coverage of healthcare systems, and cancer and access to cancer medicines.

FARMAINDUSTRIA took part in the meetings of the Board and Assembly of this Federation, held in July and November 2014, respectively, in which priorities were adopted for 2014-2015. During these meetings, the change of Presidency was confirmed for the next two years, whereby Stefan Oschmann (Merck Serono) took over from John C. Lechleiter (Eli Lilly & Co).

Over 200 representatives of international organizations, Governments, NGOs, foundations, patients' associations and the media took part in the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) Assembly

Otherwise, various subjects of interest for the sector were tackled from a global perspective, approving the Federation's 2015-2016 Strategic Plan with four priority axes: i) access to medicines, innovation and industrial property in emerging countries; ii) institutional leadership in the area of design and implementation of efficient healthcare policies at the global level; iii) promotion of confidence in the pharmaceutical industry worldwide and ethical practices, and iv) achievement of a regulatory environment favourable to innovation at the international level.

The IFPMA Assembly ended with a Conference which, under the title *Investing for Healthier Societies*, attracted over 200 representatives of international organizations (the United Nations and WHO), Governments, NGOs, Foundations, Patients' Associations and representatives of the specialist press, who debated on the need to create global public healthcare policies through multisectoral alliances in which the innovative pharmaceutical industry should be a key player.

DISEASES AFFECTING THIRD WORLD COUNTRIES

IFPMA has published various position papers and infographics dedicated to the activities of the pharmaceutical industry. In February 2014 it issued an annual report updating the R&D that is being carried out by the pharmaceutical industry on the so-called "forgotten diseases" which mainly affect developing countries and the Third World. It documents a 13% increase in 2013 in the number of projects dedicated to these diseases, rising to a total of 184 active projects, 38 of them involving vaccines and treatments already proven in clinical trials and 10 in the final stages prior to authorization. Projects include potential treatments and vaccines for tuberculosis, multi-resistant malaria, dengue fever, Chagas disease and Ebola.

IFPMA also published several infographs and one-off reports referring to the commitment of the innovative pharmaceutical industry in donating medicines, which is projected to reach the figure of 14 billion between 2011 and 2020, i.e. an average 1.4 billion treatments a year.

THE WORLDWIDE FIGHT AGAINST COUNTERFEIT MEDICINES

In May 2014, to coincide with the WHO General Assembly, IFPMA organized an event in collaboration with Interpol and the Chirac Foundation with the aim of supporting the global Medicrime Convention, and calling for a more severe regulatory environment in the global fight against counterfeit medicines.

The main international pharmaceutical industry associations (EFPIA, IFPMA, JPMA and PhRMA) have also created a coordination group to tackle counterfeit medicines and this held two meetings in 2014 in which the participants could share information about new legislative initiatives and best practices in diverse activity areas.

Se ha creado un grupo de coordinación de lucha contra las falsificaciones de medicamentos entre las principales asociaciones de la industria farmaceútica (EFPIA, IFPMA, JPMA y PhRMA)

The multilingual online communication campaign carried out by IFPMA, called 'Fight the Fakes', continues apace. This aims to unite organizations, individuals and institutions in a global movement directed at raising public awareness about this phenomenon, which, despite representing a real and increasing threat to patients across the world, continues to fail to receive the attention it merits from the media and in many cases even the authorities and governments.

The online campaign has videos in which people whose lives have been affected by taking counterfeit medicines tell their stories. A new development in 2014 consisted of an application for mobile devices which, using different technological formats, allows access to relevant information on counterfeit medicines and has been translated into languages of developing countries, especially African.

Finally, FARMAINDUSTRIA continues to collaborate actively in the mechanism jointly developed by IFPMA and the Pharmaceutical Security Institute, which aims to compile all recorded incidents relating to counterfeit medicines worldwide, producing and sending out a summary of such incidents every quarter.

UNIVERSAL HEALTHCARE COVERAGE

This concept will serve as an umbrella to cover the different objectives that will be defined by the United Nations as of 2015. It consists of focusing on the concept of "healthy lives", which will involve a new political framework that goes much further than the concepts of infectious and or non-transmissible diseases, and demands a more global consideration.

IFPMA, EFPIA, PhRMA and JPMA presented in October 2014 a joint document detailing various proposals related to public policies in this area, including: i) fair access to medicines and treatments; ii) efficiency and safety of healthcare systems; iii) universal health care, and; iv) fostering of innovation.

NON-TRANSMISSIBLE DISEASES

Coinciding with the World Cancer Congress in Melbourne at the end of 2014, IFPMA was invited to give a presentation on the contribution of the innovative pharmaceutical industry to the treatment of such diseases.

IFPMA published a document and infograph, which, under the title *Enhancing Access to Cancer Care*, compiles information on a series of initiatives on access to oncological medicines developed by the innovative pharmaceutical industry worldwide.

The aim of this material is to inform governments, health professionals and patients of the existence of these initiatives, and to report on the barriers that exist for research, development and the generalized use of available cancer medicines, while emphasizing the benefits of multilateral and collaborative initiatives between different players in this area.

3.4 THE PHARMACEUTICAL INDUSTRY IN SPAIN AND WORLDWIDE

3.4.1 THE PHARMACEUTICAL INDUSTRY IN EUROPE

Analysis of the evolution of any business sector must be placed in the context of the general evolution of the economy in the period being considered. In this sense, after two years of stagnation, the European Union and the Eurozone rebounded into growth in 2014 by recording increases in GDP of 1.3% and 0.9%, respectively.

Economic growth in Europe is still weak, however, and unequal and can be divided between the most important economies, countries like the United Kingdom, which grew at an above average rate (2.8%), those like Spain and Germany whose economies grew in line with the EU average, and others still in stagnation (France) or recession (Italy).

The European Commission has improved its growth forecasts for 2015 and 2016

The recovery of economic activity that took place in 2014 translated into greater job creation, which allowed the unemployment rate in the EU-28 to fall from 10.8% of the active population in 2013 to 9.9% in 2014, even if it is still far from the pre-crisis levels (2007 and 2008) when the rate was around 7%.

Also in 2014, fiscal consolidation progressed with the combined government deficit in the EU-28 reducing for the fifth year running, falling from 6.9% in 2009 to 2.9% today.

As for the most immediate future, although geopolitical risks persist that could affect the stability of economic growth (Greece, Russia, Ukraine, etc.), as could the possibility of deflation, there are other factors (evolution of the price of petrol, the expansive monetary policy by the European Central Bank, the Juncker Investment Plan, deprecation of the euro, etc.) which invite the thought that the positive macroeconomic data above should not necessarily be taken as given.

The former considerations do explain, however, why EU growth forecasts for 2015 are more positive. The European Commission, in its *European Economic Forecast- Spring 2015*, estimates a GDP growth rate of 18% for the EU-28 in 2015, which the same report says will continue upwards to 2.1% in 2016.

As for the pharmaceutical sector, despite the better economic perspective, fiscal adjustment continues. The Member States' health budgets continue to be subject to tight control and this is translated into containment measures as far as public health expenditure is concerned. Logically, this has a great effect on the evolution of a market such as pharmaceuticals, which depends strongly on public budgets and economic regulations.

These public pharmaceutical spending containment measures also translate into restrictions on access to the market for certain products and into growing pressure on medicine prices, which at the same time generates a cascade effect on countries which link their prices to those in other countries.

These difficulties have a special effect on European markets, although there are other factors that drive global growth in the pharmaceutical sector such as the increasing appearance of new products derived from a greater productivity in pharmaceutical R&D.

According to forecasts by consultants IMS Health1, the growth rate of the five main European markets in 2014-2018 will be in the range of 1% to 4%, above the 2.2% recorded per year in 2009-2013, but considerably below the global growth foreseen for the sector at international level, predicted to be 4-7%.

Of the five big European markets, the United Kingdom will grow most during 2014-2018 (average annual rate of 4-7%), followed by Germany and Italy (2-5%), with Spain (-1% to +2%) and France (-2% to +1%) recording close to zero growth.

As well as market growth, we highlight below other important indicators for the European pharmaceutical industry, in which Spain holds an important position.

Spain remains the fifth biggest market in Europe in terms of sales and job creation

As the table shows, Spain is the fifth biggest market in Europe in terms of sales and job creation, behind Germany, France, Italy and the UK, and the sixth biggest European market in terms of production, after these four countries and Ireland.

[1] IMS Market Prognosis, Septiembre 2014. The data correspond to the total pharmaceutical market in each country (pharmacy shops + hospitals).

GENERAL PHARMACEUTICAL INDUSTRY DATA FOR THE EU-15 (2013)

COUNTRY	Nº LAB (1)	PRODUCTION (M€) (2)	JOBS	INT. SALES (EFP) (M€) (3)	EXTERNAL TRADE (EFP) (M€) (4)	
					IMPORTS	EXPORTS
Germany	305	29,010	110,036	26,960	35,243	56,952
Austria	116	2,692	12,226	3,207	6,787	7,574
Belgium	130	7,600	33,701	4,432	30,918	36,789
Denmark	34	8,725	21,150	2,095	3,476	9,520
Spain	**190**	**14,486**	**36,992**	**13,203**	**11,435**	**10,476**
Finland	49	1,450	3,429	2,114	1,831	909
France	221	20,507	93,209	26,744	22,418	28,553
Greece	66	938	13,200	3,949	2,753	1,051
Netherlands	40	6,180	13,000	4,471	13,123	18,936
Ireland	47	18,896	25,441	1,788	4,506	21,239
Italy	186	27,611	62,300	20,941	18,793	18,777
Portugal	122	1,434	8,000	2,804	2,076	732
United Kingdom	55	18,183	73,000	16,671	21,684	24,966
Sweden	85	6,677	11,482	3,653	2,475	6,500
TOTAL UE-15	1,646	164,389	517,166	133,032	177,518	242,974

NOTE: not including Luxembourg due to its lack of representativeness.

1 Member companies of EFPIA associations.

2 Data refers to proprietary medicinal production activities and raw materials for human and veterinary use, except for Germany, Spain and Ireland, where it corresponds only to activity destined for human use.

3 Includes sales through pharmacy stores, hospitals and other distribution channels.

4 External pharmaceutical trade (SITC 54), including veterinary products.

SOURCE: FARMAINDUSTRIA from EFPIA and Eurostat (Comext Database)

3.4.2 THE PHARMACEUTICAL INDUSTRY IN SPAIN

R&D&I

As the Spanish Government itself recognizes, investment in research, development and innovation (R&D&I) is an essential factor in the development of an economy. Such activities have a positive effect on productivity, competitiveness and, therefore, long-term economic growth.[2]

In this respect, the belief in our country in research and innovation as a means to ensure a more balanced and sustainable growth was endorsed by Law 14/2011 on Science, Technology and Innovation, which in its preamble establishes that ""*… the Spanish productive model based*

[2] Passage extracted from the 2014 Spanish National Reform Programme (p34) sent by the Spanish Government to the European Commisison on 30 April 2014. Available at: http://www.mineco.gob.es/stfls/mineco/prensa/noti-cias/2014/Programa_Reformas_2014.pdf

fundamentally on construction and tourism is exhausted, such that it is necessary to foment a change through support for research and innovation as a means to achieve a knowledge-based economy which guarantees more balanced, diversified and sustainable growth".[3]

To achieve this objective, the Spanish Government prepared the 2013-2020 Spanish Strategy for Science, Technology and Innovation, which constitutes the reference framework in this field for the years to come and established, as one of its four principal objectives, strengthening leadership in R&D&I. Based on that, the document mentioned established a series of objectives to achieve this in the years to come, in which it refers to the research effort of our economy in relation to GDP and the distribution of this effort between the public and private sectors. These objectives are summarized in the following table:[4]

INDICATORS FROM THE SPANISH SCIENCE, TECHNOLOGY AND INNOVATION STRATEGY

INDICATORS OF EFFORT	2010	2016	2020
R&D spending/GDP (%)	1.39%	1.48%	2.00%
Private R&D spending/GDP (%)	0.60%	0.73%	1.20%
Ratio between private and public financing of R&D spending	0.86	1.06	1.70
% financing of R&D spending coming from abroad	5.7%	9.6%	15.0%

SOURCE: INE (National Statistics Institute)

To summarize, the aim the Government has set for 2020 is to double the research effort by the Spanish business sector in relation to GDP and keep constant the percentage represented by the public sector within our economy as a whole. This would mean, as the table shows, passing from the situation we had in 2010, when each euro invested in R&D by the public sector was matched by 0.86 euros from the private sector, to a situation in 2020 where, for each public euro invested in research, 1.70 euros would be invested by the private sector.

The latest available data (2013) show how, from 2010 to 2013, R&D spending in Spain fell by 10.8%, and its weight in relation to GDP from 1.39% in 2010 to 1.23% in 2013.

If an analysis is carried out as to the source of financing of the expenditure, it can be concluded that private initiatives have prevented R&D&I from falling even further. Specifically, during 2010-2013, R&D expenditure financed with public funds fell by 19.4%, decreasing to represent 0.56% of GDP, whereas funding in private initiatives reduced at a much more moderate rate (4.2%), such that it now represents 0.58% of GDP, more than public sector research expenditure for the first time since 2006. As a consequence of this unequal evolution in recent years, the ratio between private and public financing of R&D expenditure increased from 0.86 in 2010 to 1.03 in 2013.

[3] BOE, 2 June 2011.

[4] *Estrategia Española de Ciencia y Tecnología y de Innovación 2013-2020* (p40).- Secretary of State for Research, Development and Innovation, Ministry of Economy and Competitiveness.

The research model in Spain is thus changing, in which the main financial driver has become the private sector. The European Commission has also noted this same trend in private investment. A report by its European Research Area Committee entitled "The Spanish Research and Innovation System"[5] mentions among other recommendations the need to promote public-private collaboration directed at innovation through the establishment of initiatives led by companies, as well as the need to create a favourable environment for innovation which increases the participation of companies carrying out R&D.

In this sense, it seems only right to boost and promote the participation of the pharmaceutical industry in its role as the leading industrial sector in research, backed up by INE data, and this can be done on the basis of the following summary of considerations:

- The pharmaceutical industrial sector is the one that most invests in R&D in Spain, dedicating in 2013 over 883 million euros to research, 19.8% of total R&D spending conducted by Spanish industry as a whole. This percentage is particularly significant if one takes into account the fact that the revenues of pharmaceutical companies add up to just 2.4% of the total for all industry.

R&D ACTIVITY AMONG SPANISH COMPANIES (2013)

SECTOR	R&D PERSONNEL*	R&D SPENDING (M€)			
		INTERNAL	EXTERNAL	TOTAL	% INCR. ON 2012
All industry	37,405	3,283.88	1,182.36	4,466.23	-7.3%
Pharmaceutical Industry	**4,449**	**568.08**	**315.90**	**883.98**	**-11.3%**
Automobile	3,799	328.19	310.06	638.25	-16.2%
Other transport	4,006	567.58	192.60	760.18	-2.1%
- Aerospace	2,831	414.75	133.23	547.98	-1.5%
Computer, electronic and optical products	3,008	175.73	20.71	196.44	-3.7%

* Personnel, full-time equivalent (FTE)

SOURCE: FARMAINDUSTRIA, from INE ('Statistics on R&D activities, 2012 and 2013').

- The pharmaceutical industry leads the ranking of industrial sectors in numbers employed in research, with 4,449 professionals dedicated to these tasks full-time,[6] equivalent to 12% of total employment in R&D created by all industry. It is also highly qualified employment, since around a half of these professionals are researchers.

[5] *ERAC Peer Review of the Spanish Research and Innovation System. August 2014.* Available at: http://ec.europa.eu/research/innovation-union/pdf/erac/es__peer_review_report__2014.pdf

[6] Employment data in FTE (Full-Time Equivalent).

- The pharmaceutical industry is also the industrial sector with the highest female employment ratio in R&D. Women occupy two out of every three jobs created in this area by the pharmaceutical industry. Likewise, one in four female employees working in R&D in industry as a whole works in pharmaceuticals.

- Another important characteristic of pharmaceutical R&D is the high level of self-financing (89.9%)[7]. This particularly signification when one takes into account the volume of investments this industry makes, which makes its financial sustainability less dependent on eventual loan restrictions or any changes that can make external financing more expensive.

- Finally, despite the importance of the data cited above, it must be pointed out that the really important element for the sector is not only to be strongly committed to research, but to ensure that this translates into positive results, contributing thus to the economic development of the country. In this sense, one of the indicators of the efficiency of R&D in a sector is the percentage of companies that apply for a patent during a certain period with respect to the number of companies performing R&D tasks in that sector. On the basis of this indicator, the pharmaceutical sector is the top industrial sector in terms of research efficiency, given that 33% of the pharmaceutical companies carrying out R&D activity registered a patent during 2011-2013.

The pharmaceutical industry is leader in investment in industrial R&D in Spain, which makes it a key sector for the future economic growth of our country

The data above demonstrates the leadership of the pharmaceutical industry in the area of research and its strategic importance when configuring a new growth model for our country as described in Law 14/2011 on Science, Technology and Innovation.

One should not lose sight, however, of the fact that the pharmaceutical industry has suffered four successive years where its market has shrunk (2010, 2011, 2012, and 2013) due to constant regulatory changes, the aim of which has been to reduce public pharmaceutical costs. This has meant that the industry's rate of investment in R&D has slowed down considerably.

Nevertheless, it should also be mentioned that, in the past year, the Government has adopted some incentives and provided support for companies who perform R&D. These measures include:

- The recovery of the deduction in Social Security contributions for research personnel, retroactive from 1 January 2013. This measure involves an immediate reduction in business costs and favours the contracting of research personnel. This was brought about by Royal Decree 475/2014, which develops the 79th Additional Provision of Law 17/2012 of the General State Budget for 2013. In this way, a deduction is recovered that was eliminated by Royal Decree-law 20/2012, and the new decree makes it compatible under certain circumstances with the application of the regime for deducting R&D&I activities established in article 35 of the Consolidated Text of the Company Tax Act.

[7] Self-financing data refers only to internal R&D percentage financed with own funds, since the INE (National Statistics Institute) does not publish data on the level of self-financing of external R&D.

- The maintenance of fiscal incentives for R&D, following the tax reform and the reduction of the rate due to Law 27/2014, of 27 November, on Company Tax. Certain improvements have been introduced to this, mainly in relation to tax credit.[8] Additionally, as of 2015, the effective application of the said tax credit (which can be claimed by companies in the form of payments) allows a rebate for fiscal credit remaining unapplied, due to insufficient quota, up to a limit of three million euros a year. The first effects of this measure can be observed in the draft of the 2015 General State Budget, which provides an additional fund of 427 million euros for this concept.

However, although the measures above represent important progress, they must be completed by specific measures that allow all possibilities to be exploited by sectors that most promote R&D in our country. To advance in this objective, the development of policies would be desirable that, without compromising the spending targets or necessary fiscal consolidation in all areas of Public Administration, permit the conciliation of these objectives with the promotion of the sectors that are called upon to lead the economic recovery in our country along a path of lasting and sustainable growth.

DOMESTIC MARKET

Pharmaceutical company revenues for medicine sales in pharmacies in 2014, net of deductions (Royal Decree-law 8/2010) rose by 0.7% and in the hospital market by 1.2%, giving an overall growth in the medicines market in Spain of 0.9% in 2014.

Some 66.4% of total sales were made through the pharmacy channel, a percentage that has been decreasing in recent years.

DOMESTIC MEDICINES MARKET (EFP, MILLION EUROS)

	PHARMACIES (1)	INCR. (%)	HOSPITALS (E)	INCR. (%)	TOTAL	INCR. (%)
2012	8,863.09	-8.5%	4,317.70	+1.5%	13,180.79	-5.5%
2013	8,778.34	-1.0%	4,425.37	+2.5%	13,203.71	+0.2%
2014	8,841.48	+0.7%	4,479.04	+1.2%	13,320.52	+0.9%

1 Sales of medicines in pharmacies, net of rebates (RDL 8/2010)
E Estimated data. Historical data was recalculated using data obtained from FARMAINDUSTRIA's Annual Hospital Pharmaceutical Debt Survey. Data corresponds to medicine sales to SNS hospitals, net of discounts and rebates (in Catalonia, these only include centres belonging to ICS, the Catalan Health Institute).
SOURCE: FARMAINDUSTRIA, from IMS and own estimates.

[8] Supposing R&D costs for the taxable period are over 10% of the net revenues for the same, companies can raise the amount eligible for deduction for R&D from the company tax from three to five million euros a year..

Pharmacy market

After four consecutive years of falls in sales volumes, 2014 rebounded slightly, by 0.7% , as a consequence of the increase of 0.8% in unit numbers. Notwithstanding, the average price fell by 0.3% compared to 2013, with the decrease in the part of the market likely to be reimbursed by the SNS even more pronounced (-1.2%).

Indeed, growth has not been homogenous in all segments of the pharmaceutical market. So, although the total market grew in 2014, branded medicines by unit fell by 2%, whereas generics grew 9.9%.

Meanwhile, in July, the new reference price Order came into force with amendments established by RDL 177/2014, of 21 May, among them the creation, for the first time, of series without generic medicines. This Order added 170 new series, increasing the number in the Reference Price System to 391, although most of the new series are already included in their corresponding homogenous groups.

The updating of the homogenous groups, when a new generic medicine or competitor in the market is introduced, together with the creation of new reference series, has meant that, at the end of 2014, 78% of the units sold through pharmacies in Spain are at the same price level as the corresponding generic.

The slight 0.7% growth in pharmacy sales in 2014 has not been homogenous; so, while sales branded medicines fell by 2%, generics grew 9.9%

Therapeutic groups

The top four therapeutic groups account for 69.6% of the total market in units and 67.5% in value. The evolution of each of these varied in 2014 as a function of: i) the penetration of generic medicines; ii) the incorporation of innovations, and; iii) how they were affected by the new reference price Order, among other factors.

The Central Nervous System group grew by more than the average, both in units and value, while their average price fell by -2.7%. Some 42% of the units in this group correspond to non-narcotic painkillers, which, although they have a very low average price, recorded a fall of -6% influenced in part by the amendment of the minimum reference price threshold, which went from two euros to 1.60 euros. On the other hand, the average price of anti-psychotics, the subgroup with the most sales, fell by -6.6% due to the lowering of the price of some drugs as a result of the entry of generic rivals.

As for Cardiovascular System medicines, unit sales increased by +1.9%, although this is the group that recorded the biggest fall in its average price (-5.8%), anti-parasites apart. The medicines in this group are among those most affected by pharmaceutical policy measures introduced in recent years, and the average price has been falling every year, from 9.82 euros in 2009 down to 6.19 euros at the end of 2014.

In the case of Digestive System medicines, unit consumption remained the same in 2013, whereas their average price increased by +4.6%. Sales of this therapeutic group are mainly in two subgroups: anti-ulcer and anti-diabetes drugs. Anti-ulcerants remained steady in terms of unit sales, however their average price fell by -2.8% as a result of the dynamic of

SALES OF PHARMACEUTICAL SPECIALTIES IN PHARMACIES BY THERAPEUTIC GROUP (2014)

THERAPEUTIC GROUP	UNITS (THOUSANDS)	QUOTA (%)	INCR. (%)	EFP VALUE (THOUSANDS)	QUOTA (%)	INCR. (%)	AVERAGE EFP (€)	INCR. (%)
N Nervous system	308,046.6	24.5%	+3.7%	2,222,939.6	24.1%	+0.9%	7.22	-2.7%
C Cardiovascular system	243,498.0	19.4%	+1.9%	1,508,224.5	16.4%	-4.0%	6.19	-5.8%
A Digestive and metabolic system	202,096.0	16.1%	+0.1%	1,460,471.9	15.8%	+4.6%	7.23	+4.6%
R Respiratory system	120,471.1	9.6%	-0.5%	1,035,063.7	11.2%	+1.0%	8.59	+1.5%
G Genito-urinary production	52,220.7	4.2%	-0.2%	656,683.8	7.1%	0.0%	12.58	+0.2%
M Locomotor system	90,431.5	7.2%	-2.7%	474,071.8	5.1%	-5.3%	5.24	-2.7%
B Blood and blood-forming organs	63,536.3	5.1%	+2.9%	450,569.6	4.9%	+7.7%	7.09	+4.7%
L Cancer and immune system	6,340.5	0.5%	+0.6%	342,716.9	3.7%	-0.5%	54.05	-1.1%
J Anti-infectives via gene	48,434.7	3.9%	-6.1%	326,407.7	3.5%	-1.5%	6.74	+4.9%
D Skin	49,426.3	3.9%	-1.0%	268,879.8	2.9%	+1.8%	5.44	+2.8%
S Sensory organs	45,789.3	3.6%	-0.9%	230,674.5	2.5%	+2.8%	5.04	+3.8%
H Hormones	20,126.5	1.6%	-5.5%	189,313.0	2.1%	+2.4%	9.41	+8.3%
V Various	1,448.7	0.1%	-5.0%	45,600.3	0.5%	+1.3%	31.48	+6.7%
P Anti-parasites	1,396.7	0.1%	+10.0%	7,672.4	0.1%	-12.3%	5.49	-20.2%
K Hospital solutions	2,998.4	0.2%	+5.8%	3,180.5	0.0%	+2.9%	1.06	-2.7%
T Diagnostic agents	28.0	0.0%	-41.2%	719.7	0.0%	-43.9%	25.73	-4.6%
TOTAL	**1,256,289.3**	**100%**	**+0.8%**	**9,223,190.0**	**100%**	**+0.5%**	**7.34**	**-0.2%**

SOURCE: FARMAINDUSTRIA, from IMS data

the homogenous groups and the reference prices. For its part, anti-diabetic units increased by +2.6% and their average price by +6.3%, influenced by the introduction of therapeutic innovations for this pathology.

Medicines in the Respiratory System group recorded a fall in units by -0.5% and an increase in average price by +1.5%. Nevertheless, in this group only 53% of units sold would enter into the financed segment of the market, in which units grew by +3.4% and the average price fell by-4%.

New launches

During 2014, 345 new medicines were launched in the pharmacy channel, with total sales of 89.7 million euros. 238 of these were generic medicines and 58 of them corresponded to the 11 active ingredients that had lost their patent during the year.

In 2014, a total of seven new active ingredients were sold in pharmacies in Spain, all of them included in the SNS pharmaceutical service.

EXTERNAL TRADE[9]

The productive structure of the Spanish economy has meant that, traditionally, the country is distinctly a net importer, dependent on purchases from abroad more than it produces for foreign markets, which has always made its trade deficit one of the imbalances of the economy.

This tendency became more acute in the years of economic bonanza in which the dynamic nature of Spain's domestic demand drove imports, but less so in times of contraction or slowdown in activity, when purchases from abroad are fewer and, due to weak domestic demand, companies based in Spain find themselves obliged to sell off excess production abroad with the resulting increase in exports from the country.

The behavior of the sector abroad in recessions, together with the increase in competitiveness of the Spanish economy recorded in recent years, explains why the trade deficit in our country fell from 9.5% of GDP in 2007 (the year in which the crisis began) to 1.6% in 2013.

The recovery of the economy in 2014, however, saw a rebound in imports that in turn resulted in an increase in the trade deficit to 2.3% of GDP. As a result, the ratio of export/import coverage in Spain fell from 93.6% in 2013 to 90.7% in 2014, although it is well above the levels prior to the crisis (64.9% in 2007).

The increase in the trade deficit in 2014 is due to imports growing with more force than exports (+5.7% vs. +2.5%), which provoked an increase in the trade deficit to 24.472 billion euros.

As for external trade in pharmaceuticals, the evolution in Spain in 2014 was very similar to the global trade balance, experiencing a more positive evolution in imports (+5.2%) than exports (-2.6%), which saw the pharmaceutical sector coverage rate fall from 89.3% in 2013 to 82.6% in 2014. This is the fourth successive year, however, that this ratio is above 80%, a level unseen before 2011.

[9] The data featured in this section is limited to external trade of goods in general and pharmaceutical products in particular. In both cases, the data relating to 2014 is provisional, being susceptible to later revision, so it must be interpreted with caution.

Pharmaceutical exports remained above 10 billion euros for the fourth year running and represent 4.3% of all exports from Spain, whereas in 2000 they represented just 1.8%. Also, the weight of the pharmaceutical industry as a percentage of Spain's total exports (4.3%) triples when one looks at the revenues in the sector compared those of the total national economy (1.4%).

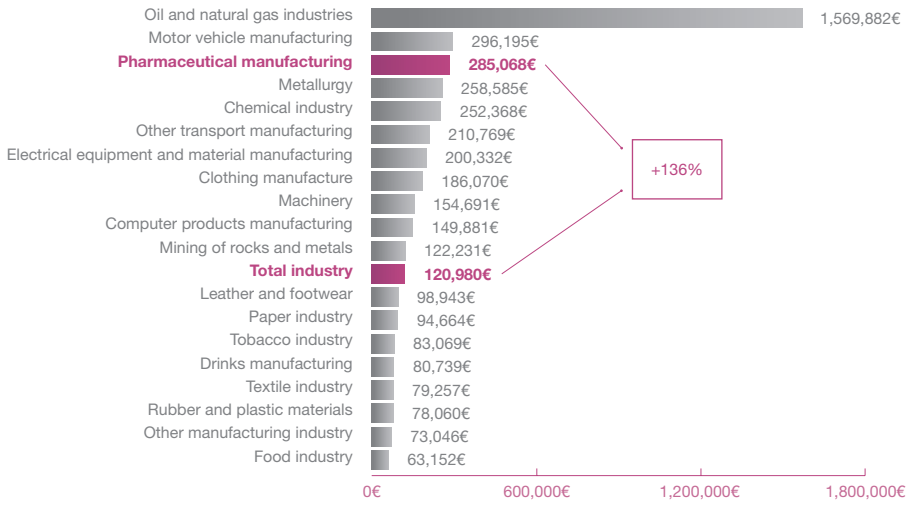
These data demonstrate the relevance of the pharmaceutical sector for Spanish external trade, through a much higher contribution in terms of exports that corresponds to it by size. This is not just the present situation; its contribution has been steady for several years, not only quantitatively but also qualitatively. To illustrate this, it can be pointed out that the pharmaceutical industry represents 21% of Spain's high technology exports (the most difficult to replace due to their complexity), which makes it, along with the aerospace industry, the most important sector in this area.

Also, if we look at the indicator "exports/revenue", the latest available data (2013) shows how the pharmaceutical industry, with a ratio of 74%, easily exceeds the average of all the industrial sectors put together (42%).

On the other hand, if we look at the indicator "exports per employee", the difference is even more remarkable, as the following chart shows, and places the pharmaceutical industry in third position in the sectoral ranking with exports worth more than 285,000 euros per employee.

The external trade coverage rate for medicines in Spain remained above 80% in 2014, for the fourth year running

MAIN SECTORS OF THE SPANISH ECONOMY IN EXPORTS PER EMPLOYEE (2013)



SOURCE: FARMAINDUSTRIA, from Secretary of State for Trade and INE data.

The geographic distribution of external pharmaceutical trade in 2014 shows how the EU-28 continues clearly to be Spain's main trade partner. Some 61% of Spanish purchases of pharmaceutical products from abroad are from our European partners, while 53% of Spain's exports go to them.

However, in recent years, the lack of dynamism in the EU pharmaceutical markets has negatively affected the value of Spain's trade with this region, such that pharmaceutical companies have been obliged to turn increasingly to markets outside the EU, which already represent almost half of exports, a phenomenon that has been especially evident for countries such as Switzerland and the United States, who have gone from jointly importing 17% of pharmaceutical exports from Spain in 2013 to 22% in 2014, as the following table shows.

ECONOMIC AREA	2013		2014 (P)	
	EXPORT	IMPORT	EXPORT	IMPORT
Total World	**100.0%**	**100.0%**	**100.0%**	**100.0%**
EU-28	**56.9%**	**60.4%**	**52.8%**	**61.1%**
France	11.0%	8.0%	9.5%	7.1%
Netherlands	5.5%	5.0%	5.5%	5.7%
Germany	8.5%	12.7%	9.2%	13.9%
Italy	8.8%	5.0%	7.7%	3.8%
United Kingdom	6.6%	11.0%	6.8%	9.5%
Ireland	0.7%	5.5%	0.8%	5.6%
Belgium	1.0%	6.9%	1.1%	7.1%
Rest of Europe	**13.5%**	**8.3%**	**15.8%**	**8.9%**
Switzerland	11.3%	7.8%	13.2%	8.6%
Rest of World	**29.5%**	**31.3%**	**31.4%**	**30.0%**
China	2.3%	2.3%	1.9%	2.6%
Japan	4.3%	0.9%	3.7%	0.7%
India	0.2%	0.8%	0.3%	0.8%
United States	5.6%	19.9%	8.6%	18.9%

SOURCE: Ministry of Economy and Competitiveness, Secretary of State for Trade. P: provisional.

SOCIAL SECURITY PHARMACEUTICAL SPENDING

According to data from the Ministry of Health, Social Services and Equality, in 2014 public spending in pharmacies rose by 1.92%, to 9.36 billion euros as a result of a 1.05% increase in the number of prescriptions and a 0.86% increase in the average spending per prescription. 2014 was the first year with a slight increase in public pharmaceutical spending following four successive years in which it decreased.

SOCIAL SECURITY SPENDING BY PRESCRIPTIONS DISPENSED IN PHARMACIES

YEAR	SPENDING (M€ EFP VAT)	INCR. (%)	NO. OF PRESCRIPTIONS (MILLIONS)	INCR. (%)	SPENDING/ PRESCRIPTION (€)	INCR. (%)
2010	12,207.7	-2.4%	957.7	+2.5%	12.75	-4.8%
2011	11,136.4	-8.8%	973.2	+1.6%	11.44	-10.2%
2012	9,769.9	-12.3%	913.7	-6.1%	10.69	-6.6%
2013	9,183.2	-6.0%	859.0	-6.0%	10.68	-0.1%
2014	9,360.0	+1.9%	868.6	+1.1%	10.78	+0.9%

SOURCE: Medical Prescription Invoicing, Ministry of Health, Social Security and Equality

REGIONAL DISTRIBUTION OF PHARMACEUTICAL SPENDING PER CAPITA

In 2014, pharmaceutical spending per capita was at 200.10 euros per inhabitant, having recorded an increase of 2.7% following the decreases of recent years, although it continues to be less than the spending per head in 2003, when it reached 209,30 euros.

There are important differences at regional level. Extremadura (€267.90) and Galicia (€247.90) have the biggest ratio of pharmaceutical spending per capita, while Madrid (€163.80) and the Balearic Islands (€162.50) have the lowest. As for the evolution of this spending per capita, it only fell in only Galicia and the Basque Country.

PHARMACEUTICAL SPENDING PER CAPITA PER AUTONOMOUS REGION, 2014

AR	SHARE OF SPEND (%)	SPENDING PER HEAD 2014	
		EUROS	INCR. (%)
Extremadura	3,1%	267,9	+6,4%
Galicia	7,3%	247,9	-1,0%
Asturias	2,7%	238,2	+3,3%
Community of Valencia	11,8%	220,6	+2,0%
Aragon	3,1%	220,3	+3,3%
Castile-La Mancha	4,8%	217,1	+2,6%
Castile & Leon	5,8%	217,0	+3,7%
Murcia	3,4%	215,8	+1,3%
Cantabria	1,3%	209,9	+3,7%
Basque Country	4,8%	205,3	-3,7%
La Rioja	0,7%	204,2	+3,5%
Canaries	4,5%	200,9	+4,4%
National	**100,0%**	**200,1**	**+2,7%**
Andalusia	17,5%	194,8	+3,0%
Navarre	1,3%	193,1	+4,7%
Catalonia	14,4%	178,7	+2,6%
Madrid	11,3%	163,8	+6,1%
Balearics	1,9%	162,5	+4,7%

SOURCE: FARMAINDUSTRIA, from the Ministry of Health, Social Security and Equality, and INE (National Statistics Institute).

4

SERVICES TO MEMBER COMPANIES

FARMAINDUSTRIA has made an important effort in recent years to broaden and improve the services it provides to member companies, as well as the own activity of the Association, of an institutional nature, carried out since it was founded. In 2013, it was necessary to modify the way in which these services were provided due to changes introduced in article 20, 1.12, of the Law on Value Added Tax (IVA).

This modification, which entered into force on 1 January 2013, declared the fees paid to the Association, for the institutional work it carries out for its activity as such a body, exempt from VAT, without the possibility of renouncing the exemption. Notwithstanding, the modification means the Association is still obliged to pass on VAT to members, or third parties distinct from them, on the amounts paid for the services provided.

In this respect, although FARMAINDUSTRIA was offering services distinct from its own as an association, both to its members and third parties, until now it had not needed to differentiate income coming from one or the other concept, since both were subject to, and not exempt from, VAT.

The legal change introduced means that the services of an associative or institutional nature are, in every case, exempt from VAT, which implies that these income streams, as of 1 January 2013, will be treated differently fiscally, such that it has become necessary to distinguish between the two kinds of services provided: FARMAINDUSTRIA's own institutional activity, and the services distinct from it.

4.1 ONLINE SERVICES

One of the main objectives of the provision of services to member companies is to keep the users with authorized access to our information systems permanently provided with documentation.

FARMAINDUSTRIA's commitment to the environment and the elimination of paperwork from practically all dispatching of information means the web services have also become a pillar of the Association with respect to communication.

NEW INTRANET – RESTRICTED AREA

The Restricted Area within the Association's Intranet supplies more than 2,000 authorized users in the pharmaceutical industry with documentation.

The Intranet contains more than 70,000 specialized documents, from circulars, flashes and bulletins to legislative texts and press summaries.

Over the past year, the needs of the users and the way they access the Intranet has been deeply analyzed, with the aim of categorizing them better and improving the search engines.

In this way, a new Intranet has been designed, which represents a turning point in the way in which information is accessed and it will respond better to the needs of the FARMAINDUSTRIA Member Companies.

New sections have been included to allow the Association to become closer to the user, which will also help guide the future development of this tool.

The new Intranet is doted with new areas, such as Alerts, Suggestions, New Developments and Subscription Management through User Profiles. A new section with relevant information from each department will also become available soon.

At the same time, inside the Restricted Area, a complete tool has been specifically developed for the management of the Association's internal Working Groups, and will soon be available for rapid sharing and organization of the information generated by each WG.

PUBLIC PORTALS

The public portal of FARMINDUSTRIA is specially designed to communicate information openly, clearly and rapidly to anyone who might inquire of the pharmaceutical industry in Spain.

It also hosts the websites for: i) Innovative Medicines, and ii) Somos Pacientes ('We Are Patients'), which have information related to the technological platforms for innovation in medicines and the collaborative environment for the used of the community of patients' associations, respectively.

Then there is the FARMAINDUSTRIA-developed *e4ethics* portal, a European initiative to control the promotion of the prescription and interact with health professionals.

The Self-Regulation System website is also immersed in a process of renewal, which we hope will finish in 2015. A special emphasis here is being placed on improving the way the information is organized to simplify and maximize the flexibility of user access to the website.

STATISTICS RELATING TO THE ONLINE SERVICES

FARMAINDUSTRIA's general portals recorded more than two million individual accesses during 2014, making it the public portal with the highest number of registered accesses, with more than 60% of all enquiries.

The United States continues to be the country source with most visits, followed by Spain, Germany, the United Kingdom and Switzerland.

The number of daily users remained steady at around an average of 7,000 individual accesses, with peaks in activity of between 10,000 and 13,000 accesses.

813,577	United States
606,743	Spain
101,019	Germany
52,401	United Kingdom
28,391	Switzerland

FARMAINDUSTRIA'S portals for the general public recorded more than two million individual accesses during 2014

4.2 WORKING GROUPS

The aims of the Working Groups of the Association focus on fostering the active participation of the member companies, informing about the initiatives of the different Public Administrations and helping to form, when the Governing Bodies request it, the position of the industry in important sectoral areas, in order to submit proposals to the Governing Bodies of the Association, which in turn communicate them to the authorities and corresponding interlocutors.

In October 2014, under the general renewal of FARMAINDUSTRIA's Governing Bodies, the Working Groups were renewed for a period of two years. New Groups were created with the aim of covering the needs facing members. Likewise, rules of operation have been redefined, although the rules in the area of competence that underpin all meetings and actions remain the same.

There are presently 21 Working Groups operating in the Association, whose subject areas and titles are as follows:

1 Sustainability and Economic Regulation.
2 Health Technologies Assessment.
3 Hospital Debt.
4 Hospital Market.
5 Technical Regulation of Medicines.
6 Biological Medicines.
7 Manufacturing and Traceability.
8 Environment.
9 Pharmacovigilance.
10 Vaccines.
11 Pharma-Biotech.
12 Medical and Research Directors (BEST).
13 Clinical Research.
14 Legal Services.
15 Tax.
16 Human Resources.
17 Code of Best Practices.
18 Competitiveness and Internationalization.
19 Relations with Autonomous Regions.
20 Communication and Corporate Social Responsibility.
21 Patients.

Additionally, due to the material they have to deal with and the lower level of participation, several ad hoc Groups have been created with the aim of deepening knowledge in diverse areas and later translating the results to the full Working Group chosen to consider them.

There now follows a summary of the activities of the Farmaindustria Working Groups during the last year.

SUSTAINABILITY AND ECONOMIC REGULATION WORKING GROUP

Analyzing all the legislation related to the pharmaceutical sector has been the focus of the work of this Group during 2014.

It should be pointed out that a good part of the work has centered on detailed monitoring of the implementation of Royal Decree 177/2014, of 21 March, regulating the reference price system and homogenous groups of medicines in the SNS, and certain information systems in the area of financing and pricing of medicines and healthcare products.

In this sense, the Group worked intensively on preparing statements on the first Ministerial Order SSI/1225/2010, developing the Royal Decree above, which Farmaindustria appealed against under contentious administrative law.

The Working Group on Sustainability and Economic Regulatory Activity analyzed in great detail all the important legislation affecting the sector to appear in 2014

Meanwhile, the correct implementation of Royal Decree 81/2014, of 7 February, establishing standards to guarantee cross-border healthcare and which modifies Royal Decree 1718/2010, of 17 December, on medical prescriptions and dispensing orders, was one of the other main items analyzed by the Group, which constituted an ad hoc Group to carry out a comprehensive monitoring in this area, developing a plan to defend brands according to the legislation in force.

At the same time, the Group continued to monitor the evolution of public pharmaceutical spending (dialoguing with the Government as part of the process) as well as the situation of new applications and indications waiting for prices to be established. The Group repeatedly pointed out the delays to MSSSI, urging it to rectify the problem. It also continuously monitored the monthly publication of the list of medicines subject to deductions under Royal Decree-law 8/2010.

The Group regularly received information on the evolution of the debt for supplies of medicines to public hospitals, as well as on the measures and instruments formulated by the State to guarantee payment to the companies. Also, in the meetings of the Group, members monitored the regulatory initiatives affecting the hospital market, both at regional and national levels.

Finally, it should be mentioned that, at the close of this Annual Report, MSSSI continued to work on the drafting of a future Royal Decree on Pricing and Financing. The Association communicated the position of the industry on different key aspects affecting the sector, both in relation to the pricing and financing procedure in the broadest sense, and on

specific aspects such as the development of article 90 of the Law on Guarantees and Rational Use of Medicines and Healthcare Products.

The Hospital Debt Working Group monitored the impact of the measures to tackle late payment to pharmaceutical companies, especially the Regional Liquidity Fund and the 2nd Suppliers' Payment Plan

HEALTH TECHNOLOGIES ASSESSMENT WORKING GROUP

The HTA-WG was created in FARMAINDUSTRIA in 2006 with the aim of producing technical papers on the main questions affecting procedures for the economic evaluation of medicines.

During the past 12 months, the Group has met on three occasions, having monitored the preparation of Therapeutic Positioning Reports by AEMPS and contributed to the submissions for the preparation of regional, national and European guidelines (EUnetHTA) on the different aspects of the economic assessment of medicines.

The Group, via FARMAINDUSTRIA's participation in EFPIA's HTA Task Force, has also simultaneously been informed on a permanent basis of the main developments in the HTA area in Europe.

Over the next year, the Group will continue to work on these and other technical questions that express the approach of the pharmaceutical industry on matters related to medicine evaluation procedures.

HOSPITAL DEBT WORKING GROUP

Over the past 12 months, the Group has, as in previous years, performed a monthly monitoring of the evolution of the debt for medicine supplies to SNS hospitals, as well as the average payment periods (Days Sales Outstanding, or DSO) of the different Regional Health Services.

The Group also monitored and quantified the impact on the pharmaceutical industry of the measures against indebtedness, especially the 2014 Regional Liquidity Fund and the 2nd Suppliers' Payment Plan, which resulted in 2014 having the best year-end situation since the problem began to be recorded in 1996, with the SNS DSO falling below 200 days for the first time.

The Group also performed a detailed monitoring of all the legislation related to late payment, such as that connected to commercial debt control mechanisms and the methodology used to calculate the average payment period for suppliers, which led it to publishing, monthly, the official average payment periods of the ARs as of September 2014. The limitations of the methodology used by the ARs, and its differences with the standard used by the private sector in the trade of goods (the DSO), were analyzed by the Group and communicated to the different stakeholders to ensure the correct interpretation of the data published by the ARs in this area.

Meanwhile, the Group set up in May 2014 an ad hoc subgroup on Electronic Invoicing with the aim of analyzing the regulatory development of Law 25/2013, of 27 December, introducing the electronic invoice and creating an accounting register of invoices in the public sector. This Subgroup performed an intensive and detailed monitoring of all state and regional legislature, and has been publishing and monitoring all the incidents related to the introduction of the

electronic invoice, while urging the ARs and MINHAP (the Ministry of the Treasury and Public Administrations) to deal with them promptly. The Subgroup reported its progress in detail to the full meeting of the Hospital Debt Working Group.

HOSPITAL MARKET WORKING GROUP

The activity of the Hospital Market Working Group focuses on monitoring the hospitals market and the analysis (economic, legal and from the perspective of market access) of the various initiatives being carried out at national and regional levels, especially concerning regulation, centralized contracting, hospital calls for tender containing significant anomalies, implementation of regional shared risk models and other management agreements, and early payment guarantees, with the aim of preparing the sector's position in these areas. The work carried out included identifying barriers to accessing innovation in hospitals.

The Group, in order to fulfill its objectives, works in close coordination with the Hospital Debt Working Group, the WG on Autonomous Regions and the Economic WG. It is made up of representatives from 47 laboratories and met three times over the year.

TECHNICAL REGULATION OF MEDICINES WORKING GROUP

Main activities of this Working Group lie in analyzing the provisions of European Community regulations and the legislation published by AEMPS in the area of the technical regulation of medicines.

During 2014, the Group reviewed the regulations in course and the observations made during the passage of the drafts. It also analyzed the questions and answers concerning information to include in technical descriptions, labels and prospectuses, which AEMPS plans to publish.

Main issues dealt with in the Group included: i) the decision to collaborate with ONCE to widen the current list of abbreviations made in Braille; ii) refusals, revocations or temporary suspensions of marketing authorizations by AEMPS; iii) the issuing of new distribution authorizations for patent-holding laboratories, and Iv) the future legislation on the unitary identification of packaging (Delegated Acts of the European Commission).

Meanwhile, the Head of the Information Systems Division at AEMPS visited the Group and explained present and future projects involving the Agency's databases, which are leaning towards increasing centralization of information at EU level.

The Biological Medicines Working Group was created in 2013 as a result of the growing importance of this type of medicine and the way it is treated by regulators

BIOLOGICAL MEDICINES WORKING GROUP

The growing importance of biological medicines, along with the regulatory problems arising due to the appearance of biosimilar medicines, justified the constitution of this Group in September 2013.

Biological medicines differ in many of their characteristics from chemical medicines and their use must take this into account. One of the differences is the obligation to prescribe these medicines by brand, a very important consideration given the appearance of biosimilars and the non-interchangeability of biological medicines. The companies belonging to the Group thus carried out a survey on how these medicines were being prescribed in hospitals and found out that many hospitals were not complying with what was foreseen in the legislation and the brand was not figuring in biological medicine prescriptions.

Another point on the agenda of the Group concerned orphan drugs. Although these have specific characteristics, they can easily come under the areas treated by the Group since many orphan medicines are biological. Each meeting heard about the initiatives being undertaken in this field in Spain and the most important aspects occurring at EU level.

The Group also monitored the international situation. Many evaluation agencies are now preparing directives and developing legislation with respect to the use of biosimilar medicines. In this sense, FARMAINDUSTRIA held, with IFPMA, a bilateral meeting of the working groups on biological medicines in both organizations with a fruitful exchange of views.

The Manufacturing and Traceability Working Group in 2014 very closely followed the problem of supply shortages caused by what is known as "reverse distribution" of medicines

MANUFACTURING AND TRACEABILITY WORKING GROUP

Since the entry into force of Royal Decree 782/2013, on the distribution of medicines for human use, the Group has been monitoring some of the main aspects regulated by this provision, such as the requirement to comply with correct manufacturing standards on the part of manufacturers and importers of active ingredients and the new distribution conditions, particularly since these new obligations risk interrupting supply where manufacturers are not able to produce the corresponding certifications. Although the laboratories have referred to some problems with suppliers, the situation has not provoked any important supply incidents.

One of the most important problems over the last year has been the shortage of medicines as a result of what is known as "reverse distribution", an illegal practice by some pharmacies in league with certain distribution warehouses, leading to medicines destined for patients in Spain being finally diverted towards other markets, causing supply shortages in the country. AEMPS, in its Inspection Technical Committee, has driven and supported legislative and operational changes to detect and report this kind of practice. Some ARs, such as Catalonia, held a forum with supply chain players to adopt measures to put an end to the practice. The large media coverage that lawsuits against this kind of practice have generated, and the recent amendment of the penal code in this respect, will also help to curb this illegal trade.

Finally, AEMPS has asked the different actors in the medicines value chain to promote the creation of a national consortium permitting the verification of medicines before they are dispensed, although we are still awaiting publication of the European Commission's Delegated Act in this area. It will detail essential requirements such as serialization of medicines, safety measures and the medicines that will be seriously affected by the

measures. The Group is monitoring the issue, and the Director of AEMPS attended one of its meetings to discuss the matter.

ENVIRONMENT WORKING GROUP

During 2014, the Environment Working Group collaborated with SIGRE to monitor legislation that is important to the sector in the area of environmental responsibility, fluorinated greenhouse gases and priority substances in the area of water policy, as well as other actions in the environmental area related to the pharmaceutical industry (waste, disposal and energy efficiency).

Farmaindustria also continued its membership of the Environment Committees of various business organizations in Spain, such as CEOE and FEIQUE.

PHARMACOVIGILANCE WORKING GROUP

Pharmacovigilance is a continuous activity, intrinsic to the marketing of medicines and constantly being perfected. This Group holds bimonthly meetings in which it deals with matters in five well-defined areas: i) inspection and audits: ii) risk management plans; iii) the Master Files; iv) spontaneous notifications, and; v) periodic safety reports. This structure allows the review, in each work session, of the most important new developments, and the submission of proposals and measures to the Group for adoption, to improve the operation of units in the laboratories themselves.

The Pharmacovigilance Working Group deals with the main questions and clarifications needed in this area as they arise at national and European level

One point that is on the agenda of every meeting of the Group is the reporting of the progress being made by the ad hoc group on Scientific Information, formed by experts from the companies. The aim is to increase knowledge about the kind of consultation requests being received by the laboratories and options for improving the efficiency of responses, among other matters.

Finally, the Group deals with the main questions and clarifications needed concerning new technical provisions in the area of pharmacovigilance, as they arise at national and European level. It meets with the official responsible for pharmacovigilance in the AEMPS once a year, in addition to maintaining regular written consultations with the Agency in this area.

VACCINES WORKING GROUP

Farmaindustria's V-WG, in constant touch with EFPIA's Vaccines Europe agency, regularly monitors issues related to vaccines in order to preserve the importance and special considerations for this type of medicine, due to its preventive nature and the healthcare role it performs.

The main issues the Group deals with include trying to improve the calendar for vaccination in Spain, launching the flu vaccination campaign, and reinforcing prevention values, both from the viewpoints of economic development and sustainability of the healthcare system. The Group also promoted various actions aimed at fostering the value of vaccines demonstrating special features with respect to other medicines, as well as the benefits they bring to society.

Finally, the Director General of Public Health was invited to one of the Group's meetings and had the opportunity to get to know the main subjects of interest for member companies marketing vaccines and explain the Directorate-General's 2015 programme in the vaccines area for 2015.

PHARMA-BIOTECH WG

This WG, made up of 35 companies, has among its objectives the promotion of cooperation between industry, small biotechnological companies and public research centres, emphasizing the differentiating and complementary value contributed by FARMAINDUSTRIA.

One of the main tasks of the Pharma-Biotech Working Group is to promote public-private cooperation instruments in biotech pharmaceutical R&D

FARMAINDUSTRIA launched the Pharma-Biotech cooperation programme in 2011. Between 2011 and 2014, it held 12 interactive meetings between the two sectors, mainly in the areas of central nervous system, oncology, respiratory system, inflammation and autoimmune diseases. Some 95 specialists took part in these meetings (33 pharmaceutical companies and 62 representatives of the biotech sector).

Each meeting was set up as a specific forum to identify the added value that can be got by exchanging information between biotech demand and supply, with sufficient differential content in the area of new therapies and innovative medicines. Two such days were held in the framework of this programme in 2014. The first took place at FARMAINDUSTRIA head office in Madrid on 4 July, while the second was held on 26 September at BioSpain in Santiago de Compostela. These dealt with different therapeutic areas, including oncology, central nervous system and neurodegenerative diseases. All the presentations are available at: www.medicamentos-innovadores.org.

From January to March 2015, various meetings were held with pharmaceutical company representatives taking part in the above meetings and representatives of the biotech sector, with the aim of verifying the level of satisfaction with the programme, identifying and confirming their most important aspects, and listening to suggestions for improvements with the aim of maximizing the usefulness of the meetings for the members. All those interviewed considered the initiative very valuable and expressed their desire that the programme continue.

The PB-WG also pursued the promotion of public-private cooperation instruments in R&D. As such, several meetings were held with the CDTI (Technological and Industrial Development Centre) and the Ministry of Economy, with the aim of studying the various funding possible in this area. A workshop held on 4 February 2015, explaining the main characteristics of such aid and the next calls for applications planned by the CDTI, were of great interest to the members.

The Group also continues to stimulate the participation of the industry in national and international pharmaceutical R&D programmes, especially in the Innovative Medicines Initiative (IMI) and the activities of the PTEMI (Spanish Technological Platform for Innovative Medicines).

MEDICAL AND RESEARCH DIRECTORS (BEST PROJECT) WORKING GROUP

This Group, set up nine years ago as a platform for clinical research excellence, comes under the Spanish Technological Platform for Innovative Medicines (PTEMI). It focuses on designing the strategy for, and promoting competitiveness in, clinical research in Spain, facilitating processes and improving performance indicators (delays, recruitment and international ranking) to achieve the best environment for performing clinical trials, with a special emphasis on early phases.

After years of work towards converting Spain into an attractive location for clinical research, the following advances can be highlighted: i) greater involvement of all the stakeholders (hospitals, researchers, scientific associations, patients, CEIC, etc.); ii) a cultural change in the consideration of clinical research as being something positive for all stakeholders; iii) improved international competitiveness of Spain, by using metrics, and; iv) more fluid dialogue between strategic players (industry, centres and ARs).

The following table presents some results from the BEST project.

The BEST Project currently includes 45 pharmaceutical companies, three scientific associations, the Hospital University of Navarre, 13 ARs and 50 centres.

		2004	2013	INCR.%	CAGR*
1	No. of clinical trials in BDMetrics	117	2.161		
	No. of trials in the industry authorized by AEMPS	473	601	+27%	+3%
2	Clinical research spending by the industry (million €)	299**	457	+53%	+5%
	R& D spending by the pharmaceutical industry (million €)	706**	928	+31%	+3%
3	*Overall time from start of first-in-patient trial (days)*	244	186	-24%	-3%
	Difference with European first-in-patient (days)	95	40	-58%	-9%
	Authorization following CEIC ruling (days)	37	20	-46%	-7%
	Processing of contracts (days)	164	126	-23%	-3%
4	Recruitment efficiency (hired/planned in %)	58%	101%***	+78%	+7%
5	Trials in initial phases (1 and 2 as % of total)	37%	49%	+32%	+3%
6	Trials with primary care centre participation (% of total)	14%	10%	-26%	-4%
7	Oncology trials (% of total)	28%	37%	+32%	+3%
	Cardiovascular trials (% of total)	15%	10%	-31%	-4%
	Neuroscience trials (% of total)	9%	5%	-38%	-6%

* CAGR: *Compound Annual Growth Rate*
** 2005 data
*** 2012 data (due to lack of sufficient data). Percentage varies by therapeutic area and Autonomous Region.

FARMAINDUSTRIA performed a study to find out more about the clinical research carried out by the pharmaceutical industry in private centres within the BEST Project. The data was presented jointly with the Institute for Healthcare Development and Integration (IDIS) in a seminar held at Madrid's Sanchinarro Hospital that focused on the oncology therapeutic area. Over 120 parties involved in pharmaceutical R&D attended the event.

The work programme for this Working Group in 2015 is the following: i) a pilot project to integrate independent clinical research data from hospitals; ii) the 3rd edition of the "Guide to Phase 1 Units"; iii) attractiveness of early-stage clinical research in Spain (previous projects were carried out in 2007 and 2010); iv) realizing the potential of clinical research in primary care via the joint working group with SEMERGEN, SEMFYC and SEMG; v) integration of data with the Spanish Clinical Studies Register of AEMPS, and vi) organization of workshops by therapeutic area with a view to recruiting more patients.

The Clinical Research Working Group informed the AEMPS about the position of the industry in areas related to the procedures followed in pharmaceutical research

CLINICAL RESEARCH WORKING GROUP

The Group monitored the year's Spanish and European legislative initiatives in the clinical research area, especially Regulation 536/2014, of the European Parliament and Council of 16 April 2014, published in the EU Official Journal on 27 May 2014, and the draft Royal Decree in Spain in this area which will be published in the months to come. Both texts pursue greater transparency, simplification and harmonization in the authorization processes, with the aim of improving competitiveness in clinical research.

FARMAINDUSTRIA held meetings with AEMPS to communicate the position of the innovative industry on the Regulation, supporting the Commission's initiative to simplify assessment and authorization procedures, reduce bureaucracy, strengthen cooperation between Member States, and increase the consistency of procedures used for research and transparency to ensure the maximum protection of people participating in the research. In this sense, the Association communicated the importance of the regulatory agencies and ethics committees conducting evaluations of the trials in parallel, in order to meet the deadlines proposed by the new legislation and considerably reduce evaluation time. FARMAINDUSTRIA also communicated its, and EFPIA's, position to AEMPS on transparency and commercially confidential information, as well as the need to modify Annex VI through a Delegated Act.

In relation to deviations from the clinical trials protocol, which have to be notified to the AEMPS, it was proposed that a joint FARMAINDUSTRIA-AEMPS Working Group be established to clarify what needs to be notified, which information should be included in the deviations and which procedure should be followed by the organizers of the trial when communicating the matter. In December 2014, a document was presented to AEMPS on this matter and is currently awaiting the approval of the Agency.

The Group also brought up the problem that exists on verification of computer systems, in hospitals in Spain, using electronic records and registers. In this sense, it is considered important to make available a certificate of validation, agreed between hospitals that perform more clinical research, in order to homogenize the documentation required on access to clinical records. The Group continues to work on this matter and has requested a meeting with AEMPS to make further progress.

Meanwhile, a working group was established a few months ago to update the Best Clinical Practices Course, with the objective of reviewing the nine modules that currently make up the course and adapting them to the new European (Clinical Trials Regulation) and national (future Royal Decree on clinical trials) legislation.

LEGAL SERVICES WORKING GROUP

Once again, the Group spent the year focused on informing and monitoring all the measures adopted at European, national and regional level, as well as analyzing the jurisprudence affecting the sector.

Legislation approved in the past year included: i) EU Regulation 536/2014 of the European Parliament and Council, of 16 April, on clinical trials of medicines for human use, which annuls EC Directive 2001/20; ii) Organic Law 1/2015, of 30 March, amending Organic Law 10/1995, of 23 November, of the Penal Code; iii) Royal Decree 177/2014, of 21 March, regulating the reference price system and homogenous medicine groups in the SNS and certain information systems in the area of financing and pricing of medicines and healthcare products; iv) Order SSI/1225/2014, of 10 July, updating the reference price system for medicines in the SNS, and; v) AEMPS Explanatory Note of 14 April on the marketing of medicine formats with national authorization (this is the object of more detailed analysis in other sections of this Annual Report).

Other legislative proposals observed to be in process include the draft law on the mercantile code and the draft patents law, as well as other initiatives undertaken by the administrations at central (framework agreements with INGESA) and regional (framework agreement on therapeutic equivalents and auctions in Andalusia, the CatSalut pharmacological tariff, etc.) levels. The Group also monitors judicial procedures and declarations affecting the sector.

The Group holds two meetings a year that are attended, and maintains regular telephone and email contact between them to resolve any questions which emerge in its area of activity.

TAX WORKING GROUP

During 2014, the Group monitored developments with fiscal implications for the sector, holding various forums to tackle important themes in this field.

It held the Seminar on Fiscal Developments, open to all members, which analyzed the main tax measures adopted in the laws supporting entrepreneurs, on environmental taxation and the General State Budgets, as well as special rules concerning temporary imputation for certain adjustments in Royal Decree-law 14/2013, of 29 November.

Meanwhile, during the year, the Group monitored new legislative developments of a fiscal nature, among them measures introduced by: i) Royal Decree-law 4/2014, of 7 March, adopting urgent measures for refinancing and restructuring corporate debt; ii) Royal Decree 2015/2014, of 28 March, approving the Organic Statute of the Independent Authority of Fiscal Responsibility; iii) Royal Decree 410/2014, of 6 June, amending the VAT Regulation, and others; iv) Royal Decree 475/2014, of 13 June, on deductions in Social Security contributions for research personnel, along with interpretative circulars on its contents, and; v) Royal Decree-law 8/2014, of 4 July, approving urgent measures for growth, competitiveness and efficiency, and later parliamentary validation through Law 18/2014, of 15 October.

The Tax Working Group followed the main legislation with fiscal implications for the pharmaceutical industry

Special mention should be made of FARMAINDUSTRIA's contributions, in coordination with the Tax Group of the CEOE, during the passage of the reform of the main tax regulations, undertaken by the Government. We made many observations on the Bills on personal income tax and earnings by non-residents, company tax and VAT, the IGIC (Spanish tax applied in the Canary Islands) and other special taxes, among others, and through public consultations and proposals for amendments tabled to parliamentary groups.

This fiscal reform, approved by Laws 26/2014, 27/2014 and 28/2014, all of 27 November, was also the object of a one-off session held by the Group with the aim of analyzing in depth its contents and the most serious implications for pharmaceutical companies. Additionally, the Group monitored all the regulatory development of the fiscal reform, including the publication of the Royal Decrees 1073/2014 and 1074/2014, both of 19 December, and the different projects modifying the Regulations relating to personal income tax and company tax, both of which were being processed as this Annual Report reached its close.

Along the same lines, the Group monitored the jurisprudence being established by the EU Courts, as well as the progress in the drafting of the Bill on base erosion and profit shifting (BEPS) and the implications this will have for companies once it is incorporated into national legislation.

Finally, it should be mentioned that the Group followed the legal declarations and resolutions by the tax administration relating to areas of fiscal interest to the industry, particularly those related to the modification of the VAT rate for various healthcare products.

HUMAN RESOURCES WORKING GROUP

HR-WG is formed by the Human Resource department managers of the pharmaceutical companies and was set up to serve the laboratories in all the areas related to labour legislation and to participate in the negotiation of the Collective Agreement through the FARMAINDUSTRIA representatives on the Agreement Negotiating Committee.

During 2014, the Group closely monitored the main developments in labour reform, participating in the consultations sent to it concerning legislative drafts in the field.

The activities in the second half of the year focused on analyzing the 17th CGIQ, which expired on 31 December 2014, with a view to presenting proposals to move forward the negotiation process that began at the end of the year on the new Collective Agreement.

Meanwhile, FARMAINDUSTRIA continued to participate in the monthly meetings of the Mixed Committee on the Interpretation of the Collective Bargaining Agreement, the Socio-Labour Commission in FEIQUE and CEOE, as well as all the equality commissions set up under the auspices of the present Bargaining Agreement, all of which report regularly to the Group.

CODE OF BEST PRACTICES WORKING GROUP

The approval at the end of 2013 of the new version of the Code of Best Practices of the Pharmaceutical Industry brought with it the need to revise (particularly taking account of the important new measures and amendments it incorporates) the document f Consultations (Questions and Answers) on the interpretation of the Code in force until now. Additionally, it was agreed to set a deadline for laboratories to submit enquiries that, if of general interest to the sector, should be analyzed by members of the Steering Committee, which would decided whether to publish them.

The Code of Best Practices Working Group reviewed in depth the document of consultations on the interpretation of the Code in force until now

As such, it is important to highlight the work carried out by the Group and the "G-9",[10] which involved the review and adaptation of existing enquiries, analysis of additional consultations sent in by the laboratories with regard to the new measures introduced by the updated Code, and the selection and adaptation of proposals approved at European level, which, where of general interest for laboratories in Spain, needed to be transposed by the EFPIA national associations to their national codes. As a result of this complex process, the FARMINDUSTRIA Governing Bodies approved the definitive version of Annex II of the Code, later ratified by the General Assembly at its June meeting.

COMPETITIVENESS AND INTERNATIONALIZATION WORKING GROUP

This Group's objective is to foster the industrial competitiveness and internationalization of the member companies. It has intensified its activities in recent years in making internationalization a key element by which Spanish companies could tackle the economic crisis.

FARMAINDUSTRIA has also stepped up its actions in this area through regular contacts with ICEX and also actively taking part in the relevant CEOE committees, the Madrid Chamber of Commerce, and institutions such as Acció in Catalonia.

During 2014, the Group continued to prioritize company and market-specific actions, reaching out in countries such as Kuwait, Poland the United Arab Emirates and Malaysia. Additionally,

[10] The G-9 is an ad hoc group formed by nine laboratories, the constitution of which was agreed in March 2013 by the Governing Bodies of FARMINDUSTRIA, taking into account the effect the new transparency commitments assumed by the pharmaceutical industry could have in the fiscal area, on competence and on data protection. It aims to promote, coordinate and support the communication strategy and launch of the new Code.

it is also working jointly with the Spanish Embassy in Japan and the Japanese pharmaceutical industry association (JPMA), with the aim of organizing a visit to the country by Spanish institutions and companies, hopefully in 2015.

The Group also continued to work on the international section of the Intranet, allowing the laboratories to consult calls for tender, documents and reports to aid their activities abroad. Use of this tool also helped regularize information sharing on individual initiatives by companies and in specific countries, with the support of the Chambers of Commerce and other pro-internationalization bodies with regard to countries such as China, Vietnam, Colombia, Mexico, Nigeria and Ghana.

The Relations with Autonomous Regions Working Group participates in the drafting of reports for the AR Observatory, which holds information on regional healthcare and pharmaceutical policy

RELATIONS WITH AUTONOMOUS REGIONS WORKING GROUP

This Group has the following objectives: i) monitor pharmaceutical policy in the ARs, especially the legislative developments and initiatives which limit medicine supply and constrain the freedom of prescription, endangering fair market access and the single market; ii) strengthen dialogue and the spirit of cooperation with Administrations; iii) find scenarios that make the sustainability of the SNS compatible with patient access to medicines and the development of industrial activity; iv) consolidate strategic alliances with different parties in the healthcare field and find areas of understanding that permit common objectives to be attained; v) set up a regional early warning system to detect and monitor regional policies of prescription-dispensing, and vi) participate in political, scientific and professional forums related to these areas.

The Group held five work meetings in 2014, participated in the drafting of reports for the Autonomous Regions Observatory, the information and consulting tool for companies on situations in the different ARs and which includes important information summaries on regional healthcare and pharmaceutical policy.

Over the past year, FARMAINDUSTRIA continued to prepare periodic reports on new developments and items of interest for the sector, such as: i) basic AR data; ii) the total budgets and healthcare budgets of the ARs for 2014 and 2015; iii) prescription by active ingredient and dispensing of generic equivalents, and; iv) medicine evaluation committees in the ARs. It also continued throughout the year to publish and distribute the Autonomous Region Information Bulletin, a fortnightly publication gathering regionally important news of interest to the pharmaceutical industry in relation to healthcare policy, pharmaceutical provision, healthcare legislation, health plans and research. Twenty-three issues of the Bulletin were published in 2014.

COMMUNICATION AND CORPORATE SOCIAL RESPONSIBILITY WORKING GROUP

A fundamental part of FARMAINDUSTRIA's communication strategy consists in identifying synergies and preparing coherent messages about the needs of the sector. The Communication and

Corporate Social Responsibility Working Group of FARMAINDUSTRIA plays a very important role in this respect.

This Group held four meetings during 2014. These sessions, held by video conference between the FARMAINDUSTRIA offices in Madrid and Barcelona, attracted enthusiastic participants from the member companies and tackled questions of great interest for the sector: relations between the sector and the media; activity in social networks; communication plans; interaction with patients' associations, etc.

The Group's meetings served for debate and agreement on communications strategies, but also allowed the member companies to identify the main issues and concerns in this important area of activity for pharmaceutical companies based in Spain.

PATIENTS WORKING GROUP

In the area of activities in relation to patients' associations, the Patients Working Group of FARMAINDUSTRIA was kept very busy last year, sharing initiatives and projects with over 30 companies that are represented in the Group.

Holding quarterly meetings, the Group collaborated in, among other matters, the definition and coordination of the participation of FARMAINDUSTRIA in EUPATI, supporting the study, EsCrónicos, and organizing the Somos Pacientes ("We Are Patients") Day, as well as content for the different agendas of the Permanent Dialogue Roundtable.

The main role of FARMAINDUSTRIA'S Barcelona Office Is to lend support and advice to the member companies that are mainly based in Catalonia, in cooperation with the rest of FARMAINDUSTRIA'S departments

BARCELONA OFFICE

FARMAINDUSTRIA's Barcelona Office aims to advise and provide services of a diverse nature to the member companies that are based mainly in Catalonia, in cooperation with the different departments of the Association. Dealing with consultations of various kinds is also a major part of its undertaking.

The Office lends its support to the coordination of the diverse Working Groups operating in FARMAINDUSTRIA and in the renewal of these Groups every two years. It additionally serves as a venue for meetings of FARMAINDUSTRIA's Governing Bodies, Statutory Groups and other healthcare sector organizations (COASHIQ, ANEFP and SIGRE, among others).

During 2014, the Office continued collaborating actively with FARMAINDUSTRIA's National Statutory Group, providing Technical Secretariat functions for its two-monthly meetings, coordinating the Group's initiatives and updating information of interest for the national companies.

Meanwhile, the Office continued to play an active intermediary role with the Catalonian health authorities in various matters that are important to the pharmaceutical sector, such as government contracts and electronic invoicing.

In its close coordination with the Hospital Debt Working Group, the Office continued to monitor comprehensively both the development of the SIGLO project in the SAS, the Andalusia Health Service, and the level of implementation of electronic invoicing in the different ARs, with special attention given to its integration in the SAS operational area.

Finally, it should be added that the Office pursued contacts with academic institutions and bodies related to the pharmaceutical sector at the regional level. It also took part in the Mixed Delegate Committee of FEDEQUIM in Catalonia, with the aim of interpreting the text of the Chemical Industry Collective Labour Agreement, and the Socio-Labour Committee of the same Federation.

4.3 SPANISH TECHNOLOGICAL PLATFORM FOR INNOVATIVE MEDICINES (PTEMI)

Over nine years since it was formed, the Spanish Technological Platform for Innovative Medicines (PTEMI) is now consolidated as an initiative promoted by the pharmaceutical industry in collaboration with academic institutions, researchers and Public Administrations to foster R&D in innovative medicines in Spain.

PTEMI is the Spanish reference for the Innovative Medicines Initiative (IMI) of EFPIA and the European Commission to promote research into new medicines, which it is hoped will reinforce Europe's position in pharmaceutical research, increase its attractiveness as a region for investing in research and, in the long term, serve European citizens better by providing them with more rapid access to higher quality medicines.

During 2014, PTEMI carried out activities aimed at fostering international collaboration and supporting organizations interested in such collaboration. It mainly participates in the IMI Forum, organized every six months by Spain's Industrial Technological Development Centre (CDTI). It has also performed an intensive monitoring of the new IMI-2 initiative within the European Union's New Research and Innovation Framework Programme planned for 2014-2020 (Horizon 2020). This initiative aims to boost the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with a big impact on public health and will mainly focus on five disease pillars: i) metabolic; ii) neurodegenerative; iii) infectious; iv) immunological, and; v) translational security. With the aim of promoting participation of Spanish organizations in IMI-2, an IMI Info Day was organized on 13 January 2015 and attended by representatives of FARMINDUSTRIA, EFPIA, the IMI Executive Office and consortia that are already up and running.

Among the activities carried out by PTEMI, one of the most important is the Pharma-Biotech Cooperation Programme launched in 2011, under which 12 interactive meetings were held between the pharmaceutical industry and the biotech sector between 2011 and 2014

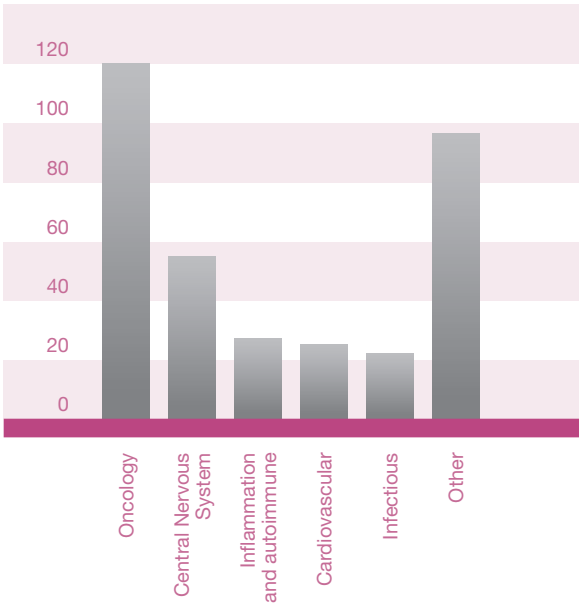
FARMAINDUSTRIA is participating in a 3rd Call IMI consortium called the European Patients' Academy on Therapeutic Innovation (EUPATI) which provides scientific, objective and complete information to patients on pharmaceutical R&D. It consists of a project made up of 29 organizations led by the European Patients' Forum, a combination of pan-European patient organizations, academic non-profit-making bodies, experts in patient and public participation, as well as EFPIA member companies and associations. EUPATI will offer high-quality, cutting-edge objective education on therapeutic innovation to patients.

Among the activities carried out by PTEMI during 2014, the Pharma-Biotech Cooperation Programme is one of the most important. Launched in February 2011 with the aim of facilitating collaboration between the pharmaceutical industry and the Spanish biotechnology sector, from 2011 to 2014 it held 12 interactive meetings between both sectors, mainly in the areas of the central nervous system, oncology, respiratory system, inflammation and autoimmune diseases.

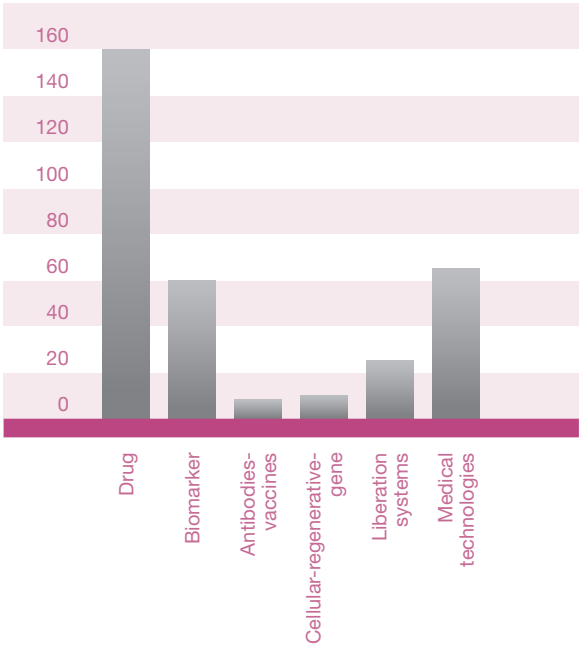
DAY	DATE	CITY	ORGANIZATION	THERAPEUTIC AREA	PROJECTS PRESENTED	FROM RESEARCH CENTRES	FROM SMALL INNOVATIVE COMPANIES	PHARMACEUTICAL LABORATORIES PARTICIPATING
Day 1	feb 11	Barcelona	FARMAINDUSTRIA Head Office	Central Nervous System	6	0	6	19
Day 2	abr 11	Barcelona	FARMAINDUSTRIA Head Office	Oncology	8	0	8	13
Day 3	may 11	Madrid	FARMAINDUSTRIA Head Office	Oncology	7	1	6	14
Day 4	jul 11	Madrid	FARMAINDUSTRIA Head Office	Various fields (1)	9	0	9	14
Day 5	mar 12	Barcelona	FARMAINDUSTRIA Head Office	Various fields (2)	7	4	3	14
Day 6	jun 12	Zaragoza	Aragon Health Service	Various fields (3)	5	3	2	6
Day 7	sep 12	Bilbao	BioSpain 6th int'l meeting	Oncology	6	0	6	Open day
Day 8	may 13	Madrid	FARMAINDUSTRIA Head Office	Various fields (4)	6	1	5	12
Day 9	jul 13	Barcelona	FARMAINDUSTRIA Head Office	Sistema Nervioso Central	7	4	3	7
Day 10	nov 13	Madrid	FARMAINDUSTRIA Head Office	Various fields (5)	7	5	2	10
Day 11	jul 14	Madrid	FARMAINDUSTRIA Head Office	Various fields (6)	8	7	1	10
Day 12	sep 14	Santiago de Compostela	BioSpain 7th int'l meeting	Various fields (7)	10	3	7	Open day

In this period, the programme received 357 candidatures for projects, from which 86 were selected and presented to biopharmaceutical companies, as well as a total of 28 new molecules, mainly in the pre-clinical research phase.

NUMBER OF PROJECTS ANALYZED BY THERAPEUTIC AREA



NUMBER OF PROJECTS ANALYZED BY TYPE



The Pharma-Biotech Cooperation Programme is discussed at length in this Annual Report, in the section on the Pharma-Biotech Working Group.

PTEMI performs a large part of its activities in the area of dissemination and promotion of actions aimed at all the actors in the science-technology-corporate system to communicate the results of research and public and private activities of interest to the sector, with the aim of promoting cooperation between these parties. On 24 and 25 March 2015, PTEMI coordinated and organized its 8th Annual Conference in Barcelona, along with the Spanish Technological Platform for Nanomedicine, Healthcare Technologies and Biotechnology Markets. Under the slogan 'The Need for Innovation', and in front of over 300 participants, new medicine R&D&I projects were presented that have a more collaborative vision, with the aim of increasing productivity and competitiveness in the sector.

PTEMI's communication vehicle is its portal (www.medicamentos-innovadores.org), which is a reference for biomedical pharmaceutical research at national level and serves as a contact point and coordination hub for activities, information and communications between all the participants. A monthly newsletter is published and sent to over 2,200 people interested in the PTEMI activities. The website appears in Spanish and English and is updated every week.

At the inauguration ceremony for the 8th Annual Conference on Biomedical Research Platforms in Madrid, 24 and 25 March 2015.

4.4 SELF-REGULATION SYSTEMS

The new Code of Practice for the Pharmaceutical Industry came into force on 1 January 2014, unifying the two Codes which until then formed part of the Farmaindustria self-regulation system. The first difference that should be commented upon in this new Code is incorporated in its article 18, on the commitments in the area of the transparency assumed by the pharmaceutical companies, "Transparency in pharmaceutical industry relations".

Without forgetting the activities carried out to disseminate the main new incorporations in the Code (of which more details will follow), it is first necessary to mention the important work performed by the Farmaindustria Working Groups on the Codes of Practice and the G-9, which revised and approved Annex II, Consultations (Questions and Answers), on the interpretation of the Code of Practice. The complexity of this work was mainly due to the need to: i) revise and adapt the consultations received to date; ii) analyze new comments from the laboratories about the changes in the Code, and; iii) select and adapt the incorporations approved at European level that, due to their general interest to the laboratories in Spain, had to be transposed by the national associations to their national codes.

The new Code of Practice for the Pharmaceutical Industry came into force on 1 January 2014, unifying the two self-regulation Codes operating until then

As a result of this complex process, the Governing Bodies of Farmaindustria approved the definitive version of Annex II of the Code, later approved by the General Assembly held in June.

The new transparency obligations imply that, during the first six months of each year, the laboratories will have to publish payments and transfers of value made during the previous year to healthcare professionals and organizations for the following concepts: i) donations; ii) training activities and scientific-professional meetings; iii) performance of services, and; iv) research and development. The first publication of this information will take place in 2016 and correspond to 2015 data.

Conscious of the opportunity an initiative of this nature represents, to generate credibility and reinforce the image of the pharmaceutical industry and healthcare sector, the Code of Practice Surveillance Unit (CPSU) focused its efforts during the second half of the year on holding meetings with the member companies and the main stakeholders with whom the industry interacts, especially health authorities and scientific associations.

Meetings held with the laboratories included the following items: i) analysis of the main new items in the Code; ii) review of the internal procedures adopted by the companies to comply, within the deadline, with the transparency obligations; iii) training actions aimed at employees, and; iv) the strategy and communication plan aimed at healthcare professionals and organizations.

The meetings held with the scientific associations discussed the following: i) the interest shown by all to get to know the main new items of the Code, especially those related to the transparency obligations of the member companies; ii) the warm welcome and acceptance of this transparency initiative at institutional level; iii) the need to adopt additional measures, to those that already exist, which explain the legitimate interaction that must exist between the pharmaceutical industry and healthcare professionals and organizations, and; iv) recognition that this initiative represents an opportunity for the healthcare sector as a whole.

The first publication of data on the transfers of value made to healthcare professionals and organizations will take place in 2016 and correspond to 2015

CODE OF PRACTICE COMMITTEE ACTIVITIES

As established by the Code of Practice for the Pharmaceutical Industry, the renewal of the members of the Code of Practice Committee took place in 2014. Thus, in line with article 25.1 of the Code, the Steering Committee of FARMAINDUSTRIA agreed, at its meeting on 29 April 2014, to renew the responsibilities of the members of the Code of Practice Committee for a period of three years, renewable.

The Code of Practice Committee held 11 meetings in 2014, in which it dealt with a diverse range of matters on which the Committee had been advising the companies and clarifying doubts raised on the interpretation of specific areas. In particular, the Committee took part in the drafting of the document of Questions and Answers, making specific proposals that form part of the Code for Practice of the Pharmaceutical Industry.

As for complaints, in 2014, 12 were presented to the Code of Practice Committee. These complaints were dealt with in line with the ordinary procedure foreseen in article 32.2 of the Code of Practice for the Pharmaceutical Industry. Some 40% of complaints presented were resolved by agreement between the parties as a consequence of the mediation work of the Committee. Of these, 15% were complaints presented by the CPSU that were resolved voluntarily. A fifth of dossiers were sent to the Self-Regulation Jury and the remaining 40% were archived due to the withdrawal of the complaint.

The complaints referred mainly to questions of: i) hospitality and meetings; ii) the scientific content of promotional material, and; iii) to a lesser extent, other promotional activities such as the distribution of promotional material, promotion via the Internet, transparency in promotion, comparative advertising, etc. The following table summarizes the complaints, grouped by different classification criteria.

CODE OF PRACTICE COMMITTEE	
Committee mediation	5
Self-Regulation Jury	2
Archived	5
TOTAL	12

COMPLAINANTS	
Member companies	41%
Adhered companies	0%
CPSU	59%
COMPLAINED AGAINST	
Member companies	84%
Adhered companies	16%

CODE OF PRACTICE SURVEILLANCE UNIT ACTIVITIES

As for the CPSU communicating the activities of the Self-Regulation System, the following should be mentioned: i) it has participated actively in national and international conferences and meetings; ii) bilateral meetings have been held with officials from the Autonomous Regions in the area of promotion and collaboration with the AEMPS; iii) training sessions have been designed specifically to respond to the needs of laboratories, and the unit has collaborated in imparting sessions relating to both Codes in the framework of courses, doctorates and specialized Masters; iv) it has contributed to the Editorial Committee of the magazine Business Compliance Journal and the publication of the article, Transparency & Compliance: Marriage of Convenience; v) it organized, in Madrid and Barcelona, the seminar, The commitment of the pharmaceutical industry to good practice; vi) prepared and disseminated the explanatory video on the commitment to transparency; vii) developed and updated the hospitality limits map approved at European level; viii) held bilateral meetings with the member companies and scientific associations to explain and analyze the new items in the Code, and performed communication actions in relation to the new transparency commitments and the measures introduced for compliance with these commitments; ix) disseminated information about the self-regulation system among suppliers to pharmaceutical companies, and; x) managed the self-regulation system website (www.codigofarmaindustria.es).

The Code of Practice Surveillance Unit of Farmaindustria continued to participate in the Association's different Working Groups and also those of EFPIA and IFPMA

The CPSU has also actively collaborated with, and participated in, the different Working Groups of Farmaindustria, EFPIA and IFPMA. Aspects analyzed in these WGs included: i) the process of transposing the modification of the EFPIA Code on Relations with Health Professionals, and the new EFPIA Code on Transparency, into national codes; ii) the monitoring of the transposition process scorecard and iegal implications with regard to personal data protection, taxation and competences; iii) advice and support to national associations of the pharmaceutical industry in order to ensure its correct transposition, etc.

During the past year, the only formal new item approved in the area of interrelations of the pharmaceutical companies with patients' organizations was limited to incorporating precepts in force as an integrated part of the new Code of Practice for the Pharmaceutical Industry, specifically articles 1, Relations with Patients' Organizations, and 18.8, Transparency of Relations with Patients' Organizations. In complying with these precepts, the laboratories have updated the information relating to collaborations carried out with patients' organizations (available at: www.codigofarmaindustria.es).

ADVICE AND COOPERATION

The CPSU has increased its collaboration and assistance work through different activities: i) the revision, adaptation and improvement of the internal procedures implemented by the member companies to ensure compliance both with the Code and the regulations that apply in the area of promotion of medicines; ii) permanent and continued support for pharmaceutical companies and third parties involved, mainly scientific societies, technical secretariats and service providers in general; iii) active participation in meetings and forums organized by FARMAINDUSTRIA with the ARs and communication media, and participation in meetings organized by EFPIA and IFPMA, consolidating the CPSU as a member of the EFPIA Code Steering Group and as chair of the IFPMA Adjudication Group.

Seven complaints were made in 2014 at the initiative of the Code of Practice Surveillance Unit of FARMAINDUSTRIA

MONITORING AND PREVENTION

The number of preventive actions carried out in 2014 was 2,180 (slightly more than the 2,112 the year before) and the total number of complaints lodged at the initiative of the CPSU was seven, six of which consisted of non-compliance related to scientific and professional meetings (article 11), and one of non-compliance in the area of distribution of promotional material on medicines (article 7). Of the seven complaints, five were archived at the request of the CPSU and the other two were resolved via mediation agreement before the Code of Practice Committee.

During 2014, 5,566 scientific-professional meetings were analyzed and verified, 612 more than in 2013, those complying increasing by three percentage points to 92%, from 89% in 2013.

Equally, in 2014, the number of market research studies communicated increased to 449 (49 more than in 2013), and the number of projects to 350 (44 more than in 2013). In the area of services, the compliance percentage increased by more than eight points to 83.4%, from 75.2% in 2013.

The following table is a summary of the main CPSU data (annual and cumulative) since the beginning of its activity in April 2004, until 31 December 2014.

CODE OF PRACTICE SURVEILLANCE UNIT ACTIVITY

		2004 APR-DEC	2005 JAN-DEC	2006 JAN-DEC	2007 JAN-DEC	2008 JAN-DEC	2009 (A) JAN-DEC	2010 JAN-DEC	2011 (B) JAN-DEC	2012 JAN-DEC	2013 JAN-DEC	2014 JAN-DEC	CUMULATIVE APR 04-DEC 14
EVENTS	Analyzed	945	1,747	2,199	2,926	3,388	3,878	5,080	5,335	5,003	4,954	5,566	41,021
	Without incident	718	1,390	1,909	2,616	3,087	3,345	4,383	4,862	4,389	4,412	5,124	36,235
	% compliance	75.98%	79.56%	86.81%	89.41%	91.12%	86.26%	86.28%	91.13%	87.73%	89.06%	92.06%	
STUDIES	Analizados						687	724	626	512	400	449	3,398
	Without incident						397	546	565	416	332	368	2,624
	% compliance						57.79%	75.41%	90.26%	81.25%	83.00%	81.96%	
SERVICES	Analizados								357	330	306	350	1,343
	Without incident								282	272	230	292	1,076
	% compliance								78.99%	82.42%	75.16%	83.43%	
PREVENTIVE ACTIONS		814	1,801	1,376	2,092	2,440	2,670	3,482	3,131	2,488	2,112	2,180	24,586
CPSU COMPLAINTS		18	11	9	18	8	12	4	3	1	9	7	100*

* 5 Cases resolved in the Courts
* 7 Clear resolutions by the Self-Regulation Jury in favour of the CPSU
* 55 Resolved by mediation before the Code of Practice Committee, recognizing the infraction and accepting corrective measures
* 20 Agreements among parties prior to the Code of Practice Committee meeting
* 12 Archived at the request of CPSU
* 1 Not upheld by the Self-Regulation Jury

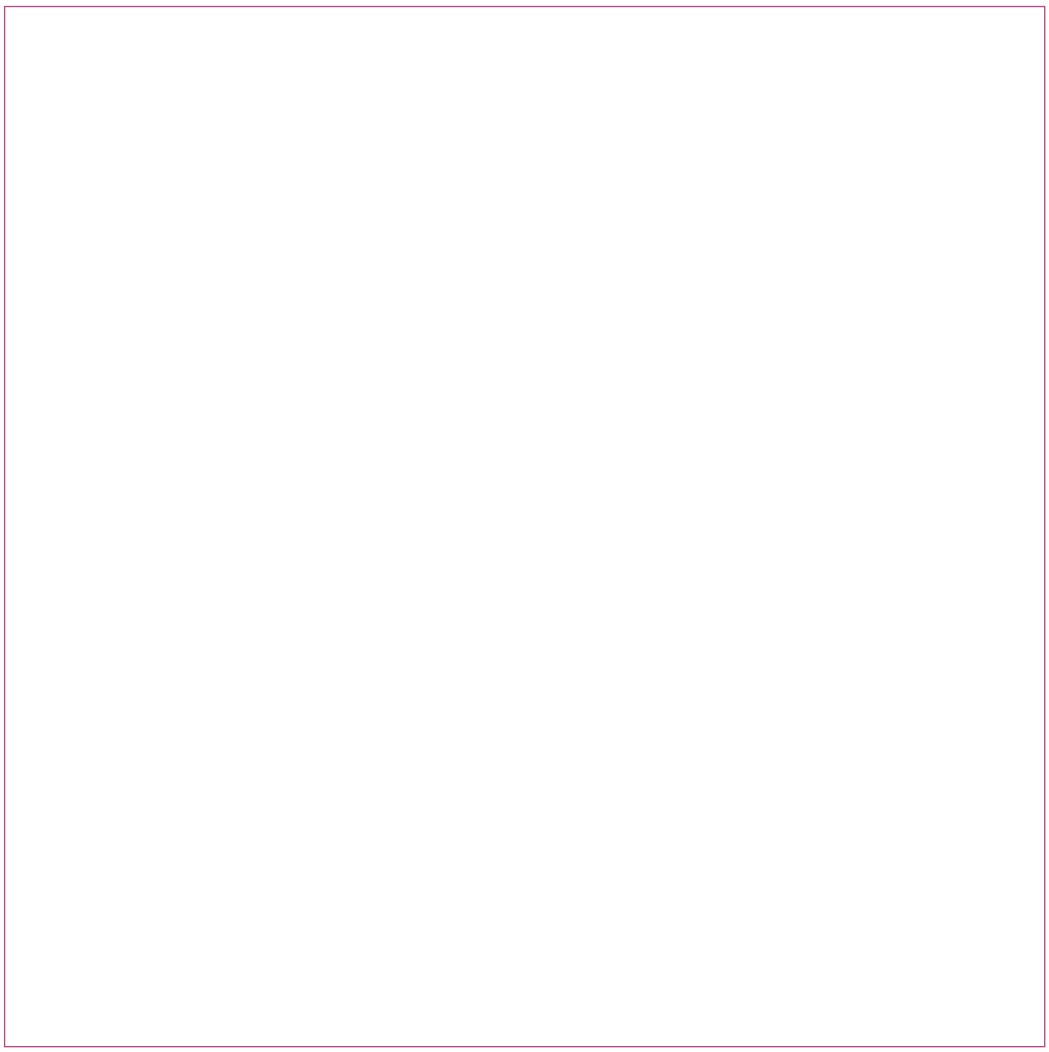
(A) System for Communicating Studies approved in the 2008 Code
(B) System for Communicating Studies approved in the 2010 Code

MANAGEMENT OF THE EFPIA 'E4ETHICS' PLATFORM

EFPIA's *e4ethics* platform, managed by FARMAINDUSTRIA, has become a reference tool for the pharmaceutical industry in Europe when participating in or sponsoring scientific-professional meetings. The collaboration agreement signed by EFPIA and FARMAINDUSTRIA refers both to the technical support needed for the design, operation and maintenance of the platform and the offering of consultancy, analysis and advisory services needed to evaluate the compliance of events, communicated via this platform, with that established in article 10 of the EFPIA Code.

e4ethics issued around 489 pre-assessment reports related to 288 scientific-professional meetings in 2014, and the platform recorded about 50,000 page visits. The statistical data show a pronounced change in the logistical organization of the meetings. Social events contrary to the EFPIA Code, as well as the presence of companions, fell from 63% in 2011 to 32% in 2014 and from 77% to 43%, respectively. The large majority of scientific-professional associations have shown a very positive attitude towards the platform in 2014. 36 of the 57 European associations who contacted e4ethics (63.2%) decided to implement changes in the logistical organization of their meetings to support the laboratories in complying with the self-regulation system.

The exceptional improvement in the logistical organization of the main European scientific-professional meetings, from the viewpoint of article 10 of the EFPIA Code on Relations with Health Professionals, is due to the strong commitment shown by the member companies and the support received from the national associations, members of EFPIA. The use of *e4ethics* is widespread: it has been assimilated into the internal procedures of the companies and is well known among the main pharmaceutical industry stakeholders.



ANNEX

SIGRE
MEDICINES AND THE ENVIRONMENT

SIGRE Medicamento y Medio Ambiente (from hereon, SIGRE) is a non-profit-making organization created by the pharmaceutical industry, with the collaboration of pharmaceutical distributors and pharmacies, to guarantee the correct environmental management of packaging and medicine waste from homes.

Pharmaceutical companies comply, through SIGRE, with both environmental legislation (Law 22/2011, on Contaminated Wastes and Soils, and Law 11/1997, on Packaging and Packaging Waste) that obliges companies to guarantee the correct environmental management of the packaging waste generated by their products, and healthcare legislation (Law 29/2006, on Guarantees and Rational Use of Medicines and Healthcare Products) which requires pharmaceutical companies to treat environmentally the remains of expired or non-used medicines from households.

All the medicines marketed in Spain for consumption in homes must incorporate the SIGRE symbol in their labeling. This is the only symbol authorized by the AEMPS and effectively accredits the participation of the manufacturing company in a system that guarantees the management of household waste.

The waste collection indicator for medicines was 82.8 grammes per inhabitant per year in 2014

2014 ENVIRONMENTAL DECLARATION

SIGRE presented the pharmaceutical sector's Environmental Declaration for last year to the Environment Departments of the Autonomous Regions.

This Environmental Declaration consists of two documents: i) the Annual Packaging Declaration (DAE), and; ii) the Third Corporate Prevention Plan (PEP) Monitoring Report for packaging in the pharmaceutical sector. Both documents bring together the actions carried out and successes achieved by the Spanish pharmaceutical industry in contributing to compliance with the environmental objectives stipulated in the Packaging Law.

In this way, the following national and AR data is collected, measured and compared in the DAE: i) the number and weight, by material, of more than 17,500 presentations of commercial medicines for household consumption; ii) the weight of the packaging waste and leftover medicines deposited in SIGRE Points in the more than 21,400 pharmacies collaborating in the scheme, and; iii) the environmental treatment applied for each of the fractions obtained during the classification process.

The weight of the packaging, empty or containing the remains of medicines, deposited by citizens in the SIGRE Points at pharmacies rose slightly, by 1.25%, in 2014, with respect to the year before. The eco-indicator for waste collection was 82.8 grammes per inhabitant per year.

It is important to highlight several aspects related to the amounts collected and managed via the SIGRE system:

- As well as the packaging, empty or containing the remains of medicines, boxes and prospectuses, the data includes para-pharmaceutical products and improper waste such as batteries, spectacles and other healthcare material.

- In 2014, there was a slight increase in the number of completely empty packages deposited by citizens, now 19% of the total, which demonstrates greater environmental, social and health awareness.

- Spain continues to perform at the European average in managing medicines waste.

The medicine packaging and waste treatment plant at Valladolid is a specifically designed facility for the environmental treatment of medicine waste

With respect to the Third Monitoring Report, finalizing the Fifth PEP (2012-2014) for packaging in the pharmaceutical sector, it shows that there has been a reduction of 3.81% in the generation of packaging waste, exceeding the reduction objective approved by the environmental authorities.

REDUCTION OBJECTIVE, 2012-2014 PEP

PERCENTAGE PROPOSED	PERCENTAGE ACHIEVED	OBJECTIVE ACCOMPLISHED
≥ -2.00% y ≤ 2.00%	3.81%	

It is also worth pointing out the high number of eco-design initiatives (556) applied by the laboratories on their packaging during the three years the Plan has been carried out. This has seen an increase of 27% in actions with respect to those carried out in the earlier Plan (the 2009-2011 PEP).

Finally, another landmark was reached in the form of over 85 million packaging units (sale, grouping and transport) to have entered the market incorporating some kind of environmental improvement (lower weight, optimization of number of packaging, incorporation of more ecological materials, etc.), a figure significantly higher than any achieved in earlier plans.

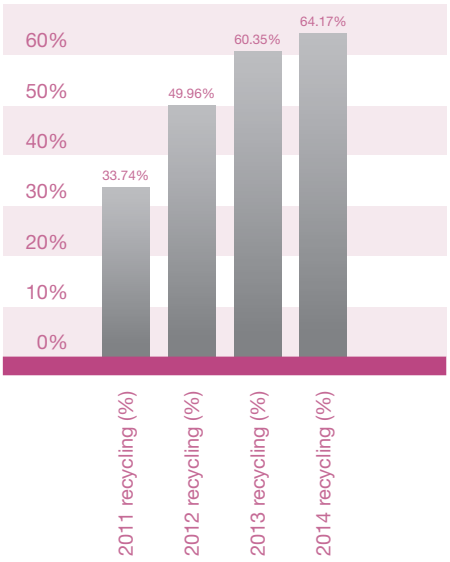
These results are a demonstration of the interest and constant work that has been carried out in the years since pharmaceutical companies signed up to incorporate the environmental component throughout the whole life cycle of their products. This has all been achieved in the face of legal, technical and safety barriers that on many occasions limited the adoption of the measures planned by the laboratories.

PACKAGING AND MEDICINE WASTE TREATMENT PLANT

The Packaging and Medicine Waste Treatment Plant, located in Tudela de Duero, Valladolid, is a facility specifically designed and built for the environmental processing of medicine waste.

Although at first the plant was designed by SIGRE to treat waste of domestic origin, over the past year the facility has also been open to managing pharmaceutical waste of an industrial nature (returns of medicines, production waste, etc.), such that the companies adhering to the system can benefit from the innovative, automatic, selection and classification processes installed, which have made this facility an international reference in the specific treatment of this kind of waste. The plant has continued to improve its processes over the last year, increasing the recycling of medicine packaging materials by over 6%.

RATE OF RECYCLING OF MEDICINE PACKAGING MATERIALS



TECHNICAL EXPERTS' COMMITTEE (CAT)

Made up of environmental specialists from the pharmaceutical companies, the Committee's main responsibility is to provide technical advice to SIGRE in those questions concerning the preparation and execution of Corporate Prevention Plans for packaging in the pharmaceutical sector.

During 2014, the work of the CAT focused on preparing the Third Monitoring Report for the 2012-2014 PEP, bringing to an end the last PEP.

Also, given the special difficulty represented by the packaging of pharmaceutical products, the CAT analyzed in detail the requirements of the standard, UNE-EN 13428/2005, *Packaging - Requirements Specific To Manufacturing And Composition. Prevention By Source Reduction*.

SIGRE COMMUNICATION COMMITTEE

The SIGRE Communication Committee is made up of representatives of the different links in the medicine chain: FARMAINDUSTRIA, the General Council of the Official Colleges of Pharmacists and the Federation of the Pharmaceutical Distributors.

This committee analyzed the management report corresponding to the 2013 Communication Plan and approved the main objectives of the 2014 Communication Plan, aimed at raising awareness among the population about the recycling of medicines and reinforcing the recognition of the role that the different agents in the pharmaceutical sector perform in this initiative.

SIGRE TRAINING SESSIONS ON THE PACKAGING DECLARATION

SIGRE organized two training sessions in Madrid and Barcelona on the functioning of the SIGRELAB 4.0 website, the computer application created for laboratories to present their Company Declarations to SIGRE.

These sessions, in which 87 representatives of member companies participated, reviewed the information the companies must provide by 28 February of each year in relation to products marketed in Spain, in order to comply with the packaging legislation in force.

14TH INFORMATION DAYS FOR COMPANIES

On 16 and 17 June 2014, in Madrid and Barcelona, respectively, SIGRE held the 14th edition of its Information Days. The day-long seminars are used to analyze the main new legislative initiatives that affect packaging and to present the results obtained by the industry in the area of prevention. The significance of digital communication and social media was also a key discussion topic at the events, as well as the importance of corporate social responsibility initiatives.

Once again, the Days counted upon the participation of different speakers from the pharmaceutical industry, who contributed their experience in the minimization of waste and offered some practical examples of measures of eco-design applied to packaging.

SIGRE AWARENESS-RAISING CAMPAIGN

SIGRE, in collaboration with the environmental authorities, continued in 2014 with the awareness-raising campaign to promote the correct recycling of medicines packaging and waste generated in the home. This campaign, another example of the effort the pharmaceutical industry is making to promote the responsible use of medicines, was carried out during November under the slogan “What would nature do without you?” It calls on the help of citizens to reach the ecological objectives the Spanish legislation establishes for this type of waste.

4TH CATALOGUE OF ECO-DESIGN INITIATIVES FOR PHARMACEUTICAL PACKAGING

SIGRE also last year published the 4th Catalogue of Eco-Design Initiatives for Packaging in the Pharmaceutical Sector, compiling the most representative measures adopted by pharmaceutical companies to reduce the environmental impact of medicines packaging during the 2009-2012 period.

During this period, the pharmaceutical laboratories incorporated 549 eco-design initiatives, which have been applied on more than 83 million packages. The Catalogue gathers only a small sample, 35 examples, with which SIGRE wished to reflect the technical, economic and innovative effort the pharmaceutical industry is carrying out in the area of packaging prevention, despite the technical and regulatory barriers that affect this activity in the sector.

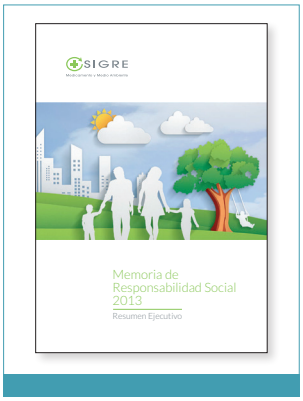
With this edition of the Catalogue, the aim is to recognize the sustainable work that member companies are carrying out, and to contribute to disseminating the actions performed in the field of eco-design, an essential discipline for reducing the quantity of waste generated and in caring for our environment.

Between 2009 and 2012, member companies incorporated 549 eco-design initiatives, applied on more than 83 million packages

PRACTICAL GUIDE ABOUT SIGRE POINTS

SIGRE also published in 2014 a new Practical Guide about SIGRE Points, an informative document for pharmacists in pharmacy stores to consult, so they can update and strengthen their knowledge about recycling of packaging and medicine waste in order to improve their advice to customers in this area.

This new guide compiles, in a practical and visual way, information on: i) what to deposit, and not to deposit, in the SIGRE Point at the pharmacy; ii) the final destination of the waste, and iii) the framework regulating this activity and how SIGRE functions.



2013 SOCIAL RESPONSIBILITY REPORT

Last year, SIGRE also published its 2013 Social Responsibility Report, detailing the main advances in the area of social responsibility achieved during 2013, within the environmental, social, economic and good governance fields.

In its pages, SIGRE details the main goals that allowed it to perform its environmental, social and healthcare mission efficiently and highlights the significant effort carried out by the pharmaceutical industry in the application of eco-design measures for packaging.

For the preparation of this Social Responsibility Report, SIGRE followed the new version 4 of the Sustainability Report Guidelines of the Global Reporting Initiative (GRI). This version

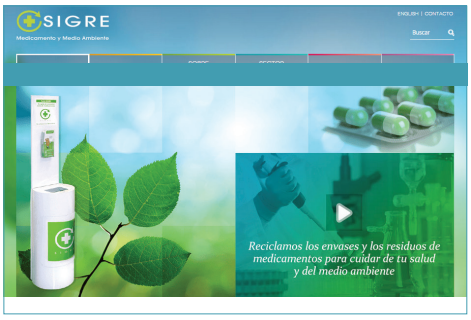
offers two options, with SIGRE choosing to follow the "comprehensive" option, which, due to its high level of informative and documentary requirements, was employed by only six other Spanish companies.

NATIONAL ENVIRONMENTAL CONGRESS

SIGRE took an active part in the 2014 National Environmental Congress in Madrid's *Palacio Municipal de Congresos* from 24 to 27 November.

The organization published two technical communications, under the titles: *Medicines Waste and Packaging Treatment Plant: a technological achievement renowned worldwide and Sustainability Reports as motors of change in organizations*.

SIGRE also presented a poster called *Eco-design in the pharmaceutical sector: achievements and efforts by the pharmaceutical industry in Spain*, and was present on a stand, from which it could offer participants information on this environmental initiative by the pharmaceutical industry.



SIGRE'S NEW CORPORATE WEBSITE

SIGRE has launched its new corporate website, www.sigre.es, which stands out for its modern design, improved structure and new multimedia contents such as videos, infographics and photographs.

The website, aimed mainly at the general public and representatives of the pharmaceutical sector, is notable for its simple navigation. It also has a specific space aimed at pharmaceutical companies in which it has compiled various materials, documents for consulting and audiovisual clips that explain the role the pharmaceutical industry performs in the SIGRE system.

An area reserved for the laboratories adhering to SIGRE has also been created, in which all the tools needed for the compliance of their environmental obligations related to SIGRE can be found.

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