2013
ANNUAL REPORT

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MESSAGE FROM THE PRESIDENT

Elvira Sanz Urgoiti
President of
FARMAINDUSTRIA

The moment has arrived for us to take stock of the year 2013, which unfurled in a hectic environment both from the economic, and institutional and social, viewpoint. It is true that we have more than enough reason to be optimistic, but we also know that this is a time for serious reflection as well as steady work — and our pharmaceutical sector is no exception. The important thing today, therefore, is to examine where we have come from.

I should begin by pointing out that 2013 ended with public pharmaceutical spending, in terms of official SNS prescriptions, having been reduced by 6%. This is the fourth year in a row that spending has fallen, resulting in an annualized 28% contraction of the market since the record high reached in May 2010. The size of this redress has been substantial. This 28% reduction placed 2013 public pharmaceutical spending, in terms of official SNS prescriptions, below 200 euros per inhabitant and year, at levels similar to 2003; a 10-year reverse, in other words. If this is measured as a percentage of GDP or of Spain's total public spending (at the end of 2013, 0.9% and 2.0%, respectively), you have to go back to 1993 (20 years ago) to find public pharmaceutical spending ratios as low as the

present ones; and if measured as a percentage of total public health spending, we are able to speak of a ratio of 14.5%, a figure that has not been recorded in Spain at least since 1983.

The hospital market also experienced a large correction in its growth rate, although unlike pharmacies, hospitals have not registered cuts in recent years. Nonetheless, the double digit growth experienced until 2009 has come down to rates of around +1% to +2% in the past three years. Indeed, had there not been administrative transfers of medicines from the pharmacies channel to their dispensing outlets in hospitals, 2011 and 2012 would have recorded net reductions in the hospital market.

All these data clearly point to the fact that pharmaceutical spending in Spain has hit bottom and prolonging its recession will put the quality of pharmaceutical provision at serious risk. In fact, the access of Spanish patients to innovative medicines has deteriorated in recent years and the warnings are sounding from many stakeholders; not just the industry, but also scientific bodies, groups of health professionals and patients' associations. All are voicing alarm over the long administrative delays in commercializing new drugs and the difficulties in obtaining innovative medicines in some autonomous regions.

There is neither reason nor room for manoeuvre in introducing further measures to reduce pharmaceutical spending, than those which are already stipulated in our present body of legislation. Indeed, the reform of the Reference Price and Homogenous Group Systems laid out in Royal Decree 177/2014 of 21 March, along with the Ministerial Order that updates groups and reference prices, and whose entry into force is planned for summer 2014, will be a source of further significant savings in the public pharmaceutical expenditure in our country. At the same time, the centralized purchasing system for medicines has already been introduced in Spain, with the award of 14 lots of medicines in three framework agreements and new calls foreseen during 2014.

The high capacity for saving under the current economic regulatory framework for the pharmaceutical sector in Spain is demonstrated by the fact that the forecasts for growth in the market in 2014, published by the main sector analysts, see the total market in our country staying at its current level. The situation of the continual eroding of the pharmaceutical market changed in the second half of 2013, and rightly so, in the sense that the outlook of the Spanish economy makes it possible for the trend to change. The latest data, and all the forecasts of the analysts, agree that Spain is at the dawn of a new period of economic growth, moderate at first, but continuous and progressive over time. In this new context, although control of the public deficit will continue to be a key objective, economic policy priorities should turn towards the consolidation of solid growth that generates employment and ensures public investment and expenditure are sustainable.

This industry, as with any other, cannot be subjected to such a permanent deterioration in its market in Spain, without prospects for growth in the future and this having negative consequences in terms of employment and investment. This is why, in the present circumstances, the time has arrived to contemplate, from a position of normality, the return to a situation of moderate growth in the Spanish pharmaceutical market, accepting that growth in the order of nominal GDP growth does not put the sustainability of public

Market growth in line with nominal GDP growth would not put the sustainability of public finances at risk

finances at risk and permits the restructuring of the sector and patient access to innovations that save lives and are generators of net savings for the whole of society in the medium and even the short term.

The new economic growth model in Spain should also steer clear of the imbalances of the past. All the experts agree that the main weaknesses in the Spanish economy are down to low productivity, poor competitiveness in export markets and thin specialization in intensive sectors such as R&D and are in large part responsible for the depth of the crisis that lashed our country and has destroyed so many jobs. At least in these respects, the pharmaceutical industry is endowed with the characteristics that position it as a very important sector of activity for contributing to the solid economic growth Spain needs.

The pharmaceutical industry is, along with the rest of the chemical industry, a leader in productivity, with a gross added value per employee that surpasses the average for Spanish manufacturing industry by more than 50%. At the same time, the pharmaceutical industry has spectacularly increased its export volumes in recent years and is currently the fifth highest exporting sector in the Spanish economy by customs category — and with a sectoral commercial balance of almost zero.

Nor should we forget the contribution of the pharmaceutical industry to R&Mr. With nearly one billion euros a year of private R&D spending in Spain, it is the leader among the industrial sectors and responsible for over 20% of the total R&D investment in Spanish industry, although, as a consequence of the contraction in the market, the rise in pharmaceutical R&D in Spain has been low in the last few years.

Now public expenditure has been adjusted, the pharmaceutical industry more than ever needs a stable and predictable regulatory framework that allows it to return to the path of growth and maximize its potential. We need to operate within the limits of a determined model, defined with common sense and respect for everyone. We cannot keep running the risk of new regulatory initiatives which, as soon as they substitute another, accumulate their effects, nor can we become the target of multiple regulators and managers. The medicines industry needs to believe it is an important asset in consolidating economic recovery in Spain, since there are few sectors with the characteristics of pharmaceuticals and its solid base in Spain.

At Farmaindustria, we are ready to do all that is necessary to help towards this objective. Proof of this is the Collaboration Protocol signed in March 2014 between our Association and the Ministry for Health, Social Services and Equality. It is important to flesh out this Collaboration Protocol with content and make it effective, a task on which we have been busy over these past few months.

The search for areas of collaboration and understanding does not end with Public Administrations, but also extends to the rest of the agents in the system. Today we have a solid relationship with health professionals with whom we share concerns and needs; likewise, with patients, the ultimate recipients of all our efforts and allies in the defence of principles

such as equity and cohesion. And we are working in many fields with pharmacists, with whom we are united concerning the defence and development of medicines, one of the most prized items in society.

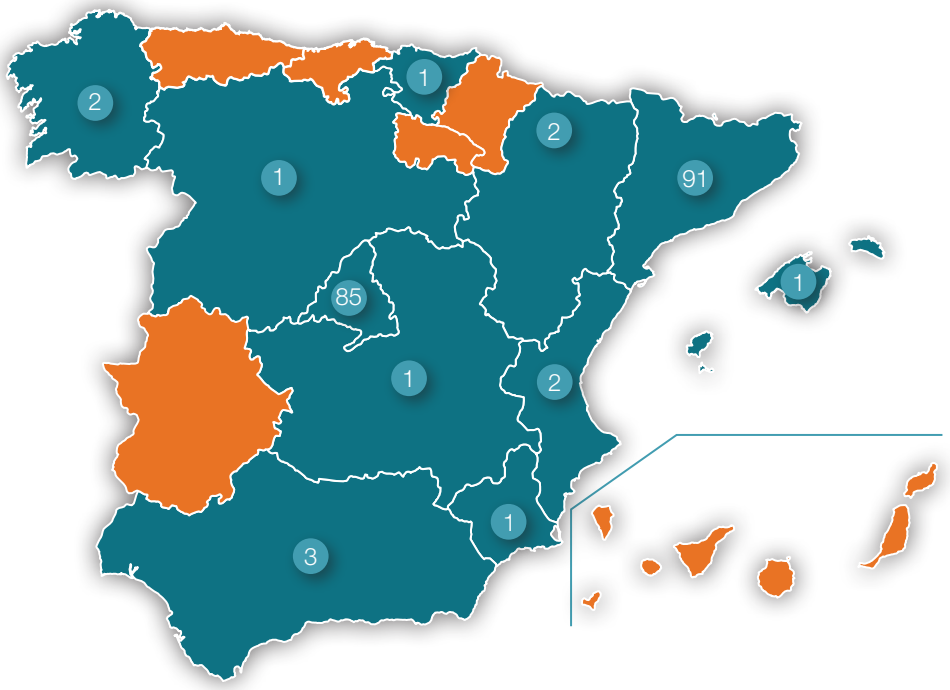
In such a difficult context as we've seen in the past year, I would not like to lose this opportunity to thank all the companies that make up FARMAINDUSTRIA for their relentless support and capacity to combine efforts in favour of our common objectives. In turn, the labour of the Working Groups has been critical in contributing to the definition of these objectives.

Finally, I would like to say that, in the past year, FARMAINDUSTRIA has carried out an important modification to its codes, harmonizing them in a single Code of Best Practices for the Pharmaceutical Industry and including important clauses such as the obligation to publish transfers of value from pharmaceutical companies to health professionals and organizations, as of 2016.

Spain should restore its place in Europe and it cannot fail in its mission to head the innovation field. We cannot lose the great opportunity we have to consolidate as important a business sector as pharmaceuticals and additionally to do so without putting at risk the sustainability of public finances. We are strongly committed and every day we seek to make our contribution — modest though it is, but full of value — to achieving these goals.

01.
MEMBER COMPANIES

At 31 December 2013, some 190 companies were members of FARMAINDUSTRIA. Their geographic distribution is as follows:



The members of FARMAINDUSTRIA represent, by their number, 47% of licensed pharmaceutical products 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 terms of sales, they represent 80% of the prescription market.

LABORATORIES BY GROUPS

National		International		
		American	European	
Total	76	20	94	
Large	6		Germany	17
Medium	7		France	14
Small	63		Mixed	27
			United Kingdom	24
			Switzerland	12

02.
ORGANIZATION

2.1.
GOVERNANCE BODIES

The General Assembly is made up of the Association's Member Companies; it is the Association's supreme governance body and expresses the collective will of the Member Companies.

Governance of the association resides in its Steering Committee, which is made up of the President of the Association and 31 representatives of Member Companies (11 Spanish-capital companies and 20 foreign-capital companies, 12 of which are European-capital businesses and eight are USA-capital concerns). The Board of Governors is made up of the President and 20 Member Companies, nine of which hold a vice-president position (3 Spanish-capital companies, 3 USA-capital outfits and 3 European-capital businesses) and 11 board members designated by the Steering Committee from among its members (4 Spanish-capital companies, 2 USA-capital concerns and 5 European-capital outfits).

The General Assembly held in Barcelona, on 20 June 2013, introduced a series of modifications to the Bylaws of Farmaindustria, mainly because of the reform implemented by Article 68 of Law 17/2012, of 27 December, on the General State Budget for 2013, in Article 1.12 of the VAT Law. The modification, which came into force with effect from 1 January 2013, declared that the quotas paid to the Association in return for works of an institutional nature carried out in the performance of its associated activity are to be exempt from Value Added Tax without the possibility of renouncing the exemption. Nevertheless, the obligation was kept for VAT corresponding to amounts paid in return for services rendered to the member companies or third parties distinct from them.

Finally, as this Annual Report closed, there was a vacancy for Vice-President of the European Group, which will not be filled until the holding of the next elections, to take place in October 2014.

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

EXECUTIVE BOARD

President

Ms. Elvira Sanz Urgoiti
PFIZER, S.A.

Vice-Presidents

Mr. Jesús Acebillo Marín NOVARTIS FARMACÉUTICA, S.A.	Mr. Jorge Gallardo Ballart ALMIRALL, S.A.
Ms. Aurora Cayetana Berra de Unamuno BRISTOL MYERS SQUIBB, S.A.	Mr. Rainer Krause BAYER HISPANIA, S.L.
Mr. Javier Ellena Aramburu LILLY, S.A.	Mr. Jordi Ramentol Massana FERRER INTERNACIONAL, S.A.
Mr. Antoni Esteve Cruella ESTEVE	Mr. Martín Sellés Fort JANSSEN CILAG, S.A.

Members

Mr. Andreas Patrick Abt ROCHE FARMA, S.A.	Ms. Inés Juste Bellosillo JUSTE, S.A. QCO. FCA.
Mr. Rogelio Ambrosi Herrera MERCK, S.L.	Mr. Juan López-Belmonte Encina LABORATORIOS FCOS. ROVI, S.A.
Mr. Ángel Fernández García MERCK SHARP & DOHME DE ESPAÑA, S.A.	Mr. Gustavo Pesquin SANOFI-AVENTIS, S.A.
Mr. Javier Font Salgado LBO.DE APLICACIONES FARMACODINAMICAS,S.A. "FARDI"	Mr. Salvador Pons Ribas LABORATORIOS MENARINI, S.A.
Mr. Ludovic Helfgott ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	Mr. Francisco Quintanilla Guerra FAES FARMA, S.A.
Ms. Cristina Henríquez de Luna GLAXOSMITHKLINE, S.A.	Ms. María Río Presa GILEAD SCIENCES, S.L.

STEERING COMMITTEE

President

PFIZER, S.A.
Ms. Elvira Sanz Urgoiti

Vice-Presidents

ALMIRALL, S.A. Mr. Jorge Gallardo Ballart	FERRER INTERNACIONAL, S.A. Mr. Jordi Ramentol Massana
BAYER HISPANIA, S.L. Mr. Rainer Krause	JANSSEN CILAG, S.A. Mr. Martín Sellés Fort
BRISTOL MYERS SQUIBB, S.A. Ms. Aurora Cayetana Berra de Unamuno	LILLY, S.A. Mr. Javier Ellena Aramburu
ESTEVE Mr. Antoni Esteve Cruella	NOVARTIS FARMACÉUTICA, S.A. Mr. Jesús Acebillo Marín

Members

ABBVIE FARMACÉUTICA, S.L.U. Mr. Antonio Bañares Cañizares	GILEAD SCIENCES, S.L. Ms. María Río Presa
ALCON CUSI, S.A. Mr. Enrique Chico Picaza	GLAXOSMITHKLINE, S.A. Ms. Cristina Henríquez de Luna
AMGEN, S.A. Mr. Roland Wandeler	JUSTE, S.A. QCO. FCA. Ms. Inés Juste Bellosillo
ASTRAZENECA FARMACÉUTICA SPAIN, S.A. Mr. Ludovic Helfgott	LABORATORIOS LETI, S.L. UNIPERSONAL Mr. Jaime Grego Sabaté
BAXTER, S.L. Mr. Luigi Antoniazzi	LABORATORIOS MENARINI, S.A. Mr. Salvador Pons Ribas
LABORATORIO BETA, S.A. Mr. Alfonso Rodríguez Alvarez	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 FARMACODINAMICAS, S.A. "FARDI" Mr. Javier Font Salgado	LABORATORIOS FCOS. ROVI, S.A. Mr. Juan López-Belmonte Encina
GRUPO FARMASIERRA, S.L. Mr. Tomás Olleros Izard	SANOFI-AVENTIS, S.A. Mr. Gustavo Pesquin
FERRING, S.A.U. Mr. Juan Carlos Aguilera Rodríguez	LABORATORIOS SERVIER, S.L. Mr. Olivier Vilaginés

2.2
EXECUTIVE COMMITTEE

FARMAINDUSTRIA has a Director-General who heads the Executive Committee, which is structured in functional departments. The Association has its headquarters in Madrid (Spain) 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

TECHNICAL DIRECTOR

Emili Esteve

INTERNATIONAL DIRECTOR

Icíar Sanz de Madrid

DIRECTOR OF RELATIONS WITH REGIONAL GOVERNMENTS

José Ramón Luis-Yagüe

DIRECTOR OF COMMUNI-CATIONS

Beatriz Lozano

03.

INSTITUTIONAL ACTIVITY

3.1.
MARKET REGULATION AND RELATIONS WITH PUBLIC ADMINISTRATIONS

During the 12-month period covered by this Annual Report, the evolution of the Spanish pharmaceuticals market has been highly influenced by the consequences of regulatory measures introduced in preceding years, especially Royal Decree-Laws 4 and 8/2010, 9/2011 and 16/2012, which brought in very important economic regulatory elements that were very effective in terms of reducing pharmaceutical spending, such as: i) discounts for sales to the National Health System (SNS) of medicines outside the Reference Price System, of 4%, 7.5% and 15% depending on the type of medicine; ii) the introduction of a new pharmaceutical co-payment scheme in function of the income and not the work status of the citizen, and; iii) the decoupling from financing of medicines for lesser illnesses.

Since the entry into force of the first of these Royal Decree-Laws up until the end of 2013, public pharmaceutical expenditure in terms of official SNS prescriptions has fallen by 28% in Spain, an example of the extraordinary savings potential of the measures mentioned above.

Nonetheless, over the past 12 months, important regulatory developments have been introduced derived from the legislation in force, such as the publication in March 2014 of Royal Decree 177/2014 of 21 March, regulating the Reference Price System and Homogenous Groups of medicines in the SNS, certain information systems in the area of financing and prices of medicines and sanitary products. This Royal Decree has become the central piece of the economic regulation of the pharmaceutical sector in Spain and will determine the potential for generating savings in public expenditure on off-patent drugs. At the time of writing this Annual Report, the Ministerial Order updating groups and reference prices is being passed and it will probably enter into force in summer 2014.

One of the most important new measures of the past 12 months in the regulatory domain has been the launch of Therapeutic Positioning Reports (IPT) on the part of the Spanish Agency for Medicinal and Healthcare Products (AEMPS). The aim of these reports is to offer relevant information, based on scientific evidence, of the position a new medicine occupies compared to already existing alternatives. These reports are carried out jointly between the AEMPS and the autonomous regions, and one of their main advantages can be their application throughout the National Health System, avoiding local re-evaluations. In fact, Law 10/2013, of 24 July, establishes, in its third additional provision, that activities oriented to determining the position of a medicine in the pharmaceutical service and its comparison with other therapeutic alternatives “will have a common scientific-technical basis throughout the SNS” and will be performed in the framework of the AEMPS positioning reports which will have a “binding character.”

During the past 12 months, very important regulatory measures have been introduced in Spain, such as the new Reference Price System

At the end of 2013, 45 IPTs had been requested and 15 finalized. However, as this Annual Report was being completed, the legislative working procedure for preparing IPTs, which

will establish more specifically the deadlines and evaluation procedures and methodologies the reports will follow, had still not been published.

Therapeutic Positioning Reports (IPTs) are an important part of the procedure for pricing new medicines and reimbursing the public and the Royal Decree for this is still in development and awaiting publication. This future Royal Decree will be of great importance for the pharmaceutical industry since it should regulate issues as critical as the methodology and procedure for analysing cost-effectiveness and budget impact, and the formulation of the procedure for reviewing the price of medicines, etc.

Another 2013 highlight was the launch of the medicines central purchasing system

Another 2013 highlight was the launch of the central purchasing system for medicines, with the award of 14 lots of medicines in three framework agreements (immune suppressors, epoetins and Factor 8), and a call and award of new framework agreements is foreseen for later in 2014. The central purchasing system will be a very important element in generating pharmaceutical spending savings in the hospital domain.

It should also be mentioned that, between January and February 2014, an important payment in this area was made from the 2013 Regional Liquidity Fund (FLA) to pharmaceutical companies (some 430 million euros), and another, derived from Section 2 of the 2013 Suppliers Payment Plan, amounting to 2.3 billion euros, covered all the bills, unpaid since May 2013, for supplying medicines to hospitals dependent on regional health services in nine member autonomous regions. Meanwhile, the Government also approved a new FLA for 2014, worth 23 billion euros, to cover maturing debt as well as payments to suppliers.

At the same time, 2013 also saw the announcement of various legislative texts which, although not specific to the pharmaceutical sector, are having, and will have in future, an important impact on companies, especially as regards Public Administration debt for supply of medicines and payment to companies. In this respect, by way of example, Law 19/2013, of 9 December, on transparency, access to public information and good governance, foresees fines, among other provisions, for public managers who commit to spending without having sufficient budgetary resources. Then Law 25/2013, of 27 December, promotes electronic billing and creates an accountable record of bills in the public sector, introducing as obligatory electronic billing of any public administration as of 15 January 2015. For its part, Organic Law 9/2013, of 20 December, controlling public sector commercial debt, will ensure control of commercial and financial debt by introducing a series of prevention, control and correction measures for non-payment that could culminate in the deduction and direct payment by the Ministry of Taxation and Public Administrations of the amounts owed by the indebted Administration to its suppliers.

Elsewhere, the previously cited Law 10/2013, of 24 July, and Law 20/2013, of 9 December, guaranteeing the single market, has introduced important elements for improving cohesion and fairness throughout the public healthcare system as a whole. This, for example, includes provisions which: i) consist of guaranteeing that regulatory measures in autonomous regions do not generate differences in the conditions of access to financed medicines; ii) prevent the existence of price differences for medicines between autonomous regions; iii) ensure the application of IPTs throughout the SNS, and; iv) introduce

The Government needs to support the pharmaceutical industry by using the public policy tools at its disposal

mechanisms for companies to communicate their views to Public Administrations as to specific obstacles they believe are fragmenting the national market so that these can be resolved flexibly.

In the regional domain, the autonomous regions have continued to develop pharmaceutical policy measures which, in some cases, have exceeded their fields of competence and where they have come into conflict with the powers of the Ministry of Health, Social Services and Equality (MSSSI). Among others, we can point out the carrying out of new auctions of drugs for dispensing in pharmacies and the call for tender for therapeutic equivalents. Farmaindustria, in defence of the interests of the companies, has lodged appeals against these and other measures with the corresponding legal and administrative authorities.

Following the major adjustment to public pharmaceutical spending, entailing spending cuts with regard to official SNS prescriptions of almost 30%, the Government needs to formulate the development of a pharmaceutical policy which aims to make use of the great potential the pharmaceutical industry has to offer as as one of the key economic sectors in Spain's economic recovery, and to undertake a necessary change of productive model to assure sustained growth for our country in the medium and long term.

To do so, the Government needs to support the pharmaceutical industry with the public policy tools at its disposal, particularly in ensuring a stable and predictable regulatory framework which refrains from unexpectedly altering the rules of the game each time the public health system goes through economic difficulties, and demonstrates an unequivocal commitment to pharmaceutical innovation.

In this respect, it is important to point out that, in March 2014, a Collaboration Protocol was signed by Farmaindustria and MSSSI, which foresees five basic areas of collaboration: i) consolidation of the Reference Price System; ii) progress in centralized purchasing procedures for medicines; iii) monitoring of the price-setting model and financing of new drugs; iv) follow-up and monitoring of spending, debt and access-to-innovation indicators; and v) promotion of industrial development and pharmaceutical R&D. The joint work between the institutions is performed via monthly meetings of the Dialogue Forum, as has occurred in recent months.

In turn, the new 2013-2016 Profarma Plan, approved in May 2013 by the Government's Executive Committee for Economic Affairs, and whose Call was published in the Official State Bulletin in September 2013, also goes some way to promote pharmaceutical industrial installations and medicinal research.

There now follows a detailed review of the main legislative texts and most important regulatory elements of the past year.

3.1.1 LEGISLATIVE FRAMEWORK

During the second half of 2013, and in the first months of 2014, important legislative development regulations were approved in the pharmaceutical area, as we explain in this section of the Annual Report. FARMAINDUSTRIA has taken part at the hearing stage and before the Council of State to have its say on these texts.

Also mentioned is the AEMPS regulatory legislative activity in its area of competence, especially concerning medicines for human use.

MODIFICATIONS TO LAW 29/2006 ON GUARANTEES AND RATIONAL USE OF MEDICINES AND HEALTHCARE PRODUCTS. LAW 10/2013.

Law 10/2013, published on 25 July 2013, amended certain technical aspects and the public financing of medicines in Law 29/2006. Among the technical aspects, this modification incorporates the European approach to pharmacovigilance, which is heading in a single direction throughout the EU independently of the type of authorization procedure by which a medicine has been previously authorized. This modification, which has Law status in itself, strengthens the guarantees in the manufacture and distribution of medicines and their principal ingredients, the legal sale of medicines over the Internet and by other telematic means, and incorporates changes aimed at preventing counterfeit medicines from entering the legal supply chain.

Among the modified aspects concerning public financing of medicines and health care products (Title VII of Law 29/2006), it should be pointed out that a new paragraph added to Article 88.1, which indicates that measures with a tendency to rationalize prescription and use of medicines and healthcare products that can be adopted by the ARs, will not produce differences in the conditions of access to medicines and healthcare products financed by the SNS, or the catalogue or prices. It also establishes that these rationalization measures will be homogenous for the entire Spanish territory and will not produce distortions in the single medicine and healthcare product market.

This provision translates the importance of the single medicine and healthcare product market into legislation for the undoubted benefit of professionals, patients and the industry.

Another change to highlight is the new text of Article 90.6 which should permit, through corresponding regulatory development, the application of the industrial medicine price when it is dispensed outside the SNS. In this area, FARMAINDUSTRIA is working on proposals for regulatory development.

Finally, among the various aspects incorporated in Law 10/2013, we must point out the Third Additional Provision which names AEMPS as the body charged with preparing the positioning reports for a pharmaceutical service medicine for all the SNS and its comparison with other alternative therapies, indicating the binding nature of these reports for all the SNS.

Law 10/2013 incorporates the importance of a single medicine and healthcare product market into the legislation

PHARMACOVIGILANCE

The modifications to European legislation in the area of pharmacovigilance, together with the reinforcement of quality standards for medicines and protection of the supply chain against counterfeit medicine, has meant a fundamental change in the legal basis of pharmacovigilance in the European Union.

The approval of various directives and Community regulations has made it necessary to review Spain's internal regulations, requiring the derogation, rather than the modification, of what was the basic Spanish regulation in the area of pharmacovigilance: Royal Decree 1344/2007, of 11 October, as well as the modification of Law 29/2006, by Law 10/2013 (in the area of pharmacovigilance and counterfeit medicines).

In this way, new basic legislation in this area has been introduced, Royal Decree 577/2013, of 26 July, by which the pharmacovigilance of medicines for human use is regulated. By this: i) precautions are hardened relating to the responsibilities of holders of authorizations, demanding from them a risk management plan which will become part of the marketing authorization itself; ii) the possibility is envisaged that citizens can notify suspected adverse reactions to medicines, and; iii) new measures to improve transparency and communication on safety of medicines are incorporated. Likewise, a new European committee has been created — the Pharmacovigilance Risk Assessment Committee — to implement fairly, fully and simultaneously decisions in all Member States.

The new Pharmacovigilance Risk Assessment Committee will fully and simultaneously implement decisions in all the Member States

REGISTRATION PROCEDURE

Royal Decree 686/2013, of 16 September, which amends Royal Decree 1345/2007, of 11 October, regulating the procedure for the authorization, registration and conditions for dispensing medicines for human use manufactured industrially, updates the marketing authorization procedures for medicines, incorporating EU Directives 2010/84 and 2012/26, which were not transposed via Royal Decree 577/2013.

At the same time, the administrative consequences are established which, for safety reasons, can affect the conditions for authorizing the marketing of medicines for human use, incorporating additionally both the regulation of certain advanced therapy medicines and the rest of the modifications introduced in their areas of application by different related European legislation.

Among the new elements that should be highlighted is the appointment of the Spanish representative of the Coordination Group, the European-level body responsible for examining all questions related to marketing authorizations for medicines authorized by European procedures, mutual recognition and the decentralized procedure. It also updates the exclusion relating to certain advanced therapy medicines in their application areas and incorporates the organization of measures to prevent counterfeit medicines entering the legal supply chain.

DISTRIBUTION OF MEDICINES

Royal Decree 782/2013, of 11 October, on distribution of medicines for human use, abolishes Royal Decree 2259/1994, which regulated pharmaceutical stores and the wholesale distribution of medicines for human use and healthcare products.

This new legislation regulates distribution and distinguishes between wholesale warehouses, contract warehouses and medicine warehouses under the control and safekeeping of customs authorities. On the other hand, it covers the regulatory gap existing in relation to the activities of drugs intermediary entities, regulating the status of brokers.

This legislation incorporates novelties introduced by the new European legislation to prevent the entry of counterfeit drugs into the legal supply chain and pharmacovigilance. All parties involved in the distribution of medicines will have to ensure they comply with good medicine distribution practices as published by the Ministry of Health, Social Services and Equality. Finally, it establishes the possibility of sale or direct supply to health professionals.

In parallel, the AEMPS has prepared the Directives for best distribution practices for medicines for human use.

All parties involved in medicines distribution should ensure they comply with best practices

DISTANCE SELLING

The large expansion of telecommunication networks in recent years and, particularly, the Internet also affects the sale and purchasing of medicines, such that at European level distance selling has been regulated by Directive 2011/62, preventing the entry of counterfeit medicines into the legal supply chain. Article 2.5 of Law 29/2006 limited the sale of medicines by telematic procedures to medicines that were not subject to medical prescription and was regulated in more detail by Royal Decree 870/2013, of 8 November, on distance selling to the public of medicines for human use manufactured industrially and not subject to medical prescription.

In this new Royal Decree, the activity of dispensing medicines sold over the Internet is reserved for qualified pharmacists in pharmacies, who identify themselves using a common logo that is recognizable across the European Union and which, at the same time, permits identification of the Member State in which the person offering the medicines via websites is established, who in turn must fulfil a series of requirements.

It envisages other measures such as the dispensation regime and delivery of medicines, the website inspection regime, health administration information campaigns and the promotion of Codes of Conduct by collective pharmaceutical organizations.

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 prescription and dispensing orders, changing the prescription system in Spain by changing the prescription form.

The Reference Price System regulation has been given Royal Decree status

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 on 23 January 2014 (No. 1436/2013).

REFERENCE PRICES

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 which has Royal Decree status. As the title indicates, it also regulates homogenous groups and information systems for the financing and prices of medicines. Nevertheless, we will have to wait for the Ministerial Order developing this to be approved for the new system to become effective. This was expected to be passed in May 2014.

ADMINISTRATIVE CONTRACTING PROVISIONS

In the area of public administration contracts, Law 22/2013, of 23 December, should be mentioned first, containing the 2014 General State Budget, especially Transitional Provisions 3 and 5, on the one hand, and the 88th Additional Provision on the other, related to the centralization of credits and de-indexing of public sector contracts, respectively.

For its part, Law 8/2013, of 26 June, on urban rehabilitation, regeneration and renovation, modified the Consolidated Text of the Public Sector Contracts Law to incorporate a new 34th Additional Provision which specifies that, in contracts concerned with the repeated supply of goods and services at unit price, demands by the Administration surpassing the maximum budget established by the tender to award the contract will have the status of modifications foreseen by the documentation governing the tender for that contract.

Meanwhile, Law 14/2013, of 27 September, supporting entrepreneurs and their internationalization, incorporates in Chapter II, relating to measures to boost public contracts for entrepreneurs, some substantial modifications to various precepts in the Consolidated Text of the Public Sector Contracts Law (Arts. 59.1, 65.1, 65.5, 96.2, 96.3, 102.5, 216.6, 216.8 and 4th Additional Provision), while adding new precepts (228 bis, 146.4, 146.5, 32 d). For its part, the Recommendation of the Administrative Contracting Consultative Committee, of 21 November 2013, has helped the correct interpretation of this legal text after the modifications cited.

In addition, Law 20/2013, of 9 December, guaranteeing the single market, modifying the denomination and area of activity of the State Contracting Platform and some of its operating principles which have an impact in the area of public contracts.

Elsewhere, the Order HAP/2425/2013, of 23 December, should be highlighted in that it publishes the limits of the different types of public sector contracts as of 1 January 2014.

Finally, at European level, EU Regulation No. 1336/2013, of 13 December of the Commission, should be mentioned in that it modifies EC Directives 2004/17, 2004/18 and 2009/81, of the European Parliament and Council, concerning the application thresholds in the area of contract award procedures. These new amounts are applicable in Spain through the Order mentioned in the previous paragraph.

As this Annual Report was being finalized, the Official Journal of the European Union of 28 March 2014 (L94) published EU Directive 2014/24, of the European Parliament and Council, of 26 February 2014, on public contracting, which annuls EC Directive 2004/18.

PROVISIONS ON ARREARS

Payment arrears relating to Public Administration contracts are the object of special attention both at European Union level and in our country. In this respect, several important provisions were published during 2013.

First, the Resolution of the General Secretary for the Treasury and Financial Policy, of 26 June 2013, publishing the legal interest rate on arrears that can be applied to commercial operations during the second half of 2013, and the Resolution of the General Secretary for the Treasury and Financial Policy, of 30 December 2013, making public the legal interest rate on arrears that can be applied to commercial operations during the first half of 2014.

Secondly, the Royal Decree 8/2013, of 28 June, detailing urgent measures against Public Administration arrears and support for local entities with financial problems, which establishes a third and final phase within the Public Administration arrears eradication process, adopting the following measures: i) establishing new measures to make supplier payment procedures more flexible; ii) clarifying existing payments of invoices; iii) contributing to the monitoring of arrears by an indicator that will show the volume of commercial debt for the corresponding Administration. Also, via this legislation, a series of modifications has been introduced to the Consolidated Text of the Public Sector Contracts Law, strengthening the centralized contracting system of the General State Administration.

Additionally, in the last days of December 2013, two laws were published in the BOE which constitute the fundamental axes of the plan to tackle Public Administration arrears: Organic Law 9/2013, of 20 December, to control commercial debt in the public sector and Law 25/2013, of 27 December, promoting e-billing and creating an accounting register of invoices in the public sector.

Two laws constituting the fundamental axes of the plan to tackle Public Administration arrears were published in the BOE in December 2013

In relation to this last law, Order HAP/492/2014, of 27 March, was published, regulating functional and technical requirements of the accounting register of invoices of entities in the area of application of Law 25/2013, of 27 December, promoting e-billing and creating an accounting register of invoices in the public sector.

SINGLE MARKET

Last December saw the approval of Law 20/2013, of 9 December, guaranteeing the single market. This law has the aim of establishing the principles and basic regulations to guarantee the single market by creating a more favourable environment for competition and investment, avoiding or minimizing distortions that can come from territorial administrative organization. The regulation envisages mechanisms of cooperation and collaboration between the different competent authorities for the supervision of economic operators, as well as communication channels between the Administration and the private sector to permit economic agents and companies to transmit to the Public Administrations the specific obstacles they believe are fragmenting the national market with the aim that they can be resolved flexibly.

Farmaindustria, through the CEOE Internal Market Committee, constituted in October 2011, took part in the preparation of an inventory of distortions, identifying all those autonomous region regulations that impact on the economic activity and representing a very high cost for Spanish companies and which signify at the same time a fragmentation of the single market, suggesting as a result proposals for harmonization.

This inventory of distortions was the initial instrument the Secretary of the Single Market Council in the Market Unit, the technical body for continuous coordination and cooperation with competent authorities, used to start work in this field on the recently approved Law.

In parallel, Farmaindustria held working meetings with representatives of the General Directorate for Economic Policy and the Secretary of the Single Market Council, both units in the Ministry of Economy and Competitiveness, in order to analyze which regulations had impact on the pharmaceutical sector and sectoral rules.

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

The AEMPS announced, in its area of competence, several clarifying and informative provisions (Informative Notes, Circulars, Instructions) which impact on the regulation of medicines for human use. Summarizing them thus, they include: i) an electronic notification channel for suspected adverse reactions to medicines both for health professionals and citizens; ii) the notification of the annual safety report (DSUR) to AEMPS via the medicine clinical trials portal; iii) the creation of the “electronic HQ” part of the AEMPS website; iv) the launch of a web application which allows laboratories to manage telematically technical files and prospectuses, as well as the launch of the Spanish Clinical Studies Registry; v) information on medicines subject to additional monitoring.

Law 20/2013 aims to establish the principles guaranteeing the single market to create a more favourable environment for investment and competition

Instructions were also announced for the communication of incidents relating to the quality of medicines for human use and a Note on the need to participate in systems which guarantee the collection of medicines waste generated in homes.

3.1.2 THE AUTONOMOUS REGIONS

Communication and dialogue with regional health authorities has intensified

FARMAINDUSTRIA has conducted intense institutional activity with regards to its relations with regional health authorities, scientific associations, professional and political organizations, institutions and social organizations, with the purpose of promoting areas of understanding that permit the expression of faithful, transparent collaboration that benefits the public health system, pharmaceutical innovation and, all in all, in the improvement of health levels of the population.

Close monitoring of the different regional initiatives related to health policy and pharmaceutical provision has also been performed, informing Member Companies when necessary of the most important aspects in this area.

FARMAINDUSTRIA-AUTONOMOUS REGION FORUMS

The forums FARMAINDUSTRIA regularly organizes with health officials from central and regional administrations have been consolidated as a meeting place where subjects of common interest can be analyzed, shared and reflected upon.

In 2013, the 16th edition of these encounters was held in Zaragoza and analyzed the modifications introduced by Royal Decree-law 16/2012, of 20 April, on urgent measures to ensure the sustainability of the SNS in financing, prices and reimbursement of medicines. The Secretary General for Health and Consumers of the Ministry of Health, Social Services and Equality, and Aragon's Director of Health, Social Wellbeing and Family inaugurated the event. Representatives of 11 ARs and INGESA participated.

As this Annual Report was heading for publication, the 17th FARMAINDUSTRIA-AR Forum, entitled 'Present situation and forecasts for the SNS pharmaceutical service', was held in Toledo, inaugurated by the Director of Health and Social Affairs for Castile-La Mancha and by the President of FARMAINDUSTRIA, and attended by representatives of 13 ARs and INGESA.

INSTITUTIONAL CONTACTS

Throughout 2013, FARMAINDUSTRIA intensified the channels of communication and dialogue with regional health authorities it had 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. We also took up those aspects specifically affecting each region. 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.

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 be mentioned. These are described in a separate section of this Annual Report.

REGULATORY INITIATIVES IN THE REGIONS

A review of the most relevant regional policies, regulations and initiatives of the past 12 months follows, as well as some of the activities performed by FARMAINDUSTRIA in this respect. Details are also included in this section of the modification of Law 29/2006, of 26 July, on guarantees and rational use of medicines and healthcare products, through Law 10/2013, wherever it has a direct repercussion in the area of pharmaceutical service in the ARs.

MODIFICATION OF LAW 29/2006, OF 26 JULY, ON GUARANTEES AND RATIONAL USE OF MEDICINES AND HEALTHCARE PRODUCTS

On 25 July 2013, the BOE published Law 10/2013, of 24 July, incorporating the Spanish transposition of EU Directives 2010/84, of the European Parliament and Council, of 15 December 2010, on pharmacovigilance, and 2011/62, of the European Parliament and Council, of 8 June 2011, on the prevention of counterfeit medicines entering the legal supply chain. It also modified Law 29/2006, of 26 July, on guarantees and rational use of medicines and healthcare products.

In all our meetings with regional healthcare officials, the strong impact of measures to contain spending was observed

Among the modifications introduced, of special interest with respect to the ARs are those relating to Article 88, which try to ensure the unity of the national market and avoid discrimination in access to the pharmaceutical service.

As such, a new paragraph was added to Article 88.1:

> "The measures designed to rationalize prescription and use of medicines and healthcare products that the Autonomous Regions can adopt will not produce differences in the conditions of access to medicines and healthcare products financed by the National Health System, its catalogue or prices. Such rationalization measures will be homogenous for the totality of the Spanish territory and will not produce distortions in the single market for medicines and healthcare products."

Three new sections were also added to Article 88 and the old section 2 was renumbered section 5, the new text being worded as follows:

> "2. The legislative provisions of the Government and Ministry of Health, Social Services and Equality and the resolutions issued by the competent management centre of said Ministry in relation to the financing of medicines and healthcare products of the National Health System will take effect in all of the Spanish territory from the date that they become applicable.
>
> 3. The industrial price for public financing, established by the competent body in the Ministry of Health, Social Services and Equality, for medicines dispensed by pharmacies via official medical prescription of the National Health System, cannot be the object of modification of discount, except where the same consists of a percentage or linear discount applicable in all the national territory.

4. Any modification of the price of a medicine or healthcare product financed by the National Health System will take effect on the same date in all the Spanish territory.

5. The Inter-territorial Council of the National Health System will be able to agree the general conditions of planning, coordination, contracting, acquisition and supply of medicines and healthcare products for the publicly owned structures and services integrated in the National Health System."

Additionally, this Law, in its Third Additional Provision, regulates the therapeutic positioning of a medicine in the pharmaceutical service, with the following wording: "The actions aimed at establishing the position of a medicine in the pharmaceutical service and its comparison with other therapeutic alternatives will have a common scientific-technical basis for all the National Health System and will be carried out within the framework of the positioning reports of the Spanish Agency for Medicines and Healthcare Products. Said reports will have a binding nature."

These modifications have large repercussions for the sector in that they signify the definition of the powers of the Ministry of Health, Social Services and Equality and the capacity of the ARs to introduce additional measures which suppose a restriction in the access to, or the de facto exclusion of, medicines, with the aim of guaranteeing the cohesion of the pharmaceutical service in all the national territory.

Electronic prescriptions and medical records continued to be introduced in the different ARs during 2013

ELECTRONIC PRESCRIPTIONS AND MEDICAL RECORDS

During 2013, the system of electronic prescriptions and medical records continued to be introduced in the different ARs.

As this Annual Report closed for publication, the ARs of Andalusia, Aragon, the Balearic Isles, the Canary Islands, Cantabria, Catalonia, Castile-La Mancha, Extremadura, Galicia, Murcia, the Basque Country and the Community of Valencia had completed the installation of the electronic prescription system in their territories and the rest of the ARs had progressed considerably in implementing it, with the objective of finishing the process during 2014.

With respect to this section, it should be noted that Royal Decree-law 9/2011 foresaw that both digital medical records and electronic prescriptions were to be fully incorporated and interoperable throughout the SNS before 1 January 2013.

Electronic medical records have been implemented in almost all of the ARs and the possibility of consulting them from any centre in a region at different levels of healthcare is becoming a reality. Given this progress, the Digital Medical Registry of the SNS is being built, a project backed by Law 16/2003, of 28 May, on the cohesion and quality of the SNS, Article 56, and Law 41/2002, of 14 November, the basic regulation for patient autonomy, specifically the Third Additional Provision.

Auctions for medicines to be introduced by the Andalusia Health Service have caused the break-up of the single national pharmaceutical market and are unfair to Andalusian patients

EXCLUSION OF BRANDED MEDICINES FROM THE ELECTRONIC PRESCRIPTION DATABASE: CASTILE-LA MANCHA AND EXTREMADURA

Legal actions undertaken by Farmaindustria during 2013 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 concluding as of writing.

As far as Extremadura is concerned, the No.1 Contentious Administrative Court in Merida, in its judgment of 16 May 2012, found partially in favour of the appeal lodged by Farmaindustria against the action undertaken by the Extremadura Health Service in December 2010, excluding certain branded medicines from the electronic prescription system. The Court declared that the ARs could not adopt measures to exclude medicines from computerized prescriptions since they had no competence over the matter, although the measure appealed against cannot be reversed due to the later legal amendments carried in different Royal Decree-laws adopted by the Government.

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 a selection procedure for medicines to 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), and, as this Annual Report closed, the Resolution of 31 March 2014 (4th auction) of the Andalusia Health Service (SAS) Management Executive concerning the selection of these medicines.

This initiative has resulted in the Government lodging a conflict-of-powers case 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.

For its part, Farmaindustria has also presented appeals against the SAS resolutions and is prepared to lodge a hierarchical appeal against the Resolution of 31 March 2014 (4th auction).

MEDICINES RELATED TO HOSPITAL DIAGNOSES (DH) 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 that were being 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 17 March 2014, the contentious administrative appeal lodged by CEOFA, the Andalusian Pharmacy Business Confederation, against Resolution SC 0403/10, of 22 December, by the SAS Management Executive, that certain medicines for treatment outside hospitals and being dispensed by hospital pharmacy services require, in the judgment of SAS, particular care, supervision and control. The judgment might not be totally clear, but it does confirm 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 belongs to the state.

Farmaindustria also appealed against the resolution above and is awaiting the judgment on this, which, in the light of the above, it hopes is likewise accepted and thus will annul, as requested, this resolution.

THERAPEUTIC ALTERNATIVES: CASTILE-LA MANCHA, ANDALUSIA AND THE CATALONIAN SOCIAL AND HEALTH CONSORTIUM

Castile-La Mancha Health Service incorporated in 2012 a new IT application that prompted the substitution of medicines by “therapeutic equivalents” in the Turriano prescription system, which caused Farmaindustria to bring several legal actions that are now nearing conclusion.

Elsewhere, in February 2013, the “Consorci de Salut i Social de Catalunya” in Catalonia published a Framework Agreement for the supply of medicines, saline solutions, enteral nutrition and contrast dyes, in which it included a lot referring to a “similar therapeutic alternative”. Faced with this initiative, Farmaindustria communicated its surprise and concern to the Catalonia health authorities and the Consorci de Salut i Social, given the clear damage this caused patients, doctors and the innovative pharmaceutical industry, as well as the doubtful legal basis of this type of tender. As a result, we proceeded to lodge a contentious administrative appeal in April 2013 which finally saw the withdrawal of certification by the Consortium Secretariat on 24 July 2013 leading to the annulment of the Framework Agreement procedure as a result of the special appeals lodged with regard to the contracting procedure.

In September 2013, the Consorci published a new Framework Agreement for the supply of medicines in which the lots were configured by active ingredient, but the finalization of the Framework Agreement and derived contracts was foreseen to be completed after the granting of the marketing authorization for a generic medicine or equivalent therapeutic alternative (a modification being introduced to correct errors). Faced with this modification, Farmaindustria presented a special appeal with regard to the contracting procedure that was upheld, resulting in the annulment of the agreement.

The competence for establishing and modifying the conditions for dispensing pharmaceutical products belongs to the state

In July 2013, Andalusia Health Service published a Framework Agreement for the homologation of the selection of active ingredients for certain indications, against which Farmaindustria lodged a special appeal, on 14 August, in the area of contracting with a request for precautionary measures consistent with the suspension of the Framework Agreement public tender award procedure. The procedure was 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.

The ruling pointed out that the award criteria contained deficiencies and was violating the principles of equal treatment, rendering them completely null, indicating that where the documents compared technical proposals about different objects (active ingredients), there could not be equal treatment among bidders, since this equality would only exist if the proposals being evaluated were about the same active ingredient. Nonetheless, the Resolution allowed, from the point of view of administrative contracting, for the utilization of various criteria to form the lots, among them, that of 'same indication'; in any case, this did not mean that active ingredients listed in the lot could be considered equivalent or interchangeable, only that they responded to a same 'functional unit' (in this case, 'therapeutic indication').

To summarize, Farmaindustria has repeatedly communicated to the health authorities its opposition to the preparation of purchasing protocols or procedures based on supposed 'therapeutic equivalents', given their negative consequences on innovation and the clear damage they cause patients, health professionals and the industry.

Farmaindustria is carrying out an active monitoring of these types of initiative and will continue to take appropriate actions against them, given that they represent a concealed attempt to exclude the affected medicines from public financing, transgressing the established legislative framework to the detriment of the value of innovation.

FRACTIONALIZING IN HOSPITAL PHARMACY

In light of the actions that are being carried out in some SNS hospitals, which fractionalize or formulate medicines with the aim of separating them from their commercial presentations, Farmaindustria has contacted the AEMPS and the Directorate-General for the Basic Portfolio of Services in the SNS and Pharmacy to communicate its concern about these practices.

Farmaindustria has repeatedly said it opposes the preparation of purchasing protocols or procedures based on supposed therapeutic equivalents, given their negative consequences on innovation and patients

In the Association's opinion, this kind of practice generates illicit competition obviously breaching industrial property, data protection and commercial exclusivity regulations in the case of orphan drugs, while weakening the system of evaluation and authorization of medicines, which is the maximum guarantee for the standards of quality, safety and efficacy of registered medicines.

Farmaindustria has also pointed out that fractionalizing, regulated by Article 7 of the Royal Decree-law 16/2012, cannot shield these practices since they must be restricted to the improvement of the effectiveness of a medicine, which would exclusively permit the adaptation of presentations to attend to the needs of specific patients who are not covered by the conditions of authorization of the medicines.

FARMAINDUSTRIA is analyzing the activities of the Public Administrations in this area with the aim of undertaking all the legal actions at its disposal in order to protect the legitimate interests of Member Companies.

Separating medicines from their commercial presentations creates illicit competition obviously in breach of industrial property rules

PRESCRIPTION ALGORITHMS: VALENCIAN COMMUNITY

The Community of Valencia approved in March 2013 Decree-law 2/2013, on Urgent Management Actions and Efficiency in Pharmaceutical and Orthoprotesic Services.

This legislation includes a series of measures which affect the selection, prescription and dispensing services for medicines and healthcare products. Among other aspects, it establishes that the Valencia Health Agency will elaborate therapeutic decision algorithms for certain pathologies, which will include clinical instructions and active ingredients to use in light of the most cost-effective options.

According to the provisions of this legislation, doctors will have to prescribe the medicine selected by these algorithms. Doctors will, however, be able to prescribe a different medicine if they can clinically justify their decisions.

In the hospital area, it is planned to maximize the centralized purchasing of medicines and the establishment of common protocols for using 'high impact' drugs.

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, in any case, the algorithms are to be used as a guide and that the freedom of the doctor to prescribe is to be respected.

FARMAINDUSTRIA continues to follow this initiative closely, observing the broad rejection it has generated among scientific associations, professional collectives and patients.

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, three algorithms have been approved to date, 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, and; iii) treatment of arthritis.

The aggregated purchasing procedure for the SNS as a whole is a savings instrument for hospital products

At the time of writing this Annual Report, algorithms are being processed for antipsychotics (clozapine, asenapine, quetiapine, risperidone, paliperidone), antidepressives and the use of pregabalin.

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

Otherwise, within this Decree-law, Instruction 2, of September 2013, of the Valencia Directorate-General for Pharmacy, was introduced, on the prescription, preparation, transport, receipt and administration of pre-charged syringes of subcutaneous methotrexate, which has been appealed by Farmaindustria since we believe it violates the legislative framework set out by Article 7 of Royal Decree-law 16/2012, as indicated under the previous heading.

SNS PURCHASING PLATFORM

In previous Annual Reports, we informed about the agreements of the Inter-territorial Council of the SNS of 18 March 2010 and 18 April 2012 by which, among other initiatives, it is planned to establish an aggregated purchasing procedure for the whole of the SNS, to which the ARs can adhere voluntarily.

In this regard, Royal Decree-law 16/2012 establishes in its Fourth Additional Provision that the Inter-territorial 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.

With the aim of launching a centralized purchasing system, the Council of Ministers of 28 December 2012 approved the call for tender for purchases for the SNS in the form of a Framework Agreement.

Fourteen ARs, INGESA and the Ministry of Defence and Penitentiary Institutions took part in the first call, which consisted of 11 lots of medicines including six erythropoietins and five immunosuppressants.

This call was suspended as a precaution by the Central Contractual Appeals Court due to appeals lodged against it. On 27 March 2013, this body issued a resolution that led to the amendment of certain aspects of the administrative clause documentation of the Framework Agreement.

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, the lots of three agreements have been called for tender and awarded: immunosuppressants, epoetins and Factor 8.

Given that the selected procedure was negotiated without advertisement, under Article 170.d) of the Consolidated Text of the Public Sector Contracts Law, the specific administrative clause documentation and technical prescription documentation are not published in any media (BOE, platform or profile of the contracting party) but are sent to the companies invited to participate in the call.

The basic aspects of the framework agreements called for tender are summarized below:

Framework agreement. Medicine	Contracting administrations	Lot constituted by	Lots offered	Lots awarded
Immuno-suppressants	- 10 ARs (Aragon, Asturias, Castile-La Mancha, Castile & Leon, Cantabria, Extremadura, Madrid, Murcia, la Rioja and Valencia) - INGESA - Min. Interior - Min. Defence	Active ingredient	9	6
Epoetins	- 5 ARs (Asturias, Castile-La Mancha, Cantabria, Extremadura and Murcia) - INGESA - Min. Defence	Active ingredient	5	4
Factor 8 coagulation	- 10 ARs (Asturias, Balearics, Castile-La Mancha, Castile & Leon, Cantabria, Extremadura, Galicia, Murcia, Navarre and la Rioja) - INGESA	Brand	4	4

MEDICINE SUPPLIERS ROUND TABLE. CATALONIA

In the framework of the collaboration relationship established with the Catalonia Generalitat, in the meeting between the Taula Generalitat ('Catalonian Government Table') and Pharmaceutical Industry held on 5 September 2012, it was agreed a Medicine Suppliers Round Table would be constituted with the aim of establishing a relationship framework to generate confidence, resolve discrepancies and approve positions on pharmaceutical provision, both from the offer and demand sides. The Round Table, in which three Vice-Presidents of Farmaindustria participate, met twice in 2013: on 11 April (constitutive meeting) and 16 September.

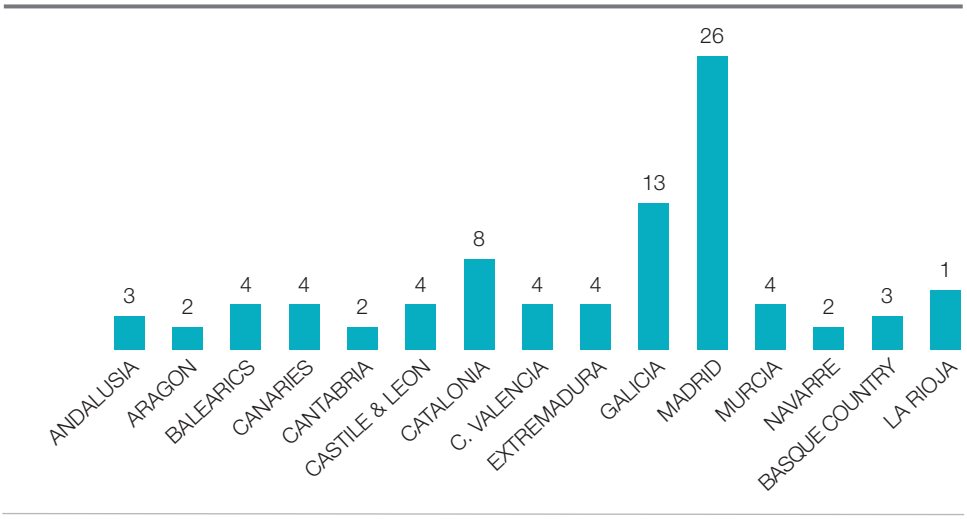
This Round Table also has a technical group that held three meetings between April and July 2013 in which it analyzed the measures foreseen by Catsalut in pharmaceutical policy and at which Farmaindustria communicated the sector's positions in the area of therapeutic equivalents and supplier discounts. With the aim of defining the implementation of these measures and respecting the industry's priorities, it was agreed that the work would be conducted on the following lines: i) disease management, sustainable prescription protocols that do not exclude medicines; ii) best practices in acquiring hospital medicines; iii) access to innovation, mechanisms to facilitate the acquisition of innovative drugs; iv) relations between public insurers and their suppliers, with reference to the area of medicines.

Additonally, continuing on the previous meetings, a meeting between the Taula Generalitat and Pharmaceutical Industry was held on 5 February 2014 attended by three Ministers of the Catalonian Generalitat (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 pharmaceutical policy developed by the Generalitat and the progress made by the Medicine Suppliers Round Table.

COOPERATION PROGRAMME WITH AUTONOMOUS COMMUNITIES IN TRANSLATIONAL CLINICAL RESEARCH. +I PROGRAMME

+i Programme projects continued to be carried out during 2013 in line with the agreements established between Farmaindustria and the ARs.

Eighty-four projects were cofinanced in total through the Programme, as the following chart shows. The Community of Madrid stands out by number of projects (26), followed by Galicia (13) and Catalonia (8). These three regions account for over 50% of the projects.



Cofinanced projects by area are shown as follows:

Description	Number 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

Different projects included in the +i Programme come under a cooperation framework between the parties, based on cofinancing.

The ARs send half-year reports to Farmaindustria on the execution of the different projects included in the +i Programme, in line with what is in the respective agreements, to ensure the coordination, development, monitoring and evaluation of the programme. These are analyzed by a Technical Secretariat, known as the Project Support Office (Deloitte), and submitted to the respective +i Programme Monitoring Committees.

In this regard, it should be remembered that the +i Programme Monitoring Committees are bodies of a regional character, established between an Autonomous Region and Farmaindustria, created through the corresponding Collaboration Agreement.

By 31 December 2012, 75 projects had been completed and by 31 December 2013 another seven. There are two projects still running at present which will end during the second half of 2014.

At the time of writing, the Project Support Office (Deloitte) is analyzing the latest reports corresponding to the second half of 2013 and 2013 as a whole, as well as the audit re-

ports 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.

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 allows 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-Presidency corresponding to business organizations for the next two years.

There remain just two +i Programmes to be completed in the second half of 2014

The Committee held three meetings last year in which it informed in areas that are of special interest concerning the operation of the SNS and, as is mandatory for the passage of certain provisions, informed on the legislative projects affecting clinical trials, cross-border healthcare, reference prices, cosmetic products and homeopathic medicines, as well as many aspects relating to the portfolio of SNS healthcare services and other subjects of interest that make up the agenda of the SNS Inter-territorial Council.

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 of which 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 received the Agency's medicines report and, in those meetings in which FARMAINDUSTRIA spoke jointly or alone, various AEMPS strategies were debated, such as the Strategic Antibiotics Plan, modifications to the size of packaging and the change in the conditions for dispensing certain medicines. The Committee is likewise informed about Therapeutic Positioning reports and evaluation reports submitted by AEMPS experts.

3.1.4 COLLECTIVE BARGAINING AGREEMENT

On 21 January 2013, after an intense negotiating process, the Spanish Chemical Industry Business Federation (FEIQUE) and the trade unions FITEQA-CCOO and FITAG-UGT signed the contents of the 17th Chemical Industry General Bargaining Agreement (CGIQ).

With the signature of the two unions mentioned above, the 17th CGIQ is once more an effective general agreement, published in the BOE, that applies to all the companies and workers included within its operational area. It is important to point out that, previous to the signing of the 17th CGIQ, FITAG-UGT adhered to the 16th CGIQ (of limited effectiveness), which in its day was signed by FEIQUE, COFACO and CCOO and in force for 2011 and 2012.

Although, as a result, the 16th CGIQ was not generally effective, the adhesion of FITAG-UGT was important since it meant the union accepted its content as a whole and this made possible the signing of the 17th CGIQ, which contains the following stipulations:

- Effective for: 2013 and 2014.
- Pay increases: 0% 2013; linked to 2013 GDP for 2014, where and when the latter is the greater than 2012 GDP, according to the following: if the increase in GDP in 2013 is less than or equal to 1%, the salary increase for 2014 will be 0.2%; if the 2013 GDP increase is greater than 1%, the 2014 increase will be 0.4%.
- Working hours: same length as in the previous agreements (1,752 hours of effective work per year).
- Compulsory retirement: suppression of compulsory retirement in line with the legal requirement.
- Stability: where it is not clear whether the Agreement will be renewed, the period established by Law for it to expire is extended from 12 to 24 months following the reporting of this situation.

The new contents negotiated for the 17th Chemical Industry General Bargaining Agreement are adapted to the present situation of our economy

The new contents negotiated are adapted to the present situation of our economy, the parties having agreed to a salary increase within the parameters recommended by the AENC 2012-2014, while safeguarding the usefulness and efficiency of the CGIQ as a tool for regulating labour relations in the chemical industry. The CGIQ was published in the BOE on 9 April 2013.

LABOUR REFORM

During 2013, labour reforms, initiated by the Government the previous year, continued apace. These included Royal Decree-law 1/2013, of 25 January, extending the professional requalification programme for those whose social protection for unemployment has run out, and adopting other urgent measures in employment and social protection for the unemployed. The Council of Ministers also approved, on 26 April 2013, the 2013-2016 Stability Programme and the National Reforms Plan to send to the European Commission, outlining the labour and Social Security reforms planned for 2013.

Support measures for entrepreneurs and incentivesi for growth and employment creation were also stipulated by Royal Decree-law 4/2013, of 22 February, and Law 11/2013, of 26 July. All of these are aimed at: i) developing a strategy for entrepreneurial activity and youth employment; ii) fostering business financing via alternative markets; iii) reducing

non-payment in commercial transactions, and; iv) fomenting the competitiveness of the Spanish economy.

In the area of retirement, Royal Decree-law 5/2013 introduced new regulations in four areas: i) work-pension compatibility; ii) early retirement; iii) part-retirement, and; iv) age discrimination.

Meanwhile, Royal Decree-Law 16/2013 establishes additional measures favouring stable contracts and improving the employability of workers, and introduces modifications in the framework of the regulation of part-time contracts.

Law 23/2013, of 23 December, regulating the sustainability factor and the revaluation index for the Social Security pension system, should also be noted. This was published with the aim of ensuring economic and financial stability of the Social Security system in the medium and long term by incorporating a sustainability factor and reformulating the index for revaluing pensions, in line with the measures in Law 27/2011, of 1 August, on updating, adapting and modernizing the Social Security System.

Support measures for entrepreneurs and incentives for growth and employment creation have been introduced

The simplification and reduction of contract models should also be highlighted. These have been reduced to just four work contract models: indefinite (permanent), temporary, training, and practical work placement contracts.

Finally, Royal Decree-law 3/2014, of 28 February, on urgent measures for the promotion of employment and permanent (indefinite) contracts, introduces the so-called “flat tariff” for Social Security contributions, using common contingencies for the contracting of new permanent employees, to which companies and self-employed people will have access, independently of their size, when they contract a new permanent worker, when this contract supposes the net creation of stable employment.

3.2
SOCIAL COMMUNICATION

One of FARMAINDUSTRIA's main objectives is to bring the pharmaceutical industry closer to society so that people better understand the social, economic and healthcare contribution of the sector. An effort has been made in this respect, in recent years, with different players who have an important place in society, such as the media, the primary information channel for citizens, and main opinion leaders.

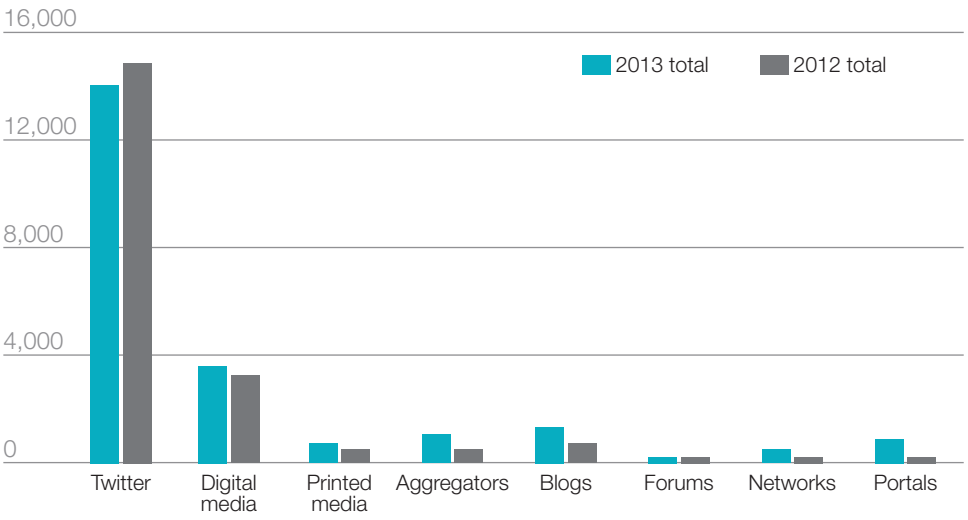
Conventional media and digital platforms, new 2.0 communication environments and the different ways of interacting with a receptive public, now form part of the daily activity of the Association.

We also continue to deepen our search for areas of common interest with patients' associations, the ultimate recipients of the efforts of the pharmaceutical industry; and all this without forgetting the importance of internal communication.

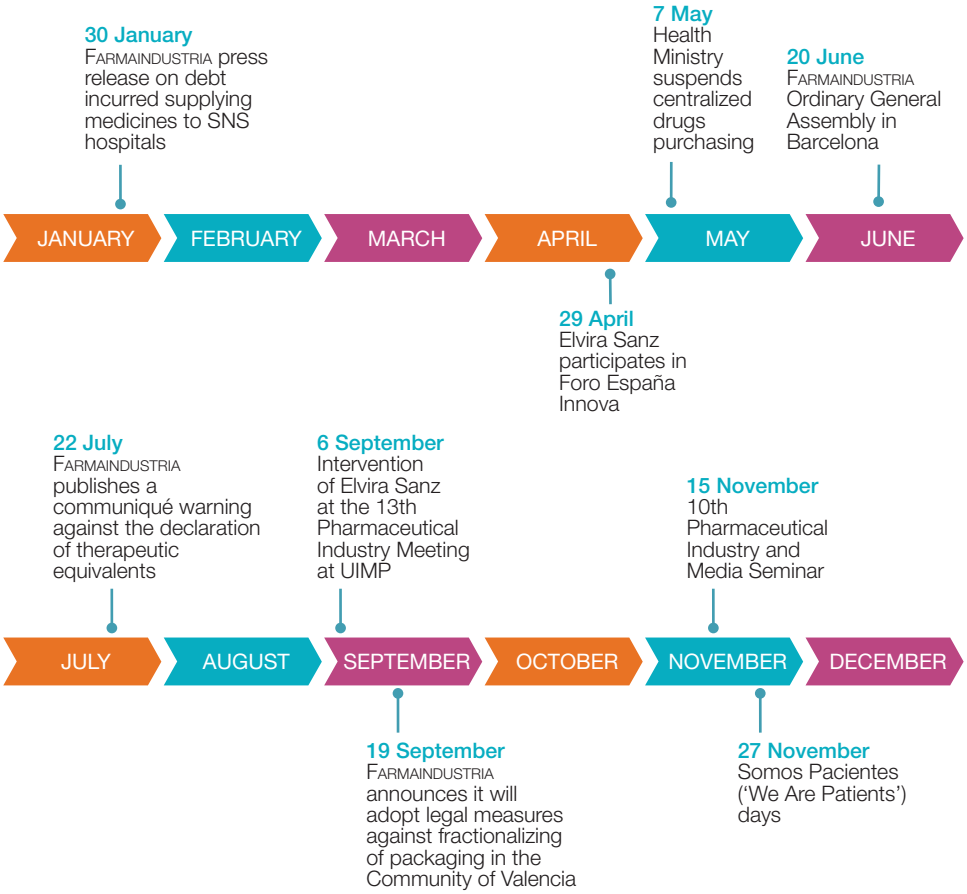
3.2.1 COMMUNICATION MEDIA

Throughout 2013, FARMAINDUSTRIA performed an important activity with the communication media, generating a significant volume of content that was particularly reflected in the written press, at national and regional, general and specialist, levels.

Although the volume of FARMAINDUSTRIA's activity, as reported by traditional media, remained stable with respect to the previous year, in the online environment (digital and social media) the activity and impact increased.



In 2013, most FARMAINDUSTRIA activity in the communication media area was channeled through press releases and communiqués published to: i) inform the position of the sector on different pressing issues; ii) communicate initiatives being carried out by the Association, and; iii) disseminate data and information of special relevance linked to the pharmaceutical industry.



On top of this, press conferences were held in different parts of Spain and commentaries and opinion pieces by representatives of the Association were published in the press on subjects as diverse as the medicines of the future, control of pharmaceutical spending, the sustainability of the SNS and pharmaceutical industry R&D, among others.

The participation of the FARMAINDUSTRIA President at Foro España Innova, organized by Nueva Economía Forum, had a great impact in both the audiovisual and written media. The event brought together around 300 people, most of them economic, political, health, public administration and media representatives. The reality of the pharmaceutical sector in Spain was examined, as well as its main challenges and future objectives.

FARMAINDUSTRIA President Elvira Sanz spoke at Foro España innova, April 2013.

FARMAINDUSTRIA was also present in the communication media via interviews and reports in which it addressed the situation of the innovative industry in Spain and crucial questions in the area of health and pharmaceutical policy.

DIARIO MEDICO ESPECIAL

POLÍTICA SANITARIA | ENTREVISTA CON ELVIRA SANZ

"EL MERCADO DE RECETA CAERÁ UN 12% ESTE AÑO Y EL DE HOSPITAL UN 1%"

El sector seguirá cayendo hasta 2016, según todas sus previsiones, tanto en botica como en hospitales

"EL ITP NO DEBERÍA INCLUIR CRITERIO ECONÓMICO"

DIARIO MEDICO ESPECIAL

POLÍTICA SANITARIA | ENTREVISTA CON ELVIRA SANZ

"EL ACCESO A NUEVOS FÁRMACOS ERA DE LOS MEJORES, AHORA CASI EL PEOR"

La presidenta de Farmaindustria, Elvira Sanz, cifra en el 33% la caída del sector en tres años por los recortes, pero confía en que no habrá más medidas

Casi recién llegada a la patronal

Cinco Días

La industria farmacéutica reclama su papel estratégico

PÁGINAS 7 A 9

ÁNGEL FERNÁNDEZ
Director general de MSD

JESÚS ACEBILLO
Presidente de Novartis

ELVIRA SANZ
Presidenta de Farmaindustria y de Pfizer

MARTÍN SELLES
Presidente de Janssen

MARC ANTOINE LUCCHINI
Presidente de Sanofi

ROGELIO AMBROSI
Director ejecutivo de Merck

FARMAINDUSTRIA, for yet another year, performed intensive institutional relations work in 2013 with many communication media (RTVE, El Economista, La Razón, ABC, etc.) and different opinion leaders, with the aim of transmitting to them at first hand the situation of the pharmaceutical industry in Spain and thus contributing to improving society's knowledge of the sector.

Institutional visit to El Economista editorial offices, July 2013.

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 allows the periodic communication of a profound analysis of various aspects relating to the Spanish pharmaceutical market to the world at large.

Expansión

EL MERCADO DEL MEDICAMENTO

El gasto farmacéutico público pierde un 29% de valor en tres años

NIVEL MÁS BAJO DESDE 2004/ La evolución del mercado está hoy determinada, principalmente, por el número de recetas dispensadas, que en el último año se han reducido en casi un 15%.

Caída del 11,5% en septiembre, pese al 'efecto rebote'

Expansión

EL MERCADO DEL MEDICAMENTO

La industria farmacéutica, a la cabeza de la inversión en I+D industrial en España

APORTA UNO DE CADA CINCO EUROS EN INVESTIGACIÓN Y DESARROLLO/ A pesar de la fuerte reducción del gasto en medicamentos en el mercado español, sigue siendo, con diferencia, el sector que más invierte en innovación.

Farmaindustria: el gasto en medicamentos se va a estancar

Throughout 2013, Association representatives took part in several days and meetings that were reported by the media. Once again, the Pelayo Menéndez International University (UIMP) hosted the 13th Pharmaceutical Industry Meeting, sponsored by Farmaindustria, which focused on analyzing the new medicine pricing systems.

13th Pharmaceutical Industry Meeting at UIMP.

In the area of the training of information professionals, Farmaindustria once again held its Pharmaceutical Industry and Media Seminar, for the 10th consecutive year. The Cuenca event attracted a large and enthusiastic representation of media professionals as well as the participation of the Federation of Spanish Press Associations (FAPE).

10th Pharmaceutical Industry and Media Seminar.

FARMAINDUSTRIA collaborated actively with the National Association of Health Communicators (NIS), taking part in the 9th Health Journalism Congress in Valladolid. Also in 2013, it signed an agreement with Unidad Editorial Conferences and Training to collaborate in the launch of the Correo Farmacéutico Training School, forming part of its Advisory Board and participating directly in the definition and organization of two of the teaching programmes.

The communication media also recognized the work carried out by the Association in various areas. The weekly Correo Farmacéutico, for instance, granted its Best Pharmacy Initiatives Award for the launch with the Cantabrian Government of the new Clinical Trials Unit at the Marqués de Valdecilla University Hospital in Santander as part of the +i Programme to promote research.

Ceremony to present the Correo Farmacéutico Awards for the Best Pharmacy Initiatives.

3.2.2 2.0 COMMUNICATION

FARMAINDUSTRIA consolidated its presence in the social networks, which grew notably during 2013. Its Twitter channel, launched three years ago, had over 10,500 followers by the end of 2013, double the number at the end of the previous year.

FARMAINDUSTRIA became the most active in 2.0 communication among the European associations representing the innovative pharmaceutical industry and one of the most influential Spanish health organizations on this stage.

FARMAINDUSTRIA's Twitter activity is centered on disseminating information about the Association's own activities and alerts about important information and content for the Spanish pharmaceutical sector. On Facebook, it has concentrated its full presence via the Association's page in the social network, which offers as much own, as third-party, content that is of interest and importance to the industry.

The Top Ten Health 2.0 Report, published in July 2013, places FARMAINDUSTRIA in third place in a ranking of the 10 users with best positioning, activity, interaction and visibility in the 2.0 health sector.

The annual report monitoring the presence and activity of FARMAINDUSTRIA and the pharmaceutical sector in the communication media and social networks reveals that in 2013 more than 23,000 articles and commentaries were published mentioning the Association, a similar figure to 2012 but with a greater percentage of positive perception (63%, compared to 56% in 2012). Activity related to FARMAINDUSTRIA on Twitter alone generated around 15 million hits in 2013, an average of over 7,400 hits per item on the network.

Elsewhere, Somos Pacientes ('We Are Patients'), the online community of patient associations promoted by FARMAINDUSTRIA, is clearly committed to being present and disseminating its activity and content on Web 2.0.

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 outstanding participation on both Twitter and Facebook. The Somos Pacientes profile on Twitter had over 6,000 followers at the end of 2013. Through this channel, the platform broadcast its new content, announced the incorporation of new member entities in the association and kept an open dialogue with more than 700 associations which follow it via the social network.

In Facebook, Somos Pacientes has a page via which it disseminates content and which, at the end of 2013, had more than 1,000 followers. The community also has a YouTube channel in which it posts all the reports and interviews in videos it publishes on the platform.

The above Top Ten Health 2.0 Report named Somos Pacientes as the main provider of original content in the 2.0 health environment.

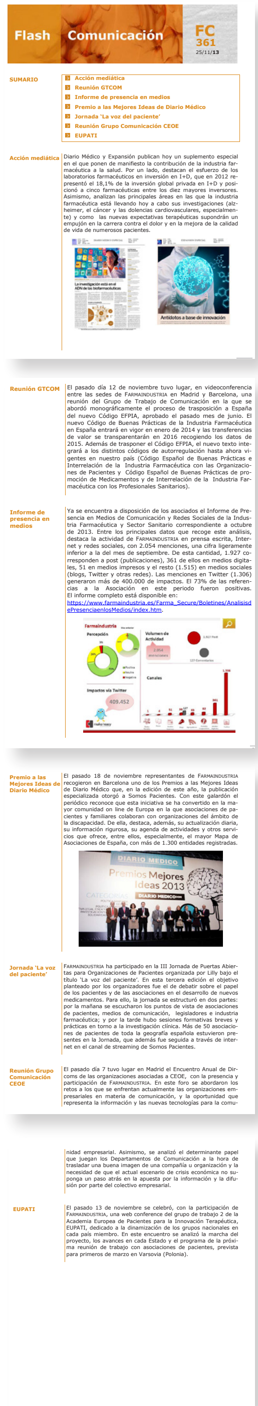
3.2.3 INTERNAL COMMUNICATION

Internal communication with member laboratories is another of the cornerstones of the Association's communications activities.

On the one hand, the Communication Working Group maintains quarterly meetings, with plenty of participation from representatives of the different companies, in which the items of greatest interest to the sector are brought up and strategies and joint positions prepared.

Internally, every Monday, the weekly communication Flash is distributed among Member Companies. Forty-two Flash were disseminated in 2013, 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 PATIENT ASSOCIATIONS

In 2013, Farmaindustria intensified its relations and collaboration with patients and the associations that represent them, through different channels: i) dialogue with associations, both directly and via the Permanent Roundtable for Dialogue with Patient Organizations; ii) the online community of associations, Somos Pacientes, and; iii) the European Patients Academy, among others.

COLLABORATION WITH PATIENT ASSOCIATIONS

Farmaindustria took part in numerous events, meetings, days, seminars, debates and diverse activities with patient organizations in 2013, to share experiences with them and support their work. The Association also continued to be present and participate actively in the Aragon Patients Forum (FAP), the Board of which it has been a member, along with 12 other entities, since the forum was founded in 2011.

Farmaindustria took part in many patient association meetings and activities in 2013, including the course annually organised by the Spanish Breast Cancer Federation (FECMA) at UIPM, and the National Kidney Disease Associations (ALCER) Day. The Association also maintained direct contacts with organizations such as FEAPS, FEAFES, FEDHEMO, AEPEF, FNETH, AME, APREM, FEDER, ALAIA and CONARTRITIS, among others.

PERMANENT DIALOGUE ROUNDTABLE

After its launch in 2012, Farmaindustria's Permanent Dialogue Roundtable with the Patient Organizations strengthened its activity in 2013 as a forum for information and debate with a representative group of federations and confederations of patient associations to tackle important issues of common 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 has no defined periodicity but meets at the proposal of any of the parties, held four meetings in 2013 and at the end of the year, bringing together some 20 large organizations and patient association federations.

At the end of 2013, We Are Patients was a voice for 1,300 registered bodies and organizations

WE ARE PATIENTS (SOMOS PACIENTES)

The online community of patient associations Somos Pacientes (www.somospacientes.com), launched by FARMAINDUSTRIA in 2012, gave a voice by the end of 2013 to more than 1,300 registered bodies and organizations also listed in the National Patient Organizational Map.

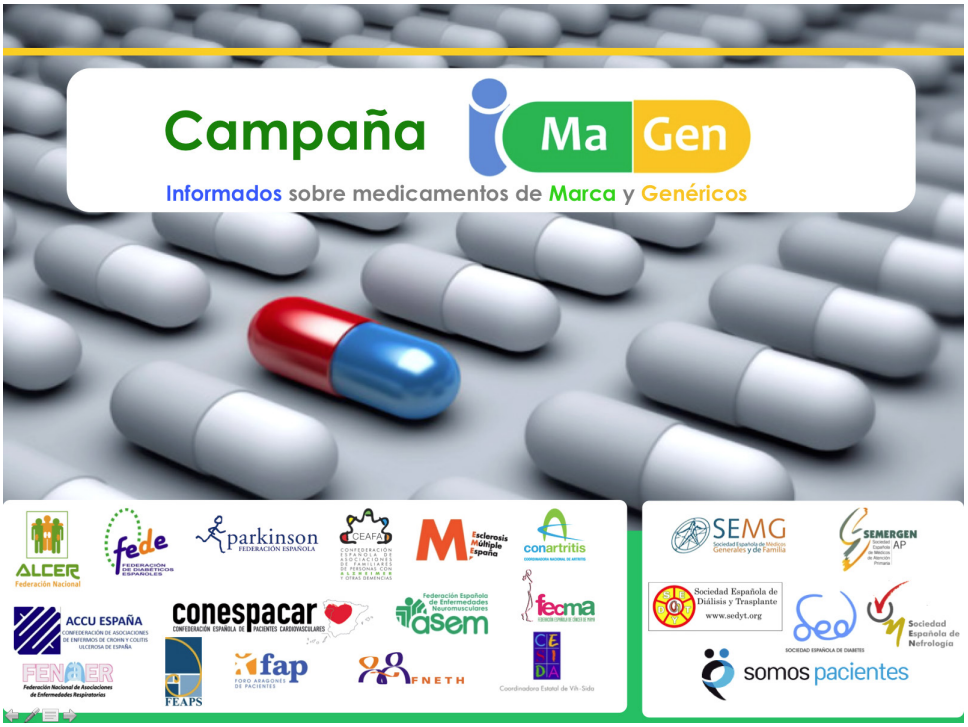
Somos Pacientes offers a shared space for information, participation, education, services and collaborative work aimed at all associations of patients and people with disabilities in our country, as well as families, carers and professionals.

Among its tools, the most used by the associations are the virtual conferences (webinars), online meetings and the video and audio streaming rebroadcast channel. Through this tool, in 2013, Somos Pacientes offered press conferences and activities by different member bodies of the community, as well as the ability to follow throughout the conference organized by AEMPS for the Clinical Trials Day and the first edition of the Somos Pacientes Day held in November.

The Somos Pacientes Day constituted a meeting point between the pharmaceutical industry and associations of patients, families and disabled people. Inaugurated by the FARMAINDUSTRIA President and Secretary General for Health, the event attracted the participation of numerous patient associations, representatives of the Government and Autonomous Regions, journalists and the Health and Social Policy director of the Ombudsman's office, among others.

Also in November, in Barcelona, FARMAINDUSTRIA representatives collected one of the Best Ideas awards made to Somos Pacientes by Diario Médico after becoming the biggest online community of patient and disabled people's associations in Europe.

In the framework of Somos Pacientes in 2013, the IMAGEN initiative was launched, an information campaign directed at patients and sponsored by more than 2,000 patient associations and scientific societies. Somos Pacientes joined in this activity to offer its support and disseminate the campaign materials. The online platform developed by FARMAINDUSTRIA streamed live the full content of the ceremony launching the initiative. It was also broadcast over the social networks and included various interviews with the people behind the project.



EUPATI, EUROPEAN PATIENTS ACADEMY

This European Commission project, of which FARMAINDUSTRIA is part, seeks to develop educational courses and material, and create 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 2013 in several working meetings involving consortium members in Barcelona, Rome and Dublin. It also coordinated the Spanish National Liaison Team (NLT), forerunner to the National EUPATI Platform in Spain, which met regularly during the year.

OTHER ACTIVITIES

FARMAINDUSTRIA continued to collaborate in 2013 with the Shared Responsibility Foundation (Fundación Corresponsables) on the 4th edition of the Shared Responsibility Awards, which look to recognize the best initiatives and practices in Social Responsibility and Sustainability in different categories of business activity.

3.3
INTERNATIONAL RELATIONS

3.3.1 EUROPEAN CONTEXT

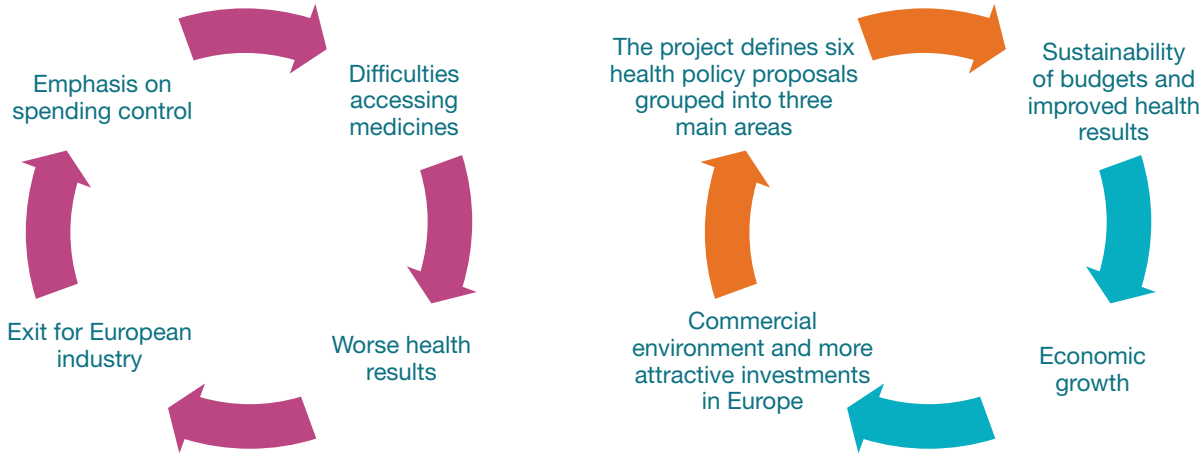
The activities of FARMAINDUSTRIA at the European level have been channeled mainly via EFPIA, the organization which in Europe represents the voice of 33 National Associations and 40 pharmaceutical companies, consolidating the participation of FARMAINDUSTRIA not only in most of the 29 committees and working groups of the European organization but also in all the meetings of the Governing Bodies to which it belongs (Board, Executive Committee and Heads of Association Committee). FARMAINDUSTRIA also has the Vice-Chair of the Executive Committee until 2015, as representative of the National Associations.

MEETINGS OF THE EFPIA GOVERNING BODIES

EFPIA's priorities, as defined by the 2013 General Assembly, are: i) access to innovations; ii) the creation of a stable scientific and regulatory environment; iii) communication and strategic alliances, and; iv) international activities. The Assembly also approved modifications to the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopting in parallel the EFPIA Code on Disclosure of Transfers of Value from Phamaceutical Companies to Healthcare Professionals and Healthcare Organizations.

One EFPIA activity that has been central to the Federation's strategy is the Health and Growth Project, which came about in parallel with the European Union's 'Growth Agenda', promoted in 2012 by the European Commission and some Member States. With the objective of collaborating in the development of the Agenda, the Governing Bodies of EFPIA agreed to update the existing statistics and data on the value contributed by the pharmaceutical industry and medicines, and to participate actively in a process of analysis of problems and the design of policies contributing to finding solutions to these problems with different stakeholders.

EFPIA has written an exhaustive report that permits decision-makers to formulate strategies taking into account the basic consideration that health is a value in itself, that it has a far-reaching influence in healthcare, economic and social terms, in which it proposes the promotion of efficient healthcare management to boost economic growth in Europe.



PRESENT VICIOUS CIRCLE **POTENTIAL VIRTUOUS CIRCLE**

The project defines six health policy proposals grouped into three main areas:

1. Improvement of health outcomes and reduction of inequalities;

2. Sustainable financing and promotion of patient access to innovations, growth and stability, and;

3. Leadership in health research and creation of incentives for innovation;

During 2013, regular meetings were held of the EFPIA Executive Committee, the Federation's governing body made up of European senior executives of companies (Heads of Europe) and heads of the main national associations. These centered on the implementation and development of activities and strategic lines in accordance with priorities defined by the EFPIA Board.

The Executive Committee very closely monitored the main national developments in the pharmaceutical policy area, focusing on the five main European markets. The monitoring of hospital debt, and the need to provide structural measures to put an end both to late payments and the growing trend towards them, merited special attention. In this respect, the solutions applied to this problem in Spain were very favourably welcomed, both the interim ones from the Regional Liquidity Fund and the Suppliers' Payment Plan, and the solutions of a more structural nature approved at the end of 2013: the Public Sector Commercial Debt Control Law, and the Electronic Invoicing Law.

Additionally, other European associations will be taking note of the reform of Article 88 of Law 29/2006, on Guarantees and Rational Use of Medicines and Healthcare Products, which defines Government powers in the area of pharmaceutical policy.

FARMAINDUSTRIA was also recognized as the benchmark in the area of building alliances and regular relations with the Government, as realized through the monthly Permanent Dialogue Platform our Association maintains with the Ministry of Health, Social Services and Equality.

As for the EFPIA Board, this governing body of the Federation has constantly monitored and reported in detail on the news and schedule of the EFPIA Code on Disclosure of Transfers of Value from Phamaceutical Companies to Healthcare Professionals and Healthcare Organizations, as well as the revision of Article 10, on gifts, of the EFPIA Code on the Promotion of Prescription Medicines and Relations with Health Professionals.

The Board also adopted in 2013 a position paper on the transparency of clinical data including that contained in marketing authorization dossiers presented to the European Medicines Agency (EMA).

Meanwhile, in the context of the Counterfeit Medicines Directive, in February 2014 the EFPIA Board approved the principles for sharing the costs of the European Medicines Verification System (EMVS) proposed by EFPIA, as well as the selection of a technological provider to begin its development, although the development remains postponed until 2015 (except for the European hub) due to the delay to the Commission's Delegated Act which will define the security measures, verification mechanisms and criteria for selecting the medicines that should be incorporated, in line with that established by Directive 62/2011 on Counterfeit Medicines.

And, throughout the past year, three meetings of the National Associations' Heads were held in which progress was heard on the implementation of the EFPIA Code on Disclosure of Transfers of Value from Phamaceutical Companies to Healthcare Professionals and Healthcare Organizations in each country. Best practices in relation to the pricing policies applied in different Member States of the EU were also discussed and the role of the National Associations in EFPIA's Health & Growth agenda was also analyzed.

The EFPIA Board in 2013 adopted a position paper on clinical data transparency including that contained in authorization dossiers for new medicines

MULTILATERAL AND BILATERAL MEETINGS

In the framework of the bilateral meetings FARMAINDUSTRIA holds with other European associations, a meeting with the Portuguese pharmaceutical industry association (APIFARMA) was held in December 2013. As well as analyzing the austerity measures adopted by their respective governments, and their impact on the industry, the APIFARMA representatives detailed the institutional dialogue actions carried out with the Troika, whose intervention — starting in 2011 — will end in 2014. Otherwise, the associations discussed around best practices and strategies concerning public expenditure control measures in the hospital domain, stable dialogue platforms with their respective governments and the nature of relations with health professionals, patient associations and other key stakeholders.

EU LEGISLATIVE INITIATIVES

Progress on the development of the different legislative initiatives during 2013 was marked by the priorities defined by the Irish and Lithuanian Presidencies, highlighting as follows:

PHARMACOVIGILANCE DIRECTIVE

After its adoption in 2010, the national transposition for medicines subject to additional monitoring for reasons of pharmacovigilance should be mentioned.

DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND COUNCIL ON COUNTERFEIT MEDICINES

Adopted in June 2011 at first reading by the European Parliament, the Directive establishes a series of obligations to prevent the entry of counterfeit medicines into the legal supply chain.

Among other requirements, the Directive obliges Member States to include safety measures in the packaging of prescription medicines (and in those without prescription which are considered high risk). This permits their individual identification and later verification, as well as the incorporation of anti-tampering devices. These security measures will have to be replaced by other equivalents where the medicine is repackaged.

The obligations relating to safety measures depend on the publication of a Delegated Act for their development, which is not expected until 2015. However, the Commission has shown itself to be favourable to a system of end-to-end traceability based on a Datamatrix code and a self-governance system among the main stakeholders, under the supervision and control of the competent national authorities.

As for importing active ingredients from third countries, the AEMPS began to apply the requirements of the Directive on 2 July 2013, such that, in conformity with the Directive, only the following can be imported into the EU: i) active ingredients which come from third countries included in a list approved by the European Commission that considers they comply with a level of protection in the area of public health equivalent to the EU. To date, Switzerland, Australia, Japan and the US are considered as such and the outcome of negotiations with Israel, Singapore, Brazil and New Zealand is pending; ii) active ingredients that come from countries non included in the previous list whose competent authorities are willing to send written confirmation, observing that the active ingredient production plant complies with levels equivalent to EU Good Manufacturing Practices and that the said plant is submitted to strict and efficient controls, and; iii) in exceptional circumstances, and at the request of a Member State, to guarantee the supply of a certain medicine, an active ingredient can be imported from a plant in a third country if it has been inspected by a competent authority in the EU and the result is that it conforms.

The Counterfeit Medicines Directive obliges Member States to include safety measures in the packaging of prescription medicines

The European pharmaceutical industry questioned the capacity of some third countries to issue written confirmations and has thus requested that companies, through their respective national associations, collaborate with the health authorities in identifying active ingredient manufacturing plants that could be affected. In this respect, FARMAINDUSTRIA, in coordination with EFPIA, informed that it would be convenient that laboratories manu-

facturing medicines in Spain would complete and forward a form on third country plants from which they import medicines, using for it the form developed in collaboration with the Directors' Group of the European Medicine Agencies.

As for Best Distribution Practices, the European Commission published in March the final version of its Guidelines for Good Distribution Practices, which will substitute those in force since 1994 in keeping with the requirements of this Directive, with the ultimate objective of guaranteeing the security of the legal supply chain for medicines in the EU. Among the most significant aspects for the pharmaceutical industry is the compliance obligation, both for pharmaceutical laboratories and wholesale distributors, and intermediaries (brokers and traders). The Guide also requires the implementation of a permanent quality system that determines the responsibilities, processes and principles of risk management in relation to the activities of medicine distribution. These requirements have been incorporated into the Spanish legislative body by Royal Decree 782/2013, of 11 October, on the distribution of medicines of human use.

As for the sale of medicines by Internet, and awaiting the adoption of an Act of Execution which defines the logo to identify legal online pharmacies, in Spain Royal Decree 870/2013, of 8 November, regulates the sale of OTC medicines via the Internet, requiring, in all cases, the physical intervention of a professional pharmacist in the process of purchasing and home delivery of the medicine.

Although the Royal Decree is already in force, it is necessary to wait for the publication of the implementing Act relative to the common logo and, as of that date, the AEMPS and the ARs will have one year to publish the lists on legally required web pages, including links to all those pharmacies which, in the opinion of the competent authority, comply with the requirements for the marketing of non-prescription medicines over the Internet.

Throughout this legislative process, Farmaindustria has made many formal approaches to the competent health authorities; in particular, through the permanent dialogue with the AEMPS, and with the medicine distributors, in order to respond to the requirements established by the European Medicines Verification System (EMVS). The EMVS is a system of end-to-end traceability and verification of medicines, based on a two-dimensional Datamatrix bar code, with the medicines being controlled at the dispensing point.

With respect to the governance of this system, EFPIA and Farmaindustria are proposing it uses what is known as the European Stakeholders' Model (ESM) in which the EMVS would be managed by the representatives of the main associations that intervene and participate in the distribution of medicines in Europe (and their respective national counterparts), guaranteeing thus that each one of the parties only accesses the information they introduce into the system and for which they are responsible. The AEMPS has revealed that it is, in principle, favourable to this model, as long as it is supervised, and access is guaranteed to the information, by the national authorities in each country.

The basis for the creation of a European court specialized in the area of patents has been established

With the aim of disseminating information about, and discussing in depth, the national implementation of this Directive and of the ESM, Farmaindustria and EFPIA organized in 2013 several Information Workshops with the participation of the AEMPS and distribution, high street pharmacy, generic medicine, OTC and hospital pharmacy representatives.

EUROPEAN UNITARY PATENT

All the Member States, except Spain, Poland and Bulgaria, signed in February 2013 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. Later in the year, in July, the European Commission 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 specialized 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.

As for the appeals lodged by Spain and Italy against this, these were rejected by the EU Court of Justice, which also considered unfounded the allegation of both countries that the protection conferred by the unitary patent would fail to create more uniformity or integration in relation to the situation resulting from the application of the regulations foreseen in the European Patent Convention. The Court said that "the unitary patent… will provide a uniform protection in the territory of all the Member States that participate in the reinforced cooperation, without prejudicing the single market or economic, social and territorial cohesion of the Union."

PERSONAL DATA PROTECTION

Following the publication of the Commission's proposal in January 2012, the pharmaceutical industry expressed its satisfaction with the efforts of the Commission to improve the harmonization of the obligations with respect to data protection in the EU, given that the inconsistent application of these obligations was preventing the pharmaceutical sector from fully carrying out its capacity to perform biomedical research.

In this regard, during 2013, EFPIA and Farmaindustria undertook a coordinated action with various stakeholders at the European and national levels to elaborate and communicate a common position that ensures the adoption of a pragmatic approach, guaranteeing that the Regulation retain a special consideration for the data used in biomedical research, thus eliminating bureaucratic obstacles, duplication of assessments, and restrictions over its use.

In this sense, in January, a communication was published by the Healthcare Coalition on Data Protection, an organization made up of various European healthcare and new technology sectoral bodies and associations (among them EFPIA), in which they expressed their concern about certain aspects of the proposal that could threaten the development

of biomedical research in Europe. The communication proposed five recommendations to improve this regulatory proposal, underlining, among other matters, the inclusion of specific provisions to regulate the protection of health and research data, the evaluation of the undesired impact of the policies of "the right to be forgotten", and the prevention of any increase in bureaucracy and administrative responsibilities in this area.

Finally, the European Parliament adopted a modified text which still included negative aspects relating to the process and use of data in the health sector. EFPIA has since then performed an intensive institutional effort lobbying for a more direct approach and harmonized in all the EU Member States concerning guarantees for the privacy of personal data in scientific research. Specifically, EFPIA and FARMAINDUSTRIA request that Member States permit the processing of data in the context of biomedical research for those cases in which it would be impossible to obtain the consent of the participant subjects, or when obtaining it would suppose a disproportionate effort, on the understanding that Code of Practice Committee reviews, data encryption and other technical and additional legal requirements already adequately protect the privacy of the participant subjects.

DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND COUNCIL OF 9 MARCH 2011 ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE. RECOGNITION OF PRESCRIPTIONS IN THE EU.

In November 2012, an Implementation Directive was approved recognizing the possibility of prescribing medicines by brand name in two cases: i) when the prescribed product is a biological medicine, in accordance with its definition in point 3.2.1.1.b of Annex I of Directive 2011/83, and; ii) where the healthcare professional esteems it necessary, in which case the prescription should include a brief justification of the reasons for the use of the brand name. The Member States had until October 2013 to transpose these precepts into the respective national laws.

The transposition to Spanish legislation was done through Royal Decree 81/2014 on cross-border healthcare provision, modifying Royal Decree 1718/2010, of 17 December, on medical prescriptions and dispensing orders, obliging the inclusion of the active ingredient to identify the medicine and, in such a case, the brand "if it consists of a biological medicine or the prescribing health professional considers it necessary from the medical viewpoint, always in conformity with that established in Law 29/2006, of 26 July, on guarantees and rational use of medicines and healthcare products. In this case, the use of the commercial name will be justified briefly in the prescription."

Throughout the passage of this Royal Decree, FARMAINDUSTRIA insisted that this amendment must only affect prescriptions that were going to be used by patients in another EU country. Finally, however, the criterion of extending it to all prescriptions was imposed.

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND COUNCIL ON CLINICAL TRIALS OF MEDICINES FOR HUMAN USE, AND TRANSPARENCY IN THE PUBLICATION OF DATA RELATING TO CLINICAL TRIALS

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. The provisions in the original text would contribute to accelerating the authorization and notification procedures, while maintaining the maximum level of security for patients, as well as the reliability and consistency of the data.

Finally, 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:

1. The creation of a single entry point in Europe for the sending of authorizations, as well as a pan-European database for all the trials performed in the EU.

2. Reduction of the delays for authorizing trials to 60 days for conventional procedures, which can be extended by another 50 days for medicines or procedures of greater complexity.

3. With the aim of giving the patient better guarantees, specific requirements are established to carry out low-intensity trials, as well as stricter requirements in the area of obtaining the informed consent of patients.

4. With regard to transparency in the publication of results, the final text of Article 78 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 assessment reports, and; iv) ensuring effective supervision of the performance of a clinical trial by any Member State.

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

TRANSPARENCY IN THE PUBLICATION OF CLINICAL TRIAL DATA. EMA PUBLIC CONSULTATION. 'PRINCIPLES FOR THE RESPONSIBLE PUBLICATION OF RESULTS IN THE AREA OF CLINICAL TRIALS'

The European clinical trials database will be accessible to the public

In parallel to the legislative development of the above-mentioned Clinical Trials Regulation, the public consultation in this area launched by the EMA in July 2013 should be mentioned, with reference to the legal dispute still surrounding it. Initially, the EU Court of Justice prohibited the EMA from publishing the information from the clinical trials of a product that had been requested by a third party and which the owner considered commercially confidential information. The judgment, in terms expressed by the Court itself, has provisional character until a decision is taken on the substance of the matter.

EFPIA and PhRMA (the United States R&D-based pharmaceutical industry association) presented midway through the year, proactively and on their own behalf, the so-called 'Principles for the responsible publication of results in the area of Clinical Trials', which reconcile publication with the privacy of patients, respect for the integrity of national regulatory systems and the maintenance of incentives for biomedical research. In this way, with respect for these principles, the European and US innovative pharmaceutical industry associations adopted five fundamental commitments in this area, that: i) data can be shared with researchers, at the request of third parties and after the evaluation by an independent scientific committee which should be created at the heart of each company; ii) public access to clinical trial information should be encouraged and clinical study reports published; iii) results should be shared with the patients taking part in the trials, through the preparation of protocols in collaboration with national regulatory authorities; iv) compliance of the principles on the part of the companies should be publicly certified, and; v) clinical trial results should be published independently of those results.

In parallel, EFPIA has prepared a response to the specific EMA consultation in which it makes reference to the commitments undertaken by EFPIA/PhRMA and focuses on three particular points: i) patient privacy; ii) integrity of the regulatory systems, and; iii) publication of commercially sensitive information.

BIOTECHNOLOGY

European biotechnology companies, which come together in the European Biotechnology Enterprises (EBE) body, under the umbrella of EFPIA, continued during 2013 the work aimed at encouraging innovation and promoting regulatory and economically favourable conditions for biopharmaceutical companies in Europe.

In this sense, the work focused around biosimilar medicines, with the publication at the end of the year, with Europabio (the European Association of Biotechnological Industries), a consensus document on biosimilars in which the specifications are detailed in relation to their authorization in the EU and functioning in the market, as well as the necessary conditions to guarantee the appropriate use of these. Among the key elements identified by this initiative was the need to promote competition in the market by using biosimilars, once the industrial property rights have expired for the original biological medicines, and decisions on their use in collaboration with health professionals.

EBE also worked jointly with the EMA in the development of its principles contributing to the strengthening of the role of biosimilars in European healthcare systems.

The most important news, however, following the holding of a strategic meeting in November 2013, was the EBE Board deciding 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 the new market characteristics, the evolution of the process of development of biological medicines and the new needs of the EBE members.

VACCINES

The Association that brings together the main companies producing vaccines in Europe, formerly known as European Vaccine Manufacturers, consolidated its change of name, corporate identity and management team in 2013, moving to call itself Vaccines Europe. In this way, the Association renovated its mission and strategic direction, defining its principal objective as to encourage initiatives which promote better access to immunization policies, ensuring better health protection through existing vaccines and those still under development. Vaccines Europe thus established two main axes for its work: i) to represent proactively the common interests and perspectives of the manufacturers of vaccines at the European level, and; ii) to contribute to developing knowledge on the value and benefits that vaccines, vaccination policies and the pharmaceutical industry manufacturing vaccines bring the economy in Europe and worldwide.

COMPETITIVENESS AND INTERNATIONALIZATION

EFPIA operates in the international context via its External Trade Policy Committee, in which Farmaindustria participates actively. The committee promotes the interests of the pharmaceutical industry in relations with both industrialized countries (Canada, the US, Japan) and emerging countries, particularly India and China, communicating the concern of the innovative pharmaceutical industry concerning the lack of industrial property rights protection in these countries.

Vaccines Europe is the association bringing together the main companies producing vaccines in Europe

With this objective, Farmaindustria has maintained permanent contacts and held specific meetings with the Trade and Investment department and bilateral meetings alongside representatives of some of the laboratories with greater involvement in external trade.

EU-US TRANSLATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP)

During 2013, three rounds of negotiations were held, debating in detail the interests of the innovative pharmaceutical industry which is lobbying for an ambitious process of mutual recognition in the regulatory field (Best Manufacturing Practices, inspections, protection of industrial property rights, exchange of scientific knowledge, registers, etc.).

Farmaindustria maintains regular contacts both with the Secretary of State for Commerce in Spain and the Brussels Permanent Representation and has organized diverse informative meetings on the position of the innovative pharmaceutical industry as regards the TTIP, both for multinational companies and Spanish SMEs wishing to develop activities in the US. Main issues brought up at these meetings include: i) the need for greater regulatory harmonization; ii) the adoption of policies which recognize the value of innovation, ensuring that price controls are applied only when medicines are refunded with public funds, avoiding international price referencing with countries subject to austerity measures, and iii) the effective application of the protection of industrial property rights.

By the end of 2013, important progress had been achieved in the area of manufacturing and plant inspections and the advances in the area of comparing standards of industrial property rights protection focused on the minimum required from third countries that negotiate with any of the two parties.

EU-CANADA COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA)

This agreement was officially adopted in October 2013 and signified an important achievement for the innovative pharmaceutical industry, which obtained the right of appeal against Canadian court decisions in the area of patent linkage, a right that generic companies already enjoyed.

The Canadian Government, however, in its first technical report based on the agreement, emphasized that this aspect could end what is known as 'dual litigation' in the legislature of this country. This is a process by which, following an unfavourable judgment concerning the innovative product, the holder was able to file an action on the grounds of patent linkage to claim economic damages from the generic company on the basis that it had infringed the patent and given it was impossible to appeal against the negative decision on the grounds of patent linkage.

This question has been the subject of an intense institutional effort with the aim of preventing the European Commission accepting these conditions.

EU-JAPAN FREE TRADE AGREEMENT

Although negotiations began at the end of 2013, it will be in 2014 that a first assessment can be made of the progress.

The main obstacle to this free trade agreement lies in some industrial sectors opposing any reduction in tariffs affecting the EU import of certain products made in Japan.

The position of EFPIA continues in any case to be one of support for a free trade agreement and with this aim it has reinforced national association contacts with Japanese embassies.

EFPIA's activity in the area of external trade of medicines was very intensive in 2013

EU-INDIA FREE TRADE AGREEMENT

Discussion on a possible free trade agreement has been suspended due to strong discrepancies in the area of industrial property and mandatory licences. EFPIA and PhRMA continue to lobby intensively for India to be included as the priority country in the Market Access Advisory Committee.

CHINA

Important progress has been made in the regulatory area, since this country is to reform its healthcare legislation in due course and specifically that concerning medicines. EFPIA held diverse meetings with the Chinese and European authorities during the year in a collaborative atmosphere. In fact, the Chinese authorities have demonstrated their willingness to carry out the reforms needed in order to meet international standards in the regulatory area.

The Association is represented on the IFPMA governance bodies and its Steering Committee

TURKEY

Problems persist in the area of registration delays, although a new Medicines Agency has been created with which EFPIA is collaborating alongside the local pharmaceutical industry association, AIFD, in the preparation of a new regulatory framework. In parallel, the possibility of including Turkey in R&D projects financed by the EU in the context of the Horizon 2020 programme is being evaluated.

RUSSIA

Despite advances in the area of clinical trials at the local level, Russia continues to be a market with highly protectionists measures (for example, the local manufacturing quota for any medicine sold in the Russian market). EFPIA continues to carry out relationship-building work with the Russian healthcare authorities with the aim of improving the environment in which the international pharmaceutical industry has to operate in the country.

TAIWAN AND THAILAND

Within the context of bilateral conversations in the case of Taiwan, and of a possible free trade agreement with the EU in the case of Thailand, EFPIA remains in permanent contact with the Trade Directorate General and the Permanent Representation in Brussels, to whom it has sent the priorities for homologation in the regulatory areas and access to innovations in both markets.

3.3.2 INTERNATIONAL CONTEXT

Farmaindustria channels its activities in this context through the International Federation of Pharmaceutical Manufacturers and Associatons (IFPMA), being represented on its governing bodies (Council and General Assembly) as well as its Steering Committee.

The activity of the Federation centers on various Committees and Working Groups, of which Farmaindustria is a member and in which it actively and regularly participates. The main ones in this respect are the Innovation Committee, Industrial Property and Trade, Socioeconomic Research Network, Global Health, Communication and the IFPMA Code of Best Practices.

The IFPMA Board approved its priorities for 2013-2014 to include: i) the development of strategies promoting access to innovation and respect for industrial property rights, especially in emerging markets; ii) the defence of policies promoting the sustainability of national health systems; iii) the generation of trust and promotion of ethical practices, and; iv) the development of research-friendly regulatory frameworks.

Other subjects of interest for the pharmaceutical industry at international level have been tackled in the meetings of IFPMA governing bodies, such as the national medicine pricing policies guide published by the WHO, transparency in the publication of clinical trial data and compliance with the Code of Best Practices.

DISEASES AFFECTING THIRD WORLD COUNTRIES. CEWG, THE NEW CONSULTATIVE EXPERT WORKING GROUP

The work of the Consultative Expert Working Group (CEWG) continued during 2013 with the presentation of the report selecting six projects aimed at encouraging R&D in diseases that affect countries in the Third World. The innovative pharmaceutical industry, through IFPMA, has carried out an intensive institutional and communication effort in this field.

In January 2013, IFPMA published the annual report updating industry R&D in the area of the so-called 'neglected diseases' that affect mainly developing and Third World countries. The report records an increase of 40% in 2012 in the number of R&D programmes led by the pharmaceutical industry aimed at discovering new or better treatments and vaccines for these diseases, which affect some one billion people worldwide. The document points out, meanwhile, that partnership and cooperation constitute a fundamental aspect in the rapprochement of the industry to these diseases, highlighting that 85% of projects are developed in the context of what are known as product development alliances.

IFPMA has also published various infographics and one-off reports which refer to the commitment of the innovative pharmaceutical industry in donating medicines. In this way, IFPMA emphasizes that the sector has committed itself to donate an average 1.4 billion treatments a year during the 2011-2020 period. These donations will contribute to eradicating or controlling the nine neglected diseases that represent over 90% of the global costs associated with these types of pathologies.

THE WORLDWIDE FIGHT AGAINST COUNTERFEIT MEDICINES

The Intergovernmental Group created by the WHO in 2012 met in Buenos Aires in November 2012 and July 2013, although its progress has been limited.

During the presentation of the work of this group at the 66th WHO General Assembly, the IFPMA representatives had the opportunity of participating in a communiqué in which support was expressed for initiatives carried out by the Intergovernmental Group and the need to adopt more specific initiatives for a growing problem impacting greatly on the world.

The multilingual online communication campaign carried out by IFPMA, called 'Fight the Fakes', 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.

Meanwhile, IFPMA published infographics containing the 10 principles of the industry against counterfeit medicines, including the classification of any support received by regulatory systems as a crime, and highlighting that this phenomenon affects all types of medicines and patients, for which it is necessary to adopt a global approach to eradicating it.

The innovative pharmaceutical industry, via IFPMA, has performed an intensive institutional and communications effort

Finally, it should be noted that FARMAINDUSTRIA actively participates in a new mechanism set up by IFPMA in collaboration with the Pharmaceutical Security Institute, the objective of which is to record all incidents in relation to counterfeit medicines at the international level, with the Association sending out a quarterly summary of such incidents. Up to now, the greatest problems in Spain have been detected in the sporting world (growth hormones and food supplements), as well as in products with active ingredients for the treatment of erectile dysfunctions, sold as infusions or food supplements.

INITIATIVES RELATED TO THE IFPMA CODE. FRAMEWORK AGREED FOR ETHICS COLLABORATION

IFPMA published infographics containing the 10 principles of the industry against counterfeit medicines

As well as the initiatives aimed at effective compliance with the IFPMA Code of Best Practices, and taking into account that trust and reputation building play an essential role, IFPMA led, alongside four other global health organizations — the International Alliance of Patients' Organizations (IAPO), International Council of Nurses (ICN), International Pharmaceutical Federation (FIP) and World Medical Association (WMA) — in adopting a Consensus Framework for Ethical Collaboration between patient organizations, professional associations and the industry itself, based on four transversal principles: i) putting the patient first; ii) inspiring research and innovation; iii) guaranteeing independence and ethical conduct, and; iv) promoting transparency and accountability.

3.4
THE PHARMACEUTICAL INDUSTRY IN SPAIN AND WORLDWIDE

3.4.1 THE PHARMACEUTICAL INDUSTRY IN EUROPE

The stagnation of economic activity in 2013 saw a bigger adjustment in employment in the public and private sectors

The poor evolution of the European economy in recent years, although it has not affected all sectors the same, has certainly influenced the lack of growth in the pharmaceutical industry.

In this sense, in the EU 28, which previously had grown during 13 consecutive years (1996-2008), activity fell sharply in 2009 (-4.5%) as a result of the economic and financial crisis. Since then, the evolution of the economy in the EU 28 has been pretty irregular, combining periods of modest growth, such as in 2010 and 2011 (+2.0% and 1.6%, respectively) with a new downturn in activity in 2012 (-0.4%) and stagnation in 2013 (+0.1%).

The countries who condition EU economic growth, however, the United Kingdom, Germany and France, recorded positive rates in 2013 (1.7%, 0.4% and 0.2%, respectively) as the main countries in recession, Italy and Spain, recorded positive growth rates in the final quarter of the year, which bodes well for 2014.

The economic stagnation that took place in 2013 has seen a bigger adjustment in employment in the public and private sectors, which increased the unemployment rate in the EU-28 from 10.4% of the active population in 2012 to 10.8% in 2013, the highest since records began in the EU.

But not all has been negative: the Member States are achieving important results in their fiscal consolidation processes, which seek to eliminate superfluous administrative costs and adopt the necessary structural reforms that will allow an increase in public revenue. This meant that, in 2013, for the fourth year running, government deficit among the EU 28 fell to 3.3% of GDP, less than half the level recorded in 2009 (6.9% of GDP in the EU 28).

At the same time, the financial markets welcomed these measures, interpreting them as heading in the right direction without representing an obstacle to EU economic growth. This resulted in a reduction of borrowing rates, which has had a particularly positive effect in the peripheral countries.

The above considerations explain improved EU growth forecasts for 2014. The European Commission, in its European Economic Forecast – Winter 2014, predicts +1.5% GDP growth for the EU 28 in 2014 which, according to the forecast, will be followed by +2.0% in 2015.

This situation, and the fact that the emphasis of economic policies adopted by the EU countries is on fiscal adjustment, is having a particular effect on the evolution of markets like pharmaceuticals, which are strongly dependent on public budgets and economic regulation.

The public spending containment measures adopted by European countries, leading in most cases to the reduction of medicine prices, produce a spill-over effect on countries which have their prices referenced to those in other countries. Added to this is the fact that, in recent years, the period for the protection of industrial property rights is expiring for the biggest-selling active ingredients.

The difficulties described were reflected in the figures for growth in the pharmaceutical markets in European countries. For example, in the international report prepared by the consultants IMS Health[1], data at the end of 2013 showed that some European pharmaceutical markets experienced, for the third year running, the biggest fall among developed markets (with the exception of Australia and Canada), placing global growth for the five big EU markets below that in North America (+3%) and way below other regions such as Latin America (+15%) and Asian countries such as China (21%), India (+10%) and Japan (+3%).

It is clear that, despite the poor performance of European markets, the industrial pharmaceutical sector, due to its special characteristics (strongly innovative, research-intensive, highly productive, a creator of qualified employment and export-oriented), unites all the conditions for producing sustained growth above the average in the economy of a country; yet it is the highly cyclical sectors, with their low productivity and scarce research activity, that have significant weight in growth calculations.

Despite the above-mentioned, paradoxically, in recent years (2009-2013), the nominal GDP of the five biggest economies in the EU (Germany, France, United Kingdom, Italy and Spain) grew by 10%, while the pharmaceutical market in these countries decreased by -1%.

Looking at 2013, in the breakdown by countries of European pharmaceutical market behaviour, the growth rates swung between +5% in Germany and -2% in France, with the Spanish market dropping down to last place (-1%) having had the worst evolution of all over the past three years.

LATEST GROWTH FIGURES FOR THE PHARMACEUTICAL MARKET IN THE MAIN EUROPEAN COUNTRIES

	Δ 2013/2012 (%)	% Sales/5-country total, 2013
Germany	+5%	37.0
France	-2%	25.2
United Kingdom	+2%	12.4
Italy	0%	13.9
Spain	-1%	11.5
Total, 5 countries	+1.5%	100.0

Source: FARMAINDUSTRIA, from IMS World Pharma Market Summary.

1. IMS World Pharma Market Summary.

Analyzing a longer period of time (2009-2013), Spain records the worst growth figures during these five years (-14%), well below Italy (-7%) and France (-4%), whereas Germany and the United Kingdom recorded positive growth in their pharmaceutical markets in the same period, of +11% and +3%, respectively.

Finally, at a more aggregated level, it should be pointed out that, in spite of the difficulties described, the Spanish pharmaceutical industry holds an important place in the European context. In the following table, it can be observed that, on the basis of the most significant indicators, Spain's position in the European pharmaceutical sector, it is the fourth most important market by sales volume, and the fifth in terms of job creation — behind Germany, France, Italy and the United Kingdom — and the sixth European market in productive terms — after these four and Ireland.

GENERAL EU PHARMACEUTICAL INDUSTRY DATA (2011)

					External trade (EFP) (m€) [4]	
Country	No. labs [1]	Production (m€) [2]	Jobs	Int. Sales (EFP) (m€) [3]	Imports	Exports
Germany	305	26,935	105,435	25,842	37,027	50,818
Austria	117	2,541	11,195	3,095	6,033	6,540
Belgium	127	7,061	32,740	4,531	26,757	35,524
Denmark	35	7,672	20,223	2,124	2,763	7,559
Spain	**185**	**14,022**	**37,971**	**13,941**	**11,670**	**9,843**
Finland	50	1,293	5,436	2,006	1,685	1,146
France	261	19,675	94,821	27,491	21,435	24,469
Greece	65	846	13,700	4,867	3,125	864
Netherlands	36	6,180	15,000	4,713	10,916	15,994
Ireland	47	19,700	24,000	1,708	4,402	26,645
Italy	199	25,137	65,000	20,272	18,087	14,679
Portugal	122	1,533	8,502	3,136	2,196	593
United Kingdom	52	20,206	65,000	13,801	19,086	26,225
Sweden	82	6,582	13,185	3,411	3,213	6,384
Total UE-15	1,683	159,383	512,208	130,938	168,395	227,283

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.

3.4.2 THE PHARMACEUTICAL INDUSTRY IN SPAIN

R&D&I

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. Spain must rely on the R&D&I sector to recover from the crisis.

These considerations do not come, as it might seem, from the innovative business sector, but the present Spanish government[2]. This reflection is nevertheless fully shared by business, as is demonstrated by a recent CEOE study on the effectiveness of public aid for R&D&I[3], in which it is stated that R&D&I activity has allowed companies to confront the crisis better, while corroborating the fact that R&D&I is the best vehicle for generating the necessary competitiveness for operating in foreign markets. The report also affirms that the growth experienced in international operations is higher in those companies which have carried out R&D&I in previous years and there are also significantly fewer job losses in these companies.

In this sense, our country's commitment to research and innovation as a means of ensuring more balanced, sustainable growth has been endorsed by Law 14/2011, on Science, Technology and Innovation, which establishes in its preamble that "…the Spanish productive model based fundamentally on construction and tourism is exhausted, such that it is necessary to foment a change through support for research and innovation as means to achieve a knowledge-based economy which guarantees more balanced, diversified and sustainable growth."[4]

To achieve this objective, the Government published the 2013-2020 Spanish Science, Technology and Innovation Strategy, which constitutes the reference in this field for the next few years and establishes, as one of four main aims, the strengthening of business leadership in R&D&I. On this basis, the document establishes a series of objectives to be achieved in the near future, with respect to the research effort of the Spanish economy in relation to GDP and the distribution of the effort between public and private sectors. These objectives are summarized in the following table[5]:

INDICATORS FROM THE SPANISH SCIENCE, TECHNOLOGY AND INNOVATION STRATEGY

Indicators of effort	2010	2016	2020
R&D spending/GDP (%) Source: INE (National Statistics Institute)	1.39%	1.48%	2.00%
Private R&D spending/GDP (%) Source: INE (National Statistics Institute)	0.60%	0.73%	1.20%
Ratio between private and public financing of R&D spending Source: INE (National Statistics Institute)	0.86	1.06	1.70
% financing of R&D spending coming from abroad Source: INE (National Statistics Institute)	5.7%	9.6%	15.0%

2. Passage taken from the 2014 Spanish National Reform Programme (p34), sent by the Spanish Government to the European Commission on 30 April 2014. Available at: http://www.mineco.gob.es/stfls/mineco/prensa/noticias/2014/Programa_Reformas_2014.pdf.

3. Efficiency of Public Aid on R&D&I activities. CEOE, November 2013. http://www.ceoe.es/resources/image/eficiencia_ayudas_publicas_i+d+i_2013_11.pdf.

4. See BOE of 2 June 2011 (page 54392).

5. 2013-2020 Spanish Science, Technology and Innovation Strategy (page 40). Secretary of State for Research, Development and Innovation, Ministry of Economy and Competitiveness.

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.

Total R&D spending in Spain fell by 8.2% from 2010 to 2012

The latest available data (2012) show how, from2010 to 2012, R&D spending in Spain fell by 8.2%, and its weight in relation to GDP from 1.39% in 2010 to 1.30% in 2012.

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. During 2010-2012, R&D expenditure financed with public funds fell by 14.6%, whereas funding in private initiatives reduced at a much more moderate rate (-2.7%). As a consequence of this different trend, the ratio between private and public financing of R&D expenditure increased from 0.86 in 2010 to 0.98 in 2012.

Therefore, in the past three years (2010-2012), the R&D effort in Spain has been sustained through private initiative. And according to the latest data published by the INE (National Statistics Institute), if there is one business sector that is truly strategic and essential for boosting R&D in Spain, it is pharmaceuticals, as the following considerations demonstrate:

- Pharmaceuticals represent the industrial sector which most invests in R&D in Spain, dedicating in 2012 over 996 million euros to research, 20.7% of total R&D spending conducted by Spanish industry as a whole. This percentage, however, has fallen from 21.6% registered in 2009 due to the lower growth in pharmaceutical R&D compared to the total in all industrial sectors, because of the tough containment measures being adopted in public expenditure on medicines. Yet, 20.7% is still particularly significant when one takes into account the revenues of the pharmaceutical companies add up to just 2.4% of the total for all industry.

R&D ACTIVITY AMONG SPANISH COMPANIES (2012)

Sector	R&D personnel*	R&D spending (m€)			
		Internal	External	Total	% incr. on 2011
All industry	37,855	3,424.09	1,393.36	4,817.45	-3.5%
Pharmaceuticals	**4,537**	**586.88**	**410.03**	**996.91**	**+1.6%**
Automobile	3,962	340.83	421.25	762.08	-3.8%
Other transport	4,059	597.64	178.88	776.52	-11.8%
Aerospace	2,701	438.53	118.00	556.54	-9.5%
Computer, electronic and optical products	3,132	179.66	24.33	203.98	-11.9%

* Personnel, full-time equivalent (FTE).
Source: FARMAINDUSTRIA, from INE ('Statistics on R&D activities, 2011 and 2012').

- The pharmaceutical industry leads the ranking of industrial sectors in generating employment in research[6], with 4,537 professionals dedicated to these tasks full-time, 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.

- The pharmaceutical industry is the industrial sector which has the highest female employment ratio in R&D: two out of every three jobs created in this area by the pharmaceutical industry are occupied by women. Likewise, one in four female employees in R&D in all industry works in pharmaceuticals.

- The pharmaceutical sector also leads the industrial ranking by volume of funding dedicated to both basic (28% of all industry) and applied research (30% of all industry).

- Another important facet of pharmaceutical research is its high level of self-financing: 90.4%[7] in the case of internal R&D spending.

- Finally, and in spite of the significance of the previously cited data, 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 a research sector is the percentage of companies which 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, along with the oil industry, the top industry and business sector in terms of research efficiency, given that 32% of the pharmaceutical companies carrying out R&D activity in 2012 registered a patent during 2010-2012.

The data described shows how the pharmaceutical industry is a leader in the area of research and reveals its strategic importance to configuring a new growth model for Spain, as described in Law 14/2011 on Science, Technology and Innovation.

At the macroeconomic level, the efforts to configure a legal framework favourable to fomenting R&D&I investment produced some progress in 2013 through the adoption by the Spanish Government of a series of measures, among which we highlight the following:

- The 2014 Spanish Budget, for the first time since 2009, produced an increase of 6.4% in non-financial provisions for R&D&I. This should be seen in the context of budgetary consolidation where the average reduction in ministerial department credits was -4.7%.

- The improvement in the conditions of loans to support R&D&I (reduction in interest rates using the Euribor as reference).

- Fiscal incentives for R&D&I[8] introduced by Law 14/2013, of 27 September, supporting entrepreneurs and internationalization, along with the incentives restored in 2012 which reduce social security contributions for research personnel.

6. Employment data in FTE (full-time equivalent).

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.

8. Two measures are highlighted, mainly: i) Tax Credit (unlimited deductions can be made for R&D spending and investment, amounting to an overall discount of 20% until exhaustion of quota); ii) Patent Box (40% of revenues lost through the ceasing of use, or of operation, of assets can be integrated into the imposable base (discount of 60%).

- The 2nd Suppliers' Payment Plan, which provided many of the SMEs owed money by regional and local governments with an important injection of liquidity; this, in many cases, allowed not only the survival of these companies but also the continuation of their research projects.

Although these measures signify important progress, they have to be complemented with specific measures if the sectors promoting R&D in Spain are to exploit their full potential. The paradigm here is the pharmaceutical industry. To advance these goals, policies fomenting the conciliation of these legitimate objectives with the development of the industrial sectors called to lead Spain's emergence from the crisis would be desirable. This can be done without compromising savings objectives, or the necessary fiscal consolidation in public administrations, and would allow Spain to return to the path of lasting and sustainable growth.

DOMESTIC MARKET

The revenues of pharmaceutical companies in 2013 from sales of medicines in pharmacies, net of deductions (Royal Decree-Law 8/2010), fell -0.1% and in the hospital market grew by +2.5%, giving a +0.2% increase overall for the total medicines market in Spain. Some 66.5% of these sales were obtained via the pharmacy channel and the rest via hospitals.

DOMESTIC MEDICINES MARKET (EFP, MILLION EUROS)

	Pharmacies (1)	Incr. (%)	Hospitals (e)	Incr. (%)	Total	Incr. (%)
2010	10,478.20	-3.4	4,211.68	5.0	14,689.88	-1.2
2011	9,685.26	-7.6	4,255.93	1.1	13,941.19	-5.1
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

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, breaking with the continuity of the estimations published in the Association's Annual Reports. Data corresponds to medicine sales to SNS hospitals, net of discounts and rebates (in Catalonia, these only include centres belonging to the ICS, the Catalan Health Institute).

Source: Farmaindustria, from IMS and own estimations.

SPANISH PHARMACY MARKET

The pharmacy channel sub-market recorded a fall in sales volume (number of units and value), although this was by less than in previous years. The reduction in this sub-market was sharper in the first months of the year due to the impact of the new co-payment system, where consumers participate in the price of the medicines, and the exclusion of 416 presentations of medicines from SNS pharmaceutical provision, measures which came into force in July and September 2012, respectively.

The preference established by Spanish legislation, however, for dispensing generic medicines at the same price as the corresponding brand medicine in the case of prescriptions by active ingredient, resulted in a very different evolution of brand and generic medicines in 2013. While sales of generic medicines recorded an increase of +14.8% in 2013, brands fell by -3.9%, a differential which rises when one considers only the active ingredients that count upon a generic in the market, in which case the fall in sales of brand medicines was as significant as -18%.

THERAPEUTIC GROUPS

The top four therapeutic groups in terms of pharmaceutical consumption are: i) Central Nervous System; ii) Cardiovascular System; iii) Digestive System, and; iv) Respiratory System, which account for 68.9% of the total market in units and 67.5% in value. The evolution of each of these varied in 2013 as a function of patent expiry, exclusion of medicines from SNS pharmaceutical provisions and the incorporation of therapeutic innovations, among other factors.

SALES OF PHARMACEUTICAL SPECIALTIES BY THERAPEUTIC GROUPS IN 2013 (PHARMACY CHANNEL)

Therapeutic group	Units (thousands)	Quota (%)	Incr. (%)	EFP value (€ thousands)	Quota (%)	Incr. (%)	Average EFP (€)	Incr. (%)
N Nervous system	296,785.4	23.8	2.4	2,202,771.4	24.0	1.7	7.42	-0.7
C Cardiovascular system	239,398.7	19.2	-0.6	1,573,045.5	17.1	-3.7	6.57	-3.1
A Digestive and metabolic system	201,991.8	16.2	-0.5	1,396,307.4	15.2	3.2	6.91	3.7
R Respiratory system	121,035.1	9.7	-3.7	1,024,785.6	11.2	-2.2	8.47	1.5
G Genito-urinary production	52,021.0	4.2	-1.9	655,484.7	7.1	-1.7	12.60	0.3
M Locomotor system	93,070.3	7.5	-9.5	500,729.1	5.5	-6.9	5.38	2.8
B Blood and blood-forming organs	61,754.2	5.0	-2.1	418,234.4	4.6	5.9	6.77	8.2
L Cancer and immune system	6,304.0	0.5	0.4	344,589.9	3.8	-7.9	54.66	-8.3
J Anti-infectives via gene	51,574.9	4.1	-1.1	331,268.7	3.6	2.7	6.42	3.8
D Skin	50,375.9	4.0	-6.8	266,170.2	2.9	-7.6	5.28	-0.9
S Sensory organs	46,228.3	3.7	-12.7	224,377.8	2.4	-8.7	4.85	4.5
H Hormones	21,300.6	1.7	2.7	184,973.4	2.0	-12.4	8.68	-14.7
V Various	1,526.1	0.1	-5.9	45,145.0	0.5	2.3	29.58	8.8
P Anti-parasites	1,270.0	0.1	3.1	8,743.6	0.1	2.4	6.88	-0.7
K Hospital solutions	2,834.0	0.2	0.1	3,089.6	0.0	-2.0	1.09	-2.1
T Diagnostic agents	47.6	0.0	-11.7	1,283.6	0.0	-5.8	26.97	6.7
Total	1,247,518.0	100.0	-1.8	9,180,999.9	100.0	-1.3	7.36	0.5

Source: FARMAINDUSTRIA, from IMS data.

The consumption of Central Nervous System medicines grew by more than the average, both in units and value, while their average price fell by -0.7%. This therapeutic group includes some of the most consumed medicines, such as non-narcotic analgesics and tranquilizers, which overall represent 60% of units in this group and which, although having very low prices, registered falls in price in 2013 for the third year running (-3.5% and -1.8%, respectively).

425 new medicines were launched on the pharmacy market in 2013

Meanwhile, Cardiovascular System medicines recorded falls in pharmaceutical consumption both in units and value and their average price fell by -3.1%. Overall, 78% of the units in this group sold at the price of the generic medicine.

In the case of Digestive System medicines, unit consumption fell by -0.5% in 2013, whereas their average price increased by +3.7%. However, if one considers only the part of the market likely to be financed, units grew +3.8% and average price fell by -0.1% with respect to 2012. Sales of this therapeutic group were mainly in two subgroups: anti-ulcer and anti-diabetes drugs, which represented 77% of total sales of this group in units and 84% in value.

Consumption of medicines in the Respiratory System group recorded a fall in units by -3.7% and an increase in average price by +1.5%. This group, as well as being the one with the highest quota of OTC proprietary medicines (26.8%), was one of the most affected by the exclusion of medicines from the SNS pharmaceutical service, such that, at the end of 2013, just 56% of the units sold were in the market likely to be financed.

The greatest falls in consumption in units belonged to groups S (sensory organs, -12.7%) and M (locomotor system, -9.5%).

Finally, it is worth pointing out the falls in consumption by value in the Anti-tumour group (-7.9%), which continue to be influenced by the transfer out of the hospital pharmacy channel of certain medicines for hospital diagnosis.

NEW LAUNCHES

During 2013, 425 new medicines were launched in the pharmacy market, with total sales of 126 million euros. 70% of these sales corresponded to 352 new generic medicines available, mainly in the Central Nervous System (103) and Cardiovascular System (82) therapeutic areas.

In 2013, a total of eight new active ingredients were sold in the high street pharmacy channel in Spain, all of them included by 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 strongly affected imports, but less so in times of contraction, stagnation or recession, as at present, in which purchases from abroad are fewer and companies additionally find themselves obliged to sell of excess production abroad (due to weak domestic demand) with the resulting increase in exports.

Added to this is the increase in competitiveness of the Spanish economy, obliged to readjust itself as a result of the crisis, which explains why the trade deficit in the country has passed from -9.5% in 2007 to -1.6% in 2013.

The trend previously indicated remains apparent in the fact that Spain's rate or ratio of export/import coverage has improved gradually during each of these seven years, passing from 64.9% in 2007 to 93.6% in 2013.

The reduction of the trade imbalance in 2013 was sustained by the growth in exports (+5.2%), which contrasted with a fall in imports (-1.3%), permitting the coverage rate to improve by 5.9% from 87.7% in 2012 to the above 93.6% in 2013.

In relation to external pharmaceutical trade, the provisional data for 2013 show that this was a year in which the value of trade flows carried out by the pharmaceutical companies based in Spain fell, a rare phenomenon in this area. Specifically, in 2013, the value of Spanish medicine exports fell by -1.5%, compared to the year before, to 10.515 billion euros. We should await the definitive data for 2013, however, before this is taken as fact.

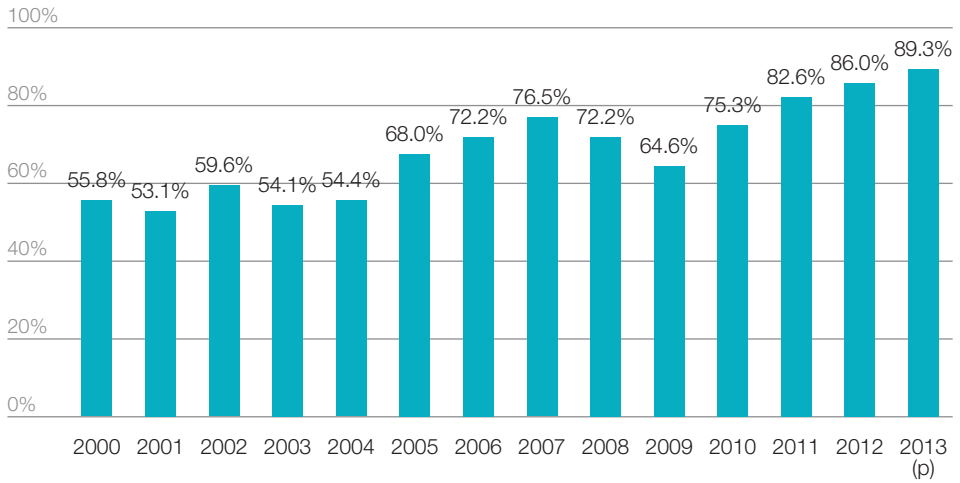
Nevertheless, in 2013, pharmaceutical exports were 4.5% of total Spanish exports, whereas back in 2000 they represented just 1.8%. It should also be noted that the weight of the pharmaceutical industry as a percentage of the country's total exports (4.5%) was three times the sector's revenues as a proportion of the total national economy (1.4%).

Elsewhere, with respect to medicine imports, their value fell more heavily than exports, by -5.1% in 2013 to 11.776 billion euros. This greater drop in imports relative to exports has favoured the Spanish pharmaceutical trade deficit, which fell by -27% in 2013 to -1.261 billion euros, its lowest level since 1997.

This effect also favoured the coverage ratio for Spain's external trade in medicines, as the chart below shows, which was 89.3% in 2013, its highest level since records were kept.

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 2013 is provisional, being susceptible to later revision, so it must be interpreted with caution.

PHARMACEUTICAL SECTOR COVERAGE RATIO (EXPORTS/IMPORTS)



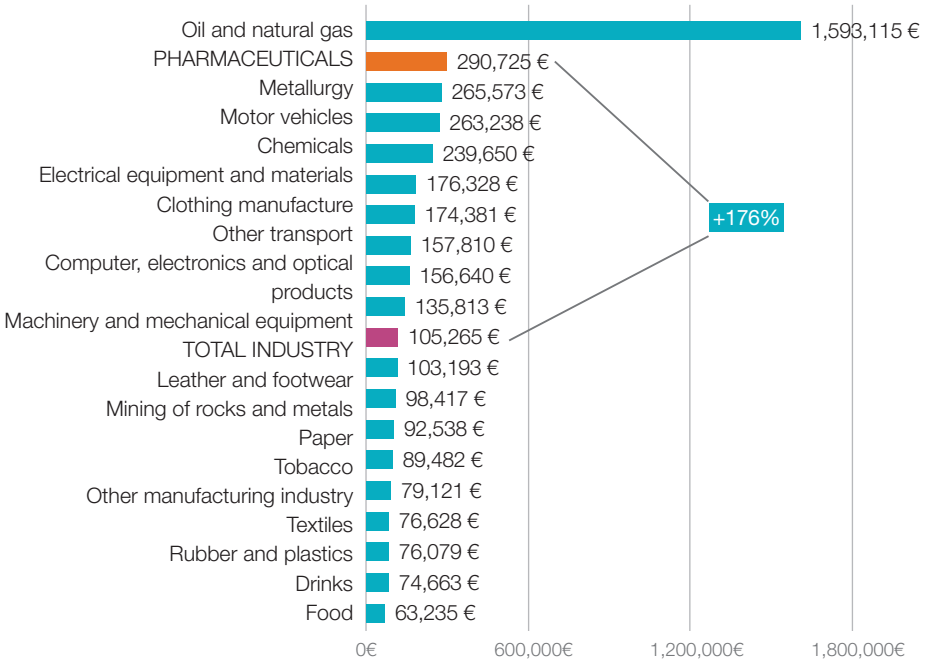
Source: Ministry of Economy and Competitiveness, Secretary of State for Trade – External Trade Statistics for Spain.

The data above shows the increasing importance of the pharmaceutical sector for external trade in Spain and its contribution to the lowering of the trade deficit via its increasing coverage ratio.

However, to analyze the external competitiveness of a sector it is recommendable we turn to relative indicators which value the number of exports in relation to their revenues and the number of employees connected to them, etc. If the indicator "exports/revenues" is analyzed, the latest available data (2012) shows that the pharmaceutical industry, with 76%, at over double the average of all industry sectors (35%).

If we look at the indicator "exports per employee", the difference is even more remarkable. Taking this as the reference, the pharmaceutical can consider itself Spain's second most competitive sector in foreign markets, with exports worth over 290,000 euros per employee, as the following chart shows:

MAIN SECTORS OF THE SPANISH ECONOMY IN EXPORTS PER EMPLOYEE (2012)



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

The geographic distribution of external pharmaceutical trade in 2013 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 57% of Spain's exports go to them. Another 14% of products are exported to the rest of Europe, meaning over 70% of sales of pharmaceutical products produced in Spain end up in other European countries.

Although this has been a constant in recent years, the lack of dynamism in the EU pharmaceutical markets has negatively affected the value of Spain's trade with this economic area, such that pharmaceutical companies have been obliged to turn increasingly to markets outside the EU (both for exports and imports).

	2012		2013 (p)	
Economic area	Exports	Imports	Exports	Imports
Total, world	100.0%	100.0%	100.0%	100.0%
UE-28	58.8%	62.5%	56.8%	60.6%
France	11.1%	11.0%	10.9%	8.0%
Netherlands	4.5%	5.0%	5.5%	4.9%
Germany	12.6%	12.5%	8.5%	12.8%
Italy	9.3%	5.0%	8.8%	5.0%
United Kingdom	6.5%	13.6%	6.6%	11.1%
Ireland	0.6%	4.8%	0.7%	5.5%
Belgium	1.0%	5.3%	1.0%	7.0%
Rest of Europe	12.6%	6.8%	13.6%	8.2%
Switzerland	10.5%	6.5%	11.4%	7.7%
Rest of world	28.6%	30.7%	29.6%	31.2%
China	1.9%	2.4%	2.3%	2.3%
Japan	3.8%	1.0%	4.3%	0.9%
India	0.2%	1.5%	0.2%	0.8%
United States	6.0%	17.8%	5.6%	19.7%

Source: Ministry of Economy and Competitiveness, Secretary of State for Trade – External Trade Statistics for Spain.

SOCIAL SECURITY PHARMACEUTICAL SPENDING

In 2013, and for the fourth year running, there was a reduction in public pharmaceutical spending in pharmacies in Spain. The fall in 2013 was -6.0%, with respect to the year before, down to 9.1832 billion euros, as a consequence of the fall of -5.9% in prescriptions and the reduction in the average spending per prescription of -0.1%, down to 10.68 euros per prescription, the lowest figure since 1998.

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	859.6	-5.9	10.68	-0.1

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

REGIONAL DISTRIBUTION OF PHARMACEUTICAL SPENDING PER CAPITA

Pharmaceutical spending per capita recorded a fall of -5.7% in 2013, down to 194.90 euros, a value similar to that in 2002.

There are important differences at regional level. Extremadura (€251.90) and Galicia (€250.50) have the biggest ratio of pharmaceutical spending per capita, while Madrid (€154.50) and the Balearic Islands (€155.30) have the lowest.

PHARMACEUTICAL SPENDING PER CAPITA PER AUTONOMOUS REGION, 2013

		Spending per head, 2013	
AR	Share of spend (%)	Euros	Incr. (%)
Extremadura	3.0	251.9	-3.8
Galicia	7.5	250.5	-1.9
Asturias	2.7	230.6	-7.4
Community of Valencia	12.0	216.3	-7.5
Aragon	3.1	213.2	-6.9
Basque Country	5.1	213.1	-4.8
Murcia	3.4	213.0	-6.0
Castile-La Mancha	4.8	211.5	-8.1
Castile and Leon	5.7	209.2	-5.2
Cantabria	1.3	202.5	-5.7
La Rioja	0.7	197.2	-6.0
Total, Spain	100.0	194.9	-5.7
Canaries	4.4	192.4	-3.3
Andalusia	17.4	189.2	-4.0
Navarre	1.3	184.4	-7.4
Catalonia	14.3	174.1	-8.7
Balearics	1.9	155.3	-4.1
Madrid	10.9	154.5	-5.1

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

04.

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, as has been indicated, 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 mean 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 more than 2,000 users with authorized access to our information systems permanently updated and documented.

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.

With both objectives and commitment simultaneously in mind, we have designed and improved different services and communication systems that allow us to maintain the users constantly informed.

Our intranet has a Restricted Area which has over 70,000 specialist documents — from circulars, flashes and bulletins to legislative texts and press summaries.

The 'Innovative Medicines' and 'We Are Patients' platforms contain information related to the Technological Platforms on Innovation in Medicine and the Collaborative Environment for the Community of Patient Associations.

The Self-Regulation System website also shows everything related to the pharmaceutical industry's Code of Best Practices and its relationships with third parties. And it serves as a management tool for the organization's work flow and event checking. Over the past year, an innovative mobile version of the website has been developed.

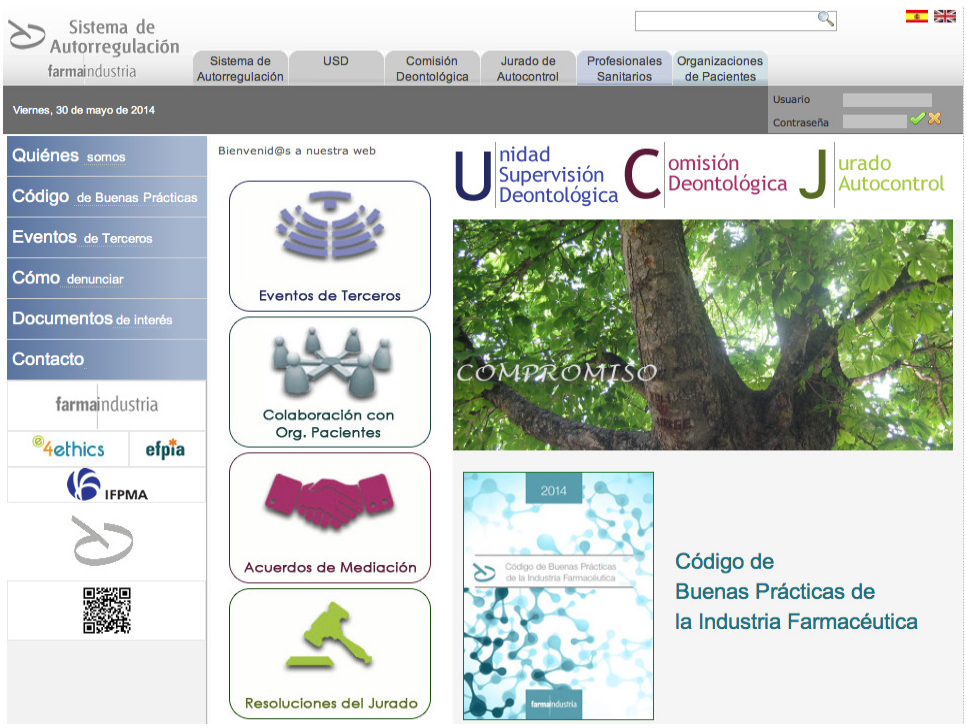
Meanwhile, the 'e4ethics' portal is a European initiative developed by FARMAINDUSTRIA to monitor the promotion of prescriptions and interactions with health professionals.

Of no less importance is the public portal, especially designed to communicate quality information (openly, clearly and quickly) to anyone who contacts the pharmaceutical industry in Spain.

Recently, the sites were incorporated to manage rebates under Royal Decree-laws 8/2010 and 9/2011 and differences in Notified Prices for De-listed Medicines (section 3 of the Annex).

During 2013, the distinct FARMAINDUSTRIA portals were analyzed in detail to make them compatible with a new concept of information system, much more complete and effective, with a more intuitive navigation and closer to the user.

Along these lines, the public portal was completely renovated (presented at the beginning of 2014), as was the Self-Regulation System website (presented in mid-2013), as a forerunner to the total renovation of the rest of the Association's web services now underway.



STATISTICS CONCERNING ONLINE SERVICES

FARMAINDUSTRIA's non-specialist portals recorded 2.2 million individual accesses during 2013, making them the public portal with the largest number of accesses supported, with over 65% of total consultations.

The most accesses came from the United States, almost double those from in Spain, which was followed by Germany, France and the United Kingdom as the five most active countries.

945,138	United States
568,119	Spain
231,476	Unidentified
108,538	Germany
67,808	France
44,862	United Kingdom

The number of daily users remained at around 7,000 individuals on average, reaching peaks of between 13,000 and 15,000 at certain times of the year.

The average number of individual daily users was around 7,000

4.2 WORKING GROUPS

The Working Groups constitute one of the principal mechanisms by which FARMAINDUSTRIA provides services to its Member Companies. In Working Group meetings, FARMAINDUSTRIA keeps participants permanently up to date with the main developments that have occurred in each area of specialization.

Following their renewal in October 2012, the FARMAINDUSTRIA Working Groups have continued to foment the exchange of knowledge and active cooperation between companies to define common positions on relevant sectoral aspects.

There are presently 22 Working Groups operating in the Association, whose subject areas and titles are as follows:

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

The Working Groups are one of the main mechanisms by which FARMAINDUSTRIA provides services to its Member Companies

Additionally, depending on the area, and due to reduced participation level, 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 2013:

SUSTAINABILITY AND ECONOMIC REGULATORY ACTIVITY WORKING GROUP (SERA-WG)

SERA-WG exhaustively monitors the economic regulatory activity affecting the sector

During 2013, SERA-WG completed an exhaustive monitoring of all the economic regulatory activity affecting the pharmaceutical sector.

It should be pointed out that a good part of the work focused on adapting the relevant declarations concerning the modification of the Reference Price System. Initially, this centered on the draft Ministerial Order prepared by the Ministry and later, following the suspension of the same as a result of the Council of State Ruling, on 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.

This involved intense activity by the Association to ensure the correct implementation of article 93.2 of the Law of Guarantees in the above-mentioned Royal Decree in the sense that, 10 years after EU authorization, a cluster can only be created if a competing medicine exists and is different from the original (and its licences) and is not generic or biosimilar. Other declarations by the Association focused on the following aspects: i) effective marketing of the presentations of medicines that facilitate the formation of series or determine the reference price; ii) the possibility in special cases of forming sub-series for setting reference prices; iii) the formula for calculating such prices; iv) minimum threshold; v) homogenous groups, and vi) Nomenclature, among others.

As this Report was about to be published, the WG was awaiting the bill for the first Ministerial Order, applying this Royal Decree, from the Ministry of Health, Social Services and Equality (MSSSI).

Meanwhile, the passage 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. The Association reiterated that this modification should only affect prescriptions which were going to be used by patients in another EU country, insisting that the text stipulates the possibility foreseen by the Law for the prescription of an active ingredient or branded medicine, and that this should be a brand in the case of biological medicines or those that cannot be substituted. Following the publication of the text, Farmaindustria is monitoring its correct implementation according to that foreseen in the Law and is carrying out different actions in several fields.

At the same time, this WG continuously monitored the monthly publication of the list of medicines subject to deductions under Royal Decree-law 8/2010, and through Farmaindustria communicated to the MSSSI the anomalies this creates and the need for this system to be corrected. It also paid special attention to the monitoring work carried out by Farmaindustria in relation to the setting of prices for new applications and pending indications, repeatedly pointing out existing delays to MSSSI and urging it to rectify the situation.

Liaising with HTA-WG, FARMAINDUSTRIA analyzed in detail the AEMPS document entitled "Collaboration Proposal for the Preparation of Therapeutic Positioning Reports for Medicines". The Association also closely monitored the processing of various amendments presented to modify Law 29/2006 on Guarantees and Rational Use of Medicines and Healthcare Products, which culminated in the publication of Law 10/2013, of 24 July, incorporating into Spanish legislation the EU Directives 2010/84, of the European Parliament and Council, of 15 December 2010, on pharmacovigilance, and 2011/62, of the European Parliament and Council, of 8 June 2011, on the prevention of the entry of counterfeit medicines into the legal supply chain, which modifies Law 29/2006, of 26 July, on Guarantees and Rational Use of Medicines and Healthcare Products.

Elsewhere, it should be noted that, at the close of this Annual Report, MSSSI continued to work on the drafting of a future Royal Decree on the pricing and financing of medicines, without a date for its publication having been determined. FARMAINDUSTRIA sent the industry's position to the Ministry, on the procedure for pricing and financing in the broadest sense, as well as in the framework of article 90 of the Law on Guarantees, with a view to the development of the above-mentioned text. Given its importance and the practical implications, an ad hoc WG, on the development and implementation of article 90.6 in the area of pharmacies, continues to work intensively on this issue, reporting its progress regularly to SERA-WG.

The HTA-WG has prepared technical documents relating to the economic assessment of medicines

Finally, the Group received regular information on the evolution of the debt for hospital supplies and economic and structural measures formulated by the State to solve this problem, as well as the initiatives carried out in the area of the hospitals market, both at regional and national (centralized purchasing) levels.

HEALTH TECHNOLOGIES ASSESSMENT WORKING GROUP (HTA-WG)

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

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

The Group, via FARMAINDUSTRIA's participation in EFPIA's HTA Task Force, has 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 papers which express the reflections of the pharmaceutical industry on matters related to medicine evaluation procedures.

HOSPITAL DEBT WORKING GROUP (HD-WG)

Over the past 12 months, the HD-WG 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 for the different Regional Health Services.

The Group also monitored and quantified the impact on the pharmaceutical industry of the measures against indebtedness, especially the Regional Liquidity Fund and the Suppliers' Payment Plan.

Additionally HD-WG was constantly analyzing all the regulatory activity related to control of the debt and the implementation of the instruments designed to eradicate it, both in relation to the commercial debt control mechanisms and the methodology for the calculation of the average payment period to suppliers, and to the implementation of the invoice accounting registry and introduction of e-billing in all Public Administrations with the subsequent implications for suppliers. Similarly, the Group monitored national and European legislation on local authority contracting.

Throughout all this process, the Association continued to take an active part in the EFPIA Task Force analyzing the evolution of hospital debt in different countries and in the CEOE's Debt Working Group, the progress of which was reported to the HD-WG on a regular basis.

HD-WG constantly monitored the evolution of debt for medicine supplies to SNS hospitals

Elsewhere, the Association continued to analyze the specifications of regional and centralized hospital calls for tender to check they conformed to public contracting legislation.

At the same time, from a legal viewpoint, it has analyzed different regional initiatives designed to permit diverse kinds of private organizations to manage public healthcare centres and the implications the process might have in the area of hospital debt.

Finally, in close liaison with the Autonomous Regions Working Group, the HD-WG held meetings with Andalusia Health Service (SAS), mainly in connection with the SIGLO project Andalusia is undertaking through the Provincial Government Contracting Platform and the implementation of EDI in all commercial transactions with SAS suppliers following the installation of many operational points in each of the Provincial Platforms to undertake this objective. The development of the SIGLO project has required the intensive involvement of the pharmaceutical laboratories when updating all the logistical and economic information contained in the pharmacy area of the SAS Goods and Services Bank. FARMAINDUSTRIA has monitored all the incidents as they occur in close coordination with SAS in order to resolve them.

The Group has also continued to keep in close contact with the Catalonian Health Institute (ICS), via the Association, in relation to the processing of new calls for tender for the supply of medicines to all its centers.

HOSPITAL MARKET WORKING GROUP (HM-WG)

The activity of the Hospitals Market Working Group focuses on monitoring of the hospitals market and the analysis (economic, legal and from the perspective of market access) of

HM-WG's carries out its work in cooperation with the Hospital Debt, Autonomous Regions and Economic WGs

the various initiatives being carried out at national and regional levels, especially concerning its regulation, centralized contracting, hospital calls for tender containing significant anomalies, installation of regional shared risk models and other management entry agreements and early payment guarantees, with the aim of preparing the sector's position in these areas.

The Group's work is carried out in coordination with the Hospital Debt Working Group and the Autonomous Regions and Economic WGs.

This WG is made up of representatives of the 41 laboratories and met twice in 2013.

TECHNICAL REGULATION OF MEDICINES WORKING GROUP (TRM-WG)

The main activities of this Working Group lie in the analysis of the provisions of Community regulations and the legislation published by AEMPS in the area of the technical regulation of medicines.

During 2013, the Group reviewed the regulations in course and the observations made during the passage of the drafts. Those with most significance during the year were on taxes, participation in systems guaranteeing the collection of medicine waste, and the registration and distribution of drugs.

The latest updates to the Notice to Applicants were presented to the Group by the AEMPS, with the aim of informing its members about European regulatory projects and the importance of the changes they imply for laboratories based in Spain. The Agency also announced a series of debates at its headquarters, open to all laboratories, to analyze the different initiatives carried out by the industry at national and Community levels in connection with the regulations, the conclusions of which will be published on its website.

MANUFACTURING AND TRACEABILITY WORKING GROUP (MT-WG)

The application of greater controls on the manufacture, import and distribution of active ingredients established by Community legislation has been transposed in Spain through Royal Decree 782/2013. This has needed very close monitoring by the WG throughout its passage. The requirement to comply with the rules for correct manufacture on the part of manufacturers and importers of active ingredients, and the new requirements for their distribution, could have caused supply shortages where manufacturers could not provide the relevant certifications. Fortunately, this did not occur in Spain, partly thanks to the close collaboration maintained in this area between Farmaindustria and AEMPS.

Otherwise, the finalization of the regulation on traceability of medicines is still pending, awaiting publication of the European Commission's Delegated Act detailing essential elements such as the serialization of medicines, safety measures and the medicines that will eventually be affected by these measures. In any case, the Group is working to provide AEMPS with a strategy for the sector's best adaptation to future requirements so that these are proportionate to the need and the risk of counterfeiting or supply shortages of the medicines concerned.

Finally, in the distribution area, the Group is particularly concerned about certain medicines supplied by laboratories which are not reaching patients and generating supply shortages as a result of non-authorized practices in the supply and dispensing chain. In this respect, FARMAINDUSTRIA is monitoring the issue very closely, both with AEMPS and some ARs in order to minimize any supply failures.

ENVIRONMENT WORKING GROUP (E-WG)

The E-WG collaborated with SIGRE in 2013 to monitor legislation that is important to the sector, such as the Bill to modify Law 27/2007, on Environmental Responsibility, the EU Directive 2013/39, of the European Parliament and the Council, of 12 August 2013, amending Directives 2000/60/EC and 2008/105/EC on priority substances in the area of water policy. It also monitored other actions in the environmental area related to the pharmaceutical industry (waste, disposal, emissions, energy efficiency and regulatory rationalization).

PHARMACOVIGILANCE WORKING GROUP (P-WG)

Activity in the domain of pharmacovigilance was very intensive in 2013, because of both the publication of new European modules on Best Pharmacovigilance Practices, and Royal Decree 577/2013, of 26 July, regulating pharmacovigiliance of medicines for human use, which entered into force at the end of July 2013.

The WG also underwent a reorganization splitting the pharmacovigilance field into five well-defined areas: i) inspection and audits: ii) risk management plans; iii) Master File; iv) spontaneous notifications, and; v) periodic safety reports. This structure allows the review, in each work session, of the most important developments, and the submission of proposals and measures to the Group for adoption, to improve the operation of units in the laboratories themselves or for communication to the Administrations.

The Group also contributed to the document of questions and answers of the above-mentioned Royal Decree on Pharmacovigilance, with numerous contributions and practical operational questions that needed to be disseminated appropriately and which we also had the possibility of presenting at a joint session with AEMPS.

Finally, the consolidation of the electronic mailing of DHPC (Dear Health Professional Communications) should be mentioned, received by healthcare professionals through the Scientific Societies. This project, a pioneer in Europe and endorsed by AEMPS given its important advantages with respect to using postal mail, has been joined by some 40 scientific societies and allows the dissemination of the DHPC to more than 100,000 healthcare professionals located in Spain.

VACCINES WORKING GROUP (V-WG)

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 singularity of this type of medicine, due to its preventive nature and the healthcare role it performs.

The Group's main activity in 2013 concerned the non-application of rebates to vaccine purchases by Administrations (finally expressed by Law 10/2013, of 24 July), reductions

in the percentages in devolution clauses, a review of the reallocation of vaccines when the post-supply cold chain is broken, and the initiation of the flu vaccination campaign.

The Group is also promoting various actions aimed at fomenting the value of the vaccines that prove useful with respect to other medicines and the benefits that they can contribute to society, as well as compliance with international recommendations in the area of vaccine coverage.

PHARMA-BIOTECH WG (PB-WG)

This WG, made up of 34 companies, has among its objectives the promotion of cooperation between industry, small biotechnological companies and public research centres, through special instruments and emphasizing the differential and complementary value contributed by FARMAINDUSTRIA.

In 2011, FARMAINDUSTRIA launched the Pharma-Biotech cooperation programme and between 2011 and 2013 it held 10 interactive meetings between the two sectors, mainly in the areas of the central nervous system, oncology, the respiratory system, inflammation and autoimmune diseases. Some 85 parties directly took part in these meetings (33 pharmaceutical companies and 52 representatives from the biotech sector).

There were also seminars configured as one-off forums identifying the added value derived from the interaction between demand and biotech supply, with sufficient differential content in the area of new therapies and innovative medicines. In the framework of this Programme, three such seminars were held in 2013. The first took place at FARMAINDUSTRIA head office in Madrid on 7 May and, for the first time, the programme was extended to mid-sized Spanish pharmaceutical companies with advanced developments in which larger laboratories could possibly collaborate. The second was held in July at FARMAINDUSTRIA's Barcelona office and focused on the Central Nervous System. The third was held in Madrid in November and its theme centered on autoimmune and cardiovascular diseases. All the presentations are available at the website, www.medicamentos-innovadores.org

Three transfer agreements were signed In the framework of these meetings. Through them, subsidiaries of multinationals established in Spain interest their decision-making centres in biotech products emerging from the meetings and can later organize visits to their installations.

The V-WG is promoting various actions designed to emphasize the value of vaccines

During October 2013, more than 15 meetings were held with representatives of pharmaceutical companies taking part in the meetings, with the aim of verifying the level of satisfaction with the programme, identifying and confirming the most important aspects of the events and inviting suggestions where they can be improved in order to maximize usefulness to laboratories. All the interviewees had a high regard for the value of this initiative and said they hoped the events would continue in the future.

During 2014, two such meetings are planned, the first in June and the second under the auspices of BioSpain, which will be held in Santiago de Compostela in September. The

first quarter of 2014 alone saw over 80 candidates from the biotech sector wishing to present their developments at these 'Cooperation encounters'.

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.

The Pharma-Biotech WG promotes public-private cooperation instruments in R&D

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

CLINICAL RESEARCH WG (CR-WG)

The Clinical Research WG in 2013 monitored Spanish and European legislative initiatives in the area of clinical research, particularly as concerns the new European Regulation proposed and the draft Royal Decree on Clinical Trials.

With regard to the Regulatory proposal, Farmaindustria held meetings with AEMPS to communicate the position of the innovative industry, supporting the Commission's initiative to simplify assessment and authorization procedures, reduce bureaucracy, strengthen cooperation between Member States, 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 transmitted the importance that assessments of the trials are done in parallel by the regulatory agencies and ethics committees, in order to meet the deadlines proposed by the new legislation and considerably reduce assessment time. There also needed to be a 'positive administrative silence' (tacit approval) in the authorization of these studies. The Regulation was approved by the European Parliament in a vote on 2 April 2014 and it should soon be published in the EU Offical Journal. The Regulation does not enter into force until 2016, although the new European clinical trials portal and its corresponding database need to be operating beforehand.

The draft new Royal Decree on Clinical Trials is aligned with that established in the new European Regulation with respect to reducing delays, transparency, single decision-making by the Code of Practice Committee, more flexible requirements for low-risk clinical trials and tacit approval. Farmaindustria communicated considered statements to the AEMPS on those aspects it considered relevant. Its definitive approval is expected at the end of 2014.

In the past few months, Farmaindustria has worked with AEMPS in launching the Spanish Clinical Studies Registry (REec). The CR-WG took part in the pilot project.

CR-WG also began working on a standardized documentation system on insurance cover for clinical trials with the aim that ethics committees can check that the rights of patients taking part in clinical research are adequately protected.

The CR-WG monitors legislative initiatives in the clinical research area

In relation to deviations from the protocol, which have to be notified to the AEMPS, it was proposed that the Agency establish a joint FARMAINDUSTRIA-AEMPS Working Group to clarify what needs to be notified, which information should be included in the deviations and which procedure should be used by the developers when communicating the matter.

MEDICAL AND RESEARCH DIRECTORS (BEST PROJECT) WORKING GROUP (BEST-WG)

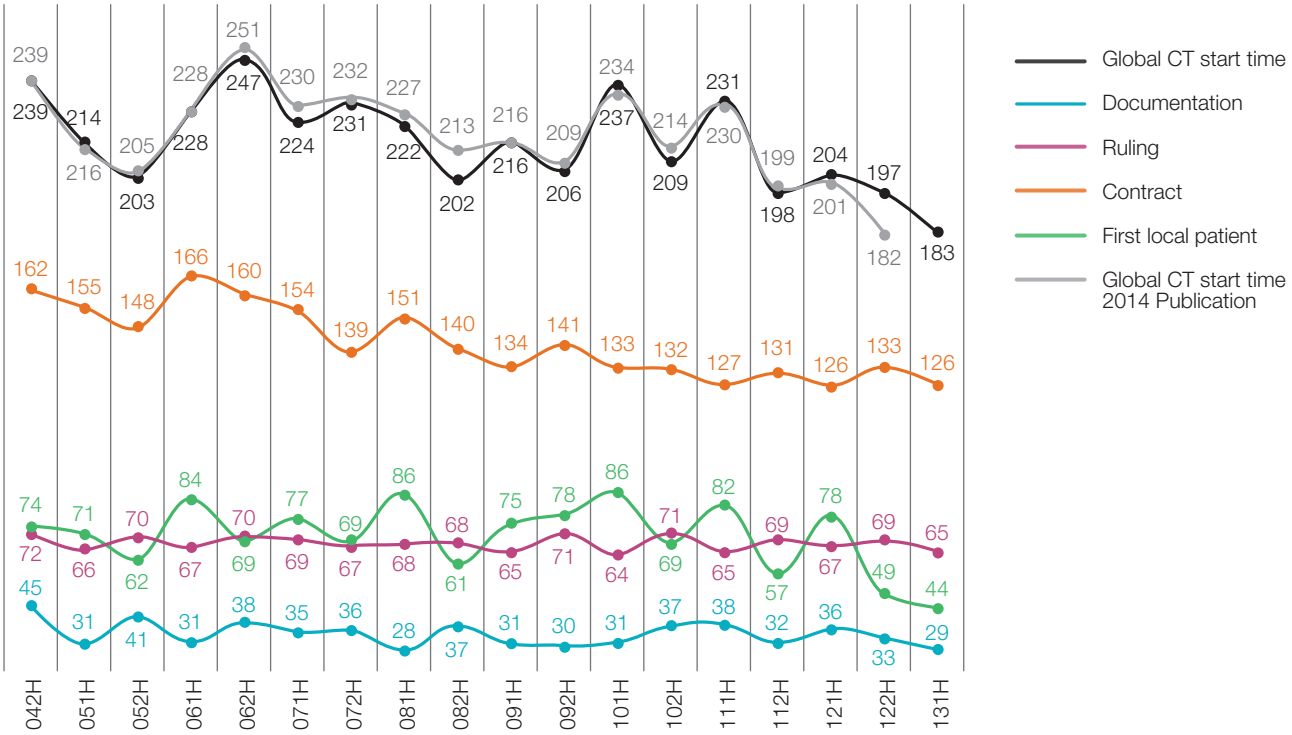
This Group, constituted eight years ago as a platform for clinical research excellence, comes within the Spanish Technological Platform for Innovative Medicines (PTEMI). It is focused on designing the strategy and promotion of competitiveness in clinical research in Spain, facilitating processes and improving performance indicators (time, recruitment, international benchmark) to achieve the best environment for performing clinical trials with a special emphasis on early phases.

The Metrics database, in its 15th edition as updated in June 2013, contains information on key indicators from 2,010 clinical trials, of which 947 have been completed. Ninety percent of these clinical trials were multi-centric (conducted at more than one medical centre or clinic) and international. The principal therapeutic areas in which the clinical trials were carried out were oncology, cardiovascular system, neuroscience and anti-infectious drugs.

An increase in early-phase clinical research, mainly Phase II, has also been noted.

The database contains indicators for the time to launch trials and the recruitment ratios for centres, as well as a section on international benchmarking. Generally, all the indicators for delays have been reduced at every half-year point at which they have been measured, mainly in the contract phase (around 120 days on average) and this consequently affects delay to the overall start time for the clinical trial (183 days on average). This trend of reducing the launch delay has become a constant since the project was launched in 2005. Nevertheless, there is one crucial aspect which could reduce time further when launching a clinical trial and that is the parallel management of contracts and the conformity of the Centre.

EVOLUTION OF KEY INDICATORS FOR CLINICAL TRIALS IN SPAIN



During 2012 and 2013, the 43 pharmaceutical companies that formed part of the BEST project decided to open it up to new participants, especially hospital centres, healthcare research institutes, research foundations, Autonomous Region health department managerial centres, and independent clinical research groups. Some 14 ARs, 57 centres and four independent clinical research groups (GEICAM, Navarre University Clinic, TTD and Solti) currently take part in the Project.

As in previous years, Farmaindustria performed a study to know more about the clinical research carried out in the BEST Project by the pharmaceutical industry in private centres. The data was presented jointly with the Institute for Healthcare Development and Integration (IDIS) in a seminar held at the Quirón Hospital in Barcelona, which was attended by over 120 parties involved in pharmaceutical R&D.

LEGAL SERVICES WG (LS-WG)

The activity of the LS-WG in the twelve months that make up this Annual Report was to inform and follow all those measures adopted by the Public Administrations at state and regional level and which have an effect of the sector.

These include both draft legislation being considered by the Association during its passage through Parliament as well as that approved during the past year. In relation to the legislation approved, the following should be mentioned: Law 10/2013, of 24 July, transposed from the EU pharmacovigilance and counterfeit medicines directives, which include important new measures derived from Law 29/2006, on guarantees and rational use of medicines and healthcare products; Royal Decree 782/2013, of 11 October, on distribution of medicines for human use; Royal Decree 8/2014, of 7 February, establishing rules governing cross-border healthcare and modifying Royal Decree 1718/2010, of 17 December, on electronic prescriptions and dispensing orders, as well as other provisions on reference prices, hospital co-payment, removal of medicines from financing, the draft Patents Bill, among others, which are the object of more detailed analysis in the legislative framework section of this Annual Report.

Given their legal implications, certain issues dealt with by other WGS — such as Hospital Debt, the Hospital Market, Code of Best Practices, etc. — have also been followed by this Group.

Legal Services Working Group members are informed about those issues that could be of interest in its field of activity

Independently of the two meetings they attended during the year, WG members were regularly informed of all the issues that could be of interest in its field of activity or whose application raised concerns.

TAX WORKING GROUP (T-WG)

The Group held various meetings throughout 2013 to tackle issues with fiscal implications for the sector.

On the one hand, as has become customary, the Annual Seminar was held to bring the laboratories up to date with information relating to fiscal developments in the year in course. These developments included: the analysis of the application of deductions for environmental investments; new items introduced by Law 16/2012, of 27 December, adopting various tax measures aimed at consolidating public finances and boosting economic activity; the reflection carried out on the updating of balance sheets, and; the analysis of the new Agreement for avoiding double taxation with the US. Likewise, the Seminar facilitated a forum for debate on the recent inspections relating to the deductions for R&D in clinical trials and in the area of Transfer Prices, as well as for reflection on the ruling by the EU Court of Justice, of 17 January 2013, on the VAT rate to be applied to medicinal substances and healthcare products.

On the other hand, during the year, the Group monitored the new legislative developments of a tax nature, among which the following should be mentioned: Royal Decree-law 4/2013, of 22 February, on support measures for entrepreneurs and stimuli for growth and job creation, and; Order HAP/864/2013, of 14 May, approving various tax declaration models.

Along the same lines, the Group also monitored: Royal Decree-law 7/2013, of 28 June, on urgent measures of a tax and budgetary nature, and fomenting research, development and innovation; Royal Decrees 828/2013, of 25 October, and 960/2013, of 5 December, modifying various tax Regulations; Organic Law 6/2013, of 14 November, creating the independent measures adapting Spanish law to the European Union legislation in the area of supervision and solvency of financial entities, and; the proposal of the EU Council for a Directive modifying EC Directive 2006/112 relating to standardized tax declarations and the common VAT system.

Special mention should be made of FARMAINDUSTRIA's active participation, via the CEOE, during the passage of both Law 14/2013, of 27 September, supporting entrepreneurs and their internationalization, and of Royal Decree 1042/2013, of 27 December, establishing certain measures in the area of environmental taxation and adopting other tributary and financial measures. In relation to the first Law, the Group communicated various observations and proposals for amendments to the text to clarify VAT funding criteria in order to improve the regulation of fiscal deductions for R&D. In relation to the Royal Decree, and following various consultations with the Ministry for Finance and Public Administrations to communicate the specific characteristics of the sector, FARMAINDUSTRIA obtained the exemption of certain inhaler medicines from the application of the Tax on Fluoride Gases.

The Group held dedicated sessions analyzing the kind of spending incurred by research activity

The Group also held dedicated sessions analyzing the kind of spending incurred by research activity, or activities directly related to it, and the Tax Directorate-General policy on what is included in the basis for deductions for R&D from the Tax on Companies.

Elsewhere, in full meetings and ad hoc group working sessions, the Group monitored fiscal aspects related to new measures introduced to the Code of Best Practices of the Pharmaceutical Industry, continuing its work in this area as this Report was being prepared for publication.

The T-WG has also monitored the judicial rulings and resolutions by the Tax Administration in relation to areas of fiscal interest for the industry.

HUMAN RESOURCES WORKING GROUP (HR-WG)

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. The Group has closely monitored the main developments in labour reform, making its observations known, including at hearings on relevant legislative drafts.

Elsewhere, 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 (the Spanish Entreprenurial Federation of Chemical Industries), as well as all those equality Commissions set up under the auspices of the present Bargaining Agreement, all of which report regularly to the Group.

CODE OF BEST PRACTICES WG (CBP-WG)

As recognized by the FARMAINDUSTRIA 2012 Annual Report, an intense workload faced this Group in 2013.

The approval by the Council of the European Federation of Pharmaceutical Industry Associations (EFPIA), and the later ratification in its General Assembly (24 June 2013), of a new Code of Transparency, necessarily involved transposing, on 31 December 2013 this Code into the Farmaindustria Self-Regulation System.

From the beginning, and with the approval of the laboratories, Farmaindustria, apart from complying with the obligation to transpose the Code mentioned above, took the decision to unify the two Codes (Healthcare Professionals and Patients' Organizations) in one document, along with other previously-existing documents that form an integral part of the same (Development and Regulatory Guides). The Group could count upon the active participation of Farmaindustria's Surveillance Unit to fulfill this objective.

Taking into account the effect of these new transparency commitments assumed by the pharmaceutical industry, on fiscal, competence and data protection matters, the Governing Bodies of Farmaindustria agreed, at the end of March, to constitute an ad hoc group formed by nine laboratories, to launch the new Code and promote, coordinate and sustain a Code communication strategy.

With the support and direct participation of the members of the ad hoc group, four large work areas related to the new Code were identified: i) validation, analyzing fiscal, competence and data protection issues; ii) commissioning of the design, planning, distribution and implementation of the internal communication plan aimed at the laboratories, as well as an external plan aimed at stakeholders; iii) risk management, directed at companies so that they approved the Code and revised their internal procedures to ensure their practices/activities complied with it, and; iv) governance, to manage its correct implementation.

Additionally, both in the full Group and the ad hoc group, different drafts were analyzed of the proposed new Code, as well as documentation from EFPIA to the National Associations and the different models existing at European level for implementing the pharmaceutical industry transparency initiative, as follows: i) the regulatory model with specific transparency legislation, as it exists for example in France, Portugal and Slovenia; ii) the co-regulation model, to be jointly implemented by the competent authorities, e.g. in Denmark, the Netherlands and Belgium, and; iii) the self-regulation model, to adopt and implement compliance with the transparency initiative through self-regulation systems, e.g. in Spain, the United Kingdom and Germany.

The Code of Best Practices Working Group has been extremely busy over the past 12 months

During 2013, nine meetings were held by both groups, four of the full Group and five of the ad hoc group.

This process ended with approval, by Farmaindustria's Steering Committee on 17 December 2013, of the New Code of Best Practices of the Pharmaceutical Industry.

COMPETITIVENESS AND INTERNATIONALIZATION WORKING GROUP (CI-WG)

The CI-WG intensified its activity in 2013, reinforcing the belief that internationalization is a key element for Spanish companies in tackling the economic crisis, although the seriousness of the crisis greatly compromised the exporting capacity of small companies.

FARMAINDUSTRIA intensified its actions with ICEX, also actively taking part in CEOE committees, the Madrid Chamber of Commerce and Acció in Catalonia.

During 2013, it continued to prioritize company — and market-specific actions, reaching out in countries such as South Korea, Canada, Israel, Ecuador and Kenya.

The Group also continued to work on the international section of the National Companies Group 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. In 2013, countries focused on included Algeria, Russia, Nigeria, Ghana, India, Angola, Mozambique and Colombia.

In parallel, the Working Group intensified its activities in the fight against trade barriers, focusing on markets such as India, Russia and Turkey, and actively took part in the drafting of joint position documents with organizations such as CEOE and Business Europe, with the aim of including specific demands from the pharmaceutical sector.

RELATIONS WITH AUTONOMOUS REGIONS WORKING GROUP (RAR-WG)

The RAR-WG has the following objectives, to: i) monitor pharmaceutical policy in the ARs, particularly 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 detecting and monitoring regional policies of prescription-dispensing, and vi) participate in political, scientific and professional forums related to these areas.

The Group is made up of representatives from 73 laboratories. During 2013 it held six work meetings.

The RAR-WG actively participates in the drafting of reports for the Autonomous Regions Observatory, the information and consulting tool for companies on situations in different ARs and which includes important information summaries on regional healthcare and pharmaceutical policy.

During 2013, the CI-WG continued to prioritize specific actions for companies and in external markets

During the past year, FARMAINDUSTRIA continued to write regular reports on the most topical and interesting issues for the sector: i) situational reports and tables of basic data taken from social and healthcare information issued by the different ARs; ii) implementation by the ARs of Royal Decree-law 16/2012; iii) INN prescription. Situation per AR; iv) 2013 Healthcare Budget — 2012 Healthcare Budget and expenditure; v) 2013 Budget: regional, healthcare and pharmaceutical; vi) evolution of the healthcare budget per AR, 2008-2012; vii) evolution of pharmaceutical expenditure, 2008-2012 and total 2013 pharmaceutical budget and per capita per AR; viii) 2014 Budget: regional, healthcare and pharmaceutical, and; ix) Medicines restricted to Hospital Dispensing. Situation per AR.

Finally, within the services provided to Member Companies, we must highlight the Autonomous Region Information Bulletin. This is a fortnightly publication which informs about the most important developments for the pharmaceutical industry in relation to the different initiatives occurring in the area of healthcare policy, pharmaceutical provision, healthcare legislation, health plans and biomedical research.

COMMUNICATION AND CORPORATE SOCIAL RESPONSIBILITY WORKING GROUP

This Working Group held quarterly meetings during 2013, well attended by representatives from different companies, in which the most relevant issues for the sector were dealt with. The Group elaborated various joint strategies and positions.

Within the services provided to the laboratories, every Monday the Weekly Communication Flash was distributed among the Member Companies. In 2013, a total of 42 editions were published to inform in detail about FARMAINDUSTRIA's activity in the communications area.

At the same time, a monthly report on the Presence of the Pharmaceutical Industry and Health Sector in the Communication Media and Social Networks was made available to the laboratories, and we published six-monthly comparisons of the evolution of this presence, as well as an annual one.

PATIENTS WORKING GROUP

The RAR-WG helped prepare reports for the Autonomous Regions Observatory

The FARMAINDUSTRIA Patients Working Group held various meetings in 2013, in which it dealt with subjects of interest to the sector, and organized the "We Are Patients" Day, as well as contents for the different agendas of the Permanent Dialogue Roundtable.

BIOLOGICAL MEDICINES WORKING GROUP

This Working Group was set up in September 2013 with the aim of acquiring greater knowledge in all aspects related to biological medicines.

One of the subjects of special interest for this Group is access to biosimilar medicines, considering the non-interchangeability of these products with original biological medicines and the need for them to be considered as new medicines by purchasing systems. There are advisable healthcare, safety and pharmacovigilance reasons for this and it is in the interests of getting patients to adhere to treatments.

The Group's task, as well as monitoring the specific legislation for biological medicines, consists of emphasizing the healthcare and social importance of these products through proposals which communicate to healthcare managers the paradigm shift occurring through increasing approval of biological medicines, including biosimilars.

The Biological Medicines Working Group emphasizes the importance of these products to healthcare and socially

ORPHAN MEDICINES WORKING GROUP

The Group debated various subjects throughout 2013, from the different actions promoting the rare diseases strategy, to Farmaindustria's position on the Health Advisory Board Working Group in which it was elaborating Basic Proposals for the Spanish Year of Rare Diseases. The event contains a special section dedicated to orphan medicines.

Meanwhile, the Group has maintained diverse contacts with other pharmaceutical industry organizations focused on orphan medicines, both at national and multinational level, helping make the "Rare Connect Day" an international forum and meeting place for the industry in this field.

BARCELONA OFFICE

Farmaindustria's Barcelona Office aims to advise and provide services of a diverse nature, in cooperation with the different departments which make up the Association, to the Member Companies based mainly in Catalonia. Dealing with consultations of various kinds is a major part of its undertaking.

The Office also performs functions as the Technical Secretariat of various Working Groups operating in Farmaindustria, lending its support to the coordination of meetings and the updating and renewing of the Groups every two years. It additionally serves as a venue for meetings of Farmaindustria's Governing Bodies, various Statutory Groups and other healthcare sector organizations (COASHIQ, ANEFP and SIGRE, among others).

During 2013, the Office continued collaborating actively with Farmaindustria's National Statutory Group, providing Technical Secretariat functions for its meetings, coordinating the Group's initiatives and constantly updating information of interest for the national companies via the Intranet situated in the Association's portal.

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. It took part in this way in the different sessions of the Working Committee constituted by the Catalonian Health Department, under the mandate of the Catalonian Parliament, to

prepare a Basic Document on sustainability, quality and equality for the Catalonian health system. The role of FARMAINDUSTRIA in this forum focused on reiterating the sectoral position in those areas that most affect the pharmaceutical industry, and harnessing a particular vote on the section relating to Provisions and Catalogue of Services, with the aim of ensuring fair access to medicines for SNS patients throughout Spain.

Finally, it should be added that the Office pursued contacts throughout the year with academic institutions and bodies related to the pharmaceutical sector at the regional level. It also took part in both 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 this Federation.

4.3
SPANISH TECHNOLOGICAL PLATFORM FOR INNOVATIVE MEDICINES (PTEMI)

Eight 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, with 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 2013, PTEMI carried out activities aimed at fostering international collaboration and supporting organizations interested in such collaboration. It participated in the IMI Forum, organized every six months by Spain's Industrial Technological Development Centre (CDTI). It 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 pillars: metabolic, neurodegenerative, infectious and immunological diseases and translational security.

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.

During 2013, the most recent three calls (9, 10 and 11) of the first Innovative Medicines Initiative were launched and a report was published on the high impact of the IMI consortia presently operating and the importance of the networks that have been established throughout Europe. Indeed, some consortia from the 1st Call were to finish work in 2014, but, due to the good results obtained, the EFPIA member companies have decided to make a new financial contribution so that they can continue for another two years.

Among the activities carried out by PTEMI during 2013, 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, it is discussed at greater length in the section on the Pharma-Biotech Working Group in this Annual Report.

PTEMI is the Spanish reference for IMI, the initiative of EFPIA and the European Commission to promote research into new medicines and strengthen the position of Europe in pharmaceutical R&D

PTEMI performed 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 4 and 5 March 2013, PTEMI coordinated and organized its 7th Annual Conference in Barcelona, along with the Spanish Technological Platform for Nanomedicine, Healthcare Technologies and Biotechnology Markets. Under the slogan 'The Health Challenge', and in front of over 300 participants, new medicine R&D&I projects were discussed 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 2,000 people interested in the PTEMI activities. The website appears in Spanish and English and is updated every week.

4.4
SELF-REGULATION SYSTEMS

In the field of self-regulation, the main milestone achieved in 2013 was the approval in December of a new version of the Code of Practice for the Pharmaceutical Industry (2014 Code).

This new version transposes the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations and unifies the two codes which until now formed part of the Farmaindustria Self-Regulation System: the Code on Interactions with Healthcare Professionals and the Code on Relationships with Patient Organizations.

There are three areas regulated by the new Code: i) the promotion of prescription medicines, Chapter I: articles 1 to 9; ii) interaction with Healthcare Professionals and Organizations, Chapter II: articles 10 to 16; iii) relationships with Patient Organizations, Chapter III: article 17. Additionally, this new version was approved to incorporate, as Title II, the Rules of Procedure for the Control Bodies (articles 25 to 37).

Chapter IV (article 18) acquires a special relevance: Transparency of the Pharmaceutical Industry's Relationships, which regulates the new commitment assumed by the industry to disclose payments and transfers of value made to healthcare professionals and healthcare organizations in relation to four categories: i) donations, applicable only for healthcare organizations; ii) contribution to educational and scientific meetings; iii) fees for service, and; iv) research and development.

For greater detail on how laboratories disclose this information, consult Annex 1 of the Code and the Disclosure Template.

With the aim of adapting and preparing the procedures and systems for collecting information from the laboratories and in the interest of ensuring compliance with such an ambitious objective, it was agreed, in line with that established in the EFPIA Code, that the first publication take place during the first half of 2016 using data from 2015.

For the Standard Code for Personal Data Protection in Clinical Research and Pharmacovigilance (the Standard Code), Farmaindustria focused in 2013 on training all those companies that had shown an interest in assessing whether to join the Code, as well as responding to all the questions put by companies adhering to the Code relating to due diligence, dissociation procedure and applicability of the Code to treatment of biological samples.

A short questionnaire was also sent to the companies adhering to the Code with the aim of evaluating the effectiveness of the Standard Code by measuring their satisfaction levels and obtaining information on the advantages of adhering to it. From the responses received, the Standard Code has contributed to improving training of personnel involved

The main milestone achieved in 2013 was the approval of a new version of the Code of Practice

in the clinical research and pharmacovigilance departments. It has also contributed to ensuring a better application of the data protection regulation and standardized work procedures of companies in relation to this regulation, and to strengthening the image of the pharmaceutical industry, valuing very positively the irreversible dissociation procedure described in the Standard Code.

The activity of the Standard Code Monitoring Committee once again focused on analyzing the requests received to join the Code, in answering consultations and studying new legislation approved, or in the pipeline (at both European and national levels), in the area of clinical research, pharmacovigilance and data protection that could result in the need to update or amend the Standard Code.

Meanwhile, FARMAINDUSTRIA, as a member of AUTOCONTROL, the Association for Self-Regulation of Commercial Communications, which adheres to the European Advertising Standards Alliance, has received the Annual Corporate Social Responsibility Certificate, through which it assumes the ethical commitment to exercise responsibly the freedom to advertise, and contributes thus to a stronger system of self-regulated advertising.

FARMAINDUSTRIA also continues to hold a seat on the AUTOCONTROL Management Board.

AUTO CONTROL

Asociación para la Autorregulación de la Comunicación Comercial

CERTIFICADO DE RESPONSABILIDAD SOCIAL CORPORATIVA

Autocontrol (Asociación para la Autorregulación de la Comunicación Comercial), es una asociación sin ánimo de lucro establecida en 1996 que se encarga de gestionar el sistema de autorregulación en España. Está formada por los principales anunciantes, agencias, medios y asociaciones sectoriales y su objetivo es contribuir a que la publicidad constituya un instrumento particularmente útil en el proceso económico, velando por el respeto a la ética publicitaria y a los derechos de los consumidores, con la exclusión de la defensa de intereses personales.

Autocontrol forma parte de EASA (European Advertising Standards Alliance) y es el único organismo privado en España incorporado a la red EJE (European Extra-judicial Network) de organismos extrajudiciales de resolución de controversias sobre órganos de resolución extrajudicial de litigios con los consumidores por cumplir los requisitos establecidos en la Recomendación 98/257/CE.

FARMAINDUSTRIA-ASOCIACIÓN NACIONAL EMPRESARIAL DE LA INDUSTRIA

Calidad de Asociado

Es socio de pleno derecho de AUTOCONTROL y mantuvo su calidad de asociado durante el periodo comprendido entre el 1 de enero y el 31 de DICIEMBRE de 2013, como así consta en la relación de asociados que publicamos en nuestra memoria anual de 2013.

Cumplimiento de Códigos Deontológicos

Se compromete a cumplir en todas sus comunicaciones comerciales el Código de Conducta Publicitaria de Autocontrol, basado en el Código de Prácticas Publicitarias de la International Chamber of Commerce.

Actividad de control previo de la licitud y corrección deontológica de la publicidad

Puede, con anterioridad a su difusión, solicitar el asesoramiento del Gabinete Técnico de Autocontrol en aquellos casos en los que tenga dudas acerca de la licitud y corrección deontológica de sus comunicaciones comerciales, con el fin de garantizar las mismas.

Sometimiento al Jurado de la Publicidad

Se compromete, así mismo, a cumplir las resoluciones emitidas por el Jurado de la Publicidad como resultado de eventuales reclamaciones presentadas ante este órgano de resolución extrajudicial de controversias, ya sea por parte de consumidores u asociaciones de consumidores, empresas de la competencia u otros sectores, u organismos de la Administración.

Para que así conste, firmo el presente certificado, en Madrid, a 28 de FEBRERO de 2014

José Domingo Gómez Castallo
Director General

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Miembro de EASA ALLIANCE

CODE OF PRACTICE COMMITTEE ACTIVITIES

Seventeen complaints were filed to the Code of Practice Committee in 2013, nearly double the number received the previous year. Some 47% of the complaints lodged were resolved by agreement between the parties as a result of the mediation work of the Code of Practice Committee. Another 12% of cases were transferred to the Self-Regulation Jury and in 23% of cases the parties had reached agreement prior to the Code of Practice

Committee meeting. The remaining 18% were filed after the withdrawal of the complaint concerned.

The complaints usually refer to questions of: i) hospitality and meetings; ii) scientific content in promotional material, and; iii) to a lesser extent, other promotional activities (distribution of promotional material, promotion via the Internet, transparency in promotion). The following table summarizes the complaints received by grouping them according to the different classification criteria:

Total	**17**
Code of Practice Committee	**14**
Committee mediation	8
Agreement prior to Committee meeting	4
Self-Regulatiion Jury	2
Archived	**3**

Complainants	
Member companies	41%
Adhered companies	6%
Code of Practice Surveillance Unit (CPSU)	53%
Complained against	
Member companies	94%
Adhered companies	6%

47% of complaints lodged with the Code of Practice Committee were resolved by agreement between the parties thanks to its mediation

NEW DEVELOPMENTS IN THE FUNCTIONING OF THE CODE OF PRACTICE COMMITTEE

As indicated at the beginning of this section, the new Self-Regulation System has introduced important changes to those also adapted by the Code Control Bodies, especially with respect to the functioning of the Code of Practice Committee and the complaints procedures. These are the new features:

- A new, urgent procedure, where the Self-Regulation Jury resolves complaints directly, can be requested by the complainant when the Code of Practice Committee, after having assessed the application, agrees to send it directly to the Panel where it believes this is justifiable.

- All the procedural aspects which can delay the process and resolution of a case have been eliminated, such as the possibility of requesting postponements of mediation meetings without justification, or extensions to complaints procedure deadlines, etc.

- The Code of Practice Committee can now issue Circulars through its Secretariat informing on areas that correspond to it by virtue of the Code.

- All the communications issued by the Code of Practice Committee must be made from a new email address created specifically for the purpose: secretariacomision@codigo.farmaindustria.es. All complaints to this body must be submitted as priority by telematic means.

ACTIVITIES OF THE CODE OF PRACTICE SURVEILLANCE UNIT (CPSU)

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) In-Company Training sessions have been carried out and training sessions given on the

Self-Regulation System as part of courses, including specialized Masters and PhDs; iv) it has contributed to the Editorial Committee of the magazine Life Science Compliance; v) has actively taken part in national congresses organized by Scientific Societies; vi) held bilateral meetings with the Member Companies to identify potential areas for improving the Self-Regulation System; vii) participated in seminars organized by the Official Madrid Pharmacists' College; viii) disseminated information about the Self-Regulation System among suppliers to pharmaceutical laboratories; ix) created and launched a specific web-site on the Self-Regulation System (www.codigofarmaindustria.es).

During 2013, CPSU activity focused mainly on collaborating and participating actively in the different national and international working groups responsible for launching and ensuring compliance with the new transparency initiative adopted by the pharmaceutical industry and which resulted in the approval of the new EFPIA Code in June and a new version of the Spanish Code in December. Among the main aspects analyzed within these working groups, the process of transposing the amended EFPIA HCP Code and the new EFPIA Disclosure Code into national codes has been important.

During 2013, the CPSU has collaborated in working groups responsible for launching the new initiative for transparency in the pharmaceutical industry

With regard to the Code on Relationships with Patient Organizations, the main activity has been updating the available information on the Farmaindustria website relating to collaboration by Member Companies with patient organizations and the incorporation of the content and main terms and conditions in the new version of the Code of Practice for the Pharmaceutical Industry, specifically in its articles 17 on Relationships with Patient Organizations and 18.8 on Transparency of the Pharmaceutical Industry's Relationships with Patient Organizations.

ADVICE AND COOPERATION

The approval by EFPIA of a new Disclosure Code involved the need to amend and adapt the Spanish code before 31 December 2013 to comply with the duty to transpose the new commitments and obligations assumed by the pharmaceutical industry. This situation was used not only to combine the two existing codes to date in a single document, but also to revise their precepts.

Apart from the new article 18 alluded to above, the following general improvements should be noted: i) the incorporation of a new specific section of definitions with the aim of facilitating understanding of the terms and concepts used throughout the articles; ii) the new structure of the Code dividing its content into titles and chapters; iii) amendments and specifications of the titles of various articles to reflect more clearly the content they regulate; iv) integration of the preexistent Guidelines as Supplementary Rules annexed to the article they develop; v) incorporation of the Rules of Procedure for the Control Bodies as Title II of the Code; vi) inclusion, as an integral part of the Code, of the Disclosure Template, Annex I.

The following specific improvements are also stipulated: i) it is clarified that the precepts related to promotion (articles 1 to 7, inclusively) refer to prescription medicines; ii) the first Supplementary Rules in the area of the digital environment (article 8) are set out; iii) article 10, Guarantees of Independence, has new content and a threshold has been fixed in article 11 to the hospitality offered associated with meals in the framework and context

of professional scientific activities, all this in compliance with the amendment approved in the EFPIA HCP Code, and iv) in relation to Title II, the Rules of Procedure for the Control Bodies, establishing as a general rule the publication of mediation agreements and including a new urgent procedure for the processing of complaints.

Without prejudice to the above, and in compliance with the function assigned by virtue of that stipulated by the Rules of Procedure for the Control Bodies for the Self-Regulation System ("perform consulting, guidance and training tasks in relation to the Code"), the Unit has increased its collaboration and assistance work through: 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; iv) assistance at international 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.

There were 2,112 preventive actions in 2013 and nine non-compliance cases lodged by the CPSU

During 2013, the Unit processed two binding queries, published nine circulars related to the Code on Interactions with Healthcare Professionals and a circular concerning the Code on Relationships with Patient Organizations.

MONITORING AND PREVENTION

The number of preventive actions carried out in 2013 was 2,112 (376 fewer than in 2012) and the total number of cases of non-compliance lodged by the ESU was nine, five of which consisted of non-compliance related to Hospitality and Meetings (article 11), three of non-compliance in the area of incentives (article 10), and one of non-compliance concerning the articles on transparency in the promotion and distribution of promotional material (articles 5 and 7, respectively). One of these was archived at the request of the ESU and the other eight were resolved via Mediation Agreement before the Code of Practice Committee.

For the second year running, the number of scientific-professional meetings analyzed and verified fell slightly in 2013: 4,954 (49 fewer than in 2012), although those without incident increased by more than one percent to 89.1% (from 87.7% in 2012). This same trend could be observed with respect to the number of market research studies communicated — 400 (112 fewer than in 2012) — and the number of services — 306 (24 fewer than during 2012). In the area of services, the percentage without incident fell by more than seven points, to 75.2% (compared to 82.4% in 2012), which implies a greater need for monitoring and control by the CPSU.

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	Accumulated apr 04 dec 13
EVENTS	ANALYZED	945	1,747	2,199	2,926	3,388	3,878	5,080	5,335	5,003	4,954	35,455
	Without incidents	718	1,390	1,909	2,616	3,087	3,345	4,383	4,862	4,389	4,412	31,111
	% Compliance	75.98%	79.56%	86.81%	89.41%	91.12%	86.26%	86.28%	91.13%	87,73%	89.06%	
STUDIES	ANALYZED						687	724	626	512	400	2,949
	Without incidents						397	546	565	416	332	2,256
	% Compliance						57.79%	75.41%	90.26%	81.25%	83.00%	
SERVICES	ANALYZED								357	330	306	993
	Without incidents								282	272	230	784
	% Compliance								78.99%	82.42%	75.16%	
Preventive actions		814	1,801	1,376	2,092	2,440	2,670	3,482	3,131	2,488	2,112	22,406
CPSC complaints		18	11	9	18	8	12	4	3	1	9	93*

* 12 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.
* 18 agreements among parties prior to the Code of Practice Committee meeting.
* 6 filed at the request of CPSU.
* 1 not upheld by the Self-Regulation Jury.
* 1 still being processed by the Code of Practice Committee.

(a) System for Communicating Studies approved in the 2008 Code.
(b) System for Communicating Studies approved in the 2010 Code.
Note: the above table summarizes data from CPSU activity (annual and accumulated) from its launch (April 2004) to 31 December 2013.

MANAGEMENT OF THE EFPIA 'E4ETHICS' PLATFORM

EFPIA's 'e4ethics' platform, managed by Farmaindustria, has become a reference tool for the pharmaceutical industry in Europe. 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 600 pre-assessment reports in 2013

e4ethics issued around 600 pre-assessment reports related to over 300 scientific-professional meetings in 2013, and the platform recorded about 65,000 page visits. Since launch in 2011, it has coordinated the contributions of 16 national associations and over 100 European scientific societies. 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 accompanying persons, fell by nearly 50%. The results are very positive, since the percentage of European scientific-professional meetings conducted fully in line with the Code has risen from 10% in 2011 to 40% in 2013.

The exceptional improvement in the logistical organization of the main scientific-professional meetings, from the viewpoint of article 10 of the EFPIA Code on Relations with Healthcare Professionals, as demonstrated by the e4ethics platform, is due to the strong commitment shown by the Member Companies. The use of e4ethics is widespread: it has been assimilated into the internal procedures of the companies and is well known by the main pharmaceutical industry stakeholders. The support and participation of the companies and scientific societies continues to increase.

ANNEX I
SIGRE: MEDICINES AND THE ENVIRONMENT

SIGRE is a non-profit-making organization launched by FARMAINDUSTRIA to allow pharmaceutical companies to comply with legal obligations related to the environmental handling of packaging and medicine waste accumulated in homes.

Environmental legislation (Law 22/2011, on Contaminated Wastes and Soils, and Law 11/1997, on Packaging and Packaging Waste) obliges companies to collect and dispose of packaging they feed into the marketplace. For its part, the healthcare legislation (Law 29/2006, on Guarantees and Rational Use of Medicines and Healthcare Products) requires pharmaceutical laboratories to manage environmentally the remains of expired or non-used medicines from households.

To achieve these objectives, FARMAINDUSTRIA has been able, for more than a decade, to count upon the collaboration of the pharmacies and distribution companies in the sector, represented by the General Board of the Official Pharmacists' College and the Federation of Pharmaceutical Distributors (FEDIFAR).

At 31 December 2013, SIGRE had 297 member pharmaceutical laboratories. Thanks to the active participation of all of these, the operational model of the organization has been consolidated as an efficient system for correctly terminating the life cycle of medicines.

2013 ENVIRONMENTAL DECLARATION

In line with the provisions of the Law, SIGRE presented the pharmaceutical sector's Environmental Statement for last year to the Environment Departments of the Autonomous Regions and Cities.

This Environmental Declaration consists of two documents: the Annual Packaging Declaration (DAE) and the 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.

Subsequently, the following national and AR data is collected, measured and compared by the DAE: i) the number and weight, by material, of more than 16,700 presentations of commercial medicines; ii) the weight of the packaging waste and leftover medicines deposited in SIGRE Points in the more than 21,200 pharmacies collaborating in the scheme, and; iii) the environmental treatment applied for each of the fractions obtained during the classification process.

The DAE observes that a slowdown has occurred in cooperation in most Autonomous Regions with respect to previous years. In 2013, nevertheless, the average weight of empty packaging, or that containing quantities of leftover medicine, deposited by citizens in SIGRE Points at pharmacies, was 81.12 grammes, a slight increase of 1.65% with respect to 2012.

Spain continues to be something of a halfway house with respect to the countries around us

It is important to highlight three aspects related to the amounts collected and managed via the SIGRE Points and collaboration among the population in general. First, the amounts collected also include waste deemed to be inappropriate: para-pharmaceutical products, for instance, batteries, spectacles and other healthcare material. Secondly, in 2013 the number of completely empty packages deposited by citizens increased by 18%, which demonstrates greater environmental awareness. And, thirdly, Spain continues to be a bit of a halfway house with respect to the countries around us.

With respect to the 2012-2014 PEP, the fifth plan the pharmaceutical industry has carried out in Spain, SIGRE presented its 2012 Monitoring Report to the Environment Departments.

During the second year of this PEP, the pharmaceutical industry applied 238 preventive measures affecting 36 million packages, contributing to making these presentations being more ecological and easier to recycle.

These results can be deemed satisfactory. In spite of the strict technical and safety requirements that the packaging has to fulfil in order to ensure the quality and safety of medicines, the cuts proposed for the three-year period have been achieved.

Since 2000, when these Plans began, SIGRE member companies have applied a total of 1,455 measures affecting over 360 million packages: optimizing their size, reducing their weight and using more recyclable materials. Thanks to these measures, the weight of pharmaceutical packaging has fallen by over 22% during this period.

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 waste deposited at SIGRE Points.

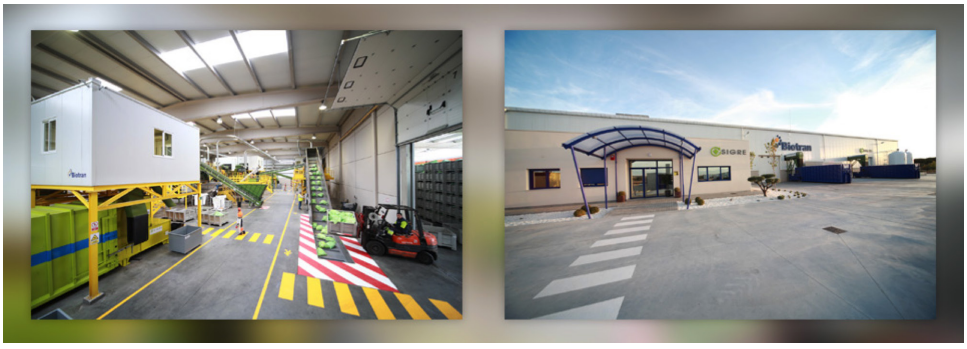
Due to its pioneering nature, its high level of automation and the innovative processes in which this is performed, the plant puts Spain at the vanguard of Europe and worldwide for the recycling of household medicine and packaging waste.

As stated in the 2013 Annual Statement on Packaging, this plant has continued to improve its processes and has increased its recycling rate for packaging materials by over 20%.

Meanwhile, the Environment Committee of the Spanish Federation of Municipalities and Provinces (FEMP) visited the facility in 2013 to check personally the process by which the classification of packaging and medicine waste is carried out.

This visit evidenced FEMP's support for the management system implemented by the pharmaceutical industry. This was later reinforced with the Waste Framework Ordinance, in which SIGRE Points are cited as the perfect way to manage household packaging and medicine waste environmentally.

The Plant also received an important institutional distinction in 2013, being selected by Castile-and-Leon Government as a model for the implementation of occupational health and safety measures at waste management facilities.



AEMPS CIRCULAR ON LABORATORIES JOINING SIGRE

Through its Circular 3/2013, the Spanish Agency for Medicines and Healthcare Products (AEMPS) launched a procedure to ensure that the medicines marketing authorization holders to be sold in Spain joined SIGRE.

It states that the companies, before marketing any new medicine, must present AEMPS with certification which testifies to their participation in the SIGRE system.

AEMPS also adds, in its Circular No. 1/2011, that the updating of the information appearing in the Patient Information Leaflets of medicines is required to include a caption informing the user of the need to deposit any medicine waste in the SIGRE Point at a pharmacy.

Through these procedures, AEMPS firmly supports SIGRE's environmental and healthcare activity and contributes to ensuring the correct management of medicine waste generated in homes.

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

CIRCULAR Nº 3/2013

DEPENDENCIA	Agencia Española de Medicamentos y Productos Sanitarios
CONTENIDO	Exigencia de participación en sistemas que garanticen la recogida de los residuos de medicamentos que se generen en los domicilios
ÁMBITO DE APLICACIÓN	Industria Farmacéutica

AEMPS INSTRUCTIONS FOR MEDICINE EXPORTS

AEMPS updated in 2013 its instructions referring to medicine exports and specifically humanitarian donations, expressly listing the recommendations made in this respect by the World Health Organization (WHO).

Following the procedures and criteria established for medicines donation, it noted that "in no circumstances should medicines returned by patients be accepted."

This led AEMPS to recognize the essential nature of SIGRE's activity in the environmental management of medicines leftover in individual households, in order to eliminate them from the cycle.

AWARENESS CAMPAIGNS

To comply with its obligations under the Operational Authorizations granted to it by the above-mentioned Environment Departments, SIGRE performed various awareness actions in 2013 to sensitize public opinion to the importance of environmental management of household medicine and packaging waste.

These initiatives are part of the communications actions Integrated Management Systems have to carry out to comply with the objectives required by environmental regulations.

Among those actions carried out, SIGRE launched the "What would nature do without you?" campaign, which aims to promote the use of SIGRE Points.

In this it calls on the population to make responsible use of medicines, insisting on their correct elimination via SIGRE Points in pharmacies.

This campaign also publicly recognizes the important role the pharmaceutical industry, and the rest of the stakeholders in the sector, play in SIGRE's healthcare and environmental activities.

SOCIAL NETWORKS

With the aim of maintaining more direct and closer contacts with the public, 2013 saw SIGRE launch its corporate profiles on the Facebook and Twitter social networks. Through these, SIGRE will inform about all its activities, and other environmentally-related subjects, with a special focus on the recycling of packaging and medicine waste.

Since their launch, these profiles have been very well received, as is reflected in rapidly increasing number of followers.

Within this 2.0 communication strategy, SIGRE has also revamped its corporate blog with a new design and fresh contents.

13TH INFORMATION DAYS FOR COMPANIES

SIGRE held the 13th edition of its Information Days for Laboratories at the Hotel Husa Princesa in Madrid on 26 June and the Catalonian Ministry for the Environment and Sustainability in Barcelona on 27 June.

These encounters, categorized as Offsetting Emissions Events, are now regular fixtures in the calendar for pharmaceutical laboratories and counted once more upon a sizeable participation from company environmental managers.

SIGRE TRAINING SESSIONS ON PACKAGING DECLARATIONS

As in previous years, SIGRE organized two training sessions to explain the operation of the SIGRELAB Form, Web version 4.0, the IT application created to enable laboratories to present their Company Declarations to SIGRE. During these sessions, the information the laboratories have to supply to conform to existing packaging regulations was analyzed and doubts over the way this data is submitted were resolved.

The sessions were well attended by those company personnel charged with compiling and contributing with the information requested by the Form.

TECHNICAL EXPERTS' COMMITTEE (CAT)

Made up of representatives of SIGRE member companies, the Committee's main responsibility is to provide technical advice to the pharmaceutical sector to help it correctly execute the Corporate Prevention Plans for packaging.

Over the past year, as well as evaluating and approving monitoring reports for the 2012-2014 PEP, CAT focused its work on analyzing the UNE 13428/2005, 13430/2005, 13431/2005 and 13432/2005 standards on specific requirements for the manufacture and composition of packaging and packing and their effects on the presentation of medicines.

IMAGE AUDIT

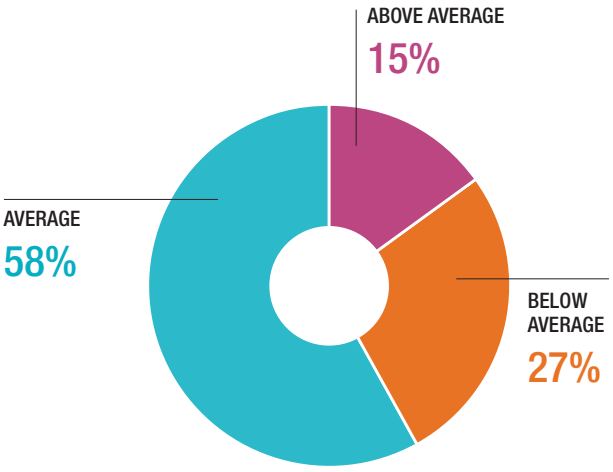
SIGRE carried out in 2013 another audit of its image among professionals working in the communications media, mainly both general and specialist reporters in the healthcare and environment fields.

The results of the audit, the third performed by the organization, placed SIGRE among the best-known Integrated Management Systems (SIG) known by journalists. Ninety-two percent said they were aware of its activity.

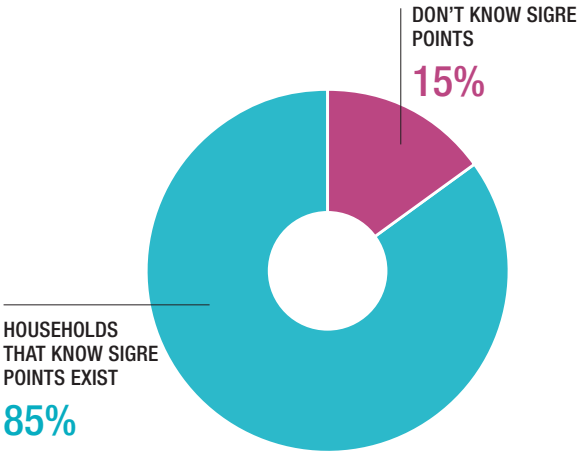
The perception these professionals have of SIGRE's operations is also very positive. From the viewpoint of management efficiency, and achievement of objectives by SIGs, SIGRE is in a small group of three (Ecovidrio, SIGRE and Ecoembes, in this order) which received the journalists' approval.

Finally, the journalists agreed in naming SIGRE as one of the best known of those SIGs most familiar to the population.

According to communications professionals, Spain is about average in Europe for its collection and environmental management of general packaging and waste.



The communications professionals believe that about 85% of Spanish households know that SIGRE Points exist.



ANNUAL SOCIAL RESPONSIBLITY REPORT

In line with its commitment to information transparency, and committed to the principles of social responsibility which typify the pharmaceutical industry, SIGRE published its 2012 Annual Social Responsibility Report.

It constitutes the fourth document the organization has published following the guidelines of the Global Reporting Initiative (GRI), the standard that enjoys the highest credibility and acceptation at the international level in this field.

The 2012 Annual Social Responsibility Report received the "A Checked" level of application from GRI, the highest qualification the organization grants to this kind of report.

With the aim of preserving natural resources, the Report is published digitally at www.memoriasigre.es and is accompanied by a brief executive summary giving an overview of what were the organization's main activity lines in 2012.

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