2012 ANNUAL REPORT

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MESSAGE FROM THE PRESIDENT

I took up the President of FARMAINDUSTRIA at the end of the third year of a process that got under way in 2009 and which, following a succession of Royal Decree Laws and a long list of measures introduced by Spain's Autonomous Regions, was leading to an enormous shift in the fundamental landscape of the Spanish pharmaceuticals market. It was a change that was leaving pharmaceutical companies (large, small or medium; Spanish or foreign) no alternative but to face the future armed with a number of premises radically different to those that had prevailed thus far.

In addition, all of this was taking place against the grim backdrop of an unprecedented economic downturn that was prompting tremendous uncertainty and made future prospects–in the short, medium or long term; at home or abroad–extremely difficult to gauge.

I eventually took up the President when FARMAINDUSTRIA's relationship with the public administrations was not at its best. Despite the exceptional efforts of my predecessor, the FARMAINDUSTRIA team of professionals and each and every one of our member companies, the sheer number of hefty regulatory blows dealt to the industry (the most recent being Royal Decree-Law 16/2012, which did away with financing for more than 400 different medicines and changed the way patients paid for medicines), and in which, more often than not, we had absolutely no say at all, all combined to create an atmosphere of distrust and came as stumbling blocks to open engagement and dialogue.

And so, in October 2012, we were standing at the very heart of the perfect storm: global economic recession, uncertain prospects, an industry heavily penalised by efforts to slash the public deficit, and the total absence of a climate conducive to cooperation and debate, a fundamental prerequisite for a heavily regulated industry like ours.

As a result, public pharmaceutical expenditure on Spanish National Health System prescriptions saw a 12.3% drop in 2012, representing the largest spending cut since such data first became available. Moreover, this reduction came in the wake of others registered in 2010 (-2.4%) and 2011 (-8.8%), making it three straight years of shrinking growth in the public pharmaceuticals market and leading to more than 23% less spending to December 2012, the worst figure on record since May 2010.

And that's not all: according to estimates by FARMAINDUSTRIA and industry analysts, a sea change in the Spanish pharmaceuticals market is still a long way off. Reduced spending is on the cards for 2013 and is expected to match 2012 levels. Further, continued reductions are forecast for years thereafter, albeit at a more moderate rate (between -1% and -5% a year), and at least until 2016. If these forecasts are reliable, public pharmaceutical spending in 2016 may well match end-2002 figures. In fact, the most recent Ministry of Health figure for public phar-

maceutical spending on Spanish National Health System prescriptions at the time of drafting this message (March 2013) showed that spending stood at July 2004 levels.

Moreover, in the hospitals market, which tends to be more dynamic because it is where innovative pharmaceuticals make their initial appearance, FARMAINDUSTRIA's own findings reveal that in both 2011 and 2012 hospital pharmaceutical spending grew by little more than 1%. Industry analysts generally agree that the fall will continue throughout the period 2013-2016 (at an annual rate of between -3% and -0.1%).

The data and gloomy predictions all point to the conclusion that pharmaceutical spending will cease to be a drain on the public coffers, if indeed it has ever really been viewed as such. All of the Royal Decree-Laws that are now in force, and the ensuing measures that are set to be developed shortly (new pricing and reimbursement regulations for pharmaceuticals, therapeutic positioning reports, economic assessment procedures for new pharmaceutical products, and so on), as well as the traditional tools used to regulate the industry economically (e.g. Reference Price Systems, Standardized Groupings Systems, etc.), all serve to guarantee continued public pharmaceutical spending, both in pharmacies and in hospitals, though not in a controlled manner but falling progressively over the next four years at least. If this happens, Spain will fall well below the EU average ratios in per capita public pharmaceutical spending, percentage of healthcare spend or in percentage of GDP.

The pharmaceutical industry has other concerns, not least the limitations and differences that are starting to become clear in Spain's different Regional Autonomies as regards access to innovative medicines. While utterly respectful of each one's sovereignty in matters of pharmaceutical spending management, we feel compelled to point out that it is likely that the regional authorities' disparate and uncoordinated measures are leading to less and less equality in Spain; in some cases, those measures set out to reduce public pharmaceutical spending, leading to a limiting effect on patients' access to the more innovative medicines and favouring lower-cost, and even more outdated, therapy options that are less effective in relative terms. Equal access to pharmaceutical innovation must stand as one of the fundamental pillars of Spain's National Health System and it is up to the Ministry of Health, Social Services and Equality to ensure it.

Spain's economic problems in 2012 were not limited to the pharmaceutical industry: overall economic activity stalled, and not for the first time. Following a brief respite in 2011, a year that saw a modicum of real GDP growth (+0.4%), in 2012 Spain was back on the slope of recession, with real GDP shrinking by -1.4 per cent. Worse still, forecasts for 2013 are dire: real GDP is expected to fall by -1.5%, although it is also true that this fall will come about against a backdrop of inter-quarterly fluctuations in GDP which are likely to be gradually less negative, and even with the possibility of growth in the latter months of the fiscal year.

In this environment, one of the most important government measures introduced in 2012 was the Suppliers' Payment Plan; thanks to the Plan, at the end of July regional authorities and local agencies managed to pay-off just about all the arrears pending with their service and product suppliers, settling unpaid bills going back to fiscal year 2011 and even earlier.

The Plan had a highly beneficial effect on pharmaceutical companies: they were able to collect more than 5 billion euro in the 14 participating regions (the Spanish state is made up of 17

Regional Autonomies in all; the exceptions were Galicia, Navarre and the Basque Country). This event alone gave Spain's pharmaceutical companies a much-needed financial shot-in-the-arm, as many of them were in a very delicate state. Unfortunately, the arrears situation has since reared its ugly head again and collection is on the wane.

In order to meet the accumulated debt, the Government has announced, as part of its National Reform Programme, its intention to introduce a new a Suppliers' Payment Plan. This will enable authorities to meet payments outstanding from FY2012 and, at least, part of the debt accrued by regional autonomies in 2013.

However, only an instrument that is capable of automatically collecting the regional autonomies' accumulated invoices, once and for all and within a reasonable period of time, will solve the arrears problem that is harrying a number of Spain's public administrations.

I'd like to end on a note of optimism. Not merely wishful thinking, but a well-founded belief capable of inspiring trust and confidence in our sector overall and in each and every one of its companies.

We have weathered this terrible storm well, yet at enormous suffering and sacrifice—on occasions, irreparable damage has been inflicted—and we continue to make every effort to fulfil our mission, namely to make the best pharmaceutical products available to one and all. At the same time, we continue to invest heavily in R&D, many companies contribute to the growth of Spain's industrial fabric, exports are thriving, we never cease to encourage and stimulate biomedical R&D at public research centres and the on-going training of Spain's doctors, and we are holding on to our competitive edge. With such splendid distinguishing features, optimism is fully-justified.

It is undeniable that the current recession is unlike any other before it, except with one difference: it is sure to come to an end. Sooner or later Europe, and with it Spain, will reap the fruits of its human potential and its status as a global benchmark and it will return to the path of growth and certainty.

We are certain that Spain's government understands us; it is aware of the efforts that it has demanded of us and knows the toll that they have taken. Accordingly, we feel certain that when we are eventually unburdened by emergencies, it will once again engage with us and understand our situation. The government is already signalling that this will be the case.

We need to continue doggedly to be ourselves and to highlight our distinguishing features (innovation, quality, competitiveness, flexibility…), and we want our sector to be treated fairly.

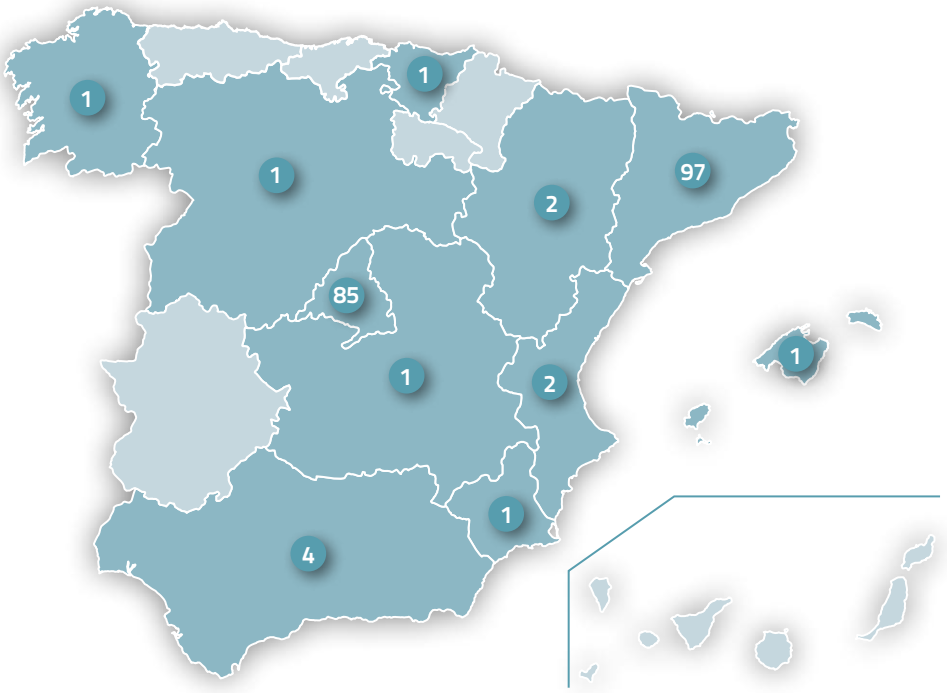
At the end of the day, it will be good for patients and Spanish society overall.

Elvira Sanz Urgoiti
President of FARMAINDUSTRIA

01.
FARMAINDUSTRIA IN 2012

1. MEMBER COMPANIES

At 31 December 2012, FARMAINDUSTRIA had 196 member companies based in differents regions in Spain, as follows:



FARMAINDUSTRIA's member companies represent 46% of licensed pharmaceutical products vendors, or their local representatives in the case of those authorized via the centralized procedure, regardless of whether or not they are engaged in trade activity. In terms of sales, they represent 82% of the prescription market.

PHARMACEUTICAL COMPANIES BY GROUPS

National		International		
		USA	European	
Total	81	22	93	
Large	6		Germany	17
Medium	8		France	15
Small	67		Mixed	25
			United Kingdom	24
			Switzerland	12

2. 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.

FARMAINDUSTRIA's governance 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) and a Board of Governors 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 Board of Directors from among its members (4 Spanish-capital companies, 2 USA-capital concerns and 5 European-capital outfits).

Elections to renew the Association's governance bodies were held in October 2012. In accordance with the Association's byelaws, which call for renewal of the President every two years, the President went to Ms. Elvira Sanz Urgoiti, who represents a company from the American Group of Members. She took over from Mr. Jordi Ramentol Massana, who headed FARMAINDUSTRIA until October and represented a company from the National (Spanish) Group of Members

In addition, the General Assembly held on 19 June 2012, saw changes in the Association's bye-laws, affecting mainly the composition of FARMAINDUSTRIA's Governance Bodies. The changes, which came into immediate effect, focused on adding another Vice-President and an additional member to each group in the Steering Committee. It was also agreed that the additional post for the Steering Committee, initially scheduled to be allocated to the European Group in 2014, should be brought forward to the October 2012 elections.

The composition of both Governance Bodies at the time of drafting this report was as follows:

EXECUTIVE BOARD

President

Ms. Elvira Sanz Urgoiti
PFIZER, S.A.

Vice-Presidents

Mr. Jesús Acebillo Marín NOVARTIS FARMACEUTICA, S.A.	Mr. Esteban Plata González ABBVIE FARMACEUTICA, S.L.U.
Mr. Rüdiger Becker GLAXOSMITHKLINE, S.A.	Mr. Jordi Ramentol Massana FERRER INTERNACIONAL, S.A.
Ms. Aurora Cayetana Berra de Unamuno BRISTOL MYERS SQUIBB, S.A.	Mr. Alberto Ros Morte BOEHRINGER INGELHEIM ESPAÑA, S.A.
Mr. Antoni Esteve Cruella ESTEVE	Mr. Martín Sellés Fort JANSSEN CILAG, S.A.
Mr. Jorge Gallardo Ballart ALMIRALL, S.A.	

Members

Mr. Andreas Patrick Abt ROCHE FARMA, S.A.	Mr. Juan López-Belmonte López LABORATORIOS FCOS. ROVI, S.A.
Mr. Javier Ellena Aramburu LILLY, S.A.	Mr. Marc Antoine Lucchini SANOFI-AVENTIS, S.A.
Mr. Angel Fernández García MERCK, SHARP & DOHME DE ESPAÑA, S.A.	Mr. Federico Plaza Piñol LABORATORIO BETA, S.A.
Mr. Javier Font Salgado LBO.DE APLICACIONES FARMACODINAMICAS, S.A. "FARDI"	Mr. Salvador Pons Ribas LABORATORIOS MENARINI, S.A.
Ms. Inés Juste Bellosillo JUSTE, S.A. QCO. FCA.	Mr. Francisco Quintanilla Guerra FAES FARMA, S.A.
Mr. Rainer Krause BAYER HISPANIA, S.L.	

STEERING COMMITTEE

President

PFIZER, S.A.
Ms. Elvira Sanz Urgoiti

Vice-Presidents

ABBVIE FARMACEUTICA, S.L.U.
Mr. Esteban Plata González

ALMIRALL, S.A.
Mr. Jorge Gallardo Ballart

BOEHRINGER INGELHEIM ESPAÑA, S.A.
Mr. Alberto Ros Morte

BRISTOL MYERS SQUIBB, S.A.
Ms. Aurora Cayetana Berra de Unamuno

ESTEVE
Mr. Antoni Esteve Cruella

FERRER INTERNACIONAL, S.A.
Mr. Jordi Ramentol Massana

GLAXOSMITHKLINE, S.A.
Mr. Rüdiger Becker

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

NOVARTIS FARMACEUTICA, S.A.
Mr. Jesús Acebillo Marín

Members

ALCON CUSI, S.A.
Mr. Enrique Chico Picaza

ASTRAZENECA FARMACEUTICA SPAIN, S.A.
Ms. Camilla H. Hartvig

BAXTER, S.L.
Mr. Luigi Antoniazzi

BAYER HISPANIA, S.L.
Mr. Rainer Krause

LABORATORIO BETA, S.A.
Mr. Federico Plaza Piñol

LABORATORIOS CASEN-FLEET, S.L.U.
Mr. Michael Vortrefflich

LABORATORIOS ERN, S.A.
Mr. David Solanes López

FAES FARMA, S.A.
Mr. Francisco Quintanilla Guerra

LBO.DE APLICACIONES FARMACODINAMICAS, S.A. "FARDI"
Mr. Javier Font Salgado

GRUPO FARMASIERRA, S.L.
Mr. Tomás Olleros Izard

FERRING, S.A.U.
Mr. Juan Carlos Aguilera Rodríguez

GILEAD SCIENCES, S.L.
Ms. María Rio Presa

JUSTE, S.A. QCO. FCA.
Ms. Inés Juste Bellosillo

LABORATORIOS LETI, S.L. UNIPERSONAL
Mr. Jaime Grego Sabaté

LILLY, S.A.
Mr. Javier Ellena Aramburu

LABORATORIOS MENARINI, S.A.
Mr. Salvador Pons Ribas

MERCK SHARP & DOHME DE ESPAÑA, S.A.
Mr. Angel Fernández García

LABORATORIO REIG JOFRE, S.A.
Mr. Ignasi Biosca Reig

ROCHE FARMA, S.A.
Mr. Andreas Patrick Abt

LABORATORIOS FCOS. ROVI, S.A.
Mr. Juan López-Belmonte López

SANOFI-AVENTIS, S.A.
Mr. Marc-Antoine Lucchini

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 OFFICES IN BARCELONA.

DIRECTOR GENERAL
Humberto Arnés

DEPUTY DIRECTOR-GENERAL
Javier Urzay

GENERAL COUNSEL AND LEGAL AFFAIRS
Lourdes Fraguas

DIRECTOR OF STUDIES
Pedro Luis Sánchez

DIRECTOR OF COMMUNICATIONS
Julián Zabala

TECHNICAL DIRECTOR
Emili Esteve

DIRECTOR OF INTERNATIONAL AFFAIRS
Icíar Sanz de Madrid

DIRECTOR OF RELATIONS WITH REGIONAL GOVERNMENTS
José Ramón Luis-Yagüe

3. ENVIRONMENTS IN WHICH FARMAINDUSTRIA OPERATES

3.1. MARKET REGULATION AND ENGAGEMENT WITH PUBLIC ADMINISTRATIONS

Over the past twelve months, Spain's pharmaceutical market has been marked by the introduction of the cuts in public pharmaceutical spending contained in Royal Decree-Law (RDL) 16/2012; further provisions and regulations stemming from this same law are likely to make their appearance over the coming months. One factor that is expected to weigh heavily on the sector is the planned Royal Decree on public pricing and refunding of medicinal products to which the Spain's Ministry of Health, Social Services and Equality is putting the final touches even as this Report is being drafted.

However, it should be said that, first of all, that June 2012, the beginning of the 12-month period spanned by this Report, saw a very important event not only for the pharmaceutical companies that market their products in Spain but also for other companies with regular contracts with Spain's administrations (national, regional and local). This event was none other than the effective application of the so-called Suppliers Payment Plan; the latter settled more-or-less the regional and local administrations' entire outstanding debt with their respective products and services suppliers, as pending in payments due tax year 2011 and prior.

The Suppliers Payment Plan was processed initially in 25 February 2012 for local authorities and 6 March 2012 at the regional level. The Plan set out to settle arrears prior to 1 January 2012 and was backed by 30 billion euro from a pool made up of 26 banks and comprising Spain's major financial services players, including Instituto de Crédito Oficial (ICO).

As regards the regional governments' payments outstanding, the Plan culminated on 27 and 28 June 2012, when suppliers received payment of a total 17.7 billion euro, plus a further 9.3 billion euro that they had received from local authorities on 31 May 2012.

The Plan had a highly beneficial effect on pharmaceutical companies: it enabled them to receive payment of five billion euro in the 14 Autonomous Regions that participated in the Plan (the Spanish State is made up of 17 Autonomous Regions in all; Galicia, Navarre and the Basque Country did not take part in the Plan) and further allowed them to amortize nearly 96% of the Plan's target debt. As a result, the average payment period of Spain's National Health System to pharmaceutical companies fell from 600 days, as registered in May 2012, to 193 just one month later.

The Supplier Payments Plan reduced from 600 to 193 days the average time taken by the National Health System to settle payments with pharmaceutical companies

This came as a financial shot-in-the-arm for many pharmaceutical companies that were facing an extremely delicate situation.

July 2012 saw the effective coming into force of new system involving users' payment of medicinal products, as laid down by RDL 16/2012. The new arrangement involved the introduction of variable user-contribution for active users (40%, 50% or 60% of RRP) according to the user's annual income bracket (less 18,000 euro; 18,000 -100,000 euro, or more than 100.000 euro, respectively), and provided exemption for users on Social Integration Income, non-subsidized unemployed persons, workplace accident related treatment and the differently-abled, according to specific applicable legal conditions. In turn, with this new co-payment scheme, pensioners began to pay 10% of the RRP of financed medicinal products, with payment limits of 8 or 18 euros depending on whether their annual income is below 18,000 euro or between 18,000 and 100,000. Pensioners with an annual income in excess of 100,000 euro p.a. pay 60% of the RRP, with a monthly spending limit of €60. In turn, persons on non-contributory pensions are exempt from copayment.

September 2012 saw the introduction of yet another measure aimed at trimming pharmaceutical spending, included in RDL 16/2012 and which was finally implemented by way of Resolution 2 August 2012, by the Directorate-General of the Basic Portfolio of Services of Spain's National System of Health and Pharmacy: the updating of the list of medicinal products that fall beyond the scope of the pharmaceutical services offered by the National Health System. This Resolution included a total of 416 medicinal presentations, of which 91 are still financed by the National Health System for certain indications.

The combined impact of these two measures, in terms of the reduction of public pharmaceutical spending, is leaving initial forecasts well behind. In the nine months between July 2012 (when copayment came into effect) and March 2013 (when this Report was being drafted), the number of National Health System prescriptions filled in pharmacies fell by 15.3% on the same period of the previous year; and in terms of public pharmaceutical spending, the fall was -19.5% in a comparable period.

These measures, in conjunction with RDLs 4/2010, 8/2010 and 9/2011, are the main causes for which public pharmaceutical spending in March 2013 was more than 3.4 billion euro lower than the figure registered in May 2010, a record month that marked the high point for public pharmaceutical spending in Spain.

If current FARMAINDUSTRIA estimates turn out to be correct, at end-2013 public pharmaceutical spending will barely reach 8.6 billion euro, which will mean the overall contraction of the public pharmaceutical market in Spain, representing a fall of more than 4.1 billion euro p.a. on the all-time high. This means that the market has shrunk by 33%. It should be remembered that at end-2012 the market had already dipped by 23%.

Similarly, Spain's Autonomous Regions have been cutting pharmaceutical spending continuously over the past twelve months; some of their measures were legally questionable, either because they encroached on the jurisdiction of the State or because, quite possibly, they violated the rights of pharmaceutical companies and healthcare players. The most notable cases were:

▪ The medicinal product auctions held in Andalusia (Southern Spain) and which were met with an appeal in Spain's Constitutional Court by the Ministry of Health, Social Services and Equality based on the argument that they encroached on the exclusive jurisdiction of the State;

▪ In certain autonomous regions, medicinal products were eliminated from prescription programs and were automatically replaced with other medicines prescriptions;

▪ The growing trend in autonomous regions involving the wrongly called "Therapeutic Equivalents" in the processes of acquiring medicines or in prescription handbooks, among others measures.

Meanwhile, throughout 2012 and in early 2013, pharmaceutical companies' receipts from sales to hospitals belonging to regional healthcare services were considerably low. At end 2012, pharmaceutical companies had received only roughly a third of outstanding payments for medicinal products sales to SNS hospitals, generating a new stock of debt, not quite as large as the one settled by the first Suppliers' Payment Plan, but nonetheless sizeable.

However, as regards the debt accrued in in 2012 and early 2013, the Spanish government has already announced in its National Reform Program 2013, presented to the European Commission for its approval last 30 April 2013, "the start of Phase III of the Suppliers' Payment Plan with the intention of meeting payments pending not only in Autonomous Regions but also with local authorities inverted commas missing". Despite this declared intention, at the time of drafting this Report no details have been announced concerning this operation (e.g. financing, the invoices affected, collection dates, etc.).

In this environment of controlled public pharmaceutical spending, the time may well have come for the Administration to consider carrying out a pharmaceutical policy aimed at leveraging the pharmaceutical industry's full potential to position itself as a key economic sector, as a means towards rekindling the Spanish economy and undertake a much-needed transformation in the productive model to ensure sustained growth in Spain in the medium and long term.

Accordingly, there is a need for the Administration to lend its support to the pharmaceutical industry with its arsenal of public policy tools; above all it needs to guarantee a stable and predictable regulatory framework and an unswerving commitment to pharmaceutical innovation and to avoid unexpected changes in the pharmaceutical playing field each time recession rears its ugly head.

Spain's Administration needs to support the pharmaceutical industry with the public policy tools that it has at its disposal, and, above all, it has to guarantee a stable regulatory framework

3.1.1.
THE REGULATORY FRAMEWORK

In 2012 a total 29 Royal Decree-Laws were passed, marking a record number of regulations justified by reason of "extraordinary and urgent need" in a single year.

RDL 16/2012

The implementation of the health services reform carried out by RDL 16/2012 was one of the major issues of 2012, and it will no doubt continue to remain in the spotlight in 2013. Some of the regulatory aspects of this RDL are still pending and they are a cause for considerable concern for the pharmaceutical industry. The most worrying aspect is the application of Article 90 of Law 29/2006 which has led FARMAINDUSTRIA to create of a specific Working Group aimed at advancing the practical aspects of the regulatory conditions required for ensuring the correct application of Art. 90 overall; it further seeks to ensure legal certainty for the companies in the run up to the Ministry of Health, Social Services and Equality's (Spanish abbreviation MSSSI) thumbs-up to pricing and financing as already anticipated by the abovementioned RDL.

Implementing Article 90 is one of the most delicate points of the development of RDL 16/2012

Also, Spanish Competition Authority has issued a Report (IPN/ 81/12) on the Draft Law for the modification of Law 29/2006 on Guarantees and Rational Use of Medicinal Products and Healthcare Products (30 October). A section is devoted to Art. 90 and states that intervention in pricing must be limited to those medicinal products financed by the National Health System and only for prescriptions issued within the realm of the state system.

In addition, by means of Resolution 2 August 2012, issued by the Directorate-General of the Basic Portfolio of Services of the National System of Health and Pharmacy (Spanish abbreviation DGCBSF) in August 2012, the MSSSI implemented another of the raft of measures introduced by RDL 16/2012: the de-financing of medicinal products for minor symptoms. This Resolution led to the upgrading of the list of medicinal products excluded from National Health System financing. The Resolution also held implications for the application of Art. 90 given that Annex 3 of the Article states that the medicinal products affected by the Resolution and which are included in the subgroups indicated in the Annex will continue to receive a state subsidy exclusively for the indications laid down for each case. The medicinal products among the exceptions established by Annex 3 are eligible for a price subsidized by the National Health System and a higher notified price in the case of non-SNS prescriptions, providing the corresponding pharmaceutical company gives due notice in accordance with Art. 85 of Law 29/2006 and the MSSSI raises no objection to that price.

As a supplement to Resolution 2 August, the DGCBSF's Resolution of 18 February 2013 updates the list of medicinal products excluded from SNS subsidies and calls for prior approval of the prescription of certain medicinal products excluded from SNS subsidies but which continue to be subsidized in certain cases depending on which therapeutic group they are included.

At the end of the year, RDL 28/2012, which brought with it consolidation measures and guarantees for the Spain's Social Security system, modified Art. 94 bis of the Law of Guarantees and Rational Use of Medicinal and Healthcare Products, which establishes that " outpatient pharmaceutical provision is subject to contribution from the user". An MSSSI news release

dated 4 December 2012 stated that the ultimate aim of this modification is to "set medical prescriptions at the same level as outpatient dispensation and [„] adjust to the reality of hospital pharmacy, which is not only made up of medicines administered to inpatients, but also those that are dispensed to outpatients, albeit at hospitals".

The same news release went on to specify that "no inpatient is obliged to pay for the medicines and healthcare products that he or she requires" and that "patients who require so-called hospital-use medicines are likewise totally exempt from the need to contribute in any way. This is the case of retrovirals for HIV/Aids and others in the same situation, such as interferon beta, anticoagulants, and so on".

The norm establishes that hospital-dispensed medicines are subject to copayment, although apparently at a lower rate. "This measure is aimed at medicinal and healthcare products that are currently dispensed in pharmacies, as well as in hospital pharmacies, and which are subject to contribution from the user. This may also be applicable when they are prescribed for outpatient hospital dispensation. The National Health System operates a reduced-contribution system (up to a maximum 4.13 euro) in order to guarantee access to medicinal products –both hospital- and pharmacy-dispensed– for the seriously or chronically ill".

At the time of drafting this Annual Report, this norm had yet to be implemented in practical terms.

Provisions for administrative contracts

As regards the regulation of public administrative contracts, special mention should be made firstly to Law 17/2012, 27 December, namely the General State Budget 2013, and in particular the 72nd Additional Provision, concerning the deductions applicable to central procurement bodies or other inter-administration cooperation instruments, and the 28th Final Provision, concerning the modification of the Consolidated Wording of the Public Sector Contracts Law, approved by Royal Legislative Decree 3/2011, 14 November.

The regulation states that hospital dispensation medicines are subject to copayment

With regard to the 72nd Additional Provision, the norm opens the door to the possibility that the State, with the prior agreement of a given Autonomy Regions, be allowed to retain or make a deduction from the amount that it contributes to meet the payment of these purchases.

In addition, and as regards the 28th Final Provision, the MSSSI is empowered, through the Secretariat-General of Health and Consumer Affairs, to call on the National Institute of Healthcare Management (Spanish abbreviation INGESA) to bring into effect and close the centralized purchase procedures, taking into account the National Health System, for all or some medical and healthcare products. In this respect, on 13 February 2013, the Spanish Official Gazette (commonly referred to as 'BOE') published the INGESA Resolutions issuing a call for the first Framework Agreements for the selection of medical and healthcare product suppliers for a number of Autonomous Regions and Central Government Agencies, and in which 14 Autonomous Regions, the Ministry of Defense and Spain's Home Office all take part.

In addition, within the framework of the Youth Employment and Business Creation Strategy 2013-2016, special mention should be made of RDL 4/2013, 22 February, which brought

with it a raft of measures aimed at providing support for business and job creation. This RDL added, by means of Article 15 and the 6th Final Provision, a number of amendments and provisions to the Consolidated Wording of the Public Sector Contracts Law (Spanish abbreviation TRLCSP). Specifically, amendments were made to the following articles: Art. 216.4 (concerning price payment), Art.222.4 (contract fulfillment and reception of the service due), and the 16th Additional Provision, section 1, letter 'f' (the use of digital media, IT and telematics in legally regulated procedures). Likewise, RDL 4/2013 includes a batch of new Additional Provisions (APs 32 and 33) that introduce changes in the joint formalization of framework agreements on service contracts that facilitate labor mediation and the mandatory presentation of invoices in an administrative register, and the identification of organs.

Finally, at the European level, mention should be made of a number of rulings, reports and draft directives on public contracts:

1. The ruling issued by the CESE on the European Parliamentary Commission's communication to the Council of Europe, the European Economic and Social Committee and the Committee of the Regions. A strategy for pubic e-contracting (DOUE, 15 January 2013);

2. The European Parliament Report, dated 11 January 2013, on the European Parliament's and the Council's draft proposal on public contracts (COM [2011] 0896 - C7-0006/2012 - 2011/0438 [COD]);

3. The European Parliament's and the Council's draft proposal on public contracts (DOUE 5 April 2012);

4. The European Parliament's and the Council's draft proposal on the awarding of concession contracts (DOUE 5 April 2012).

Provisions on arrears

Arrears by Autonomous Regions in their payments due to suppliers is an issue that is still very much under the spotlight in both Spain and the EU. In this respect, a number of important dispositions saw the light of day in 2012.

First of all, reference should be made to Organic Law 2/2012, 27 April, on Budgetary Stability and Sustainable Financing, which set out to meet three main goals:

1. Ensure the financial sustainability of all of Spain's Public Administrations;

2. Boost confidence in the country's economic stability;

3. Strengthen Spain's commitment to the EU where budgetary stability is concerned.

In its 1st Additional Provision, this law enables all Autonomous Regions and Local Authorities to request from the State access to extraordinary measures to facilitate cash flow.

Within the framework of this provision, RDL 21/2012, 13 July, which sets out to facilitate cash flow for Public Administrations and in the financial sphere, has brought with it a mechanism

capable of supporting cash flow for Autonomous Regions, of a temporary and voluntary nature, to meet the collection dates for their outstanding debt, as well as to obtain the necessary resources for financing debt, as envisaged by the regulations on budgetary stability, For its part, Article 2 of RDL 6/2013, 22 March, which sets out to protect the holders of certain investment and savings products and introduces other financial measures, has amended the 5th Additional Provision of RDL 21/2012, 13 July, which is designed to facilitate cash flow for Public Administrations and in the financial sphere.

At a later date, Organic Law 4/2012, 28 September, which amended Organic Law 2/2012, 27 April, on Budgetary Stability and Sustainable Financing, amended the 1st Additional Provision of Organic Law 2/2012 in an effort to extend, by means of the Agreement of the Government's Delegate Commission for Economic Affairs, the periods for accessing the extraordinary cash-flow mechanisms. Similarly, a new Additional Provision has been added to the Organic Law on Budgetary Stability and Sustainable Financing concerning the payment to service financial debt. With the new AP, Public Administrations are required to have treasury plans in place in order to display the capacity to meet payments to service financial debt.

All of Spain's public administrations are required to have liquidity plans in place that reflect their capacity to meet their financial obligations

In turn, the abovementioned Wording introduces into Spanish law the European Parliament's and the EU Council's Directive 2011/7/EU, 16 February 2011; the latter sets out to combat arrears in commercial transactions and, among other measures, amends the criteria for calculating the legal interest rate on arrears. In compliance with these new provisions, Spain's Secretariat-General of the Treasury and Financial Policy published Resolution 27 February 2013, which amends Resolution 3 January 2013, and which publishes the legal interest rate for arrears applicable to commercial transactions in the first half of FY2013.

Finally, at the time of closing this Report, the following regulatory changes had been made:

1. The Secretariat-General of the Treasury and Financial Policy published Resolution 4 March 2013. It defines the Principle of Prudence applicable to the financial debt operations of the Autonomous Regions (common regime) and cities with a Statute of Autonomy which draw on ICO-CC.AA. 2012 direct financing and the Autonomous Regions Liquidity Fund;

2. Secretariat-General of the Treasury and Financial Policy published Resolution 1 April 2013. The latter upgrades the annex to Resolution 4 March 2013 and defines the Principle of Prudence applicable to the financial debt operations of the Autonomous Regions (common regime) and cities with a Statute of Autonomy that draw on ICO-CC.AA. 2012 direct financing and the Autonomous Regions Liquidity Fund;

Reference Prices

The Reference Price System (RPS) was reformed as a result of the coming into effect of RDL 16/2012, which amended Law 29/2006 on Guarantees. At the time of drafting this Annual Report (April 2013), the Draft Order was still in its review and comments period; however, it is expected to broaden extensively the number of groupings affected by the RPS, which means that these will be able to get by without the need for the existence of a generic given that the project includes the creation of new groupings when the original medicinal product has a minimum ten years' prior authorization in Spain and, in addition, the National Health System's pharmaceutical service includes medicines other than the originals and their co-

rresponding permits. Also, and as occurred with previous provisions of the RPS, the future Order envisages the creation of groupings when a generic medicine or biosimilar medicinal product already exists.

The consolidation of the RPs as a cost-control instrument makes sense always providing that it sets up a space for financing innovation in medicinal products and it is sufficiently flexible to avoid a fall in price that pharmaceutical companies cannot take on, or that jeopardize the financing or marketing of the affected medicinal products.

The Draft Order contains a number of positive elements, e.g. the obligation to effectively market a lower cost/treatment/day, or work out a weighted cost/treatment/day for groupings that include medicinal products that:

· Come in special doses that contain smaller amounts of active ingredient; 0

· Help in the treatment of serious illness;

· With recently revised prices, having displayed low profitability.

Even so, FARMAINDUSTRIA has presented a number of allegations against the Draft Order, and the most important one refers to falls in prices that pharmaceutical companies cannot take on. For these cases, it would be necessary to restore the minimum threshold that has always been the PRS's distinguishing feature, and to lend special consideration to certain medicinal products within a same grouping, in order to ensure an adequate supply for pharmacies and top-quality pharmaceutical service capable of covering patients' medical and healthcare needs.

Draft amendment of Law 29/2006

The Draft Law that is set to introduce EU Directives 2010/84/EU of the European Parliament and European Council, of 15 December 2010 (concerning pharmacovigilance) and 2011/62/EU of the European Parliament and European Council, of 8 June 2011 (as regards the prevention of the entry into the legal supply chain of falsified medicinal products) into Spanish law, have been studied by a number of FARMAINDUSTRIA Working Groups.

This change in law will be followed by three Royal Decrees to implement it. They will include a number of core aspects of EU law as regards pharmacovigilance, distribution and the legally required authorization and registration of medicinal products, thus completing the transposition of the abovementioned Directives.

This Draft Law has been reported on by Spain's Council of State and the Economic and Social Council. Their ruling states that in the hypothetical case of two medicinal products with the same price, it would not appear to be fair to oblige the pharmacist to opt for the generic drug: in such a case it may also be substituted by a cheaper or equally-priced branded drug. Yet again, this evidences the need to introduce a legal amendment aimed at eliminating the discrimination against branded drugs.

3.1.2.
THE AUTONOMOUS REGIONS

FARMAINDUSTRIA has carried out an intensive institutional activity as regards relations with Spain's Autonomous Regions, regional healthcare authorities and agencies, scientific societies, professional bodies and political institutions and social organizations. In accordance with Association's byelaws it has continued to drive communication and engagement with representatives of these parties and to defend the various interests of FARMAINDUSTRIA's member companies.

The Association has monitored the Autonomous Regions' initiatives on health policy and access to pharmaceutical services, and has kept its members abreast of all relevant developments.

Autonomous Regions e-Newsletter

The Association has continued to publish this twice-monthly e-newsletter for its members. It contains relevant information for the pharmaceutical industry as regards regional public healthcare and pharmaceutical policy, healthcare organization, healthcare plans and biomedical research.

Autonomous Regions Observatory

This section of the FARMAINDUSTRIA website offers members an information digest on regional public healthcare and pharmaceutical policy. It consists of reports compiled in conjunction with members of the Association's Autonomous Regions Working Group.

In 2012 it continued to compile themed and situation reports on leading pharmaceutical industry issues:

- Situation reports and basic data on regional socio-healthcare matters.
- Implementation of RDL 9/2011 by the Autonomous Regions.
- Prescription by Active Ingredient. Situation in each Regional Autonomy.
- e-Prescriptions. Situation in each Regional Autonomy.
- Restricted medicines in Hospital Dispensation. Situation in each Regional Autonomy.
- Public Healthcare Budget 2012 – Budget and Healthcare Expenditure 2011.
- Public Healthcare Budget 2012: regional, healthcare and pharmaceutical.
- Evolution of the Healthcare Budget 2008–2011 per Regional Autonomy.
- Evolution of the Pharmaceutical Budget 2008–2010 and the Total and per capita Pharmaceutical Budget 2011 per Regional Autonomy.
- Inequalities in the regional financing of medicinal products.

FARMAINDUSTRIA-Autonomous Regions Forums

The Forums organized regularly by FARMAINDUSTRIA with representatives of central and regional governments have consolidated their foothold as a meeting point fort serious debate on issues concerning the medicinal products and pharmaceutical services delivered by Spain's National Health System, and in which the pharmaceutical industry as a whole is keen to contribute and share its thoughts.

Thorough monitoring has been carried out on regional initiatives on healthcare and access to pharmaceutical services

FARMAINDUSTRIA has stepped up its longstanding communication and dialog with regional healthcare authorities

On 7 and 8 February 2012, the Association held its 16th FARMAINDUSTRIA-Autonomous Regions Forum, in Zaragoza (northern-central Spain). The event focused on the amendments introduced by RDL16/2012 in the financing, pricing and refund of medicinal products. The forum was opened by Spain's Secretary General for Health and Consumer Affairs and by representatives of the Aragon Regional Counselor for Health, Social Wellbeing and Family, and they were accompanied by the President of FARMAINDUSTRIA. The Managing Director of the Aragon Regional Healthcare Services brought the event to a close. Representatives from eleven Autonomous Regions and from INGESA took part in the Forum.

Institutional Contacts

FARMAINDUSTRIA has stepped up its longstanding communication and engagement with regional healthcare authorities. It has kept up its regular institutional contact with regional Healthcare and Pharmaceutical officials from different Autonomous Regions, informing them of the sector's priorities and concerns and addressing specific issues raised in each region.

Special mention should also be made of the intense round of institutional meetings held in 2012 to manage, monitor and evaluate the progress of the +I Program for Cooperation on Clinical Research and Knowledge Transfer. This program is described in detail in a specific section in this Report. Throughout these meetings, FARMAINDUSTRIA representatives gave the regional authorities detailed accounts of the pharmaceutical industry's economic health.

Regulatory initiatives at the regional level

There follows a review of the year's most relevant policies, regulations and regional initiatives, as well as some of the activities carried out by FARMAINDUSTRIA as a result of them.

RDL 16/2012 and its regional implementation

RDL 16/2012, of 20 April, introducing urgent measures aimed at ensuring the sustainability of Spain's National Health System and improving the safety and quality levels of its services, has yet brought about certain amendments to Law 29/2006, concerning guarantees of and the rational use of medicinal and healthcare products. Among other particularly relevant aspects at the regional level, these amendments address the prescription type (branded drugs or by active ingredient), the exclusion of medicines form public financing or the pharmaceutical copayment system.

FARMAINDUSTRIA, working alongside the Regional Authorities Working Group, has monitored these regional regulatory changes and made contact with the regional authorities to ensure that the definanced medicinal products remain in the Health Services' doctors' database of prescriptions.

FARMAINDUSTRIA has compiled a report that highlights the application of copayment, the dispensation criterion applied in branded-drug prescriptions in homogenous groupings and the implementation o e-prescriptions.

Summing up, it should be mentioned that in a number of Autonomous Regions, namely Andalusia, Asturias, The Balearic Isles, The Canary Isles, Castile-Leon, Madrid, Navarre and The Basque Country, the prescription system automatically recommends prescription by active ingredient INN prescription. This form of prescription leads to the dispensation of generic

drugs, even though they have the same price as the corresponding branded drugs. However, in these Spanish regions it is possible to prescribe branded drugs, but to do so the doctor has to save a number of screens on his/her PC.

Similarly, Galicia continues to run its own catalog; at the moment, it coincides, basically, with the homogenous groupings and so, in practice, the prescription criterion is the lowest-priced branded drug.

In the Valencia region, doctors are free to choose between prescribing INN or the lowest-priced branded drug.

In the remaining regions (and Autonomous Cities), INN is optional and there are no limits to prescribing branded drugs always providing that the prescribed drug comes at a lower price.

e-Prescriptions and Medical records

2012 saw the continued implementation of e-prescriptions and e-medical histories at the regional level.

The Autonomous Regions of Andalusia, The Balearic Isles, The Canary Isles, Cantabria, Catalonia, Extremadura and Galicia have completed the implementation of e-prescriptions in the regions, while the remaining Autonomous Regions have made considerable progress and have their sights set on completing the process sometime in 2013. At the time of drafting this Annual Report, regional regulations are in place in Andalusia, Catalonia, Extremadura and Galicia.

In relation with this section, it should be underlined that RDL 9/2011 envisaged that both Medical records and e-prescriptions should be fully implemented and inter-operative across the entire SNS by 1 January 2013.

Medical records are implemented in just about every Regional Authority and the possibility of accessing them from any healthcare center within the region between both assistance levels is well on the way to becoming commonplace. These advances are serving as the basic building blocks of the SNS's Medical records, a project supported by Law 16/2003, 28 May, as regards the cohesion and quality of Spain's National Health System, Article 56; and Law 41/2002, 14 November which provided the basic regulation of the patient's autonomy, 3rd Additional Provision. At the time of drafting this report, twelve Regional Authorities have e-patients' histories that can be shared accessed by the entire SNS.

All regions have made significant progress on implementing e-prescriptions and they all aim at completing the process sometime in 2013

Branded drugs excluded from the e-prescriptions database: Castile-La Mancha

In 2012 the legal actions undertaken by FARMAINDUSTRIA against the steps taken to exclude branded drugs form the e-prescriptions that were rolled-out in the Castile-La Mancha region (central-southern Spain) followed their course and the rulings are still pending.

As concerns the region of Extremadura (southeast Spain), Administrative Court No. 1 of Merida, in ruling 16 May 2012, partially accepted the appeal lodged by FARMAINDUSTRIA against the Extremadura Regional Public Health Authority for excluding certain branded drugs form the e-prescriptions system. The Court ruled that Autonomous Regions do not have the power to

exclude drugs form the e-prescriptions system because this does not fall within their jurisdiction; however, the current situation cannot overruled owing to a number of legal changes that came into effect at a later stage through several central government-promoted Royal Decree-laws.

Automatic substitution of prescriptions: Castile-La Mancha, Navarre and The Basque Country.

The ruling on several appeals lodged FARMAINDUSTRIA against the Autonomous Regions of Castile-La Mancha, Navarre and The Basque Country as a result of changes introduced in their respective e-prescription systems and by which certain prescriptions were substituted by active-ingredient drugs.

Auctions of pharmacy-dispensed drugs: Andalusia

Decree-Law 3/2011, 13 December, as regards urgent measures on the pharmaceutical services of the Andalusia Regional Health System, amended Law 22/2007, 18 December, on the Andalusia Pharmacy Services and introduced, among others, Article 60 bis. The latter establishes a selection procedure for the medicines that are dispensed that may be dispensed within this southern Spanish region in those cases in which the doctor prescribes active-ingredient drugs.

On the basis of this provision, the Directorate-General of the Andalusia Health Authority ruled Resolutions 25 January 2012, and 20 December 2012, on the selection of these medicinal products.

As a result of this initiative, the Government filed a formal complaint with Spain's Constitutional Court alleging a positive conflict of jurisdiction, claiming sole jurisdiction in such cases for the central government.

FARMAINDUSTRIA has also lodged an appeal against the abovementioned Andalusia Health Authority resolutions.

NHS Procurement Platform

In its 2011 Annual Report, FARMAINDUSTRIA explained its agreements with the National Health System's

Inter-Territorial Council (18 March 2010 and 18 April 2012). Among the various initiatives envisaged by the agreements, one stands out in particular: the setting-up of an aggregated procurement procedure for the whole of the SNS, in which Regional Authorities may participate on a voluntary basis.

In this respect, the 4th Additional Provision of RDL 16/2012 calls on the Inter-Territorial Council to foster joint actions with the public health services of Spain's different Autonomous Regions in an effort to acquire products with features that make them eligible for joint and centralized procurement.

With the aim of a Central Purchasing System, the Cabinet Meeting held on 28 December 2012 issued a call for a procurement tender for the SNS in the form of a Framework Agreement

published in the EU's and Spain's official gazettes (DOUE and BOE) on 6 and 13 February 2013 respectively.

Fourteen Autonomous Regions, INGESA , the Ministry of Defense and Spain's Penal Institutions took part in this first call for tender for 11 lots of medicinal products (6 EPO and 5 Anti-TNF).

The tender was suspended provisionally by the Court of Contract Appeals in response to the appeals lodged. On 27 March, this body issued a ruling that led to the modification of a number of aspects of this Framework Agreement' administrative clauses.

Shift from hospital-diagnosis medicines to the dispensation in hospital pharmacies/ inclusion in the list of hospital drugs

In 2010, a number of Regional Authorities ruled that certain medicinal products be dispensed solely in hospital pharmacies.

In tis respect, in March 2012 the SNS's Directorate-General of the Basic Healthcare Services Portfolio issued a Resolution concerning the list of drugs that were to be included among those to be dispensed by hospital pharmacies and which, as such, were left without their corresponding labels. The list included 79 medicines, of which 52 came into effect on 1 March, and the remaining 27 on 1 April 2012.

This list turned out to be a list of minimum requirements and by no means binding, leaving the each Regional Authority to decide for itself, unilaterally, on which medicinal products should be restricted to hospital pharmacies in the region.

In March 2012, the DGCBSF announced that 79 medicines would cease to be dispensed in regular pharmacies and would only be available in hospital pharmacies

However, the reader should be reminded that there are three rulings (one by the Regional High Court of La Rioja, 4 May 2011; and two by the Regional High Court of Cantabria, 21 and 26 September 2011) that state that this is the exclusive jurisdiction of the MSSSI.

Therapeutic alternatives

The FARMAINDUSTRIA Annual Report 2011 mentions an initiative launched by the Castile-La Mancha Regional Health Service, namely a new IT application that encouraged the mutual substitution by active ingredients that share the same therapeutic indication. This led to legal actions by FARMAINDUSTRIA.

Given the transcendental nature of this type of initiatives, FARMAINDUSTRIA has actively monitored the process and undertaken the appropriate legal action. The Association believes that the initiative is a covert exclusion of certain medicines from public financing and that it further violates the established regulatory framework and diminishes the importance of innovation.

Prescription algorithms: Valencia

At the time of drafting this Report, the Valencia Regional Autonomy passed Decree-Law 2/2013, 1 March, on Urgent Management Measures and Efficiency of Pharmaceutical and Orthoprosthetic Services. Among other aspects, it calls on the Valencia Health Authority to

draw up therapeutic-decision-making algorithms for certain pathologies, including clinical guidelines and mandatory active ingredients, considering the most cost-effective options.

In accordance with this rule, doctors are required to prescribe the medicinal product selected on the basis of these algorithms. However, doctors may also prescribe another medicine, providing they justify their decision in clinical terms.

In the case of hospitals, efforts are required for developing centralized procurement and the setting-up of common protocols for the use of "high impact" pharmaceutical products.

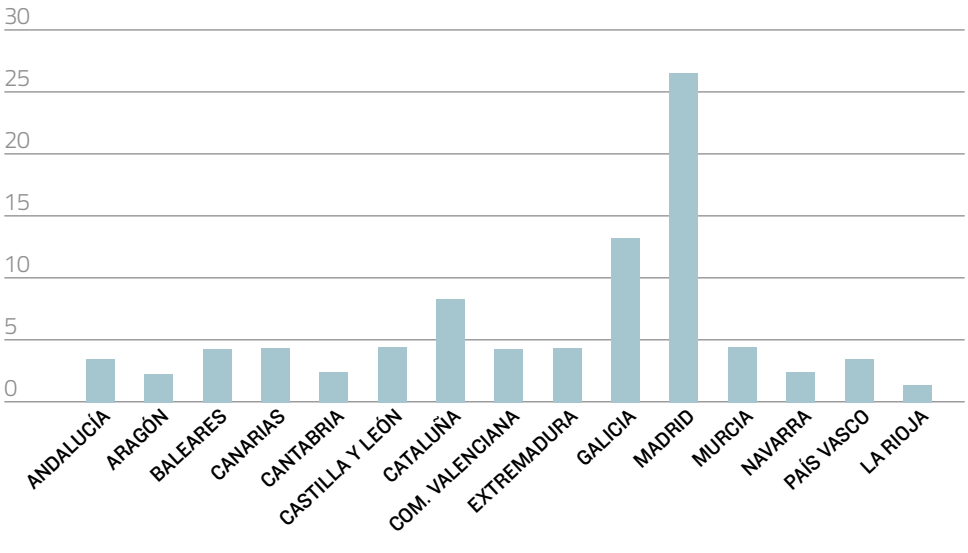
This initiative , which has given rise to a considerable response from the full range of collectives, is being looked at very carefully by FARMAINDUSTRIA in an effort to safeguard the legitimate interests of its member companies.

Cooperation Program with Regional Authorities in Clinical Research Knowledge Transfer. Programa "+i"

2012 saw continued activity and cooperation in the '+i' Program projects, in accordance with the accords reached between FARMAINDUSTRIA and the Autonomous Regions.

By the number of projects financed, the Madrid region leads the way with 26, followed by Galicia (13) and Catalonia (8). These three regions account for more than 50% of total projects.

NUMBER OF PROJECTS



The different projects that make up the '+i' Program take place within a shared framework agreement based on mutual cooperation. In this respect, the following table shows the participation of each of these organizations and the total budget of the projects

Regional Authority	FARMAINDUSTRIA CONTRIBUTION	Regional Auth. Contribution	Total	No. of projects
Andalusia	8,000,000 €	9,765,000 €	17,765,000 €	3
Aragon	1,500,000 €	1,500,000 €	3,000,000 €	2
Balearic Isles	1,200,000 €	1,380,000 €	2,580,000 €	4
Canary Isles	1,998,000 €	1,932,000 €	3,930,000 €	4
Cantabria	600,000 €	600,000 €	1,200,000 €	2
Castile-Leon	2,483,500 €	2,848,000 €	5,331,500 €	4
Catalonia	7,000,000 €	18,394,370 €	25,394,370 €	8
Valencia	5,000,000 €	5,712,054 €	10,712,054 €	4*
Extremadura	1,200,000 €	906,846 €	2,106,846 €	4
Galicia	2,454,126 €	2,644,505 €	5,098,631 €	13
Madrid	6,000,000 €	5,998,682 €	11,998,682 €	26
Murcia	1,500,000 €	1,551,500 €	3,051,500 €	4
Navarre	600,000 €	560,000 €	1,160,000 €	2
Basque Country	2,000,000 €	2,214,000 €	4,214,000 €	3
La Rioja	300,000 €	495,000 €	795,000 €	1
Total	41,835,626 €	56,501,957 €	98,337,583 €	84

* The Valencia Regional Authoriy runs four different programs comprising 17 projects in all.

In order to ensure the correct coordination, execution, monitoring and evaluation of the '+i' Program, and in accordance with the terms and conditions of each accord, the Regional Authorities file half-yearly reports with FARMAINDUSTRIA on the execution of the different projects covered by the reports; these are analyzed by the Technical Department–known as the Project Support Office (Deloitte)–and are submitted to the Program's various Monitoring Commissions.

In this respect, it should be remembered that the '+i' Program's various Monitoring Commissions are regional bodies, set up jointly by the region and FARMAINDUSTRIA, and created in accordance with the corresponding Cooperation Agreement.

At 30 June 2012, a total 27 projects had been completed: 16 in Madrid, one in the Basque Country, one in Cantabria, one in La Rioja, two in Andalusia, three in Galicia and three in Catalonia.

At the time of drafting this Report the second half's reports and the yearly report (2012) were being analyzed and so too the Reports on the audit of expenditure attributed to FARMAINDUSTRIA. All of the Regional Authorities, without exception, have filed their respective expenditure and audit reports with FARMAINDUSTRIA. The Project Support Office (Deloitte) has detected no irregularity worth mentioning.

FARMAINDUSTRIA had a seat on the Advisory Committee of the Health Ministry's Inter-territorial Council and the AEMPS's Medicines for Human Use Committee

While the information is still preliminary in nature, because it has yet to be approved by the corresponding Monitoring Commissions, nearly all of the projects will be completed sometime in 2013.

3.I.3. ADVISORY AND EXPERT COMMITTEES

FARMAINDUSTRIA sits on a number of the Ministry of Health, Social Services and Equality's advisory and expert committees; this enables the Association to inform the healthcare authority on the sector's position within a framework of greater participation and transparency. FARMAINDUSTRIA sits on the following committees:

Advisory Committee to the SNS's Inter-territorial Committee

TThis committee is chaired by the Secretariat-General of Public Health and is made up of representatives from the administrations (local, regional and central), labor unions and business organizations, including FARMAINDUSTRIA, which will hold the vice-president of the Business Organizations grouping for the next two years.

The committee convened on four occasions in 2012 and informed on issues of particular interest to the workings of the National Health System. Moreover, given that its is a formal requirement when certain provisions on are processed, the committee informed on regulatory projects that were likely to affect healthcare services, their financing and pharmaceutical expenditure,

The AEMPS Committee on Medicines for Human Consumption

The Committee on Medicines for Human Consumption is made up of 22 members, ten of whom are appointed by virtue of their position and twelve are designated by the Agency's Steering Committee; one is appointed by FARMAINDUSTRIA.

This Committee's main mission is to safeguard the efficiency and transparency of the procedures for authorizing medicines, providing mandatory and non-binding information during the procedures for the authorization, relevant modification, suspension or overruling of medicines for human consumption. Also, and at the request of the Agency's Director, it may be called upon to provide reports on the procedures related to medicines for human consumption.

The committee's usual activity depends on the issues arising for debate in each meeting and the decisions taken which, along with the issues arising for information, make up the committee's workload. The committee has acknowledged on several occasions the Agency's hard work and intense efforts in the field of authorization of new medicinal products. In 2012, the AEMPS stood out in particular for its activity as a speaker, co-speaker or member state of reference in many EU procedures.

3.2.
SOCIAL COMMUNICATION

In 2012 FARMAINDUSTRIA continued to make considerable efforts in the sphere of social communication, and worked particularly hard to improve the pharmaceutical industry's presence, access and visibility, and to take the Association closer to society at large by engaging with a number of technical, economic and social players.

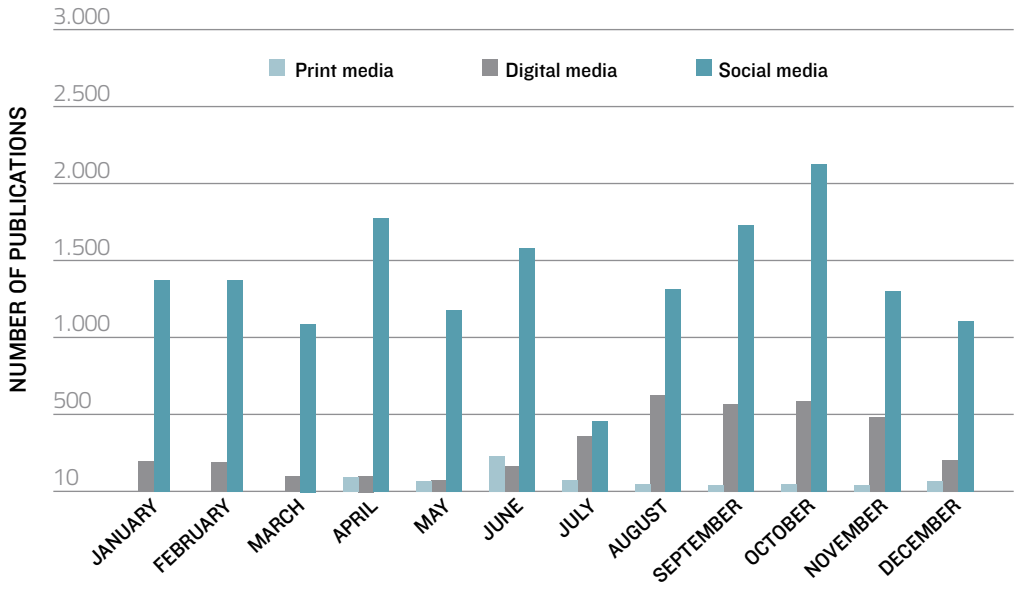
This involved working hard to attratct media attention to the Association's activities; the media are society's main channels of information transmission and they have the power to shape public opinion, wthout forgetting the increasing relevance of so-called "Communication 2.0", i.e. a new way of engaging with the public at large and based on ongoing technological progress and innovation.

Similarly, also in the field of social communication, in 2012 FARMAINDUSTRIA continued to develop and strengthen its institutional relations with the foremost social stakeholders, and committed at all times to internal communication with its member companies.

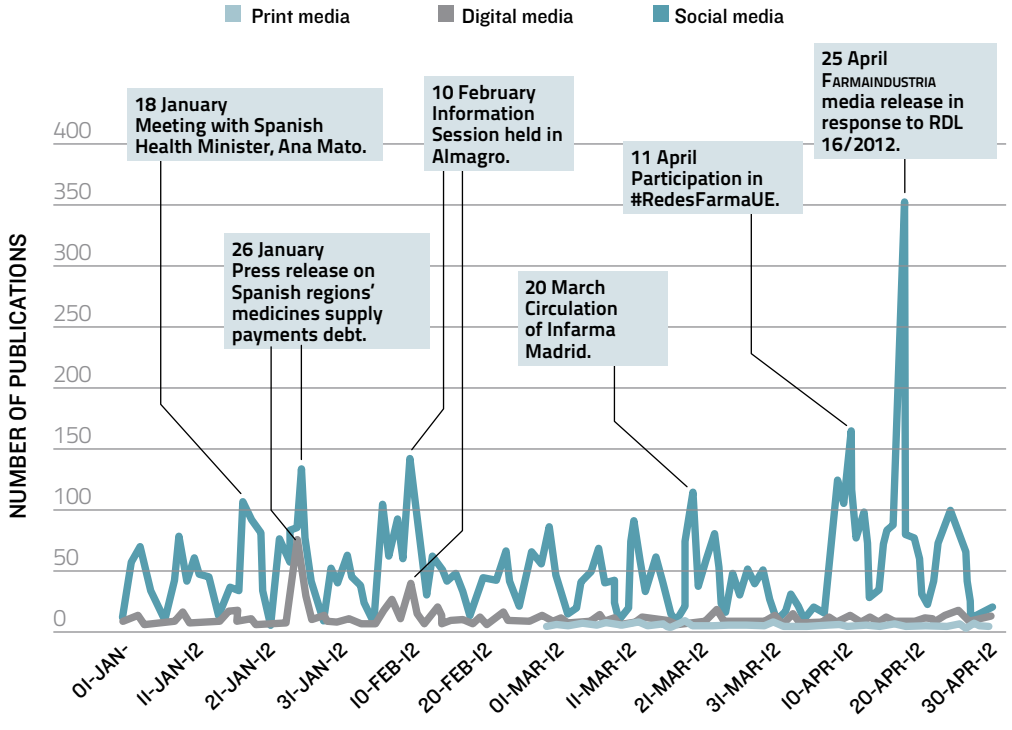
3.2.1.
THE MEDIA

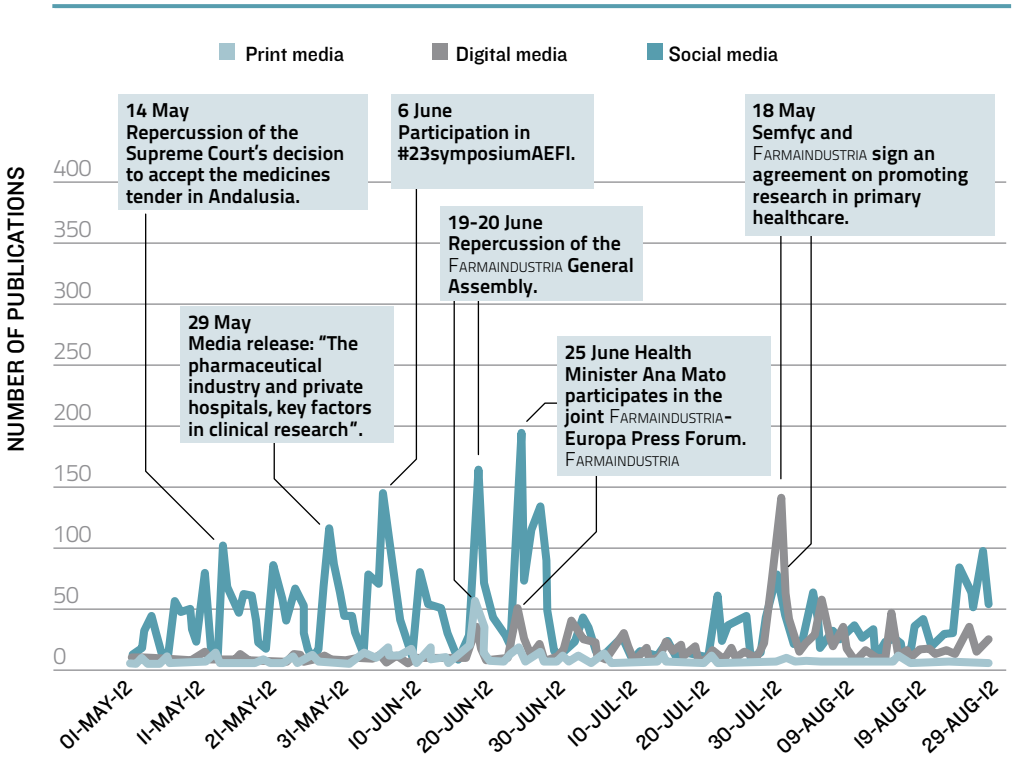
FARMAINDUSTRIA strives permanently to make greater headway in the pharmaceutical industry's communication processes and reaches out to society at large through its main manifestations. Accordingly, the Association continues to be totally committed to working alongside the media. In this respect, in 2012, FARMAINDUSTRIA generated a considerable amount of media content in the shape of news releases, media conferences, interviews and opinion articles which drew the attention of general and specialist print media, e-media, radio, TV and others all over Spain. In fact, 2012 saw an important year-on-year rise in FARMAINDUSTRIA's information activities, particularly in the traditional media, but also in e-media, especially during the latter half of the year.

In 2012, FARMAINDUSTRIA issued a considerable amount of information content in the shape of numerous news releases, media conferences, interviews and opinion articles that were picked up by digital, radio and audiovisual media



From the point of view of newsworthiness, the most relevant event of 2012 was the pharmaceutical industry's positioning on RDL 16/2012 which the Association expressed by means of an array of communication actions, including media conferences, news releases and special information sessions with opinion leaders.




Print media
Digital media
Social media
NUMBER OF PUBLICATIONS
400
350
300
250
200
150
100
50
0
14 May
Repercussion of the Supreme Court's decision to accept the medicines tender in Andalusia.
6 June
Participation in #23symposiumAEFI.
18 May
Semfyc and FARMAINDUSTRIA sign an agreement on promoting research in primary healthcare.
19-20 June
Repercussion of the FARMAINDUSTRIA General Assembly.
29 May
Media release: "The pharmaceutical industry and private hospitals, key factors in clinical research".
25 June Health Minister Ana Mato participates in the joint FARMAINDUSTRIA-Europa Press Forum. FARMAINDUSTRIA
01-MAY-12
11-MAY-12
21-MAY-12
31-MAY-12
10-JUN-12
20-JUN-12
30-JUN-12
10-JUL-12
20-JUL-12
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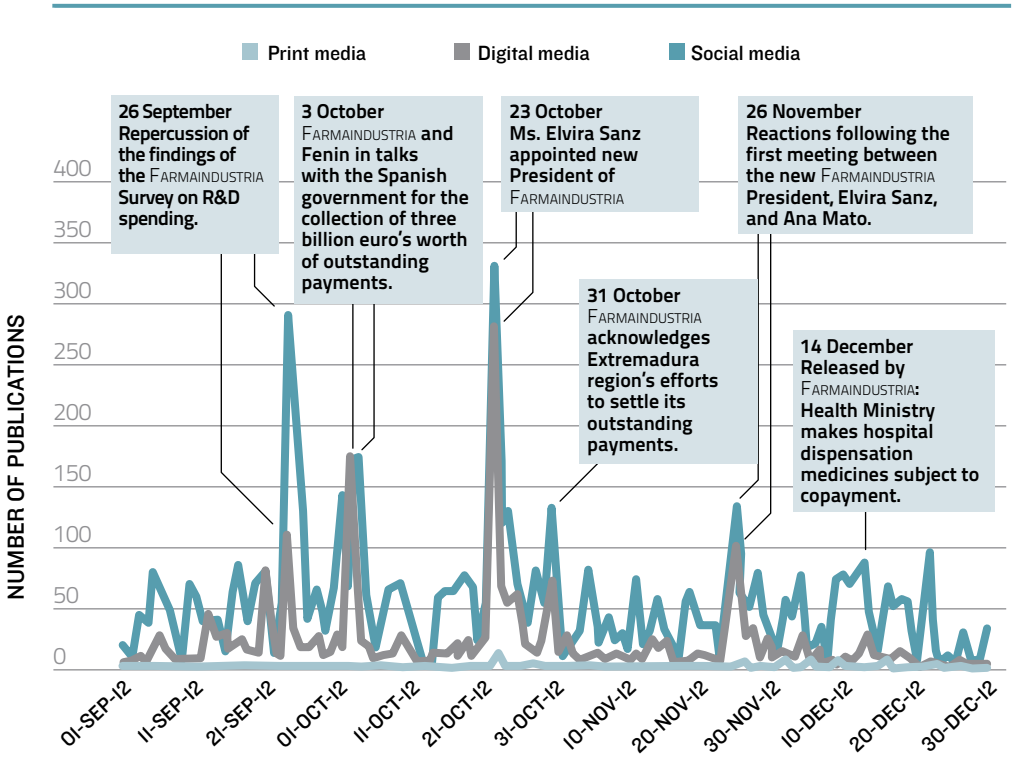
09-AUG-12
19-AUG-12
29-AUG-12


Print media
Digital media
Social media
NUMBER OF PUBLICATIONS
400
350
300
250
200
150
100
50
0
26 September
Repercussion of the findings of the FARMAINDUSTRIA Survey on R&D spending.
3 October
FARMAINDUSTRIA and Fenin in talks with the Spanish government for the collection of three billion euro's worth of outstanding payments.
23 October
Ms. Elvira Sanz appointed new President of FARMAINDUSTRIA
26 November
Reactions following the first meeting between the new FARMAINDUSTRIA President, Elvira Sanz, and Ana Mato.
31 October
FARMAINDUSTRIA acknowledges Extremadura region's efforts to settle its outstanding payments.
14 December
Released by FARMAINDUSTRIA: Health Ministry makes hospital dispensation medicines subject to copayment.
01-SEP-12
11-SEP-12
21-SEP-12
01-OCT-12
11-OCT-12
21-OCT-12
31-OCT-12
10-NOV-12
20-NOV-12
30-NOV-12
10-DEC-12
20-DEC-12
30-DEC-12

Other issues that drew considerable media attention included the Association's stance on the settling of arrears with Public Administrations and its articulation by means of a Suppliers Payment Plan set-up by the Government, pharmaceutical industry investment in R&D, and a raft of pharmacuetical policies, such as medicinal products auctions in Andalusia, the withdrawal of financial support for medicines and the new Reference Price System, among other topics.

The media (the print media in particular) were also interested in the change in the Asociation's President , as well as interviews with and opinion articles by a number of FARMAINDUSTRIA representatives on a range of current affairs, with particular emphasis on the pharmaceutical industry-related topics.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«O aportamos más o renunciamos a la calidad de nuestra sanidad»


DOSSIER EMPRESARIAL

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DIARIO MEDICO

"No esperamos más recortes de precios porque esa vía ya está agotada"


elEconomista

EL GASTO FARMACÉUTICO SIGUE BAJANDO

To enhance its relationship with the media, FARMAINDUSTRIA has striven to help its communication professionals by providing comprehensive training that can be applied to specific fields at a later date. This aim was behind the 9th Pharmaceutical Industry and the Media Seminar held in Almagro (Ciudad Real, central Spain)) in February 2012, an event was attended by 30 or so representatives of all kinds of media from all over Spain. The heads of the Associations various departments and the Director General were on hand to give a detailed explanation of the current situation of Spain's pharmaceutical industry against a backdrop of recession and the changes in pharmaceutical policy made by the central and regional governments.

Almagro (in Spain's Ciudad Real province) hosted the 9th Annual Pharmaceutical Industry and the Media Seminar.

Mention should be made also of the hard work that has gone into bolstering and consolidating the Association's institutional relations with the media, relevant figures and opinion leaders in an effort to give them a first-hand and accurate account of the sector's situation. In 2012, FARMAINDUSTRIA representatives took part in a number of special debates hosted by leading Spanish print media (which received ample coverage by the same media), in online forums, round tables and a variety of debates and discussions on current issues affecting the pharmaceutical industry.

The "Ideas+Dialog" Forum, organized jointly by FARMAINDUSTRIA and Spain's Europa Press news agency, brought together, for yet another year, a number of leading figures from politics, business and healthcare, including Spain's Minister of Health, Social Services and Equality, Ms. Ana Mato, before a large, live audience. Not for the first time, these professional gatherings

became a healthcare-debate benchmark and highlighted the pharmaceutical sector's enormous weight not just in industrial terms, but also as a political and economic force.

June 2012. Health minister, Ana Mato, speaking at the Ideas-Dialog Forum.

FARMAINDUSTRIA continues to compile the Medicines Market Status Report published each month by the Spanish business daily Expansión; the report has become an industry benchmark and a much sought-after source of information on developments in pharmaceutical spending in Spain.

Last year saw ample media coverage of FARMAINDUSTRIA's presence and participation in many and varied public events in which the Association addressed the role of the pharmaceutical industry, its situation, its main demands and the challenges that lie ahead for the sector. Accordingly, the Association was to be seen in a number of different settings, such as the ceremony to mark its formal membership of the Royal Academy of Medicine's "Infanta Margarita" Museum of Medicine project; a meeting with Spanish prime minister, Mr. Mariano Rajoy, along with representatives of business organizations, SMEs and the self-employed, in a session aimed at explaining the Suppliers Payment Plan; the 2nd Annual Conference on "The Power of Innovation: Intellectual and Industrial Property", organized by the US Chamber of Commerce in Spain; the 12th Annual Pharmaceutical Industry Encounter at the Menéndez Pelayo International University (UIMP), Santander (northern Spain) under the theme "Efficient Assessment of Medicines"; or the Pharmaceutical Industry Encounter organized by the IESE business school in Barcelona, among many others.

The President of FARMAINDUSTRIA, along with other business representatives, is welcomed to the prime minister's official residence by the Spanish Prime Minister, Mariano Rajoy, in March 2012.

Several FARMAINDUSTRIA representatives took part in the Conference entitled: "The Power of Innovation: Intellectual and Industrial Property", organized by the American Chamber of Commerce in Spain.

FARMAINDUSTRIA took part in the 12th Annual Pharmaceutical Industry Conference at the Menendez Pelayo International University (UIMP), in Santander .

3.2.2.
RELATIONS WITH PATIENTS' ASSOCIATIONS

In 2012 FARMAINDUSTRIA carried out a number of activities aimed at patients, especially with the organizations that represent them. The lion's share of this activity went on two main areas: direct engagement with Patients' Associations and the setting-up of a Permanent Pharmaceutical Industry-Patients' Associations Round Table; and the "Somos Pacientes" ["We are patients"] initiative, an online platform that provides information, training, services for Patients' Associations, families, carers, healthcare professionals and the general public. The Association also kept active its specific Group on Patients.

Collaboration with Patients' Associations

In 2012, FARMAINDUSTRIA took part in a long list of encounters, meetings, one-day events, lectures, seminars, etc. with Patients' Associations to share experiences and lend its support to the different Associations.

Since the creation in 2011 of the Aragon Patients' Forum (FAP), of which FARMAINDUSTRIA is a founder-member, the Association has sat uninterruptedly on the Forum's Board and has taken part regularly in a variety of activities, such as the 1st Sessions on Education for Healthcare, held in Zaragoza (northern-central Spain). The FAP Board is made up of the following: the DFA Foundation, ASAPME, the Zaragoza Doctors' Association, COCEMFE Aragon, ASANAR, SAMFYC, FEAPS Aragon, AECC Aragon, ASEM Aragon, the ARBADA Association, the Aragon Federation of Alzheimer Sufferer's and FARMAINDUSTRIA.

FARMAINDUSTRIA took part in a many lectures, conferences, seminars and assemblies, all organized by Patients' Associations. Examples include an encounter on the "Sustainability of the National Health System and the Healthcare Compact: Priorities for Patients", held at the UIMP under the auspices of the Spanish Federation of Breast Cancer Patients (FECMA); the National Kidney Patients Meeting, held in Madrid; or the Meeting organized by Rosae, an association for women with cancer, to mark World Breast Cancer Day, and many others.

In order to collaborate with the Patients' Associations, FARMAINDUSTRIA made information materials available in an effort to clarify the conditions of prescription and dispensation createdby RDL 9/2011. The Association published a simple two-page brochure aimed at the general public, and particularly for people either interested or somehow affected, healthcare professionals, patients and the man and woman on the street. The material was supported by a number of scientific associations and bodies.

At a later stage, and prompted by the coming into effect of this legislation, another document was published, also addressing the situation as regards prescription and dispensation. Based on the interpretation made public by the Ministry of Health, Social Services and Equality (MSSSI), the document set out to sum up in simple terms the different scenarios and to offer a practical explanation for healthcare professionals and patients alike. Once again, this document was distributed among the various collectives that were likely to be affected by the legal changes.

2012 saw the launch of the beta (trial) version of "Somos Pacientes", an online patients' community (www.somospacientes.com), an innovative and ambitious FARMAINDUSTRIA initiative

As representative of the entire pharmaceutical industry, FARMAINDUSTRIA was awarded the CEAFA 2012 Award in the Research category. This acknowldegement comes from the Spanish Confederation of Associations of the Families of Alzheimer patients and other forms of Dementia, and recognizes the importance of research into this terrible illness and the efforts of the pharmaceutical industry to make new medicines available to patients.

For yet another year, FARMAINDUSTRIA took part in the Pfizer Patients' Associations Dialog Forum 2.0 held in Madrid. The event could be followed in real time online via streaming and generated considerable activity on Twitter.

Round Table for Permanent Dialog

In 2012 FARMAINDUSTRIA set up the Pharmaceutical Industry Round Table for Permanent Dialog with Patients' Asociations, a space for discussion, information and debate with a representative of groups of federations and confederations of patients' associations aimed at adressing current issues and other topics of common interest. The main goal is to raise levels of mutual trust and to become more fully-acquainted with the needs and concerns of patient groupings.

There is no regular calendar of meetings; rather these are convened when any of the parties calls for one. The agenda may include issues ranging from healthcare policy, technical queries on research activities and developments in medicines to legislation, public financing of medicinal products (approval or inclusion) and inequalities in access to pharmaceutical services.

The Somos Pacientes (We are Patients) Platform

2012 saw the launch of the beta (test) version of Somos Pacientes (www.somospacientes.com) an online community of patients' associations. This ambitious and groundbreaking FARMAINDUSTRIA initiative was designed to bring together activities and tools with patients in mind and to create new services for their representative bodies.

A central feature of Somos Pacientes is the National Map of Patients' Associations, a directory of more than 1,260 Patients' Associations, each one with a space of its own where it can publish, freely and with total independence, all kinds of information.

Thus, Somos Pacientes provides a common space for information, participaction, learning, services and colaborative effort, all aimed at patients' associations and differently-abled collectives in Spain, as well as their families and carers, and healthcare professionals.

This community has been created as a meeting point for dialog for anyone and everyone interested, directly or indirectly, in healthcare, and especialy for patients' associations. It is an open, participatory network, with spaces and content of interest for associations, individual patients, families, the general public and healthcare professionals.

Somos Pacientes provides up-to-date information on a daily basis, as well as interviews, news on events, videos, forums, learning opportunities, debate and engagement overall.

While still only a few months old and at the beta stage, Somos Pacientes has become the standard for information on the sector, and in 2013 it wll continue to develop new applications and innovative services.

European Academy of Patients

FARMAINDUSTRIA is one of the 30 or so members of a consortium known as the European Academy of Patients for Technological Innovation (EUPATI for short), a European Comission -sponsored initiative through the Initiative on Innovative Medicines

Along with the EFPIA and the European Patients' Forum. The Academy sets out to provide training courses and learning materials, as well as bringing together an online library. This is all aimed at give patients' representatives and the general public a good grounding in the processes involved in the development of medicinal products.

In its role as member of EUPATI's Executive Comittee, in 2012 FARMAINDUSTRIA took part in a variety of national and international events and met up with fellow consortium members, other players and various parties interested in the intiative, such as patients' associations and research bodies.

Moreover, Spain leads the creation of the so-called National Liaison Teams (NLT), i.e. special working groups that subsequently go to make up EUPATI's Country Platforms in each of the twelve member nations that make up the Academy. Thus, Spain is the pilot in this initiative and stands as an example for other countries.

The Academy was presented at FARMAINDUSTRIA HQ in Madrid to inform patients' organizations, business and institutions interested in the network and encourage their support.

Later, Barcelona hosted a meeting with NLT representatives form the twelve member nations to address, among other issues, the progress made by the Spanish group.

Other activities

FARMAINDUSTRIA's ad hoc Patients Group held several meetings throughout 2012 and addressed a variety of issues of interest to the industry.

FARMAINDUSTRIA collaborated for yet another year with Spain's Fundación Corresponsables, on the 3rd Corresponsables Awards; these acknowledge the best initiatives and best practices in Corporate Social Responsibility and Sustainability in a variety of categories, namely Large Companies, SMEs, Public Administrations and Agencies, and Not-for-Profit Organizations.

FARMAINDUSTRIA is a member of the European Patients' Academy on Therapeutic Innovation (EUPATI))

3.2.3.
COMMUNICATION 2.0

FARMAINDUSTRIA has been on Twitter and Facebook since 2011 and with its own profiles, as well as having a YouTube account.

The Association has two Facebook profiles: one sets out to spread the word on FARMAINDUSTRIA's activities and to engage with Patients' Associations and third sector collectives (at end 2012 it had 600 followers, mainly Patients' Associations), and the other is aimed more at the media/journalists; with 300 followers at end-2012, this channel carries the Association's news releases and links to relevant news items in the media.

At end-2012, FARMAINDUSTRIA had more than 5.000 followers on Twitter, making it the European innovative pharmaceutical industry association with the greatest impact and activity on this social networking site

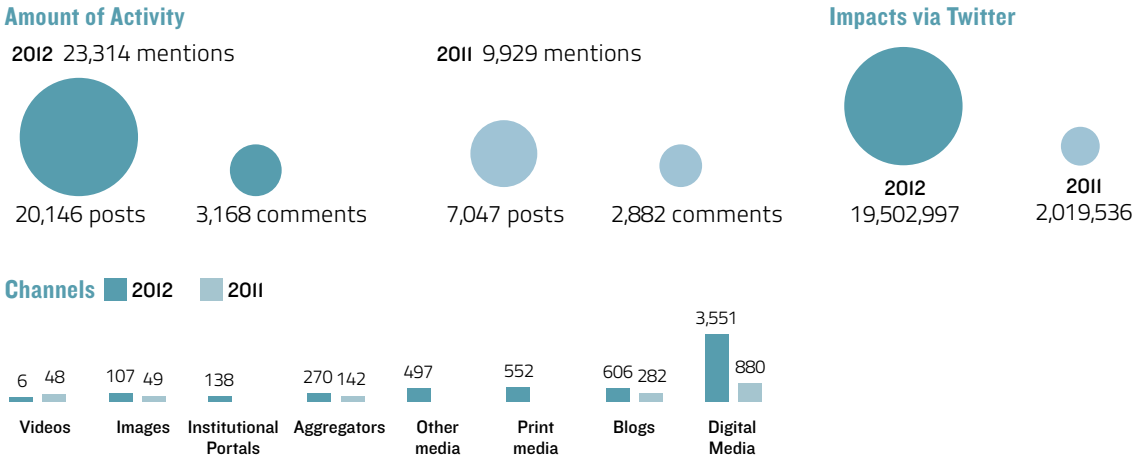
FARMAINDUSTRIA set up its Twitter profile back in January 2011; it has since become a communication and engagement channel for the Association's news releases, pictures and activities, as well as links to relevant news items; and as a means of sending messages out to other users depending of strategic interest to the Association. At end-2012 FARMAINDUSTRIA had totted up more than 5,000 followers, making it Europe's most high-profile pharmaceutical industry association on Twitter, and one the most influential Spanish healthcare players on this social networking site.

Comunicación 2.0. Monitoring

The 2012 annual report on the monitoring of media coverage and social networking presence of FARMAINDUSTRIA and the pharmaceutical sector overall counted a total 23,000 publications and references to the Association, and growing steadily over time, along with FARMAINDUSTRIA's increased own activity in these communication environments.

According to the report, in 2012 FARMAINDUSTRIA's activities logged up more than 19 million impacts on Twitter alone, a ten-fold increase on 2011. Each of the Association's messages on this social networking site translate into an average 1300 impacts.

FARMAINDUSTRIA 2012 VS. 2011



For its part, in the pharmaceutical industry generated nearly 150,000 mentions (published items and comments); of these, 17,000 were articles in online media, and the remainder was posts and comments on blogs or social networking sites.

Ad hoc Group on Communication 2.0

In March 2012, FARMAINDUSTRIA's Working Group on Communication decided to set up the Ad Hoc Group on Communication 2.0 and Social Networks; it was eventually rolled out formally in April with the participation of around twenty member companies. This group, which had already convened on a number of occasions, had a number of objectives; the main ones included sharing experience garnered from activities in a Communication 2.0 environment; knowledge transfer and exchange on mechanisms and tools for analysing and monitoring the pharmaceutical industry's presence on the internet and social networking sites, and evaluating and weighting opportunities, limitations and risks involved in the use of these new communication channels.

Communication 2.0. The Somos Pacientes online platform

Somos Pacientes has a clear vocation for communication 2.0. As well as giving its users and visitors the chance to use the platform to distribute and disseminate content across social networking sites, this online community has a major presence on Twitter and Facebook.

The Somos Pacientes Twitter profile kicked off in late 2012 with almost 2,000 followers. The platform uses this particular channel to spread new content, announce new member companies and generally engage with the 500 or so associations that it follows on this social networking site.

On Facebook, Somos Pacientes has its own page and uses it to disseminate content. The page had more than 500 followers at the end of 2012. The online community also has a YouTube profile that it uses to launch its own special video features and interviews.

FARMAINDUSTRIA'S Weekly News Bulletin continues to take pride of place in the Association's internal communication activities, with up-to-date information for member companies.

The community also has a Youtube profile and uses it to disseminate video reports and interviews.

3.2.4. INTERNAL COMMUNICATION

The communication aimed at member companies is another of FARMAINDUSTRIA's main communication lines. In 2012 the Association strengthened the channels and instruments that are designed to get member companies more involved in the Association's communication tasks and become better acquainted with them.

This goal gave rise to the roll-out of a new system that monitors the Association's and the pharmaceutical industry's presence in print and digital media and on social networking sites. This monitoring process got under way in May 2012 and the monthly reports look at the most active and influential media as regards issues of interest affecting the pharmaceutical industry, as well as checking on FARMAINDUSTRIA's progress in "2.0" environments or the Association's and industry's presence in print and digital media an on social networking sites.

Similarly, the Communication Working Group, made up of the Communication Managers of our member companies, continues to meet regularly to address major issues concerning the sector and to draw up strategies and joint positions sector-wide.

Among FARMAINDUSTRIA's internal communication efforts overall, the weekly news bulletin for members continues to play a leading role. In 2012, the bulletin went out on 43 occasions giving detailed accounts of the Association's communication activities.

3.3. MEMBER SERVICES

3.3.1. ONLINE SERVICES

FARMAINDUSTRIA continues to thoroughly update its paper-free information systems.

Following measures taken in previous years when FARMAINDUSTRIA ceased to turn out print/paper-based publications (among them this Annual Report), we have now consolidated the process by marking our second year of almost 100% paper-free, digital communication and publications.

Today, FARMAINDUSTRIA operates online portals that bring together and facilitate access to all kinds of documents. These portals contain publications that help users stay up–to-date, via daily, weekly and monthly newsletters, on the documents that are added to the portal and the issues they cover.

All of these policies require planning and web applications that allow controlled, nimble and secure access for each user to the document that he or she wishes to consult.

This explains why each year FARMAINDUSTRIA refreshes the content of its public and private corporate portals (and its different themed portals that address specific topics) practically from top-to-bottom.

In this sense, we continue to work on the continuous improvement and adaptation of our themed portals, namely I) the Media Portal; II) the Patients Portal; III) Innovative Medicines; IV) Intranet (National Members); V) the "e4ethics" Portal, and VI) the Governing Bodies' Intranet.

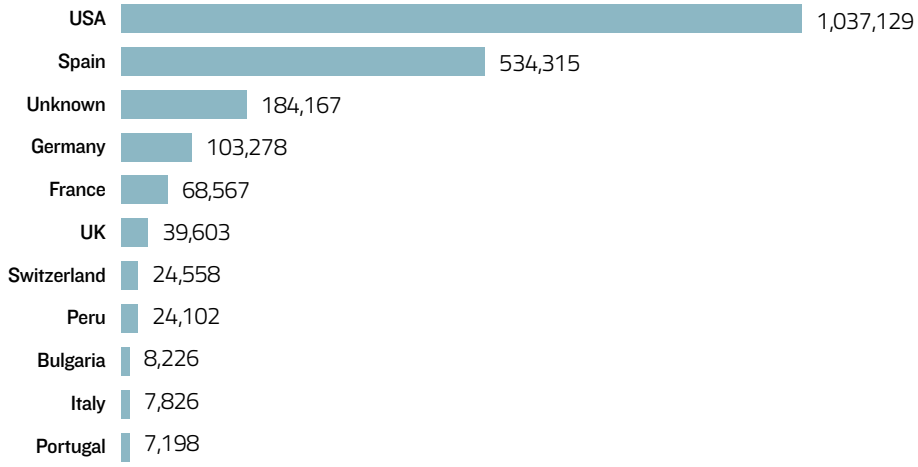
2012 was the second year in which nearly 100% of the Association's communication and publications were delivered in digital format

Our online services, by the numbers

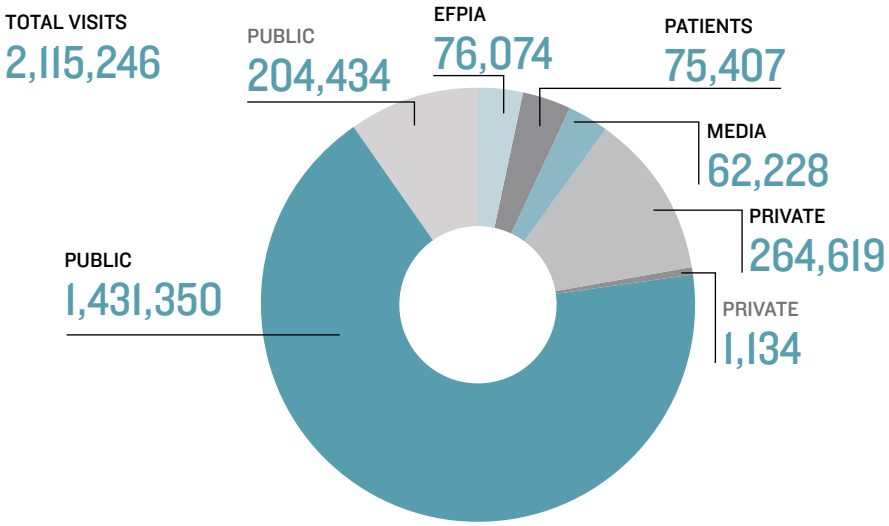
In 2012, FARMAINDUSTRIA's general portals logged up more than 2.1 million individual visits (80% more than 2011), making it the public portal that registered the greatest increase, growing more than 70% and currently handling more than 60% of all the queries received by the Association.

The USA now doubles Spain in the number of visits, followed by Germany, France and the UK, making them the five most active countries.

NUMBER OF VISITS



USER VISITS TO DIFFERENT WEBSITES



The daily number of users of our online services has risen by more than 15%, i.e. more than 7,000 individual users on average, hitting peaks of 12,000-14,000 users.

New portals for managing RDL 8/2010

The new mechanism established in February 2012, with the implementation of the system whereby deductions are transferred via a financial services provider, came as a new challenge to the service overall, involving the design of new portals for the financial services provider (aimed at controlling collection processes and managing transfers to Professional Associations) and for the General Council of Pharmaceutical Associations as regards their control and supervision functions.

The RDL 8/2010 management portals handle 30,000 connections a year, from more than 500 individual users.

3.3.2.
WORKING GROUPS

In 2012, the Association's different Working Groups continued to foster the exchange of knowledge between member companies and their full and active involvement with FARMAINDUSTRIA in an effort to define the industry's collective stance on relevant industry issues and pass their proposals on to the Association's Governance Bodies.

In October 2012, as a result of the renewal of FARMAINDUSTRIA's governance bodies, the Working Groups were renewed for a further two years. Accordingly existing groups were shut down or reactivated and new ones were created to cover member companies' needs.

At the time of drafting this Report, FARMAINDUSTRIA had 20 WGs in all, as follows:

1. Sustainability and Economic Regulatory Activity.
2. Health Technologies Assessment.
3. Hospitals Debt.
4. Technical Regulation of Medicines.
5. Manufacture and Traceability.
6. The Environment.
7. Pharmacovigilance.
8. Vaccines.
9. Pharma/Biotech.
10. Clinical Research.
11. Medical and Research Directors (BEST).
12. Orphan Medicines.
13. Legal Services.
14. Tax.
15. Human Resources.
16. Code of Good Practice.
17. Competitiveness and Internationalization.
18. Relations with Autonomous Regions.
19. Communication.
20. Patients

Notwithstanding the foregoing, there follows a summary of the FARMAINDUSTRIA Working Groups (WGs) that were operational in 2012, prior to their update.

The Sustainability and Economic Regulatory Activity WG (SERA-WG)

In 2012, SERA-WG kept up its monitoring work on regulatory activity and institutional initiatives concerning the economic regulation and sustainability of the National Health System. Particular mention should be made of the thorough and detailed analysis of the content, economic effects and implementation of RDL 16/2012, and its complementary legislation, which came against a broader backdrop of unprecedented levels of public spending cuts as a result of Spain's pledge to trim its budget deficit.

In 2012, the Association's Working Groups encouraged knowledge exchange and the hands-on participation of FARMAINDUSTRIA member companies

In particular, as well as analyzing the copayment scheme and the centralized procurement system envisaged by the RDL, the WG paid particular attention to the implications of the amendments affecting prescription and dispensation, lowest/highest prices and homogeneous groupings (Articles. 85 and 86, and Additional Provision 14 of the Guarantees Law). In this respect, FARMAINDUSTRIA's position vis a vis the Ministry of Health was a decisive factor when it came to coming up with mechanisms designed to avoid selecting a lowest-priced medicine that is not available on the market.

FARMAINDUSTRIA, in turn, kept up its call for the elimination of discrimination against branded drugs offered at the same price as a non-branded one when doctors prescribe by active ingredient, as established by the abovementioned RDL; and to safeguard prescription by commercial name (which the law allows) always providing that it is carried out in an efficient manner from the National Health System's point of view. It should be remembered that the rules on PPA adhere to the Reference Price System and homogeneous groupings and that, in this respect, the Association has continued to defend branded drugs' right to occupy the space assigned to it by law and that prescriptions for efficient branded drugs be respected.

The WG also analyzed the de-financing of medicinal products (Art. 85; 3rd of the Guarantees Law) and carefully monitored the processing and publication stages of the DGCBSF's Resolution of 2 August 2012 which updated the list of medicines that are excluded from the Health System's pharmaceutical services, and looked at the same Resolution's scope and practical implementation as regards the products contained in its Annex 3.

Similarly, SERA-WG monitored RDL 8/2010's monthly list of medicines subject to deductions and, via the Association, informed the Ministry of the case studies that point to an opportune review and amendment. In turn, the Ministry paid particular heed to FARMAINDUSTRIA's monitoring activities on the approval procedure for new medicinal products and the Association kept the Ministry constantly abreast of cases and delays.

FARMAINDUSTRIA continued to defend its active position on eliminating the discrimination against branded drugs at similar prices to non-branded drugs in the case of active ingredient prescriptions, and on safeguarding trademark prescriptions

Also, the Association, in coordination with SERA-WG, made considerable institutional efforts to ensure the correct implementation of Art. 93.2 of the Guarantees Law. This was a relevant feature of the talks with the Ministry for when it comes to drawing up the Draft Order on medicine sets and their reference prices, and when the reference prices previously established for the sets are reviewed. At the time of drafting this Report, the final decision had yet to be published. With regards to this same issue, SERA-WG helped to prepare the industry's allegations; special mention should be made of the Association's request for a return to the 2-euro minimum threshold in order to minimize the risk of stock shortages and to favor the economic viability of hundreds of medicinal products, among other allegations.

Another point worth mentioning is that, at the time of drafting this Report, the Ministry was still working on a planned Royal Decree on Price and Financing (publication dates have yet to be set). FARMAINDUSTRIA has forwarded to the Ministry two position documents: one on the evaluation process for new medicinal products, and another on the new procedure for pricing and financing within the framework of Art. 90 of the Guarantees Law, and with a view to the future development of the wording. Owing to its considerable importance and

practical implications, special mention should be made of the creation of an ad hoc WG on the development and subsequent implementation of Art. 90. This WG's progress is reported regularly to SERA-WG.

Finally, the WG has been informed regularly on the initiatives carried out in the hospitals market, both at a national scale (centralized procurement) and at a regional level (Andalusia or Catalonia, among others).

Health Technologies Assessment WG (HTA-WG)

FARMAINDUSTRIA set up this WG back in 2006 with the aim of drafting technical documents on the main issues affecting procedures for the economic evaluation of medicinal products.

Over the past twelve months, the WG has met on three occasions, having monitored and contributed with its work to the drafting or EU-wide guidelines on the different aspects of the economic evaluation of medicinal products carried out by the EUnetHTA (European Network for Health Technology Assessment).

In turn, the WG drew up a technical document on the critical aspects and procedural issues that need to be resolved in the economic evaluation of medicinal products, and it looked very closely at the concept of "therapeutic equivalence". It drew up a document that analyzed the various implications from the point of view of economic evaluation of medicinal products and the current cases that have appeared around this topic.

Over the coming year, the WG will continue to work on this and other technical documents that manifest the pharmaceutical industry's approach to issues related to the evaluation of medicines.

Over the past twelve months, the Health Technologies Assessment. Working Group (HTA) looked very closely at therapeutic equivalence and came up with a document that analyzed its various implications

Hospitals Debt WG (HD-WG)

Throughout 2012, by means of the initially quarterly and later monthly Hospital Debt Survey processed by FARMAINDUSTRIA, the HD-WG continued to monitor the evolution of the hospitals market in the various Autonomous Regions, and kept tabs on the volume of regional debt and arrears with suppliers of medicines to public hospitals.

In view of the current figures, and in an effort to solve the serious problem of the accumulated debt at 31 December 2011, FARMAINDUSTRIA and representatives of other business organizations tackled the issue by carrying out numerous institutional contacts, eventually getting the Government to agree to a number of initiatives aimed at enabling the public administrations to settle their outstanding payments with suppliers.

In this respect, through RDLs 4/2012, 24 February, and 7/2012, 9 March, a raft of measures was introduced aimed at establishing an agile system to settle payments and cancel debt with the suppliers of Local Authorities and the Autonomous Regions; this step was subjected to detailed scrutiny and analysis by FARMAINDUSTRIA and its Hospitals Debt WG in an attempt to overcome the problems that arose along the way.

The process was completed in late June 2012 when the suppliers received all of the sums laid down by the Plan. In the case of pharmaceutical companies, around 96% of arrears to 31 December 2011 were finally settled, amounting to 6.3 billion euro.

From a legal perspective, the mechanisms designed to settle outstanding healthcare debt was mirrored in a number of relevant Provisions that are explained in greater detail in the Regulation & Legislation section of this Report and which were analyzed by the HD-WG.

Throughout the entire process, the Association played an active role in the EFPIA Task Force—a body that monitors hospitals debt in European countries—and the Spanish Confederation of Employers' Organizations' Arrears WG; the latter's progress was reported regularly to the Association's HD-WG.

At the same time, the WG continued to monitor the collection of arrears by hospital supplies from 1 January 2012 onwards. It observed with certain concern that the level of arrears had risen slightly yet again during the tax year owing to the Autonomous Regions' liquidity difficulties. To overcome this problem, the Government passed RDL 21/2012, regarding Autonomous Regions' liquidity, setting-up the Autonomous Regions Liquidity Fund (FLA), a stopgap measure intended to bring financial relief to the Regions and to give them access to credit. The nine Autonomous Regions that adhered to the FLA in 2012 had received funds worth up to 12.6 billion euro; this sum was intended to meet public debt payments and to help service the public deficit, derived from arrears with suppliers, giving priority to essential public services, e.g. education, public health or social services. The entire process fell under the highly watchful eye of the HD-WG and the Association.

The FLA is still active in 2013, with the mission to help meet the financing needs of the various Autonomous Regions, and it will continue to do so while the current difficulties to access the markets persist. To deal with this problem, RDL 21/2012, 13 July, extended the FLA for another tax year, with a further 23 billion euros in funds from the State's Annual Budget. At the time of drafting this Report, there are eight Autonomous Regions adhered to the FLA, namely Andalusia, the Balearic Isles, the Canary Isles, Castile-La Mancha, Cantabria, Catalonia, Valencia and Murcia, and the Fund has begun to make the first payments to suppliers.

The Hospitals Debt Working group continued to monitor payments for hospital supplies from I January 2012, and observed that the year registered a new rise in arrears caused by the Autonomous Regions' liquidity shortage

Changing tack, the Association continued to monitor the terms and conditions of hospital tenders in an effort to ensure that they meet legal requirements as concerns public contract regulations. In this respect, FARMAINDUSTRIA has had to deal with a few irregularities and sent out letters requesting the affected parties to remedy the situation by modifying the terms and conditions; in other cases, the Association has had to lodge an appeal against several calls for tender.

Similarly, the WG monitored Spanish and EU legislation on administrative contracts, as detailed in the Regulation & Legislation section of this Report.

Finally, working shoulder-to-shoulder with the Autonomous Regions WG, the HD-WG held a number of meetings with the Andalusia Health Service (SAS) concerning, primarily, the SIGLO project (short for Sistema Integral de Gestión Logística, i.e. Integrated Logistics Ma-

nagement System) that is being carried out in the southern Spanish region through the Provincial Platforms for Administrative Contracts, and through the introduction of EDI in all commercial dealings with the SAS's suppliers.

In turn, the Association maintains constant engagement with the Catalonian Institute of Health, addressing the processing of new calls for tender for the supply of medicines to all of the Services' healthcare centers.

The Technical Regulation of Medicines WG (TRM-WG)

There are constant adaptations of EU directives and provisions issued directly by the Spanish Agency for Medicinal and Healthcare Products (AEMPS) to provide the technical regulation of medicines, and it is the TRM-WG's task to report on the regulatory projects.

At every TRM-WG meeting, every effort is made to include the participation of a representative of the Administration who not only addresses the main issues of the day but also puts forward a project of interest to the industry. Last year, the AEMPS presented a project designed to create and modify the fact sheets and information leaflets of medicines and which sets out to structure and break down the texts in such a way as to make them more accessible for the AEMPS's IT applications, and also making it easier to make variations, especially when they are requested simultaneously.

Each year, the WG reviews the current regulations regarding technical regulation and the allegations that arise during their processing period. In 2012, the most noteworthy were those concerning the amendments to Royal Decrees that regulate the registration and distribution of medicinal products.

The Association continued to monitor the terms and conditions of hospital tenders in order to make sure that they met all public-contracts legal requirements

Manufacture and Traceability WG (MT-WG)

The mandatory development of the EU directive on preventing falsified medicinal products from entering the legal supply chain led this WG to review the Royal Decree on Distribution; the latter introduced substantial changes in the way raw materials are imported from third countries and also amends a number of provisions of RDL 824/2010 by which pharmaceutical companies are regulated.

The WG is monitoring this subject very closely, synchronizing its efforts with those of the EFPIA given that, for the time being at least, it is hard to say which decisions will be finally adopted by the European Commission and by the authorities of the member states in July 2013 on active ingredient imports from third countries that are not currently included in the European Commission's list of authorized countries. Their exclusion stems from the fact that the Commission considers that they do not meet public health safety standards similar to the EU's, and that they do not provide a certificate from the relevant authority in each country ensuring that the manufacturing plant of the active ingredient meets the equivalent of the EU's Good Manufacturing Practice (GMP) for medicines, nor is the plant subject to strict and efficient checks (regular inspections).

Finally, this WG has addressed a number of relevant issues concerning the distribution of medicinal products and, specifically, the need to be particularly on the lookout for unlawful trading practice by unauthorized traders.

In 2012 FARMAINDUSTRIA monitored the new European law on pharmacovigilance and the EMA's explanatory documents

The Environment WG (E-WG)

In 2012, the Environment WG, in conjunction with the Integrated Management System for the Collection of Drug Product Containers (SIGRE for short), monitored important legislation of importance to the industry, such as Law 26/2007, 23 October, on Environmental Responsibility, the implementation of the IT application of the Model of Environmentally Responsible Procurement (Spanish acronym MORA), modifications to the Integrated Prevention and Control of Pollution Law (IPPC), the review of the European Waste List, the Draft Law aimed at regulating certain taxes concerning the Justice Administration and Spain's Toxicology and Forensic Sciences Institute, and also monitored other environmental actions that have repercussions for the pharmaceutical industry (waste, discharge and emissions).

Also, FARMAINDUSTRIA continued to sit on the Environment Committees of a number of business organizations (CEOE, FEIQUE) and stepped up its collaboration with the Spain's Ministry of Farming, Food and the Environment on issues that affect the pharmaceutical industry.

The Pharmacovigilance WG (P-WG)

In 2012 this WG monitored the new EU legislation on Pharmacovigilance as well as the new explanatory documents published by the European Medical Agency (EMA) in an effort to become better acquainted with the implications for CAT scanners and the main lines for their transportation in Spain.

At the EU level, one of the more important issues was the review and allegations, via the EFPIA, concerning 11 of the 16 expected modules on Pharmacovigilance Good Practice. Also, comments were filed on the position document on the implementation of the black triangle that indicates medicinal products subject to additional monitoring. The latter include medicines that contain a new active ingredient, biological medicines and those that are obliged to provide additional information concerning the period following their official authorization. As regards this issue, meetings have been held with the AEMPS to establish how this requirement is to be implemented in Spain.

The WG provided information used for the preparation of the Royal Decree on Pharmacovigilance, focused on adapting definitions and demands on the requirements of EU Directive 1235/2010, on the protection of the confidential commercial information of the CAT scanners, and on the fostering of prescription using the commercial name of the medicine so as to make it easier to identify, especially in the case of biotech medicines. As regards the possibility of the European Commission or member states requesting post-authorization efficiency studies, special care has been taken to ensure that the cases in which these studies may be required in Spain comply exactly with what is laid down by the Directive. Also included are the transitional provisions needed for establishing reasonable implementation periods for the new demands, such as notification for patients and the reporting to EudraVigilance of any suspected non-serious reactions, among others.

The local-level transposition of the pharmacovigilance law has been a constant and priority issue in FARMAINDUSTRIA's relations with the AEMPS. In this respect, both worked shoulder-to-shoulder to draft a Q&A document on the law's implementation, and on the pilot phase of en electronic system for filing regular reports on safety issues.

The WG was behind the roll-out of a particularly important project, namely the electronic transmission of so-called "Dear Health Professional Communications" (DHPC for short) to healthcare professionals through scientific societies. This project, a pioneering initiative in Europe and with the backing of the AEMPS, brings important advantages over the use of land mail, such as immediacy and the modernization of message transmission, the possibility of tracking, forwarding to third parties and interaction with the recipients, cost savings, environmental responsibility and mutual collaboration between players. To roll-out the project, FARMAINDUSTRIA signed a collaboration agreement with FACME and came to a collaboration arrangement with each of the scientific societies that were interested in taking part. The more than 30 societies that joined the project made it to send out DHPCs to more than 96,000 healthcare professionals up and down Spain.

The Pharmacovigilance WG launched an important new project, namely DHPC (Dear Health Professional Communications) electronic transmissions to healthcare professionals via their respective scientific societies

The Vaccines WG (V-WG)

FARMAINDUSTRIA's Vaccines WG coordinates its agenda with the European Vaccine Manufacturers (EVM), which reports to the EFPIA. It regularly monitors the range of issues related to vaccines in an effort to preserve the importance, singularity and correct use of these medicines.

One of the main issues addressed by this WG has to do with the importance of having a stable and predictable regulatory framework in place, especially where vaccine purchase procedures are concerned, the need to make explicit in the terms and conditions the deductions envisaged by RDLs 8/2010 and 9/2011, or improvements in the policy concerning reimbursement by the Autonomous Regions, or a review of the restocking of products after these have been delivered correctly. These are just some of this WG's main requests that have been forwarded to the pertinent authorities.

The V-WG has also been involved in a number of actions aimed at fostering the value of vaccines and compliance with international recommendations on vaccine coverage.

The Pharma-Biotech WG (PB-WG)

This WG, made up of 34 companies, has a number of objectives, such as encouraging cooperation between the pharmaceutical industry, small biotech outfits and public research centers, with accurate instruments and highlighting the differentiation and the complementary role that FARMAINDUSTRIA can contribute.

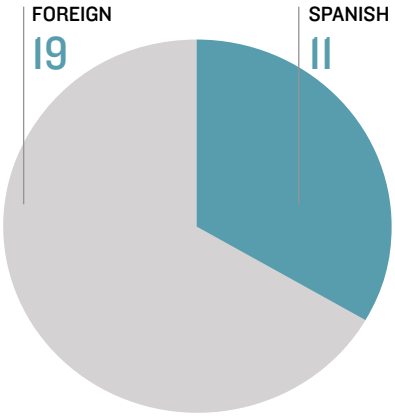
In 2011, FARMAINDUSTRIA launched a Pharma-Biotech cooperation program, and between 2011 and 2012 it held seven interactive encounters between both sectors, mainly in the fields of central nervous system. Cancer, respiratory system, inflammation and autoimmune illness. Seventy direct agents took part in these meetings, i.e. 30 pharmaceutical companies and 40 representatives from biotech outfits).

Each session takes the form of a tailored forum aimed at identifying the value-added derived from the information exchange between the biotech demand- and supply-sides, with enough differentiated content in the sphere of new therapies and innovative medicinal products. Within this Program, In 2012 two of the Sessions were held outside of the usual venues (the Madrid and Barcelona offices) and were held in Zaragoza, in collaboration with the Aragon Healthcare Sciences Institute, and in Bilbao, as part of BioSpain annual international meeting on biotech, and the collaboration agreement reached by Asebio and FARMAINDUSTRIA. As a result of these Meetings, 2012 saw the signing of Transfer Agreements between both sectors.

DISTRIBUTION OF PHARMACEUTICAL COMPANIES AND PROJECTS

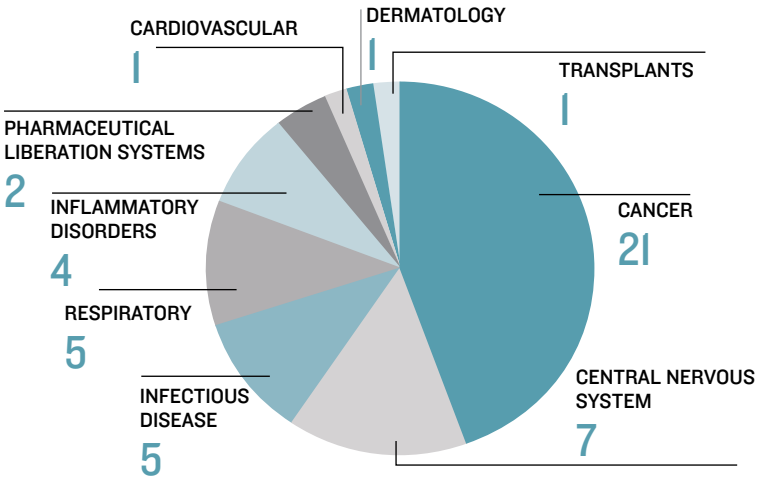
Distribution of pharmaceutical companies (by place of origin)

30 participating companies



Distribution of projects according to therapeutic areas

47 projects presented



In 2012, three conferences were held: the first took place in the FARMAINDUSTRIA offices in Madrid on 7 May and, for the first time ever, the program was extended to medium-sized Spanish pharmaceutical companies with advanced projects and keen to collaborate with the large companies. The other two conferences were held last July and October. The different presentations are all available at the website www.medicamentos-innovadores.org

Similarly, this WG also seeks to stimulate industry participation in Spanish and international pharmaceutical research programs, especially in the Innovative Medicines Initiative (IMI) and in the Spanish Technological Platform for Innovative Medicines.

Clinical Research WG (CR-WG)

Over the past year, the Clinical Research WG monitored Spanish and EU legislation initiatives on clinical research, especially those related to the new proposed Regulation and the draft RD on Clinical Trials.

As regards the Regulation, meetings have been held with the AEMPS to inform them on the innovative industry's position, supporting the Commission's initiative to simpli-

fy evaluation and authorization procedures, reduce red tape, strengthen cooperation between the member states and increase the consistency of research procedures, all of which aims at guaranteeing the protection of all the parties involved in the research.

To this end, it has been stressed how important it is to ensure that the research evaluations carried out by regulatory bodies and ethical committees take place at the same time; this ensures that the schedules proposed by the new law are met, as well as reducing evaluation times considerably. Emphasis has also been placed on the need for affirmative administrative silence to authorize these studies.

Given that this proposed Regulation will lead to hefty legal changes in Spain, FARMAINDUSTRIA has conveyed to the AEMPS the need to implement a system Single IT to transmit information on clinical trials, available to all of the parties involved in the process. The Association also requested the necessary amendments to guarantee the parallel evaluation of the study by other agents and the signing of the contract by the corresponding research center, including a condition precedent that enables it to be so, and favoring the possibility of the creation of a Single Contract Model for clinical trials in Spain. Other requests include the regulation of the fees for this kind of research, as predictable and uniform as possible for each research centre and with amounts that reflect the workload.

Similarly, the Health Ministry's Sub directorate-General for Public Health worked on speeding up import/export authorizations for biological samples that come from or headed to non-EU customs territories. This makes it possible to make electronic applications for authorization and obtain export/import authorization even before actually having the necessary authorization for the start of the trials (permission to start trials would thus depend on obtaining or not the export/import permit),

The Pharma-Biotech WG attempts to get industry players involved in national and international pharmaceutical R&D programs

One of the important projects on which the WG worked alongside the AEMPS was the roll-out of the Spanish Register of Clinical Trials (ReEC). The WG took part at the pilot stage of introducing data to detect room for improvement in the tool that will be used to manage the information. The ReEC is already available for use in Phase II and IV studies and for all of the pediatric phases approved by the AEMPS as of January 2013.

As regards the EU procedure for authorization for clinical trials from regulatory bodies (VHP), the CR-WG put forward proposals for improvement at the CEIC level, calling for evaluation to be carried out in parallel and asking that the modifications to the VHP study do not draw out the procedure for authorization by the Committees. In this respect, the AEMPS plans to undertake a pilot study with the CEIC, enabling the latter to evaluate the information obtained by the parallel study using the VHP procedure, thus avoiding delays at the start of the studies.

The Medical and Research Directors (BEST) WG (BEST-WG)

This WG was set up seven years ago as a platform for excellence in research and is part of the Spanish Technological Platform for Innovative Medicines (PTEMI). It focuses on designing the strategy for and promotion of competitiveness in clinical research in Spain. The WG facilitates processes and improves performance indicators (times,

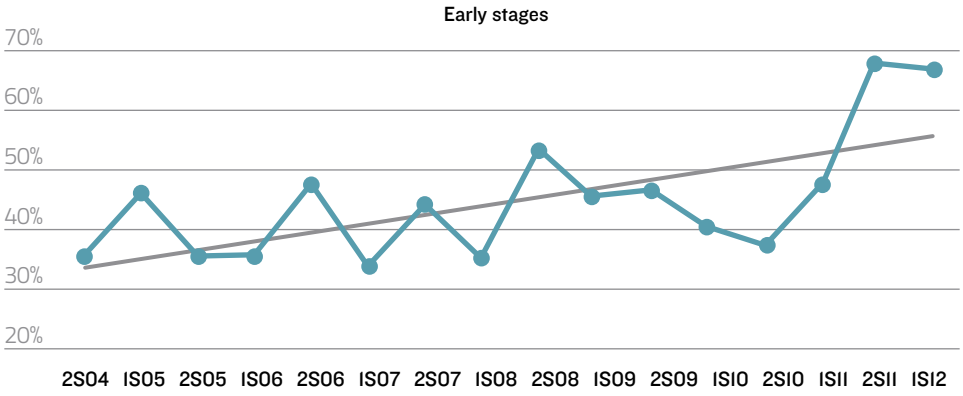
recruitment, international benchmarking...) in order to enhance the environment for clinical trials, with particular emphasis on the early stages.

The 13th edition of the Metrics Database, updated June 2012, contains information of key performance indicators from 1,675 clinical trials, 0f which 841 have been completed. A total 90% of these trials are multi-center and international trials. The main therapeutic areas covered by these trials are cancer, cardiovascular, neurosciences and anti-infectives.

In turn, an upward trend in the early phases of clinical research has been detected, mainly at Phase II.

OVERALL PERCENTAGE OF THE CLINICAL TRIALS AT PHASES IA, IB AND II SOBRE OVER THE TOTAL NUMBER OF COMPLETED CLINICAL TRIALS IN EACH SIX-MONTH PERIOD

The proportion of Clinical Trials at early stages is growing all the time



The Clinical Research WG worked alongside the AEMPS on a major project: the roll-out of the Spanish Clinical Studies Register (ReEC)

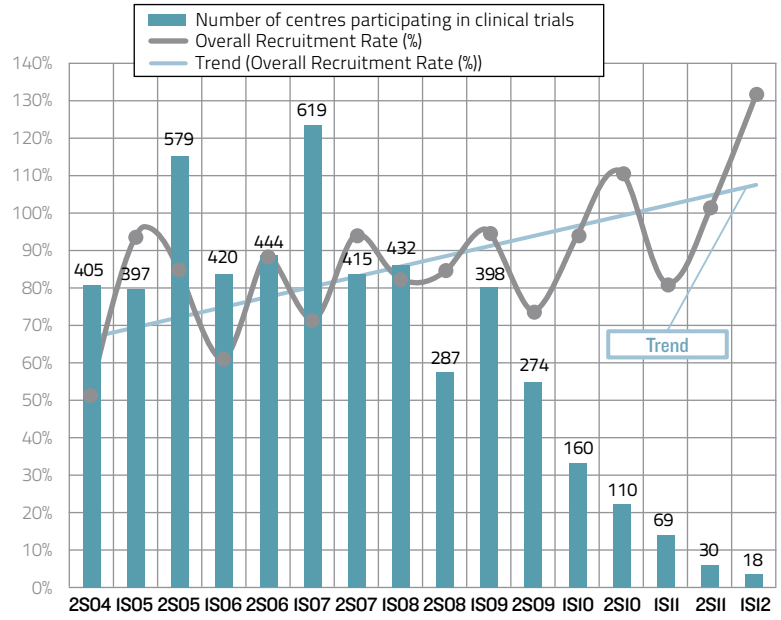
The database brings together start-out times of the trials themselves and the recruitment rates at research centers; there is also a section on international benchmarking. In general, all the time indicators have fallen in each six-month period, mainly at the contract phase (around 120 days, on average) and in the overall time for clinical trial start-out (an average 190 days). This has been a constant trend from the outset of project in 2005; however, carrying the contracting and authorization (from the corresponding Center) processes at the same time would go a long way towards speeding up start-out times.

As the graph below indicates, the patient recruitment rates measured at the trials have improved constantly over the recent six-month periods.

RECRUITMENT RATES

The average recruitment rate for completed clinical trials is 79%.

The rate improves over time.



In meetings in 2012 held with pharmaceutical companies that take part in the BEST project, it was decided that the moment had arrived to open the project to new participants, especially hospitals, healthcare research centers, research foundations, management areas at the regional Public Health Departments and contract research organization (CROs). On 19 December 2012, FARMAINDUSTRIA hosted a meeting attended by many potentially new participants in the BEST Project where they received detailed information on the terms and conditions of participation. Later, a group of independent researchers, the Spanish Breast Cancer Research Group, announced its interest in joining the Project, bringing the number of project members to 70 in all: 12 Autonomous Regions, 52 research centers, 5 CROs and newcomer GEICAM.

EXTENDING THE BEST PROJECT TO OTHER PLAYERS

12 Autonomous Regions

Andalusia
Aragon
Balearic Isles
Cantabria
Castile-Leon
Catalonia
Extremadura
Galicia
Madrid
Murcia
Navarre
Basque Country

52 HEALTHCARE CENTERS

C. M. de A Coruña
C. M. U. de Santiago
C. M. de Vigo

C. A. U. de Salamanca
H. Clínico U. de Valladolid
H. U. Río Hortega
C. A. de Zamora
C. A. U. de Burgos
C. A. U. de León
C. A. de Ávila

C. M. de Granada
C. M. de Jaén
C. M. Reina Sofía
C. M. Virgen de la Victoria
C. M. de Málaga - Carlos Haya
C. M. Virgen del Rocío
C. M. Virgen de la Macarena
C. M. Ntra. Sra. de Valme
C. M. de Huelva
C. M. de Cádiz
Hospital Costa del Sol

Hospital Marqués de Valdecilla

H. U. de Araba
H. U. de Cruces
Hospital de Basurto
Hospital de Galdakao
Hospital Biodonostia

C. M. de Navarra

H. Sant Joan de Deu
P. Sanitari Sant Joan de Deu
Hospital Clinic
Hospital Parc Taulí
Hospital Vall D'Hebron
Hospital Bellvitge
H. de la Santa Creu i Sant Pau
Instituto Oncológico Catalán
Hospital del Mar
Hospital de Granollers

H. General U. de Valencia
H. Clínico U. de Valencia
H. Malvarrosa
H. U. La Fe

H. U. de Getafe
H. Clínico San Carlos
Fundación H. de Madrid
H. U. de la Princesa
H. U. de la Paz
H. U. Puerta de Hierro
H. U. Ramón y Cajal
H. Fundación Jiménez Díaz
H. Gregorio Marañón
H. Rey Juan Carlos
H. U. Infanta Elena

A group of independent researchers teamed up in a major Scientific Association.

In 2012, FARMAINDUSTRIA carried out a study to become better acquainted with the clinical research conducted by pharmaceutical companies at private research centers within the BEST Project. The findings were announced, in conjunction with Spain's Healthcare Development and Integration Institute (IDIS), at a one-day conference held at Madrid's Quiron Hospital. The event was attended by more than 170 players involved in medicines R&D. Updated findings were presented on 25 April at the Quiron Hospital in Barcelona.

The Legal Services WG (LS-WG)

2012 saw a number of legal changes as a result of measures introduced by the Public Administrations. Accordingly, the LS-WG focused on carrying out a detailed study of the legal issues that most affected the sector, at national and regional levels.

One of the main issues was the study and review of the Articles included in 16/2012, 20 April, regarding urgent measures to safeguard the sustainability of Spain's National Health System and improve the quality and security of its various services, the interpretation of some of the provisions, as well as other measures introduced at the regional level.

At the national level, the LS-WG provided regular information on the process for the legal hearing granted to the Association in projects in process, such as the Draft Law on Guarantees and the Draft RD on Distribution, and others.

At the regional level, and given the ever-increasing regulatory activity carried out by the Autonomous Regions, FARMAINDUSTRIA undertook legal proceedings against the initiatives that it deemed damaging to the pharmaceutical industry.

As is now usual, this particular WG also addresses issues (e.g. hospitals debt, the industry's collective bargaining agreements, the Code on Promotion of Healthcare Professionals and Patients) that are usually dealt with by other FARMAINDUSTRIA WGs; but because they all have legal implications, they are also studied by the LS-WG.

Regardless of the two face-to-face meetings held in 2012, FARMAINDUSTRIA works closely with and advises the WG (over the phone or by email) on issues of potential interest to its activities.

The Tax WG (T-WG)

In 2012, the WG held its usual annual seminar on tax issues, an event designed to keep member companies abreast of changes, or expected changes, in tax law. One of the most important tax changes to take place in 2012 was the one concerning Income Tax; special attention was focused on changes in the e-notification process, store-rooms/warehouses as a permanent establishment as concerns VAT and manufacturing/trading structures as a result of legal precedent stemming from rulings by Spain's Supreme Court.

The Legal Services WG analyzed the main legal issues of interest to the pharmaceutical industry

Throughout 2012, the WG reported regularly on tax changes: one of the most important was RDL 12/2012, 30 March, which introduced new tax and admin measures aimed at trimming the public deficit. The new law introduced several important changes, not least changes in the deferred payment of Corporate Tax which, as well as the changes introduced by RDL9/2011, should be taken into account by large companies when they come to filing their tax returns 2012 and 2013.

Along similar lines, mention should be made of the monitoring activity carried out by the T-WG on RDL 16/2012, 20 April, as regards urgent measures aimed at safeguarding the sustainability of Spain's National Health System and improving the quality and security of its various services; Organic Law 2/2012, 27 April, regarding budgetary stability and financial sustainability; Finance and Public Administrations Ministry (HAP) Order /1182/2012, 31 May, which passed Model 750; Law 2/2012, 29 June, on the National Budget for 2012, and Law 7/2012, 29 October, amending existing tax and budget law and adapting it to financial law in order to step up the fight on tax fraud.

In turn, the T-WG closely monitored the debate on and eventual publication of RD 1619/2012, 30 November, passing the regulatory law on billing procedure, which came into effect on 1 January 2103. This regulation sets out to bring into Spanish law EU Directive 2010/45/UE, which modifies Directive 2006/112/CE on the common VAT system as regards billing requirements and other aspects that simplify VAT rules and improve the overall workings of the internal market.

Along similar lines, we should highlight the T-WG's analysis of RDL 20/2012, 13 July, regarding measures aimed at ensuring budgetary stability and fostering competitiveness;

among other changes, the law introduced new measures affecting several types of tax, in some cases amending or extending the reforms introduced by RDLs 9/2011, 20/2011 and 12/2012, all of which set out to trim Spain's public deficit.

The Tax WG monitored very closely the processing and publication of RD 1619/2012, 30 November, approving the Regulatory Regulation on billing obligations

The T-WG also monitored legal and tax authority rulings that affected the industry, including legal doctrine on the general limitations on tax deduction of financial costs, and VAT on the contributions per sales volume envisaged by the 6th AP of Law 29/2006, 26 July, on guarantees and the correct use of medicines and healthcare products.

Similarly, the Association continued to on the Public Subsidies Committee of the CEOE's R&D Commission to debate, among other issues, the business organization's proposals to improve and increase the effectiveness of tax deduction on R&D and Innovation (RDI).

The Human Resources WG (HR-WG)

In 2012, this WG, made up of members of the HR teams at FARMAINDUSTRIA member-companies, focused on the negotiations on the 16th Chemical Industry Collective Bargaining Agreement, the pre-agreement to which was signed on 21 December 2012. It also centered its attention on the draft changes in labor law to which it was invited to comment.

FARMAINDUSTRIA also continued to sit on the monthly meetings of the Mixed Committee on the Interpretation of the Collective Bargaining Agreement, the FEIQUE's Socio-Labor Commission, and other equality commissions set up under the auspices of the existing Agreement. Moreover, it sat on the CEOE's Labor Relations Commission and Social Engagement Commissions, among others.

Codes of Best Practices WG (CBP-WG)

In order to continue to monitor progress in self-regulation, in 2012 this WG worked in both its plenary and reduced modes. In the latter case, and with the active participation of FARMAINDUSTRIA's Ethics Supervision Unit, two ad hoc groups were set up to analyze the implementation of Articles 16 and 17 of the Code (services rendered by healthcare professionals and/or their professional associations), and the proposals of the Communication WG on best practices as regards the pharmaceutical industry's relations with the media.

For its part, the Board of the European Federation of Pharmaceutical Industries and Associations (EFPIA) gave the green light to a new Transparency Code; it is scheduled for transposition in Spain before the end of 2013.

At the time of drafting this Report, this WG was working on a new version of the Spanish Pharmaceutical Industry's Code of Best Practices; apart from transposing the abovementioned EFPIA Transparency Code, it will unify the current wordings of the Code of Best Practices and the Patients' Code.

The Competitiveness & Internationalization WG (CI-WG)

This WG, which sets out to foster our member companies' industrial competiveness and international expansion, stepped up its activities in 2012 as the consolidation of interna-

tionalization became an increasingly important priority for Spain's pharmaceutical companies to offset the slump in domestic demand.

Budget cuts also hit state subsidies for internationalization. FARMAINDUSTRIA stepped up its efforts in this sphere by maintaining regular contact with the Spanish Institute for Foreign Trade (ICEX) and played an active role in the corresponding CEOE committees; indeed, the Association put forward specific proposals on internationalization that were reflected in the business association's Industry Summit in November 2012.

This WG boosted tailored priority actions for markets of interest. In 2012, actions of this kind, aimed at international expansion, were carried out Chile, China, Ecuador and Canada.

FARMAINDUSTRIA also set up, in coordination with embassies, business encounters with Spanish pharmaceutical companies and their counterparts in India, Egypt and South Korea, to explore avenues of mutual cooperation and business in those countries.

Efforts have also been made to keep up the international section of the National Employment WG's intranet; the latter gives members access to documents and reports that help companies in their international thrust. Using this tool has helped to standardize the selection and transmission of information on individual initiatives by specific companies and/or countries. This area is expected to be enlarged in 2013 with a section that will include organizations that can help companies to expand internationally; this will help member companies to access to those organizations independently.

Finally, FARMAINDUSTRIA kicked-off bilateral cooperation efforts with other industry associations, such as Fenin or Fedequim, aimed at looking at the possibilities of future cooperation opportunities capable of leveraging synergies during the internationalization processes of Spain-based companies.

The Relations with Autonomous Regions WG (RAR-WG)

This WG sets out to review, analyze and monitor regional pharmaceutical policy, as well as fostering collaboration arenas with the regions, scientific societies, professional and political associations, social institutions and organizations that help to shape a market conducive to pharmaceutical innovation and capable of defending pharmaceutical market unity in Spain overall.

In 2012, the RAR-WG was made up of 58 companies representing all of the Association's statutory groupings. It convened on six occasions in all and some of the meetings were attended by the President of the Spanish Family and Community Medicine Society (SemFyC for short) and representatives of the Catalonian and Balearic islands Academies of Medical Sciences.

This WG has been particularly active in analyzing and monitoring regulatory initiatives at the regional level and their development, as regards healthcare policy and access to pharmaceutical services, and in fostering communication and internal information mechanisms.

The Good Practices WG is still working on the new version of the Spanish Code of Good Practice for the Pharmaceutical Industry which will transpose the EFPIA's Transparency Code and unify the wording of the Code of Good Practice, the Development Guide and the Patients' Code

The Autonomous Regions WG made considerable efforts to monitor and analyze the Regions' initiatives as concerns the pharmaceutical sphere

Over 2012, the WG focused in particular on the following:

I) the implementation of RDLs 9/2011 and 16/2012 by regional authorities;
II) the problems derived from Active Ingredient Prescription;
III) automatic prescription substitution in the regions of Castile-La Mancha, The Basque Country and Navarre;
IV) Galicia's prioritized medicines catalog;
V) medicines auctions in Andalusia;
VI) regional committees to evaluate medicines;
VII) hospital diagnostic medicines' switch to hospital pharmacy dispensation status;
VIII) the Medicines Central Procurement Agencies;
IX) the SNS Procurement Platform, or
X) e-prescription and patient clinical records, among other issues.

The Barcelona Office

FARMAINDUSTRIA's Barcelona Office is there primarily to provide advice and technical support to our member companies in Catalonia, in conjunction with our Association departments.

It continued to offer advice and field queries from member companies, mainly on tax, public contracts, hospitals debt and e-billing, among others.

In 2012, the Office continued to engage with the Catalonia Healthcare Institute (ICS) in the processing of the new Framework Agreement on Medicine Supplies for all of the centers that depend directly on the ICS, as well as monitoring progress on the SIGLO Project and the introduction of electronic data exchange in the Andalusia Regional Public Health Services.

During 2012 the Barcelona Office continued to help coordinate and provide technical support to the Association's various WGs; their meetings helped to step up active participation and knowledge exchange between FARMAINDUSTRIA and its member companies. In the same way, the Office hosted the meetings of the Association's governance bodies, statutory groups and other organizations (e.g. COASHIQ, ANEFP, SIGRE, and so on).

The Office continued to work shoulder-to-shoulder with the Association's National Statutory Group, taking part in meetings in the role of Technical Secretary providing constant updates on issues of interest to the Group via the FARMAINDUSTRIA intranet.

Last but not least, in 2012 the Office continued to engage with academic institutions and pharmaceutical industry-related parties at the regional level, and to sit on the FEDEQUIM Delegated Mixed Commission (Catalonia) in an effort to interpret the wording of the Chemical Industry Collective Bargaining Agreement, as well as sitting on the FEDEQUIM Socio-Labor Commission.

3.3.3.
THE SPANISH TECHNOLOGICAL PLATFORM FOR INNOVATIVE MEDICINES (PTEMI)

Seven years after it was originally set up, THE SPANISH TECHNOLOGICAL PLATFORM FOR INNOVATIVE MEDICINES (PTEMI), today stands consolidated as an initiative promoted by the pharmaceutical industry in collaboration with academic institutions, clinical researchers and public administrations, in an effort to encourage and boost R&D in innovative medicines in Spain.

In 2012, PTEMI, like FARMAINDUSTRIA, played an active role in the Alliance for Research and Innovation in Healthcare (ALINNSA), promoted by Spain's "Carlos III" Institute. FARMAINDUSTRIA holds a seat on the ALINNSA governing body and is also a member of three of the Alliance's committees, namely Strategy, Cooperation (FARMAINDUSTRIA presidents this committee) and Internationalization.

PTEMI is Spain's benchmark in the Innovative Medicines Initiative (IMI), an EFPIA-European Commission venture that sets out to enhance Europe's position in pharmaceutical research, make Europe a more attractive proposition for long term research investment, and give EU citizens speedier access to higher-quality medicinal products. In 2012,PTEMI carried out a number of activities designed to encourage international cooperation and to lend support for organizations interested in this kind of collaboration. Efforts focused primarily on organizing Information Days and the six-monthly IMI Forum, hosted by Spain's Center for the Development of Industrial Technology (CDTI).

FARMAINDUSTRIA participated in an IMI consortium at the Third Call, known as the European Patients' Academy on Therapeutic Innovation (EUPATI) which will give patients scientific, objective and comprehensive information on pharmaceutical R&D. The project brings together 29 organizations and is led by the European Patients Forum which, in turn, is made up of several EU-wide patients' organizations, academic organizations and a number of NGOs specializing in patient- and general public participation, as well as EFPIA member businesses/associations. EUPATI provides objective, high-quality and cutting-edge learning opportunities for patients on Therapeutic Innovation.

In 2012, the Innovative Medicines Initiative launched four calls (5th, 6th, 7th and 8th) and more than 200 million euro's worth of funds are still available. The corresponding call for applications will be issued sometime in 2013.

The new EU Framework Program on Research and Innovation, known as "Horizon 2020" and which is scheduled to come into effect sometime in 2014, envisages the launch of the planned Public-Private Partnership (PPP) for Healthcare Research (the future "IMI-2"), which broadens its focus to cover public healthcare needs, instead of limiting itself exclusively to the development of pharmaceutical products.

PTEMI carried out a broad range of activities in 2012 and we should highlight the Pharma-Biotech Cooperation Program, the latter got under way in February 2011 and seeks to ease cooperation between Spain's pharmaceutical and biotech sectors (there is more on this topic farther on in this Report).

The PTEMI is the Spanish reference for the Innovative Medicines Initiative (IMI), and EFPIA –EC joint initiative aimed at promoting research into new medicines

The PTEMI's main communication channel is its web portal; it is a nationwide reference for biomedical/ pharmaceutical research and stands as a meeting and coordination space for all industry players

The PTEMI's activities focus primarily on the dissemination and promotion of its activities aimed at all of the players in the triple field of science, technology and business; this is designed to make known extensively the findings of research activities or the public and private initiatives of interest to the industry with the ultimate aim of promoting mutual cooperation between industry players. On 20 and 21 March 2013, PTEMI coordinated and hosted its 6th Annual Conference in Barcelona, along with the Spanish Technological Platform for Nanomedicine, the Platform for Healthcare Technologies Platform and the Biotech Markets Platform. The event's theme was "Fostering Innovation in Healthcare" and the audience of 270 people received information on R&D projects in new medicines with a more collaborative vision and, overall, to increase production and competitiveness in the sector. All of the event's presentations and videos are available at the following website:

www.medicamentos-innovadores.org

PTEMI's communication channel is the Platform's web portal (www.medicamentos-innovadores.org); it is a nationwide benchmark in biomedical pharmaceutical research and stands as an arena and coordination point for activities, information and communication between its many participants.

It publishes a monthly newsletter which goes out to more than 1,900 people interested in PTEMI activities. The website is available in Spanish and English and is updated weekly.

3.3.4. SELF-REGULATION SYSTEMS

The Spanish pharmaceutical industry's Self-Regulation System rests on three Codes:

- The Spanish Code of Best Practices in the Promotion of Medicines and Relations between the Pharmacuetical Industry and Healthcare Professionals (Relations with Healthcare Professionals Code - RHPC for short).

- The Spanish Code of Best Practices in the Promotion of Medicines and Relations between the Pharmacuetical Industry and Patients' Organizations (Relations with Patient' Organizations Code – RPO for short).

- The FARMAINDUSTRIA Standard Code for Personal Data Protection in Clinical Research and Pharmacovigilance (Standard Code – SC for short).

As concerns the RHPC, and regarding hospitality and meetings, efforts have been made to disseminte and explain important changes on the Code that was approved in 2010. These changes concen, primarily, national events hosted by third parties.

In the services sphere, it is important to point out that in 2011, for the first time since the communication procedure got under way, the Ethics Supervision Unit provided the Association's member companies with data on the type of services that were communicated, the number of healthcare professionals hired to provide the services, their scope and their sphere of development.

Our member companies themselves detected the need to analyze and put forward objective elements that help to meet the requirements mentioned in Articles 16 and 17 of the Code as regards the hiring and execution involved in this kind of services.

As regards the Type Code, in 2012 the efforts to disseminate this code centered on the Association's participation in a number of data protection conferences, and on providing tailored training courses for pharmaceutical companies and CROs that requested them in order to weigh up their possibilities of becoming members.

In an effort to improve the application and implementation of the Type Code as regards the data handled by the hospitals, and to ensure the developer's compliance with due diligence as concerns the rest of parties that take part in a clinical trial, the Association, working in close collaboration with the Spanish Personal Data Protection Agency and the three Autonomous Regions, drew up a draft letter of intent on data protection that was forwarded to hospital managers at the main hospitals that account for most of the clinical research conducted in Spain

For its part, the Type Code Monitoring Committee's efforts work on analyzing recent membership applications, as well as all the legal changes currently under way in Europe concerning pharmacovigilance, data protection and clinical research and which are likely to lead to future changes/updates in the Type Code.

The Ethics Supervision Unit gave pharmaceutical companies data on the types of services sought, number of professionals hired for those services, the scope and the sphere of development

Ethics Committee Activities

The Ethics Committee entered its tenth year in 2012. Its origins reside in the 2002 Code of Best Practices on the Promotion of Medicines which is also the cornerstone of the current self-regulation system. Two of its members in particular, Dr. Josep Torrent and Dr. Miquel Vilardell, have renewed their mandate twice in a row since the Committee was first set up, while Dr. África Mediavilla was appointed in 2008; she replaced the late Dr. Juan Manuel Reol Tejada.

During its first ten years, the Committee has dealt 241 incidents in all, of which 84 were reported by the Ethics Supervision Unit. Nearly six out of ten (59%) of these incidents were resolved by the parties involved, with the Ethics Commission acting as mediator; 31% were forwarded to the Self-Regulation Panel, 3% were filed because the parties reached a prior agreement, and the remainder, 7%, were suspended because they were being processed simultaneously by the Health Authorities.

The reports deal mainly with the scientific content of promotional/advertising materials and other promotional activities (distribution of the promotional materials, incentives, samples, etc.). The table below sum up the total number of reported incidents over the past ten years, under a variety of headings.

The Ethics Committee entered its tenth year of service in 2012

Total	241
Ethics Committee	217
Intermediation by the Commission	106
Prior agreement	21
(Pre-Commission)	8
Filed	5
Dismissed	77
Self-Regulation Panel	1
Agreements	9
Rejected	4
Dismissed	63
	17
Administrative recourse	7

Reports	
Member Companies	59%
Member Companies	3%
Ethics Supervision Unit (ESU)	35%
Third Parties	3%
Reported	
Member Companies	95%
Member Companies	4%
Others	1%

Ethics Supervision Unit Activities

Among the many activities designed to disseminate of the self-regulation system, the following stand out in particular:

I) an active role in conferences and meetings at home and abroad;

II) bilateral meetings with the national pharmaceutical associations of Bulgaria, Mexico and Colombia; III) bilateral meetings with the heads of regional authorities to discuss promotional activity; IV) cooperation by hosting special training sessions on both Codes, as part of courses, PhD studies and specialist Masters' courses; V) participation in national congresses hosted by Scientific Societies; VI) meetings with pharmaceutical companies to study the market situation and identify room for improvement in the self-regulation system; VII) in-company training sessions designed to meet the needs of the pharmaceutical companies; VIII) advise other business associations on self-regulation systems; IX) and sit on the editorial committee of the journal "Life Science Compliance".

In 2012 the Ethics Supervision Unit stepped up its advisory work and collaboration with scientific societies, and with the Technical Secretariats responsible for the organization of events, in an effort to secure the possible participation of pharmaceutical companies.

On 1 January 2012, a new version of the Code on Relations with Patients' Organizations came into effect; the main change affected Article 5 on Transparency. From now on, pharmaceutical companies are required to disclose not only the scope and nature of their collaborations and services rendered/contracted, but also the monetary value or the total amount spent on those items.

Advice and Cooperation

Relations between the pharmaceutical industry and healthcare professionals have a positive effect on services for patients and aid advances in research. In order to ensure that pharmaceutical companies meet the most stringent ethical requirements, as far as their professional activities and responsibilities are concerned, in June 2012 the EFPIA General Assembly ratified an initiative that sets out to bring greater transparency to the relations between the pharmaceutical industry and healthcare professionals. Since this commitment was adopted, the Ethics Supervision Unit has been talking an active part in the different WGs that were set up to launch, develop and implement the initiative.

1 September 2012 saw the coming into effect of the extended version of the Code of Best Practices of the International Federation of Pharmaceutical Manufacturers Associations' (IFPMA), a body that regulates the pharmaceutical industry's relations with healthcare professionals, scientific societies and patients' organizations worldwide. This new version of the Code not only covers the interaction between the pharmaceutical industry and other players, but also makes a clear distinction between gifts, promotional items and items that useful from a healthcare point-of-view; principles for the correct way of carrying medical training, plus a section the dissemination of information of clinical trials. The same document also contains guidelines for report irregularities, prohibits promotional activities related to medicines pending authorization or organizing shows (entertainment events) in the course of medical events sponsored by pharmaceutical companies, and also lays down guidelines on gifts for healthcare specialists.

Pharmaceutical industry/ healthcare professionals relations have a positive effect on patient services and on the development of medicines research

In addition, in compliance with the function assigned to it by the Self-Regulation Systems Governance Bodies (namely, "to carry out advisory tasks and to offer guidance and training, all related to the Codes"), the Unit has stepped up its collaboration and assistance by:

I) reviewing, adapting and improving the internal procedures implemented by the laboratories to guarantee compliance with the Code and the mandatory regulations on the promotion of medicines;

II) providing permanent and continued support for pharmaceutical companies and third parties involved, such as, and primarily, scientific societies, technical secretariats and service providers overall;

III) taking on an active role in meetings and forums hosted by FARMAINDUSTRIA with Autonomous Regions and the media;

IV) taking part in international meetings organized by the EFPIA and IFPMA, with the Ethics Supervision Unit Director as member of the Code Steering Group, Vice-President of the Compliance Committee, President of the EFPIA's Code Committee and President of the IFPMA Adjudication Group (The Court of First Instance in the Complaints Procedure of the IFPMA).

Five circulars were published in 2012 on the Code of Relations with Healthcare Professional and a further circular on the Code of Relations with Patients' Organizations.

Non-incident communications analyzed as a percentage of the total number of incidents reported came to more than 80% —a figure that is still relatively high

Control and Prevention

The number of preventive actions carried out in 2012 came to a total of 2,488 (643 less than in 2011), with only one reported incident compared with three in 2011. The reported case was eventually settled when the parties reached an agreement through the Ethics Committee's Mediation Agreement.

2012 saw a fall in the number of events that were analyzed; even so they exceeded the 5,000 barrier for the third year in a row: 5,003 in 2012, 332 less than in 2011. Similarly a drop was registered in reports received as regards both studies and services (512 and 330, respectively, as opposed to 626 and 357 in 2011). In any event, the percentage of reports analyzed without incident compared with the total reports made by pharmaceutical companies, in compliance with the Self-Regulation Governance Bodies' mandatory reporting requirements, continues to be high , in excess of 80% (87.7% for events, 81.2% for studies and 82.4% for services).

ETHICS SUPERVISION UNIT

Spanish Code of Best Practices in the Promotion of Medicines and the Pharmaceutical Industry's Relations with Healthcare Professionals and Patients' Organizations

Activity 2004-2012

		2004	2005 Abr-Dec	2006 Jan-Dec	2007 Jan-Dec	2008 Jan-Dec	2009 (a) Jan-Dec	2010 Jan-Dec	2011 (b) Jan-Dec	2012 Jan-Dec	Accumulated Abr 04-Dec 12
EVENTS	ANALYZED	945	1,747	2,199	2,926	3,388	3,878	5,080	5,335	5,003	30,501
	Without incidents	718	1,390	1,909	2,616	3,087	3,345	4,383	4,862	4,389	26,699
	% Adaptation	75.98%	79.56%	86.81%	89.41%	91.12%	86.26%	86.28%	91.13%	87.73%	
STUDIES	ANALYZED						687	724	626	512	2,549
	Without incidents						379	546	565	416	1,924
	% Adaptation						57.79%	75.41%	98.26%	81.25%	
SERVICES	ANALYZED								357	330	687
	Without incidents								282	272	554
	% Adaptation								78.99%	82.42%	
Preventive Actions		814	1,801	1,376	2,092	2,440	2,670	3,482	3,131	2,488	20,294
Cases reported to the ESU		18	11	9	18	8	12	4	3	1	84*

* 12 firm rulings by the Self-Regulation Panel in favor of the ESU.
* 62 rulings settled through mediation before the Ethics Commission acknowledging the irregularity and accepting corrective measures.
* 4 settlements between the parties prior to the Ethics Commission hearing.
* 5 filed at the request of the ESU.
* 1 not admitted by the Self-Regulation Panel.

(a) Studies Reporting System approved by the 2008 Code.
(b) Studies Reporting System approved by the 2010 Code.
NB. This table shows the Unit's data (annual and accumulated) as of the beginning of its activities until 31 December 2012.

Management of the EFPIA's "e4ethics" Platform

The EFPIA's "e4ethics" Platform, managed by FARMAINDUSTRIA, grew in 2012 and consolidated its standing as an EU pharmaceutical industry benchmark. The collaboration agreement between the EFPIA and FARMAINDUSTRIA envisages not only the technical support required for design, functioning and maintenance of the platform, but also the provision of advisory, analysis and consulting services to gauge the extent to which the events reported via this platform adapt to the conditions laid down by Article 9 of the EFPIA Code.

A clear sign of the platform's consolidation is the number of visits to its website (www.efpia-e4ethics.eu) and the exchange of emails that takes place via info-e4ethics@efpia.org, both of which are managed by the Association. In 2012, the platform received more than 70,000 visits (compared with the 6,300 since the web was launched in July 2011 until December of the same year), giving rise to the exchange of 5,300 emails (compared with 1,650 in 2H2011).

Also, the events reported to e4ethics increased, up to 237 in 2012 from 160 in 2H2011, amounting to a rise in the total number of evaluations, from 248 to 552. relations with European medical societies also improved considerable: in 2012 contacts were held with more than 65 societies, as opposed to 27 in 2011.

The Self-Regulation System Satisfaction Survey

In 1Q2013 a survey was sent out to the heads of pharmaceutical companies that take an active part in the Self-Regulation System, to get their point-of-view on a number of issues, such as the following:

I) how the different market players perceive the System;
II) how far the Code adjusts to companies' different activities;
III) the need for greater transparency and
IV) the levels of satisfaction as regards the governances bodies.

Most of the respondents thought that the Self-Regulation System benefits all players industry-wide, and that it has improved the pharmaceutical industry's image overall. They also expressed their overall satisfaction with the Governance Bodies' work, and showed their support for a possible increase in transparency in the different activities. Overall, the companies that took the Survey consider that the activities organized or sponsored by pharmaceutical companies meet the Codes' requirements.

The Survey also uncovered an area for improvement: the respondents suggested that the pharmaceutical industry's image could be enhanced by working harder to increasing the overall visibility of the sector's efforts to achieve higher standards of self-regulation.

3.3.5.
LABOR ISSUES

16th Chemical Industry Collective Bargaining Agreement

On 21 January 2013, in the wake of intense negotiations, FEIQUE (the Spanish Chemical Industry Business Federation), and union representatives at the Associations of Textile, Leather, Chemical and Related Industries (FITEQA) and the Federation of Industry and Farmworkers (FITAG) signed the content of the 17th Chemical Industry Collective Bargaining Agreement (CGIQ for short).

With the signing by Spain's two majority trade unions (CCOO and UGT), the 17th CGIQ is once again an Public Efficacy Agreement published as such in the Official Gazette, applicable to the companies and employees that fall within the CGIQ's functional scope. It should be underlined that, prior to signing the Agreement FITAG-UGT had already signed the 16th CGIQ (limited in its range) also signed by FEIQUE, COFACO and CC.OO., effective during 2011 and 2012.

Although this does not make the 16th CGIQ a General Efficacy Agreement, this labor union participation is important because it means that FITAG-UGT accepts the entire content of the Agreement, and this is what made the signing of the 16th Agreement possible in the following terms:

- Period: years 2013 and 2014.
- Wage increases: 2013, 0% and 2014, related to 2013 GDP figures, always providing it is higher than the 2012 GDP figure, in the following increments: if the 2013 GDP figure is lower than or equal to 1%, the 2014 wage increase will be 0.2%. If GDP rises by more than 1% in 2013, the 2014 wage rise will be 0.4%.
- Working Hours: The same as previous Agreements (1,752 effective working hours per annum).
- Mandatory Retirement: the elimination of mandatory retirement is a legal requirement.
- Stability: The legal period for the expiry of the Agreement, once the latter is revoked and there is no agreement on its renewal, has been extended from 12 to 24 months

The new negotiated content has been adjusted to Spain's current economic reality; moderate wage increases have been agreed, within the limits recommended by the National Agreement on Employment and Collective Bargaining (AENC) 2012-2014, at the same time safeguarding the value of the CGIQ as a useful and efficient tool for regulating labor relations within the pharmaceutical industry.

The 17th CGIQ was published in the Official Gazette on 9 April 2013.

With the signing of the 17th Pharmaceutical Industry Collective Bargaining Agreement by Spain's two main labor unions, the Agreement recovered its "General Efficacy" status, as published in Spain's Official Gazette. The Agreement is applicable to all the companies and workers that fall within its functional area

Labor Reform

Spain's labor reform has been a major issue in 2012. This reform was passed in the Council of Ministers of 10 February 2012 by RDL 3/2012 and was validated by Resolution 8 March 2012 prior to being forwarded for processing as a Draft Law. Following its debate, parliament passed Law 3/2012, 6 July, regarding urgent measures for Labor Market Reform.

3.4 INTERNATIONAL RELATIONS

3.4.1. THE EUROPEAN CONTEXT

FARMAINDUSTRIA's activities in the European arena focused primarily on the Association's participation in the EFPIA, which gives voice in Europe to 32 national associations and 35 pharmaceutical companies, consolidating FARMAINDUSTRIA's participation in 16 of the 29 committees and working groups that make up the European business organization, as well as taking part in all the meetings of its governance bodies: FARMAINDUSTRIA has a seat on all of them, namely the Board, the Executive Committee and Heads of Associations Committee.

The economic recession dominated the EFPIA's agenda for 2012; the latter focused on coming up with initiatives aimed at the following three goals:

· Ensuring the sustainability of the EU's National Health Systems;
· Boosting the innovative pharmaceutical industry's growth and competitiveness, and
· Taking on a commitment to the EU's Horizon 2020 research and innovation program, and to greater transparency in the industry's relations with healthcare professionals.

At the same time, the EFPIA's governance bodies gave the green light to its Strategic Plan 2012-2013. The latter centers on the following:

I) Developing national and EU-wide competitiveness policies in order to improve access to innovation by updating the EU regulatory model;
II) Guaranteeing security in the medicines distribution chain by setting up an EU-wide medicines traceability and verification system;
III) Recovering the pharmaceutical industry's role as a credible and trustworthy partner;
IV) Guaranteeing the EU's Industrial Property model as an incentive for innovation, and ensure entrepreneurial flexibility;
V) Meeting all environmental requirements, and
VI) Promoting a positive attitude towards data protection, in order to aid companies' scientific advancement and improve service for patients.

FARMAINDUSTRIA and LEEM (the association representing the R&D pharmaceutical industry in France) were called on to represent all of Europe's associations before the Board of the EFPIA, thus consolidating FARMAINDUSTRIA's presence in the upper echelons of the governance bodies, and giving the Association the vice-chair of the Executive Committee for a two-year period.

Meetings with the EFPIA Executive Committee

In 2012, the EFPIA Executive Committee intensified its activity. The Committee is a governance body made up of the European pharmaceutical company senior executives ("Heads of Europe"), and the Heads of the EU's main national associations, whose mission it is to implement activities and strategies, in line with the priorities set down by the Board.

The year saw a number of meetings aimed at optimizing synergies between the national associations and the EFPIA. Apart from the usual analysis and monitoring of the international markets as regards measures aimed at containing included public pharmaceutical spending, activities focused mainly on the following:

I) hospitals debt in the Mediterranean market,
II) the different regulations concerning the obligation to supply pharmaceutical products in Europe, and
III) the need to step up engagement with the European Commission's Directorate-General for Competition.

The Executive Committee also addressed other issues, namely a more strategic line of action focused on developing actions aimed at giving rise to a new European industrial policy for innovative pharmaceutical companies, promoting framework agreements with national governments on the basis of economic indicators adjusted to market reality, and, at the same time, excluding from international price references countries that have been bailed out or that have been forced to take exceptional measures to reduce their public deficits.

Furthermore, and within the framework of direct relations with national associations, and to improve the coordination of industry strategies, several Spanish Country Team meetings were held, in which FARMAINDUSTRIA addressed a number of issues of interest to the industry overall and initiatives concerning a structural solution to hospitals debt, brand positioning and reconciling SNS sustainability and innovation.

Growing concern on hospitals debt in Europe's Mediterranean area gave rise to a new EFPIA working group, to which FARMAINDUSTRIA and other national associations report regularly on progress in this area. In this respect, the Suppliers' Payment Plan launched in Spain in mid-2012 was pointed to as a model for other countries with similar problems.

Multilateral and Bilateral Meetings

Last year saw two events that gathered the national associations of the five main European markets, namely Germany, France, Italy, Spain and the United Kingdom. On both occasions, the associations' representatives seized the opportunity to exchange fresh information on the recent cost-cutting measures taken by their respective governments, and best practices in strategic talks with public administrations, promoting stable and predictable scenarios for the innovative pharmaceutical industry. Similarly, special bilateral working sessions were held with the national associations of Italy, Portugal, Greece and the UK to identify and implement best practices in the internal and external workings of the national associations, leveraging to the full the impact of their strategies and actions in an environment of budgetary austerity.

FARMAINDUSTRIA and the French R&D pharmaceutical industry association, LEEM, were chosen to represent all of Europe's associations before the Board of the EFPIA

Legislative Initiatives in the EU

Progress on EU legislative initiatives in 2012 was led by the priorities defined by the Danish and Cypriot EU-presidencies. There follows a list of EU initiatives with direct implications for the pharmaceutical industry.

The EU Directive on Pharmacovigilance

This directive was adopted in 2010, and the member-states have been working since July 2012 on its transposition to their respective legal environments.

At the same time, the European Commission worked on drafting a legal document aimed at putting a triangle symbol on the information leaflets for certain medicinal products. This symbol is an easy way of telling patients and healthcare professionals alike that patients taking these medicines must be monitored carefully and that any unexpected adverse reaction must be reported through the established national information channels.

Directive 2011/62/UE of the European Parliament and of the European Council on falsified medicinal products

Adopted in June 2011 after its first reading in the European Parliament, the Directive introduces a number of provisions, not least among them the obligation of member states to display safety measures on prescription medicines (and on OTC products considered high-risk, enabling their individual identification, along with safety devices. These safety measures must be replaced by other similar ones when the product is re-packaged.

Although the general aspects of the Directive are already being adapted to members states' local laws, the Commission continues to work on various fronts:

I) three guides on best practices in the manufacture of excipients, best distribution practices for intermediaries, and principles for inspections in third countries;
II) an Act to Implement (EU-wide logo for safety in online medicine sales), and
III) five Delegated Acts (characteristics and technical specifications of safety measures; a list of prescription medicines that need not adopt these measures, as well as OTC medicinal products are under obligation to adopt these measures; a procedure for reporting suspect medicines, a fast-track evaluation and decision-making process for suspect medicines; means of verification of safety measures applied by manufacturers, distributors and pharmacies; and the setting-up, management and accessibility to a data repository).

Growing concern on hospitals debt in Europe's Mediterranean area gave rise to a new EFPIA working group

The Delegated Acts will be published sometime in the coming months; member states have between three and six months for their effective implementation depending on whether or not the member states have national identification and/or traceability systems in place.

As part of its efforts to develop these points, this year the European Commission launched four public consultations:

I) criteria for customs seizure of medicines not intended for sale in the EU;
II) importing active ingredients into the EU;
III) best practices in the manufacture of active ingredients , y
IV) safety measures + a single identifier and verification system.

As regards safety measures, Spanish authorities filed a response document highlighting among its priorities the authorities' preference for the Datamatrix system as a means of verifying medicines, as well as the possible exclusion of medicines with national authorization that are on sale exclusively in Spain (this would mean considerable savings for

the smaller companies). Similarly, they advocated for a governance system with the direct involvement of the authorities of each member state.

At the same time, FARMAINDUSTRIA is working alongside the EFPIA on the design of a European Stakeholder Model (ESM) based on a European center connected to national and overseas databases that, by means of contracts with binding services, guarantee the required interoperability, functioning and levels of security. Moreover, the European Medicines Verification Organization (EMVO) will run the European center and its attendant resources.

In an effort to make this Directive and the ESM better-known and to further their implementation at the national level, FARMAINDUSTRIA and the EFPIA organized several information sessions on "The Future of Traceability in the EU"; the sessions provided information on new RDs that regulate the distribution of medicines for human consumption and the distance sale of medicines, as well as updating RD 824/2010 on the manufacture and importing of medicines and active ingredients. Other participants in the events included the Spanish Agency for Medicines and Healthcare Products (AEMPS).

Importing active ingredients from third countries

One of pharmaceutical companies' biggest concerns is the coming introduction of the new requirements for importing active ingredients from third countries, scheduled for July 2013.

The Directive states that the only active ingredients that can be imported into the EU are the following:

I) those that come from third countries on the EC-approved list because they meet public health safety standards equivalent to those in place in the EU[1],
II) those that come from third countries not on the EC-approved list but whose authorities are capable of producing written confirmation certifying that the active ingredients' manufacturing plant meets standards equivalent to the EU's Good Manufacturing Practices and that the plant undergoes regular, stringent and efficient checks (regular inspections), and
III) in exceptional circumstances, and at the request of a member state to guarantee the supply of a certain medicine, it is allowed to import an active ingredient from a plant in a third country, providing that plant has been previously checked and passed by EU inspectors.

At the time of drafting this Report, the following countries had applied to the European Commission: Switzerland, Japan, the United States, Israel, Australia, Singapore and Brazil. Switzerland is the only country on the list so far.

In view of the date set for the implementation of this EU provision, and considering the workload that this new requirement implies, the European pharmaceutical industry has questioned the capacity of some third countries to provide the corresponding certifications. Accordingly several national associations have requested them to collaborate with public health authorities in identifying the active ingredient manufacturing plants that might be affected.

[1] At the time of drafting this Report, the following countries had applied to the European Commission: Switzerland, Japan, the United States, Israel, Australia, Singapore and Brazil. Switzerland is the only country on the list so far

In this respect, FARMAINDUSTRIA, in coordination with the EFPIA, informed its associates that it might be convenient if medicinal products manufacturers in Spain were to complete and then forward a form on the manufacturing plants of their active ingredients suppliers in third countries, using a form designed by the Directors' Group of the European Medical Agencies.

Similarly, it was decided that the pharmaceutical companies should expressly request the respective national agencies to provide details of the corresponding official inspections of active ingredient manufacturing plants in third countries, not included in the abovementioned circumstances.

The European Commission continues to shift a very heavy workload, including bilateral meetings with the main countries affected, in an effort to ensure the uninterrupted supply of active ingredients to the EU, in the strictest compliance with the new requirements laid down by Directive 62/2011.

The Informed Patient's Directive

Member states' failure to reach an agreement, and the reservations expressed concerning some of the measures, meant that the proposal was not on the agenda for any of the EU Presidencies in 2012. As a result, the initiative has been scrapped to all intents and purposes.

Review of the Transparency Directive

In early 2012, following the mandatory public consultation period, the CE published a revised proposal of Directive 89/105/CEE, regarding the transparency of the measures intended to regulate price and reimbursement of medicines, "to give patients speedy access to medicines". The proposal set out to shorten the national decision-making periods on prices and recall, from the current 180 days to 120 days in the case of innovative medicines, and to 30 days in the case of generic drugs, including penalties when member states fail to meet those deadlines, "which is a regular occurrence", according to the Commission. FARMAINDUSTRIA believes that the proposal is very positive; however the Association emphasizes the need to continue to improve patients' access to innovations.

The EFPIA, in coordination with FARMAINDUSTRIA, has drawn up a position document that FARMAINDUSTRIA forwarded to the corresponding national authorities and to the Spanish Euro-MPs responsible for processing the directive, highlighting, among other points, the need to abide by the period proposed by the Commission.

The European Unitary Patent

In July 2012, during the European Growth Summit, 25 member states reached an agreement on the erstwhile Community Patent. Spain and Italy both appealed against the language regime and opted to stay out of the agreement. Among the measures adopted, one stands out in particular, namely the setting-up of a Unified Patent Court (UPC). The latter will be based in Paris; however, owing to the technical complexity of the legal proceedings, themed courts have been set up in Munich (Mechanical Engineering) and London (Health Sciences, including pharmaceutical patents). The Community Patent will be processed and granted by the European Patents Office (EPO).

One of the objectives of the Draft Directive on Transparency is to shorten the established periods for national decision-making on prices and reimbursements, from the current 180 days to 120 days in the case of innovative medicines

Similarly, the European Parliament adopted in a plenary session held in December 2012, a raft of legal measures on this initiative (two regulations and a language regime), later ratified by the Council. The process will end with the signing of an Inter-government Agreement that will, in turn, lead to the creation of a Single European Patent Court, signed by all the member states, with the exception of Spain, Poland and Bulgaria. It should be said that the Advocate-General of the European Court of Justice published its ruling dismissing the appeal lodged by Spain and Italy that sought to make void the language regime adopted by means of the enhanced cooperation procedure.

As regards Industrial Property, in October 2012, the Spanish coastal city of Alicante hosted the first plenary meeting of the European Observatory on Counterfeiting and Piracy, held at the Office of Harmonization for the Internal Market (OHIM). At the meeting, FARMAINDUSTRIA and other Spanish and European stakeholders addressed a range of issues, not least the different methodologies used to compile statistics on industrial and intellectual property infringements in the EU. FARMAINDUSTRIA seized the occasion to make clear the priorities of the innovative pharmaceutical industry in Spain and the EU.

Personal Data Protection

In 2012, the European Commission announced its intention to upgrade and modernize Directive 95/46/EC, on the protection of individuals with regard to the processing of personal data and on the free movement of such data, aimed at presenting a new legislative proposal (in the shape of a regulation) before 2014.

Following the proposal's publication in January 2012, the pharmaceutical industry expressed its satisfaction with the Commission's efforts to strengthen the harmonization of data protection requirements in the EU, given that the lack of consistency in the application has severely hampered the pharmaceutical industry's efforts to leverage its full potential for biomedical research; the industry also listed the specific stumbling blocks to compiling and reporting data on the security of medicines.

The EFPIA and FARMAINDUSTRIA teamed up to roll-out a coordinated action with stakeholders across Europe in order to develop and transmit a common position capable of guaranteeing the adoption of a practical focus. Overall, the aim is to ensure that the data used in biomedical research continue to enjoy a privileged position in the Regulation, thus doing away with red tape, duplicated evaluations and restrictions on use.

Directive 2011/24/UE on the application of patients' rights in cross-border healthcare. Recognition of prescriptions issued in another Member State.

After the EC published the summary findings of the public consultation on measures for improving the recognition of prescriptions issued in another Member State, FARMAINDUSTRIA took part in a meeting hosted by the Spanish Ministry of Health, Social Services and Equality on the transposition of this Directive, adopted in April 2011. Representatives of the European Commission and the Ministry of Health who delivered presentations on the reforms that are set to stem from the transposition of this Directive. Towards the close of the event, the floor was opened to discussion and FARMAINDUSTRIA used the occasion to convey the European pharmaceutical industry's position, particularly as concerns recog-

nition of prescriptions issued in another Member State, and highlighting the importance of guaranteeing brand-name prescriptions EU-wide.

Lab experiments on animals. The next steps ahead.

Following the approval of Directive 2010/63 on the protection of animals used for scientific purposes, the EFPIA and the national associations focused their efforts on monitoring the transposition to the respective national laws to avoid the adoption of provisions of a local nature that would duplicate the ones already included in the Directive and increase red tape.

Similarly, the EFPIA, alongside FARMAINDUSTRIA, actively promoted the implementation of this Directive through a range of activities, namely training opportunities, communication activities, exchange of best practices and actions aimed at cutting away red tape; at the same time, it spurred coordinated efforts to set up an EU-wide network of benchmark research centers on animal research.

The EFPIA's training and dissemination schedule featured a Guide to the Directive aimed at pharmaceutical company executives and other interested stakeholders. These actions set out to enable self-assessment of the levels of effective implementation of the so-called "Three Rs" in R&D, brought to the process by different players:

I) Replacing animal testing with other models, always providing that it is scientifically possible;
II) Reducing the number of animals required for the tests, and
III) Refining techniques that avoid or minimize the discomfort and/or suffering of the animals used in research.

The pharmaceutical industry expressed its satisfaction with the Commission's efforts to strengthen the harmonization of data protection requirements in the EU

Review of the Clinical Trials Directive

In July 2011, the European Commission published a Proposal for a regulation on clinical trials for human use and the repeal of current EU Clinical Trials Directive (2001/20/EC), and aimed at simplifying the regulation on clinical trials and fostering clinical trials across the EU.

The measures included in the Proposal speed up and simplify the authorization and notification procedures, while ensuring maximum safety for patients, and providing accuracy and consistency in the data. In addition, the Proposal provides a better distinction of obligations, according to the risks involved in the trials, and also increases transparency in trials conducted in third countries. The Commission's new draft law comes in the legal form of a regulation (direct application); it guarantees that the requirements concerning clinical trials are identical across the EU, thus clearing the way for multinational clinical trials within the Union. FARMAINDUSTRIA warmly welcomes the proposed regulation, and underlines the importance of seizing this unique opportunity to recover the EU's role as a ground for clinical trials. In the period 2007-2011, the number of clinical trials in the EU fell by 25%, according to EFPIA data.

The Proposal also envisages the creation of a single e-portal for the digital transmission of the study documentation within the EU; this would take away part of the mass of paperwork currently involved in information transmission. Similarly, a European database

would be set up bringing together all the documentation for the study, making access to information and the follow-up process much easier.

However, the Proposal does not lay down provisions for neither the workings nor the coordination of Ethics Committees on Clinical Research. Nor does it envisage the common, single transmission of documentation for different studies currently under way on the same product, nor the use of English as the EU's common scientific language.

The EFPIA and the USA's Pharmaceutical Research and Manufacturers of America (PhRMA) trade group published a joint position statement, which was distributed by FARMAINDUSTRIA among its member companies. The document highlighted the transparency currently displayed by pharmaceutical R&D processes and also called for initiatives of this nature to be carried out with all due precaution to guarantee patients' rights and the defense of Industrial Property rights.

Biotechnology

The biotech member-companies of the European Biotechnology Enterprises (EBE), which come under the EFPIA umbrella, have focused their efforts on improving the framework in which SMEs carry out their activities. Accordingly, during the debate on the Regulation Proposal for Clinical Trials during the month of July, the EBE supported and welcomed the creation of a single portal for checking applications for clinical trials, thus closing the gap between large corporations and SMEs; in the EBE's opinion the latter have been blighted by regulatory charges in Europe.

The measures included in the Proposal on Clinical Trials speed up and simplify the authorization and notification procedures, while ensuring maximum safety

It is also worth highlighting the document-manual on stem cells published by the EBE. This publication aimed at being a reference for companies during their dialog with the European and national authorities on research with regard to future EU research programs (Horizon 2020). Generally speaking, FARMAINDUSTRIA and the EFPIA acknowledge that despite the possible ethical concerns raised, research in this field must be carried out under strict control, and steps must be taken to ensure that the potential of this kind of research benefits patients.

Competitiveness and internationalization

FARMAINDUSTRIA coordinated its efforts in this field with the EFPIA and the Working Group of the same name. Further information is available in other chapters and sections of this Annual Report.

The EFPIA participated in the international arena through its Foreign Trade Committee (in which FARMAINDUSTRIA participates actively), as well as in talks on Free Trade Bilateral Agreements, or high-level meetings on Industrial Property and Trade.

EU-USA Priority Trade Agreement

This Agreement was launched officially in 2013 by the European Commission and FARMAINDUSTRIA contributed to it by conveying the pharmaceutical industry's position with regard to three lines of actions, namely:

I) greater progress on regulatory harmonization;

II) excise duty exemption on molecules used in research, and
III) respect for Industrial Property rights.

EU-Canada Priority Trade Agreement (CETA)

This Agreement has seen scant progress. Its most relevant aspects as far as our sector is concerned are as follows:

- recognition of the security levels of the EU's Supplementary Protection Certificate;
- recognition of the periods concerning data protection rights, and
- the effective implementation of the right to appeal for innovators in the event of patent violations.

In addition, in 2012 FARMAINDUSTRIA was behind the three meetings between the three permanent Spanish delegations in Brussels and Canada's innovative pharmaceutical industry negotiating team (Rx&D).

EU-Japan Free Trade Agreement

In November 2012, the EU's Council on Trade decided to open talks on a Free Trade Agreement between the EU and Japan. For the past two years, the EFPIA has been holding regular meetings with Commission members and Japan's regulatory bodies as part of negotiations aimed at reaching an agreement. On the side of the European pharmaceutical industry, the negotiating team drew up an ad hoc road map with a number of priorities, such as transparency and predictability in the price and reimbursement processes, or mutual recognition in the sphere of Best Manufacturing Practices.

EU-India Free Trade Agreement

Both the EFPIA and FARMAINDUSTRIA carried out a number of actions at the European and national levels, highlighting the fundamental importance of the pharmaceutical industry for both territories.

Russia

After joining the World Trade Organization (WTO) in February 2012, there are a number of issues pending concerning the innovative pharmaceutical industry:

I) the non-alignment to EU levels of the time-limits for the protection of data on medicines;
II) the lack of transparency in time-limits and criteria for admission to national reimbursement lists;
III) the preference for local manufacturers;
IV) the requirement to conduct clinical trials at the national level.

The EFPIA played an active role in a number of meetings between the corresponding Department of the EU's Trade Directorate–General and the Russia authorities on these issues.

The EBE supported and welcomed the creation of a single portal for checking applications for clinical trials, thus closing the gap between large corporations and SMEs

In 2012 FARMAINDUSTRIA's activities with the IFPMA focused on work with the Innovation, Industrial Property and Trade Committee; the Socio-economic Research Network; Global Healthcare, Communication, and the IFPMA Code of Best Practices

3.4.2. THE INTERNATIONAL ENVIRONMENT

FARMAINDUSTRIA's international activities are channeled through the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and FARMAINDUSTRIA has a seat on its governance bodies (The Council and the General Assembly), and on the Steering Committee.

The Federation's activity revolves primarily around a number of Committee's and Working Groups, of which FARMAINDUSTRIA is an active and regular member. In 2012 FARMAINDUSTRIA focused on work with the Innovation, Industrial Property and Trade Committee; the Socio-economic Research Network; Global Healthcare, Communication and the IFPMA Code of Best Practices.

Last June's IFPMA Council Meeting set priorities for the period 2012-2013; the most relevant are as follows:

I) initiatives for Non-Transmissible Diseases (NTDs);
II) the global fight on counterfeit and piracy;
III) the harmonization of Industrial Property regulation;
IV) R&D partnerships with developing nations;
V) biosimilar products, and
VI) the ongoing review of the Code of Best Practices.

Diseases affecting the Third World. The IGWG, a new Expert Advisory Group.

Last May, during the WHO's 65th General Assembly, the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) presented its conclusions on alternative financing for R&D on diseases that affect the Third World.

The IFPMA carried out intensive institutional and communication efforts in an attempt to ensure the presence of the innovative pharmaceutical industry in this process. One of the key lynchpins of this strategy was the publication of the report entitled "Assembling the pharmaceutical R&D puzzle for needs in the developing World"; the latter lays out in detail a number of ground-breaking proposals aimed at encouraging R&D on this kind of disease, as well as for evaluating its practical application and its potential efficiency.

The Report presented by the CEWG lays out six proposals, but does not include a binding global R&D consortium (the former Agreement on R&D), which would force certain countries to cooperate with a percentage of GDP. In accordance with the conclusions that were presented, the WHO adopted a final resolution which made no direct reference to the specific legally-binding instruments in this sphere.

Since then, the IFPMA has published two new reports, namely:

- "Policies that encourage innovation in middle-income countries 2012"
- "Pharmaceutical R&D Projects to Discover Cures for Patients with Neglected Conditions".

Both publications (also available online in digital format) detail a range of pharmaceutical industry actions being carried out, as concerns both access to medicine and research into the Third World's predominant diseases.

The worldwide fight on counterfeit medicines

In 2012, activity in this field centered on the new international mechanism for the fight on counterfeit medicines, led by a number of States, and for which the WHO is an advisory body. The first official meeting convened in Argentina in November 2012, and ended without an agreement.

Regardless of this inter-governmental group's activities, the IFPMA's strategy continues to rest primarily on actions designed to create a wide-scale international agreement on the fight on counterfeit medicines under the auspices of the United Nations or a UN agency. At the regional level, efforts were made to compile official data on reported cases of counterfeit medicines, and to organize tailored regional awareness campaigns, with the accent on internet medicine sales.

The IFPMA's strategy aims at creating a wide-scale international agreement on the fight on counterfeit medicines under the auspices of the United Nations or a UN agency

Non-Transmissible Diseases (NTDs)

The IFPMA collaborates closely with the WHO and member states on the implementation of "Plan 25x25", adopted in May 2012, and which sets out to reduce the mortality rate of these diseases by 25% by the year 2525.

Accordingly, the IFPMA Council adopted a strategic framework on Non-Transmissible Diseases featuring a range of actions and initiatives to be developed alongside stakeholders during 2012-2014. In essence, this framework strategy has a threefold objective:

I) to position the IFPMA and its members as allies in the quest for solutions that help meet the challenges posed by NTDs, by cooperating with national governments, UN bodies and other major players;
II) display and obtain recognition for the efforts of IFPMA members in the fight on NTDs and to keep up a constructive and permanent dialog on the need to preserve incentives for innovation, and
III) raise awareness on the extreme complexity of the strategies with which to approach the fight on NTDs.

4. SIGRE MEDICINES AND THE ENVIRONMENT

SIGRE Medicamento y Medio Ambiente, S.L. [SIGRE Medicines and the Environment S.L.], or SIGRE for short, is a not-for-pofit organization created under the auspices of FARMAINDUSTRIA that functions with the active participation of the entire range of industry players (pharmaceutical companies, pharmacies and distrution outfits).

Through SIGRE, pharmaceutical companies comply with current environmental law (Laws 22/2011 on Waste and Land Pollution, and1/1997 on Packaging and Packaging Waste), and public health law (Law 29/2006 on Guarantees and the Rational Use of Medicines); SIGRE ensures the proper environmental management of packaging waste and leftover medicines generated by private households.

On 31 December 2012, SIGRE comprised 284 member pharmaceutical companies, making it possible to establish a safe and convenient means of succesfully completing the life-cycle of medicines.

The Urgent Environmental Measures Law

As a result of the processing of RDL 17/2012, on Urgent Environmental Measures, the Spanish Lower House passed Law 11/2012, 19 December, making important amendments to Law 22/2011 on Waste and Land Pollution.

One of the major changes concerned the manufacturer's greater responsibility over waste management. The legal figure was clearly defined; so too were criteria for integrating the manufacturers in the collective systems, the authorization procedure and the particpation mechanism for manufacturers and other economic players .

This way, the collective systems, known formerly as Integrated Management Systems, are required to adapt to the rules established by the corresponding legal figure, guaranteeing the particpation of manufacturers according to objective criteria, as well as their rights to information, to formulate allegations and their resoultion in accordance with existing regulations.

Similarly, the law envisages, with regard to each waste flow, the particpation of distributors and other economic players in the collective systems.

Framework Bye-Law on Waste Collection

The Spanish Federation of Town and Provincial Councils (FEMP for short) drew up a Framework Bye-Law on Waste Collection that helps Local Councils to adapt to the new legal framework on the collection, transport and management of waste generated by households, commercial establishments and services.

As regards medicines packaging waste and leftover medicines in private households, the FEMP welcomes the management system introduced by SIGRE, for its numerous environmental and socio-sanitary benefits.

Accordingly, Article 19 of the Framework Bye-Law on Waste Collection establishes the following: "Users will return expired, unused and leftover medicines and their packaging to the SIGRE collection points at pharmacies that offer them"

Similarly, it indicates that if collection points are unavailable locally, users may dispose of this kind of waste at their local Municipal Waste Collection Point. Nearly 98% of the Spanish population has a local pharmacy and there are more than 21,000 SIGRE Collection Points availabe in pharmacies up and down the country.

Annual Environmental Statement 2012

Every year, SIGRE presents an Annual Environmental Statement to the respective Environment Departments of Spain's various Autonomous Regions. The Statement presents the results of SIGRE's contribution to the overall recycling and reuse goals set by Spain's Packaging Law: I) the number and total weight of medicines marketed; II) the weight of the waste (medicines packaging and others) collected, and III) the environmental processing of each of the fractions obtained during the classification process.

In 2012, SIGRE Collection Points located at pharmacies collected an average 79.8 grams/inhabitant of packaging and assorted medicines waste (including non-applicable waste such as para-pharmaceutical products, batteries, glasses and others), placing Spanish households among the EU average.

There are more than 21,000 SIGRE Collection Points available to the general public in pharmacies up and down Spain

At the same time, thanks to the introduction of new waste classification processes, there was a significant rise in the percentage of materials for recycling, going from 33.7% in 2011 to 50% in 2012.

In addition, Spain's pharmacuetical industry stepped up its efforts to reduce the environmental impact of its medicines packaging, according to the results of the Corporate Prevention Plan (CPP) 2009-2011 and the new targets set by the CPP for 2012-2014.

Despite a number of legal, technical, economic and design-related limitations, during the first year of CPP 2012-2014's application, the total weight of packaging went down yet again, this time by 1.82%.

OVERALL REDUCTION (%) IN 2012

	2011	2012	Overall reduction (%)
Kr: total amount, in weight (kg of medicines packaging waste generated in a year)	66,054,081	62,517,259	
Kp total amount, in weight (kg of packaged products consumed in that same year)	100,238,202	96,667,576	
(Kr/Kp) overall	0.659	0.647	-1.82%

It should be underlined that since 2000, the year when PEP's were first implemented, SIGRE member companies have applied a total 1,207 measures, affecting a total 339,000,000 packaging items, and have optimized their dimensions, reduced their weight or used more recyclable materials. Thanks to these measures, the period 2000-2012 saw pharmacuetical products packaging reduce their weight by more than 22%.

New medicines waste and packaging treatment plant

In January 2012, BIOTRAN Gestión de Residuos (BIOTRAN Waste Management) became SIGRE's official provider of a number of services including the collection, classification and environmental treatment of medicines packaging and returned to SIGRE Collection Points located at pharmacies.

These waste products are being managed at the new BIOTRAN-owned Medicines Waste and Packaging Treatment Plant in Tudela de Duero (Valladolid, central Spain).

This highly innovative and automated plant optimizes waste management processes and leads to not only significant cost savings, but also a substantial increase in the percentage of recycled packaging (cardboard, plastic, glass, etc.).

This new facility is authorized to manage pharmacuetical products waste such as non-specification drugs, expired medicines, para-pharmacy products, etc.

The new medicines waste and packaging treatment plant and its Board of Directors

R&D and Innovation Project on Waste Management Improvement

SIGRE and BIOTRAN, with the help of the CARTIF Technological Center and financing from Spain's Center for Industrial Technological Development (CDTI), have rolled-out an R&D and

Innovation project that sets out to improve the environmental treatment of pharmaceutical blister packs.

With the introduction of new techniques for separating materials, the project aims at increasing the recycling percentage of components (plastics and aluminum) of a type of packaging that is commonplace in the pharmaceutical industry.

Environmental Awareness Campaigns

One of SIGRE's main functions is to carry out campaigns designed to raise awareness among consumers and users to encourage them to collaborate with dealing correctly with pharmaceutical products waste. Ultimately, these efforts are aimed at helping to meet the overall waste reduction, recycling and reuse targets set by the law.

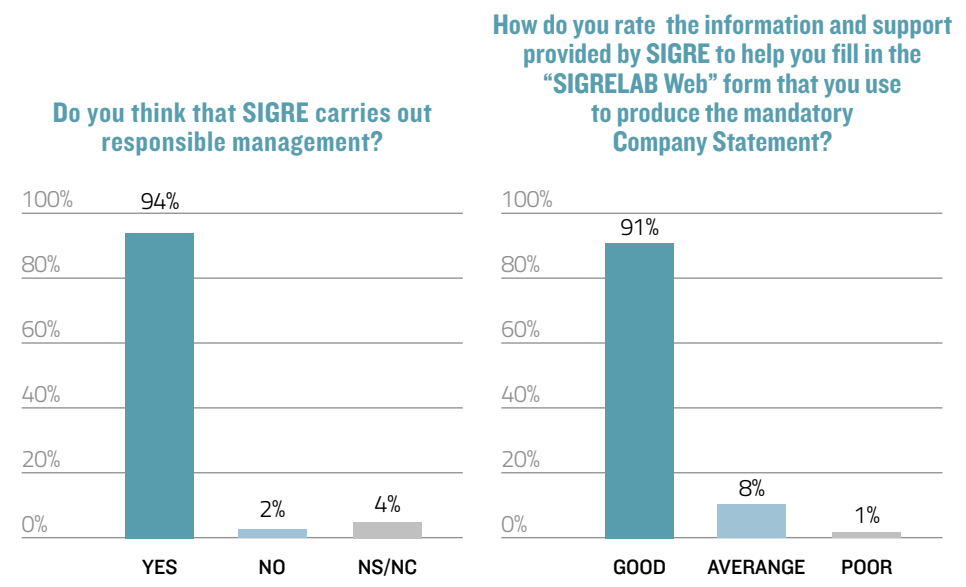
Accordingly, in 2012 Sigre committed to continuing its existing communication campaign, entitled "Recycling Medicines: A Healthy Habit", which first got under way in 2010. The main messages have been reinforced and show society at large how waste collected at the SIGRE Collection Points located in more than 21,000 member pharmacies is treated.

To support this communication campaign, SIGRE carried out a range of actions aimed at reaching out to new audiences, namely agreements with publishing houses to take the SIGRELANDIA web page (www.sigrelandia.es) to classrooms; organizing the 2nd Annual Audiovisual Competition "Giving medicines a happy ending", and collaborating with bloggers on social networking sites.

Pharmaceutical Companies' Opinion Survey 2012

The Survey was conducted in December 2012 among pharmaceutical companies' Environment Department heads and set out to find out what they thought of the service provided by SIGRE and to see what they knew about this particular environmental activity.

The main findings of this bienial survey show that 96% of the respondents are satisfied with their professional dealings with SIGRE and that 8 out of 10 belive that SIGRE's activities help spread the word on the pharmaceutical industry's commitment to the environment.



12th Annual Information Sessions

SIGRE held its 12th Annual Information Sessions for Member Companies on 19 and 21 June 2012 in Barcelona and Madrid, respectively. These special sessions drew a large audience made up of pharmaceutical industry representatives, and highlighted the most relevant aspects of SIGRE's activities.

The Information Sessions not only weighed up progress and highlighted the main challenges ahead, but also looked closely at recent changes in environment law that affect the sector; the industry's actions on medicines packaging risk prevention and the main milestones achieved, and SIGRE's Corporate Social Responsibility performance.

The new Medicines Waste and Packaging Treatment Plant and the new method for the reuse of pharmaceutical products waste in cement factories, applied by SIGRE, came under the spotlight during the Information Sessions.

Lourdes Martínez, Director-General of the Madrid Regional Department for Environment Quality, officialy opened SIGRE's 12th Annual Information Sessions

Forums and Conferences

SIGRE is a regular at a number of forums and conferences where it spreads the word on the pharmaceutical industry's efforts to protect the environment.

In 2012, SIGRE took part in the CONAMA National Congress on the Environment and the 18th National Pharmaceutical Congress, as well as special courses and lectures at a variety of universities.

Similarly, SIGRE sits on the Executive Committee of the Spanish Network of the UN Global Compact; it is a member of the Spanish Environment Club, and has a seat on the Technical Committee of AENOR Standardization/AEN/CTN 49 for standardization in packaging waste management, terminology, distribution and transportation, tactile markings and design.

In addition, SIGRE, in its role as an international benchmark in household waste management generated in the home, was invited by Brazil's National Pharmaceutical Association to take part in the World Social Forum, a globally respected event on economic, social and enviromental issues.

Corporate Social Responsibility

The creation of SIGRE by FARMAINDUSTRIA is an accurate reflection of the entire pharmaceutical industry's willingness to embrace the spirit of social responsbility, having take on a mission that goes well beyond legal requirement on the environment.

SIGRE has committed to identify and meet the expectations of this environmental and healthcare intiative's different stakeholders and takes on the responsibility for the impacts that it has on society at large.

True to this commitment, in 2012 SIGRE carried out the following actions: I) it published its 2011 CSR Annual Report (www.memoriasigre.es), with GRI Application Level "A"; II) it compiled its 3rd Global Compact Communication on Progress, obtaining "Advanced" level, the UN's highest rating, for the implementation of principles and the transparency of the porgress reports, and III) its renewed its four-fold AENOR certfication for its Quality, Environment, Energy Efficiency and Occupational Risk Prevention systems.

02.
THE PHARMACEUTICAL INDUSTRY IN SPAIN AND THE WORLD

1. THE PHARMACEUTICAL INDUSTRY IN EUROPE

The evolution of the European pharmaceutical market over recent years cannot be looked at separately from the current economic environment. After thirteen successive years of economic growth (1996-2008), EU activity fell sharply in 2009 (-4.3%) as a result of the economic and financial recession that started in America midway through 2007 and which eventually spread to the rest of the world. Since then, the EU economy has made very erratic progress, alternating between periods of modest growth in 2010 and 2011 (+2.1% and +1.5%, respectively), with new dips in activity, such as in 2012 (-0.3%).

In 2012, a close look at growth rates shows that in all the main EU countries (with the sole exception of the UK), the worst slowdowns appeared in the final quarter of the year, which does not bode well for 2013.

Economic slowdown in 2012 led to a higher EU unemployment rate, which went from 9.7% in 2011 to 10.5% in 2012, the worst figure in the recorded history of unemployment in the Union.

Higher unemployment led, in turn, to lower direct and indirect tax revenues and to greater public spending in the way of state subsidies, jeopardizing the deficit targets taken on by the member states. This circumstance leads to a huge lack of confidence by the financial markets, further aggravated by the possibility that the exceptional adjustment measures introduced by the member states with the worst imbalances were to end up hitting growth particularly hard, which would lead, in turn, to higher financing costs for the sovereign debt of the member states. This vicious circle is being felt particularly in the EU's peripheral countries.

In 2012, and for the second year running, the European pharmaceutical markets registered the sector's worst anywhere in the world

In view of these circumstances, growth forecasts for 2013 are nothing short of gloomy: the European Commission, in its "European Economic Forecast - Winter 2013", predicted a +0.1% increase in EU GDP growth in 2013.

This situation, along with the fact that the economic policies being put into practice at the moment are all focused on budgetary adjustments, is having a noticeable effect on the pharmaceutical market, highly dependent as it is on public spending and economic regulation.

In turn, the measures taken to rein in public pharmaceutical spending in EU countries, and aimed, in most cases, at lowering medicine prices, are having a cascade effect on those countries where medicine prices are indexed to those in other EU countries. And, in addition, in the past few years the patents on many high-demand medicines are running out.

All of the abovementioned difficulties have impacted the growth of EU pharmaceutical markets. So, for example, the latest "World Pharma Market Summary", published by the firm of consultants IMS Health, reveals that end-2012 data show that, for the second year in a row, the EU's pharmaceutical markets shrank more than any other in the developed world, registering a figure of 2% negative growth, trailing considerably behind markets such as Latin America (+18%), Australia (+3%), or Asian players such as China (+21%), India (+11%) or even Japan (+1%).

Despite the current context, the pharmacuetical industry has what it takes to make a positive contribution to European economic growth

In any case, despite poor performance by EU markets, the pharmaceutical industry's own peculiarities (a highly innovative, research intensive sector, highly productive, capable of creating qualified employment, and highly dynamic when it comes to foreign trade) combine to offer sustained, above-average growth in any country.

Even so, it comes as something of a paradox to see that, in economic terms, the EU pharmaceutical industry performed below average in 2012: the sector registered -2.1% negative growth in the EU's five main countries, in stark contrast to the progress made in nominal GDP in those same countries (up +2,3% in 2012).

In addition, 2012 was the second consecutive year of negative growth for the EU pharmaceutical industry (following the 1% dip registered in 2011), despite increases in both population growth and life expectancy across the Union.

PHARMACEUTICAL MARKET PERFORMANCE IN THE MAIN EU COUNTRIES

	Δ 2012/2011 (%)	Product sales as a percentage of total sales in the top 5 EU countries. 2012
Germany	+1%	35.3
France	-2%	25.8
United Kingdom	-2%	13.4
Italy	-5%	13.9
Spain	-8%	11.7
Total 5 countries	-2.1%	100.0

Source: FARMAINDUSTRIA, based on the "IMS World Pharmaceutical Market Summary".

A country-by-country analysis reveals that growth rates ranged between +1% for Germany and -8% for Spain; the latter, for the third year in a row, turned in the worst performance in this group of top-five EU markets.

Finally, in a more aggregate context, it should be emphasized that despite the numerous difficulties it encountered in 2012, Spain's pharmaceutical industry continues to be a major player both in the EU and worldwide. The table below shows how Spain ranks in the EU:

- 4th in sales volume
- 5th in terms of job creation
- 6th in terms of industrial output.

PHARMACEUTICAL INDUSTRY PERFORMANCE IN THE EU OVERALL IN 2010

Country	No. of companies[1]	Production (€ million)[2]	Jobs	International Sales (Pharma Company Price) (€ million)[3]	Foreign Trade (PCP) (€ million)[4]	
					Imports	Exports
Germany	325	26,888	103,208	27,022	35,989	49,832
Austria	119	2,447	10,705	3,022	5.499	6.458
Belgium	124	6,815	31,563	4,428	32,014	38,864
Denmark	36	6985	20223	2,150	2,598	6,883
Spain	186	14,387	39,932	14,858	11,492	8,920
Finland	54	1,195	5,333	2,005	1,672	996
France	274	23,485	97,645	27,334	21,538	26,304
Greece	65	910	12,500	5,047	3,555	1,014
Holland	39	6,180	16,900	4,686	10,496	11,990
Ireland	50	19,700	25,000	1,766	3,463	24,156
Italy	204	24,996	66,700	19,909	16,396	13,291
Portugal	126	1,679	9,580	3,428	2,251	501
United Kingdom	49	19,994	67,000	13,583	18,092	25,965
Sweden	79	6,954	13,773	3,172	3,089	6,934
TOTAL EU-15	1,730	162,615	520,035	132,410	168,144	221,808

NB: Does not include Luxembourg (not particularly representative).
(1) EFPIA association members.
(2) Data refers to activities related to the production of pharmaceutical specialties and raw materials for human and veterinary consumption, except in the case Germany, Spain and Ireland, where data shows activity related to human consumption only.
(3) Includes sales in pharmacies, hospitals and other distribution channels.
(4) Foreign pharmaceutical trade (SITC Code: 54). Includes veterinary products.

Source: FARMAINDUSTRIA, based on EFPIA and Eurostat.

2. THE PHARMACEUTICAL INDUSTRY IN SPAIN

2.1. R&D AND INNOVATION (I+D+i)

As Spain's Minister of Economy and Competition put it: "Corporate investment in I+D+i is a key variable in defining a competitive economy, and is a strategic tool for enhancing the competitive position of Spain's businesses on the international markets; it influences the ability to create jobs and constitutes a key factor in the development and structuring of the relationships between the system's various players" [1].

Spain's commitment to research and innovation as a means of guaranteeing more balanced and sustainable growth was further endorsed by Law 14/2011 on Science, Technology and Innovation. Its Preamble states the following: "Spain's productive model, based primarily on construction and tourism, is no longer serviceable. This calls for a major shift to a knowledge-based economy, drawing on research and innovation as a means of guaranteeing more balanced, diversified and sustainable growth".

To meet this goal, Spain's government has drawn up the Spanish Strategy on Science and Technology 2013-2020, which comes as a benchmark in this sphere for the coming years and has four main goals, not least of which is to drive business leadership in I+D+i.

In this respect, this strategy document states that "given that large companies' R&D expenditure is currently very low in Spain compared with other EU countries, there is an urgent need to encourage higher investment levels as a means of driving corporate R&D overall and consolidating Spain's competitive position. [...] This, in turn, calls for measures from public administrations, aimed at:

(a) encouraging public-private ventures;

(b) helping to develop an attractive financial environment for businesses, and one specializing in financing innovation projects with a high potential for ROI; and

(c) creating a legal framework that favors business growth at every stage, in an effort to raise growth and business maturity rates, helping business to acquire a size that enables them to take on the challenges posed by global markets [...]".

Accordingly, the abovementioned document establishes a number of objectives for the next few years as concerns our economy's research efforts in relation to GDP growth, and

[1] Paragraph included in the Spanish Strategy on Science and Technology 2013-2020 (page 24). State Secretariat for Research, Development and Innovation. Ministry of the Economy and Competition (SPAIN). The full Report is available at:

http://www.idi.mineco.gob.es/portal/site/MICINN/menuitem.7eeac5cd345b4f34f09dfd1001432ea0/?vgnextoid=49c1a9d3a268c310VgnVCM1000001d04140aRCRD

the distribution of those efforts among the private and public sectors. The table below sums up these objectives:

SPANISH STRATEGY ON SCIENCE, TECHNOLOGY AND INNOVATION – KEY INDICATORS

Performance Indicators	2010	2016	2020
R&D expenditure as a percentage of GDP	1.39%	1.48%	2%
Private sector R&D expenditure as a percentage of GDP	0.60%	0.73%	1.2%
Ratio of Public/Private financing of R&D spend	0.86	1.06	1.70
Percentage of foreign financing of R&D	5.7%	9.6%	15%

Source: The Spanish Strategy on Science and Technology 2013-2020 (page 40). State Secretariat for Research, Development and Innovation. Ministry of the Economy and Competition (SPAIN).

In a nutshell, the Government's objective is to double research efforts by Spain's business community as a percentage of GDP by 2020. As the table above shows, this calls for efforts to improve on the current situation: at the moment, the private sector spends €0.86 on R&D for every euro spent by the public sector, and the target is for the private sector to invest €1.70 for every euro spent by the public sector.

It is certainly an ambitious goal and, as the document itself is quick to acknowledge, it will only be met by leveraging the full potential of Spain's R&D front-runners. In this sense, the pharmaceutical industry has a major role to play, as Spain's National Institute of Statistics' snapshot of R&D in Spain (2011) showed.

- Pharma is the Spanish industrial sector that has invested most in R&D –more than €980 million, accounting for 19% of Spanish industry's total R&D spend. However, this percentage dipped from 21.6% in 2009 (and from the figure of 19.8% registered in 2010) as a result of the slower relative growth of R&D investment in relation to the entire set of industrial sectors, stemming from severe cuts in public pharmaceutical spending. Even so, this figure of 19% of all industrial R&D spending is particularly significant when you bear in mind that the total turnover of Spain's pharmaceutical companies comes to just 2.5% of Spanish businesses' total industrial turnover.

The pharmaceutical industry is the sector that invests most in R&D (nearly one billion euro in 2011), despite the fact that the total turnover of Spain's pharmaceutical companies comes to just 2.5% of Spanish businesses' total industrial turnover

R&D ACTIVITY BY SPANISH COMPANIES (2011)

Sector	Dedicated R&D Staff (1)	R&D Investment (€ millions)			
		Internal	External	Total	% increase on 2010
Industry Total	38,012	3,626.26	1,363.35	4,989.61	2.2
Pharmaceutical Industry	4,683	635,56	345,38	980,94	1.5
Automotion	3,264	357.43	434.76	792.18	-4.3
Other Transport	4,360	673.46	207.00	880.47	14.9
Aerospace	2,924	482.43	132.55	614.98	19.4
IT, Electronics and Optical	3,408	208.11	23.43	231.55	-9.9

(1) Full-time personnel.
Source: FARMAINDUSTRIA, based on Nat. Inst. of Statistics figures (Statistics on R&D activity; 2010 and 2011).

- The pharmaceutical industry is also the biggest job creator in R&D, with a total 4,683 full-time, dedicated professionals, amounting to 12% of total R&D employment created by Spain's industrial sector overall. Moreover, it is highly-qualified employment given that more than half of these employees are research professionals.

- The pharmaceutical industry also tops the industry table in terms of volume of funds dedicated to basic research (18% of the industry total) and applied research (32% of the industry total).

- Another standout feature of Spain's pharmaceutical industry is that its gross cash flow is high, bearing in mind the industry's considerable volume of investment and Spain's current credit squeeze; these restrictions are not likely to weigh heavily on future pharmaceutical investment decisions bearing in that Spain's Pharma companies registered an 84.3% gross cash flow rate in 20112.

- Finally, despite the clear relevance and significance of the abovementioned data, the most important thing for a sector is not just to commit to innovation, but to obtain positive results from that commitment, contributing to a country's economic development. In this respect, one of the indicators of the degree of efficiency of research is the number of companies in a given sector that file for patents over a given period, as a percentage of the total number of companies engaged in R&D in that sector. On the basis of this indicator, the pharmaceutical sector is by far Spain's leading industrial and business sector as regards the efficiency of its R&D activities: no less than 31% of pharmaceutical companies engaged in R&D in 2011 registered at least one patent in the period 2009-2011.

The abovementioned data underscore the leading position of Spain's pharmaceutical industry in R&D and its strategic importance when it comes to designing a new growth model for Spain, as described in Law 14/2011 on Science, Technology and Innovation.
However, and notwithstanding the above, we should remember at all times that Spain's official statistics point to a certain lull in the pharmaceutical industry's R&D efforts in recent years. Undoubtedly, this phenomenon stems from recent measures aimed at reducing public

[2] The data on self-financing refer exclusively to the percentage of domestic R&D financed by companies' own funds, given that Spain's National Institute of Statistics does not provide data on external self-financing of R&D projects.

It would be wise to implement public policies aimed at aiding the development of Spain's pharmaceutical industry, which is a sector that is set to lead Spain out of the recession

pharmaceutical spending, which were particularly intense from 2010 onwards and caused the domestic pharmaceutical market to shrink considerably. Thus, in the period 2009-2011, the annual average change in the pharmaceutical industry's R&D expenditure was +0.7%, while in the 10 previous years (1999-2008) the figure came to 10.6%.

The outlook for 2012 points to a similar trend which will lead to another year of stagnation or even a further reduction in R&D spending compared with 2011.

This scenario, of a shrinking market and constant regulatory changes at both the national and regional levels, has been worsened by the temporary measures for 2012 and 2013 introduced by RDL 12/2012, 30 March, that brought with it a number of tax and administrative changes aimed at trimming the public deficit. These measures reduce the corporate tax deduction percentages, and tax breaks for R&D activities were of significant importance for the pharmaceutical industry.

On the other hand, and on a more positive note, there are a number of government initiatives that deserve a special mention:

- The return of an incentive, namely discounts on employers' contributions for R&D staff introduced by the 79th Additional Provision of Law 17/2012, Annual State Budget 2013; this time, as opposed to previous occasions, the tax breaks were compatible with the Tax Breaks Regime for I+D+i Activities established in Article 35 of the Reworded Corporate Tax Law.

- The Suppliers Payments Plan, which led to the payment of arrears by regional and authorities to SMEs in June 2012, gave those companies a much-need financial shot-in-the-arm and not only enabled them to survive but also contributed to the continuity of their R&D activities.

Even so, and in order to make progress towards meeting the 2% target for R&D as a percentage of GDP by 2020, it would be wise to introduce public policies that, without jeopardizing the savings targets that have been set to aid fiscal consolidation in every sphere of Spain's administration, aimed at aiding the development of the industrial sectors that are poised to lead our country out of the recession and put it back on the path towards sustained and sustainable economic growth.

2.2. SPAIN'S DOMESTIC MARKET

In 2012, pharmaceutical companies' revenues from medicine sales in pharmacies fell by -8.5%, and by -1.5% in the hospitals market, representing a 5.5% dip in Spain's medicines market overall, measured by the Company Sales Price (CSP). Of these sales, 67.2% took place in pharmacies and the rest in hospitals.

THE SPANISH MEDICINES DOMESTIC MARKET (CSP, € MILLIONS)

	Pharmacies [1]	Change.(%)	Hospitals [2]	Change.(%)	Total	Change. (%)
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

[1] Sale of medicines in pharmacies, net of the related tax credits (RDLs 8/2010 and 9/2011).

[2] Estimated figure. The historical data series has been reconstructed on the basis of data from Farmaindustria's Annual Survey on Hospitals' Pharmaceutical Debt, and the outlook trends shown by surveys published in the Association's earlier Annual Reports has changed. The data is for state hospital medicine sales, net of the related tax discounts (in the case of the Catalonia region, only hospitals include in the Regional Health Service's hospital network have been taken into account).

Source: Farmaindustria, based on IMS data and own estimations.

Spain's Pharmacy Channel Market

In 2012, this market segment was particularly affected by the measures introduced by RDLs 9/2011 and 16/2012.

Early 2012 saw the introduction of the Directorate-General of Pharmacy and Healthcare Products' Resolution 28 December 2011, which added 31 new sets of medicines to the Reference Price System and revised those created by previous Orders on the basis of modifications introduced by RDL 9/2011. This included, among others, the possibility of creating sets of "non-replaceable" medicines, given that the regulation on replacement was left out of the Reference Price System and now falls within the sphere of Homogeneous Groupings. It also did away with the concept of graduality and eliminated the protected status of Galenic innovations when the first generic appears.

With the introduction of the abovementioned Resolution, there are now 221 sets included in the Price Reference System in the pharmacies market; they represent a 55% market share in unit terms and 28% in value terms of the prescription market (excluding non-subsidized medicines). The average price fall in this market segment in 2012 came to -22%.

The impact of reference prices was joined by a succession of price reductions in medicines included in the Homogeneous Groupings in order to set themselves at the same level of the lowest-priced drug, as established by RDL 9/2011. The Ministry of Health publishes quarterly lists of these Groupings with information on the lowest prices.

In 2012, the revenue from medicines sales in pharmacies fell by -8.5%, and by -1.5% in hospitals, meaning that the Spain's medicines market overall shrank by -5.5% in CSP terms

In Spain, 67% of units in the prescription market and 40% of the same market in value terms are marketed at generic prices

RDL 16/2012 establishes the possibility of new voluntary omissions from the list below the lowest prices, without the need to change the National Code, always providing these are of 10% or over. It also gives pharmaceutical companies the chance to align those prices with the lowest-priced drug published monthly on a list on Homogeneous Groupings with the lowest price and those with a "lower price", if there were such a case, to inform the pharmaceutical companies. Each time an active ingredient drug is prescribed, there exists the obligation to dispense the lowest-priced medicine and, as established by RDL 16/2012 when two medicines are marketed available at the same time, the generic drug will prevail.

In 2012, a total 27 generic drugs (or medicines denominated "generic") came onto the market with new molecules, joining the Homogeneous Groupings. Despite the fact that medicines in those Grouping are not legally required to lower their prices, virtually every medicine affected is priced at the level of the lowest-priced drug in its particular Grouping. In this respect, and considering the medicines in the Homogeneous Groupings and/or in the Reference Price System, it is safe to say that 67% of the Spanish prescription market in unit terms and 40% in value terms is marketed at generic medicine prices.

In addition, RDL 16/2012 introduced two measures that had an important impact on the pharmacies market:

- 1 July 2012 saw the coming into effect of a new user-participation system in the medicine prices, with contribution percentages that vary according to the user's income levels in the case of the working population, and with a maximum 10% for pensioners, with monthly spending limits based on income.

- Resolution 2 August 2012, issued by the Directorate-General of the Basic Portfolio of Services of the National Health and Pharmacy System came into effect on 1 September 2012, and updated the list of medicines that are excluded from the pharmaceutical services of the National Health System. This Resolution covers a total 416 medicine presentations, of which 91 continue to be subsidized by the National Health System in the case of certain indications. All of these presentations have seen a major fall in sales following the introduction of this Resolution: sales fell by -40% in the period Sept.-Dec. 2012 compared with the same period of 2011.

These two measures hit medicine sales hard in unit terms and led to a 3.7% fall in 2012, something unseen since 1994. This drop in unit sales, along with the lower prices imposed by the Reference Price System and the dynamics of the Homogeneous Groupings, led the market to shrink by 8.5% in 2012.

THE SPANISH PHARMACUETICAL SPECIALTIES MARKET (PHARMACY CHANNEL) (EFP; 2012)

	Units (thousands)	Change (%)	Sales CSP(€ thou.)	Change (%)	Sales CSP - tax breaks	Change (%)
Prescription	1,184,631	-3.7	8,970,277	-8.5	8,523,948	-8.6
Branded Drugs	807,916	-9.0	7,665,699	-11.1	7,219,369	-11.4
Generic Drugs	376,714	10.2	1,304,579	10.6	1,304.579	10.6
OTC	86,983	-4.2	339,144	-4.9	339,144	-4.9
Total	1,271,614	-3.7	9,309,421	-8.4	8,863,092	-8.5

Source: FARMAINDUSTRIA, based on IMS data and own estimates.

The table above shows how differently generic and branded drug sales fared in 2012. While generics rose by 10.2% in unit terms and by 10.6% in value terms, branded drugs dipped by 9% (units) and 11.4% (value). This difference is even more pronounced when we take into account only the molecules that have a generic on the market; in this case, the fall in branded drug sales comes to 14% (units) and 40% (value).

Another measure that hit the prescriptions market was the shift to hospital dispensation of 79 hospital-diagnosis drugs (52 medicines at 1 March 2012, and 27 at 1 April). These medicines correspond to 14 molecules with a market share of 1.3% in 2011.

Therapeutic Groups

Nearly all therapeutic groups have been hit, to a greater or lesser extent, by the abovementioned measures and most of them registered a slump in sales, in both value and unit terms.

While all generic pharmaceutical products have registered a 10.2% increase in unit terms and 10.6% in value terms, branded drugs have fallen by -9% (units) and -11.4% (value) in 2012

SALES OF PHARMACEUTICAL SPECIALTIES BY THERAPEUTIC GROUPS IN 2012 (PHARMACY CHANNEL

Group	Units (thousands)	Market Share (%))	Change (%)	CSP Value (thousands)	Market Share (%)	Change (%)	Average CSP (€)	Change (%)
A. DIGESTIVE & METABOLISM	203,560.7	16.0	-3.6	1,366,465.2	14.2	-5.0	6.71	-1.4
B. BLOOD & BLOOD-FORMING ORGANS	63,091.8	4.8	-1.3	395,629.3	3.9	-0.5	6.27	0.8
C. CARDIOVASCULAR	240,485.5	18.6	-2.3	1,631,154.7	18.5	-13.0	6.78	-11.0
D. DERMATOLOGICAL	54,620.1	4.5	-7.2	289,795.1	3.2	-9.5	5.31	-2.5
G. GENITO-URINARY	53,478.2	4.2	-3.8	668,675.4	7.1	-7.0	12.50	-3.3
H. HORMONES	20,617.1	1.5	1.6	200,467.5	2.2	-8.7	9.72	-10.1
J. ANTI-INFECTIVES	52,163.0	4.1	-3.5	322,654.1	3.3	-2.8	6.19	0.8
K. HOSPITAL SOLUTIONS	2,832.1	0.2	-1.7	3,152.3	0.0	-1.2	1.11	0.5
L. CANCER AND IMMUNE SYSTEM	6,278.7	0.5	-2.9	374,095.5	4.8	-22.9	59.58	-20.6
M. LOCOMOTOR SYSTEM	102,814.7	8.5	-8.3	538,153.1	6.0	-11.9	5.23	-3.9
N. CENTRAL NERVOUS SYSTEM	289,834.5	22.3	-1.4	2,167,468.3	22.8	-6.6	7.48	-5.3
P. ANTIPARISITIC PRODUCTS	1,231.8	0.1	1.9	8,542.2	0.1	-2.9	6.93	-4.7
R. RESPIRATORY SYSTEM	125,977.3	10.3	-7.1	1,051,405.8	10.9	-5.2	8.35	2.0
S. SENSORY ORGANS	53,023.0	4.3	-6.0	246,582.6	2.7	-10.0	4.65	-4.2
T. DIAGNOSTIC AGENTS	53.9	0.0	4.5	1,362.1	0.0	32.0	25.27	26.3
U. VARIOUS	1,551.0	0.1	-3.5	43,817.5	0.5	-4.2	28.25	-0.7
TOTAL	1,271,613.5	100.0	-3.7	9,309,420.6	100.0	-8.4	7.32	-4.9

Source: Farmaindustria, , based on IMS

The first four therapeutic groups, which account for a total 67% of the market's unit sales and 66.8% of its value sales, stayed at 2011 levels.

The Central Nervous System Group (22.3% market share in unit terms and 22.8% in value terms) shrank less than the average in both terms, while the fall in the average price was greater. This Group includes the medicines that are consumed most, such as non-narcotic analgesics and tranquilizers which, all told, account for 60% of the units consumed in this Group and which, despite their low prices, have seen prices go down over the past two years (down 7% in 2012 and by 11% in 2011).

For the second year in a row, the Cardiovascular Group (18% market share in unit terms and 1.5% in value terms) has registered one of the biggest average price falls (down 11). This is one of the groups in which prices have been most affected by the introduction of new generics, which have forced down the prices of their branded counterparts.

Overall, the fall in prices in the Digestive and Metabolism Group has matched the market's average price drop, and the Group's average price has fallen even lower. Forty-two percent of the units are in the sub-group that includes antacids, antiflatulents and anti-ulcer drugs, whose unit sales fell by 3.2% as a result of the elimination of subsidies on certain medicines in this sub-group and because of the new copayment scheme. The average price fell by 16% owing to the fall in the prices of medicines included in the Reference Price System and in the Homogeneous Groupings.

The Respiratory System Grouping is among those that registered the lowest price fall in unit terms (down 7.1%) resulting from the fact that 30% of the medicines excluded from the National Health System's offering belong to this therapeutic group. On the other hand, the average price in this group rose by 2%, possibly as a result of the price rise registered in OTC products; the latter represent 24% of this group.

In addition, sales fell by 22.9% in Group L: Anti-cancer. This group comprises 11 of the 14 hospital diagnosis molecules that passed to hospital dispensation in 2012.

New Launches

The year 2012 saw 452 new pharmaceutical products come onto the market, with a combined sales figure of 8 million euro, of which 78% are the new generic medicines or are marketed under generic names.

The new products fell mainly under two therapeutic areas:

- Central Nervous System, with 118 products, of which 110 are generics
- Cardiovascular, with 97 new products (88 generic).

452 new pharmaceutical products came on to the Spanish market in 2012, with total sales of 87 million euro: 78% of them were either generic or sold under a generic name

2.3.
FOREIGN TRADE[3]

Spain's economy has traditionally registered a trade deficit. This permanent deficit stemmed from a productive structure that made our country a net importer that relied more on buying abroad than on producing at home for foreign markets.

However, the current economic cycle has added new dimensions to this trend increasing it in the boom years, when a dynamic domestic demand boosts imports, and reducing it when recession bites or when activity slows down or slumps completely, such as at present, when buying abroad slows down and, in addition, when Spain-based companies are forced to take their production surplus abroad (a result of slack domestic demand, leading to a subsequent increase in exports).

Add to this the increased competitiveness of Spain's economy, which has been forced to make readjustments as a result of the recession, and that explains why Spain's trade deficit has gone from 9.5% of GDP in 2007 (the year the crisis started) to 2.9% in 2012.

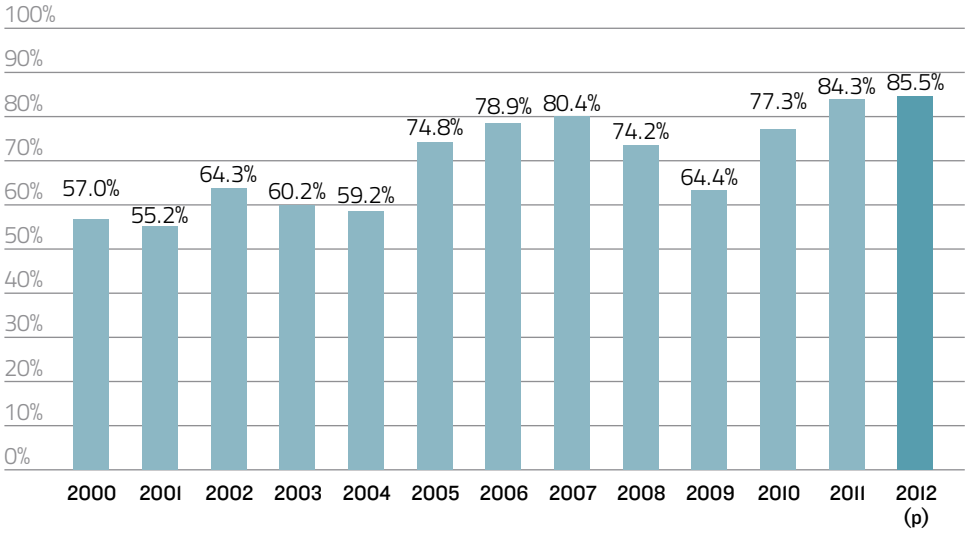
The aforementioned trend can be seen in the fact that Spain's export/import coverage ratio has improved gradually over the past five years, going from 64.9% in 2007 to 87.9% in 2012.

The lower trade imbalance registered in 2012 was sustained not only by export growth (up 3.8%) but also by slower imports (down 2.8%), which led to a 6.1 percentage point improvement in the country's coverage ratio in the past year, going from 81.8% in 2011, to the above-mentioned 87.9% in 2012, Spain's best coverage ratio since 1988.

As far as Spain's pharmaceutical foreign trade is concerned, the exports coverage ratio reached 85.5 in 2012, the highest figure on record.

[3] The data provided in this section refer exclusively to the foreign trade of general goods and pharmaceutical products in particular. In both cases, data for 2012 are provisional, and are subject to subsequent review. Accordingly they should be approached and interpreted with caution.

EXPORT/IMPORT COVERAGE RATIO



Source: Ministry of the Economy and Competition. State Secretariat for Trade. Spain Foreign Trade Statistics.

Pharmaceutical exports accounted for 3.8% of total Spanish exports in 2012, when in the year 2000 they accounted for just 1.8%.

It is also important to take into account that the pharmaceutical industry's weighting in Spanish exports overall (3.9%) triples the weighting of the industry's turnover in the total economy (1.3%).

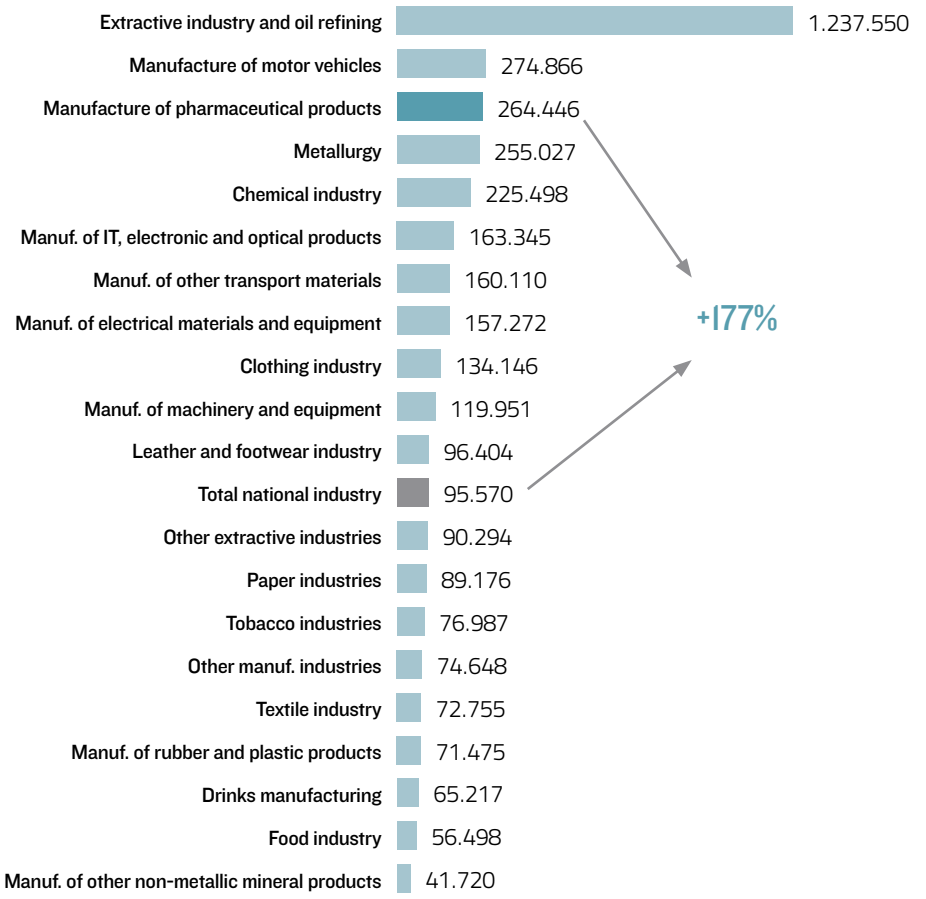
Just how important pharmaceutical exports are is highlighted by looking closely at the export ranking, per export duties: this kind of product went from 17th place in the table in 2000, to 5th position in 2011.

Nonetheless, to get a more accurate look at how well the sector competes abroad, it is a good idea to look at relative indicators that highlight the sector's exports in terms of sales in relation to its turnover, headcount, and so on:

- The industry's exports/turnover ratio, at 68%, is double the Spanish industry sectors average.
- The industry's exports per employee ratio is even bigger; in terms of this indicator the pharmaceutical industry is the country's number three sector in terms of foreign trade, with exports in excess of 264,000 euro per worker.

Pharmaceutical products rank 5th (in customs duties) in the Spanish exports table

SPAIN'S LEADING SECTORS IN TERMS OF EXPORTS PER EMPLOYEE (2011)



Source: FARMAINDUSTRIA, based on data from the Sate Secretariat for Trade and the National Institute of Statistics.

75% of Spanish pharmaceutical exports manufactured in Spain are destined to the European market, and almost 60% of them go to EU countries

In a nutshell, the past few years have seen Spanish exports rise, and also grow compared to imports. In part, this phenomenon is down to the fact that Spain's pharmaceutical market shrank noticeably in the period 2010-2012; as a result, many companies turned to markets abroad to break with their traditional reliance on the home market.

The geographical distribution of Spain's pharmaceutical foreign trade in 2012 highlights how the EU-27 continues to be, and by far, our main trading partner: our EU trading partners account for 67% of Spanish pharmaceutical sales abroad and they absorb 58% of our export capacity. Add to this latter figure an additional 15% of exports to the rest of Europe (especially Switzerland), and the result is that 75% of Spanish pharmaceutical exports go to Europe.

SPANISH PHARMACEUTICAL FOREIGN TRADE - BREAKDOWN BY COUNTRY

	2011		2012 (p)	
Economic Area	Export	Import	Export	Import
Total world	100%	100%	100%	100%
EU-27	59.1%	62.9%	58.2%	67.3%
France	10.7%	10.9%	12.4%	13%
The Netherlands	4.9%	5.5%	5.6%	5%
Germany	9.6%	13.5%	9.4%	13.5%
Italy	9.5%	4.9%	9.4%	5.6%
United Kingdom	7.9%	10.6%	6%	13.8%
Ireland	0.7%	6.1%	0.5%	5.3%
Belgium	1.1%	5.0%	1%	4.8%
Rest of Europe	12.6%	7.3%	15.4%	5.3%
Switzerland	10.3%	6.8%	12.9%	4.9%
Rest of the World	28.3%	29.7%	26.4%	27.4%
China	1.6%	1.5%	1.8%	2%
Japan	4.7%	1.1%	4.5%	1%
India	0.2%	0.6%	0.3%	0.7%
USA	6.3%	19.1%	2%	17.7%

Source: Ministry of the Economy and Competition. State Secretariat for Trade. Spain Foreign Trade Statistics.

2.4.
SOCIAL SECURITY PHARMACEUTICAL SPENDING

With the change in mandatory user contribution (copayment) introduced by 16/2012, in July 2012, the number of prescriptions began to fall: in fact, in 2012 they were at their lowest in the last decades, falling to 6.1% This slowdown was accompanied by a fall in the average spend per prescription (-6.6%) which, in turn, led to a 12.3% overall fall in public pharmaceutical spending, which came to just under 9.8 billion euro (9,769.9 million to be exact).

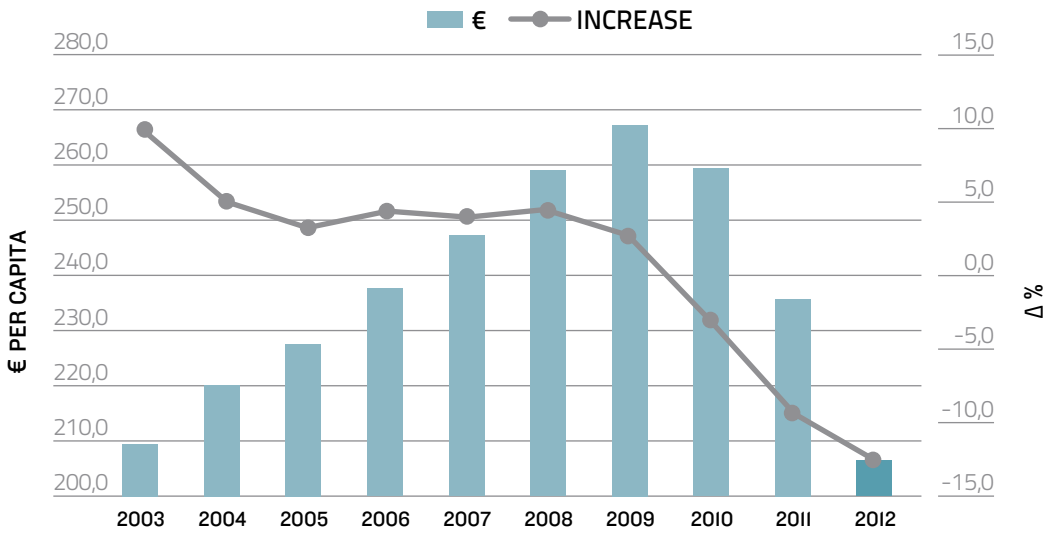
SOCIAL SECURITY SPENDING PER PRESCRITPTION DISPENSED IN PHARMACIES

Year	Spending (€m RRP VAT)	Change (%)	No. Prescriptions (million)	Change (%)	Gto./Prescrip. (€)	Change (%)
2007	11.191,3	5,2	843,4	6,0	13,27	-0,7
2008	11.960,5	6,9	889,5	5,5	13,45	1,3
2009	12.506,2	4,5	934,0	4,9	13,39	-0,5
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

Source: MSSSI, medicines prescriptions turnover.

Regional average per capita pharmaceutical spending

In 2012, average per capita pharmaceutical spending fell by -12.4%, coming to 206.7 euro, a figure similar to 2003.



The regions with the highest average per capita pharmaceutical spending are Extremadura (261.9 €) and Galicia (255.4 €), while Madrid (162.8 €) and the Balearic Isles (162.0 €) have the lowest.

REGIONAL PUBLIC PHARMACEUTICAL SPENDING PER CAPITA, 2012

Region	Share of spend (%)	Per capita spending 2012	
		Euro	Change (%)
Andalusia	17	197.1	-9
Aragon	3.2	229.1	-12
Asturias	2.7	249.2	-15
Balearic Isles	1.9	162	-11.8
Cantabria	1.3	214.8	-9.9
Canary Isles	4.3	198.9	-13.2
Castile-La Mancha	5.0	230.2	-9.7
Castile-Leon	5.8	220.7	-15
Catalonia	14.8	190.6	-14.6
Cantabria	1.3	214.8	-9.9
Ceuta	0.1	156	-10.8
Extremadura	3	261.9	-11.9
Galicia	7.3	255.4	-13.9
La Rioja	0.7	209.8	-14.5
Madrid	10.8	162.8	-10.9
Melilla	0.1	133.4	-13.4
Murcia	3.4	226.5	-13.7
Navarre	1.3	199.2	-13.7
Basque Country	5	223.8	-8.5
Total SPAIN	100	206.7	-12.4

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