ANNUAL REPORT 2009

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Letter from the **President**

JESÚS ACEBILLO MARÍN
President of
FARMAINDUSTRIA

The period that concluded with the presentation of this FARMAINDUSTRIA 2009 Annual Report has been very complex, with two perfectly differentiated parts and an ending, which, at the time of writing these words, still presents various uncertainties regarding the practical application of some of the measures to control pharmaceutical expenditure recently passed by the Spanish Government and Parliament.

From a macroeconomic perspective this twelve month period began with the confirmation that, after 60 consecutive quarters of economic growth, Spain had technically entered into a recession at the end of 2008. A recession that has accompanied us throughout all of 2009 and which, although it seemed to have ended in the first quarter of 2010, the quarter's low rate of growth (+0.1%) meant that neither could it be categorically stated that Spain had overcome the economic recession, especially due to the effects that the financial crisis affecting the Spanish State may have upon the economy.

Thus, after the high public deficit levels with which 2009 ended (equivalent to 11.2% of the Gross Domestic Product), the Government has adopted a plan to reduce this deficit to 3% of GDP by 2013. This plan includes a series of measures, the scope of which will affect public investment in infrastructure, the wage bill of public employees, pensions increases, and other areas of public expenditure amongst which are found measures to reduce pharmaceutical expenditure with the aim of making savings of more than 2,500 million Euros annually and which could have devastating consequences for the main operating variables of the pharmaceutical companies based in Spain.

Thereby, and moving onto the microeconomic area of the pharmaceutical industry, the year that has finished has had two very distinct parts. The first part covers 2009 and the first two months of 2010, and is marked by a certain regulatory calm in which the pharmaceutical companies could begin the consolidation of the main elements of the Understanding outreached with the Government at the start of 2009. Thus, according to the data available up to now, during 2009, the pharmaceutical industry: i) in a general environment of the contraction of international trade, notably increased exports of medicines climbing up to 5.1% of all Spanish exports, ii) at a time of general crisis and an exponential increase in unemployment levels in our country, it kept its volume of employment levels at reasonable limits, and iii) started up the *+i Clinical and Translational Research Co-operation Programme*, with the signing of agreements with a large number of Autonomous Regions.

However, the regulatory calm was notably disturbed with the passing of Royal Decree-Law 4/2010, of 26 March, on rationalising pharmaceutical expenditure charged to the National Health System, which included amongst its stipulations a rebate in the price of generic medicines which could outreach 30% of their RRP, and a modification of the Reference Price System which notably toughens the application conditions. The negative impact of this Royal Decree-Law on the pharmaceutical industry will easily exceed 1,300 million Euros due to its effect on the public as well as the private market.

But, despite the considerable impact upon the accounts of the pharmaceutical laboratories, the measures contained in Royal Decree-Law 4/2010 follows a certain logic, on trying to transfer to the end price of generics the discounts that already existed in that market and which never outreached the end purchaser. Furthermore, these measures respected pharma-

ceutical innovation, by focusing on the ambit of medicines subject to the Price Reference System, and as such, without a patent in force in Spain.

However, hardly two months after the passing of Royal Decree-Law 4/2010, the Prime-minster of the Government announced in Congress a package of measures to reduce the public deficit, amongst which were a new cut of pharmaceutical expenditure, but this time on medicines not affected by the Price Reference System.

Thus, Royal Decree-Law 8/2010, of 20 May, by which extraordinary measures were adopted for the rebate of the public deficit, includes a series of measures which impose: i) an obligatory rebate of 7.5% in the retail price of non-generic medicines for human use and which are unaffected by the PRS, that are dispensed in pharmacies and charged to the pharmaceutical service of the National Health System and ii) a rebate of 7.5% on the price of non-generic medicines and which are unaffected by the PRS acquired with public funds charged to the National Health System, through hospital, health centre and primary health care body pharmacies.

The impact of this Royal Decree-Law on the public pharmaceutical market will exceed 1,000 million Euros a year, of which at least 750 million will come directly from the income of the pharmaceutical companies.

The measures included in this Royal Decree-Law are very damaging for the industry, given that :i) they affect products with a patent in force, penalising pharmaceutical innovation; ii) they recurrently affect pharmaceutical laboratories year after year in so far as such the rebate remains in force; and iii) the diagnosis is mistaken given that, if all public pharmaceutical expenditure in Spain is due to the growth in demand for prescriptions and not to the growth in prices, which have been stagnant for more than three years, why are they taking action on prices? The answer has much more to do with the financial needs of the State, with the urgency to make savings and the target being an easy one politically, than with the economic rationality of the measure itself.

As the only lesser evil of Royal Decree-Law 8/2010, it can be said that the measure has been posed under the formula of a rebate in the RRP for medicines acquired by the public health system and not as a rebate in the industrial price of the product. A rebate in prices would have affected the public as well as the private market and would have had a depressing effect upon the international price of these products in the countries which take Spain as a reference to set or modify their prices.

To sum up, the two Royal Decree-Laws, recently introduced by the Government in our country, will have a joint impact on the pharmaceutical companies in excess of 2,000 million Euros a year, about 14% of the size of the domestic pharmaceutical market measured at laboratory sale prices. An impact of this nature, not only puts the viability of many pharmaceutical companies in Spain at risk, but also means an almost irreversible blow to the capacity of the pharmaceutical companies to boost production and R&D investment in our country.

Today more than ever the Spanish Government needs to evaluate the outreach of these measures and react to alleviate their impact on an innovative industry, key to the future of our country and our health system.

THE SPANISH GOVERNMENT NEEDS TO EVALUATE THE OUTREACH OF THE PHARMACEUTICAL EXPENDITURE COST REBATE MEASURES AND REACT TO ALLEVIATE THEIR IMPACT ON AN INNOVATIVE INDUSTRY, KEY TO THE FUTURE OF OUR COUNTRY AND OUR HEALTH SYSTEM


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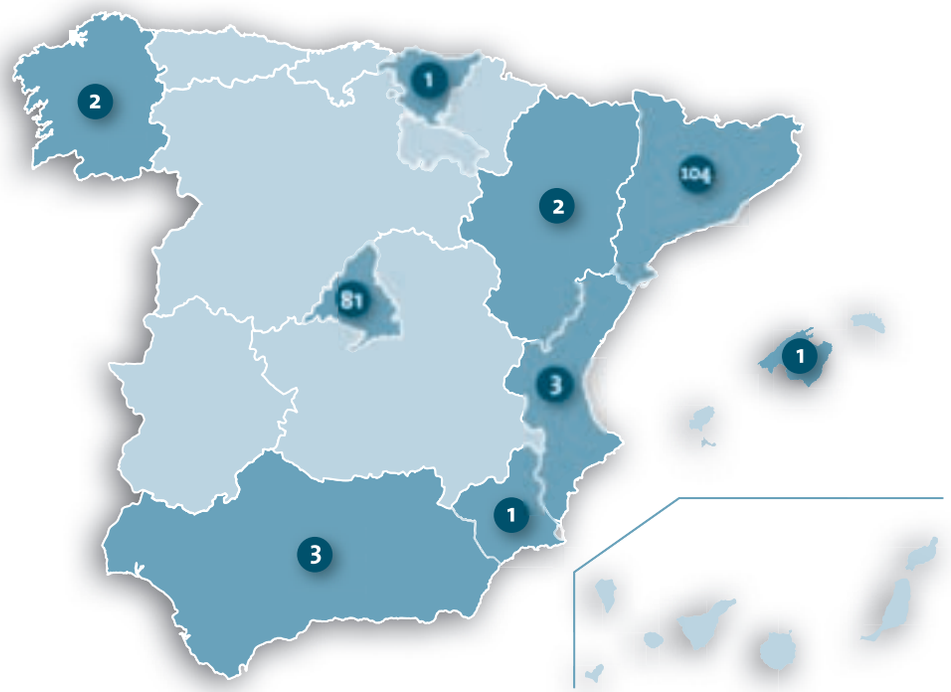
Farmaindustria in 2009

1. MEMBERS

At 31 December 2009, 198 laboratories were associated to FARMAINDUSTRIA, whose geographical distribution is as follows:



The laboratories associated to FARMAINDUSTRIA represent, by number, 37% of all holders of authorisations for marketing medicines, or their local representatives in the case of those authorised by a central process, whether or not they possess production activity. In sales terms, they represent 84 % of the national prescription market.

LABORATORIES BY GROUP		
	NATIONALS	INTERNATIONALS
Large	7	31
Medium	7	21
Small	73	59
TOTAL: 198	87	111

2. ORGANISATION

2.1. GOVERNING BODIES

The General Assembly, made up of all the members of the Association, is the supreme Governing Body, through which members express their collective will.

The Governance of the Association is the responsibility of the Steering Committee, which is made up of the President of the Association and 30 representatives of member companies, and the Executive Board, made up of the President, seven Vice-Presidents and nine Directors appointed by the Steering Committee from among its own members.

In the FARMAINDUSTRIA General Assembly held on 16 June 2009, a new Second Additional Provision was passed in the by-laws which set the number of companies in the Steering Committee at 30, 11 companies with capital of national origin and 19 companies with capital of international origin. With regard to the Executive Board, this body grew to 16 members, of which six correspond to companies with capital of national origin and ten to companies with capital of international origin. The number of Vice-presidents from companies with capital of international origin was set at four.

The composition of these two Governing Bodies at the moment of finalising this Report was the following:

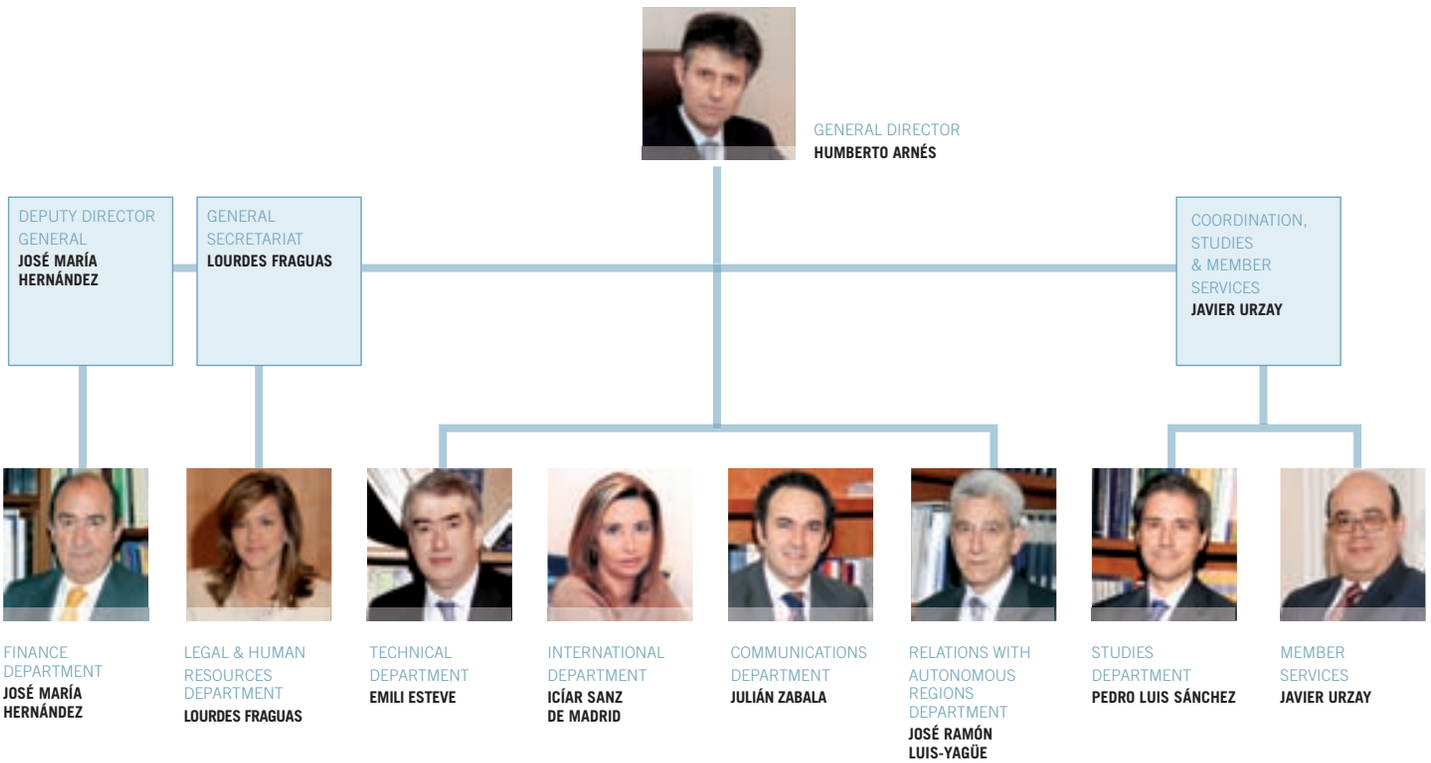
EXECUTIVE BOARD	
PRESIDENT	
D. Jesús Acebillo Marín NOVARTIS FARMACEUTICA, S.A.	
VICE-PRESIDENTS	
D. Javier Ellena Aramburu DISTA, S.A.	**D. Manuel García Garrido** BOEHRINGER INGELHEIM, S.A.
D. Antoni Esteve Cruella ESTEVE	**D. Rafael Juste Sesé** JUSTE, S.A. QCO. FCA.
D. Jorge Gallardo Ballart LABORATORIOS ALMIRALL, S.A.	**D. Antonio Pérez Mosquera** SCHERING-PLOUGH, S.A. (MSD)
DIRECTORS	
D. Andreas Patrick Abt ROCHE FARMA, S.A.	**D. Jordi Marti Pi Figueras** AMGEN, S.A.
D. Javier Font Salgado FARDI	**D. Jorge Ramentol Massana** FERRER FARMA, S.A.
D. Paul Hudson ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	**Dª. Elvira Sanz Urgoiti** PFIZER, S.A.
D. Claudio Lepori ANGELINI FARMACÉUTICA, S.A.	**D. Jérôme Silvestre** SANOFI-AVENTIS, S.A.
D. Juan López-Belmonte López LABORATORIOS FCOS. ROVI, S.A.	**D. Theo van der Loo** QCA. FCA. BAYER, S.L.

STEERING COMMITTEE	
PRESIDENT	
NOVARTIS FARMACEUTICA, S.A. **D. Jesús Acebillo Marín**	
VICE-PRESIDENTS	
LABORATORIOS ALMIRALL, S.A. **D. Jorge Gallardo Ballart**	ESTEVE **D. Antoni Esteve Cruella**
BOEHRINGER INGELHEIM, S.A. **D. Manuel García Garrido**	JUSTE, S.A. QCO. FCA. **D. Rafael Juste Sesé**
DISTA, S.A. **D. Javier Ellena Aramburu**	SCHERING-PLOUGH, S.A. (MSD) **D. Antonio Pérez Mosquera**
DIRECTORS	
ALCON CUSI, S.A. **D. Enrique Chico Picaza**	LABORATORIOS LETI, S.L. UNIPERSONAL **D. Jaime Grego Sabaté**
AMGEN, S.A. **D. Jordi Marti Pi Figueras**	NOVARTIS CONSUMER HEALTH, S.A. **D. Francisco Ballester Cañizares**
ANGELINI FARMACÉUTICA, S.A. **D. Claudio Lepori**	NOVO NORDISK PHARMA, S.A. **D. Luis Silva Castillo**
ASTRAZENECA FARMACÉUTICA SPAIN, S.A. **D. Paul Hudson**	NYCOMED PHARMA, S.A. **Dª. Lide Isabel Verdugo Martínez**
QCA. FCA. BAYER, S.L. **D. Theo van der Loo**	PFIZER, S.A. **Dª. Elvira Sanz Urgoiti**
LABORATORIOS ERN, S.A. **D. David Solanes López**	ROCHE FARMA, S.A. **D. Andreas Patrick Abt**
FAES FARMA, S.A. **D. Francisco Quintanilla Guerra**	LABORATORIOS FCOS. ROVI, S.A. **D. Juan López-Belmonte López**
LBO.DE APLICACIONES FARMACODINÁMICAS, S.A. "FARDI"/ **D. Javier Font Salgado**	SANOFI-AVENTIS, S.A. **D. Jérôme Silvestre**
FERRER FARMA, S.A. **D. Jorge Ramentol Massana**	LABORATORIOS SERVIER, S.L. **D. Pierre Faraldo**
GILEAD SCIENCES, S.L. **D. Roberto J. Urbez Plasencia**	LABORATORIOS UPSA, S.L. **Dª. Aurora Cayetana Berra de Unamuno**
J. URIACH & CIA., S.A. **D. Enrique Trias Vidal de Llobatera**	LABORATORIOS VIÑAS, S.A. **D. Antonio Buxadé Viñas**
JANSSEN CILAG, S.A. **D. Martín Sellés Fort**	WYETH FARMA, S.A. **Dª. Elvira Sanz Urgoiti**

2.2. EXECUTIVE COMMITTEE

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

The functional organisational chart is as follows:



3. AREAS OF ACTIVITY

3.1. MARKET REGULATION AND GOVERNMENT RELATIONS

One of the main characteristics of the industry and the Spanish pharmaceutical market is its high level of public regulation, which stems from two main sources: Central Administration, with competences basically on the supply side and Regional Administration with competences to regulate the pharmaceutical market on the demand side.

In the last twelve months, sector regulatory activity and FARMAINDUSTRIA 's relationship with Government have gone through two totally different phases.

THE PHARMACEUTICAL INDUSTRY, IN MARCH 2009, MADE PUBLIC A COMMITMENT WITH THE GOVERNMENT AND THE SPANISH PUBLIC TO IMPROVE AND MAINTAIN EMPLOYMENT, RAISE INVESTMENT IN R&D AND INCREASE THE INTERNATIONALISATION OF THE COMPANIES

At the start of 2009, the Government made a statement committing itself to keep all social payments in place, including pharmaceutical ones, during the crisis that the Spanish economy was going through , considering them to be essential in maintaining social cohesion, with the aim of protecting those most affected by the economic situation. As a response to this declaration, in 2009 the pharmaceutical industry made public a commitment with the government and the Spanish public to intensify its efforts in three fundamental areas i) maintaining employment and improving the level of qualifications; ii) raising pharmaceutical R&D investment in Spain, and iii) improving the internationalisation activities of the companies that make up the basis of the pharmaceutical industry in our country. At the same time its commitment included the setting up of a fund to develop public-private co-operation projects in the Autonomous Regions, finally resulting in the *+i Clinical and Translational Research Co-operation Programme*, to which extensive reference is made in a specific section of this Report.

This commitment had the explicit backing of the Spanish Government, from the then Health Minister D. Bernat Soria, as well as later on from his successor in charge of that ministerial portfolio, Dª Trinidad Jiménez, and the Employment and Immigration Minister, D. Celestino Corbacho, in a later presentation held in that Ministry's buildings.

Thus, during the rest of 2009, the contacts between Farmaindustria, the Ministry of Health and Social Policy and the Autonomous Regions notably intensified in order to push on with the implementation of the Understanding, giving place to the signing of collaboration and co-financing agreements for research projects with 14 of the 17 Spanish Autonomous Regions, up to the time of this report being produced.

However, the negative development of the Spanish economic situation, and particularly, the rapid deterioration of public accounts, prompted a budgetary adjustment in order to get the national deficit to 3% of GDP for 2013.

This plan affected practically all areas of Government, and despite the chronic financial deficit of Spanish public health and the urgent need to provide more financial resources in view of its widely recognised under-funding, it has also affected the health budgets, amongst them, pharmaceutical expenditure.

Thus, between the months of March and May 2010, the Government introduced two Royal Decree-Laws: i) Royal Decree-Law 4/2010 of 26 March, on the rationalisation of pharmaceutical expenditure charged to the National Health System and ii) Royal Decree-Law 8/2010 of 20 May, which adopted extraordinary measures to reduce the public deficit. Both Royal Decree-Laws are analysed in detail in a specific section of this Report.

The first of the aforementioned Royal Decree-Laws defines measures to control the growth in public expenditure in medicines subject to the Reference Price System (RPS) which will have a huge impact on the pharmaceutical companies which operate in our country and receive income from the sales of this type of product. In fact, it is estimated that Royal Decree-Law 4/2010 will reduce the annual income of the pharmaceutical companies by more than 1,300 million Euros.

The second Royal Decree-Law, 8/2010 also seriously affects the innovative pharmaceutical industry by envisaging: i) an obligatory rebate of 7.5% of the retail price of dispensed non-generic medicines not affected by the application of the RPS, charged to the pharmaceutical budget of the National Health System, and ii) a rebate of the same percentage (7.5%) in the purchase price of the medicines that hospital, health centre and primary healthcare bodies pharmacy services acquire. It is estimated that the impact of this Royal Decree-Law on the income of the pharmaceutical companies will exceed 750 million Euros annually.

In FARMAINDUSTRIA's opinion, the publication of the two previous Royal Decree-Laws, particularly 8/2010, has meant a very important change to the legal framework controlling the pharmaceutical sector in our country and not only will it make it impossible that the pharmaceutical industry adequately carry out the aims of the Commitment, as was expressed a year before the publication of both Royal Decree-Laws, but also they can furthermore cause irreversible damage to the pharmaceutical industry established in Spain, in employment terms as well as in production in investment, in R&D and in the industrial fabric.

In fact, the income that the Spanish pharmaceutical companies will stop receiving as a consequence of the implementation of the Royal Decree-Laws 4/2010 and 8/2010 (around 2,100 million Euros) is practically double the figure of the results of the 2008 financial year for the pharmaceutical industry in Spain as a whole, which according to the Industrial Companies' Survey of the National Statistical Institute (INE) amounted to 1,063 Million Euros.

It is unthinkable that an impact of this kind will not affect the current industrial structure of the pharmaceutical sector in Spain, as well as the future prospects for an innovative, dynamic, industry, intensive in R&D and knowledge, and an example of the new productive model that our country has to put in place in order to overcome the current economic crisis.

3.1.1. LEGAL FRAMEWORK

In the current year, Law 29/2006, of 26 July, on Guarantees and the Rational Use of Medicinal Products and Medical Products has continued to develop by way of new provisions. Additionally, various updates and amendments to the Law have occurred, amongst which stand out, for their technical and economical importance for the sector, those outlined below.

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Pharmaceutical expenditure: Ministerial Order on reference prices[1], Royal Decree- Law 4/2010[2] and Royal Decree- Law 8/2010[3]

Besides the Ministerial Order on setting up new groups and the updating of existing reference prices which are published annually, the economic crisis and the need to reduce the public deficit has led to the enactment of two Royal Decree-laws, which were later ratified by Parliament.

The first of these two Royal Decree-Laws, Royal Decree-Law 4/2010, imposes a lowering of the price of generic medicines and notably toughens the Reference Price System (RPS).

The second Royal Decree-Law, Royal Decree-Law 8/2010 imposes an obligatory rebate of 7.5% i) on the retail price of non-generic medicines dispensed not affected by the application of the RPS charged to the pharmaceutical budget of the National Health System, and ii) a rebate of the same percentage (7.5%) in the purchase price of the medicines that hospital, health centre and primary healthcare bodies pharmacy services acquire.

Royal Decree-Law 4/2010. According to calculations from the Ministry of Health and Public Policy, the application of Royal Decree-Law 4/2010 will achieve a saving of approximately1,500 million Euros annually in the National Health System, of which approximately 75% will come from the lowering of income of the pharmaceutical laboratories which operate in Spain.

The main measures, although not the only ones, outlined in this Royal Decree-Law which affect the pharmaceutical industry most directly are the following:

1 Order SAS/3499/2009, of 23 December, which defines the new medicine groups, their reference prices and which revises the reference prices set and revised by Order SCO/3803/2008, of 23 December.

2 Royal Decree-Law 4/2010, of 26 March, on rationalisation of pharmaceutical expenditure charged to the National Health System.

3 Royal Decree-Law 8/2010, of 20 of May which adopted extraordinary measures in order to reduce the public deficit.

- Rebate in the industrial price of generic medicines financed by the National Health System by an average of 25%.

- Amendment of the Reference Price System in the following fundamental areas: i) reference price of each group set in function of the lowest cost/treatment/day, in place of the three cheapest, as has occurred up to now; ii) rebate from three to two years for the period of gradualisation which the holders of the original medicines can take up so as to assume the rebate in its price to the Reference Price, with minimal rebates of 50% a year, compared to the 30% minimum previously; iii) rebate in the minimum Reference Price threshold of a group from a RRP of € 3.12 to a RRP of € 1.56 and, iv) rebate of 30% in the price of medicines that do not have a generic equivalent in Spain but which do have a generic medicine or biosimilar in any of the EU member states not subject to exceptional or transitory intellectual property systems, compared to the 20% in force up to now.

- More precise regulation of the discounts applied for prompt payment or by sales volume on the prices of medicines financed by distributors (wholesalers and laboratories) to pharmacies. The new legal obligation limits these to a maximum of 5 % as a general rule, which can be extended to 10% in the case of generic medicines.

- Modification of the system for setting and revising medicine prices, keeping the reference of prices of the EU countries not subject to transitory intellectual property systems, but eliminating the reference to its average price.

- Suppression of the temporary limitation of the non-administrative revision of the price of a medicine during a year.

THE MEASURES INCLUDED IN THE ROYAL DECREE-LAW 8/2010 ARE DESIGNED WITH THE AIM OF MAXIMISING THE SAVINGS FOR THE NATIONAL HEALTH SYSTEM IN THE SHORTEST TIME POSSIBLE

As can be seen, all the measures included in Royal Decree- Law 4/2010 are designed to shape a new, much more aggressive Price Reference System on the prices of the products which it affects, with the aim of maximising savings for the National health system in as short a period of time as possible after the setting up of the different groups.

Royal Decree-Law 8/2010. This Royal Decree-Law includes various stipulations geared towards reducing different areas of public expenditure; more precisely, and among other measures, reducing the public sector wage by 5%; suspending the revaluation of pensions for 2011; suppressing the backdating of dependency payments to the day of the presentation of the application; eliminating the payment for births or adoptions, and imposing a series of obligatory rebates of 7.5% on the price of medicines dispensed by National Health System pharmacies or for purchases of medicines carried out health services of the National Health System.

In regard to the stipulations of Royal Decree-Law 8/2010 which affect pharmaceutical laboratories, the following stand out:

- Pharmacies will apply a rebate of 7.5% on the retail price of industrially produced medicines for human use charged to the pharmaceutical service of the National Health System. For the purposes of the sharing out of this rebate, the distributor will apply a rebate of 7.5% on the distributor's sale price and the laboratory will apply a deduction of 7.5% on the maximum industrial price . Exceptions to this are generic medicines and the medicines affected by the application of the RPS, excepting those making up inactive groups.

In the purchases of the same medicines as in the previous point carried out by the pharmacy services of hospital, health centre and primary healthcare bodies, a rebate of 7.5% on the purchase price is set.

The estimated savings from the previous two items are of 1,050 million Euros a year.

- The possibility that the Spanish Medicines Agency authorise the dispensing of fixed units for certain medicine and pathological groups was established, with the aim of reducing the units dispensed to the duration of the treatment. The Government estimates a saving of 250 million Euros annually by applying this measure.

- The possibility of creating a centralised state medicine and health products purchasing system was established, which Autonomous Regions and local bodies can join if they decide to do so.

As can be seen, the measures set out in Royal Decree-Law 8/2010 and referring to the health system have turned out to be extremely aggressive ones for the pharmaceutical laboratories that market innovative products in Spain, given that these measures are specifically aimed at the income from medicine sales which still have a patent en vigour.

The impact on the laboratories is very high and it is foreseeable that it will have significant repercussions on the level of employment and investment of the innovative pharmaceutical companies that operate in our country. However, the fact that this cost-saving measure has been orchestrated by price rebates of medicines to the public health system and not as an obligatory lowering of prices, means that it has some advantages, amongst which stand out the fact that it does not affect the private domestic market nor does it cause an automatic lowering of the prices in countries which have the their medicine prices referenced to the price of the same product in Spain.

Other amendments to Law 29/2006, on Guaranties and the Rational Use of Medicines and Health Products

The amendments introduced by what is known as the Omnibus[4] Law in Law 29/2006 refer to the abolition of the specific classification procedure of a medicine as advertised medicines. From the coming into force of this amendment, medicines that meet certain conditions (which do not need a prescription, are not financed by the NHS and which do not contain narcotics nor psychotropic agents) can be subject to advertising aimed at the public once the Ministry of Health and Social Policy has verified that the message intended to be transmitted meets a series of specific conditions.

Furthermore, Law 29/2006 has been amended[5] to include chiropodists, as well as doctors and dentists, as professionals able to prescribe medicines and also allows nurses to be able to indicate, use and authorise the dispensing of medicines not subject to prescription, and health products by means of the corresponding dispensation order.

Royal decree regulating the availability of medicines in special situations[6]

This royal decree unifies the various cases of using medicines in different conditions to those of the register and marketing per se. In particular it regulates: i) the conditions of use of the medicines in clinical research when the patient is not a part of the clinical trial stage (compassionate use); ii) the access to authorised medicines in other countries but not in Spain, and iii) the use of medicines that could be used in conditions not foreseen in the specifications.

4 Law 25/2009, of 22 December, on amending various laws for their adaptation to the Law on free access to the activities and their exercise (Omnibus Law).

5 Law 28/2009, of 30 December, on modifying Law 29/2006, of 26 July, on the guarantees and rational use of Medicines and health products.

6 Royal Decree 1015/2009, of 19 June, which regulates the availability of medicines in special situations.

The regulation has meant an improvement in the administering of these applications, especially since the introduction of a computerised system known as Management of Medicines in Special Situations which is available in the AEMPS web site to channel this type of request.

Regulatory Drafts

At the time of the production of this report the following Royal Decree drafts are being processed.

Draft Royal Decree on Laboratories. This draft includes, amongst other aspects, the obligations deriving from the amendments to EU regulations regarding the raw material producers, and likewise institutes both registers for manufacturing pharmaceutical laboratories and/or importers and for laboratories that hold marketing authorisations.

Draft Royal Decree amending Royal Decree 1345/2007, of 11 October, on the Register. The aim of this draft regulation is to apply Commission Regulation (EC) 1234/2008, of 24 November, regarding the examination of variations to the terms of marketing of medicines and the directives on the development of all the variations, including national ones, since January 2010.

Draft Royal Decree on Prescriptions and Hospital Dispensing Orders. This draft updates the legislation upon which the basis for prescription and dispensation by electronic means is regulated. Its passage is being particularly complicated given that, up to the time of this report being presented, two drafts of the future regulation have been submitted for consideration and there is the possibility that a third one may be presented for opinions.

FARMAINDUSTRIA has reiterated that, whatever the system is that is finally decided upon to regulate this area in our country, all authorised medicines, should, without exception, be capable of being prescribed under the same conditions with the new technology available.

3.1.2. THE AUTONOMOUS REGIONS

Throughout the last twelve months, FARMAINDUSTRIA has intensified its activities in the area of autonomous regions in two ways. On one hand, to maintain information systems and follow-up of the initiatives of the autonomous regions relating to health policy and access to pharmaceutical services, and on the other hand, to continue a line of communication and dialogue with the health authorities of the autonomous regions that aides the representation, and where necessary, the defence of the interests of FARMAINDUSTRIA's members.

Information Gazette of the Autonomous Regions

In the information field, the publication of the Information Gazette of the Autonomous Regions has continued, which includes the regional news of greater interest to the pharmaceutical industry, and which is sent fortnightly to members. The Gazette has prioritised the information relating to matters of health and pharmaceutical policy, health planning, health plans and R&D.

Autonomous Regions Monitor

The production of reports on the status and themes on areas of interest for the sector has continued. Below, some of the reports, which are available to members on the FARMAINDUSTRIA web page, are listed.

- Status reports, including the revision and updating of health and social information of the Autonomous Regions of Andalucía, Asturias, Castilla y León, Castilla-La Mancha, Extremadura, Galicia, Islas, Baleares, Madrid and Murcia.
- Health budget 2010 – Health budget and expenditure 2009 – National Health System.
- Evolution of the health budget 2008–2010, including the information corresponding to the health budget and pharmaceutical service for the years 2008, 2009 and 2010 for each autonomous region.
- Evolution of pharmaceutical expenditure 2008–2009 and pharmaceutical budget 2010, data on total and per capita pharmaceutical expenditure for 2008 and 2009 and the budget for the pharmaceutical service for 2010 gathered for each autonomous region.
- Official vaccination calendars of the NHS.
- Prescription by Active Ingredient. Status by Autonomous Region, listing, amongst other matters, the information available on the quota of this method of prescription in relation to the total number of prescriptions by autonomous region, as well as the correlation with the evolution of the main indicators of pharmaceutical expenditure.

Institutional Contacts

FARMAINDUSTRIA has intensified its line of communication and dialogue with the health authorities of the autonomous regions begun in previous years. Thus, it has maintained institutional contacts with regional health ministers and those responsible for Pharmacies in the different Autonomous Regions. In these contacts the sector's priorities have been put across and those particular matters that affect specifically each autonomous region have been tackled.

It is worth pointing out that the round of institutional meetings held during the months of July and August 2008 with the regional authorities to present them with the most relevant matters of the Understanding, and especially the *+i Clinical and Translational Research Co-operation Programme* for which there is a specific section of this Report.

FARMAINDUSTRIA- Autonomous Regions Forums

During 2009 the FARMAINDUSTRIA- Autonomous Regions Forums have continued, where through the meetings of those in charge of health in Central and Regional Government, current and relevant subjects for the pharmaceutical industry are tackled.

In the last twelve months, FARMAINDUSTRIA has organised three forums, in which Regional decision-makers together with representatives of the Ministry of health have participated:

- XI FARMAINDUSTRIA- Autonomous Regions Forum (26-27 February 2009) held in Palma de Mallorca (Islas Baleares), under the theme *Counterfeiting Medicines: new challenges*. This event was closed by the Balearic Minister for Health.

- XII FARMAINDUSTRIA- Autonomous Regions Forum (17-18 September 2009) held in Madrid. This forum, which was closed by the Community of Madrid Minister of Health, was dedicated to the Clinical and Translational Research Co-operation Programme, and was attended by representatives of the 17 Autonomous Regions.

- XIII FARMAINDUSTRIA- Autonomous Regions Forum (6-7 May 2010), held in Cáceres. Focused on public-private co-operation in R&D. The forum was opened by the Minister of Health for Extremadura was attended by a wide range of decision-makers from regional health authorities.

DURING 2009 THE TAKE-OFF OF THE ELECTRONIC PRESCRIPTION AND MEDICAL RECORD IN THE AUTONOMOUS REGIONS HAS CONTINUED

Scientific Societies & Professional Organisations

During 2009, contacts have continued with professional organisations and scientific societies, especially those concerned with primary care (SEMFYC, SEMERGEN, SEMG), the pharmaceutical field (SEFH, SEF, SEFAP), health directors and primary care (SEDISA, SEDAP), heath law, health IT, as well as with societies in specialist fields (oncology, geriatrics, etc.) with which it maintains fluid communication channels. At the same time, FARMAINDUSTRIA has had a notable presence in the different congresses organised by these scientific societies.

Regulatory initiatives in Autonomous Regions

Below, the most relevant regional policies, regulations and initiatives from the last twelve months are outlined, as well as some of the activities carried out by FARMAINDUSTRIA in this area.

Electronic prescription and clinical record. During 2009 the electronic prescription and clinical record have continued to take off in the Autonomous Regions. To date, the Autonomous Regions of Andalucía, Cataluña, Extremadura and Galicia have their own regulations.

Prescription by Active Ingredient and generics. There have not been any significant changes in regard to the tendency observed in previous years of coexistence of different models of Prescription by Active Ingredient (PAP), although it seems that the limiting of this mode to the active ingredients which have a generic seems to have consolidated . Thus the Andalucian Health Service encourages the PAP, whilst other services such as in Castilla y León, Extremadura, Canarias and Murcia, have the PAP closer to medicines with generics, excluding medicines with a narrow therapeutic range from it.

Furthermore, a strong tendency to promote the prescription of generic medicines as a cost-saving measure has been observed. In fact, a large number of Autonomous Regions, amongst others, Castilla-La Mancha, Cataluña, Comunidad Valenciana, Galicia, Murcia, Navarra or The Basque Country el País Vasco, have developed their own programmes for such a purpose.

In line with the activity carried out in previous years, FARMAINDUSTRIA has continued to make clear in different forums the importance of branded prescriptions and the importance of the Reference Price System (RPS), as a tool in moderating the increase in pharmaceutical expenditure. The comparisons that are frequently made on the quota of generic prescriptions in Spain in relation to other countries does not take into account, in our case, the RPS levelling the price of generics and branded medicines, offering branded medicines at generic prices. For this reason, it can be said that the situation in force in Spain is perfectly comparable to countries such as Holland and is even better than that of countries such as Portugal, Austria or Sweden. More precisely, in Spain with the data from December 2009 and according to IMS information, the market quota for medicines at generic prices (due to being included in the PRS) accounted for 34.4% by units and 17.9% by value.

Central Purchasing of Medicines. Various Autonomous Regions have continued the trend towards promoting the starting up of projects aimed at centralising medicine purchasing for centres and hospitals through Central Purchasing Units.

In this area, FARMAINDUSTRIA has participated with those in charge of the Catalan Health Institute, in the process of producing the documentation for the technical prescriptions of the Framework Agreement for purchasing medicines for their hospitals. Likewise contacts have continued with the Andalucian Health Service where an Integrated Logistical Management System (SIGLO) was studied.

Regional Committees for evaluating medicines. FARMAINDUSTRIA has carried out the monitoring of the various regional initiatives aimed at setting up committees, commissions or assessment boards to evaluate medicines, aimed, in this case, at regional authorities with the aim of clarifying those matters about which doubts were raised and which could affect the sector. To date articles on this matter have been adopted by the Autonomous Regions of Andalucía, Aragón, Cataluña, Galicia, Madrid and Navarra.

Passing of medicines from hospital diagnosis to dispensing services in hospital pharmacies/ inclusion of medicines in the scope of hospitals. During 2009, and within the framework of the measures to control pharmaceutical expenditure through prescriptions by the Autonomous Regions, the trend seen in previous years where certain medicines diagnosed for use in hospitals go on to be dispensed in hospital pharmacies has continued. This largely involves medicines for oncological processes, rheumatoid arthritis, psoriasis, ovarian stimulation and acromegaly.

Catalan Medicine Round Table. On the initiative of the Catalan Health Ministry the Catalan "Mesa del Medicament" was set up in September 2009. The aim of the Round table, in which FARMAINDUSTRIA, took part, was to identify the sector's uncertainties and produce recommendations on those areas which require coordinated action.

The Round Table was structured with a Plenary, with representation from all involved, and three Working Groups: i) medicine research; ii) rational use and sustainability of the pharmaceutical service and iii) the patient as his treatment administrator. Each group was made up of representatives from different bodies related to the subjects that they were going to tackle, with the aim of analysing specific areas in order to carry out the appropriate recommendations.

The conclusions of this Round Table, to which FARMAINDUSTRIA made a large number of observations defending the interests of the sector, were presented in the Plenary held on el 3 March 2010 under the presidency of the Ministry. At the time of the production of this Report, the final document of the Round Table had still not been received.

Draft Bill on the Creation of an Association of Medical Visitors in the Community of Valencia. By resolution of the Director General of Justice and the Child in the Community of Valencia the request made to the Regional Federation of Health Information Officers from Alicante, Castellón and Valencia in reference to creating a Health Visitors' Association was rejected.

3.1.3. +I CLINICAL AND TRANSLATIONAL CO-OPERATION RESEARCH PROGRAMME

In compliance with the agreement adopted by the Governing Bodies of FARMAINDUSTRIA and ratified in the Extraordinary General Meeting in March 2009, the Association's President presented to the then Minister of Health and Consumer Protection, D. Bernat Soria, a commitment from the pharmaceutical industry to Spanish society in the areas of employment, internationalisation and R+D. This commitment arose as a response to the call made by the Government to the pharmaceutical Industry, so that at a time of economic

crisis and faced with the Government's determination to keep social services, including pharmaceutical services, it would increase its investment efforts in research and in that way contribute to fostering a new model of economic growth in which the sectors with high productivity and which were innovation intensive would have more weight.

The commitment was ratified by the new holder of the Health and Social Policy portfolio, Dª. Trinidad Jiménez, including four new fundamental elements: maintaining and improving employment, increase investment in R+D, increasing the internationalisation of the sector, and co-operating with the Government and the Autonomous Regions to improve the rational use of medicines and boost clinical and translational research.

From the public presentation of the *Ministry of Health and Social Policy-Farmaindustria Understanding*, the Association has dedicated a large part of its efforts to starting up a co-operation commitment with the Autonomous Regions to boost clinical and translational research.

This commitment has taken the form of, amongst other initiatives, the *+i Clinical and Translational Research Co-operation Programme*, set to develop public-private co-operation programmes with the Autonomous Regions in coordination with the Ministry of Health and Social Policy (MSPS) and the Carlos III health Institute (ISCIII).

One of the first tasks taken on by Farmaindustria was to internally define and contrast with the MSPS and the ISCIII, the possible collaboration areas with the Autonomous Regions which could be carried out within the +i Programme. Taken together, the projects that could be financed in this programme should meet the following characteristics:

- Precompetitive Character: they should be projects of a horizontal or transversal nature, thus giving preference to research programmes or support platforms, with special attention given to aspects of management and infrastructure.

- Mutual interest and co-financing: the aims of the projects should be shared and meet public-private needs. The common interest should be reflected in a contribution by both parties, to be negotiated depending on the project.

- Institutional mechanisms: the way of governing the projects, their operating rules, and their management and monitoring should be shared, with the most appropriate formula for each project.

- Professional management, excellence and national and international projection.

- Instrument: the legal framework will be a collaboration agreement between the corresponding autonomous region and Farmaindustria, in which the institution that will manage the projects or programmes will also be designated, which could be a research foundation or other body.

- Partners: the partners of each project will be Farmaindustria and the corresponding autonomous region, to which other bodies, public or private, could adhere (universities, investigation centres, hospitals, scientific societies, etc.), as well as, where appropriate, the MSPS and the ISCIII.

- Duration: the resulting structures of the projects will be of a permanent nature, but the financial commitment will be for up to three years.

- Synergies with other national (ISCIII) and international biomedical research programmes (especially the *Innovative Medicines Initiative* –IMI-, and *VII European Union Framework Programme*).

Without discounting the possibility of financing outstanding projects that meet the previous criteria, the following will be considered as priority collaboration areas:

- Programmes/support structures carrying out clinical trials.
- Programmes/support structures for Primary Care clinical research.
- Regional bio-bank programmes.
- Investment and improvement in hospital centres for their accrediting as Health Research Institutes.

Once the basic characteristics of the projects and the priority collaboration areas were defined, during the months of June and July 2009 a round of bilateral meetings were held with all the autonomous regions to present them with the most relevant aspects of the Understanding, and in particular, the *+i Clinical and Translational Research Co-operation Programme*.

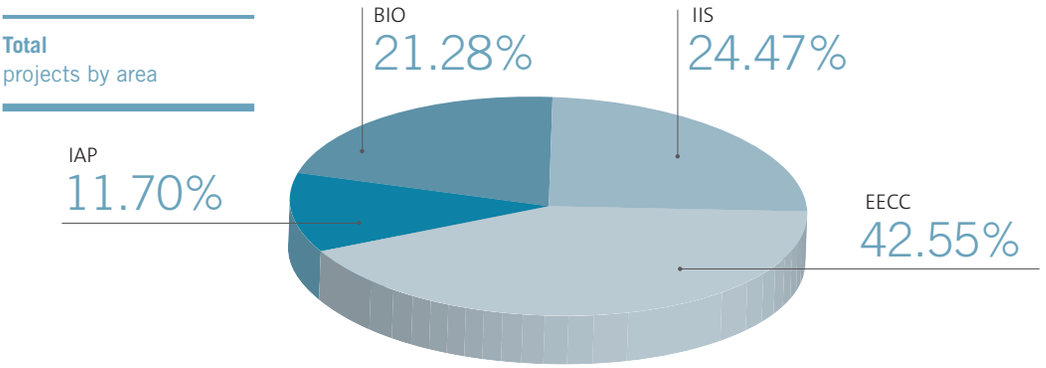
Afterwards, the Autonomous Regions were formally invited to participate in the programme, by a letter to the regional ministers, sent in September 2009, opening up a presentation period for projects.

Furthermore, the XII FARMAINDUSTRIA-Autonomous Regions Forum, held in Madrid on 17 and 18 September 2009, was dedicated to analysing the organisational and co-ordination aspects of the programme with representatives of the Autonomous Regions.

With the aim of contrasting the adaption of the projects presented by the Autonomous Regions to the areas defined as priority ones, an independent Assessment Group was set up, made up of five renowned expects in the area of clinical and translational research and in health management, to which a representative of the ISCIII was invited to join.

To summarise we could state, that in total, the Autonomous Regions presented 94 projects to the +i Programme whose distribution by priority area is as follows:

- Clinical Trial support (a total of 40 projects). Examples: autonomous trial management units; hospital support units; support to CEIC; specialist units (paediatric trials, in elderly people, in phase 1); and training.
- Clinical Trial support in primary care (a total of 11 projects Examples: autonomous networks; strengthening existing management units; intensification; training; administrative and methodological support units.
- Bio-banks (a total of 20 projects). Examples: specialised bio-banks (brains, nervous system tissue, tumours, blood, umbilical cord etc), be they newly created or strengthening existing ones, at regional level and in specific centres.
- Health Research Institutes (a total of 23 projects). Examples: projects to create new Health Research Institutes (consultancy and start-up); specific infrastructures for new IIS; common research support.



As a conclusion of this phase of the process, and at the time of the finalising of this Report, it can be pointed out that 14 Autonomous Regions have signed up to co-operation agreements for the +i Programme.

In all cases, the different projects will have the corresponding indicators of objectives and results and control procedures have been established which allow the guaranteeing of the correct use of funds and the Programme's transparency. Likewise, it has been agreed and this appears in the different agreements, that in each region a Monitoring Committee will be set up, which will verify that each project meets the different milestones of the programme.

SUMMARY OF THE AGREEMENTS SIGNED WITH AUTONOMOUS REGIONS. +i PROGRAMME

Autonomous Region	Date of signing Agreement and Addenda	No. PROJECTS BY PRIORITY AREAS				
		Clinical Trial Support	Primary Care Clinical Research Support	Bio-banks	Health Research institutes	TOTAL
Andalucía	05/02/10	1	-	1	2	4
Aragón	27/04/10	2	-	-	-	2
Baleares	26/01/10	1	1	1	1	4
Castilla y León	24/02/10	1	-	2	1	4
Canarias	21/01/10	4	-	-	1	5
Cataluña	23/02/10 27/04/10	1	1	2	4	8
C. Valenciana	21/01/10	4	-	-	-	4
Extremadura	24/02/10	1	1	1	1	4
Galicia	27/04/10	6	3	1	3	13
La Rioja	23/12/09	1	-	-	-	1
Madrid	05/02/10	10	1	9	6	26
Murcia	05/02/10	1	1	1	1	4
Navarra	23/12/09	1	1	-	1	3
País Vasco	23/12/09	1	-	1	1	3

It is important to point out that these agreements were signed for the applications of the first Programme funds, which was assigned 50 million Euros, coming from contributions made by the laboratories in 2009. However, the exceptional measures for cuts in pharmaceutical expenditure by the Government, by means of the two Royal-Decree Laws in 2010, will stop the pharmaceutical companies continuing to finance the funds that were expected to be launched in 2010 (60 million Euros) and 2011 (70 million Euros).

THE PARTICIPATION OF FARMAINDUSTRIA IN THE VARIOUS TECHNICAL COMMITTEES FORMED UNDER THE AUSPICES OF THE MINISTRY OF HEALTH AND SOCIAL POLICY IS FUNDAMENTAL TO PASS ON TO THE ADMINISTRATION THE FEELINGS OF THE SECTOR

3.1.4. TECHNICAL COMMITTEES

The participation of FARMAINDUSTRIA in the various Technical Committees formed under the auspices of the Ministry of Health and Social Policy is fundamental in order to pass on the feelings of the sector to the Administration, bringing about a debate that makes the Administration's task easier and allows the improving of institutional relations with the authorities. FARMAINDUSTRIA has representation on the Committees mentioned below.

Consultation Committee of the Inter-territorial Board of the National Health System

This Committee, presided by the Secretary General of Health, has as a mission to inform the Inter-territorial Board of the National Health System on the main matters in the health field that the Ministry of Health and Social Policy has to make decisions on. Amongst others it is worth pointing out, the different implementation stipulations of Law 29/2006 and the monitoring of the evolution of pharmaceutical expenditure. The Consultation Committee of the CISNS is made up of representatives of the different administrations (local, regional and state), trade unions and business organisations, amongst them, FARMAINDUSTRIA.

Evaluation Committee for Medicines for Human Use (CODEM)

The CODEM is the professional body of AEMPS for technical and scientific assessment of everything relating to the authorisation of new medicines. CODEM is made up of 16 members, five of which are designated due to their position and the rest designated due to their knowledge in areas of evaluation of medicines. Although the designation is made by the Ministry of Health and Social Policy, four of the directors of the Committee are proposed by the organisations most representative of patients, doctors, pharmacists and industry. The director corresponding to the pharmaceutical industry is designated by FARMAINDUSTRIA.

The Committee informed the Subgroups which are charged with preparing specific reports on generic medicines or on non-prescription medicines.

3.2. SOCIAL COMMUNICATION

As in any other field, business, politics or social, communication in the pharmaceutical industry consolidates day after day as an extraordinarily effective tool to achieve the main aims of this industrial sector most successfully. FARMAINDUSTRIA is aware of this and has been prioritising for some time the area of activity with the objective of improving on one hand, the presence and influence of the industry in the media, and on the other, improving access to decision and opinion environments.

To that end, the central principles upon which its communication has been based in 2009 has been i) national and regional media, reinforcing the information activities of the Association; ii) opinion leaders iii) the instruments at the service of media professionals and the institutional relationship with them; iv) patient organisations; v) scientists and the main protagonists of bio-medical research in Spain; vi) society in general; and vii) of course, the pharmaceutical sector itself.

3.2.1. MEDIA

In 2009 FARMAINDUSTRIA continued to work intensely to improve the access, presence and influence of the Association in the media and to transmit correctly the values and strategic messages of the pharmaceutical industry based in Spain.

In this sense, the aims set in relation to the media were orientated towards: i) supporting the strategic approaches of the Association; ii) improving the image of the pharmaceutical industry in society ; iii) contributing to the creation of alliances with publishing groups; iv) raise the industry's image in the media; v) generate currents of influence in different decision environments and vi) recognise the exclusive characteristics of the sector, especially the social contribution of medicine and the leadership of the pharmaceutical industry in R+D.

News activity

2009 was characterised by the increase in news activity of the Association, centred, above all, on the Understanding reached with the government in the areas of R+D, competitiveness, internationalisation and its public presentation in the Ministry of Health in September, making both into important subjects related to our activity which the media has dedicated the most attention.

This event, and other important news moments throughout the year has given place to 20 press releases, the publication of numerous opinion pieces by various FARMAINDUSTRIA representatives in generalist press as well as specialised press, and above all, more than 30 interviews in all types of platforms (radio, TV, general and specialised press, etc.) especially after the public presentation of the Understanding. It also is worth pointing out the increase in the presence of the Association in web based media.

ABC

Gobierno y farmacéuticas acuerdan la mayor inversión en I+D de España

However, together with the Understanding reached with the Government in the areas of R+D, competitiveness and internationalisation, there were other important moments from a news point of view in 2009 for Farmaindustria amongst which should be pointed out the celebration of the EFPIA Annual Assembly which took place in May 2009 in Sevilla.

As in previous years, the news activity of Farmaindustria has been strengthened with the Association's institutional advertising, which this year newly presented a new creativity for the ceremony of the *Awards for the Best Initiatives in Patient Care*, which is held annually by the Farmaindustria Foundation.

Coming together with opinion leaders and meetings with regional media

As in previous years, in 2009 Farmaindustria carried out numerous meetings with panelists, columnists, editors and radio and television news producers, with the aim of directly informing them of the main areas of interest for the innovative pharmaceutical industry in Spain. In all during 2009 almost 30 opinion

leaders were told first hand by various representatives of the Association about the situation of the pharmaceutical sector, its principle demands, aim and concerns.

Furthermore, in 2009 meetings with regional media were consolidated as an important way of coming together between FARMAINDUSTRIA and Autonomous Regions, favouring in all of them more and better understanding of the pharmaceutical industry. Specifically, different meetings were held with an ample representation of media from Andalucía, Cataluña, Islas Baleares and Madrid.

IN 2009 MEETINGS WITH REGIONAL MEDIA WERE CONSOLIDATED AS AN IMPORTANT WAY OF COMING TOGETHER BETWEEN FARMAINDUSTRIA AND THE AUTONOMOUS REGIONS

Training for news professionals

For the seventh consecutive year, FARMAINDUSTRIA held in 2009 the *Pharmaceutical Industry and the Media* Seminar, which brought together in Córdoba more than 30 representative of the news panorama of all Spain. In co-operation with the National Association of Health Publicists (ANIS), the Association of Economic Information Journalists (APIE) and the Federation of Spanish Press Associations (FAPE), these meetings have consolidated as a reference point for information, converting the Association into an active agent of communication, which is close to, and known by the media which can thus demarcate more precisely the reality of the pharmaceutical sector in Spain.

On the same lines, FARMAINDUSTRIA took part in the V National Health Journalists Congress, held in October 2009 in Madrid with an ample representation of media professionals from all over Spain.

Press Web

In September FARMAINDUSTRIA announced the updating of its press web page with a higher multimedia content and with a more appropriate design for new technology, without forgetting the importance of being able to rapidly and simply access the contents.

Through the address http://prensa.farmaindustria.es, journalists and anyone interested, can access press releases and announcements, issued by FARMAINDUSTRIA, consult publications, consult the summaries of the daily press, download the latest interviews, reports or opinions made by the Association to the written and audiovisual media, etc.

Another new highlight is the Multimedia Zone where all the corresponding archives relating to FARMAINDUSTRIA activity in forums and conferences as well as those relating to activity in radio and television can be listened to or seen.

3.2.2. RELATIONS WITH PATIENTS' ORGANISATIONS

During 2009 the activities of FARMAINDUSTRIA relating to patient groups increased notably. To the now traditional activities in this field (*Pacientes* magazine and the *Awards for the Best Patient Care Initiatives*) other important activities have been added such as the celebration of the "I Conference of the Pharmaceutical Industry with Patients' Associations" and the updating of the National Map of Patients' Associations. Furthermore, in the heart of FARMAINDUSTRIA a new work group orientated towards deepening the work that the industry carries out in the patient field has been created. It is an 'ad hoc' Patients' Group, which has arisen as a subgroup of the Functional Communication Group.

IN THE HEART OF FARMAINDUSTRIA A NEW WORK GROUP HAS BEEN CREATED ORIENTATED AT DEEPENING THE WORK THAT THE INDUSTRY DEVELOPS WITH PATIENT ORGANISATIONS

'Awards for the Best Patient Care Initiatives'

On 15 December 2009 the ceremony took place for the *2009 Awards for the Best Patient Care Initiatives* organised by the FARMAINDUSTRIA FOUNDATION. This year's event introduced a new section for recognition of journalism within the Media category. With the passing of time, these awards have become the main reference point in patient organisations, having gone from 90 candidates presented in the inaugural ceremony to more than 300 received for the fifth ceremony in 2009.

The Autonomous Regions with most bodies and organisations presented at the Awards ceremony were Madrid (64), Cataluña (47), Valencia (37), Andalucía (35) and Castilla y León (19). As is the normal rule, a multidisciplinary jury chose the winners.

The ceremony for the *2009 Awards for the Best Patient Care Initiatives* was held in the *Real Fábrica de Tapices* (former Royal Tapestry Mill) in Madrid and had a large public attendance. New on this occasion was the presenting of an accrediting diploma to all the finalists and the full event was recorded in video. The corresponding photos and videos of the event are available in the multimedia zone of the FARMAINDUSTRIA press site (http://prensa.farmaindustria.es) and in the web www.premiospaciente.com where also information, documentation and photographs of previous awards ceremonies can be consulted.

2009 AWARDS FOR THE BEST PATIENT CARE INITIATIVES
PATIENTS' ASSOCIATIONS
Health Education Initiatives
Award: Association of Relatives of Alzheimer Sufferers and other Dementias of Valdepeñas **Runner-Up:** Andalucian Federation of Parents with Children with Autism "Autismo Andalucía" **Runner-Up:** Spanish Association of People Affected by Lymphoma
Social Consciousness Initiatives
Award: Association of Psychiatry and Life **Runner-Up:** Autism Federation of Castilla y León **Runner-Up:** Spanish Association of Patients with Cephalagia
Member Services Initiatives
Award: Spanish Federation of Associations of Celiacs **Runner-Up:** Heart and Life Association **Runner-Up:** Spanish Association of Amyotrophic Lateral Sclerosis
Commitment to Research
Award: FEDER Foundation **Runner-Up:** National Federation of Associations ALCER **Runner-Up:** Foundation of People Affected by Fibromyalgia and Chronic Fatigue Syndrome
SOCIAL GROUPS
Award: Antena 3 Foundation **Runner-Up**: Blas Méndez Ponce Foundation. Help for Oncologic Children **Runner-Up:** Manos Unidas
HEALTH ENVIRONMENT
Scientific and Professional Societies
Recognition: Spanish Society of Clinical Biochemistry and Molecular Pathology
Attendance Centres
Recognition: Sant Joan de Déu Hospital **Recognition:** Management of Patient Care of the Madrid Health Service of the Community of Madrid Regional Health Ministry
MEDIA
Media
Recognition: Joly Group for its Health supplement
Journalist
Recognition: D. Ramón Sánchez Ocaña **Recognition 'ex aequo':** Jose María Catalán
CAREER
Extraordinary Recognition: D. Josep Carreras for his work in the battle against leukaemia

Associations' Map

Five years after the publication of the study *The patient in Spain. National Map of Patient Associations*, the FARMAINDUSTRIA FOUNDATION last year updated this directory with the inclusion of new patients' organisations and new content, in order to provide a wider and more precise image of the associations movement in Spain at the moment. The *2009 National Map of Patient's Associations* allows the classification of these organisations by resources, province, regional community in which they are based, the type of pathology they represent, etc.

IN THE "I PHARMACEUTICAL INDUSTRY CONGRESS OF PATIENTS' ASSOCIATIONS" MORE THAN 150 ORGANISATIONS AND REPRESENTATIVES OF THE PHARMACEUTICAL INDUSTRY PARTICIPATED

Conference of Patients' Associations

The "I Pharmaceutical Industry Conference of Patients' Associations" was held in the European Commission headquarters Madrid in June 2009. More than 150 patients' associations and representatives of pharmaceutical industry, Administration, health professionals and media took part in it.

This Conference, which was hatched with an intention to continue in the future, was set up as a forum to interchange information and opinions between different people involved. Amongst the speakers, stand out the scientific publicist Eduardo Punset, the president of the Spanish Patients' Forum, Albert Jovell, the scriptwriter and film director Albert Espinosa, or the Chair in Sociology Juan Díez Nicolás. To ease access for as many participants and organisations as possible for this Conference, all the seminars and presentations could be followed live though the FARMAINDUSTRIA web page.

Collaboration with patients' organisations

During 2009, FARMAINDUSTRIA heeded numerous calls and invitations from patients' organisations to share experiences and support their work. Representatives of FARMAINDUSTRIA maintained institutional contacts, attended assemblies, took part in congresses, conferences and round tables with institutions such as the General Assembly of Patients (AGP), the Spanish Patients' Forum (FEP) or the Spanish Rare Diseases Foundation (FEDER). Some of these conferences in which FARMAINDUSTRIA took part were the V Multiple Sclerosis Congress which was held in the Palacio Euskalduna in Bilbao; the Information Conference on Lymphoma Research, organised by the Spanish Association of People Affected by Lymphoma, Myeloma and Leukaemia held in the National Oncological Research Centre ; or the "Patients' Associations: an essential area to improve the Health System" Conference, organised by the Management of Patient Care of the Madrid Health Service of the Community of Madrid Regional Health Ministry.

'Pacientes' Magazine

During 2009 the FARMAINDUSTRIA FOUNDATION edited issues 13, 14 and 15 of the *Pacientes* (Patients) magazine. In the first of these, the space sector was analysed to see how it has become a productive laboratory for research and development of new technology and treatments which can later be applied to all areas of science, including medicine. Issue 14 was wholly dedicated to analysing the current state of Health in Spain in the various Autonomous Regions, its strong and weak points, as well as the perception that they have of the different agents involved. The final issue of 2009 involved a wide-ranging report on umbilical cord banks in Spain, which made evident that our country is third worldwide in units of stored umbilical cords, only behind the USA and Taiwan.

3.2.3. RELATIONS WITH OTHER INTEREST GROUPS

FARMAINDUSTRIA considers that a priority in recent years has been the creation of new strategic bases upon which the communication activities aimed at positively influencing the social perception of the Pharmaceutical Industry can operate. Following this line, activities have taken place to come together with new groups which had not previously occurred. The scientific and research world, NGOs or personalities from the different intellectual fields are some of those types of activities which are aimed at.

'Redes de Investigación en Medicamentos' Magazine

Five years after its inception, the *Redes de Investigación en Medicamentos* (Medicine Research Networks) magazine has consolidated as a point of reference for information in the biomedical research field carried out in Spain. Thus, the wide ranging scientific community that performs its work in Spain, have found in this publication a focus for knowledge, interest and uncertainties, contributing to creating a favourable climate for innovation and also for its recognition by society. The creation of the Scientific Network Committee, made up of the co-ordinators and scientists responsible for networks and research centres to which various issues have been dedicated, meets twice a year, has meant more convergence between the reality of these groups and the aims of the publication.

In 2009 issues 12 and 13 of this magazine came out, dedicated respectively, to AIDS Research Network (RIS) and the Biomedicine Research Centre Network focused on physiopathology, obesity and nutrition (CIBERobn), both dependent on the Carlos III Health Institute.

FARMAINDUSTRIA Social Council

The FARMAINDUSTRIA Social Council has consolidated as an important assessment body for the association, providing an objective and effective external view of the position of the sector and the institution in the various opinion and decision making environments. In 2009, the Social Council has held three meetings in which those attending have backed the search for opportunities for public presence based on responsibility at a time of crisis, and innovation as a differentiating element of the sector and a benchmark as new productive model.

From this year, the FARMAINDUSTRIA Social Council has incorporated Dª Isabel Aguilera as a new member. Her proven experience in the area of new technologies and her excellent profile with her knowledge of the latest trends in social communication in this environment will help to enrich the contributions to the Social Council.

Activities with NGOs

With the aim of continuing to deepen the mutual knowledge between the pharmaceutical industry and society in general, FARMAINDUSTRIA keeps frequent contact with non-governmental organisations in the form of conferences, colloquiums and congresses.

As a consequence of collaborating with the Farmamundi NGO, the vision of FARMAINDUSTRIA regarding access to medicines for the poorest sections of society has been included in the book *Essentials for Life. Conferences on the problem of access to essential medicines and possible solutions*.

3.2.4. CORPORATE SOCIAL RESPONSIBILITY

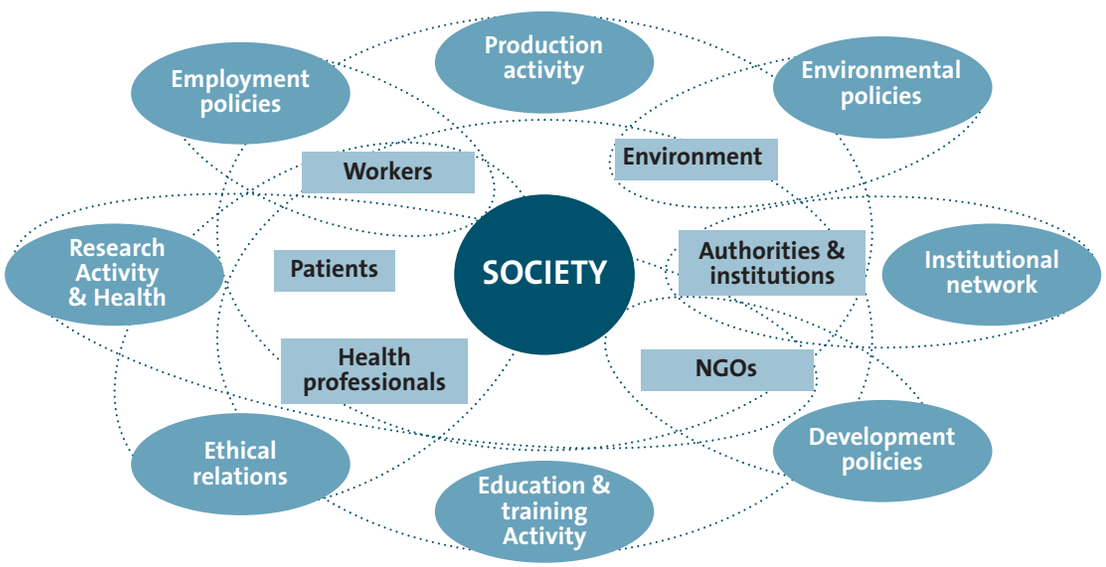
Within the area of Corporate Social Responsibility (CSR), in which FARMAINDUSTRIA has been working for many years, new activities carried out in 2009 have been included, such as the incorporation of the Association to the CEOE Business Social Responsibility Commission, the creation of an 'ad hoc' CSR group, the sponsoring of a study on Health Foundations or the participation in numerous forums and meetings with other organisations.

Furthermore, FARMAINDUSTRIA as a member of the Association for the Self-regulation of Commercial Communication (AUTOCONTROL), adhered to the European Advertising Standards Alliance, has received an annual Corporate Social Responsibility certificate, by which it assumes the ethical commitment to responsibly exercise freedom in commercial communication, contributing to strengthening advertising self-regulation.

The past 20 April 2010 the AUTOCONTROL General Assembly was held, after which there was a partial renewal of the Association's Board of Directors, in which FARMAINDUSTRIA was again chosen as a director.

'Ad hoc' Corporate Social Responsibility Group

In the final quarter of 2009 an 'ad hoc' CSR group was set up, created from the Functional Communication Group, with the aim of becoming aware of and evaluating the multiple activities relating to CSR that are carried out in the sector and recognising their value, to the point of positioning the pharmaceutical industry as a reference point for CSR. The first task of the Group consisted of defining what Pharmaceutical Industry Social Responsibility is and eight complementary areas were listed: from own production activity and R+D of medicines that benefit society, to development policies or philanthropy, through employment and environmental policies, education and training activity, ethical relations or encouraging private-public alliances amongst others.



FARMAINDUSTRIA SPONSORED THE CARRYING OUT OF THE STUDY, 'HEALTH FOUNDATIONS IN SPAIN: THE CURRENT SITUATION AND PERSPECTIVES' PRODUCED AND PRESENTED BY THE SPANISH ASSOCIATION OF FOUNDATIONS

Public acts of Corporate Social Responsibility

FARMAINDUSTRIA has been present at many conferences, talks and colloquiums on CSR, such as "The Pharmaceutical Sector and Corporate Social Responsibility" conference, which brought together in the Madrid Chamber of Commerce, representatives of the industry and the heads of Regional and Central Administration.

Furthermore, FARMAINDUSTRIA sponsored the carrying out of the study, *Health Foundations in Spain: the current situation and perspectives*, produced and presented by Spanish Association of Foundations. Prior to the presentation of the study, the FARMAINDUSTRIA headquarters in Madrid held a meeting of the Health Foundations Group of the Spanish Association of Foundations.

3.2.5. OTHER ACTIVITIES

Conferences and Sponsorships

As has been usual, FARMAINDUSTRIA has collaborated on numerous Conferences and Meetings with the aim of creating awareness of the positioning of the sector in those forums of debate which tackle areas of interest for the pharmaceutical industry. The traditional "Meeting of the Pharmaceutical Industry in the Menendez Pelayo International University", which in 2009 reached its ninth event was dedicated to the contribution of the pharmaceutical sector to the new model of Spanish growth, is another example of this collaboration.

In the media field, in September, FARMAINDUSTRIA sponsored a television programme for the first time, in this case the *Redes* (Networks) programme directed and presented by the scientist Eduardo Punset, and with the title "The Drugs of the Future", which was wholly dedicated to the R+D process of medicines and their evolution through the years, as well as the distinct clinical and pre-clinical trial stages and the enormous investment that they require.

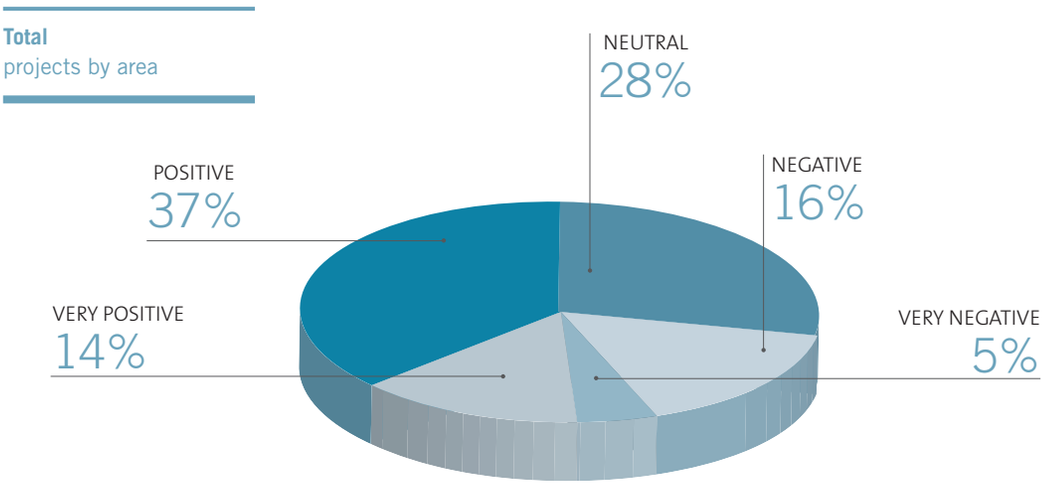
Internal Communication

Weekly Communication Flash. In 2009, FARMAINDUSTRIA distributed amongst its members every Monday a total of 42 weekly communication flashes, which periodically informed on the activities carried out by the Association in the area of communication and relations with interest groups for the pharmaceutical sector.

Independently of the weekly editions, at certain times if there was an issue of particular importance to communicate to members a Special Communication Flash would be distributed, generally on a single theme, with full and detailed information on a particular matter.

Analysis of Media Presence. During 2009 12 monthly reports were produced with at total of more than 3,400 items being registered, analysed and evaluated. Besides information connected to specific business information (billing, profits, mergers, corporate changes and restructurings etc) which affect individual companies or certain business groups, the areas most dealt with by the media in relation to the sector as a whole were i) those relating to the Understanding reached by FARMAINDUSTRIA with the Government and society as a whole in the areas of employment, internationalisation and investment in R+D; ii) the R+D of the pharmaceutical industry and the support of the sector in changing the Spanish production model; iii) pharmaceutical expenditure and its management by the Autonomous Regions; iv) the appearance and management of the Type A influenza by the administration and its relationship with the pharmaceutical industry for the development of a vaccine against virus H1N1; v) the Spanish pharmaceutical market; and vi) other specific issues which occupied a large amount of space in regional and national newspapers such as the counterfeiting of medicines, medicine traceability, the European Commission report on the investigation opened into the pharmaceutical sector, current issues relating to FARMAINDUSTRIA and its Foundation, etc.

With respect to the favourability shown in the information gathered and by the valuation given to each of them (between +2 and -2), the average index of the more than 3,400 news items analysed were positive (+0.35), with a total of 719 pieces of news valued as negative or very negative, 971 neutral and 1,761 positive or very positive.



3.3. SERVICES TO MEMBER LABORATORIES

3.3.1. ONLINE SERVICES

Public and private FARMAINDUSTRIA web portals

During 2009, work has been carried out on adjusting the FARMAINDUSTRIA public and private web portals to the particular needs of the users and improving their contents with new information environments.

Restructuration of the Code Zone and USD. The implementation of the new "Data Protection Code Type" and the special access volume that this zone of the web bears, has recommended its restructuring, separating the different codes and the USD into two zones within a format that currently has available: i) a 'Code' section that groups together the contents of each one of them: "Health Professional Code" and "Patient Organisations" and "Data Protection Code Type", and ii) a new section for the USD, where all the information is found grouped together.

'The most read' and 'The latest'. These two areas filter all the information showing the most read and most recently uploaded, whenever there is a relationship with the information that the user is viewing at any particular time.

Both options have consolidated as very useful tools for users, on giving a fuller vision of other related information.

Corporate Image for the Documentation

During 2009 the process of normalisation and standardisation of Circulars, Flashes and Bulletins with the new corporate image for the documentation produced by the Association has continued.

Press web portal. During 2009 a new web portal for the communication area finished being developed: http://prensa.farmaindustria.es, becoming fully operative in the third quarter of the year. In order to do this it was necessary to adjust the corporate design to the graphical needs of the media; completely restructuring the area and giving it specially orientated contents, such as the Multimedia Zone or the Graphic Archive.

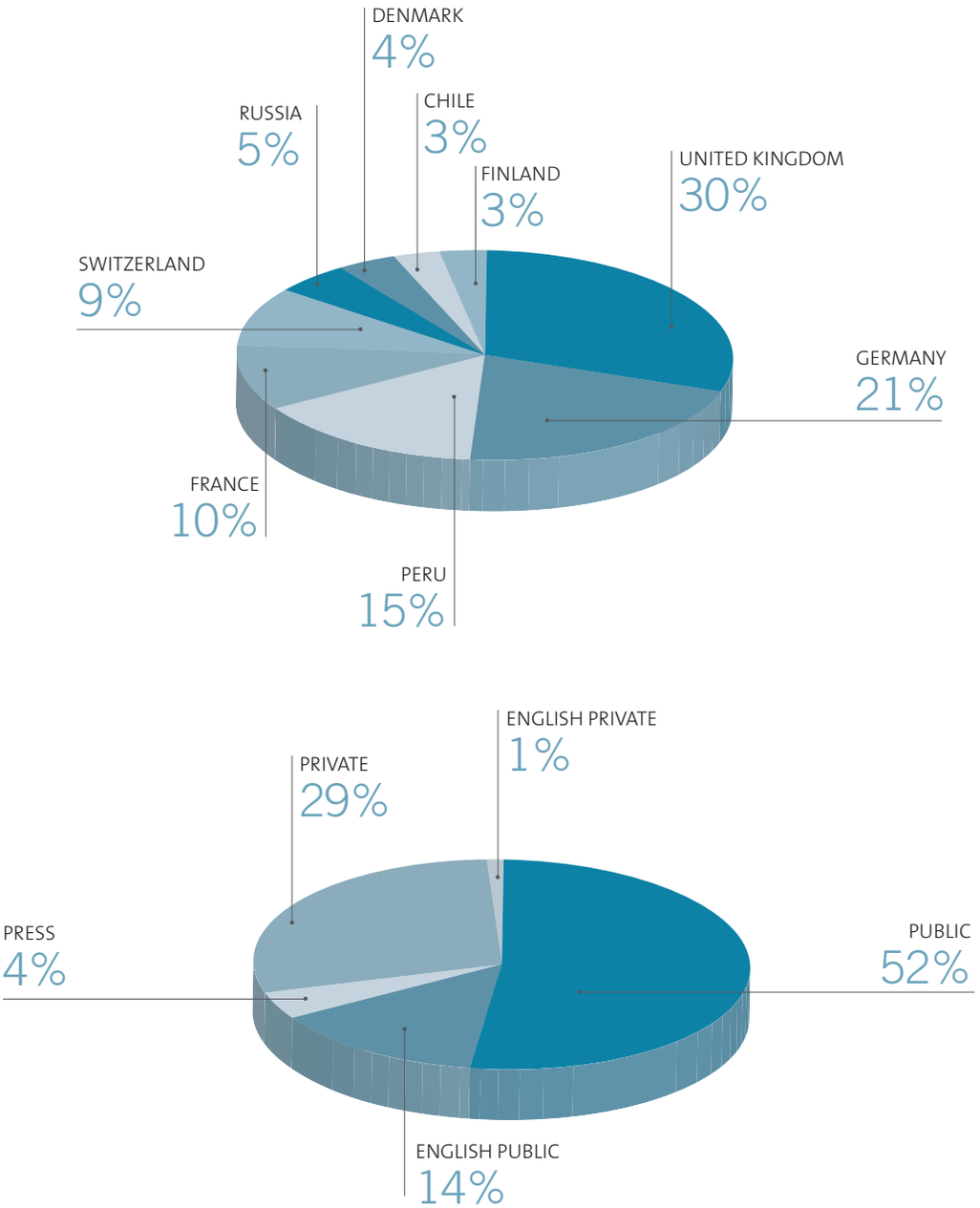
In the press web portal there are also Press Summaries, Clippings, Press releases or the "FARMAINDUSTRIA in the Media" section, the latter differentiating between press, radio or television.

Online services statistics. At the moment there are more than 60,000 documents available, mainly Circulars, Flashes and Bulletin, besides press and legal information. At the same time more than 20 documents each day are uploaded, which are sent to the companies through the *Daily Information Bulletin Information for Members*. In 2009 for the first time the number of accesses numbered more than a million, reaching 1,090,000 different accesses for the web portals as a whole.

The download volume surpassed 160,000 Mb, equivalent to 2 million circulars or 150,000 copies of this Report.

The majority of internet accesses are for the public web portal (be it in English or Spanish), covering more than 65% of the total.

IN 2009 THE NUMBER OF ACCESSES WAS MORE THAN A MILLION FOR THE FIRST TIME REACHING 1,090,000 DIVIDED BETWEEN THE WEB PORTALS AS A WHOLE



THE WORKING GROUPS AND FUNCTIONAL GROUPS IMPROVE THE MEMBER LABORATORIES' PARTICIPATION IN ALL THE AREAS OF INTEREST FOR THE PHARMACEUTICAL SECTOR

3.3.2. WORKING GROUPS AND FUNCTIONAL GROUPS

Since their updating in October 2008 due to the renewal of the FARMAINDUSTRIA Governing Bodies, the Working Groups and Functional Groups have continued to fulfil a fundamental role in the daily activities of the Association, on improving the member laboratories' participation in all the areas of interest for the pharmaceutical sector.

Generally, the various FARMAINDUSTRIA Working Groups and Functional Groups are controlled by a series of operating regulations common to all of them, they are renewed every two years and depending on their type, they can be defined as follows:

Working Groups (WG): created by the Governing Bodies to analyse specific areas, devise an industry position and follow specific action plans on strategic matters.

Functional Groups (FG): coordinated by the various FARMAINDUSTRIA departments, their mission concerns the study of subjects and matters common to the sector, fundamentally the technical aspects.

The current operative groups in FARMAINDUSTRIA are the following:

- **8 Working Groups:** 1) Employment, Training and Development; 2) Competitiveness and internationalisation; 3) R&D and Biotechnology; 4) Sustainability and Economic Regulation; 5) Relations with the Autonomous Regions; 6) Code of Good Practice; 7) Hospital Market, and; 8) Legislative Developments with a Technical Scope.

- **17 Functional Groups:** 1) Clinical Research; 2) Environment; 3) Pharmacovigilance; 4) Manufacturing and Traceability; 5) Registers; 6) Medical Directors and Research (BEST Project); 7) Human Resources; 8) Personal Data Protection; 9) Legal Services, 10) Taxation, 11) Health Technologies Assessment, 12) Medical Visits; 13) Communications; 14) Hospital Debt; 15) Vaccines; 16) Rare Diseases and Orphan Medicines, and 17) International Relations.

A summary follows of the activities of the different Working Groups and Functional Groups of FARMAINDUSTRIA in 2009.

WORKING GROUPS

Working Group on Employment, Training and Development. This Working Group in its second year of operation, has as its main aim, the analysis of the state of the sector in the areas of employment and future perspectives, studying the steps to continue advancing in the implementation of the Understanding in the areas of employment, in co-operation with the Ministry of Employment and Immigration.

On 22 September 2009, after a meeting between FARMAINDUSTRIA and the Minister of Employment and Immigration, D. Celestino Corbacho, and members of his team, a public presentation of the commitment of the pharmaceutical industry to quality employment, through its efforts to attract highly qualified professionals to be contracted, to continue to increase the importance of female employment and sustain the investment in continuous training for its workers. This act was written into the ambit of Understanding of the Industry with the Government of Spain and makes obvious the commitment of the sector to a new model of growth based on innovation.

Working Group on Competitiveness and Internationalisation. This Working Group, whose aim is to promote the industrial competitiveness and internationalisation of member laboratories, has been very active in 2009 given that internationalisation is one of the four pillars upon which the Understanding reached by FARMAINDUSTRIA with the Government is based, where the industry committed to make exports in the 2009-2011 period of a value of 22,500 million Euros, thus increasing its share of Spanish industrial exports as a whole.

In 2009, a Collaboration Agreement was signed between FARMAINDUSTRIA, the Latin-American Pharmaceutical Industry Federation (Fifarma) and the Argentinian Chamber of Specialist Medicines (CAEMe) within the framework of a strategy to increase the competitiveness of our pharmaceutical companies.

Likewise, intensive institutional contacts have been maintained with national and regional bodies and institutions for export, such as ICEX; Invest in Spain, Promomadrid and Acció. Exactly for that reason, an *Approach to the European Institutions Programme* was organised in collaboration with the latter two insti-

tutions, jointly promoted by the Madrid Chamber of Commerce and FARMAINDUSTRIA. The meeting allowed the gaining of first-hand knowledge of the European Commission and Parliament initiatives of importance for the sector, and at the same time, transmit to these institutions the role of our sector in the new economic growth model.

At the same time, various meeting were held with bodies, business delegations and authorities from the health field from other territories identified as priority ones, as is the case of Taiwan and Turkey and it has regularly participated in the International Relations Group of the OECD.

Working Group on R&D and Biotechnology. This is a newly created Work Group from the old biotechnology section and made up of 25 companies. Its role is to prepare positions and proposals for the sector for collaboration with the relevant institutions, to pay special attention to the cooperation between the industry and small biotechnological companies, putting instruments in place for this cooperation, taking advantage of the synergies with the pharmaceutical industry and bringing to the forefront the differential and complementary characteristics that FARMAINDUSTRIA can offer. Likewise, this Group also intends to stimulate the participation of the industry in national and international R&D programmes, especially in the Innovative Medicines Initiative (IMI).

Within the ambit of co-operation between the pharmaceutical industry and biotechnological start-ups and with the aim of improving the sector's knowledge base, FARMAINDUSTRIA commissioned the carrying out of a specific study on this area, which is currently in the process of being finalised. In the near future the possibility of carrying out some sort of joint venture of use to individual companies as well as the sector as a whole will be considered, and which will be useful from an institutional point of view, without replicating already existing activities.

Working Group on Sustainability and Economic Regulation. Throughout 2009, within the framework of the Understanding reached with the Ministry of Health and Social Policy (MHSP) this Working Group continued to carry out an intensive monitoring of all the legislative proposals related to economic regulation, sustainability of the National Health System and measures for containing spending, drawing up strategic documents on the position of the pharmaceutical industry.

In particular, the work carried out relating to the processes of revision of prices of some innovative products have meant the drawing up of a document that gathers together the industry's arguments on this matter. This document was sent to the MHSP and was better received than in the Administration, which led to an increase in the procedural guarantees of the laboratories affected by the revision process taking place: a change in the revision criteria, higher importance given to the declarations formulated by the laboratories to defend the special features of their products or individual analysis of each case, amongst others.

In the heart of this Working Group, a permanent monitoring of the detailed examination of the approval of medical innovations for therapeutic use has been carried out. At the same time, an exhaustive analysis has been made of SAS/3499/2009, of 23 December, which defines the new medicine groups, their reference price, and revises the reference prices set by Order SCO/3803/2008, of 23 December, initially preparing the statements for the draft of the order, and later, after its passing, carrying out an impact study of the Order, to quantify it from a public pharmaceutical expenditure perspective as well as from a sector point of view.

On a different matter the Working Group has carried out a monitoring of other matters of interest for the sector and of the economic reach, such as i) the work of the MSPS in the area of the Health Pact and the Strategic Plan for Pharmaceutical Policy; ii) the coming into force and the practical application of the list of lower prices, in the national as well as regional ambit; iii) the processing, publication and contents of Law 25/2009, of 22 December, amending various laws for their adaption to the Law on the Free Access to Activities of Services and Their Exercise (Omnibus Law), which has amended some points of Law 29/2006, on Guarantees and Rational Use of Medicines and Medical Products; iv) the including of medicines in the ambit of hospitals; v) the equality of prices for different presentations of the same product, etc.

At the moment, the work of the Group is focused on the evaluation of the economic impact and implementation of Royal-Decree Laws 4/2010 and 8/2010, the complementary regulations relating to them, as well as the passing through parliament of the Draft Bill on Economic Sustainability, which is of great interest to the sector.

Working Group on Relations with the Autonomous Regions. The aim of this group is to review, analyse and monitor the pharmaceutical policies of the Autonomous Regions, as well as developing areas for collaborating with Autonomous Regions, professional organisations and scientific associations which helps create a favourable environment for pharmaceutical innovation and preserves the unity of the pharmaceutical market in Spain as a whole.

This Working Group was reorganised at the start of 2009, with the aim of permitting the raising the number of representatives of member laboratories that had requested being a part of it. Thus, it was structured into a Plenary in which 47 laboratories participate and a Commission of 25 companies.

This Working Group carries out monitoring and analysis on the regional legislative and management initiatives which are taken on in the Autonomous Regions in the area of pharmaceutical planning and policies, at the same time as participating in the production of regional and technical situation reports produced by Farmaindustria. Furthermore, the Working Group also intends to achieve a relationship of mutual understanding and confidence with the Autonomous Regions which helps industrial stability and the sustainability of the SNS.

THE WORKING GROUP ALSO INTENDS TO ACHIEVE A RELATIONSHIP OF MUTUAL UNDER-STANDING AND CONFIDENCE WITH THE AUTONOMOUS REGIONS WHICH HELPS INDUSTRIAL STABILITY AND THE SUSTAINABILITY OF THE SNS

During this past year, the Working Group has carried out an important activity focused upon the monitoring of legislative initiatives in the Autonomous Regions and increasing internal information mechanisms. The Working Group has in this way analysed the implications of different regulations such as those relating to regional medicine evaluation commissions and committees, the administrative procedure of medicines from hospital diagnosis to dispensing in hospital pharmacies and, prescription by active ingredient and generics policy, or the regional health budgets and electronic prescription, amongst others matters.

Working Group on the Code of Good Practice. Throughout 2009, this Working Group has continued to monitor the functioning of the system of self-regulation and has worked on the implementation of the texts of the Codes approved by the General Assembly in June 2008.

In this sense, the Working Group has carried out a monitoring of the putting into operation of the obligatory communication of studies laid our in article 14.3 of the *Spanish Code of Good Practice for the Promotion of Medicines and Interaction of the Pharmaceutical Industry with Healthcare Professionals*. The analysis carried out has allowed the studies generated throughout the year to be looked at case by case, having detected a need to clarify some aspects relating to this area. Thus, the Working Group has begun the production of a *Guide for Carrying Out Studies* with the aim of setting common norms of behaviour for all the companies, which will help to comply with the Code.

Furthermore, a close monitoring was carried out of the provisions contained in the *Spanish Code of Good Practice of Interaction of the Pharmaceutical Industry with Patient Organisations* in general, and in the transparency area in particular, having completed the mandate set out in the Code which requires the that the companies publish before 30 April 2009, the list of patient organisations with which they have collaborated since 1 February 2008.

Likewise, the Working Group has carried out monitoring of the consultations resolved by the Deontological Commission, proposing to the Board of Directors of FARMAINDUSTRIA the publication of everything of general interest with the aim of strengthening the principle of transparency in the self-regulation system.

At the moment, the Working Group is working on the proposal to modify articles of the *Spanish Code of Good Practice for the Promotion of Medicines and Interaction of the Pharmaceutical Industry with Healthcare Professionals*, a *Development Guide*, and the corresponding article of the Regulations relating to studies and services provided by professionals and their organisations, with a view to adapting them to new legislation in the area of post-authorisation studies and defining clearly the deontological regulations applicable to them.

Working Group on the Hospital Market. This Working Group, created in 2008 with the aim of monitoring and analysing the hospital market from the economic point of view, from market access and legal perspectives, has continued its work of analysis of this market in the SNS and has carried out monitoring of related areas with the same aim.

In this sense, one of the Working Group's tasks has been to carry out an analysis of the processes of creating central purchasing units that some Autonomous Regions are carrying out in the hospital framework, by way of adapting their contracting systems to the Public Sector Contracts Law (LCSP).

Furthermore, in coordination with the Autonomous Regions Working Group, the Hospital Market Working Group actively participated in the process of the Framework Agreement for the provision of medicines to all centres dependant upon the Catalan Health Institute, which will be in force for two years in Cataluña.

Likewise, the Working Group has carried out monitoring of regional initiatives of various types, such as the creation of regional evaluation commissions for hospital medicines in the public system as well as the resolutions of some Autonomous Regions which define the inclusion of certain medicines in the list of drugs to be dispensed in hospitals.

Working Group on Legislative Developments of a Technical Scope. The central aim of the activities of this Working Group are matters of a technical nature regulated on the initiatives of the Spanish Medicines and Health Products Agency (AEMPS) as a consequence of the implementation of Law 29/2006 or of the incorporation into our legislation of community provisions. At the same time this Working Group carries out monitoring of the various initiatives of AEMPS itself and its normal operation.

In the technical field, the draft royal decree on laboratories is probably the most relevant regulation of the implementation of Law 29/2006. During the administrative procedures of this draft royal decree, la AEMPS and FARMAINDUSTRIA have been in constant communication, allowing for better defence of the observations formulated by the industry.

In relation to the application of European Union dispositions, it is worth pointing out the will to apply the same process rules to modifications of the register of marketing authorisations of medicines granted purely by national procedures, followed by from January 2010, that for all authorisations granted by community procedures (Centralised, Decentralised and Mutual Recognition). To apply this parallel, an amendment to Royal Decree 1345/2007, regulating the medicine register is in process, which the Working Group also informed upon.

Another of the areas analysed by the Working Group refers to the obligation of the holder of the marketing authorisation to have the medicine instructions available in appropriate formats, for blind people or the partially sighted, incorporating community legislation, set out in article 15.5 of Law 29/2006. The

Spanish National Organisation for the Blind (ONCE) has contacted various industry associations, including FARMAINDUSTRIA, to apply this obligatory regulation. The Working Group has compiled the information on the situation on accessibility for blind people or the partially sighted in the various EU member states, and it is possible that in the coming months, progress will be made on this initiative which has the full co-operation of AEMPS.

Finally, the Working Group has carried out monitoring tasks on the operation of AMPS covering strategic texts such as the *AEMPS Strategic Plan 2009-2012*, up to surveys on the processing time of the Agency or observations on various provisions and instructions relating to tax rebates, presentation of translations and packaging, instructions and technical information, adaption to the legibility demands of the instructions, etc.

FUNCTIONAL GROUPS

Functional Group on Clinical Research. A large part of the activities of the Group during 2009 has focused on the collaboration with the Spanish Medicines and Health Products Agency (AEMPS) and the Co-ordinating Centre for Clinical Research Ethical Committees (CC-CEIC) in the implementation of the telematic transmission of documentation to the Agency and the CEIC by version 2 of the SIC CEIC application. The Group has proposed various improvements to the application that will allow a single transmission of information relating to various clinical trials and the administration of dispatch notifications and security reports, in a way that they can be accessed by AEMPS, the CEIC implicated and the Autonomous Regions participating in the studies.

Regarding the Andalucian application that allows telematic transmission of clinical trial documentation (Panakeia), a pilot stage of the implementation of this application has been participated in, detecting areas for improvement on the correct transmission of documentation to the CEIC of this region.

With the growing international public awareness on the need for regulated and periodical training for researchers in the Area of Good Clinical Practice, an 'ad hoc' group has been set up to draw up a Good Clinical Practice training manual adapted to the legislation in force in our country that will allow this to be done on-line, which will be validated by The Medicine Faculty of the Autonomous University of Madrid and permit the accrediting of the training of researchers to this respect.

Likewise, a specific sub-Group has analysed the suitability of the new proposals of contract models such as those from Canarias, Extremadura, Navarra and Valencia. At the moment this Working Group is revising the points for improvement in the Andalucian contract that will allow the making easier, simplification and speeding up of the administration of the clinical trial and of its financial aspects.

Finally, the Group has focused its activity on finding out how the adverts on patient recruitment are managed, in drawing up a consent model aimed at patients taking part in a trial of a particular genetic make-up, and in making proposals in the European ambit focused on the rebate of the bureaucratic processes in carrying out clinical trials.

In the regulatory area, the Group has taken part in the statements sent to the competent authorities in relation to the draft Order of Castilla y León relating to the register of studies that are carried out in that region, to the draft Order that regulates the carrying out of post-authorisation studies in our country, and to the draft regulation that regulates the availability of medicines in special situations, with special emphasis on the revision of the sections corresponding to the compassionate use of medicines in research.

Functional Group on the Environment. During 2009, the Functional Group on the Environment performed the monitoring of various legislative developments such as the Regulation of the Partial Implementation of the Environmental Responsibility Law (environmental risk analysis and financial guarantees), the Waste Directive Framework, as well as other acts in the environmental field which were related to the pharmaceutical industry(waste, pollution and emissions).

Given the complexity of the administrative regulations in the environmental field this Group allows regular brainstorming. Furthermore, with the collaboration of SIGRE, the FARMAINDUSTRIA representation on the environmental commissions of various business organisations (CEOE, FEIQUE) has been maintained and the co-operation has become closer with the Ministry of Rural and Marine Environment, as well as with the various regional Ministries of the Autonomous Regions, in matters that have some sort of impact upon the sector in this area.

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Functional Group on Pharmacovigilance. During 2009 the Group has actively collaborated with the Spanish Medicines and Health Products Agency (AEMPS) with the start-up of a pilot stage of their electronic transmission of suspected adverse reactions to medicines through an online application and in XML format, as well as in the evaluation of areas for improvement in the application.

In relation to the security of information from clinical trials, an 'ad hoc' group has been set up to reduce the bureaucratic process and speed up the sending of notifications issued and of the security reports to the AEMPS, CEIC and the Autonomous Regions implicated in the study.

The collaboration with AEMPS also extends to the participation of three representatives of the Group in a multidisciplinary group set up by AEMPS to draw up the Good Pharmacovigilance Practice document Contemplated in Law 29/2006, which states how local obligations and the European recommendations should be carried out in this area and which serves as the basis for the inspections held on the holders of marketing authorisations who market medicines in our country.

FARMAINDUSTRIA is also present in an AEMPS group made up of different experts who revise which medicines are susceptible to include the pictograph on the packaging of the medicines which could have effects upon the ability to drive.

In relation to the new legislative proposals, the Group has focused its attention upon the new draft Ministerial Order which regulates post-authorisation studies (EPA) in our country, proposing the concession of shorter authorisation periods independently of whoever is the promoter of the study, as well as eliminating the need to sign contracts with the management of the centres in which the non-EPA observational studies will be carried out. At the moment the Group is evaluating the implications of the putting into place of the document's definitive version and how to deal with the difficulties which it may come across.

It is important to highlight the monitoring of the legislative proposals carried out by FARMAINDUSTRIA in the pharmacovigilance field, especially during the months that our country held the Presidency of the European Union, informing our members and other European associations interested in the area.

Functional Group on Manufacturing and Traceability. The counterfeiting of medicines is one of the main problems facing the innovative pharmaceutical industry, which is the first one interested in promoting the adoption of a single European system which permits the carrying out of the efficient traceability of the medicines with the aim of i) minimising the risk of counterfeits and ii) favouring the identification of the packaging at the moment of dispensing, which would allow monitoring up to the patient himself and notable advantages for the health system. This model has been proposed and trialled with success and is based on the individualised identification of the packages employing the Data Matrix symbols as it is considered

THE INNOVATIVE PHARMACEUTICAL INDUSTRY WANTS TO PROMOTE THE SETTING UP OF A SINGLE EUROPEAN SYSTEM WHICH PERMITS THE CARRYING OUT OF THE EFFICIENT TRACEABILITY OF MEDICINES TO MINIMISE THE RISK OF COUNTERFEITS

much more feasible to implement that other alternatives, from an economic point of view as well as a technological one. Data Matrix is indeed much more feasible to implement since it is based upon a proven technology in terms of printing, reading and the speed that production lines require.

This Group has been carrying out monitoring of EFPIA initiatives as well as in a pilot project promoted by the Ministry of Health, which intends to compare, with a reduced number of medicines and operators, the Data Matrix technology in comparison with a Radio frequency alternative. In view of the approach of the Ministry of Health's pilot project and after considering the industry position in this area as well as the analysis carried out by the Functional group, the Governing Bodies of FARMAINDUSTRIA, backed by EFPIA, took the decision to decline FARMAINDUSTRIA's participation in the pilot.

At any rate, with the European regulations to reduce the risk of counterfeit medicines entering the legal channel still in process, there are still many questions that remain to be answered in this field. It is currently not known which medicines will be included in the individualised identification devices as well as the level of harmonisation of such devices in the different member states. Until these critical matters are resolved, any approach to this matter would be premature.

Functional Group on Registrations. The Functional Group on Registrations carries out a periodical check on regulatory matters relating to the authorisation procedures and register of medicines. This group, the largest in FARMAINDUSTRIA, has experts from a large number of companies interested in the evolution of the authorisation procedures and registration of drugs, the interest generated creates important debates at the heart of this group allowing them to make contributions based on the specific needs that arise in each moment.

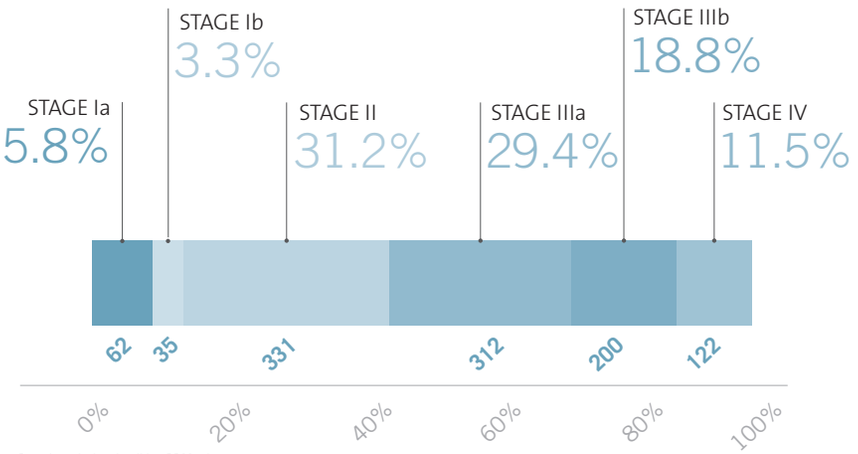
The proposal of categorisation of variations, the electronic register of medicines (eCTD and NeeS), the drawing up of a document with examples as references on the discrepancies of criteria between evaluations of the Spanish Medicines and Health Products Agency (AEMPS) or the survey carried out by the AEMPS, have taken up a large part of the group's activities during the past year.

Functional Group on Medical and Research Directors (BEST Project). This group, formed four years ago as a platform for excellence in clinical research, is part of the Spanish Technological Innovative Medicines Platform (PTEMI). Over the past year, a series of initiatives have been launched with the aim of continuing to improve efficiency and quality in the clinical research processes in Spain and has continued with the maintenance of the *Metrics Database* (*BD Metrics*).

BD Metrics, updated in June 2009, the seventh edition, contains information about key indicators from the 1,062 clinical trials by 28 pharmaceutical companies. The principal therapeutic areas in which the clinical trials are carried out are oncology, cardiovascular, neuroscience and anti-infectious drugs.

At the same time, an increase in the early stages of clinical research, mainly Stage II, has been noticed. The database gathers indicators of the time taken to launch clinical trials and recruitment ratios for the centres, as well as having a section on international benchmarking.

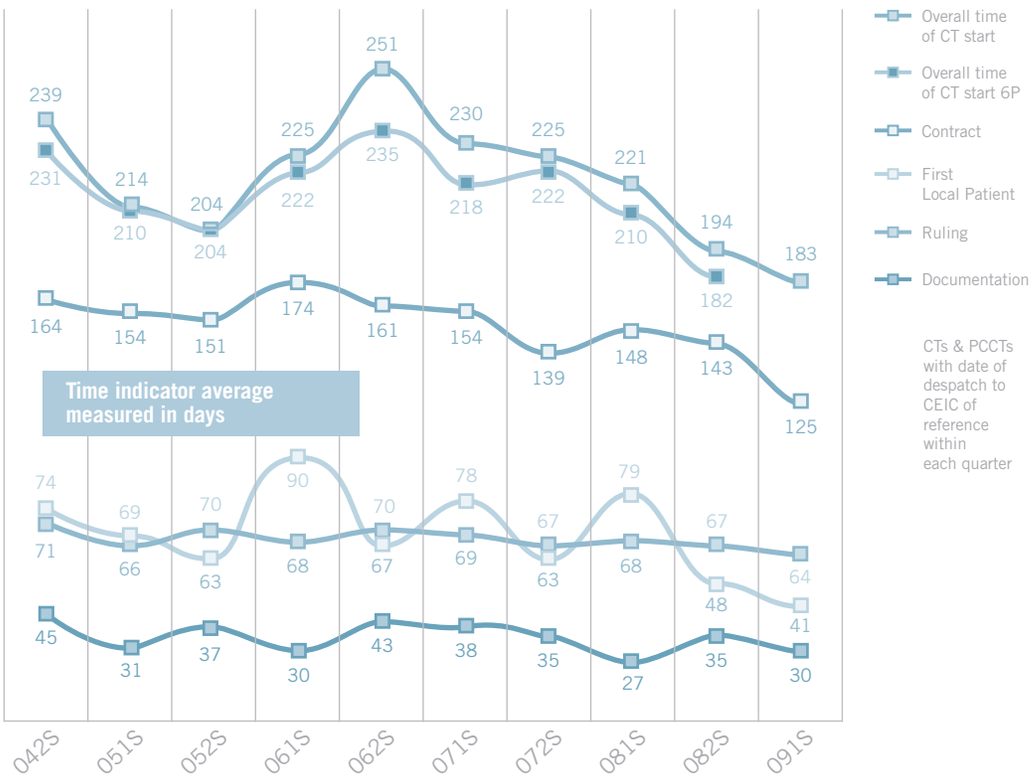
DISTRIBUTION OF THE 1,062 CLINICAL TRIALS BY RESEARCH STAGE



Data & analysis 7th edition BDMetrics
15 February 2010

In general all the time indicators in the distinct quarters have been decreasing, principally in the contract stage (around 125 days on average) and thus the global time of the start of a clinical trial (183 days on average). This tendency has moderated although constant since the project start up in 2005.

EVOLUTION OF THE TIME INDICATORS



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THE FUNCTIONAL GROUP ON PERSONAL DATA PROTECTION HAS CONTINUED WITH ITS WORK ATTENDING TO THE APPLICATIONS OF THE AEPD AFTER THE PRESENTATION OF THE PERSONAL DATA PROTECTION CODE TYPE IN THE AMBIT OF CLINICAL RESEARCH AND PHARMACO-VIGILANCE

During 2009 the project has had a very favourable response from the Autonomous Regions, bilateral meetings having considerably increased between them and FARMAINDUSTRIA, where, starting from a detailed analysis of the situation in each region, with specific information, it was decided to implement instruments for improvement by both parties, with the aim of creating a favourable climate to encourage clinical research.

A notable increase in the hospital centres has also been detected, which in an individualised form have requested their specific information. All the work carried out within the BEST Project during recent years have helped the starting up of the *+i Clinical and Translational Research Co-operation Programme* mentioned in a specific section of this Report.

The big advantage that *BD Metrics* gives is that it is a reliable platform for the discussion and improvement of efficiency, and allows the search for shared solutions involving promoters, researchers, management and administrations. Improving the approval times and the start up of trials is a key tool to position Spain better in the competitive recruitment processes. It is then a necessary condition but not enough to be amongst the leaders. It is also necessary to foster excellence in research groups, value their work and provide them with the necessary means. All the expanded and broken down data is available at www.medicamentos-innovadores.org, including diverse analysis by Autonomous Region.

The work of spreading the Project has also increased, and the contacts and work meetings have intensified not only with the Regional Ministries but also with the Scientific Societies, the CIBER and with Biomedical Research Support Network Board (CAIBER).

Functional Group on Human Resources. Made up of the Heads of Human Resources of pharmaceutical companies which are members of FARMAINDUSTRIA, this group has focused its activity in 2009 on the future negotiation of the XVI General Agreement of the Chemical Industry, given that the current one ran out on 31 December 2009. However, given the actual environment of economic crisis that the country is facing, the signatory parties agreed to extend the XV Agreement up to 31 December 2010.

One of the questions that the Group discussed, was the monitoring of the measures adopted by the MSPS in the fields of prevention faced with the Type A Influenza pandemic, as well the protocols for action.

Furthermore, FARMAINDUSTRIA has continued to participate in the monthly meetings of the Mixed Commission for the Interpretation of Collective Agreements, the Social-Labour Commission at the heart of FEIQUE, as well as all those working committees created under the ambit of the current Agreement. Additionally, FARMAINDUSTRIA took part in the OECD Labour Relations Commission.

Functional Group on Personal Data Protection. In 2009, this Group, with the collaboration of the Clinical Investigation Pharmacovigilance Functional Groups, has continued with its work aimed at clarifying the aspects necessary in order to attend to the applications of the Spanish Data Protection Agency (AEPD) after the presentation of the *Personal Data Protection Code Type in the ambit of Clinical Research and Pharmacovigilance*, in the register of the AEPD in September 2008.

Thus, various work meetings have been held with representatives of the AEPD with the aim of drawing up a document which collects all of the obligations that the regulations demanded in the data protection area. Finally, on 17 June 2009 the Director of the AEPD, through a resolution, agreed to proceed to inscribe the Code Type in the General Register of the AEPD. After the inscription, FARMAINDUSTRIA has continued to carry out activities to spread the information and prepare a Questions and Answers document.

Legal Services Functional Group. As in previous years, in 2009 this Group, made up of the heads of legal services of FARMAINDUSTRIA member laboratories, has held two six-monthly meetings, consolidating as a major forum for the interchange of juridical information in legal areas of interest to the industry.

Amongst the main areas for discussion in 2009, the following stand out: i) the Understanding reached between the Government and the pharmaceutical industry in the areas of employment, internationalisation and R+D; ii) the analysis of the regulation implemented by Law 29/2006; iii) the regional regulations of interest for members; iv) the monitoring of legislation passing through Parliament; v) the legislative implementation of the Law on Public Sector Contracts; vi) the study of Community jurisprudence in those areas of interest for the industry (competition, publicity, parallel trade, etc); vii) a review of the state of process of the different judicial procedures initiated by FARMAINDUSTRIA ;viii) other areas, which due to their contents are the subject of debate in other FARMAINDUSTRIA Working Groups, on having legal repercussions, which are also discussed in the heart of this Group (Code Type, Taxation, Collective Agreements, Deontological Code, Technical Matters etc.)

The report issued by the Consultative Board of Administrative Contracting has also been the subject for analysis as a result of the questions raised by FARMAINDUSTRIA on the joint interpretation of Law 29/2006, of 26 July, on Guarantees and the Rational Use of Medicines and Health Products and Law 30/2007 on Public Sector Contracts.

Taxation Functional Group. In 2009 this Group has held its traditional annual Seminar on new tax initiatives, in which information relating to new tax initiatives in the current year has been updated.

In particular, the main modification to Corporation Tax, the application of the General Accounting Plan and recent jurisprudence relating to director remuneration and share plan irregularities, have been analysed. In the same way, a regulatory evaluation was made of the implementation of the new legislation on related party transactions and the problem of transfer prices in the pharmaceutical sector, having had the attendance of a representative of the Tax Office in order to report on inspection activities in this area to pharmaceutical companies.

Throughout 2009, the Group has followed with interest the administrative procedures of various legislative initiatives, such as the implementation of regulatory changes in general and in the VAT area in particular, with the aim of incorporating EU directives and jurisprudential criteria of the Luxemburg Tribunal, coming into force on 1 January 2010, into Spanish law.

Likewise, the Group has been monitoring the Bill on Economic Sustainability in relation to the implications that the text will have regarding the taxation of R&D&i. At the finalisation of this Report the bill is still going through parliament.

In the same manner, throughout the year and continuously, the Group has received through FARMAINDUSTRIA updated information on new legislation relating to taxation and on judicial decisions and from the tax authorities relating to areas of interest for the industry.

Health Technologies Assessment Functional Group. This Functional Group set up in FARMAINDUSTRIA in 2006 with the aim of developing documents of a technical nature referring to the main questions which affect the economic evaluation procedures for medicines.

During 2009 the Group has met on three occasions, having finished a document of a technical nature on the use of models in the drug evaluation procedures.

Currently the Group is the process of drawing up a document on the analysis and study of the main organisational and procedural questions of the most representative medicine evaluation institutes and international bodies, and during the coming year it will continue to work on other documents of a technical nature which express the approaches of the pharmaceutical industry in matters relating to medicine evaluation procedures.

Medical Visits Functional Group. This Group carries out monitoring of the regulatory projects at national and autonomous region levels which could affect medical visits and prepares the sector's positions in this area

Given its aims, this Group meets depending upon the appearance of new legislation on the medical visits area and their development. In this sense it is worth pointing out its participation in the drawing up of a new regulation on medical visits in the Community of Madrid, which has still not been passed.

It also carried out monitoring of Service Order no. 1/2009, from the board of INGESA, regulating medical visits in the health institutions dependent upon this institute (Ceuta and Melilla) which FARMAINDUSTRIA appealed against.

Hospital Debt Functional Group. During 2009, this Group continued to carry out a constant monitoring of the evolution of the Hospital Supplies Debt and has exhaustively tracked all the legislative initiatives relating to electronic billing initiatives and regulatory development of the Act 30/2007, of 30 October, on Public Sector Contracts.

As is usual, this Group carried out a constant monitoring of the various regional initiatives aimed at solving the problem of debt for hospital drug supplies, the most important of which have come from Andalucía and the Community of Valencia.

Latest available data for the sector as a whole indicates that, at the end of 2009, the National Health System (SNS) owed pharmaceutical companies 3,185 million Euros for supplies of medicines and medical products to its hospitals and that the average payment time was 290 days, much more than the 60 days established by Act 3/2004, of 29 December, establishing measures to fight against late payment in commercial transactions.

The budgetary restrictions in the various Autonomous Regions have meant that the debt as a whole of the SNS has increased by 17.6% in 2009. In fact, only Andalucía and the Community of Valencia have managed to reduce their hospital debt in 2009. This situation is seriously affecting the financial viability of numerous pharmaceutical companies, especially small and medium-sized ones which cannot take on such prolonged payment times.

Throughout the year, the Group has continued to examine hospital tenders, watching to see that they are decided on in strict compliance with the applicable legislation in the area of public contracting. Therefore, they have continued to send letters to various heads of hospital management urging their modification to adapt them to the Public Sector Contracts Law and the policy of the Administrative Contracting Consultation Board.

In the same manner, incidents occurring in the billing processes of some hospitals have been analysed, having produced a legal report on legal, taxation, financial and accounting peculiarities of the system on delivery and handover by Public Administrations of them in the performance of supply contracts.

Furthermore, in close coordination with The Autonomous Regions Working Group, members of the Hospital Debt Functional Group have held meetings with the Andalucian Health Service (SAS) to find out about the progress of the SIGLO project which Andalucía is carrying out with the aim of simplifying the medicine purchasing processes and obtaining an interchange of data in a standardised format in the commercial transactions carried out with its suppliers. Therefore, and in relation to this aim of electronic data transmission, at the close of this Report the carrying out of a pilot trial amongst some of the hospital centres dependent on the SAS and various medicine suppliers is pending.

Finally, other tasks of the Functional Group through 2009 have been the following: i) analysis of the regulatory developments of the Public Sector Contracts Law; ii) monitoring of legislative initiatives in the area of debt, in a national as well as a European ambit, which will amend Law 3/2004 on Measures in the Fight Against Debt in Commercial Transactions; and iii) in the area of electronic billing, participating in the work carried out by the Group set up in this area by the CEOE to respond to the public consultation launched by the Ministry of Industry, Tourism and Commerce, aimed at becoming aware of the opinions of those with an interest in different aspects of electronic billing, as a prior step to the drawing up of the Plan for the generalisation of the use of electronic billing, provided for in the Law on Measures to Encourage the Information Society.

Vaccines Functional Group. The FARMAINDUSTRIA Vaccines Functional Group carries out monitoring in Spain of the European Vaccine Manufacturers (EVM), strategic agenda depending on EFPIA. Thus, the Functional group has shaped the Spanish position in repsonse to the various consultations from the EVM on the perception of vaccination in the various member states.

Without prejudice to actions that laboratories carry out on a individual basis, also debated in the heart of the Group are the actions FARMAINDUSTRIA carries out in public health, the form of disseminating the recent international recommendations on the coverage of certain vaccines or the possessing of a single vaccination calendar in our country, all of this aimed at transferring to the different interested parties, relevant aspects on the value of vaccines.

Functional Group on Rare Diseases and Orphan Medicines . This is a newly created Group made up from nine companies. In accordance with that passed by the Governing Bodies of FARMAINDUSTRIA it is aimed at carrying out the analysis of initiatives to stimulate the research and development of those medicines, the access of patients to them, their approval and financing as well as the collaboration with authorities, researchers and patient organisations.

International Relations Functional Group. This Functional Group was set up in 2008 and its aim is to provide information and carry out monitoring of the developments in the area of pharmaceutical policy at a European as well as an international level, in addition to their possible repercussions at national level. The first meeting of the Group took place in March 2009 in which the conclusions of the Final Report on the investigation into the pharmaceutical sector that the Directorate General for Competition of the European Commission carried out was revised, and the keys to the principle legislative initiatives at European level were studied in detail: pharmaceutical package, cross border health, animal welfare etc.

Barcelona Office. During 2009, the FARMAINDUSTRIA Office in Barcelona has carried our a notable technical support function to the Madrid headquarters, working together with the different departments of the Association in all those matters of interest to member laboratories.

In particular, it has closely collaborated with the processing of a Medical Supplies Framework Agreement with all the centres depending upon the Catalan Institute of Health, as well as in meetings with heads of other health services in matters relating to electronic billing and hospital supplies.

Further to this, the Office has continued to carry out its task of resolving the consultations of various kinds formulated by the member laboratories, amongst which stand out those related to matters of taxation, public sector contracts legislation (hospital supplies) and electronic billing amongst others.

Throughout the year the Office in Barcelona has held continual meetings in situ and by videoconferencing for the different FARMAINDUSTRIA Working Groups and Functional Groups, which has allowed it to strengthen its active participation and the interchange of knowledge on behalf of the member laboratories. Also, the Office has served as a meeting point for the Governing Bodies of the Organisation, statutory groups and other organisations (Coashiq, Anefp, SIGRE, etc.)

In the same way, the Office has been present at many events considered to be relevant in the Catalan regional ambit, participating in academic, institutional and various other acts.

In 2009, the Office in Barcelona has continued to form a part of the Delegated Mixed Commission for Cataluña of Fedequim with the aim of interpreting the Collective Agreement of the Chemical Industry and has participated in the meetings of the Social Labour Commission of the Federation. All these activities have had as an ultimate aim to become aware of all the new issues related to the pharmaceutical sector and offer a better service and assessment to the member laboratories based in Cataluña.

3.3.3. SPANISH INNOVATIVE MEDICINES TECHNOLOGICAL PLATFORM (PTEMI)

After more than four years in operation, the Spanish Innovative Medicines Technological Platform (PTEMI) has consolidated as an initiative promoted by the pharmaceutical industry in collaboration with academic institutions, clinical researchers and public administrations, to encourage R+D in innovative medicines in our country.

The PTEMI is the Spanish benchmark of the Innovative Medicines Initiative (IMI), an EFPIA and European Commission initiative to encourage research into new medicines, with the intention of strengthening the position of Europe in pharmaceutical research, increase the attractiveness of Europe for investment in research and, in the long term, provide European citizens with faster access to higher quality medicines. Since the second half of 2009, the IMI has had full operational capability to execute its own budget and has a Managing Director, who is their legal representative and the person in charge of its management.

During 2009, PTEMI has carried out activities with the aim of encouraging international collaboration and help support the entities interested in such collaboration. Not only has it actively worked on organising Information Days and other events, but has also attended all the meetings organised by the IMI as well as the EFPIA.

In a similar vein, the support given to the participation of Spanish bodies with the aim of competing in the first tender for proposals of the IMI (30 April 2008) and in the second tender for proposals (27 November 2009) can be highlighted. In the first half of 2010 all the contracts with the boards were finalised for the first tender for proposals, which has been a long process, due to the size of the board (sometimes, up to 18 members between public and private members) as well at the tender for proposals being a new one. In the first tender for proposals 18 areas were selected, although in the end 15 were financed. The Spanish participation was very positive, as eight proposals were classified in first place, with a total budget of 6.5 million Euros.

The second tender for proposals for projects, with nine conditions, aimed to speed up the development of new medicines against diseases such as cancer and inflammatory and infectious diseases.

At the same time the PTEMI has been a proactive intermediary with Public Administration, more precisely with the Carlos III Health Institute and with the CDTI in all the meetings, activities and forums on the IMI that have been organised.

There have been many activities carried out by PTEMI during 2009:

- In the area of clinical research, the Best Project has consolidated as a Clinical Research Medicine Platform of Excellence in Spain. Standing out in this area is the second Guide of Stage I Clinical Research Units which has been carried out in collaboration with 23 clinical research units. With regard to the first Guide, the new version incorporates four new Units, some of which have been set up very recently. The texts are in a bilingual Spanish-English version and can be consulted at: www.medicamentos-innovadores.org.

- Within the section on Instruments to promote Preclinical Investigation, the *Guide to Screening Centres in Spain* is notable, which represent an instrument to spread the research capacity of our country in the preclinical research stages in new medicines and also attract research in these stages. It has been carried out with the collaboration of 19 Screening Platforms and four chemical libraries from all over Spain. The Guide was presented on an event sponsored by the PTEMI on *Public-Private Collaboration to Discover Pharmaceutical Drugs in Spain* held in Santiago de Compostela, on 19 November 2009.

- The PTEMI carries out a large part of its activities in the area of the spreading and promotion of acts aimed at all players in the science-technology-company-system, to make them aware of the results of their research activities or existing public or private actions of interest to the sector with the objective of promoting co-operation amongst them. Thus, the Biobank Reality in the *Light of the New Regulatory Framework. Challenges and Implications* Event, carried out in the Salamanca Cancer Research Centre, in October 2009, or the *IMI Second tender information day*, carried out in the CDTI in November 2009, are two examples of them.

THE ANNUAL CONFERENCE FOR TECHNOLOGICAL PLATFORMS OF BIOMEDICAL RESEARCH ORGANISED BY THE PTEMI HAD MORE THAN 320 ATTENDEES

On 23 and 24 February 2010, the PTEMI coordinated and organised its Annual Conference in Barcelona with the Spanish Technological Platform for Nanomedicine and Health Technologies under the general heading *Annual Conference for Technological Platforms of Biomedical Research*. This Conference had more than 320 attendees representing public and private institutions. The operation of these Platforms allows the presentation of a wide range of initiatives and projects of public-private co-operation in this area. In the Conference, the current panorama of biomedical research in Spain was presented with the new structures that have been started up by Central Administration as well as Autonomous Regions to achieve open networks for participation and collaboration of the distinct research bodies, of the universities and of the National Health System's own centres with private entities, to achieve results transferable to improving the health of the public.

The PTEMI communication vehicle is its web portal (www.medicamentos-innovadores.org) which presents as a benchmark pharmaceutical biomedical research on a national scale and acts as a meeting point and place to co-ordinate activities, information and communication among participants. A newsletter is edited monthly which is sent to more than 1,400 people interested in the activities of PTEMI. The web is available in a Spanish and English version and is updated every week. Currently, a new web page is being worked on, due to the need to make it with swifter, be more flexible and have new functionalities in the computing tools.

3.3.4. SELF-REGULATION SYSTEMS

Currently, the self-regulation system of the Spanish pharmaceutical industry is made up of three Codes:

- ***Farmaindustria Code Type of Personal Data Protection in the ambit of Clinical Research and Pharmacovigilance*** (henceforth, "Code Type").

- ***Spanish Good Practice Code on the Promotion of Medicines and the Inter-relation of the Pharmaceutical Industry with Health Professionals*** (henceforth, "Code of Interrelation with Health Professionals").

- ***Spanish Good Practice Code on the Promotion of Medicines and the Inter-relation of the Pharmaceutical Industry with Patients' Organisations (***henceforth, "Code of Interrelation with Patient Organisations").

'Farmaindustria Code Type of Personal Data Protection in the ambit of Clinical Research and Pharmacovigilance'

With the aim of carrying out a correct treatment of personal data (health data) of whoever undergoes a clinical trial or experiments an adverse reaction to a medicine, Farmaindustria has drawn up, in close collaboration with the Spanish Data Protection Agency (AEPD) the *Farmaindustria Code Type of Personal Data Protection in the ambit of Clinical Research and Pharmacovigilance*. Various Working Groups of the Association took part in the drawing up of the code, specifically those from an 'ad hoc' Group made up from various

laboratories The Code Type was registered in the General Register of the AEPD, by means of a resolution of its Director dated 17 June 2009.

The pharmaceutical laboratories who are promoters of clinical research or who are holders of marketing authorisations for medicines (members or not of FARMAINDUSTRIA) and the Contract Research Organisations (CRO), can adhere to the Code Type in the personal data mode or non-associated mode. However, due diligence exists for those who adhere with respect to the rest of the agents involved (hospitals, researchers, monitors, auditors) who should also collaborate with them (laboratories and CROs) in compliance with the obligations set out in the Code Type, hence its expansive vocation.

The Code Type contemplates the different scenarios that may arise in the daily running of the clinical research and pharmacovigilence activities and sets out for them action protocols to follow, depending upon the option that the adhered party has decided upon, for the use of the data protection option as well as the non-associated data option. With the use of these protocols, it is considered that the security is complying with the regulations in the data protection area in the case of having chosen to deal with personal data. If non-association is chosen, this regulation will not be applicable as it is considered that it is a non-association which is irreversible and has been carried out conforming to the Code.

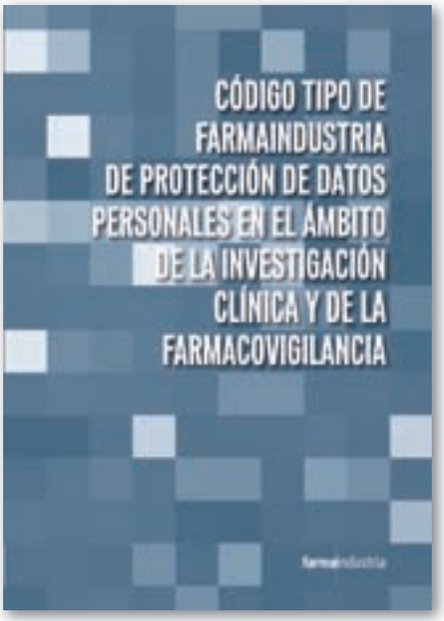
The current Code Type likewise includes the minimum information contents on the data protection area to be supplied to the subjects of the investigation and the consumers who wish to notify a suspected adverse reaction. It also includes orientations to produce confidentiality agreements and clauses to be signed with those in charge of the treatment and to fill in register applications of files in the AEPD, and mention the fundamental directives that should be followed for the attention of the exercising of their ARCO Rights (Access, Rectification, Cancellation and Opposition) on behalf o those affected.

A system of supervision of the compliance with the obligations of that described was also set up, through the Committee of Monitoring of the Code Type, amongst whose more notable functions are the monitoring its application and coordinating its dissemination, promotion, interpretation and compliance, as well as analysing the adhesion applications received.

The Committee was set up in December 2009 and is made up of D. Francisco Abad Santos, Doctor in Medicine and Clinical Pharmacology at the Hospital Universitario de la Princesa in Madrid; Dª. María del Mar García Arenillas, Doctor in Medicine and Clinical Pharmacology at the Hospital Clínico in Madrid; D. Carlos Romeo Casabona, Doctor in Law and in Medicine, Director of the Chair of Law and Human Genomes of the Universidad de Deusto and Chair in Penal Law; and Dª. Lourdes Fraguas Gadea, Director of the Legal Department and General Secretary of FARMAINDUSTRIA.

Regulations in the area of data protection also make a series of obligations after the inscription, amongst them diffusion of the Code Type. Amongst these Code Type diffusion activities in the current year, the staging of four events in Madrid and Barcelona should be pointed out, aimed at member laboratories as well as the rest of the interested parties (centres, researchers, CEIC and CRO).

This Code Type means, definitively, a solution to a complex situation, such as is the management of personal data in research and in pharmacovigilence, which can be implemented without too many difficulties for the laboratories and CROs, providing notable added value and the security of complying with regulations in the data protection area.



'Spanish Good Practice Code on the Promotion of Medicines and the Interaction of the Pharmaceutical Industry with Health Professionals' and 'Spanish Good Practice Code on the Promotion of Medicines and the interaction of the Pharmaceutical Industry with Patient Organisations'.

During the second half of 2009 the pharmaceutical companies and the control bodies of the self-regulation systems, prepared and adapted their procedures with the aim of monitoring the compliance of the important new aspects introduced by the *Code on the Interaction with Health Professionals* (especially in the studies area), as well as the new *Code on the Interaction with Patients' Organisations*. From 2009 it is now possible to provide specific information on each one of the Codes.

Throughout 2009 the meetings of the FARMAINDUSTRIA Self-regulation Monitoring Commission have continued, aimed at co-ordinating the procedures for the Code's application, as well as the necessary self-regulation mechanisms. A good part of the activity of this Commission has focused on the monitoring of the regulatory proposals with an impact on the self-regulation system and the contents of the previous Codes.

Actions of the Deontological Commission

During 2009 a slight increase in the number of incidents reported to the Deontological Commission compared to 2008 has been noticed. As is reflected in the figures which are shown following, 48% of the reports presented have been resolved by agreement between the parties as a consequence of the mediation work of the Deontological Commission, transferring only 25% of the cases to the Self-Regulation Tribunal and closing the remaining 17% due to the parties reaching agreement prior to the Commission meeting.

The number of cases presented to the Deontological Commission for the presumed infringement of the code was 31, mainly relating to the scientific content of promotional material and other promotional activities, and one for the infringement of the *Spanish Good Practice Code on the Promotion of Medicines and the Interaction of the Pharmaceutical Industry with Patients' Organisations*, which was applied for the first time in 2009.

The following chart summarises the total number of cases recorded in 2009, grouped by different classification criteria:

TOTAL INCIDENTS REPORTED	**31**
Upheld	28
Rejected	3
ACCUSER	
Member Laboratories	15
Non-member Laboratories	3
USD	12
Private	1
ACCUSED	
Member Laboratories	30
Non-member Laboratories	1
MEDIATION BT THE DEONTOLOGICAL COMMISSION	**15**
Agreements	15
REFERRAL TO THE SELF-REGULATION TRIBUNAL	**11**
PRIOR AGREEMENT TO THE MEDIATION MEETING	**2**
REJECTED	**3**

Legal proceedings

Also notable is the ending, by final sentences, of the legal proceedings initiated by FARMAINDUSTRIA in 2006 where it claimed the payment of amounts owed by some laboratories derived from Resolutions of the SELF-REGULATION Tribunal. The sentences were favourable to the interests of FARMAINDUSTRIA, condemning the laboratories sued to pay the amounts owed.

Actions of the Deontological Surveillance Unit (USD)

Dissemination of the Self-regulation System. In relation to the dissemination of the self-regulation system, numerous activities and initiatives have been carried out whose central aim is to share information relating to the interaction Codes with health professionals as well as patient organisations. Amongst them the following stand out: i) active participation in conferences of a national and international scope; ii) organisation in Madrid and Barcelona of Events on *The Value of Self-regulation Systems in Society*; iii) holding of bilateral meetings with the heads of the promotional area of medicines in the Autonomous Regions; iv) In-company training sessions and collaboration in the giving of training sessions relating to both Codes in a framework of courses, doctorates and masters; v) participation in congresses organised by scientific societies.

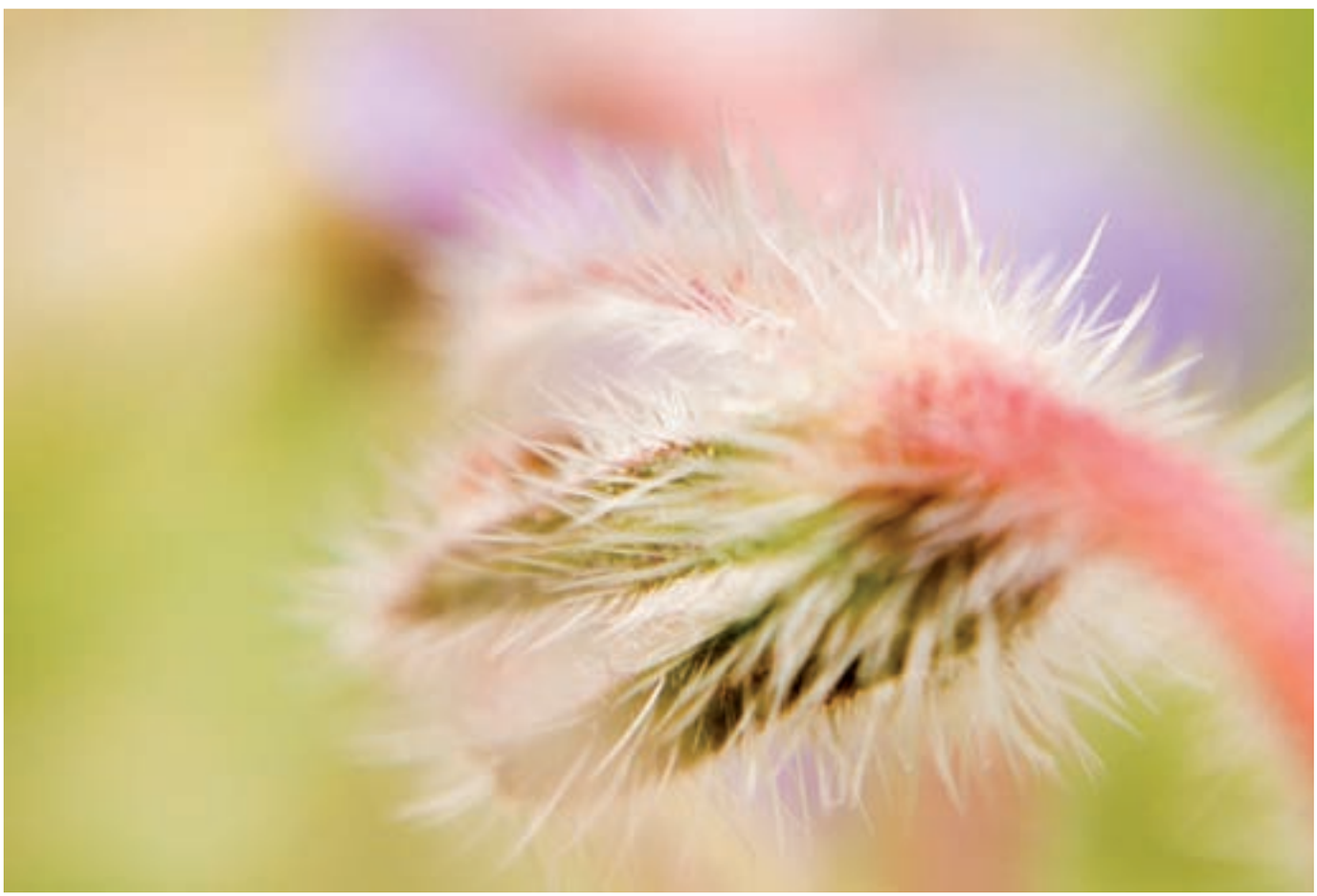
In relation to activities specifically related to the Code of Interaction with Health Professionals, the following can be pointed out: i) initiation of a web page of third-party events to the general public; ii) dissemination and publication of the Information Document on the Area of Hospitality and meetings aimed at health professionals; iii) joint organisation with the Research and Pharmaceutical Marketing Group (AIMFA) of the *Pharmaceutical Industry and Market Studies: Implementation of the Spanish Good Practice Code for Health Professionals* Events held in Madrid and Barcelona; iv) working events with diverse interest groups, such as for example Meeting Professionals International.

Regarding the Code of Interaction with Patient organisations it is worth pointing out the open publication in the FARMAINDUSTRIA web page since April 2009, of the collaborations of laboratories with patient organisations, providing detailed information regarding the scope and nature of the collaboration provided, as well as the financial amounts provided.

Assessment and collaboration. In the assessment and collaboration area it is important to differentiate the activities aimed fundamentally at members, from those aimed at other agents or external entities with which, despite not forming a direct part of our system, a close collaboration is held.

In this manner, during 2009 bilateral work meetings have been held with representatives of various international pharmaceutical associations, highlighting those held with the CAEMe (Argentinian Chamber of Medical Specialities), JPMA (Japan Pharmaceutical Manufacturers Association), CANIFARMA (National Chamber of the Pharmaceutical Industry of Mexico), and with LIF (Trade Association for the Research-Based Pharmaceutical Industry in Sweden) agreeing with the latter a common working procedure in the area of hospitality and meetings.

Notwithstanding the continuous work of assessment given to the pharmaceutical companies, two areas have taken up the majority of the consultations received: i) the obligation to communicate –within certain parameters-of the studies contemplated in article 14.3 of the *Code of Interaction with Health Professionals*, and ii) the open publication of the list of events organised by third-parties in the FARMAINDUSTRIA web.



The experience and knowledge acquired during 2009, as well as the initiatives passed in the area of studies, has allowed the detection of the opportunity to modify and adapt certain aspects of article 14 of the Code with the aim that the activities carried out by the pharmaceutical industry in the area are reflected in a more detailed and concise way.

Furthermore, public access through the web to the electronic events system provided a larger number of consultations coming from laboratories, professional congress organisers, technical secretaries, scientific societies, health professionals and from health authorities. This initiative has meant a massive dissemination, especially amongst our interest groups, of the self-regulation system in the pharmaceutical industry, which has reinforced and strengthened two of our essential pillars: transparency and credibility.

Finally, amongst other assessment and collaboration activities carried out in 2009 the following can be highlighted: i) intervention in meetings and forums organised by FARMAINDUSTRIA with Autonomous Regions and media; ii) revision, adaptation and improvement of internal procedures implemented by the laboratories to guarantee compliance with the Code as well as that required by regulations in the area of promotion of medicines; iii) continuous assessment of pharmaceutical companies and interested third parties, mainly scientific societies, technical secretaries, and service suppliers in general; iv) maintenance of a close col-

laboration and active participation in international meetings organised by EFPIA and IFPMA (the International Federation of Pharmaceutical Manufacturers Associations), the Deontological Supervision Unit remaining as a member of the Code Steering Group of EFPIA and as President of the IFPMA First Instance Tribunal.

During 2009 five binding consultations have been processed and 13 circulars related to the *Code of Interaction with Health Professionals* have been published and a circular relating to the *Code of Interaction with Patient Organisations*.

Control and Prevention Activities. The growing trend of preventative actions carried out continues reaching a total of 2,670 in 2009 (2,440 during 2008). At the same time, in 2009 the USD presented a total of 12 cases (8 in 2008). Of these 12, one was resolved by the AUTOCONTROL Tribunal; two were filed at the request of the USD itself; one was resolved by means of an agreement prior to the hearing of the mediation meeting of Deontological Commission and eight were resolved by means of mediation agreements before the Deontological Commission.

In relation to the analysis and verification of events and scientific meetings communicated, during 2009 this amounted to 3,878 events (490 more than in 2008) representing an increase of more than 14%.

Deontological Surveillance Unit 2004-2009							
	2004 Apr.-Dec.	2005 Jan.-Dec.	2006 Jan.-Dec.	2007 Jan.-Dec.	2008 Jan.-Dec.	2009 Jan.-Dec.	Accumulated Apr.'04 - Dec.'09
EVENTS analysed	945	1,747	2,199	2,926	3,388	3,878	15,083
EVENTS analysed without incidents	718	1,390	1,909	2,616	3,087	3,345	13,065
STUDIES analysed						687	687
STUDIES analysed without incidents						397 (i)	397 (i)
PREVENTIVE ACTIONS	814	1,801	1,376	2,092	2,440	2,670	11,193
CASES	18	11	9	18	8	12	76

* 12 Final resolutions by the USD Self- Regulation Tribunal
* 58 Resolved by mediation with the Deontological Commission with recognition of the infringement and acceptance of correcting measures
* 1 Previous agreement between the parties before the Deontological Commission was held
* 4 Filed at the request of the USD
* 1 Not considered by the Self-Regulation Jury

(i) Result of the analysis of the study area in January 2010
Note.- This data summarises USD data (annual and gathered) from the start of its activity from 31 December 2009.

Finally, a new highlight during 2009, complying with that laid out in article 14, "Studies of *Interaction Code with Health Professionals*", the USD has received information regarding the studies carried out by pharmaceutical companies. The total number communicated was 687, of which approximately 58% were verified and analysed without incident.

3.3.5. LABOUR MATTERS

Due to the economic crisis situation and its strong impact on employment, the Ministry of Employment and Immigration has had a heavy legislative workload this year. The new legislation in the employment ambit during 2009 has been aimed fundamentally at articulating the mechanisms that widen the coverage of those workers who have used up their welfare rights payment for unemployment to impede or mitigate the risk of social exclusion (Law 14/2009, 11 November, which regulates the temporary programme of protection against unemployment and insertion and Law 27/2009, of 30 December, on urgent measures to maintain and encourage employment and the protection of unemployed people). Likewise, other measures have been adopted to compensate for the rebate in the contribution to Social Security of workers affected by redundancy, measures aimed at self-employed workers, and for co-operatives and employment societies.

The Minimum Inter-professional Wage for 2009 was set at 624 Euros a month representing an increase of 4 % with respect to that in force during 2008.

XVI General Collective Agreement of the Chemical Industry

The expiry date of the XV General Collective Agreement of the Chemical Industry was 31 December 2009. Thus, on 26 February 2010 the Negotiating Commission was set up, with the participation of three FARMAINDUSTRIA representatives, members of the Association's Human Resources Functional Group. However, the same day as the Negotiating Commission was set up an agreement was made between FEIQUE, FITEQA-CC.OO and FIA-UGT which consisted of extending the period from 1 January 2010 to 31 December 2010 for the full content of the XV General Collective Agreement of the Chemical Industry and postponing the negotiation of the XVI Agreement until 2011. This agreement was justified mainly by the current economic crisis, as the signatory organisations of the Agreement understand that at times such as the current one, the conditions are not right to proceed to renew its content.

In view of this Agreement, the companies will keep salaries unaltered for that period, being the same as that which they have been paying since December 2009, postponing until 31 December 2010 the application of the Salary review clause laid out for 2009 in article 38 c) of the XV Collective Agreement, including, however, for these purposes, the current Retail Price Index, which the INE established at that time for 2010.

3.4 INTERNATIONAL RELATIONS

3.4.1. EUROPEAN CONTEXT

As in all years, the activities of FARMAINDUSTRIA in a European setting have been mainly channelled through its participation in the European Federation of Pharmaceutical Industries and Associations (EFPIA), consolidating FARMAINDUSTRIA's presence in 15 of the 29 existing Working Groups in the federation, as well as in its Governing bodies, through the Board and the Directors of Associations' Committee.

EFPIA represents the voice of 32 national associations and 44 pharmaceutical companies in Europe. On 1 January 2010 a new President of EFPIA took possession of his office for a two year period, Andrew Witty, Chief Executive Officer (CEO) of GlaxoSmithKline, succeeding Arthur Higgins, who had been carrying out the task since 2006.

AIMS Programme

ONE OF THE FUNDAMENTAL OBJECTIVES OF THE AIMS PROGRAMME IS TO GUARANTEE THE INTEGRITY AND SECURITY OF THE LEGITIMATE MEDICINE SUPPLY CHAIN IN EUROPE

During 2009, the activities of FARMAINDUSTRIA have concentrated on the development of the strategy defined in 2007 by the then President of EFPIA, Arthur J. Higgins, based on four courses of action (Access, Innovation, Mobilisation and Security), whose initials form the acronym AIMS.

Access. In relation to patient access to the medicines which they need, the work of EFPIA is aimed at drawing up a set of good practice principles in the area of HTA. Thus, EFPIA representatives met with the Executive Director of the European Medicines Agency (EMA), D. Thomas Lönngren, in order to look for a degree of consensus in this area.

Innovation. With regard to innovation, the priority action areas of EFPIA have been orientated towards the development of new medicines to benefit the patient, focusing its activities on the Innovative Medicines Initiative (IMI), whose second session was presented in 2009, and in which there are currently 15 Projects in process with a high rate of participation from Spanish companies.

Also notable in this area is the Communication and work of the European Commission on the seizing of medicines in transit in Europe, in which doubts are harboured about violating intellectual property rights. The main aim is to find a certain balance between access to medicines for developing countries and the legitimate defence of the owners of intellectual property rights.

Mobilisation. In this strategic area, EFPIA as well as FARMAINDUSTRIA have carried out intense institutional work to unblock the progress of the Draft relating to patients included in the Pharmaceutical Package.

Security. This strategic pillar has as an essential aim to guarantee the integrity and security of the legitimate medicine supply chain in Europe, improving the traceability of drugs. In parallel to work relating to the directive on counterfeit medicines, the traceability pilot project carried out EFPIA in Sweden in the final months of 2009 is notable. In this pilot a verification system based on the use of bi-dimensional bar codes was tested (Data Matrix ECC 200), which includes the product code, the batch number, the expiry date, and a unique random number to allow the individual identification of the medicine and its verification at the time of dispensing.

With this pilot, EFPIA replied to the European Commission Draft Directive which intends to reduce the risks of counterfeit medicines entering into the legitimate supply chain, and provide a legal basis to introduce the obligation to incorporate security measures into the packaging, allowing its authentication at the time of dispensing, This project was carried out in Stockholm with the collaboration of pharmacies, manufacturers and distributors, and monitored more than 100,000 medicines belonging to 14 companies. The success of the pilot trial has been put into a report which has been sent to the European Commission.

EFPIA Annual Assembly in Sevilla

Sevilla held the XXXI General Assembly of EFPIA, on 13, 14 and 15 May 2009. The Assembly had the participation of the Secretary General of Health, D. José Martínez Olmos, who underlined in his Address the importance of the Understanding reached with FARMAINDUSTRIA and backed a path of dialogue and cooperation to surmount the difficulties.

The different EFPIA meetings had a marked institutional component, being notable amongst others the reception that the President of Andalucía, D. José Antonio Griñán, gave for the presidents of EFPIA and FARMAINDUSTRIA and to the Heads of Europe pharmaceutical member companies of EFPIA, as well as the presence of other high ranking Andalucian and National professionals.

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Also notable is the organisation of a Conference which, under the title: *Fostering health*: *the pharmaceutical industry calls for partnerships*, had amongst others, the address by the then, European Health Commissioner, the Cypriot Androulla Vassiliou, Secretary General of Health, D. José Martínez Olmos, the President of EFPIA, Arthur Higgins, the President of Almirall, D. Jorge Gallardo, and representatives of Patients' Organisations. The participants of this Conference emphasised the need for cooperation between authorities and industry to improve the health of the European citizens and contribute to economic and sustainable development.

Finally, during the three days of the Assembly, various Workshops were held, on the market access delays and the rate of penetration of the innovative pharmaceutical drugs.

Changes in the European Union Institutions: Parliament, Commission and Council

In June 2009 elections were held to elect the 763 new representatives of the European Parliament, who will remain in the positions during the 2009-2013 legislative period. Likewise, during November, D. José Manuel Durão Barroso, President of the European Commission, announced the make-up of his new Cabinet, who will remain in their roles until 2014 and confirmed the restructuring of various Directorate Generals of this institution, notably the Pharmacy Unit, up until then part of the Directorate General of Enterprise and Industry, and from 2009 a part of the Directorate General of Health and Consumer Protection. The European Medicines Agency, the Cosmetics Unit, the European Centre for Disease Prevention and Control, the European Food Safety Authority, the Health and Consumer Protection and the Community Plant Vari-

ety Office have also passed to depend on this Directorate General and designated the Maltese, John Dalli, Commissioner of Health and Consumer Protection. When he was named for the post, Mr. Dalli was Minister for Social Policy in his country of origin, and has held various positions of public responsibility since 1997, including the portfolios of Finance or Foreign Affairs.

Also notable is the preparation work of FARMAINDUSTRIA with the aim of supporting the Spanish Government during the first half of 2010 when it holds the Rotating Presidency of the European Union. FARMAINDUSTRIA has displayed an intense institutional activity with the aim of preparing the priorities of the Presidency in the Health area, obtain the active participation of the pharmaceutical industry in various of the High Level Conferences in the ambit of health, as well as in technical meetings that AEMPS calls.

Pharmaceutical Package

The European Commission published in 2008 the group of legislation initiatives known as the Pharmaceutical Package, made up of a Communication from the European Commission and three Draft Directives. The Draft Directives include three types of initiatives:

- The fight against the growing counterfeiting and illegal supply of medicines in Europe, through various security systems which allow the identification and traceability of medicines.
- Access of patients to high quality information on prescription medicine, recognising the role of the pharmaceutical industry as a legitimate information source.
- Reinforcing and improving the transparency of the pharmacovigilence systems, thus intensifying the level of patient protection in Europe.

In general, it can be said that significant advances have been made in the proposals on counterfeiting of medicines and pharamcovigilence, where there appears to be higher consensus, delaying the processing of the proposal on patient information, which has caused a lot of controversy, and its being turned down by a large number of the Member States in the Council.

Sector investigation on the pharmaceutical sector

On 28 November, 2008 the Directorate General for Competition of the European Commission presented the preliminary report on the investigation of the pharmaceutical industry which began on 15 January of the same year believing that there may be problems due to the lack of competition in the European pharmaceutical market and in July 2009 the final report was published. This final report lessened the tone considerably of the preliminary report, at the same time as recognising the importance of the pharmaceutical industry and its innovative efforts, admitted the existence of multiple regulatory barriers that impede the access to the market of innovative medicines and generics in Europe, highlighting that these delays cannot be exclusively attributable to presumed illegitimate practices of the pharmaceutical industry and finally made a series of recommendations, such as creating a European Patent Tribunal, quickening the work on the Community Patent and the creation of a unified system of dispute settlements, recognising the importance of intellectual property rights.

As parte of its work of coming together of institutions, FARMAINDUSTRIA transmitted to the Cabinet of D. Joaquín Almunia, the new European Competition Commissioner, the main concerns of the pharmaceutical industry with regard to this process.

Revision of Directive 86/609 on Animal Welfare

On 5 November the European Commission published a proposal for a Directive on the protection of animals used in scientific experiments updating Directive 86/609 on the subject, aligning it with the European Union Animal Welfare Protocols. This legislative proposal pursues standardising the requirements required from the industry, as well as improving the quality of the research carried out in Europe, intending to minimise the number of animals used in scientific research.

The European pharmaceutical industry, has actively participated in the legislation developments in 2009. In May last year, the European Parliament passed the first reading of a very balanced text which outlined the main demands of our sector. However, after the change in the EU institutions, the documents published by the Council, as well as new amendments introduced by the new parliament have not matched the industry's expectations in as much as they have returned to limit the use of certain animals in 'life threatening' diseases. The co-decision process will continue throughout 2010 and the pharmaceutical industry will deploy an intense institutional effort, generating a factual debate on the best options for the protection of the laboratory species that at the same time allows the maintenance of the European Union as an enclave of high quality research.

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European Biopharmaceutical Enterprises (EBE)

During 2009 the activities of the European Biopharmaceutical Enterprises (EBE) focused on developing a series of rules in collaboration with the European Medicines Agency (EMEA) to guarantee the correct evaluation process of the products in bio-similar monoclonal antibodies, which allow quicker access to the market. Furthermore, a new industrial platform was created, headed by the EBE, whose priority is the creation of a favourable environment for the development of personalised medicine in the European Union. In December 2009, coinciding with a the publication of a study financed by the European Commission, on financing and development of pharmaceutical medicines in Europe, a Workshop took place, co-organised by EBE and the European Commission relating to the access of small and medium sized biopharmaceutical companies to financing.

Actions in other countries

EFPIA acts in an international context through its Overseas Trade Committee, and FARMAINDUSTRIA has actively participated in all the processes related to this area within the European Union, such as the negotiations of Bilateral Agreements and Free Trade, or the high level meetings on Intellectual Property and Trade, guaranteeing through its actions the interests of the pharmaceutical industry in those processes with emerging countries, especially those known as the 'BRIC' (Brazil, Russia, India and China).

Among the main activities carried out, notable are the Free Trade Agreement negotiations in the EU and Korea, which are at a very advanced stage, and will finally include various stipulations which strengthen the respecting of intellectual property rights and higher transparency in the medicine price and repayment processes. Likewise, this Committee continues to participate in negotiations relating to tariffs, intellectual property and mechanisms to obtain trading authorisations in Singapore, Canada and India.

With regard to conflicts related to intellectual property rights, an intense institutional workload has been carried out in Thailand (compulsory licences), Russia and Japan (regarding the 6 and 8 year periods of data protection respectively), continuing also with the work relating to the regulatory harmonisation of market access in China and in Japan.

3.4.2. INTERNATIONAL CONTEXT

FARMAINDUSTRIA channels its participation in this context through its participation in the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). FARMAINDUSTRIA actively participates in all the IFPMA committees, whose work throughout 2009 was carried out in a two-fold sense: the monitoring of the IGWG Process, and the preparation faced with the influenza pandemic after the appearance of the new Type A virus.

In July 2009 meetings took place in Sevilla of the Committee of Directors and the Board of IFPMA, as well as the meeting of the Dolder Group. Both meetings had FARMAINDUSTRIA's presence. The Dolder Group meeting, made up of the CEOs of the principle global pharmaceutical companies, had D. Carlos Martínez Alonso in attendance, at that time, Secretary of State for Research, who outlined the Spanish policy of supporting biomedical R+D.

Likewise, in January 2010, FARMAINDUSTRIA held a meeting in Geneva with the Permanent Representative Ambassador of Spain to the International Organisations, D. Javier Garrigues Flórez, and the then secretary of the IFPMA, Alicia Greenidge, with the aim of finding mechanisms to strengthen the relations of Spain with the Latin American countries. In this meeting it was agreed to start up a platform which, with the support of the Embassy and the Spanish Ministry of Health, will promote the establishment of regular contacts with the competent health authorities thus facilitating the understanding of the industry position in the distinct initiatives and policies where consensus has been reached in the WHO member states.

On 4 November 2009 the Governing bodies of IFPMA designated as President Mr. Haruo Naito, president and CEO of Eisai, who will remain in the post until the next General Assembly of IFPMA in the Autumn of 2010. Mr. Naito succeeded Mr Fred Hassan, president and CEO of Schering-Plough. In taking up his position Mr Naito expressed his will to continue the path begun, in particular, relating to the multilateral interaction with all types of players (WHO, WIPO, WTO, NGOs), paying special attention to developing countries.

IGWG. Expert Working Group Report of the WHO

After the publication of the report of the WHO Commission on Public Health, Innovation and Intellectual Property, the 60th Assembly of the WHO adopted in 2006 resolution WHA 59.24 which created an intergovernmental working group whose objectives were to "assure and foment a sustainable basis for a R&D essential in health, relative to the diseases that affect developing countries disproportionally, proposing concrete objectives and priorities in R&D, and defining the needs of financing in these areas".

This Group (IGWG) concluded with the publication of a global strategy adopted by resolution 61.21 (passed unanimously at the 61st WHO Assembly in May 2008), and the publication of a proposal of an Action Plan. One of the matters contemplated in this resolution consisted of the creating of an Expert Working Group to examine the financing and coordination of R+D, and to introduce possible proposals to find new sources of financing which could incentivise R+D in countries with medium and low incomes. The executive summary of the report was published at the end of 2009, after the hearing stage for all interested parties, including the innovative pharmaceutical industry, and presented a very balanced view of the innovative ways of financing R+D in the third world respecting in general, intellectual property rights. It is expected that the final report will be published at the WHO General Assembly, which will be held in Geneva in 2010.

Preparation for the Influenza Pandemic

In May 2009, the WHO General Assembly requested from its Directorate General that it "facilitate a transparent process which will permit arriving at an agreement on areas where there was previously no consensus" in the context of the work in preparation for an influenza pandemic. As a part of this process, the WHO drew up a document on the Essential Principles for the Implementation of Benefit Access Agreements with the Producers of Anti-influenza Vaccines.

In October 2009 the WHO Directorate General organised a meeting with the Member States with the aim of revising the Essential Principles document and reaching satisfactory solutions for other of the more relevant matters. The IFPMA has drawn up a position document that expresses the position of the vaccine manufactures in relation to the Essential Principles, underlying that the Type A Pandemic showed that the Member States, vaccine manufacturers and international organisations, can jointly collaborate in an efficient manner in order to provide a rapid and resounding response when faced with public health emergencies. Likewise, in its position document the IFPMA affirmed that the access to the influenza vaccine should not be restricted under any circumstances, thus allowing the development of additional capacities to respond to pandemics.

The document furthermore highlights that intellectual property rights encourage innovation, so, in not respecting them, the innovation required to respond rapidly and resoundingly to future pandemics is put at risk and advocates why these Essential Principles support intellectual property rights.

Bilateral Meetings

As in previous years, in 2009 FARMAINDUSTRIA organised various bilateral meetings. Thus, in July a bilateral meeting took place between FARMAINDUSTRIA and the Japanese Pharmaceutical Industry Association, JPMA, with the aim of analysing common themes and exploring collaboration possibilities between companies from both countries. Special attention was paid to both countries' pricing and reimbursement systems, the impact of the economic crisis on the biomedical sector, the Understanding reached by FARMAINDUSTRIA with the Spanish government, the local production of vaccines or international medicine trade barriers.

Furthermore, in 2009 initial meetings took place with the French Enterprise Association (LEEM), with the aim of interchanging points of view of that association with the French speaking countries, as well as with The Association of the British Pharmaceutical Industry (ABPI), dealing on this occasion with the new stage of the Pharmaceutical Pricing Regulating Scheme, the sector's regulation scheme in the United Kingdom. For its part, FARMAINDUSTRIA, analysed the implications of Article 90 of Law 29/2006 on Guarantees and the Rational Use of Medicines and Health Products, referring to the non-extraterritoriality of price controls by the Governments. For this end, it is worth pointing out that in the United Kingdom, there have been various cases of shortages during 2009, caused by parallel trade and the depreciation of Sterling.

4. FARMAINDUSTRIA FOUNDATION

The Farmaindustria Foundation has kept to its line of actions focused on developing, in accordance with its aims, the promotion of actions that favour scientific investigation and that contribute to the better development of Spanish healthcare, promoting in particular biomedical and pharmaceutical investigation, the training of healthcare professionals and healthcare education for the population.

V Awards for the Best Initiatives for Patient Service.

Amongst the activities carried out by Farmaindustria Foundation in its eight years, the *V Awards for the Best Initiatives for Patient Services* merit a special mention. These awards were born out of the commitment of the pharmaceutical industry to patients and its aim is to recognise the best actions in favour of patients performed by differing local participants.

The meeting for these awards had an extraordinary reception as more than 300 candidates were presented and evaluated by a multidisciplinary jury, made up of representatives of all the sectors related to the world of patients, healthcare and medicine.

As usual, the *Real Fábrica de Tapices* (former Royal Tapestry Mill) in Madrid was the scene for the handing out of awards, held on 15 December 2009, an event that gathered together authorities and institutional representatives from the academic world and from the pharmaceutical industry.[6]

'Pacientes' Magazine

On another note within the Framework of activities aimed at this Group, the publication of *Pacientes* magazine continued last year as the main Communications channel for patients and their associations. This magazine reflects the daily matters of distinct patients' organisations in Spain, the opinions of some of their representatives, and includes news of interest and an activity agenda for this Group.

In issue 13 of *Pacientes* magazine the study directory was updated: *The Patient in Spain: National Map of Patient Associations*, incorporating new associations and contents and offering an exact picture of the association movement in Spain at the current time.

Furthermore this new issue includes an extensive interview with the President of the Spanish Cancer Association, Dª. Isabel Oriol, where prevention, information, support and accompanying the affected are highlighted, as well as volunteers and research which are the main points of action of this association.

Issue 14 of *Pacientes* magazine was wholly dedicated to the current state of healthcare in Spain, analysing the healthcare systems of the Autonomous Regions, their strong and weak points, their main healthcare indicators, as well as the perception that they have of the different agents implicated in them.

Likewise, the Heads of the Medical School Organisation (OMC), D. Juan José Rodríguez Sendín, of the General Board of the Official Pharmaceutical Schools, Dª. Carmen Peña, and of the General Nursing Board D. Máximo González Jurado offered their opinion on the challenges currently facing Spanish healthcare.

Finally, issue 15 of *Pacientes* magazine dedicated the issue to the third place that Spain occupies worldwide in the number of units of umbilical cords stored, only behind the USA and Taiwan.

6 The list of award winners appears in the Social Communication Section of this Report.

This time, *Pacientes* magazine tackled the development of palliative care units in Spain, a field in which our country occupies an important position in Europe, being the seventh country in the development of palliative resources that provide physical, psychological and emotional care to patients with terminal illnesses and their families.

Other reports included in this issue deal with the reality of diabetes in Spain, or the importance of vaccines in a society's healthcare. Also, we can read an interview with the president of the Spanish Association of Patients with Cephalgia, Elena Ruiz de la Torre, or the actress Charo López.

Finally, the latest issue of *Pacientes*, which had a new image with a different layout and structure, looking in detail at the day to day activities of the Spanish Brittle Bones Association (AHUCE) or of those affected by Osteogenesis Imperfecta, a rare illness that affects around 4,000 people in our country.

Other activities

Finally, on another note, throughout 2009 the FARMAINDUSTRIA FOUNDATION has continued to sponsor courses and seminars, amongst which the VI Meeting of the Pharmaceutical Industry should be pointed out, organised by the Menéndez Pelayo International University, as well as the collaboration on the "4th International Meeting of Translational research and Individual Medicine", organised by the Jiménez Díaz Foundation, the sponsorship of educational activities in the healthcare field developed by the Spanish Pharmacological Foundation, or the participation in the production of the wholly dedicated programme: *Medical Drugs of the Future*, in the *Redes* (Networks) television programme on La 2.

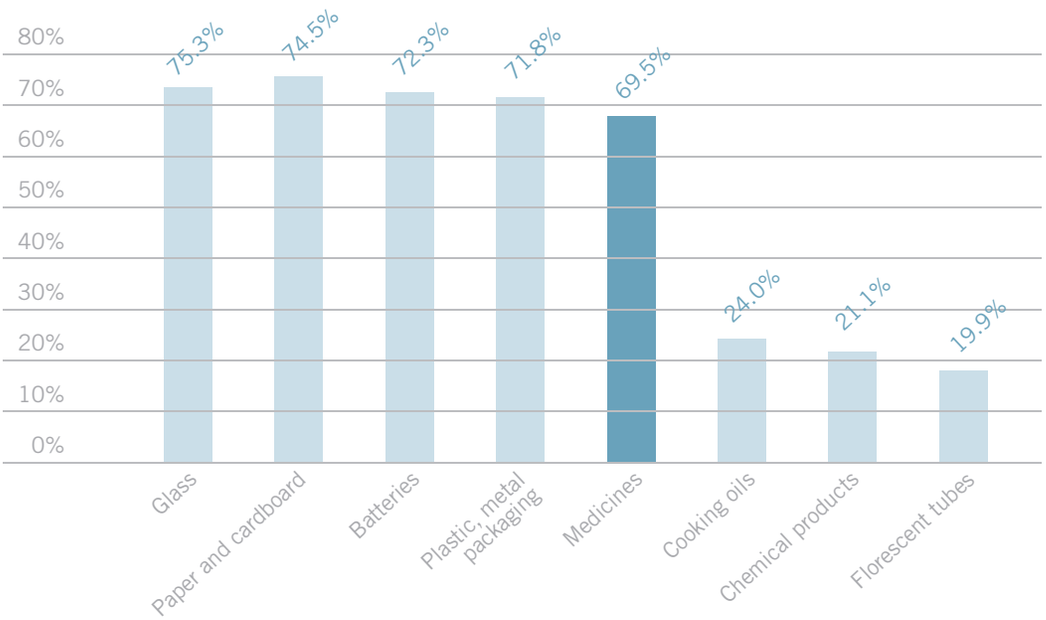
5. SIGRE MEDICINE AND THE ENVIRONMENT

The pharmaceutical industry, through FARMAINDUSTRIA, took the initiative to create SIGRE Medicine and the Environment. Its aim is to make an easy and efficient system available to the public to collect the packaging and left over medicine from homes, and guarantee their correct environmental treatment.

In this way the pharmaceutical industry complied with the existing regulations in the area of packaging, establishing voluntarily a specific management system for the pharmaceutical sector which allows, not only the correct management of packaging, but also of left over medicines, an advance on the environmental area which years later would be incorporated into Law 29/2006, on Guarantees and the Rational Use of Medicines and Health Products.

Thanks to the intense awareness efforts carried out by SIGRE, the recycling of left over medicines and their containers has become a part of the health and environmental habits of Spaniards. This is reflected in the results of the Household and Environmental Survey carried out by the National Institute of Statistics (INE). Here, it was stated that 69.5% of Spanish households use the SIGRE Point at the pharmacy, placing medicines in the leading group of household waste which is recycled.

PERCENTAGE OF HOMES WHOSE RESIDENTS PLACE WASTE IN ITS SPECIFIC COLLECTION POINT

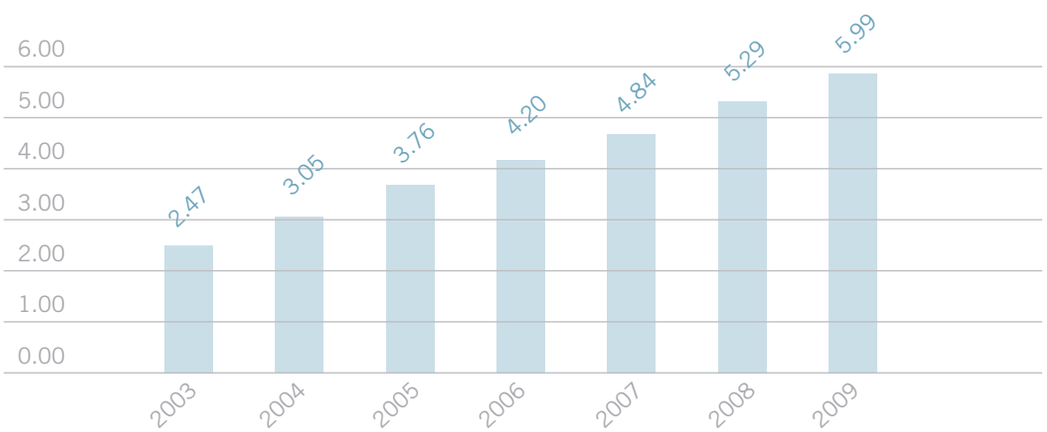


Environmental Declaration 2009.

Each year, SIGRE has to present an Environmental Declaration to all the Environmental Ministries of the Autonomous Regions. The 2009 Declaration included, amongst other matters the amount of packaging and left-over medicines collected in the more than 20,600 SIGRE Points, as well as the environmental treatment applied to each one of the fractions that are obtained in the waste Medicines classification Plant.

The notable increase (above 13%) experienced in 2009 in the ratio for monthly collection per 1,000 inhabitants, is a true reflection of the way that this initiative by the pharmaceutical industry continues to be well received by Spanish society.

KILOS COLLECTED PER 1,000 INHABITANTS PER MONTH



Further to this, SIGRE has designed a new method to evaluate left over non-dangerous medicines energetically, based on the RDF (Refuse Derived Fuel) manufacturing techniques. This new method, designed due to the problems detected in the treatment of non-dangerous medicines, the explanation for which SIGRE has requested from the managers responsible, allows the diversification of the options available for the energetic evaluation of this fraction, conforming to that laid out in the European Waste List.

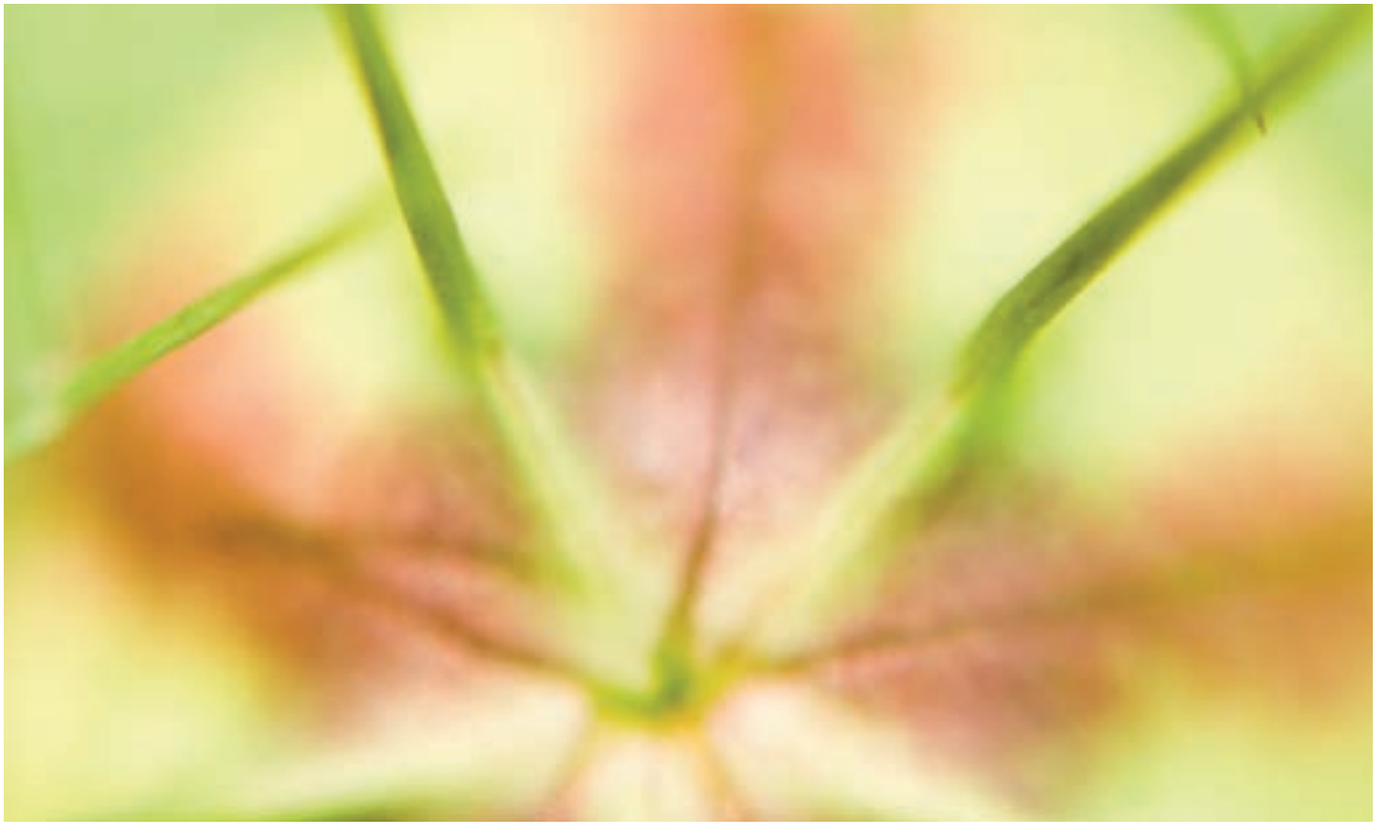
SIGRE HAS DESIGNED A NEW METHOD TO EVALUATE LEFT OVER DANGEROUS MEDICINES ENERGETICALLY, ALLOWING THE DIVERSIFICATION OF THE OPTIONS AVAILABLE, CONFORMING TO THAT LAID OUT IN THE EUROPEAN WASTE LIST

New Packaging Prevention Plan 2009-2011

SIGRE is the body responsible for encouraging and co-ordinating Business and Prevention Plans in the Pharmaceutical Sector.

In this manner, in 2009, SIGRE presented to Regional Environmental Ministries, the new *Business and Prevention Packaging Plan (PEP)* corresponding to the period 2009-2011, where once more the commitment of the pharmaceutical laboratories is reflecting in reducing the environmental impact of the medicine packaging that is on the market.

Prior to this 2009-2011 Plan, the pharmaceutical industry has carried out three triennial Business and Prevention Plans, where they managed to reduce the volume and/or weight of pharmaceutical pack-



aging by almost 15%, optimising the size of the packaging in transportation, distribution and sales, at the same time as using materials that are less contaminating and easier to recycle.

At the moment of setting the objectives of the 2009-2011 Plan, the growing complexity for the laboratories in applying prevention measures has been taken into account. However, the pharmaceutical industry continues with its commitment to the care and protection of the environment in all facets of research, production and marketing of its products.

Communication campaigns

The pharmaceutical industry is conscious of the important role that communication fulfils in making the public aware of the need to use medicines responsibly. For this purpose, SIGRE started up the second stage of the "Natural, like it has always been" campaign at the end of 2009.

This campaign invites the public awareness of the importance of collaborating with the care and protection of our environment, through diverse graphic materials presenting beauty spots with a comparison of their current state and how they were years ago.

Among the main actions carried out online, SIGRE has updated its web page, www.sigre.es, giving it a new design and contents and adapting it to new 2.0 communication standards.

This new institutional web page intends to bring the recycling of medicines closer to the public and has been designed complying with SEO indexing parameters, which allowing better positing in search

engines and adapting to level A of the W3C Consortium guidelines, facilitating the access for users with a disability.

www.sigre.es incorporates as one of its principle novelties, a reserved zone specifically designed for laboratories, in which they can find and consult different work documents, and can fill out the SIGRELAB form online.

Furthermore, during 2009, SIGRE has developed a group of activities that have allowed it to increase its presence in the main 2.0 platform, generating video channels in audiovisual pages, creating groups of photographs and managing and periodically updating various blogs.

Laboratory Information Workshops

The IX Laboratory Information Workshops was held in Madrid and Barcelona in 2009. Through these sessions, the new principal issues of the System are transmitted to the member laboratories, updating the aspects relating to legislation on medicine waste management and analysing the coming challenges for the sector in the environmental field. The IX event gathered together more than 100 people responsible for the environment in pharmaceutical laboratories.

Public recognition of the activities of SIGRE

In 2009, SIGRE was awarded by the MAPFRE Foundation with an award for the *Best Environmental Action*. With this award, which the foundation presents annually, the commitment and effort that the pharmaceutical industry carries out through SIGRE has been recognised, in the field of prevention as well as the management of left over medicines and their packaging.

Forums and Congresses

SIGRE, as a demonstration of the total commitment of the pharmaceutical industry to sustainable development, has decided to use the money received from the MAPFRE Foundation in order to sponsor events such

as "Emissions Compensated Events", various acts which are organised in the heart of the pharmaceutical industry. Through these sponsorships, it will contribute to complying with the Kyoto Protocol and compensate greenhouse gas emissions deriving from the holding of such events.

Within this commitment, SIGRE has sponsored the VI Castilla y León Pharmaceutical Congress, the first event in this region certified as a "Compensated Emissions Event", as well as Information Sessions for laboratories, on acquired emission rights for environmental compensation projects of CO_2 and the rest of the greenhouse effect gases in India and Nicaragua.

Furthermore, within the framework of the Hispack Fair, held in Barcelona, SIGRE participated in the constitution of the Containers and Packaging Platform (E+E), an initiative of blue chip business associations, universities and technological centres. Also, SIGRE was named member of the Rector Board of the Platform, the principle governing body of this initiative, a role which clearly shows the commitment and concern of the pharmaceutical sector in offering a response to current R&D&i needs in the environmental, regulatory, commercial and distribution ambits..

Adhesion to the Global Compact

During 2009, SIGRE formalised its adhesion to the United Nations Global Compact, an initiative made up of more than 7,000 bodies distributed amongst 130 countries worldwide.

In this way, SIGRE has integrated into a work network in which the participating bodies, United Nations, its sector organisations, the global NGOs and the international trade unions, promote the aims and principles of the pact, and with which SIGRE will collaborate in the formulation of joint responses to open up new paths which reconcile the interests and corporate processes with social values and needs.

With this adhesion, SIGRE commits to respect, support and develop the ten principles of conduct and behaviour outlined in this Pact in the area of human rights, employment, environment and the fight against corruption.

Opinion polls

In line with the quality commitment followed in all its activities, SIGRE periodically carries out opinion polls amongst its target public, through which it learns their points of view, improves services provided for society and tests the efficiency of its communications activities relating to the recycling of medicines.

In 2009, SIGRE carried out a study with the double objective of knowing the habits of consumers on the use, conservation and form of disposing of medicines, and at the same time verifying the attitudes that the pharmacist has in his role as an environmental assessor to the public.

Among the main results of this study, the revision of the first aid kit is highlighted, given that 85% of Spanish homes do this every so often.

With regard to the pharmacists, the study reflects the good evaluation given to SIGRE, as 97% of the professionals interviewed have a positive perception of the System and almost unanimously consider that the ideal place to have a SIGRE Point for public information and collection of left over medicines is in the pharmacy.


02

The pharmaceutical industry in Spain and worldwide

1. THE PHARMACEUTICAL INDUSTRY IN EUROPE

The economic and financial crisis, whose first effects were noticed in Europe during the second half of 2007, has had a severe impact in 2009. In this year the GDP of the EU-27 recorded a real fall of -4.2% compared with growth of +0.8% the previous year.

The fall in GDP was especially pronounced during the first half of the year, whilst in the last two quarters of 2009 a slight improvement in activity was noticed which has led to positive quarter on quarter growth rates in countries such as France, Germany and the United Kingdom, and which thus come out of the technical recession situation that they were in.

The difficulties described have not exclusively affected Europe. The USA saw its GDP fall by -2.5% and Japan by -5.3%. Only the exceptions of countries like China or India, which grew by +8.3% and +6.3% respectively, has led to the severe recession in the more developed countries diluting at global level, placing the worldwide fall in economic activity at -0.8%.

As is logical, the fall in production activity has had a consequent effect upon unemployment. More precisely, and referring to Europe, the unemployment rate in the EU-27 rose from 7.6% of the active population in 2008 to 9.6% in 2009, whilst in the Euro-zone in the same period it went from 8.2% to 10.0%. With all this, the most serious thing is that not only has the rate of unemployment increased but, for the first time in many years, the number of people in employment has fallen. Concretely, in 2009 the number of people in work fell, in the EU-27 as well as the Euro-zone, by 1.8% with respect to the end of 2008, which in absolute terms, meant a fall of 4.0 and 2.7 million people less in work respectively.

Faced with this critical situation, the EU member states have adopted a series of agreed measures to support the most sensitive sectors of the economy, especially finance, and particularly expansive monetary and taxation policies have been carried out.

In the monetary field the central authorities, in an attempt to reactivate economic activity, have reduced the price of money to historic minimums. Specifically, the Central European Bank reduced the official interest rate from 2.50% to 1.00% in 2009, this being the lowest level since the organism was created. But it has not been an isolated incident, other central banks such as the Bank of England or the US Federal Reserve also closed 2009 with the lowest interest rates in their history (0.50% in the Bank of England and 0.00%/0.25% in the Federal Reserve).

The low level of inflation (+0.9% in the Euro-zone at the close of 2009) has helped the adoption of these very expansive monetary policies, at least in Europe. This low inflation rate has largely been a consequence of the favourable evolution of the price of oil in 2009.[7]

With regard to the tax stimulation policies, the EU member states have not spared any expense in measures nor assistance in order to guarantee the correct operation of their financial systems, help the sectors most affected by the crisis and minimise, as much as possible, the effects in the fall in activity on employment. However, these ambitious plans of taxation policy combined with the rebate in taxation income deriving from the fall in economic activity and of the increase in unemployment, have led to serious problems in the public accounts of some member states, which, as is logical, largely jeopardises the compliance with the objectives set in the Stability and Growth Plan.

Thus, after a 2008 in which the public deficit was reasonably controlled (2.3 % of the GDP in the EU-27 and 2.0% in the Euro-zone), the early information for 2009 placed it at 6.8% and 6.3% of the GDP respectively in the previously mentioned areas. With regard to this it is worth pointing out the objective set by Brussels in

7 The price of a Barrel of Brent from the North Sea fell, by the yearly average, 36.7% in 2009 with respect to the previous year.

the Framework of the Stability and Growth Plan is to regain the 3% limit of GDP as the maximum acceptable deficit for the public accounts as a whole for each member state in 2013. Some of the Euro-zone countries have great difficulties in this regard, such as the case of Ireland, Spain, Portugal and particularly Greece.

With regard to the future, the main international organisms agree in pointing out that in 2010 there will be a return to positive growth rates which will be around 1.0%, for the EU-27 countries as well as for the Euro-zone. However, the growth will be unequal amongst the countries and in the majority of cases, will not be enough to reduce the current rates of unemployment. Key in 2010 will be keeping the current monetary stimulus in the area of controlled inflation, as well as confirming up to what point the tax adjustment plans of certain member states are achieved and their effect upon the economic activity of those countries and Europe as a whole.

No economic sector is free from the effects of the crisis. However, in industries such as the pharmaceutical industry, its effects have a temporary delay compared to other industries, as its evolution is also influenced to a large degree by factors of a different nature such as the scope of the social protection polices applied in each country or the measures adopted by the different states to make such policies financially sustainable, which are not so immediate as the decisions taken by private bodies. This has meant that the industry has kept, despite the adversity, positive, although moderate, growth.

However, and despite its lower dependence on the economic cycle, the fact that the pharmaceutical sector is also facing major difficulties should not be ignored, such as the increasingly important public budget restrictions and the imminent coming to an end of the industrial protection period of some mass consumer goods which will be very difficult to replace. Clear evidence of these difficulties are the personnel cuts that various pharmaceutical companies have announced and the merger processes that that the sector is going through –that has experienced some of the most important mergers and take-overs seen in the business world in recent years– in search of the optimisation of cost structures and product portfolios of the companies to face the market's difficulties in a better position.

That said, the pharmaceutical industry due to its peculiarities (a sector which is very innovative, R+D intensive, highly productive and a generator of highly qualified employment), meets the essential conditions to present sustained economic growth above the country's average, especially in times of crisis.

To summarise, the behaviour of the European pharmaceutical market in 2009 could be said to be relatively moderate with a weighted average growth of the five main markets of 3.1%.

EVOLUTION OF THE PHARMACEUTICAL MARKET IN THE MAIN EUROPEAN COUNTRIES

	2009 / 2008* (%)	% Total sales of the 5 countries in 2009*
Germany	5	31.9
France	1	26.9
United Kingdom	3	12.4
Italy	2	15.1
Spain	4	13.8
TOTAL 5 COUNTRIES	**3.1**	**100.0**

(*) Data 12 months to November 2009 v 12 months to November 2008
Source: FARMAINDUSTRIA from IMS Retail Drug Monitor

This growth varied between 5% in Germany and 1% in France, Italy and the United Kingdom having registered growth of 2% and 3% respectively.

In the case of the Spanish market, the 4% rate is the lowest registered in the last 20 years, although it may lower even more in 2010 as a consequence of the aggressive cost-control measures adopted by the Spanish government through Royal-Decree Laws 4/2010 and 8/2010 which are outlined in detail in other sections of this Report.

Despite the modest growth recorded in 2009, 2010 is even more complicated if anything for the pharmaceutical companies in Europe given the urgent need of numerous member states to reduce the imbalance in their public accounts. For this reason, it is expected that the measures to reduce public expenditure in general and pharmaceutical expenditure in particular, will toughen in many countries. Whatever the case, the effects upon the growth of the European pharmaceutical market in 2010, although difficult to quantify, will be significant.

Finally, and focussing the analysis on the Spanish pharmaceutical market, the relevance that this has acquired within a European and global context must be pointed out. Thus, in 2008, Spain was already appearing as the fourth most important market in the continent by sales volume[8], fifth in terms of employment generated and sixth in the European market in production terms.

8 The sales figures taken into consideration are the total LSP sales (sales of medicines through pharmacies + hospital sales + sales through other channels). It should be qualified that the market figure for the United Kingdom is distorted by the negative evolution of the exchange rate of the Pound Sterling against the Euro in 2008 (-14.1% on annual average 2008 vs. 2007).

GENERAL DATA ON THE PHARMACEUTICAL INDUSTRY IN THE EU (2008)

COUNTRY	No. Labs (1)	Production (€ Mil) (2)	Employment	Int. Sales (RRP) (€ Mil)	Overseas Trade (LSP) (€ Mil) (3)	
					Import	Export
Germany	304	27,105	105,843	26,523	32,524	46,723
Austria	121	2,082	10,534	2,921	4,266	4,970
Belgium	146	5,518	29,600	4,189	29,744	33,552
Denmark	37	5,551	17,019	2,006	2,316	5,472
Spain	**211**	**14,108**	**40,385**	**13,949**	**10,371**	**7,734**
Finland	64	987	6,002	1,978	1,668	798
France	270	34,600	103,384	26,196	17,540	22,637
Greece	66	825	13,500	5,573	3,653	863
Holland	39	5,664	16,000	4,680	9,569	8,792
Ireland	56	17,540	24,500	1,811	2,867	16,917
Italy	202	22,729	69,500	17,464	13,626	11,311
Portugal	136	2,054	10,244	3,660	1,997	406
United Kingdom	64	22,857	72,000	12,826	14,154	21,659
Sweden	65	6,372	15,725	3,172	2,879	6,220
TOTAL UE-15	**1,781**	**167,992**	**534,236**	**126,948**	**147,172**	**188,053**

Luxemburg is not included due to its low representation
(1) Member laboratories of the EFPIA associations.
(2) The data refers to production activities of pharmaceutical and raw materials for humans and veterinary use except in Germany, Spain and Ireland where the data corresponds exclusively to that destined for human use
(3) Overseas Pharmaceutical Trade (SITC 54). Includes veterinary products.

Source: FARMAINDUSTRIA from EFPIA, Pharmaceutical Industry Associations of each country, INE and Eurostat.

2. THE PHARMACEUTICAL INDUSTRY IN SPAIN

R&D&i

R&D&i makes up, and the majority of economic experts agree on this, an essential factor in the competitiveness of an economy, and the basis for future growth. In times like the present, marked by financial difficulties, it is more necessary than ever to back a model of sustainable growth based on sectors which are highly productive and R&D intensive.

For that reason, it is not unusual that the more advanced countries give more importance to policies which help boost investment in R&D activities. In this sense, the European Union though the *Lisbon Strategy*, propose achieving in 2010 two fundamental objectives in the area of R&D:

- Increase expenditure on R&D up to reaching 3% of the GDP of the EU.
- Achieve that at least two thirds of this expenditure comes from the private sector.

At the present time, these objectives seem far from being reached, if we take into account that at the close of 2008, the 27 EU countries invested in R&D the equivalent of 1.9% of their GDP, with business financing making up 55%.

Spain for its part, is even further from reaching the objectives set by the *Lisbon Strategy*, given that, in 2008 our country invested in R&D the equivalent of 1.35% of GDP, which places us not us not only significantly below the European average, but also below countries such as Portugal, Ireland, Slovenia or the Czech Republic. With regard to the percentage of private business financing of R&D, Spain is way below the European average as well as the commitment to the objectives, given that in 2007, this percentage was 45.5%.[9]

Despite everything, in recent years a clear effort to increase Spanish R&D investment has been noticed, and that has been reflected in higher convergence with the EU-27 average. In fact, the difference between Spain and the average of the EU-27 of the percentage of expenditure in research of the GDP, has passed from 0.95 percent in 2001, to 0.55 percent in 2008.

In relation to the aforementioned *Lisbon Strategy*, it is worth pointing out that the two objectives raised are closely linked, as in order to achieve that R&D exceeds 3% of GDP, it is necessary that the private sector act as a motor and principle financer of research, especially in a context of economic crisis and public deficit as serious as at the moment. There also exists a strong correlation between research effort and the level of involvement of the private sector in the financing of these activities.

9 Latest data available at the time of writing this Report.

R&D EXPEDITURE ACCORDING TO THE SOURCE OF THE FUNDS (2007)

	Expediture in R&D (% /GDP)	ORIGEN OF THE FUNDS		
		Contrib. S. Priv. %	Contrib. S. Pub. %	Overseas and other
Japan	3.44%	77.7	15.6	6.7
USA	2.35%	66.2	28.3	5.5
EU-27	1.85%	55.2	33.0	11.8
Spain	**1.27%**	**45.5**	**43.7**	**10.8**

Source: Eurostat.

In comparison with the three major economic blocks, private R&D investment in Spain is relatively low, representing only 46% of the total, against 78% in Japan and 66% in the USA or 55% of the EU-27. Furthermore, far from improving, the percentage of investment in R&D financed by the private sector in Spain in 2007 is the lowest since 1997.

IT IS ABSOLUTELY ESSENTIAL THAT OUR COUNTRY ENCOURAGES AND CARRIES OUT POLICIES THAT INCENTIVISE PRIVATE R&D

It is absolutely essential that our country encourages and carries out policies that incentivise private R&D, stimulating especially the investment decisions in the more technologically intensive sectors. For that reason the contribution of the pharmaceutical industry seems to be essential. It is not for nothing that it is the most important sector of those categorised as high technology manufacturing sectors, on representing 51% of annual turnover and 56% of Gross Added Value[10] generated by this industrial sector group.[11]

Currently, the pharmaceutical industry is leader in industrial R&D as reflected in the latest results of the *Statistics on R&D Activities* published by INE and referring to 2008. Thus:

- The pharmaceutical industry is that which invests most in research in Spain, with a big difference (49.1%) over the following sector. The pharmaceutical companies assigned more than 914 million Euros to research in 2008, in such a way that the pharmaceutical industry carried out 20.3% of the total R&D expenditure made by Spanish industry as a whole. This percentage turns out to be especially significant if we compare it to the turnover of the pharmaceutical companies, which only amounts to 2.4% of the industry total. Seen from another perspective, the pharmaceutical industry dedicates 6.0% of its sales volume to R&D, whilst industry as a whole assigns an average of 0.7%. Likewise, it is important to highlight that in an economic context as adverse as in 2008, the pharmaceutical industry has been the only one of the R&D intensive industrial sectors which has recorded positive growth rates in its research effort, as can be appreciated in the box below.

R&D ACTIVITY OF SPANISH COMPANIES (2007)

Sector	Personnel in R&D*	Expenditure on R&D (€ Mil)			
		Internal	External	Totals	% Incr. on/2007
Total industry	39,949	3,580.27	924.90	4,505.90	-5.8
Pharmaceutical Industry	**4,388**	**647.28**	**267.03**	**914.31**	**3.4**
Automobile	3,065	294.99	64.44	359.43	-20.3
Other transport	3,840	420.50	192.70	613.20	-3.6
Aerospace	2,406	280.24	149.69	429.93	-12.2
IT, electronic and optical products	4,071	272.77	27.19	360.53	---

(*) Personal Full Day Equivalent (FDE).
Source: Farmaindustria from INE (Statistics on R&D Activities 2007 and 2008)

10 Source: INE (High Technology Sector Indicators. 2008).
11 The remaining high technology manufacturing sectors are the following: Manufacture of IT, electronic and optical products (CNAE 26) and Aeronautical and Space construction (CNAE 30.3); **Source:** INE (High Technology Sector Indicators. 2008).

12 Employment data in Full Day Equivalent (FDE).

13 Quotient between innovative expenditure and annual turnover.

- The pharmaceutical industry leads the industrial R&D ranking in internal expenditure (R&D carried out fully within the company) as well as in external expenditure (R&D contracted to third parties).

- The pharmaceutical industry is the industrial sector which generates most employment in research[12] with 4,388 professional wholly dedicated to these tasks. This concerns, furthermore, highly qualified employment as practically half of these professionals are researchers. With regard to the make-up of this employment, the high level of female employment that characterises biomedical research in Spain is notable, the highest in the business sectors as a whole. In 2008, 66% of research posts generated by the pharmaceutical industry were taken up by women. Thus, 25.8% of total female employment in research generated by the industrial sectors as a whole came from the pharmaceutical industry.

- The pharmaceutical industry is very innovation intensive. In fact, it is the second industrial sector by percentage of innovative companies out of the total with 66.9%, as well as in terms of innovative intensity[13], with a ratio of 5.55%.

- Another important characteristic of pharmaceutical R&D is that it is carried out from a basis of constant sustained financial effort over time, which contrasts with other sectors which are also research intensive but much more cyclical in this area. If the average growth in research investment of the pharmaceutical industry over the last ten years is analysed and compared with the rest of the R&D intensive sectors, it is evident that that pharmaceutical industry surpasses the rest of the sectors with regard to average growth of investment over prolonged periods of time.

ANNUAL AVERAGE RATE OF CHANGE (1998-2008)	
Sector	**R&D Expediture**
Total industry	5.9%
Pharmaceutical Industry	**11.9%**
Automobile	-1.0%
Other transport	6.6%
Aerospace	7.4%

Note: Based on the data available the corresponding data for 1998 not being available (in CNAE 93)
'IT, electronic and optical sector, thus it has not been included in the box.
Source: FARMAINDUSTRIA from INE (Survey on Technological Innovation. 1998 and 2008).

- Finally, in percentage terms of companies that request registration for patents, the pharmaceutical industry is also a notable leader in the Spanish industrial sectors as a whole. Thus, 36.7% of pharmaceutical companies that carried out R&D activity registered a patent in the period 2006-2008.

Definitively, all the highlighted data demonstrates the extraordinary strategic importance of the pharmaceutical sector in the area of R&D in our country. Not only due to the magnitude of resources that it assigns to these activities, but also due to its high and sustained rate of growth, efficiency of resource management and its capacity to generate employment in this area.

However, a high risk business model such as the pharmaceutical one, characterised by long term research processes, which are ever more expensive and which are subject to growing demands from regulatory bodies need a stable regulatory framework which allow the companies to adequately plan their invest-

ments. In this manner, the measures to restrict expenditure contained in the Royal Decree-Laws 4/2010 and 8/2010 will mean an important rebate in resources for the pharmaceutical companies, which will without doubt make its capacity to finance R&D projects more difficult.

ACCORDING TO IMS DATA FOR 2009, 96.8% OF SALES THROUGH PHARMACIES CORRESPOND TO PRESCRIPTION MEDICINES AND THE REMAINING 3.2%, OVER THE COUNTER MEDICINES

2.2. INTERNAL MARKET

The sales of medicines in Spain during 2009 recorded an increase of 5.7%, reaching a total of 14,744.09 million Euros at Laboratory Sale Price (LSP). 73.6% of these sales were carried out through pharmacies, the rest through hospitals.

INTERNAL MEDICINES MARKET (LSP, MILLIONS OF €)						
	Pharmacies [1]	Incr. (%)	Hospitals [e]	Incr. (%)	Total	Incr. (%)
2007	10,019.12	8.3	3,184.50	10.0	13,203.62	8.6
2008	10,458.66	4.4	3,490.21	9.6	13,948.87	5.6
2009	10,852.46	3.8	3,891.63	11.5	14,744.09	5.7

[1] Sales of medicines to pharmacies.
[e] Estimated data.
Source: FARMAINDUSTRIA from IMS own estimates.

Regarding sales through pharmacies and according to IMS data for 2009, 96.8% correspond to prescription medicines and the remaining 3.2% over the counter medicines. The latter, as occurred in 2008, has shown a significant tendency to lowering, with falls in sales of -7.8% by units and -0.8% by value in 2009. However, the average price of this market segment has recorded a positive growth of +7.6%.

PHARMACEUTICAL SPECIALTIES MARKET THROUGH PHARMACIES (LSP)						
	Units(000')	Incr. (%)	Value (000' of €)	Incr. (%)	Average LSP	Incr. (%)
Prescription	1,196,349	2.3	10,505,103	3.9	8.78	1.6
OTCs	98,300	-7.8	347,361	-0.8	3.53	7.6
TOTAL	**1,294,649**	**1.5**	**10,852,464**	**3.8**	**8.38**	**2.2**

Source: FARMAINDUSTRIA from IMS.

The prescription market, for its part, has been affected by a new Reference Price Order (Order SCO/3803/2008), which has added 13 new groups to those already existing. In 2009 the growth in the prescription market was 3.9%, the lowest in recent decades and the average price also increased slightly (1.6%).

Furthermore, in December 2009 Order SAS/3499/2009 was enacted, which came into force on 1 January 2010 and by which 20 new groups were added to the RPS and the corresponding reference prices of the groups created by orders in 2006,2007 and 2008 were revised. With this new Order, five groups were eliminated from the RPS for various reasons, such as the lack of sufficient presentations in a group, for the lack of a generic, or for having all the presentations of these groups with a RPS lower than the minimum threshold of 3.12 Euros laid out in the legislation. In this manner, currently there are 175 groups in the RPS, corresponding to 159 molecules or associations.

GROUPS CREATED BY ORDER SCO/3997/2006						
Group	Active Ingredient	Method of administration	Group	Active Ingredient	Method of administration	
C1	Aceclofenac	Oral	C41	Citalopram	Oral	
C2	Acetylcysteine	Oral	C42	Clarithromycin	Oral	
C3	Acyclovir	Oral	C43	Clarithromycin Paediatric	Oral	
C4	Acyclovir	Paediatric Oral	C44	Clindamicyn	Parenteral	
C5	Alendronic Acid	Oral	C45	Clotrimazole	Vaginal	
C6	Allopurinol	Oral	C46	Dacarbazine	Parenteral	
C7	Alopurinol	Oral	C47	Defl azacort	Oral	
C8	Alprazolam	Oral	C48	Desmopresine	Nasal	
C9	Ambroxol	Oral	C49	Dexamethasone	Parenteral	(2)
C10	Amikacin	Parenteral	C50	Diclofenac	Oral	
C11	Amlodipine	Oral	C51	Diclofenac	Rectal	
C12	Amoxicilin	Oral	C52	Dilthiazem	Oral	
C13	Amoxicilin	Paediatric Oral	C53	Doxazosin	Oral	
C14	Amoxicilia/Clavulanic Acid	Oral	C54	Doxorubycin	Parenteral	
C15	Amoxicilia/Clavulanic Acid	Paediatric Oral	C55	Ebastine	Oral	
C16	Atenolol	Oral	C56	Enalapril	Oral	
C17	Azithromycin	Oral	C57	Spironolactone	Oral	
C18	Azithromycin Paediatric	Oral	C58	Etoposide	Parenteral	
C19	Bisoprolol	Oral	C59	Famotidine	Oral	
C20	Budesonide	Nasal	C60	Finasteride	Oral	
C21	Captopril	Oral	C61	Fluconazole	Oral	
C22	Carboplatin	Parenteral	C62	Fluorouracil	Parenteral	
C23	Carvedilol	Oral	C63	Fluoxetine	Oral	
C24	Cefaclor	Oral	C64	Flutamide	Oral	
C25	Cefaclor	Paediatric Oral	C65	Fluvoxamine	Oral	
C26	Cefazolin	Parenteral	C66	Folinic Acid	Parenteral	
C27	Cefixime	Oral	C67	Fosinopril	Oral	
C28	Cefixime	Paediatric Oral	C68	Gabapentin	Oral	
C29	Cefonicide	Parenteral	C69	Gemfi brozil	Oral	
C30	Cefotaxime	Parenteral	C70	Glimepiride	Oral	
C31	Cefotaxime	Paediatric parenteral	C71	Hydrochlorothiazide/Captopril	Oral	
C32	Ceftazidime	Parenteral	C72	Hydrochlorothiazide/Enalapril	Oral	
C33	Ceftriaxone	Parenteral	C73	Hydrochlorothiazide/Lisinopril	Oral	
C34	Ceftriaxone	Paediatric parenteral	C74	Ibuprofen	Oral	
C35	Cefuroxime	Parenteral	C75	Ibuprofen	Paediatric Oral	
C36	Cetirizine	Oral	C76	Indapamide	Oral	
C37	Cetirizine	Paediatric Oral	C77	Isosorbide mononitrate	Oral	
C38	Ciprofl oxacin	Oral	C78	Itraconazole	Oral	
C39	Ciprofl oxacin Paediatric	Oral	C79	Lamotrigine	Oral	
C40	Cyproterone/Ethilnylestradiol	Oral	C80	Lansoprazole	Oral	

(2) Withdrawn by Financial Report of Order SAS/3499/2009.

Group	Active Ingredient	Method of administration	
C81	Levodopa/Carbidopa	Oral	
C82	Lisinopril	Oral	
C83	Loratadine	Oral	
C84	Loratadine Paediatric	Oral	
C85	Lorazepam	Oral	
C86	Lormetazepam	Oral	
C87	Losartan	Oral	
C88	Lovastatin	Oral	
C89	Meloxicam	Oral	
C90	Metotrexate	Parenteral	(1)
C91	Mirtazapine	Oral	
C92	Moclobemide	Oral	
C93	Naproxen	Oral	
C94	Naproxen sodium	Oral	
C95	Nifedipine	Oral	
C96	Nimodipine	Oral	
C97	Nitrendipine	Oral	
C98	Norfl oxacin	Oral	
C99	Ofl oxacin	Oral	
C100	Omeprazole	Oral	
C101	Ondansetron	Oral	
C102	Paracetamol	Oral	
C103	Paroxetine	Oral	
C104	Pentoxifiline	Oral	
C105	Pergolide	Oral	(1)
C106	Piroxicam	Oral	
C107	Pravastatin	Oral	
C108	Quinapril	Oral	
C109	Ramipril	Oral	
C110	Ranitidine	Oral	
C111	Risperidone	Oral	
C112	Roxithromycin	Oral	
C113	Salbutamol	Pulmonary	(1)
C114	Selegiline	Oral	
C115	Sertraline	Oral	
C116	Simvastatin	Oral	
C117	Sotalol	Oral	
C118	Sumatriptan	Oral	
C119	Tamoxifen	Oral	
C120	Tamsulosin	Oral	
C121	Terazosin	Oral	
C122	Terbinafine	Oral	
C123	Ticlopidine	Oral	
C124	Timolol	Ophthalmic	
C125	Tobramycin	Parenteral	(2)
C126	Torasemide	Oral	
C127	Tramadol	Oral	
C128	Tramadol	Paediatric Oral	
C129	Tramadol	Parenteral	
C130	Tramadol	Rectal	(2)
C131	Triflusal	Oral	
C132	Trimetazidine	Oral	
C133	Vancomycin	Parenteral	
C134	Venlafaxine	Oral	
C135	Vincristine	Parenteral	
C136	Zolpidem	Oral	

GROUPS CREATED BY ORDER SCO/3867/2007

Group	Active Ingredient	Method of administration	
C137	Amysulpiride	Oral	
C138	Bicalutamide	Oral	
C139	Cefoxitin	Parenteral	
C140	Cefpodoxime	Oral	(2)
C141	Cefuroxime	Oral	
C142	Domperidone	Oral	
C143	Fenofibrate	Oral	
C144	Fosinopril/Hydrochlorothiazide	Oral	
C145	Glucosamine	Oral	
C146	Granisetron	Oral	(2)
C147	Ibuprofen salt	Oral	
C148	Oxcarbazepine	Oral	
C149	Pantoprazole	Oral	
C150	Topiramate	Oral	

(1) Withdrawn by Order SCO/3803/2008.
(2) Withdrawn by Financial Report of Order SAS/3499/2009.

GROUPS CREATED BY ORDER SCO/3803/2008			
Group	Active Ingredient	Method of administration	
C151	Anastrozole	Oral	
C152	Famciclovir	Oral	
C153	Fentanyl	Transdermic	
C154	Fexofenadine	Oral	
C155	Losartan/Hydrochlorothiazide	Oral	
C156	Metamizole	Oral	
C157	Metoclopramide	Oral	
C158	Octreotide	Parenteral	
C159	Olanzapine	Oral	(3)
C160	Paracetamol	Paediatric Oral	
C161	Perindopril	Oral	
C162	Quetiapine	Oral	
C163	Ropinirole	Oral	

(3) Suspended until final legal sentence.

GROUPS CREATED BY ORDER SAS/3499/2009			
Group	Active Ingredient	Method of administration	
C164	Mycophenolic acid	Oral	
C165	Risedronic acid	Oral	
C166	Atorvastatin	Oral	(3)
C167	Bisoprolol/Hydrochlorothiazide	Oral	
C168	Cilazapril	Oral	
C169	Diosmin	Oral	
C170	Donepezil	Oral	(3)
C171	Epirubicin	Uretral	
C172	Fluvastatin	Oral	
C173	Galantamine	Oral	(3)
C174	Irbesartan	Oral	
C175	Lactulose	Oral	
C176	Letrozole	Oral	
C177	Levocetirizine	Oral	
C178	Levofloxacin	Oral	
C179	Nebivolol	Oral	
C180	Perindopril/indapamide	Oral	
C181	Pramipexole	Oral	(3)
C182	Prednisone	Oral	
C183	Tizanidine	Oral	

With regard to generic medicines, during 2009 206 million units have been marketed with a total value of 713 million Euros at LSP, the average price being € 3.46. The market quota for these medicines is placed at 6.8% by value and at 17.2% by units. At the same time, in 2009 14 new molecules have been marketed, with which the number of molecules or associations that have a generic marketed in Spain has risen to 165.

Therapeutic groups

A detailed analysis of the market shows notable differences in the evolution of distinct therapeutic groups, in function of the impact of the introduction of new groups in the RPS, of the therapeutic advances or the importance of self-care in each group.

Four therapeutic groups: Central Nervous System, Cardiovascular System, Digestive System, and Respiratory System, make up 65% of the total market by value and 67% by units. At the same time, the three former (which make up 56% of the market), recorded above average growth, by unit as well as by value.

PHARMACEUTICAL SALES THROUGH PHARMACIES BY THERAPEUTIC GROUP (2009)							
	Units (thousands)	Share (%)	Incr. (%)	Value (€)	PVL (%)	Incr. (%)	EFP Av. (€)
A Digestive and Metabol. System	200,573.4	15.5	2.0	1,366,959.5	12.6	6.7	6.82
B Blood and Hematop. Organs	58,536.2	4.5	5.0	475,255.2	4.4	6.9	8.12
C Cardiovascular System	232,764.5	18.0	3.6	2,286,430.7	21.1	4.5	9.82
D Dermatology	63,007.1	4.9	-1.2	324,443.5	3.0	-1.1	5.15
G Genito-Urinary Products	55,231.3	4.3	-0.2	718,716.1	6.6	3.3	13.01
H Hormones	18,875.2	1.5	2.5	214,157.3	2.0	5.7	11.35
J Anti-infectious	54,932.0	4.2	-4.1	433,816.8	4.0	-5.8	7.90
K Hospital solutions	2,767.4	0.2	1.1	3,184.2	0.0	0.4	1.15
L Antineoplastics / Inmun. Agents	6,555.2	0.5	1.4	633,546.0	5.8	1.3	96.65
M Locomotor System	110,738.9	8.6	2.4	689,086.8	6.3	3.5	6.22
N Nervous System	292,982.5	22.6	1.6	2.299,984.2	21.2	4.2	7.85
P Anti-parasitics	1,130.0	0.1	4.5	8,615.4	0.1	35.2	7.62
R Respiratory System	140,370.0	10.8	-1.1	1,093,260.0	10.1	3.2	7.79
S Sensory Organs	54,409.6	4.2	2.1	261,017.8	2.4	5.0	4.80
T Diagnostic Agents	74.0	0.0	-23.2	1,201.1	0.0	-19.8	16.22
V Various	1,701.4	0.1	-10.3	42,789,6	0.4	7.2	25.15
TOTAL	**1,294,648.9**	**100.0**	**1.5**	**10,852,464.2**	**100.0**	**3.8**	**8.38**

Source: FARMAINDUSTRIA from IMS.

In the case of the Central Nervous System, 44% of the units sold are included within the RPS, which translates into an average price for the group slightly inferior to the market average, despite being one of the groups where a good part of the new molecule launches are concentrated.

For its part, the average price of Cardiovascular System medicines, are above that of the market, influenced probably because 53% of the new products are included in this group. However, the market percentage in reference prices of this group exceeds 40%, and furthermore it is where 43% of the new generics marketed have entered, counteracting the upward tendency of the new molecules on the average price of the group, placing the increase at only 0.9%, compared to 2.2% of the market as a whole.

Regarding the Digestive System, the existence of two subgroups with disparate behaviour relating to prices is notable. 39 % of this group's units correspond to the Antacids, Anti-flatulence and Anti-ulcer sub-group. In this sub-group, the market subject to reference prices rises to 78% in units, which gives as a result a variation in its average price of -5%. On the other hand the Anti-diabetic sub-group, which captures 18% of the units in the Digestive System Group, has recorded an increase in the average price of 9.5%, way above the average, due especially to the improvements in the methods of administration and the therapeutic innovations which have appeared for the treatment of a pathology that is affecting an ever increasing number of people.

In the case of the Respiratory System, the fall in sales of units of medicines in this group is notable. An important part of this fall is explained by the of 9% in the sales of over the counter and non-financed medicines of this group, which has a quota of 26%.

The Locomotor System, which holds the fifth position in market quota, is growing above the average by unit and value, at the same time that it maintains a price below the market average.

The Anti-infectious Drugs experienced falls in units (-4.1%) as well as in value (-5.8%). Practically 90% of the units in this group correspond to Antibiotics, a subgroup which, as in 2008, recorded a fall in units and value of -5% and -6.2% respectively. This group is the one that has the highest quota of products included in the RPS (67.2% by units and 42.3% by value), which accounts for the fall of -1.8% in the average price of this group.

Finally, the Anti-neoplastics Group experienced growth below the market average for units as well as value.

New launches

During 2009 278 new medicines have been marketed, whose sales have amounted to 97 million Euros. Of these products, 193 are generic medicines and 22 correspond to newly marketed molecules or associations. In total, the new products have focused fundamentally on two therapeutic areas: Central Nervous System with 83 products, of which 64 are generic and the Cardiovascular System, with 62 products of which 48 are generic. The supply of the sales by therapeutic groups of the newly marketed in 2009 has been the following:

SALES OF NEW PRODUCTS BY THERAPEUTIC GROUP STRUCTURE (%)

	Total		New molecules		Generics	
	Units	Value	Units	Value	Units	Value
A Digestive and Metabol. System	24.2	33.2	4.2	2.9	18.4	11.2
B Blood and Hematop. Organs	3.6	4.2	13.7	12.3	1.8	4.3
C Cardiovascular System	29.6	26.0	53.4	37.7	43.7	50.7
D Dermatology	1.5	5.7	0.2	17.4	0.2	0.1
G Genito-Urinary Products	8.0	5.7	5.2	5.4	1.0	1.5
H Hormones	2.1	0.3	-	-	4.9	1.0
J Anti-infectious	2.8	2.1	-	-	5.6	4.6
L Antineoplastics / Inmun. Agents	0.5	2.1	0.0	0.1	1.3	7.9
M Locomotor System	3.0	1.6	-	-	4.5	3.6
N Nervous System	17.2	16.2	13.8	19.6	16.5	14.3
R Respiratory System	4.3	1.2	-	-	2.1	1.0
S Sensory Organs	2.8	1.4	9.4	4.5	-	-
V Various	0.3	0.4	0.1	0.1	-	-
TOTAL	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

Source: FARMAINDUSTRIA from IMS.

2.3. EXTERNAL TRADE [14]

The trade deficit has traditionally been one of the most important macro-economic imbalances in our country. However, in 2008 and especially in 2009, this imbalance notably reduced and the trade deficit has gone from being 9.5% of GDP in 2007, to 4.8% in 2009, being estimated at 50,182 million Euros at the close of the year.

14 The data that appears in this section is confined to external trade of merchandise in general and pharmaceutical products in particular. In both cases, the data relating to 2009 is provisional, being susceptible to later change.

This rebate in the imbalance of our balance of payments is due, principally to the sharp fall in imports, which fell -26.2% with respect to 2008. For its part, exports, although also falling considerably (-15.9), did so with lower intensity which has translated into an improvement in the coverage rate of 11.5 percent, placing this indicator at 75.9% at the close of 2009.

With regard to external pharmaceutical trade, the trade exchanges in this sector maintain in general, relatively autonomous patterns of behaviour. Thus, in 2005 and 2006, in a context of growing trade deficit, the external pharmaceutical balance experienced a notable recovery which led to its positioning its deficit at the lowest levels since 1999. However, this tendency was inverted in 2007 and has continued into 2008 and particularly 2009, at the end of which, the coverage rate of the pharmaceutical trade balance was placed at 67.6%. The differential behaviour is largely explained by two circumstances:

- On one hand, the fall in internal demand for merchandise that provoked a severe economic crisis, which the Spanish economy is experiencing, justifies by itself the sharp fall recorded in our imports of goods, and largely explains the improvement in the trade balance of the economy as a whole.

- On the other hand, and as a counterbalance to that previously stated, the pharmaceutical sector, and more precisely the medicines subsector, is characterised amongst other things, by a fairly stable internal demand, due to the nature of its products and the high percentage of public coverage in its financing. However, and despite the growing dynamism of the pharmaceutical industry based in Spain having increased our exports of medicines three times greater–in terms of variation rate– than in 2008, they have not managed to counteract the higher growth of imports in the pharmaceutical balance of trade.

In 2009 exports of pharmaceutical products grew by 5%, reaching a value of 8,123 million Euros, which has placed the weight of pharmaceutical exports as a proportion of the national total at 5.1% in 2009.

By its constituent parts, it can be seen that, contrary to the external pharmaceutical sector's normal behaviour, the coverage rate of pharmaceutical raw materials has recorded a lower level (53%) than that of pharmaceutical products and medicines (69% and 74% respectively).

TOTAL EXTERNAL PHARMACEUTICAL TRADE 2009 (millions of €)					
	Import.	**09/08 (%)**	**Export.**	**09/08 (%)**	**Balance**
Raw Materials	966.01	58.8	515.79	-5.8	-450.22
Pharmaceutical Products	11,056.27	12.8	7,607.39	5.8	-3,448.88
** Medicines*	*8,850.82*	*17.0*	*6,553.79*	*5.5*	*-2,297.03*
TOTAL	**12,022.29**	**15.5**	**8,123.19**	**5.0**	**-3,899.10**

Note: The data from 2009 is provisional and corresponds to the aggregation of the monthly data from D.G.A.I.E However, the increases take as their base the consolidated data from 2008, meaning that the resulting variations should been read with caution.
Source: Ministry of Industry, Tourism and Trade. Spanish External Trade Statistics.

With regard to the geographical supply of external pharmaceutical trade, the EU-27 continues to be our main trading partner by a large margin, given that around 70% of Spanish purchases of external pharmaceutical products come from our European partners and more than 61% of our export contingent is destined for them, proportions which are very similar to those recorded in the previous year. Within the EU the largest part of the trading exchanges takes place with Germany, France and the United Kingdom, in that order. These three markets, by themselves, are the origin or destination of more than half of the trading exchanges of our country with the EU-27.

Outside of the EU's ambit, there are two countries, which for their quantitative importance in our external pharmaceutical trade, are worth highlighting:

- Switzerland, which consolidated in 2009 as the third most important destination for our pharmaceutical products, after Germany and France, with the difference that in the case of Switzerland, the pharmaceutical trade balance is in Spain's favour.

- The USA, with which our trading relations have intensified notably in recent years, up to becoming our first trading partner globally. In fact, the trading exchanges with this country (imports + exports) increased by 23.8% in 2009, and more than 60% of the total transaction volume of pharmaceutical products with non-European countries as a whole took place with this country.

EXTERNAL PHARMACEUTICAL TRADE STRUCTURE BY COUNTRY

	2008		2009	
	Import.	Export.	Import.	Export.
GLOBAL TOTAL	**100.00**	**100.00**	**100.00**	**100.00**
European Union (UE-27)	70.4	62.1	68.3	61.6
France	11.5	11.5	11.7	11.4
Germany	14.3	12.6	13.0	12.8
Italy	5.8	9.0	5.5	9.1
United Kingdom	11.9	9.4	10.5	8.5
Rest of Europe	7.7	12.7	6.9	13.5
Switzerland	7.4	10.5	6.4	11.2
Rest of World	21.9	25.2	24.8	24.9
USA	17.3	8.7	20.9	6.8

Source: Ministry of Industry, Tourism and Trade. Spanish External Trade Statistics. Consolidated Report 2008 and 2009 monthly summaries.

ACCORDING TO DATA FROM THE MINISTRY OF HEALTH AND SOCIAL POLICY, DURING 2009 934 MILLION PRESCRIPTIONS CHARGED TO SOCIAL SECURITY WERE DISPENSED

2.4. SOCIAL SECURITY PHARMACEUTICAL EXPENDITURE

According to data from the Ministry of Health and Social Policy, during 2009 934 million prescriptions charged to Social Security were dispensed, which meant an increase of 4.9% with respect to the previous year. These prescriptions resulted in public expenditure of 12,506.2 million Euros, corresponding to an increase of 4.5% with respect to 2008, the lowest in the last 20 years. At the same time, the average cost per prescription suffered a fall of 0.5%. These figures are largely explained by the coming into force of the new Price Reference Order which created 20 new groups and the revision of the reference prices of those already in existence, as well as being due to effects of the policies in the pharmaceutical area carried out by the various administrations.

SOCIAL SECURITY EXPENDITURE BY PRESCRIPTIONS DISPENSED BY PHARMACIES						
	Expend. (mill € RRP VAT)	Incr. (%)	No. Prescriptions (Millions)	Incr. (%)	Cost/presc. (€)	Incr. (%)
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

Source: Ministry of Health and Consumption (Summaries of billing for prescriptions).

It is a notable fact that the average cost per prescription in 2009 (€13.39) is at practically the same level as that recorded in 2006 (€13.36), the year that the Law 29/2006 on Guarantees and the Rational use of Medicines and Health Products was enacted, and nevertheless the prescriptions have experienced a growth of 17.3%. This data clearly demonstrates the growth in pharmaceutical expenditure in recent years, and especially since the enactment of Law 29/ 2006, is due to the growth in the number of prescriptions and not under any circumstances can it be blamed on the growth in prices.

Supply of average expenditure *per capita* by Autonomous Region

In 2009, average *per capita* pharmaceutical expenditure was €267.5, 3.2% more than the previous year. By Autonomous Region big differences exist, the highest figure corresponding to Galicia (€330.9) and the lowest to Baleares (€203.5), excepting the autonomous cities of Ceuta and Melilla.

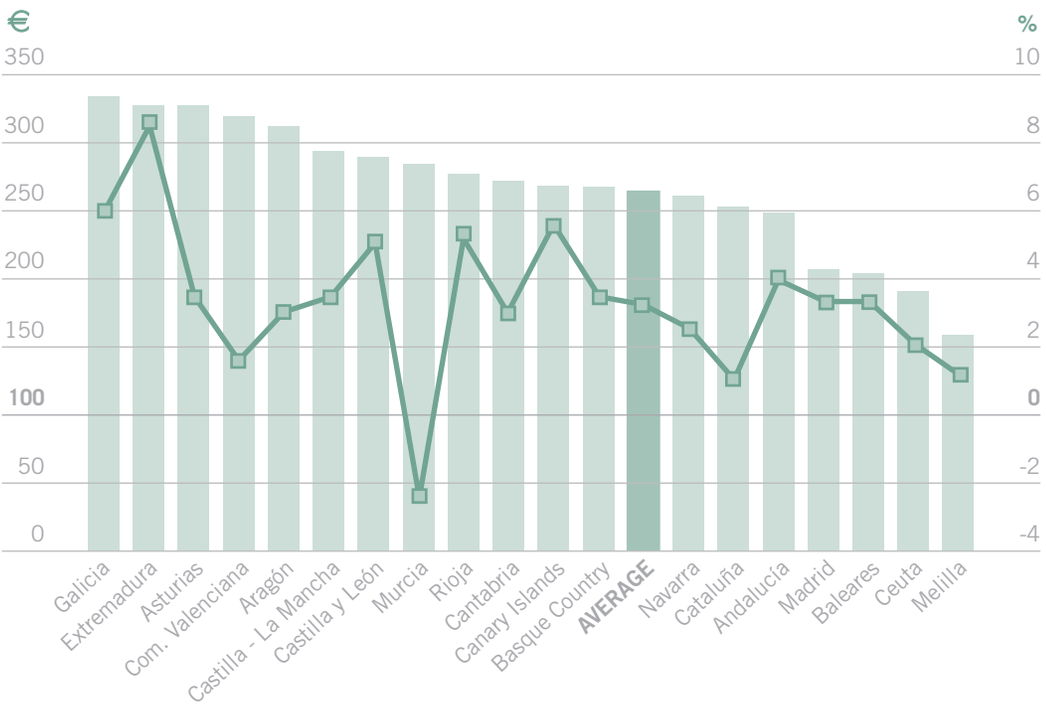
In terms of the rate of growth, Extremadura is the region which presents the highest *per capita* growth in expenditure, followed by Galicia (6%) and the Canary Islands (5.8%). At the opposite end the rebate in *per capita* pharmaceutical expenditure in Murcia (-2.3%) is notable and the low growth of Cataluña (0.8%) and Valencia (1.7%) are notable.

The moderation in the increase recorded by Autonomous Regions which carry a great weight in the expenditure of the State as a whole, Cataluña, Valencia and to a lesser degree, Madrid, has contributed to the slowing down of growth of average per capita expenditure from 4.7% in 2008 to 3.2% in 2009.

PHARMACEUTICAL EXPENDITURE *PER CAPITA* BY AUTONOMOUS REGION 2009

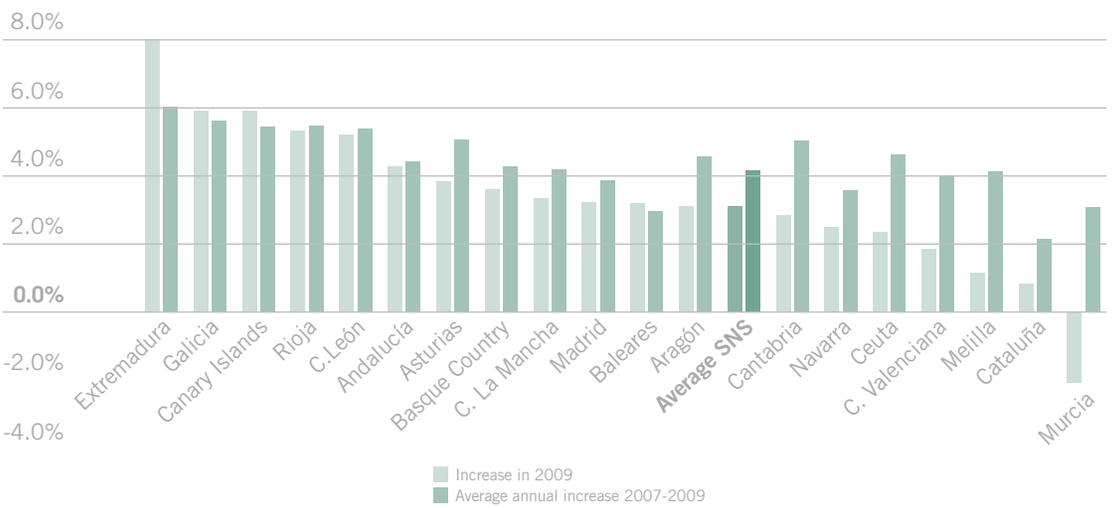
Autonomous Region	Expenditure Quota (%)	Expenditure *per capita*	
		Euros	Incr / on 2008 (%)
Galicia	7.4	330.9	6.0
Extremadura	2.9	325.3	8.4
Asturias	2.8	325.1	3.7
Comunidad Valenciana	12.8	315.0	1.7
Aragón	3.3	304.5	3.2
Castilla - La Mancha	4.9	295.2	3.3
Castilla y León	5.9	289.2	5.0
Murcia	3.3	285.0	-2.3
Rioja	0.7	278.8	5.1
Cantabria	1.3	272.1	3.0
Canary Islands	4.6	270.9	5.8
Basque Country	4.7	270.1	3.5
AVERAGE	-	**267.5**	**3.2**
Navarra	1.3	264.4	2.4
Cataluña	15.1	252.1	0.8
Andalucía	16.5	248.2	4.1
Madrid	10.5	206.4	3.3
Baleares	1.8	203.5	3.3
Ceuta	0.1	189.5	2.2
Melilla	0.1	163.9	1.1

EXPENDITURE *PER CAPITA* AND INCREASE BY AUTONOMOUS REGION



Of as great an interest as the previous data, referring to 2009, is observing the trend of the behaviour of *per capita* pharmaceutical expenditure of the Autonomous Regions. Thus, the following graph compares the growth in *per capita* expenditure of the Autonomous Regions in 2009 with the average annual increase of the period which goes from 2007 (the first year of the application of Law 29/2006) to 2009.

PHARMACEUTICAL EXPENDITURE EVOLUTION *PER CAPITA* BY AUTONOMOUS REGION




03

New legislation

3. NEW LEGISLATION

ELECTRONIC ADMINISTRATION

Royal Decree 1671/2009, of 6 November, which partially implements Law 11/2007, of 22 June, on the electronic access of the public to health services.

HEALTH CARE

Royal Decree 1430/2009, of 11 September, which implements in accordance with regulations Law 40/2007, of 4 December, on measures in the area of Social Security on the payments for temporary incapacity.

Order SAS/1904/2009, of 8 July, which amends annex III of Royal Decree 1030/2006, of 15 September, which lays out the portfolio of common services of the National Health System and the procedure to update Health Care.

CLINICAL RESEARCH ETHICS COMMITTEES

Resolution, of 30 October 2009, of the Director of Health Planning of the Basque Government, which grants accreditation to the Basque Clinical Research Ethics Committee.

UNFAIR COMPETITION

Law 29/2009, of 30 December, which amends the legal status of unfair competition and advertising to improve the protection of consumers and users.

AUTONOMOUS REGION OF ANDALUCÍA

Decree 5/2009, *of 13 January,* of the Regional Ministry of Governance of the Government of Andalucía, which creates the Andalucian Alerta Network of Consumer Products and which is regulated by the adoption of preventative administrative measures.

Decree 307/2009, *of 21 July,* of the Regional Ministry of Health of the Government of Andalucía, which defines the actions of nurses in the ambit of the pharmaceutical service of the Public Health Service in Andalucía.

Order, of 7 October 2009, of the Regional Ministry of Health of the Government of Andalucía, which establishes the use of electronic means in accrediting the professional competence level of health professionals in the Andalucian Public Health Service.

Resolution SC 0358/09, of 31 July, of the Management Board of the Andalucian Public Health Service, application of Decree 307/2009, of 21 July, which defines the actions of nurses in the ambit of the pharmaceutical service of the Public Health Service in Andalucía, relating to non-hospitalised patients.

Resolution SC 0369/09, of 7 August, of the Management Board of the Andalucian Public Health Service, standardising the criteria for use of medicines in the Andalucian Health Service.

AUTONOMOUS REGION OF ARAGÓN

Law 8/2009, *of 22 December,* of the President's Office of the Aragón Government, which amends Law 6/2002, of 15 April, on Health in Aragón, relating to Living Wills.

Decree 197/2009, *of 17 November,* of the Aragón Government, which passes the Regulation to implement Law 4/1999, of 25 March on Pharmaceutical Planning, in the area of Pharmacies and First-Aid Boxes.

Order, of 22 October 2009, of the Regional Health Ministry of the Aragón Government, which regulates the start-up and operation of the Medicine Evaluation Commission of the hospitals in the Aragón Public Health System.

Order, of 15 December 2009, of the Regional Health Ministry of the Aragón Government, which regulates the start-up and operation of the New Medicines Evaluation Committee in Primary Care in Aragón.

AUTONOMOUS REGION OF CANARIAS

Decree 49/2009, of 28 April, of the Regional Health Ministry of the Canarias Government, which regulates the Health Professionals Registers in Canarias.

Order, of June 18 2009, of the Regional Health Ministry of the Canarias Government, which regulates the procedure for the recognition of the right to public health care for people without sufficient financial resources.

AUTONOMOUS REGION OF CANTABRIA

Decree 48/2009, of 4 June, of the Governing Board of Cantabria, which passed the Regulation of the Organisation and Operation of the Cantabrian Consumer Protection Agency.

Decree 50/2009, of 18 June, of the Governing Board of Cantabria, which regulates the control of industrial atmospheric pollution in the Autonomous Region of Cantabria.

Order SAN/28/2009, of 8 September, of the Regional Health Ministry of Cantabria, which passed the charter of Citizens' Rights and Duties in the Regional Health System of Cantabria.

AUTONOMOUS REGION OF CASTILLA-LA MANCHA

Decree 33/2009, of 28 April, of the Regional Ministry of Public Administration and Justice of the Local Governments of Castilla-La Mancha, which abolishes the need to provide certain documents for administrative procedures of the Administration of the Local Governments of Castilla-La Mancha and its connected or dependent bodies.

Resolution, of 27 February 2009, of the Managing Board of the Health Service of Castilla-La Mancha (SESCAM), by which the Circular 1/2009 was passed, on the use, access, ceding of data and keeping of Clinical Records in the ambit of the SESCAM.

AUTONOMOUS REGION OF CATALUÑA

Law 1/2009, of 12 February, of the President's Department of the Government of Cataluña, on the Catalan Competition Authority.

Law 18/2009, of 22 October, of the President's Department of the Government of Cataluña, on Public Health.

Decree 13/2009, of 3 February, of the Health Department of the Government of Cataluña, which passed the Statutes of the Catalan Health Institute.

Decree 56/2009, of 7 April, of the Department of Governance and Public Administrations, to encourage the implementation of electronic means in the Government's Administration.

Decree 145/2009, of 15 September, of the President's Department of the Government of Cataluña, on the Creation of the Catalan Board of Research and Innovation.

Decree 175/2009, of 10 November, of the Innovation, Universities and Enterprise Department of the Government of Cataluña, on the creation of an Inter-departmental Research and Innovation Commission and of a Research and Innovation Coordination Office.

AUTONOMOUS REGION OF EXTREMADURA

Decree 23/2009, of 13 February, of the Regional Ministry of Health and Dependency of the Government of Extremadura, which regulates the composition and operation of the Bioethics Assessment Board of the Autonomous Region of Extremadura.

AUTONOMOUS REGION OF GALICIA

Decree 14/2009, of 21 January, of the Department of the President's Office, Public Administration and Justice of the Government of Galicia, which passed the Regulations on foundations of Galician interest.

Decree 15/2009, of 21 January, of the Department of the President's Office, Public Administration and Justice of the Government of Galicia, which passed the Regulations on the Register of Foundations of Galician interest.

Decree 29/2009, of 5 February, of the Health Department of the Government of Galicia, which regulates the use of and access to the electronic clinical record.

Decree 429/2009, of 3 December, of the Health Department of the Government of Galicia, amending Decree 177/1995, of 16 June, which regulates the health card.

AUTONOMOUS REGION OF MURCIA

Law 3/2009, of 11 May, of the President's Office of Murcia, on the Rights and Duty of users of the Murcian Health System.

Decree 26/2009, of 27 February, of the Governance Board of Murcia, amending Decree 92/2005, of 22 July, which regulates the individual health card and conditions of use in Murcia.

Decree 339/2009, of 16 de October, of the Governance Board of Murcia, which implements the information and register system for health professionals in Murcia.

Decree 435/2009, of 11 December, of the Board of Governance of Murcia, which implements the regulation of pharmacy services and the medicine deposits and health products of the health structures of primary care in Murcia and regulates the authorisation procedure.

AUTONOMOUS REGION OF LA RIOJA

Law 3/2009, of 23 June, of the President's Office of the Government of La Rioja, on Technology and Innovation.

Decree 55/2009, of 17 July, of the Regional Ministry of Health of the Government of La Rioja, which creates and regulates the Health Professionals Register of La Rioja.

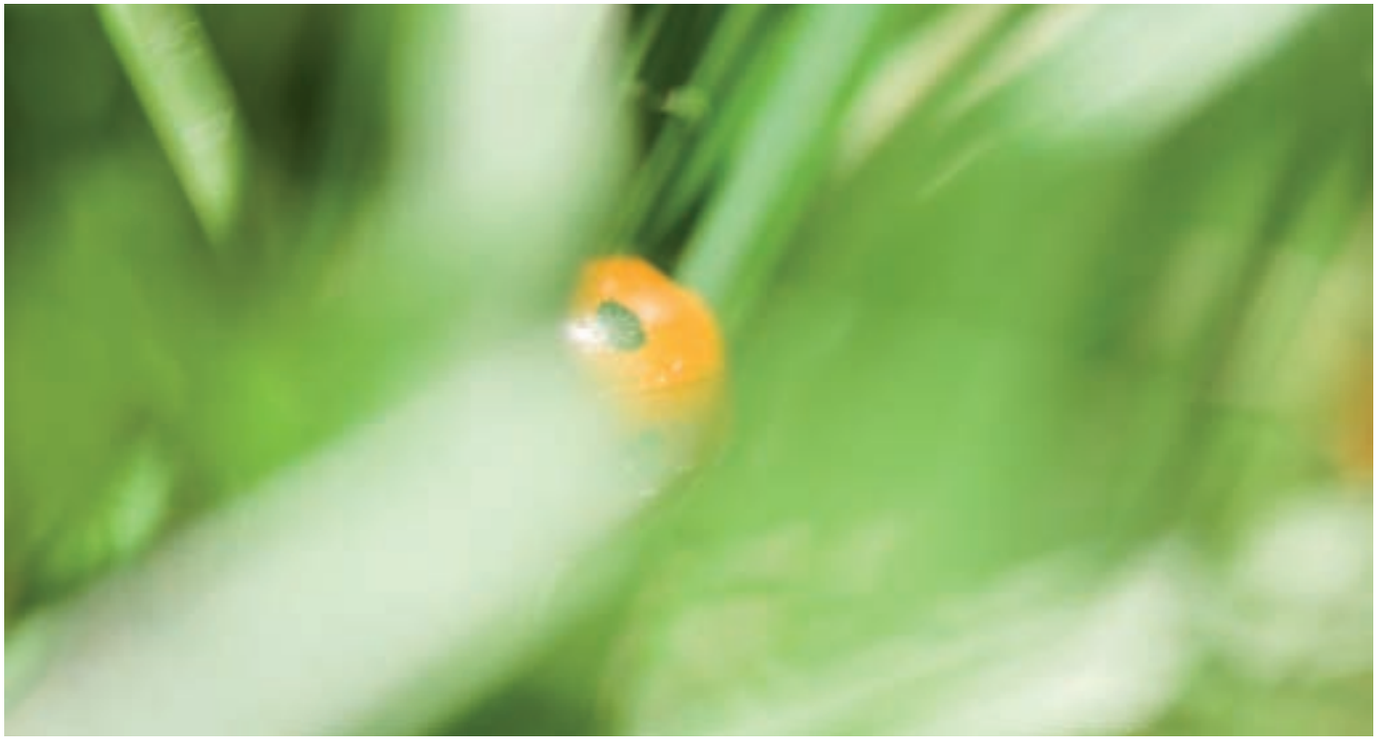
Decree 80/2009, of 18 December, of the Regional Ministry of Health of the Government of La Rioja, which lays out the legal basis and procedure for the authorisation and register of centres, services and health establishments in the Autonomous Region of La Rioja.

Order 3/2009, of 13 July, of the Regional Ministry of Health of the Government of La Rioja, which guarantees the right to free and public health care to people who cease paying into the social security system due to their employment activity ending.

AUTONOMOUS REGION OF LAS ILLES BALEARS

Decree 33/2009, of 19 June, of the Regional Ministry of Finance, Taxation and Innovation of the Government of Las Illes Balears, which modifies Decree 107/2006, of 15 December, on regulation and use of Electronic signatures in the ambit of the Administration of the Autonomous Region of Las Illes Balears.

Decree 41/2009, of 26 June, of the Regional Ministry of Health and Consumer Protection of the Illes Balears, which regulated the orthoprothesis service.



Decree 66/2009, of 9 October, of the Regional Ministry of Health and Consumer Protection of Las Illes Balears, which passed the Planning Regulation of the Inspection Health Services of Las Illes Balears Health Service.

AUTONOMOUS REGION OF THE BASQUE COUNTRY

Order, of 15 January 2009, of the Vice-Presidency of the Basque Government, which regulates the control of the admission of electronic certificates.

AUTONOMOUS REGION OF THE PRINCIPALITY OF ASTURIAS

Decree 18/2009, of 4 March, of the Regional Ministry of Education and Science of the Principality of Asturias, on the creation of the Asturian Board of Science, Technology and Innovation.

Decree 66/2009, of 14 July, of the Regional Ministry of Health and Health Services of the Principality of Asturias, which regulates the Structure and Operation of the areas and clinical management units of the Health Service of the Principality of Asturias.

AUTONOMOUS REGION OF CASTILLA Y LEÓN

Decree 15/2009, of 5 February, of the Regional Ministry of Finance and Employment of the Government of the Regions of Castilla y León, which regulates the exercising of the functions of the Region of Castilla y León in the area of free competition.

Decree 23/2009, of 26 March, of the Regional Ministry of the Family and Equal Opportunities of the Government of Castilla y León, of measures relating to the simplification of documentation in administrative procedures.

Order ADM/941/2009, of 2 May, of the Regional Ministry of Administration of the Government of Castilla y León, which implements Decree 23/2009, of 26 March, on measures relating to the simplification of documentation in administrative procedures.

Order ADM/942/2009, of 2 May, of the Regional Ministry of Administration of the Government of Castilla y León, on the standardisation of forms associated to administrative procedures.

AUTONOMOUS REGION OF MADRID

Law 6/2009, of 16 de November, of the President's Office of the Regional Ministry of Madrid, on freedom of choice in Health in the Autonomous Region of Madrid.

Decree 62/2009, of 25 June, of the Board of Governance of the Autonomous Region of Madrid which regulates the use of Electronic, IT or telematic means in public contracting in the Autonomous Region of Madrid.

Decree 65/2009, of 9 July, of the Board of Governance of the Autonomous Region of Madrid, which regulates the certification procedures of pharmacies and pharmacy services that make up pharmaceutical compounds and officinal preparations and of authorisation for their elaboration for third parties, and a corresponding Register was created.

AUTONOMOUS REGION OF NAVARRA

Law 1/2009, of 19 February, which amends article 51 of Law 6/2006, on Public Contracts in Navarra.

Law 13/2009, of 9 December, on amendment to article 9 of Law 6/2006, on Public Contracts.

Decree 25/2009, of 30 March, which adapts Law 6/2006, of 9 June, on Public Contracts, to the new Community Thresholds and amends its annexes I and II.

Decree 92/2009, of 28 December, which updates the Community Thresholds of Law 6/2006, of 9 June, on Public Contracts.

AUTONOMOUS REGION OF VALENCIA

Decree 25/2009, of 13 February, of the Board of the Government of Valencia, which creates and regulates a Register of Health Professionals of the Autonomous Region of Valencia.

Decree 86/2009, of 19 June, of the Board of the Government of Valencia, which regulates the second medical opinion in the ambit of the Valencian Public Health System.

Decree 98/2009, of 17 July, of the Board of the Government of Valencia, which passed the Portfolio of Services of the Valencian Public Health System.

Decree 149/2009, of 25 September, of the Board of the Government of Valencia, which regulates the agreement for health care to private patients.

Order, of 31 March 2009, of the Regional Health Ministry of the Government of Valencia, on modifying the Order of 14 November 2005, of the Regional Health Ministry, which creates and regulates the Register of licences granted by the Regional Health Ministry to establishments of bespoke manufacturing and distribution of health products.

Order, of 31 March 2009, of the Regional Health Ministry of the Government of Valencia, which regulates the recognition of health interest for acts of a scientific nature which take place in the Region of Valencia.

Order, of 28 May 2009, of the Regional Health Ministry of the Government of Valencia, which updates the functions of the Tissue and Cell Bank of Valencia.

Resolution, of 30 September 2009, of the Sub-Secretary of the Regional Health Ministry of the Government of Valencia, which passed the model for requesting the subscription to the health care agreement for private patients with the Government and the third party maintenance model for payments by direct debit, laid out in Decree 149/2009, of 25 September, of the Regional Ministry, which regulates the health care agreement of private patients.

Resolution, of 15 October 2009, of the Regional Health Secretary of the Government of Valencia, which sets out the procedure for application, treatment and cession of data of a health nature to the information system of outpatient care of the Abucasis Valencian Health Agency

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REGIONAL HEALTH MINISTRIES

Decree 43/2009, of 24 March, of the Department of Health and Consumer Affairs of the Aragón Government, which amends Decree 6/2008, of 30 January, of the Aragón Government, which approved the organic structure of the Department of Health and Consumer Affairs and the Aragón Health Service.

Decree 171/2009, of 19 May, of the Regional Health Ministry of the Government of Andalucía, which lays out the organic structure of the Regional Health Ministry and Andalucían Health service.

Decree 310/2009, of 28 May, of the Regional Health Ministry of the Government of Galicia, which lays out the organic structure of the Regional Health Ministry.

Decree 32/2009, of 30 June, of the Regional Ministry of Public Administration and Local Policy of the Government of La Rioja, which lays out the organic structure and functions of the Regional Health Ministry in implementing Law 3/2003, of 3 March, on the Organisation of the Public Sector of the Autonomous Region of La Rioja.

Decree 86/2009, of 7 July, of the Regional Ministry of Health and Social Welfare of the Local Governments of Castilla-La Mancha, amending Decree 139/2008, of 09/09/2008, which lays out the organic structure and competences of the Regional Ministry of Health and Social Welfare.

Decree 579/2009, of 3 November, of the Department of Health and Consumer Affairs of the Government of the Basque Country, which lays out the organic and functional structure and functions of the Department of Health and Consumer Affairs.

Decree 99/2009, of 23 December, of the Board of Governance of Cantabria, on the partial modification of the organic structures and of the relationship of the positions of the Regional Ministry of Health and the Management Board of the Cantabrian Health Service.

AUTONOMOUS ASSESSMENT COMMITTEES

Order 851/2009, of 30 November, of the Regional Health Ministry of Madrid, which creates the Pharmacy Assessment Committee in the Madrid Region.

CONSUMERS AND USERS

Royal Decree 487/2009, of 3 April, which modifies Royal Decree 894/2005, of 22 July, which regulates the Consumers and Users' Committee.

Royal Decree 863/2009, of 14 May, which modifies Royal Decree 231/2008, of 15 February, which regulates the Consumers' Arbitration System.

FREE COMPETITION

Resolution, of 30 January 2009, of the Presidency of the National Competition Commission, which creates an Electronic Register and lays out the general requirements for its application in certain procedures.

Resolution, of 11 December 2009, of the Presidency of the National Competition Commission, which includes new Procedures and Stages in the Electronic Register of the Organism.

Communication, of 6 February 2009, of the National Competition Commission, on quantifying the sanctions deriving from infringements of Articles 1, 2 and 3 of Law 15/2007, of 3 July, on Free Competition and articles 81 and 82 of the European Community Treaty.

FUNDAMENTAL STIPULATIONS

Law 17/2009, of 23 November, on free access to services, activities and their exercise.

Law 25/2009, of 22 December, on amending different Laws for their adaption to the Law on free access to services, activities and their exercise.

Law 28/2009, of 30 December, on amending Law 29/2006, of 26 July of guarantees and rational use of medicines and health products.

DRUG TAKING IN SPORT

Royal Decree 641/2009, of 17 April, which regulates the control processes for drug testing and the authorised analysis laboratories, and which lays out the complementary measures for prevention of drug-taking and health protection in sport.

Royal Decree 1462/2009, of 18 September, which amends Royal Decree 641/2009, of 17 April, which regulates the control processes for drug testing and the authorised analysis laboratories, and which lays out the complementary measures for prevention of drug-taking and health protection in sport.

Resolution, of 27 May 2009, of the Technical General Secretary of the Ministry of External Affairs and Co-operation, on the amending of Annexe II, Regulations for the concession of authorisations for use with therapeutic ends, in force since 1 January 2009, of the International Convention against drug taking in sport, signed in Paris on 18 November 2005 and published in the Official State Bulletin no.41, of 16 February 2007.

Resolution, of 18 December 2009, of the Presidency of the Sports Council, which passed the list of prohibited substances and methods in sport.

DRUGS

Law 4/2009, of 15 June, on control of drug precursors.

RARE DISEASES

Decree 171/2009, of 24 July, of the Regional Ministry of Health and Dependency of Extremadura, which creates the Assessment Committee on Rare Diseases of the Extremadura Public Health System.

Order SLT/233/2009, of 30 April, of the Health Department of the Catalan Government, creating an Assessment Commission for Rare Diseases.

CLINICAL TRIALS

Resolution, of 16 October 2009, of the Sub-secretary of Health and Social Policy, which authorised the presentation through the electronic register of the department of certain documents, communications and applications relating to clinical trials with medicines directed towards Clinical Research Ethics Committees of the Spanish Medicines and Health Products Agency.

Decree 73/2009, of 5 June, of the Government of Valencia, which regulates the administration of clinical trials and post-authorisation studies with medicines and health products.

Order SAN/2206/2009, of 24 November, of the Regional Ministry of Health of Castilla y León, which creates a Register of Clinical Trials and Observational Post-authorisation Studies with medicines in Castilla y León.

Resolution, of 16 July 2009, of the Government of Valencia, which approves the contract model which has to be subscribed to between the Management of a Health Centre, the promoter and the researchers, to carry out a clinical trial or observational post-authorisation studies of medicines and health products in the organisations of the Valencian health services.

Resolution, of 16 July 2009, of the Regional Ministry of Health of Valencia, on the regulation of the procedures, documentation and periods to be observed in the presentation and amendment clinical trial or observational post-authorisation studies of medicines and health products in the organisations of the Valencian health services.

POST-AUTHORISATION STUDIES

Order SAS/3470/2009, of 16 December, which publishes the directives on post-authorisation studies of an observational nature for human use.

Order, of 19 January 2009, of the Department of Health and Consumer Affairs of the Aragón Government, which amends the administration and payment of the charge 08,point 2, of Payment 20, for the evaluation for the authorisation, where necessary, of the post-authorisation studies of an observational nature with medicines.

DRUGS AND PSYCHOTROPIC SUBSTANCES

Order SAS/1916/2009, of 8 July, which includes the substance 1- benzylpiperazine (BZP) in annexe I of Royal Decree 2829/1977, of 6 October, which regulates the manufacture, distribution, prescription and dispensing of substances and prepared psychotropic drugs.

Official Communication, of 20 November 2009, of the Spanish Medicines and Health Products Agency, importing the active drug codine.

HEALTH COHESION FUND

Order SAS/3351/2009, of 10 December, which updates Annexe III of Royal Decree1207/2006, of 20 October, which regulates the Management of the Health Cohesion Fund.

CARLOS III HEALTH INSTITUTE

Royal Decree 246/2009, of 27 February, which modifies the Statute of the Spanish National Oceanographic Institute (IEO), passed by Royal Decree 1950/2000, of 1 December; the Statute of the National Institute for Agricultural and Food Research and Technology (INIA), passed by Royal Decree 1951/2000, of 1 December; the Statute of the Energy, Environmental and Technological Research Centre (CIEMAT), passed by Royal Decree 1952/2000, of 1 December; the Statute of the Geological and Mining Institute of Spain (IGME), passed by Royal Decree 1953/2000, of 1 December; the Statute of the Carlos III Health Institute (ISCIII), passed by Royal Decree 375/2001, of 6 April; and the Statute of the State Scientific Research Council Agency (CSIC), passed by Royal Decree 1730/2007, of 21 December.

Royal Decree 1672/2009, of 6 November, which amends the Statute of the Carlos III Health Institute, passed by Royal Decree 375/2001, of 6 April.

SCIENTIFIC RESEARCH

Royal Decree 326/2009, of 13 March, which attributed functions to the Government's Delegate Commission on Scientific and Technological Policy.

Royal Decree 332/2009, of 13 March, which abolishes the Commission on Science and Technology laid out in Law 13/1986, of 14 April, on encouragement and general co-ordination of scientific and technical research.

Royal Decree 785/2009, of 30 April, which sets up the Joint Co-ordination Committee between the Ministry of science and Innovation and the Ministry of Health and Social Policy, in relation to the Carlos III Health Institute.

Royal Decree 1042/2009, of 29 June, which implements the Base Structure of the Ministry of Science and Innovation.

Resolution, of 6 August 2009, of the Industry Secretary General, which set out the regulatory basis of PROFARMA (2009-2012): Encouragement of the competiveness of the Pharmaceutical Industry.

PROFESSIONAL MARGINS

Resolution, of 24 June 2009, of the Sub-secretary of the Ministry of the Presidency, which provides for the publication of the Joint Resolution of General Mutual Insurance of State Civil Servants, the Legal General Mutual Insurance, and the Social Institute of the Armed Forces, for the monitoring of Royal Decree 2130/2008, of 26 December.

MEDICINES IN SPECIAL SITUATIONS

Royal Decree 1015/2009, of 19 June, which regulates the availability of medicines in special situations.

Information and Recommendations of the Spanish Medicine and Health Products Agency, on the electronic transmission and on the notification of suspected adverse reactions when using medicines in special conditions.

Instructions, of 7 August 2009, of the Director General of Pharmacy and Health Products of the Valencian Health Agency, in relation to the implementation of Royal Decree 115/2009, of 19 June, which regulates the availability of medicines in special conditions.

COUNTERFEIT MEDICINES

Directive on the Actions of the Holders of Marketing authorisations on the detection of counterfeit medicines in Legal commercial channels.

NON-SUBSTITUTABLE MEDICINES

Information Note, of 24 April 2009, of the Spanish Medicine and Health Products Agency, medicines which should not be the object of substitution by other medicines with the same active ingredient without the express authorisation of the prescribing doctor.

ENVIRONMENT

Ratification instrument of the Protocol on Registers of Emissions and Transfers of Contaminants, drawn up in Kiev on 21 May 2003.

Royal Decree 1514/2009, of 2 October, which regulates the protection of subterranean water against contamination and deterioration.

Resolution, of 20 January 2009, of the Secretary of State for Climatic Change, which published the Agreement of the Cabinet which passed the National Integrated Waste Plan for the period 2008-2015.

Law 1/2009, of 26 February, of the Presidency of the Government of Castilla y León, amending Law 11/2003, of 8 April, on Environmental Prevention in Castilla y León.

Law 5/2009, of 4 June, of the Presidency of the Government of Castilla y León, on Noise in Castilla y León.

Law 20/2009, of 4 December, of the President's Department of the Government of Cataluña, on the prevention and environmental control of activities.

Law 4/2009, of 14 May, of the Presidency of Murcia, on Integrated Environmental Protection.

Legislative Decree 1/2009, of 21 July, of the President's Department of the Government of Cataluña, which passed the Revised Text of the Law regulating waste.

Decree 59/2009, of 26 February, of the Regional Ministry of the Environment and Sustainable Development of the Government of Galicia, which regulates the traceability of waste.

Decree 60/2009, of 26 February, of the Regional Ministry of the Environment and Sustainable Development of the Government of Galicia, on potentially contaminated soil and the procedure for the declaration of contaminated soils.

Decree 50/2009, of 18 June, of the Regional Ministry of Governance of Cantabria, which regulates the atmospheric industrial pollution in the Autonomous Region of Cantabria.

Order MAM/248/2009, of 3 February, of the Regional Ministry of the Environment of the Government of Castilla y León, which lays out the procedure and notification model for emissions and transfers of contaminants in Castilla y León.

Order of 20 July 2009, of the Regional Ministry of the Environment, Territory and Infrastructures of the Government of Galicia, which regulates the contents of the studies of minimising the production of waste which the producers of waste in Galicia should present.

Order PRE/2827/2009, of 19 October, which amends the quantities of the sector assignations set out in the National Plan for the Assignation of Greenhouse Gas Emission Rights, 2008-2012, passed by Royal Decree 1370/2006, of 24 November.

Resolution of 11 September 2009, the Regional Ministry of the Environment, Territorial Planning and Infrastructures of the Principality of Asturias, which passed the Technical Instruction for the elaboration of Monitoring Plans for greenhouse gas emissions in the Principality of Asturias.

MINISTRY OF HEALTH

Royal Decree1041/2009, of 29 June, which implements the basic organic structure of the Ministry of Health and Social Policy and amends Royal Decree 438/2008, of 14 April which passed the Basic organic structure of ministerial departments.

Order SAS/1845/2009, of 29 June, which amends Order of 21 July 1994, which regulates files with data of a personal character administered by the Ministry of Health and Social Policy.

BIOLOGICAL SAMPLES

Order SAS/3166/2009, of 16 November, which replaces the annexes of Royal Decree 65/2006, of 30 January, which sets out the requisites for the import and export of biological samples.

REFERENCE PRICES

Order SAS/3499/2009, of 23 December, which sets new medicine groups, their reference prices and revises the reference prices set and revised by Order SCO/3803/2008, of 23 December.

Resolution, of 16 February 2009, of the Directorate General of Pharmacy and Health Products, which publishes the relation of pharmaceutical laboratories and medicine presentations which have taken on the gradual rebate of their laboratory sale price conforming to that set out in the fifth additional stipulation of Order SCO/3803/2008, of 23 December, which set the new group prices of medicines and their reference prices.

HEALTH PRODUCTS

Royal Decree 1591/2009, of 16 October, which regulates Health Products.

Royal Decree1616/2009, 26 October, which regulates Active Implantable Health Products.

Resolution, of 6 July 2009, of the Sub-secretary of Health and Social Policy, which publishes the common technical specifications for diagnosis "In Vitro" Health products contained in Decision 2009/108/CE of the Commission, of 3 February 2009.

Decree 41/2009, of 26 June, the Regional Ministry of the Health and Consumer Affairs of Las Illes Balears, which regulates the ortoprotesic service.

INTELLECTUAL PROPERTY RIGHTS

Ratification instrument of the treaty of Singapore on Trademarks Law, drawn up in Singapore on 27 March 2006.

Amendments to the Regulations of the Cooperation Treaty in the area of patents (PCT) (Official State Bulletin of 7 November 1989), adopted at the 33rd Session of the Assembly of the International Co-operation Union in the area of patents, Geneva 5 October 2004.

Amendments to the Regulations of the Co-operation Treaty in the area of patents (PCT) (published in the Official State Bulletin of 7 November 1989), adopted at the 34th Session of the Assembly of the International Cooperation Union in the area of patents, 5 October 2005.

Amendments to the Regulations of the Co-operation Treaty in the area of patents (PCT) (published in the Official State Bulletin of 7 November 1989), adopted at the 35th Session of the Assembly of the International Cooperation Union in the area of patents, 3 October 2006.

PRESCRIPTIONS

Order SAS/2022/2009, of 20 July, which repeals the Order of 7 November 1985, which set the medicines for use in human medicines to be dispensed with or without prescription.

Decree 91/2009, of 9 June, of the Health Department of the Government of Cataluña, which amends letter h) of article 2 of Decree 159/2007, of 24 July, which regulated electronic prescriptions and the telematic processing of pharmaceutical services of the Catalan Health Service.

Decree 93/2009, of 24 April, of the Regional Ministry of Health and Dependency of the Government of Extremadura, which regulates the implementation of Electronic prescriptions in the ambit of the Public Health system in Extremadura.

Resolution of 19 January 2009, of the Regional Ministry of Health of the Government of Valencia, on the implementation of a programme for electronic and /or computerised prescriptions for drugs in the ambit of public health care in Valencia.

ENVIRONMENTAL HEALTH

Decree 95/2009, of 10 July, of the Regional Ministry of Health of the Government of Valencia, which creates the health surveillance service on environmental risks.

EXTERNAL HEALTH

Order SAS/3160/2009, of 16 November, which creates the Computerised External Health System.

HEALTH SERVICES

Decree 13/2009, of 3 February, of the Department of Health of the Government of Cataluña, which passed the Statutes of the Catalan Institute of Health.

Decree 311/2009, of 28 May, of the Regional Health Ministry of the Galician Government, which establishes the organic structure of the central services of the Galician Health Service.

Decree 66/2009, of 14 July, of the Regional Ministry of Health and Health Services of the Principality of Asturias, which regulates the Structure and Operation of the areas and clinical management units of the Health Service of the Principality of Asturias.

CHARGES

Information note of 20 October 2009, of the Spanish Medicine and Health Products Agency, return of Paid and Unused Charges.

Clarification note, of 20 October 2009, of the Spanish Medicine and Health Products Agency, document to help request the reimbursement of charges.

TRANSFER OF FUNCTIONS AND SERVICES

Royal Decree 3/2009, of 9 January, on the transfer of functions from the State Administration to the Basque Country Regional Government in the area of scientific, technical and innovation research and development.

TRANSPLANTS

Royal Decree 1825/2009, of 27 November, which passed the Statute of the National Transplant Organisation.

Order, of 23 January 2009, of the Regional Ministry of Health of the Galician Government, which created a Hematopoietic Progenitor Cell Transplant Register.

VARIATIONS

Instruction, of 23 January 2009, of the Spanish Medicine and Health Products Agency, for the Renewal of the Certificate of Conformity with the Principle Plasma Archive (CAPP).

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