farmaindustria

ANNUAL REPORT 08

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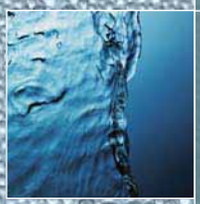


LETTER FROM THE **PRESIDENT**

JESÚS ACEBILLO MARÍN

FARMAINDUSTRIA
President

The 12-month period ending with the publication of this Annual Report has been particularly intensive for the sector. Over the past year we have witnessed important events affecting the institutional and regulatory framework for the pharmaceutical industry.

We began 2008 with the creation of the Ministry of Science and Innovation as a new ministerial department of importance to pharmaceutical companies, having assumed responsibilities and incorporating in its departmental structure key bodies for the pharmaceutical companies traditionally connected to the Ministries of Industry and Health. The pharmaceutical industry is a priority sector for the Ministry of Science and Innovation for a very good reason: pharmaceutical companies carry out almost 20% of all Spanish industrial R&D.

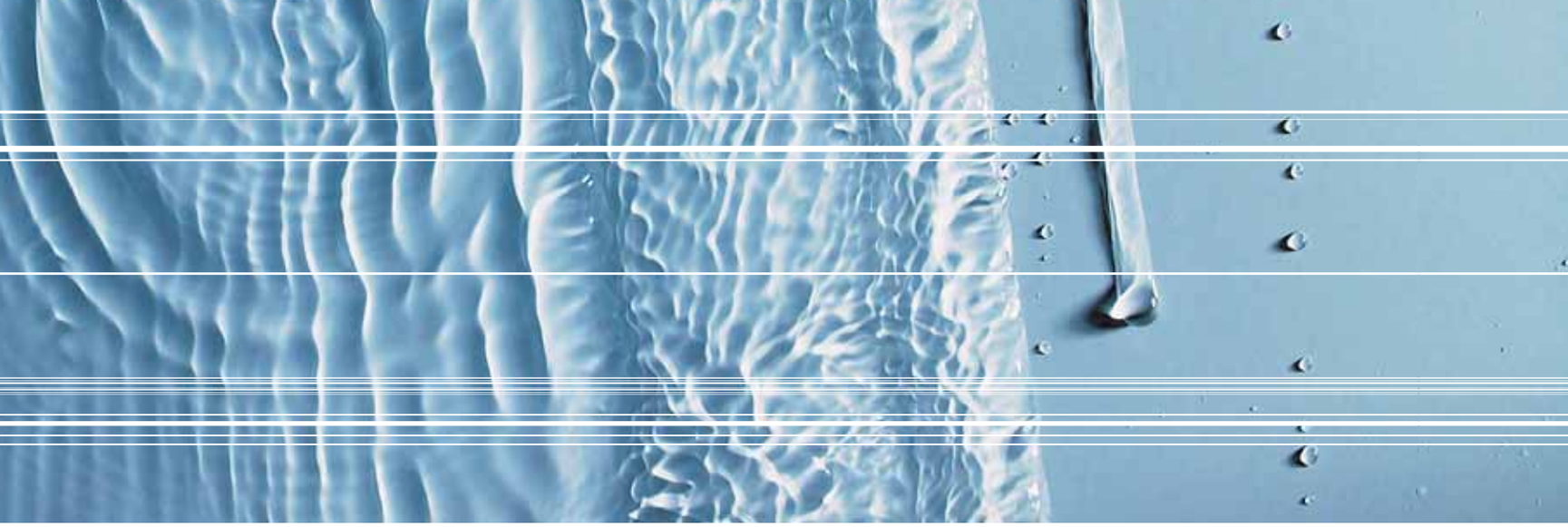
The year ended with the coming into force of a new Reference Prices Order, consolidating the Reference Price System as a fundamental pillar of economic regulation for the sector in Spain. Thus, since its effective implementation in March 2007, the new Reference Price System provided regulatory stability and certainty to the pharmaceutical companies and is being shown to be an effective tool for guaranteeing the economic sustainability of public pharmaceutical services in Spain. In fact, in the two years before the new Reference Price System came into force, pharmaceutical spending grew by an average of 5.7% and, according to the latest data available, its growth in April 2009 was 5%.

But, since last October when I took over the Presidency of FARMAINDUSTRIA from Dr Antoni Esteve, to whom I must thank for all the effort and excellent work carried out in his period at the head of the Association, events have overtaken us in the pharmaceutical sector as well as the country as a whole.

In the most recent quarters, the Spanish economy has entered into recession and has experienced a deteriorating situation with respect to production and employment levels which is unprecedented in our recent history. In this context, and just over two months ago, in March 2009, the pharmaceutical industry demonstrated an important commitment to Spanish society in terms of employment and investment, to which I will come shortly. At the same time, and as a consequence of the economic crisis, this April saw a remodelling of the Spanish executive in which the Ministry of Health also came to assume responsibilities in the area of Social Policy, resulting in a shake-up at the top with the arrival of Trinidad Jiménez García-Herrera as the new Health and Social Policy Minister, replacing the former Minister for Health and Consumer Affairs, Bernat Soria Escoms.

Nevertheless, from a macroeconomic perspective, 2008 marked a turning point for our country, not only because in the fourth quarter, a period of continuous growth in the Spanish economy came to a halt after 60 previous consecutive quarters of growth (from the fourth quarter of 1993, to be precise), but also, more importantly, since the current economic crisis has demonstrated in the crudest possible way that Spain needs to change its model of economic growth to guarantee sustainable development in the 21st Century.

The task will be neither simple nor rapid, and nor should the change in the growth model imply a general reconsideration of Spain's competitive advantages,



nor of the capacity of our traditional ways of generating economic value. Our country needs deep, but selective, changes.

Changing the growth model should imply an important transformation both in the priority actions of the public sector and the incentives set before private economic organisations. In this way, change in the growth model is intended among other things to allow sectors with a high technological and innovative component to grow substantially as a function of the Gross Domestic Product. This means that Spain will improve significantly in terms of productivity and for this it is necessary to depend upon sectors intensive in research, development and innovation. The pharmaceutical industry is one of these sectors which can drive the change in the economic model that Spain requires.

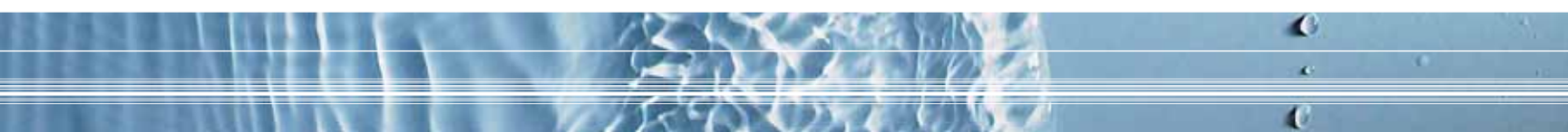
The main advantage of the pharmaceutical industry over other economic sectors with the same characteristics is that it is not necessary to attract the pharmaceutical industry to Spain through economic and fiscal incentives, etc. The pharmaceutical industry is already in Spain, has been established for many years in Spain and has already created an extraordinarily interesting industrial fabric, and, most importantly, has enormous possibilities to expand in the country.

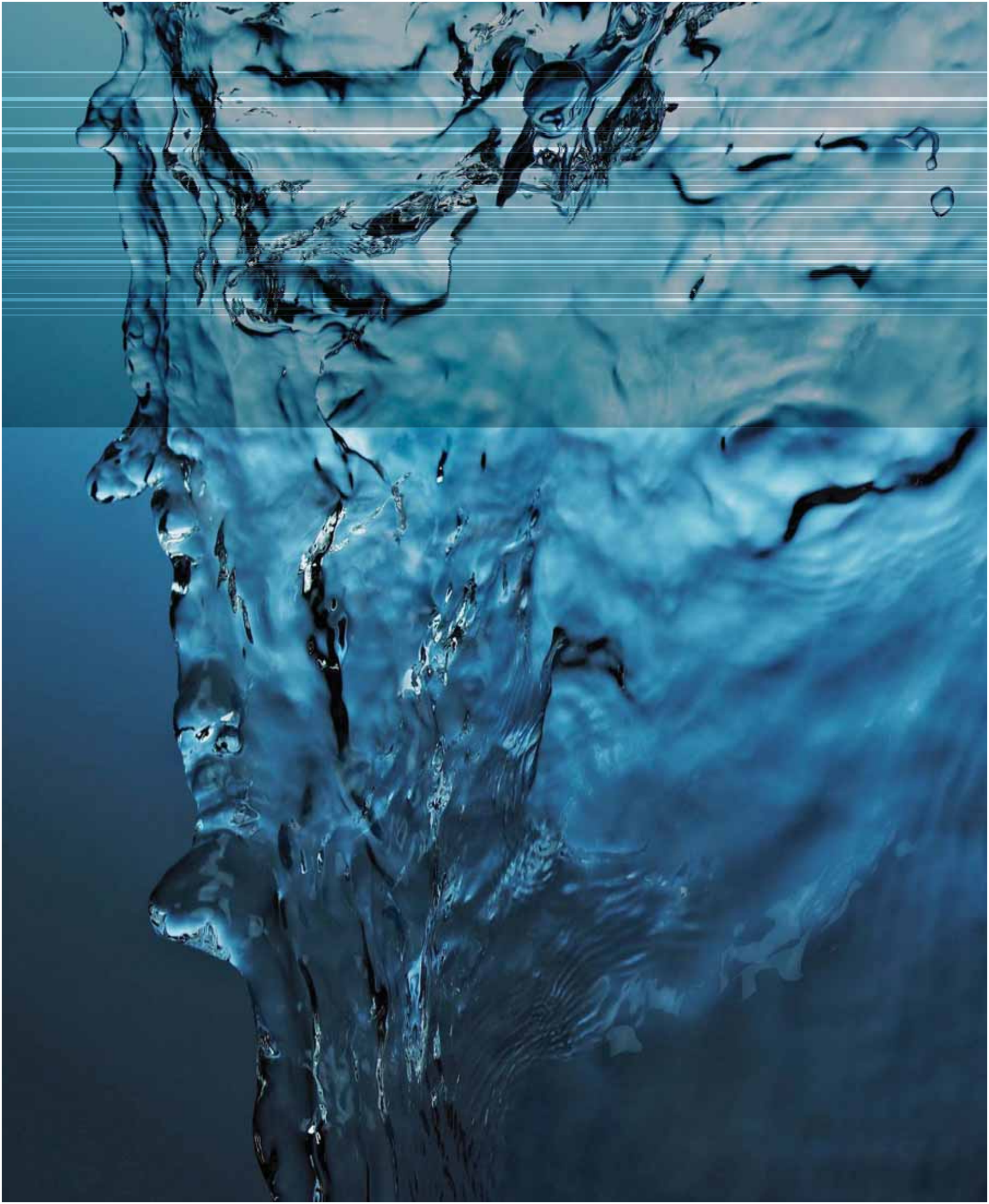
The pharmaceutical industry occupies one of the leading positions in the industrial sector ranking in terms of productivity. It is the clear leader in industrial R&D investment in Spain. It is a source of highly qualified employment and, due to its above-mentioned characteristics (high productivity and R&D intensity), has a large capacity to generate wealth and employment in other economic sectors, with an estimated ratio of four indirect jobs generated for each employee in pharmaceutical companies. Additionally, the pharmaceutical industry established in Spain is far from its potential capacity for development, as can be seen from a comparison with other countries in our geographical and cultural environment.

For this reason, and in response to a call by the Spanish Government to the pharmaceutical industry so that, in a moment of economic crisis such as the current one, it increases its investment efforts in research and contributes in this way to developing a new growth model, Farmaindustria, representing the whole pharmaceutical industry established in Spain, expressed, in March 2009, its commitment to Spanish society over the next three years in four fundamental vectors: i) maintaining employment and improving qualified job profiles; ii) increasing the internationalisation of pharmaceutical companies and the volume of exports; iii) substantially increasing pharmaceutical R&D investment; iv) developing public-private partnership projects to the value of 180 million euros.

With this decision, the pharmaceutical industry has taken a step forward and wishes to show its responsibility to Spanish society, by beginning the journey along the only route that can return our economy to a path of solid and sustainable growth in the long term. At Farmaindustria we are ready to contribute our efforts and added value to encourage a greater involvement of the innovative and hi-tech sectors in the Spanish economy without forgetting our obligations in guaranteeing a public health service that is of high quality and sustainable financially.

The pharmaceutical industry has taken a step forward and wishes to show its responsibility to Spanish society





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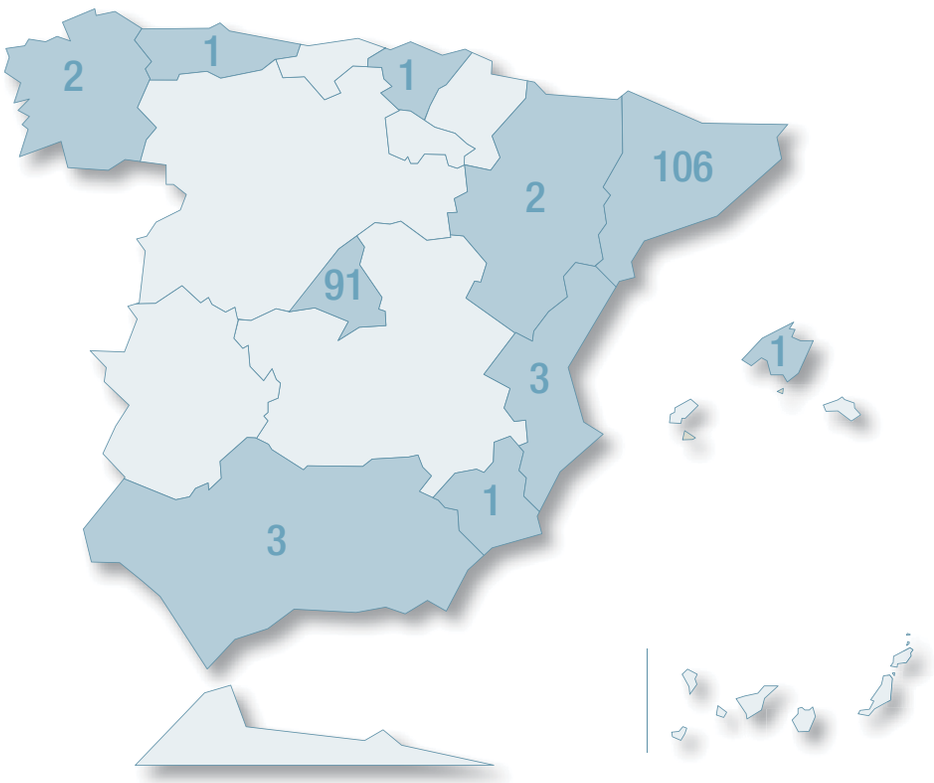
FARMAINDUSTRIA IN 2008

01.

1. MEMBERS

At 31 December 2008, 211 laboratories were associated to FARMAINDUSTRIA. Geographically, they were distributed in the following way:



The laboratories associated to FARMAINDUSTRIA represent, by number, 48% of all holders of authorisations for marketing medicines, having, or not, production and/or marketing activity. In sales terms, they represent 86% of the market.

Laboratories associated to FARMAINDUSTRIA represent 86% of the market

LABORATORIES BY GROUP		
	National	International
Large	10	30
Medium	7	23
Small	81	60
TOTAL: 211	**98**	**113**

01.

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 will collectively.

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, six Vice-Presidents and nine Directors appointed by the Steering Committee from among its own members.

In October 2008, elections were held to renew the Governing Bodies of the Association. In complying with the statutory provision establishing the rotation of the Presidency every two years, Mr Jesús Acebillo Marín was appointed President, representing the International Group, taking over from Mr Antoni Esteve i Cruella, who was President until that date, representing the National Group.

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

The Governing Bodies of the Association were re-elected in October 2008

EXECUTIVE BOARD

PRESIDENT

D. Jesús Acebillo Marín / NOVARTIS FARMACÉUTICA, S.A

VICE-PRESIDENTS

D. Antoni Esteve i Cruella / ESTEVE	**D. Manuel García Garrido** / BOEHRINGER INGELHEIM, S.A.
D. Ángel Fernández García / SCHERING-PLOUGH, S.A	**Dª. Belén Garijo López** / SANOFI-AVENTIS, S.A.
D. Jorge Gallardo Ballart / LABORATORIOS ALMIRALL, S.	**D. Rafael Juste Sesé** / JUSTE, S.A. QCO. FCA

DIRECTORS

D. Luc Dirckx / ROCHE FARMA, S.A	**D. Carlos M. Maicas Hernández** / SOLVAY PHARMA, S.A.
D. Javier Ellena Aramburu / DISTA, S.A	**D. Emilio Moraleda Martínez** / PFIZER, S.A
D. Paul Hudson / ASTRAZENECA FCA. SPAIN, S.A	**D. Juan Puig Corcoy** / LABORATORIOS MENARINI, S.A
D. Claudio Lepori / ANGELINI FARMACÉUTICA, S.A	**D. Jorge Ramentol Massana** / FERRER FARMA, S.A.
D. Juan López-Belmonte López / LABORATORIOS FCOS. ROVI, S.A	

STEERING COMMITTEE

PRESIDENT

D. Jesús Acebillo Marín / NOVARTIS FARMACÉUTICA, S.A.

VICE-PRESIDENTS

LABORATORIOS ALMIRALL, S.A. / **D. Jorge Gallardo Ballart**	JUSTE, S.A. QCO. FCA. / **D. Rafael Juste Sesé**
BOEHRINGER INGELHEIM, S.A / **D. Manuel García Garrido**	SANOFI-AVENTIS, S.A. / **Dª. Belén Garijo López**
ESTEVE / **D. Antoni Esteve i Cruella**	SCHERING-PLOUGH, S.A / **D. Ángel Fernández García**

DIRECTORS

AMGEN, S.A. / **D. Jordi Martí Pi Figueras**	ANGELINI FARMACÉUTICA, S.A. / **D. Claudio Lepori**
ASTRAZENECA FCA. SPAIN, S.A. / **D. Paul Hudson**	QCA. FCA. BAYER, S.L. / **D. Theo van der Loo**
DISTA, S.A. / **D. Javier Ellena Aramburu**	LABORATORIOS ERN, S.A. / **D. David Solanes López**
FAES FARMA , S.A. / **D. Francisco Quintanilla ***	FARDI, Lbo. de Aplic. Farmacodinámicas, S.A. / **D. Javier Font Salgado**
FERRER FARMA, S.A. / **D. Jorge Ramentol Massana**	GILEAD SCIENCES, S.L. / **D. Roberto J. Urbez Plasencia**
J. URIACH & CÍA., S.A. **D. Enrique Trías Vidal de Llobatera**	JANSSEN CILAG, S.A. / **D. Martín Sellés Fort**
LABORATORIOS MENARINI, S.A. / **D. Juan Puig Corcoy**	LABORATORIOS NORMON, S.A. / **D. Jesús Govantes Esteso**
NOVARTIS CONSUMER HEALTH, S.A. / **D. Francisco Ballester**	NOVO NORDISK PHARMA, S.A. / **D. Luis Silva Castillo**
PFIZER, S.A. / **D. Emilio Moraleda Martínez**	ROCHE FARMA, S.A. / **D. Luc Dirckx**
LABORATORIOS FCOS. ROVI, S.A. / **D. Juan López-Belmonte López**	LABORATORIOS SERVIER, S.L. / **D. Pierre Faraldo**
SOLVAY PHARMA, S.A. / **D. Carlos M. Maicas Hernández**	LABORATORIOS UPSA, S.A. / **D. Frank C. Pasqualone**
LABORATORIOS VIÑAS, S.A. / **D. Antonio Buxadé Viñas**	WYETH FARMA, S.A. / **Dª. Elvira Sanz Urgoiti**

* New representative as of the Steering Committee meeting of 21/04/08, replacing Mr Eduardo Fernández de Valderrama.

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 organigram is as follows:

GENERAL DIRECTOR
Humberto Arnés

DEPUTY GENERAL DIRECTOR
José María Hernández

GENERAL SECRETARIAT
Lourdes Fraguas

COORDINATION, STUDIES & MEMBER SERVICES
Javier Urzay

FINANCE DEPARTMENT
José María Hernández

LEGAL & HUMAN RESOURCES DEPARTMENT
Lourdes Fraguas

TECHNICAL DEPARTMENT
Emili Esteve

INTERNATIONAL DEPARTMENT
Icíar Sanz de Madrid

COMMUNICATIONS DEPARTMENT
Julián Zabala

RELATIONS WITH AUTONOMOUS REGIONS DEPARTMENT
José Ramón Luis-Yagüe

STUDIES DEPARTMENT
Pedro Luis Sánchez

MEMBER SERVICES
Javier Urzay

01. 3. AREAS OF ACTIVITY

3.1. Market regulation and Government relations

The pharmaceutical industry finds itself subject to strict public regulation, both on questions of a technical kind and on economic matters. Given the decentralised nature of the Spanish National Health System, both Central Government and the Autonomous Regions have regulatory competences over the pharmaceutical industry in Spain, dual responsibilities which have on occasions been the source of conflict between central and regional government.

The pharmaceutical industry has expressed its commitment to Spanish society in the areas of employment, R&D, competitiveness and internationalisation

During the past 12 months, the Reference Price System was consolidated as the mechanism for economic regulation of the pharmaceutical industry in Spain. Indeed, over the past two years, the RPS has succeeded in significantly moderating the rate of growth of public pharmaceutical spending in our country. Economic regulation of the industry, based upon the application of the RPS, brings with it a significant level of uncertainty for companies, which has had positive repercussions both on pharmaceutical R&D investment in our country and the international credibility of our regulatory framework.

The most important event to occur in recent months concerning the relationship between the pharmaceutical industry and central and regional governments was the help offered by the companies, through their organisation FARMAINDUSTRIA, to the Spanish Government and society as a whole, in the current economic climate, to: i) maintain overall employment levels in the pharmaceutical industry for the next three years, improvement on qualifications and its quality; ii) increase substantially R&D investment in Spain, to an average annual cumulative rate of 15% between 2009 and 2011, with the aim of surpassing, by the end of the period, 20% of all the R&D carried out by Spanish industry as a whole, and; iii) improve corporate internationalisation activities, which form the base of the pharmaceutical industry in Spain, working to increase pharmaceutical company exports to reach 22.5 billion Euros over the three-year period (2009-2011) and increasing the contribution of the pharmaceutical industry to Spain's balance of payments situation to around 6%.

This commitment was greatly welcomed by the social institutions in Spain and had the explicit support of the Spanish Government, both from the then Health Minister, Bernat Soria, and the First Vice-President of the Government, María Teresa Fernández de la Vega.

During the 12-month period ending with the publication of this Report, there were important new developments in the institutional framework which affect the pharmaceutical industry in our country. The Ministry of Science and Innovation has been established as a ministerial department for contact with the pharmaceutical industry in the field of research and development of new medicines and medical products, having assumed the competences in this area and incorporating in its departmental structure what are key organisations for the pharmaceutical companies, traditionally firmly connected to the Health Ministry (such as the Carlos III Health Institute) or the Industry Ministry (such as the Centre for Industrial Technological Development, CDTI).

A reshuffle at the top of the Health Ministry took place recently, with Bernat Soria being replaced by Trinidad Jiménez, the new Minister for Health and Social Policy. It should be mentioned that, in her first official intervention before the Senate, the new Minister for Health expressed her full support for and satisfaction with the commitment made by FARMAINDUSTRIA and which was endorsed at the time by the then holder of this ministerial portfolio, Bernat Soria.

Finally, inside the Association, the statutory re-election of the Governing Bodies of FARMAINDUSTRIA took place in october 2008, and Jesús Acebillo Marín was elected as President of the Association for the period, 2008-2010, representing the International Group of companies and replacing Antoni Esteve i Cruella, who had held the Presidency during the two-year period, 2006-2008, representing the National Group.

3.1.1. LEGAL FRAMEWORK

Following the large number of provisions resulting from the development of Law 29/2006, of 26 of July, on Guarantees and Rational Use of Medicinal Products and Medical Devices, approved during 2007, the procedure for drafting regulations was established in 2008, illustrating the importance of the provisions and drafts for the sector, as described below.

Legal procedures affecting the sector were established in 2008, following the high number of provisions established in 2007

Ministerial Order determining new groups of medicines and medical products, their reference prices and reviewing previously fixed reference prices [1]. The Ministerial Order in force effectively began to be applied in March 2009 and brought about the creation of 13 new groups, the review of reference prices of the groups already existing and the updating of the list of lower prices.

According to data from the Ministry of Health and Consumer Affairs, the present Order will mean savings of 344 million euros, equivalent to 2.9% of the public pharmaceutical expenditure in pharmacies registered at the end of 2008. From the business perspective, the impact of the new Order on pharmaceutical company revenues is around 300 million euros in the first year it is applied.

Royal Decree on Margins[2]. This Royal Decree confirms the right of laboratories carrying out direct distribution to receive the corresponding margin. The Special Additional Provision attaches this margin to the accreditation of compliance with the requirements established in Article 70 of the 29/2006 Act, although it is considered that, from the moment direct distribution and all the obligations that go with it are assumed, no barrier to receiving the said margin should exist. Whatever the case, it will be necessary to pay attention to the practical execution of the Royal Decree.

Draft Royal Decree by which the availability of medicines and medical products in special situations is regulated. This draft unifies the various supposed uses of medicines and medical products for different conditions to those for which they were registered and originally marketed. It especially regulates the conditions of use of medicines and medical products still being researched, the use of medicines and medical products authorised for indications that have not been stated in the technical description and the import of medicines and medical products that are not authorised for use in Spain.

In the document of arguments put forward by FARMAINDUSTRIA, the Association insists that medicines and medical products used in different conditions to those authorised in Spain must have (as and according to stipulations of the law) be of an exceptional nature, since to a certain degree it means a transgression of the conditions of authorisation guaranteed in the registration application file, appropriately evaluated by the Medicines Evaluation Agency.

As this Report closed for publication, this legislative draft was still being debated.

Draft Order on homeopathic medicines. In the framework of the regularising process for homeopathic medicines, at a hearing it was informed that an order had been drafted to determine the minimum criteria and procedure for the communication of the intention to adapt homeopathic medicines marketed under the protection of the 2nd Transitory Provision of Royal Decree 2208/1994. FARMAINDUSTRIA's arguments were oriented to simplifying the documentation and requirements, and considering the adjustment of the special taxes for these medicines. As has been seen in different areas, this dynamic prospers where there is a lack of fully efficient instruments to carry out the coordination function which corresponds to the Interterritorial Council and its Pharmacy Committee in a fully decentralised National Health System.

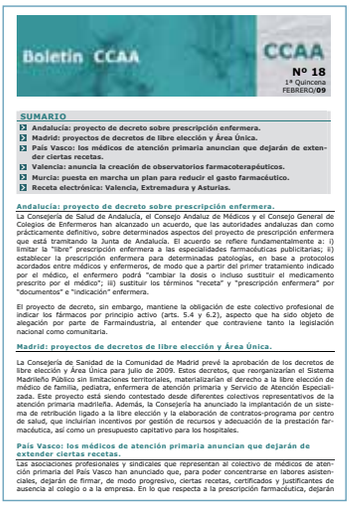
3.1.2. THE AUTONOMOUS REGIONS

The autonomous regions, in exercising their competences in the area of public health, planning and management of health care, increasingly carry out legislative activity, including organising pharmaceutical services, which on occasions can cause risks of market fragmentation through the introduction of specific and different requirements in each region.

In this context, it is increasingly necessary to promote initiatives which further the provision of information on the situation and evolution of the most important aspects for the sector in the area of health and pharmaceutical policy at the regional level, at the same time as strengthening efficient channels for dialogue and cooperation with regional authorities.

1 Order SCO/3803/2008, of 23 December, determining new groups of medicines and medical products, their reference prices and reviewing reference prices determined by Order SCO/3997/2006, of 28 December, and Order SCO/3867/2007, of 27 December (BOE 315, of 31 December 2008, later amended in BOE 26, of 30 January 2009).
2 Royal Decree 823/2008, of 16 May, by which the corresponding margins, reductions and discounts are established for the distribution and dispensing of medicines and medical products for human use (BOE 131, of 30 May 2008).

With this aim, FARMAINDUSTRIA has launched an internal *Autonomous Regions Information Bulletin (Boletín Informativo de Comunidades Autónomas)*, a fortnightly publication bringing together the news of greatest interest for the pharmaceutical industry which, in each period, could have emerged at the regional level. Preparation of the annual regional reports has also continued, as well as thematic reports on questions of interest, such as INN (International Non-proprietary Names) prescribing, electronic prescriptions, agreements with the pharmacists' colleges, regional health budgets, etc., and they are accessible for members through the FARMAINDUSTRIA website.


Boletín CCAA

CCAA

Nº 18
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FEBRERO/09

SUMARIO

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- Madrid: proyectos de decretos de libre elección y Área Única.
- País Vasco: los médicos de atención primaria anuncian que dejarán de extender ciertas recetas.
- Valencia: anuncia la creación de observatorios farmacoterapéuticos.
- Murcia: puesta en marcha un plan para reducir el gasto farmacéutico.
- Receta electrónica: Valencia, Extremadura y Asturias.

Andalucía: proyecto de decreto sobre prescripción enfermera.

La Consejería de Salud de Andalucía, el Consejo Andaluz de Médicos y el Consejo General de Colegios de Enfermeros han alcanzado un acuerdo, que las autoridades andaluzas dan como prácticamente definitivo, sobre determinados aspectos del proyecto de prescripción enfermera que está tramitando la Junta de Andalucía. El acuerdo se refiere fundamentalmente a: i) limitar la "libre" prescripción enfermera a las especialidades farmacéuticas publicitarias; ii) establecer la prescripción enfermera para determinadas patologías, en base a protocolos acordados entre médicos y enfermeros, de modo que a partir del primer tratamiento indicado por el médico, el enfermero podrá "cambiar la dosis o incluso sustituir el medicamento prescrito por el médico"; iii) sustituir los términos "receta" y "prescripción enfermera" por "documentos" e "indicación" enfermera.

El proyecto de decreto, sin embargo, mantiene la obligación de este colectivo profesional de indicar los fármacos por principio activo (arts. 5.4 y 6.2), aspecto que ha sido objeto de alegación por parte de Farmaindustria, al entender que contraviene tanto la legislación nacional como comunitaria.

Madrid: proyectos de decretos de libre elección y Área Única.

La Consejería de Sanidad de la Comunidad de Madrid prevé la aprobación de los decretos de libre elección y Área Única para julio de 2009. Estos decretos, que reorganizarían el Sistema Madrileño Público sin limitaciones territoriales, materializarían el derecho a la libre elección de médico de familia, pediatra, enfermera de atención primaria y Servicio de Atención Especializada. Este proyecto está siendo contestado desde diferentes colectivos representativos de la atención primaria madrileña. Además, la Consejería ha anunciado la implantación de un sistema de retribución ligado a la libre elección y la elaboración de contratos-programa por centro de salud, que incluirían incentivos por gestión de recursos y adecuación de la prestación farmacéutica, así como un presupuesto capitativo para los hospitales.

País Vasco: los médicos de atención primaria anuncian que dejarán de extender ciertas recetas.

Las asociaciones profesionales y sindicales que representan al colectivo de médicos de atención primaria del País Vasco han anunciado que, para poder concentrarse en labores asistenciales, dejarán de firmar, de modo progresivo, ciertas recetas, certificados y justificantes de ausencia al colegio o a la empresa. En lo que respecta a la prescripción farmacéutica, dejarán

Elsewhere, institutional contacts have intensified with top health and pharmacy officials in the various Autonomous Regions and the priorities of the sector have been communicated, as have one-off situations specifically affecting each Autonomous Region been addressed, in such exchanges. Equally, a continuity has been established to meetings with regional health representatives, where the themes that most pressing and important to the industry have been addressed. Thus, over the past year, FARMAINDUSTRIA has organised three forums, in which regional health officials have taken part alongside central government Health Ministry representatives:

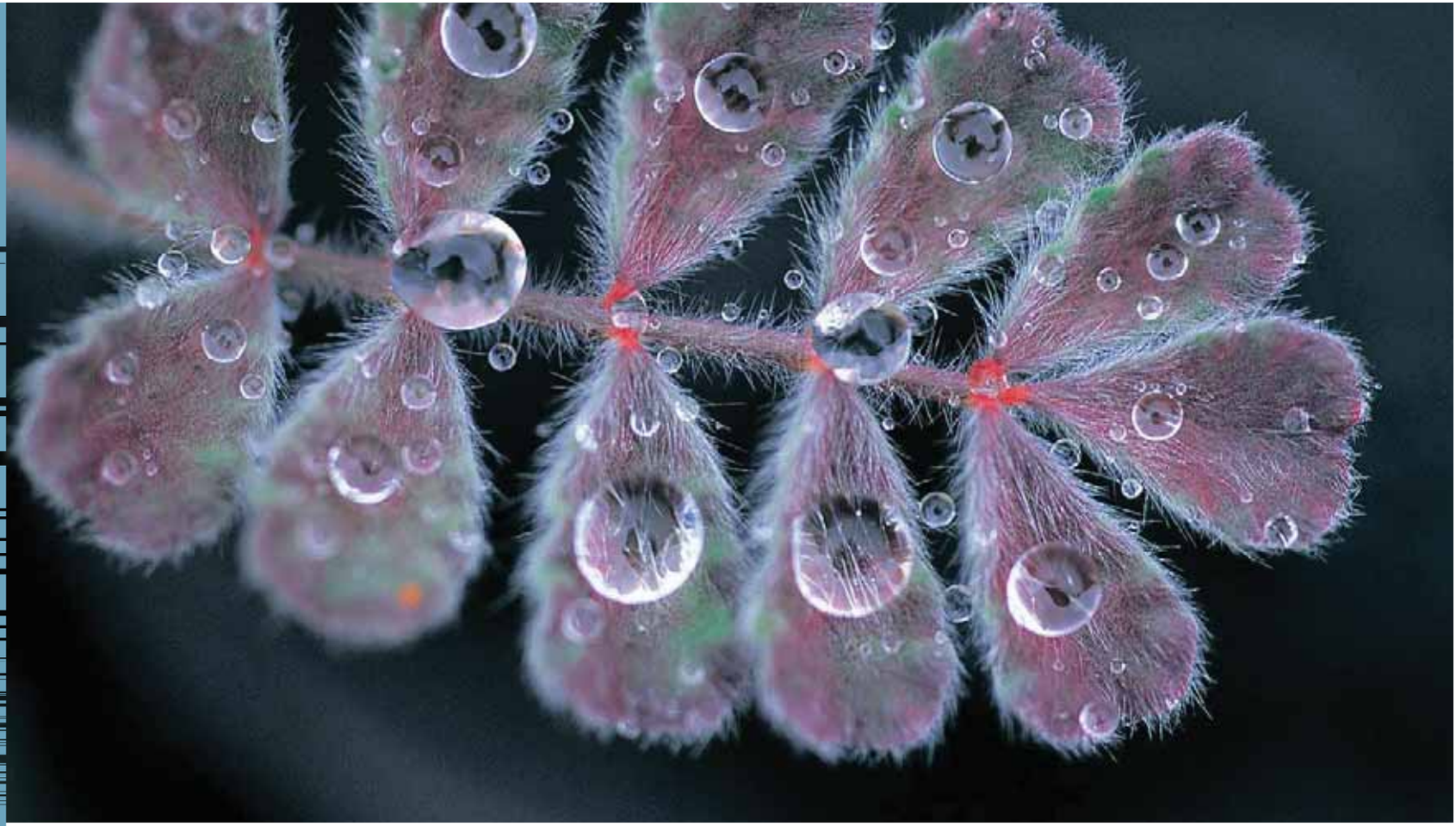
- The IX FARMAINDUSTRIA-Autonomous Regions Forum, held in Seville and inaugurated by the Andalucian Government Health Ministry, on electronic prescriptions;
- The X Forum, focusing on research, held in the Canary Islands and similarly inaugurated by the Health Ministry of this Autonomous Region;
- The XI Forum, focusing on counterfeit medicines, held in Baleares in the presence of the Balearic Health Ministry.

At the same time, also in the Canary Islands and in cooperation with its Pharmacy and Medical Products Directorate-General, and with the pharmacists' colleges and distributors, a conference was held on the supply of medicines and medical products in an island economy, which was awarded Best Initiative in 2008 by the *Correo Farmacéutico* publication.

Contacts with professional organisations and scientific societies have also been improved, especially in primary care (SEMFYC, SEMERGEN and SEMG), the pharmaceutical area (SEFH and SEFAP), for the management of health centres and services (SEDISA, SEDAP), health care law, health care information technology, as well as with associations in specialist areas such as oncology and geriatrics, with whom fluid communication channels have been established, enabling the analysis of different themes of mutual interest. FARMAINDUSTRIA has also had a prominent involvement in different congresses organized by the scientific associations.

There now follows a summary of the most important policies and regulations, and activities undertaken by FARMAINDUSTRIA with respect to them.

Electronic prescriptions and clinical records. During 2008, the implementation of the electronic prescription and clinical records in the Autonomous Regions has moved forward, albeit at different rhythms. The Andalucian, Catalan and Galician Autonomous Regions now have their own legislation governing electronic prescriptions and, at the time of preparing this Report, Extremadura was debating its law. The electronic prescription proves an element that strengthens the cohesion of the public health system and equal access to medicines and medical products, but it could also prove to be an instrument which puts the unity of the national pharmaceutical market at risk and which conditions medical prescriptions and the dispensing of the prescribed product. This is why FARMAINDUSTRIA has pronounced upon these questions, as well as the need to ensure the interoperability of the different models of electronic prescription, in the framework of the preparation of the legal regulations.



INN (International Non-proprietary Names) prescribing. The trend observed in previous years has continued, whereby different models of INN prescribing co-exist, although it appears that the activity has consolidated around active ingredients which have a generic. The Andalucian Health Service is considering and encouraging this practice without limits, while in other health services, such as those of Castilla & León, Extremadura, the Canary Islands and Murcia, they approximate INN prescribing to the medicines and medical products with a generic, excluding medicines and medicinal products with narrow therapeutic ranges and attempting to avoid confusion by continuous changes in medication. At the same time, some Autonomous Regions, such as the Basque Country and Madrid, encourage not so much INN prescribing but prescription of generic medicines.

FARMAINDUSTRIA has continued to demonstrate the weakness of INN prescribing and the risks it carries for specific groups of patients at various forums. These risks include confusion, weakened adherence to treatment and worsening doctor-patient relationships, at the same time as the imposition of this system could restrict a doctor's freedom to prescribe. Neither can it be upheld that INN prescribing is a practice that favours the rational use of medicines, as afforded by the World Health Organisation definition, and it limits the efficiency of pharmacovigilance. FARMAINDUSTRIA has also highlighted that, from the point of view of an independent international organisation such as the International Society of Drug Bulletins, INN prescribing has significant limitations.

FARMAINDUSTRIA organised three forums in which regional health officials took part alongside the Ministry of Health

Finally, the economic attractiveness of INN prescribing for regional health administrations has lost some credibility, especially with the new, consolidated Reference Price System, which reduces to a minimum the differences in prices between medicines and medical products sharing the same active ingredient and method of administration.

Centralised purchasing of medicines. The trend has continued for different Autonomous Regions to launch projects aimed at the centralised purchasing of medicines for its hospitals and hospital services, through purchasing centres.

In this area, FARMAINDUSTRIA has held working meetings with the Andalusian Health Service (SAS) in which the so-called Integrated System of Logistical Management (SIGLO) has been analysed. Although this project does

not include, initially, procedures aimed at centralising purchases for SAS hospitals, its launch will have a certain effect upon the acquisition of medicines and medical products for hospital use.

In the same sense, the Association has maintained contacts with officials in the Madrid Health Service, with the aim of transmitting the sector's thoughts on such initiatives.

Finally, in the first few months of 2009, it held a working meeting with officials from the Catalan Health Institute (ICS) in which FARMAINDUSTRIA was informed about plans to build a purchasing centre which, through an open tendering process, will acquire all the medicines and medical products for its hospitals. FARMAINDUSTRIA is studying this model with a view to transmitting its related observations to ICS, while at the same time making clear its availability to cooperate in the preparation of the specifications of conditions of the calls for tender that could be launched.

Act 1/2008, of 17 April, by the Valencian Government, on guaranteeing the supply of medicines and medical products. FARMAINDUSTRIA presented a series of modifications to this draft, most of which were incorporated, and has monitored its parliamentary passage very closely with the aim of channeling a technical improvement that will allow interested laboratories to contribute the necessary information on medicines that could be affected by short supply situations. This proposal was finally accepted in the text of the Act. Once the law was approved, FARMAINDUSTRIA continued to hold different working meetings with top officials at the Health Ministry, with the aim of communicating its position and the will of the sector to cooperate in developing the legislation.

Bill arranging pharmaceutical care in the Basque Country. This draft, which has seen FARMAINDUSTRIA present the relevant arguments, is suspended due to the dissolution of the Basque Parliament before the elections held on 1 March 2009.

Act 22/2007, of 18 December, on Andalucian pharmacies. The Andalucian Parliament approved the text of the Pharmaceutical Planning Law on 4 and 5 December 2008. It was published in the official bulletin of the Andalucian Government on 28 December. FARMAINDUSTRIA presented relevant arguments concerning the Act and various Articles of the Act are subject to appeal before the Constitutional Court, brought by the Partido Popular political party.

Valencian Region Bill to create a College of Visiting Doctors. Through a Decision, of 9 September 2008, the Director General of Justice and Minors in the Valencian Region, began the public information process for the Bill on the request to form a College of Visiting Doctors. FARMAINDUSTRIA presented its arguments, in which it declares its support for the professional development and recognition of the work of these professionals while highlighting the pecularities of the sector and the working connection of the visiting doctors with laboratories.

Decision of the Andalucian Health Service (SAS) on the harmonisation of criteria for using medicines and medical products in SAS centres. In relation to Decision SC 0089/08, of 21 February 2008, by the SAS General Secretariat, relative to the harmonisation of criteria for using medicines and medical products in SAS centres, and considering that its application could constitute an important barrier to the introduction of innovative medicines and medical products in hospitals, as well as signifying a possible invasion of Central Government competences, FARMAINDUSTRIA applied for the suspension of the Decision by the health care authorities and presented the relevant administrative appeal. At the time of writing, this Decision was still to enter into force.

3.1.3. TECHNICAL COMMITTEES

The institutional contribution of FARMAINDUSTRIA in various technical committees created by the competent authorities is of great importance in transmitting the points of view of the pharmaceutical industry, maintaining in addition the necessary communication with various Government officials.

Consultative Committee of the National Health System Interterritorial Council. The Consultative Committee of the CISNS is made up of representatives of the various governments (local, regional and central), trade union representatives and those from employers' organisations, among them FARMAINDUSTRIA. This Committee informs on the main themes in the health care field under the responsibility of the Ministry of Health and Consumer Affairs. The main items have been, naturally, the legislation developed from Act 29/2006 and questions related to the analysis of the evolution of pharmaceutical spending. In this sense, the parties concerned are becoming increasingly aware of the importance of the pharmaceutical industry and the role it plays in a modern, healthy society.

Evaluation Committee for Medicines for Human Use (CODEM). CODEM is the collegiate body of the Spanish Medicines Agency (AEMPS) for the technical and scientific assessment of all to do with the authorisation of new proprietary medicinal products. The composition of the Committee members was determined by Order SCO/932/2005, of 14 March. It has to re-appoint its members in 2009. CODEM is composed of members appointed for the nature of their work and members appointed for their knowledge in the area of evaluating medicines and medical products. Although the appointments are made by the Ministry of Health and Consumer Affairs, four of the members of the Committee are proposed by organisations more representative of patients, doctors, pharmacists and industry. The director corresponding to the pharmaceutical industry is designated by FARMAINDUSTRIA.

Sub-groups inform the Committee and are entrusted with preparing specific opinions on generic medicines or medicines and medical products which do not require prescriptions.

3.2. Social communications

The activities carried out by FARMAINDUSTRIA in the area of communications in 2008 were defined by the Communications and Partnership Plan approved by the Association's Governing Bodies for the two-year period, 2007-2008.

The progressive work carried out in communications in the past few years has allowed the improvement of the Association's presence and the influence of industry in communications media, as well as access to decision-making and opinion environments. The Association's relations with society have improved as well and the visibility and positioning of both the sector and FARMAINDUSTRIA in strategic areas has increased.

In this sense, the axes around which communications have revolved in 2008 were, on the one hand, the social commitment, communications media and the environments of influence (patients, doctors, etc.) and, on the other, the differentiating elements of the sector: innovation, contribution to medicinal progress, without forgetting the strategic thematic priorities of FARMAINDUSTRIA.

For this, together with the already established traditional activities, a series of initiatives have been launched with the aim of exploring new communication formulas and how to get closer to society. Development tools for monitoring have also been pursued, which allow the evolution of the image of the sector to be followed, actions to be prioritised and resources optimised.

The presence of the pharmaceutical industry in the communications media increased and improved in 2008

3.2.1. COMMUNICATIONS MEDIA

In 2008, FARMAINDUSTRIA continued working intensively to improve the access, presence and influence of the Association in the communications media so as to transmit the strategic values and messages of the pharmaceutical industry established in Spain.

Working with the media, both from the information and the business and institutional point of view, permits the support and strengthening of the Association's strategic approaches, contributing to improving the ima-

ge of the pharmaceutical industry in society, advancing its credibility in the media, generating currents of influence in various decision-making environments and increasing the value of the exclusive characteristics of the sector, such as the social contribution of medicines, leadership of the pharmaceutical companies in the area of R&D and its economic and industrial value.

For this, FARMAINDUSTRIA has consolidated its relationships with the main editorial groups, maintaining a direct contact with people who contribute to form public opinion (panelists, columnists, media directors, television and radio news and information directors, etc.), working in training programmes aimed at information professionals and, briefly, keeping open stable channels of communications with the leading figures in various fields across the information spectrum.

Information activity. Generally the information activity of FARMAINDUSTRIA in 2008 was maintained at the intensity of previous years, although, differently from that which has occurred at other moments, it did not revolve around one, potentially strategic, specific theme for the Association.

A total of 16 press releases were diffused and 14 opinion columns by different FARMAINDUSTRIA representatives published in the general and specialized press. Over 20 interviews were given to all types of communications media (daily newspapers, magazines, radio, the online press and television). The pharmaceutical sector's leadership in the area of R&D, the growing problematic represented by counterfeit medicines in industrialised countries, pharmaceutical innovation as an element of competitiveness, the development of a sectoral plan and the lack of harmonisation in Spain with respect to Europe in the area of industrial property were the questions that generated most informational activity.

It is worthwhile emphasising the important information repercussions that the *Status Report: The Pharmaceutical Market in Spain (Boletín de Coyuntura del Mercado del Medicamento)* has. This is prepared every month by FARMAINDUSTRIA and as well as being widely distributed by the economic daily, *Expansión*, every month, also has a significant impact in several titles in the national and regional press.

As in recent previous years, the information activity of FARMAINDUSTRIA has been strengthened by the institutional publicity of the Association, which, during 2008, maintained advertising creativity in defending the pharmaceutical brand and recognising the value of medicines and medical products, and in research being carried out by the pharmaceutical industry.

R&D, counterfeit medicines and innovation as a competitive instrument were among the themes which had the most informational activity in 2008

Getting closer to opinion leaders and meeting regional media. During 2008, FARMAINDUSTRIA carried out meetings with more than 20 panelists, columnists, media directors and directors of news and information for television and radio stations in order to get across directly the main messages of the innovative pharmaceutical industry in Spain.

At the same time, FARMAINDUSTRIA started a series of meetings with media in the Autonomous Regions in 2008, with the aim of helping them get closer to the reality of the innovating pharmaceutical sector in Spain.

In the regions, the Association met with the *Heraldo de Aragón* newspaper, the *Periódico de Aragón*, Aragón Television, Aragón Radio and Aragón Press, as well as the offices of the news agencies Europa Press and Efe in each Autonomous Region in 2008. Other encounters took place with: *Las Provincias, Levante, Información, Valencia Hui, Canal Nou, El Periódico Mediterráneo*, and in the Valencian Community offices of *El País, El Mundo, Grupo Zeta* and the Efe Agency; *Diario de Sevilla, Diario de Cádiz, La Opinión de Granada, El Ideal de Granada,* Canal Sur Radio & TV, and the Andalucian offices of Efe, Europa Press and *El País*; *El Día de Tenerife, La Opinión de Tenerife,* TV Canaria and the Canary Islands offices of the Efe agency.

Training for information professionals. FARMAINDUSTRIA continues to work to establish itself as the information reference and active communications agent, encouraging sources and communications media to work together to define the reality in a more precise way and see it reflected in various communication supports. In this way, FARMAINDUSTRIA has continued to develop training programmes for journalists. Thus, in November 2008, Barcelona played host to the 6th Pharmaceutical Industry and Communications Media Seminar, jointly held with ANIS, the National Association of Health Communicators; APIE, the Association of Economic Information Journalists; and FAPE, the Federation of Spanish Press Associations. Some 40 journalists from communications media from all over Spain took part in the seminar.

The 4th National Health Journalism Congress, held in Zaragoza in October, attracted more than 200 communications professionals.

The Code of Good Practices on Relationships between the Pharmaceutical Industry and Patient Organisations was published in 2008

Press website. The FARMAINDUSTRIA press website (http://prensa.farmaindustria.es) continued to be an efficient communications instrument, facilitating the flexibility of information needed in many moments. In the last year prior to its renovation, the FARMAINDUSTRIA press website confirmed itself as an indispensable tool for a modern and efficient communications being increasingly used by members and communications media professionals. In May 2008, a record for access since the creation of the website was reached. Over 400 daily visits were recorded and the number of visits for the whole month rose to 12,300, and around 250,000 for the whole of 2008.

3.2.2. RELATIONS WITH PATIENTS' ORGANISATIONS

Taking into account that the FARMAINDUSTRIA Communications Plan for the two-year period, 2007-2008, not only concerned communications activities, but its scope also took in those of partnerships, the Association continued in 2008 to seek intensively ways of getting closer to different stakeholders, among whom no one is more important than the patients.

As in previous years, FARMAINDUSTRIA's relationship with this important community basically focuses upon two main activities: the magazine *Patients* (*Pacientes*), and the call by the FARMAINDUSTRIA FOUNDATION for candidates for the annual Awards for the Best Initiatives for Patients' Services. Both these activities seek to share actions, intensify the bi-directionality of information between both parties and, briefly, to advance in the mutual support and understanding between prominent players in the health care systems.

2008 was also the year that the *Code of Good Practices on Relationships between the Pharmaceutical Industry and Patient Organisations* was published, resulting in the transposition of the new EFPIA Code in this area. Its area of activity takes on all forms of relationships between pharmaceutical companies and patients' organisations, starting from the standpoint that the parties have common interests and to ensure that the relations between both are undertaken in an ethical and transparent way.

***Patients* magazine.** Four new issues of the magazine *Patients* were produced in 2008: nos. 9, 10, 11 and 12, in which varied questions were analysed, from the new Biomedicine Act to the influence of televised series with health care themes on society and the serious health care problems represented by counterfeit medicines.

Awards for the Best Initiatives for Patients' Services. The ceremony to present the *2008 Awards for the Best Initiatives for Patients' Services* took place on 16 December under the auspices of the FARMAINDUSTRIA FOUNDATION. The 4th year of these awards introduced a new category, "Society and Patients", for which an award of 30,000 Euros was to be made to the NGO or foundation which had achieved the best social reaching in those actions destined to disadvantaged communities, humanitarian programmes and development cooperation.

For yet another year, a multidisciplinary jury was entrusted to select the winners from more than 220 candidacies presented.

A large audience once again turned out for the *2008 Awards for the Best Initiatives for Patients' Services* prize-giving ceremony at the Royal Tapestry Factory in Madrid, where patients' associations from all over Spain gathered, as well as central and regional health ministry and pharmaceutical industry representatives, and other health care players.

2008 AWARDS FOR THE BEST INITIATIVES FOR PATIENTS' SERVICES
A) PATIENTS' ASSOCIATIONS
Health education initiatives
Runner-up: Valencian Association for Families of Patients with Eating Disorders.
Runner-up: Spanish Confederation of Families of Patients with Alzheimer and Other Dementias.
Winner: FEAFES (Spanish Confederation of Associations of Families and People with Mental Illness), Castilla & León.
Presence in society
Runner-up: Spanish Patients' Forum.
Runner-up: Spanish Federation of Neuromuscular Diseases.
Winner: Spanish Federation for Rare Diseases.
Quality of service to associated patients
Runner-up: Multiple Sclerosis Foundation.
Runner-up: Association of Families of Patients with Alzheimer and Other Dementias, "Los Calatravos", Lower Aragón area.
Winner: Young Children's Oncology Association, Madrid Community.
Commitment to research
Runner-up: Association for People Affected by Neurofibromatosis.
Runner-up: Spanish Multiple Sclerosis Federation.
Winner: National Alzheimer Association.
B) SOCIETY AND PATIENTS
Winner: Pharmacists Without Borders.
C) HEALTH PROFESSIONALS AND PATIENTS
Scientific & professional societies
Recognition: Spanish Rheumatology Society.
Health care centres
Recognition: Paediatric Home Hospitalisation Unit.
D) COMMUNICATIONS MEDIA
Recognition: *La Razón* daily newspaper, for its supplement *A Tu Salud*.
E) INDIVIDUAL AWARD
Recognition: Dr. Pedro Alonso.

3.2.3. RELATIONS WITH OTHER INTEREST GROUPS

FARMAINDUSTRIA has considered it a priority over the past few years to create new strategic substrata in addition to those around which revolve the communications activities pursued to improve the social perception of the pharmaceutical industry. In this respect, actions have been carried out to get closer to new interest groups to which the Association previously did not have access. The scientific and research world, non-governmental organisations and personalities from different intellectual fields are among recent target groups formed.

***Medicine Research Networks* magazine (*Redes de Investigación en Medicamentos*).** This magazine has established itself as a reference and meeting point for the research community in Spain. In 2008, a Scientific Advisory Committee was created for this publication, made up of the people responsible for all the thematic networks analysed in each edition. As a consequence of each new edition, meetings with representatives and coordinators of the different thematic networks and opinion leaders in the biomedical scientific field have also been held.

Editions 10 and 11 of the *Medicine Research Networks* were published in 2008, in which the state and challenges of biomedical research in Spain were examined in depth, as well as the research being carried out at the Centre for Biomedical Research of the Respiratory Diseases Network (CIBERES).

Editions 10 and 11 of *Medicine Research Networks* were presented at a press conference at FARMAINDUSTRIA's Madrid headquarters.

Meeting of the Scientific Advisory Committee for the *Medicine Research Networks* magazine.

'Medicine Research Networks' magazine has established itself as a reference and meeting point for the Spanish research community

FARMAINDUSTRIA Social Board. The Social Board met on three occasions in 2008 with the aim of analyzing each time the latest developments in the pharmaceutical industry and contributing to a multidisciplinary vision of the positioning of the sector. The Board members are: Guillermo de la Dehesa (Chairman of the European Central Bank and Vice-Chairman of Goldman Sachs Europe), Federico Mayor Zaragoza (Chairman of the Foundation for a Culture of Peace), Joaquín Moya Angeler (Chairman of the Andalucian Technological Corporation), Joan Mulet (Director General of COTEC), Pedro

FARMAINDUSTRIA worked hard to get closer to NGOs in 2008

Nueno (Holder of the IESE Bertrán Foundation Chair of Entrepreneurship) and Joan Rodés (Ex-Chairman of the Health Advisory Board).

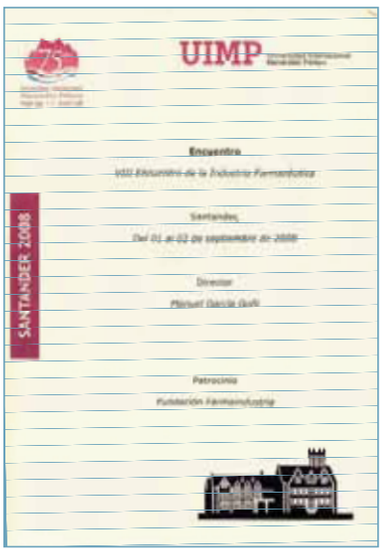
Activities with NGOs. FARMAINDUSTRIA worked hard to get closer to the NGO community in 2008 and took part in several seminar conferences, round tables and debates organised by these organisations. "The Other News", in the Ciclo de Cine Forum series, organised by the Economists Without Borders NGO at the Madrid Círculo de Bellas Artes, the "Health in the Millennium: A Signature Pending" campaign, and the "Essential For Life" Meeting organised by Farmamundi in Zaragoza, were among the forums in which FARMAINDUSTRIA was present to inform about the work being carried out in the pharmaceutical industry and the social value of the activities concerned.

FARMAINDUSTRIA took part in several forums, round tables and other activities organised by NGOs in different parts of Spain.

3.2.4. OTHER ACTIVITIES

3rd Survey on the perception of the pharmaceutical industry and medicines and medical products. A study of the image of the pharmaceutical industry and medicines and medical products in Spain was carried out in 2008, the third such survey carried out by the Gabinete Sociología y Comunicación for FARMAINDUSTRIA. The others were carried out in 2005 and 2002. The aim of these surveys is to dispose of a reliable and rigorous information system on the state of opinion of Spaniards towards the pharmaceutical industry, as well as on the image perceived for medicines and medical products and the pharmaceutical industry in general. From the study, it can be concluded that the image of the sector is evolving positively and in a homogenous way with respect to its different areas of activity, even if there are areas with room for improvement. The latest survey included a comparison with other sectors in terms of perception, as well as a section dedicated to analysing the level of knowledge of basic concepts of health care policy in the population.

Conferences and sponsorship. FARMAINDUSTRIA maintained an important public presence at events and forums in 2008, both organised by the Association itself and by member laboratories, and in response to invitations by other bodies, all of which were directed at transmitting FARMAINDUSTRIA's concepts and strategic thematic areas. Among them were: the 1st Conference on Innovation in the Health System, held in Málaga; the 2nd *Innovative Medicines Initiative Information Day,* held in March in Madrid; the 7th Pharmaceutical Industry Meeting, held in September at the Menéndez Pelayo International University in Santander, and; the participation of FARMAINDUSTRIA at BioSpain 2008, held in September in Granada.



FARMAINDUSTRIA played an active part at BioSpain 2008, held in Granada in September.

Internal Communications

Flash Communication. A total of 41 weekly bulletins were circulated on Monday afternoons to members in 2008. They informed about the main activities carried out by FARMAINDUSTRIA in the communications area.

FLASH COMUNICACIÓN SEMANAL Nº 122

farmaindustria

09 de junio de 2008

SUMARIO

- Encuentro con medios de comunicación regionales
- Análisis de presencia en medios
- SIGRE presenta sus resultados en la Comunidad de Madrid

Encuentro con medios de comunicación regionales

El pasado jueves, 5 de junio, representantes de FARMAINDUSTRIA mantuvieron un encuentro en Valencia con responsables de los principales medios de comunicación de la comunidad autónoma. Como ya se hizo recientemente con la prensa aragonesa, el objetivo es trasladar la realidad del sector farmacéutico innovador en España a los medios regionales. En esta ocasión, asistieron a un almuerzo organizado por FARMAINDUSTRIA los responsables (en su mayoría, redactores jefe de los medios locales y delegados de los medios nacionales) de *Las Provincias*, *Levante*, *Información*, *Valencia Hui*, *Canal Nou*, *El Periódico Mediterráneo*, *El País*, *El Mundo*, *Grupo Zeta* y *agencia Efe*. Además, los representantes de la Asociación visitaron la redacción del diario *Las Provincias*, donde fueron recibidos por su director, Pedro Ortiz.

Análisis de presencia en medios

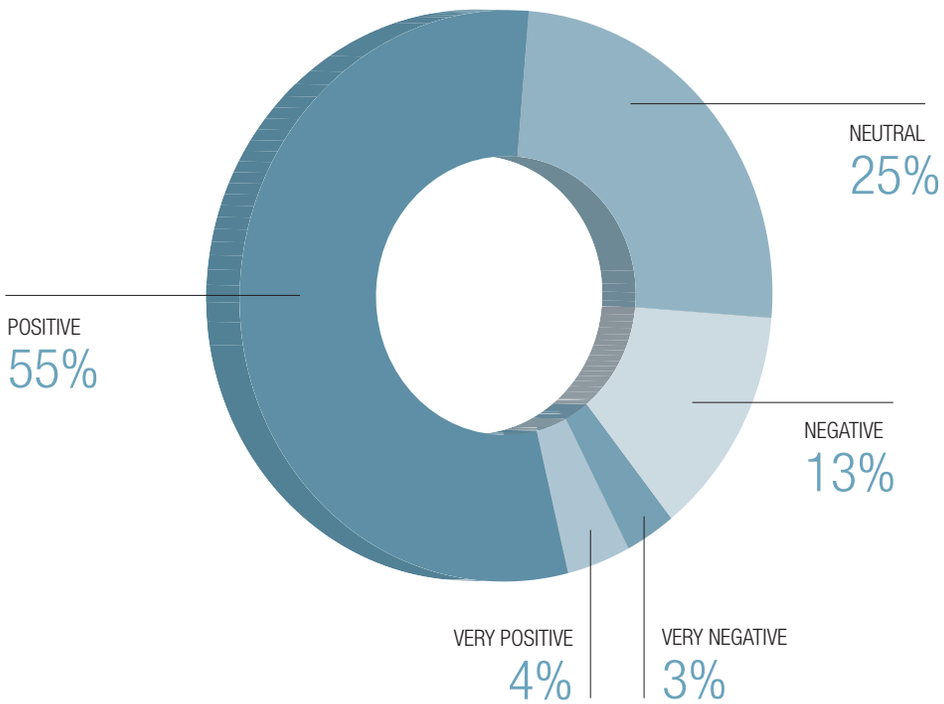
Se encuentra disponible para los asociados el Análisis de Presencia en Medios correspondiente al mes de mayo, en el que se incluyen más de 270 informaciones publicadas por los medios de comunicación sobre la industria farmacéutica. El índice de favorabilidad (entre +2 y -2) se situó en +0,65, lo que representa un importante crecimiento respecto a la cifra de abril (+0,43) aunque el dato es menor que el correspondiente al mes de mayo del año anterior (+0,79), que fue uno de los índices más elevados de 2007. Como novedad, el tema que con mayor frecuencia fue abordado por los medios de comunicación en relación con la industria farmacéutica durante el mes de mayo fue el que engloba a las informaciones sectoriales y las relacionadas con FARMAINDUSTRIA. A continuación, el asunto más tratado fue el de la investigación y el desarrollo, gracias, entre otros factores, a la presentación en rueda de prensa de los datos correspondientes a las inversiones realizadas por la industria farmacéutica innovadora durante el pasado año. Ambos asuntos (informaciones sectoriales e I+D) fueron, además, los que presentaron los índices de favorabilidad más elevados (+0,83 y +0,97, respectivamente). Por otro lado, ha descendido el número de informaciones publicadas sobre gasto farmacéutico, patentes y precios de los medicamentos.

Página 1 de 2

FARMAINDUSTRIA took part in several forums, round tables and other activities organised by NGOs in different parts of Spain

Analysis of Media Presence. Fifteen analyses of media presence (12 monthly, two six-monthly and one annual) were carried out during 2008, with 3,700 items collected, analysed and evaluated. As well as news on concrete products or business information (revenues, profits, mergers, restructuring, etc.) affecting individual companies or certain groups of companies, the most reported upon themes in the press concerning the sector as a whole during 2008 were: i) R&D-related issues, especially following the creation of the Ministry of Science and Innovation; ii) competition between generic and innovative medicines and related aspects (prices, patents, intellectual property, etc.); iii) relations between the pharmaceutical industry and different administrations; iv) the Spanish pharmaceutical market; v) other subjects occupying a lot of space in the media from time to time (counterfeit medicines, European Commission research in the sector, news related to FARMAINDUSTRIA, etc.).

In line with the valuation given to each of the items analysed (between +2 and -2), the average favour index of the more than 3,700 items analysed was positive (+0.53), with a total of 593 items evaluated as negative or very negative, 929 neutral and 2,246 positive or very positive.



3.3. Services to associated laboratories

3.3.1. ONLINE SERVICES

New public and private FARMAINDUSTRIA portals. After a long development process, the new public and private FARMAINDUSTRIA portals came into service in October 2008. While the public portal contains general information for open use, the private is of restricted access for member companies and users authorised by them.

PUBLIC PORTAL

PRIVATE PORTAL

Aims. The main objective of the portal was to satisfy the need of end users for rapid and intuitive access to information. This meant re-cataloging the more than 50,000 documents in the database with content management tools, regrouping and categorising (through key words) each of the files. Advantage was also taken of this need to review all the information that needed renewing and to update formats and designs, from circulars to bulletins and the Flashes. At the same time, it was necessary to move all this volume of information without affecting download times; any page had to be visible in no more than two seconds. The new portal is the first of FARMAINDUSTRIA's to respect AA accessibility standards and can be found in Spanish and English. Thus, four portals have been developed, two for the public zone and two for the private.

New sub-portal for the Code of Practice Surveillance Unit. At the end of 2008, the Spanish Code of Practice on Relationship between the Pharmaceutical Industry and Patient Organisations came into force and it was necessary that the new FARMAINDUSTRIA portal took into account all its functions and responded in this way to its needs. The required functionalities were developed for this and were fully operational at the beginning of 2009.

'The Most Read' and 'The Latest'. Depending on the type of contents to be accessed, two windows have been constructed in which the last ten documents to be added and the ten most downloaded are shown. These windows are sensitive to the section in which they can be seen, so that if one is accessing the Economic Information Circulars, for example, the most read Economic Information Circulars (in recent weeks) are shown as well as those most recently downloaded.

At the same time, on accessing a certain document, the documents related to it are shown through a system of key words throughout the portal (not just the section concerned).

New corporate image for documentation. It is increasingly normal to depend upon images, presentations, archives, sound or video recordings in information systems. FARMAINDUSTRIA's systems also have been affected by these new formats, making necessary a redefinition of each one of the documents the Association uses to deliver content to its members.

In this way, an image has been assigned to each of the portal sections (Circulars, Bulletins, Autonomous Regions, Legislation, International, News, Publications and Agenda), only varying the tone or colour of the background. Equally, the Association has been working on the Bulletins and Flashes. Finally, the Circulars also have the same image, distinct in their colour and tone, according to the area they represent. This gives coherence to the portal as a whole together with its contents and it is possible to know at any moment which kind of document or information one is working upon.

Sections

Bulletins and Flash updates

Circulars

Statistics from the new portal. The new portal has more than 50,000 documents, most of which are Circulars, Flash updates and Bulletins, press and legal information.

Daily, an average of 20 documents are loaded and sent to member companies (more than 2,000 users) through the *Daily Information Bulletin for Members*.

Although the portal has only been operating for three months, it has seen a notable growth in the number of users accessing it, in the total number of visits and information downloaded.

3.3.2. WORKING GROUPS AND FUNCTIONAL GROUPS

Working Groups and Functional Groups have continued to play a fundamental role in the regular activities of FARMAINDUSTRIA, permitting the member laboratories to take part actively in all areas of sectoral interest.

Generally speaking, we can summarise the objectives of the Working Groups and Functional Groups in the following way:

- **Working Groups (WGs):** these are established by the Association's Governing Bodies in order to tackle specific problems, make proposals, elaborate industry positions and monitor specific action plans on strategic themes. The compositions of the Working Groups are approved by the Governing Bodies following criteria of representativeness, suitability and operability.

- **Functional Groups (FGs):** coordinated by the different departments of FARMAINDUSTRIA, they cooperate with the Association to study common themes and positions of the sector, mainly in technical/functional aspects. With a general character, these groups can operate in full (for information sessions or work by email) or in committee (a more reduced operational group, selected by the coordinator for specific themes). When the subject requires the preparation of a relevant sectoral position, it is channelled through the Executive Board.

With a general character, and without prejudicing the particularities that can exist in some concrete cases, the diverse Working Groups and Functional Groups in FARMAINDUSTRIA organise themselves upon a series of common operating rules which are updated every two years.

Thus, at the FARMAINDUSTRIA General Assembly of 21 October 2008, the Executive Board, Steering Committee and Presidency for the following two years was re-elected. By virtue of the same provision, the Working Groups and Functional Groups of FARMAINDUSTRIA were re-selected. Following this procedure, FARMAINDUSTRIA could count upon the following groups:

- 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 of a technical scope.

- 17 Functional Groups: (1) Clinical research; (2) Environment; (3) Pharmacovigilance; (4) Manufacturing and traceability; (5) Registrations; (6) Medical directors and research; (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; (17) International relations.

A summary follows of the activities of the different groups of FARMAINDUSTRIA in 2008.

Working Groups

Working Group on Employment, Training and Development. In the framework of the FARMAINDUSTRIA Strategic Plan, put to work following the re-election of the Governing Bodies of the Association in October 2008, the WG on employment, training and development aiming at examining the situation in which the sector finds itself in the area of employment and the future forecasts for the next two or three years, in order to evaluate the actions of the pharmaceutical industry in this area. The pharmaceutical industry is well positioned and can be an emblematic sector for the new productive model which Spain needs, among other factors for the highly-qualified employment it generates.

The Working Groups constitute a basic pillar in the functioning of FARMAINDUSTRIA

Working Group on Competitiveness and Internationalisation. The WG on competitiveness and internationalisation is a newly created group in FARMAINDUSTRIA which is beginning its mission following the approval of its constitution by the Association's Governing Bodies. Its main aim is to promote industrial competitiveness and internationalisation of member laboratories, strategic aspects for the pharmaceutical industry today. Initially, the group will focus on identifying indicators which allow the evaluation of added value that the internationalisation effort involves.

Working Group on R&D and Biotechnology. A newly created group from the old biotechnology section and made up of 25 companies. As approved by the FARMAINDUSTRIA Governing Bodies, its role is to prepare positions and proposals for collaboration with the Ministry of Science and Innovation and to pay special attention to the cooperation between the industry and small biotechnological companies, as well as to launch financial and non-financial instruments for this cooperation, taking advantage of the synergies with the pharmaceutical industry and bringing to the fore front the differential and complementary characteristics that FARMAINDUSTRIA can offer. This group is therefore responsible for stimulating the participation of the industry in national and international R&D programmes, singularly in the *Innovative Medicines Initiative* (IMI).

Working Group on Sustainability and Economic Regulation. In line with the work carried out in previous years, during 2008 this group continued to carry out an intensive monitoring of all the legislative proposals related to economic regulation, sustainability of the SNS and measures for containing spending, in particular the legislative developments and implementation of the economic aspects of the Law 29/2006, on Guarantees and Rational Use of Medicinal Products and Medical Devices, having prepared various strategic position documents for the pharmaceutical industry.

It has also carried out a close monitoring of the work performed by the *ad hoc* group of the Inter-Ministerial Price Commission in the preparation of fixed-dose price and reimbursement criteria for the medicines and medical products associations, as well as the practical application of the Order, SCO/2874/2007, of 28 September, which establishes the medicines and medical products which constitute an exception to the possible substitution by pharmacists, in agreement with Article 86.4 of Act 29/2006, of 26 July, establishing the relation of medicines that cannot be replaced by a pharmacist without the express authorisation of the prescribing doctor. As far as the latter is concerned, it should be pointed out that the efforts made by the Association to obtain clarification from the Ministry of Health on the scope of this Order have yiel-

ded the confirmation that the non-substitution by a pharmacist without the express authorisation of the doctor is applicable both in pharmacies and hospital pharmacy services.

Special mention should go to the work of the Group in forwarding carefully prepared proposals to the Spanish Medicines and Medical Devices Agency (AEMPS) in order to clarify the evaluation criteria for applications for medical innovations of therapeutic interest (IGIT) and developing a transparent procedure for their declaration, which has resulted in greater predictability for interested laboratories and has confirmed the independence of the IGIT declaration process with respect to the financing process for the SNS and fixing of the price.

An exhaustive analysis has also been carried out of Order SCO/3803/2008, of 23 December, which determines new medicine groups, their reference prices and reviews the reference prices set by Order SCO/3997/2006, of 28 December, and Order SCO/3867/2007, of 27 December. The group initially prepared the arguments for the draft Order and later, following its approval, carried out a study of the sectoral impact of the Order to quantify it both from the point of view of public pharmaceutical spending and from a business perspective.

Elsewhere, the group carried out a monitoring of other subjects of sectoral interest and economic scope, such as: i) contributions by sales volume to the National Health System (SNS), relating to the Sixth Additional Provision of Act 29/2006; ii) the entry into force and practical application of the list of lower prices, and; iii) the situation regarding price and reimbursement procedures and decisions to include medicines in the SNS service.

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 spaces for collaborating with Autonomous Regions, professional organisations and scientific associations which helps create a favourable environment for pharmaceutical innovation and preserves the single pharmaceutical market in Spain.

The pharmaceutical policies of the Autonomous Regions are also analysed by FARMAINDUSTRIA

Given the transversal nature of the subjects it handles, this WG contributes elements of analysis and debate on regional initiatives and carries out advanced, proactive monitoring of the legislative initiatives which are taken on in the Autonomous Regions in the area of pharmaceutical planning and policies.

Elsewhere, the group also strives to create relationships of mutual understanding and confidence with the Autonomous Regions, which facilitate industrial stability and sustainability in public pharmaceutical spending.

Spain's Code of Good Practices on Relationships between the Pharmaceutical Industry and Patient Organisations came into force on 1 July 2008

During this past year, the WG has carried out an important activity focused upon the monitoring of legislative initiatives in the Autonomous Regions and increasing internal information mechanisms. The group has in this way analysed the implications of different regulations such as: the Decision of the Andalucian Health Service (SAS) on harmonisation of criteria for use of medicines and medical products in SAS centres, which has been challenged by the Association; Decree 206/2008, of 28 August, of the Galician Government, regulating electronic prescriptions, and; the Order by the Catalan Health Department, SLT/72/2008, developing Decree 159/2007, of 24 July, regulating electronic prescriptions.

Finally, the collaboration and contributions of this WG have enabled the preparation of annual Autonomous Region reports, in which information of the greatest interest is gathered for the sector, as well as different thematic reports, such as those on electronic prescriptions, agreements with pharmacists' colleges and regional health budgets, among others.

Working Group on the Code of Good Practice. The objective of this group is to monitor the functioning of the system of self-regulation and prepare proposals for improving its effective application.

The EFPIA Board approved the revision of the *European Code of Practice for the Promotion of Medicines* and a new *European Code of Practice on Relationships between the Pharmaceutical Industry and Patients' Organisations,* pressing member associations to adapt and transpose these texts nationally.

By virtue of this mandate, during 2008 the Code of Practice WG continued working to update the texts of the *Spanish Code of Practice for the Promotion of Medicines and Interaction with Healthcare Professionals*, as well as its *Operational Guide* and the Regulation governing the Code of Good Practice control bodies with the double objective of adapting them to the standards approved by EFPIA and to the new regulations and the experience acquired over several years of full functioning of the system of self-regulation.

In the same way, the WG undertook the transposition of the EFPIA Code on relations with patients' organisations, culminating in the approval of the *Spanish Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations* and its respective *Operational Guide,* as the procedural regulation common to both Codes.

All texts agreed by the WG were approved by the Governing Bodies of FARMAINDUSTRIA and ratified by the General Assembly of the Association on 30 June 2008, entering into force on 1 July (except that relating to the communication of studies foreseen in Article 14.3 of the Code, which was obliged to be in force as of 1 January 2009).

Likewise, the group has carried out a monitoring of the consultations and resolutions of the Code of Practice Committee, proposing to FARMAINDUSTRIA's Steering Committee the publication of all those that result of general interest in order to strengthen the principle of transparency of the system of self-regulation.

Elsewhere, the group worked to contribute its observations to the draft of the document prepared by the Madrid Region Health Department in agreement with the Catalan Government on valid supports to be used in the area of promoting medicines and medical products aimed at health care professionals.

The group is currently working on the implementation of the new Codes, in particular on the compulsory communication of studies foreseen by the *Spanish Code of Practice for the Promotion of Medicines and Interaction with Healthcare Professionals*, and on the provisions contained in the *Spanish Code of Practice onRelationships between the Pharmaceutical Industry and Patient Organisations* in the area of transparency.

Working Group on the Hospital Market. This WG was created in 2008 with the aim of monitoring and analysing the hospital market with respect to three main areas: economic (study of the Spanish pharmaceutical hospital market); access to the market (analysis of the barriers to access for new hospital medicines and medical products), and legal (monitoring of legislative developments in the hospitals area).

One of the main characteristics of the functioning of this WG is its coordination with other WGs and FGs in FARMAINDUSTRIA, such as those handling the Autonomous Regions, technical legislative developments and hospital debt.

The group carried out an analysis of the reply received by the Consultative Board on Administrative Procurement (*Junta Consultiva de Contratación Administrativa, JCCA*) to the arguments presented by FARMAINDUSTRIA in the consultation process for interpreting Act 30/2007, of 30 October, on public sector contracts, and the Law 29/2006, of 26 of July, on Guarantees and Rational Use of Medicinal Products and Medical Devices, in the area of hospital supplies (Report 17/2008 of 28 July). Specifically, the JCCA's reply served to confirm that: i) with respect to price interventions, medicine prices cannot be used as criteria for evaluating offers relating to their acquisition in hospital tenders; ii) non-replaceable medicines which can be provided by different suppliers cannot be excluded from public bids, whereas, where there is a sole supplier, the acquisition could be effected by the negotiated procedure without advertisement; iii) except in cases where the product is defective, the obligation to maintain and use it before the expiry date is the administration's responsibility and, as such, the specifications cannot contain administrative clauses contradicting this premise.

Working Group on Legislative Developments of a Technical Scope. The entry into force of the different provisions of the development of Act 29/2006 has given a certain legislative stability regarding national regulations in the period covered by this Report, in a way that the activities of this group have been oriented mainly towards specific international provisions which will be applied in our country in the future. This is the case with the Regulation and Directive which will regulate, as of 1 January 2010, amendments to the authorisation conditions for medicines and medical products and the package of proposals of the European Commission modifying the common legislation in force, in particular the proposal referring to actions foreseen to fight against counterfeiting more efficiently.

This group has also reviewed and commented upon the document prepared by the Spanish medicines agency (AEMPS), *Strategy against counterfeit medicines*, and created, in coordination with the Manufacturing and Traceability Functional Group, an *ad hoc* WG entrusted with presenting to the AEMPS an action protocol on activities that should be carried out by laboratories in the case where counterfeit medicines appear in official channels.

Finally, and in relation to regulations tracked by the WG, the draft Royal Decree regulating the availability of medicines and medical products in special situations should be mentioned. This would establish conditions of access to medicines for patients: i) in clinical research; ii) in conditions of use different from that authorised; iii) when imported from another country without a valid marketing authorisation in Spain.

Functional Groups

Functional Group on Clinical Research. This FG worked on the updating of the document *Clarifications on the application of legislation regarding clinical trials with medicines for human use* in 2008, to adapt it to the requirements of the new European guidelines and establish how protagonists should act in relation to certain aspects of clinical trials. In the legislative area, the group has also collaborated with the Spanish medicines agency (AEMPS) in translating the document, *Good Clinical Research Practices*, and has assessed the implications of the new version of the Helsinki Declaration on the different

The Environment FG monitored activities in the environmental area affecting the pharmaceutical industry

parties who take part in research, especially in relation to the obligation to register clinical trials and publish their results in publicly accessible databases.

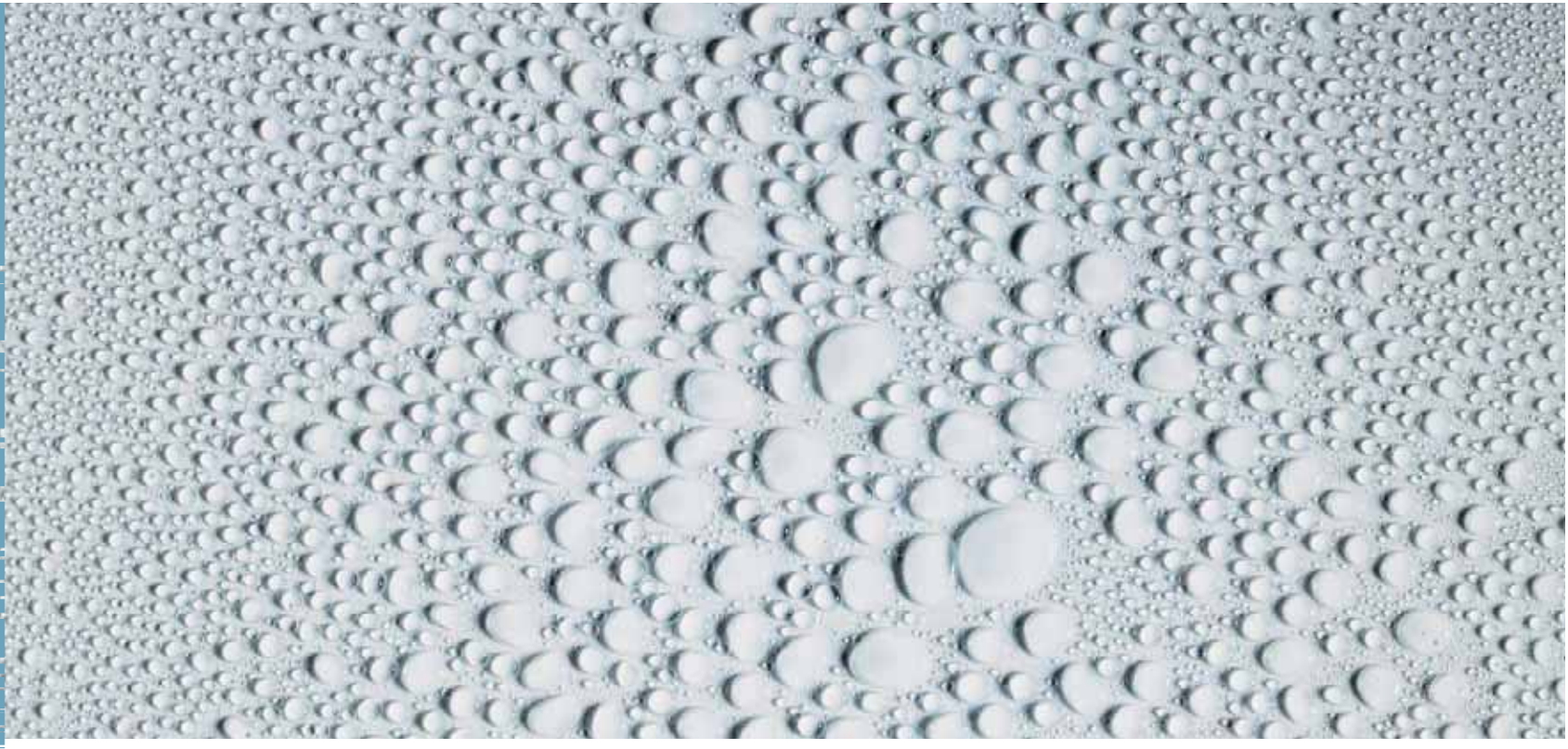
The group collaborated actively with the AEMPS in the implementation of electronic sending of clinical trial documentation to the Agency, through CD/DVD electronic support or telematic sending of information. With respect to the latter tool, 14 laboratories belonging to the group collaborated in the pilot phase of the telematic sending of clinical trial documentation to the Agency and to the Clinical Research Ethical Committees, which, once operational, will speed up authorisations and reduce the bureaucratic burden on the studies and help harmonise the documentation to send to the Clinical Research Ethical Committees.

Likewise, a specific working subgroup has analysed the suitability of new proposals for model contracts such as those in the Canary Islands, Madrid, Basque Country and Murcia Autonomous Regions.

As far as the drafting of the Code for personal data protection in the area of clinical research and pharmacovigilance, a subgroup collaborated in the preparation of a procedure summarising the legislation, authorisation procedures and monitoring of clinical trials, as well as the interrelation between different agents involved in the research and how to proceed in carrying out clinical research with anonymous data and those in which personal data is gathered from the participants and subjects of the research.

Functional Group on the Environment. During 2008, the Environmental FG monitored different legislative developments (the Packaging Bill, draft regulation developing the Environmental Responsibility Act, the National Integrated Waste Plan and the Waste Framework Directive), and the activities in the environmental area of importance to the pharmaceutical industry (assessment of the environmental risk of medicines, expired medicines management, waste, emissions, etc.).

Given the complexity of the administrative provisions in the environmental domain, the group regularly organises common positions. In collaboration with SIGRE, it also maintains the representation of FARMAINDUSTRIA on Environmental Committees in different organisations, such as CEOE and FEI-



QUE and has collaborated closely with the Ministry for Environment, Rural Development and Seas, as well as different departments in the Autonomous Regions on subjects which have an effect of the sector in this area.

Functional Group on Pharmacovigilance. The main activities of the group during 2008 were focused upon evaluating the implications of the new updates of Volume 9A, which encompasses the pharmacovigilance regulations for medicines for human use at the EC level, and in the legislative development of Royal Decree 1344/2007, which regulates the pharmacovigilance of medicines for human use in Spain. At the same time, the group worked on: proposals for question-and-answer documents prepared by the AEMPS and related to instructions for the inclusion of the yellow triangle on promotional material for medicines; the electronic notification and transmission of suspected adverse reaction through online loading in XML format, and; periodic safety reports. It has also worked in collaboration with the AEMPS in translating the Royal Decree 1344/2007 on pharmacovigilance and in establishing criteria for inclusion in pictograms on photosensitivity and driving of vehicles, representing FARMAINDUSTRIA in the working group the Agency formed for this purpose. It is also collaborating with AEMPS on the updating of the document, *Good Pharmacovigilance Practice,* published in 2002 to incorporate the changes in Volume 9A and the requirements of the new local legislation in this area.

The group has also established and presented to AEMPS the criteria which, on the basis of a retrospective study of Spanish journals which publish most of the suspected adverse reactions produced in Spain, should be followed in carrying out regular bibliographical searches as stipulated in Volume 9A.

The achievements of the group should also be mentioned in arriving at the definition, by AEMPS, of its favourable position on the notification of suspected adverse reactions to medicines taking into account the commercial name of the products involved, making special mention of the biological products for which the presentation, concentration and number of the batch would be other important aspects to consider.

The Pharmacovigilance FG has collaborated extensively with the Spanish medicines agency (AEMPS)

Finally, the group worked upon the drafting of the working procedure for pharmacovigilance, including the Code for protecting data, which deals with how laboratories should manage the personal data of health care professionals, consumers and other notifying parties when they decide to work with them and when, on the other hand, they are interested in working with dissociated data where the identity of the subjects involved is not revealed in the notification.

Functional Group on Manufacturing and Traceability. The full traceability of medicines is of interest to all the agents in the drugs supply chain. It is evident that whatever legislative amendment that generates changes in the rules of the game in this area means investment for the parties and changes in manufacturing processes and the marketing of medicines and medical products, more than enough justification for the activities this group carries out.

One of the initiatives reviewed by the group was the proposal for technical prescription specifications to apply in the open procedure for carrying out a pilot project to determine the most appropriate automatic identification system for the traceability of medicines and medical products (Datamatrix/RFID), prepared by the Ministry of Health and Consumer Affairs. The pilot test should contribute information for the option of the individualized medicine identification system.

At the moment, for the pharmaceutical industry, the only feasible alternative is Datamatrix. At the international level, EFPIA has already stated it is in favour of Datamatrix and some countries have already legislated in this direction in the search for harmonisation and thus Spain should avoid the potentially harmful isolation in the manufacture of medicines and medical products in the current international context. Datamatrix 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. From the economic point of view, Datamatrix is more advantageous and allows fulfillment of the objectives of minimising counterfeiting and the advantages derived from the individualised identification of medicines, for example, in the area of electronic prescriptions.

Functional Group on Registrations. This FG, 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 by new authorisation procedures and modification of the conditions of medicine authorisations create important debates at the heart of this group some of which are passed on to the AEMPS in order to attempt to improve and simplify the procedures.

The new requirements for the presentation of documentation (doing away with paper applications), the new application by AEMPS for the declaration of the marketing situation for authorised medicines and the finalisation of the Question-and-Answer document on the Royal Decree on Registration took up a good part of the activities of this group over the past year.

Functional Group on Medical and Research Directors (BEST project). This group, formed three years ago as a platform for excellence in clinical research, is part of the Spanish Technological Platform Innovative Medicines (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). Also, with the aim of ensuring that laboratories have greater flexibility in designing their own proposals, retaining always the individuality and confidentiality of data, a new informatics tool has been developed.

BD Metrics, updated in June 2008, contains information about key indicators from the 818 clinical trials by 26 pharmaceutical companies. 90% of these clinical trials involve more than one centre and are international. 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 phases of clinical research, mainly Phase 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. BD Metrics contains information on 57 clinical trials in which centres have managed to begin the trial in less than 100 days and whose typology is not very different from the rest of the samples in the database and they have served as examples for Spain to improve its standards and maintain its competitive capacity.

Over the past year, the project has had a good reception in the Autonomous Regions, having increased considerably their number of bilateral meetings with FARMAINDUSTRIA.

The work to disseminate the information has also increased and the contacts and working meetings has intensified with not only government departments, but also scientific associations (SEFH and SER) and the CIBER networks (Respiratory Diseases, Rare Diseases, Diabetes, etc.). It is worth mentioning the presentation of the BEST Project on clinical trials in oncology at the General Conference on Strategies against Cancer in October 2008.

Functional Group on Human Resources. This FG is made up of the heads of human resources of pharmaceutical companies which are members of FARMAINDUSTRIA and continued in 2008 on the same line of activity as in previous years, exchanging information on those aspects of labour law which affect our sector.

In 2008, mainly marked by the beginning of the difficult economic crisis, social dialogue between the different social actors was based on the need to adopt proposals which help to safeguard employment without reducing labour contracts.

FARMAINDUSTRIA has continued to take an active part in Working Groups and those FEIQUE (Spanish Chemical Industry Federation) Committees constituted under the auspices of the new Agreement (the Joint Sectoral Committee for Equal Opportunities and the Professional Classification Technical Committee), as well as those already established (the Socio-Labour Committee and the Mixed Committee of Interpretation for the Collective Agreement). At the same time, it has been represented at different meetings of the Labour Relations Committee of the Confederation of Employers and Industries of Spain (CEOE).

Functional Group on Personal Data Protection. The activity of the group during 2008 focused upon studying the provisions in Royal Decree 1720/2007, of 21 December, approving the Regulation developing the Organic Law 15/1999, of 13 December, on personal data protection, with respect to the related Codes.

With the Clinical Research and Pharmacovigilance FGs, the group prepared the Standard Code for Clinical Research and Pharmacovigilance, which it presented to the FARMAINDUSTRIA Governing Bodies, who, in their meeting of July 2008, approved its transfer to the Spanish Data Protection Agency (AEPD). Following its lodging with the AEPD in September, FARMAINDUSTRIA held several meetings with representatives of the Agency in order to develop in more detail certain aspects of the text, on which it will continue to work in 2009 until it is registered in the General Data Protection Registry.

Legal Services Functional Group. During 2008, this FG held two six-monthly meetings as foreseen. The group is made up mainly of officials from the legal departments of the member laboratories and serves as a forum for exchange of opinions on areas of a legal nature which are of importance to the pharmaceutical sector.

The Legal Services FG serves as a forum for exchanging opinions on legal matters

The activity of the group continued with the analysis of the legislative developments of the Safeguards and Rational Use of Medicines and Medical Devices Act, 29/2006, of 26 July, as well as important legislation in the Autonomous Regions. It has also carried out a monitoring of the judgments of the European Court of Justice in areas which could be of interest (parallel trade, advertising and competition), as well as the research begun in January by the European Commission's Competition Directorate-General on the pharmaceutical sector.

At the same time, it informed upon the latest judicial decisions in the area of patents and progress in different legal procedures begun by FARMAINDUSTRIA.

The Taxation FG analyses developments at an annual seminar

The group also analysed the Report by the Consultative Board for Administrative Procurement following the arguments put forward by FARMAINDUSTRIA on the joint interpretation of the Safeguards and Rational Use of Medicines and Medical Devices Act and Act 30'2007 on public sector contracts.

Additionally, it analysed themes which, for their content, are being handled by other WGs but have a legal nature upon which the group can also discuss seriously and inform.

Taxation Functional Group. Composed of financial managers and tax experts from the member laboratories, this FG continued to hold its traditional annual seminal on new taxation measures, during which information relating to new fiscal developments for the year in course was addressed, as well as legal judgments in this area, the doctrine of the Taxation Directorate-General and other fiscal aspects of interest to pharmaceutical companies such as an analysis of the fiscal implications of the new General Accounting Plan and the new legislation on transfer prices.

In this sense, it should be remembered that during 2008 the legislative passage of the development of Act 36/2006, of 29 November, on Measures to Prevent Tax Fraud and Modification of Company Tax, was of special importance given the significance the area has for the sector, having culminated in the approval of Royal Decree 1793/2008, of 3 November, modifying the Regulation on Company Tax.

Equally, through FARMAINDUSTRIA and in coordination with the CEOE, the group carried out a constant defence of the importance of maintaining deductions for R&D&I from 2011, having finally obtained a satisfactory response from the Government on the recent approval, at the close of this Report, of Royal Decree 3/2009, of 27 of March, on Urgent Measures in the Area of Taxation, Finance and Competition in the face of the current economic crisis, which declares that the deduction for R&D&I activities will be kept indefinitely in company taxation with the aim that companies have a secure, unlimited framework on which to plan their investment decisions for this type of activities.

Elsewhere, a special mention should be made of the reply obtained from the Taxation Directorate-General to the binding review presented by FARMAINDUSTRIA in order to clarify the type of VAT applicable to services provided both for Contract Research Organizations (CROs) and other bodies (foundations and hospitals) which regularly collaborate with laboratories in carrying out clinical trials and studies in general.

Health Technologies Assessment Functional Group. This FG began activities 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.

The group met on four occasions during 2008, finalising a technical document on the use of measurement variables for results in the evaluation of medicines and medical products.

The group is presently in the process of finalising a document on the use of modeling techniques and in 2009 will continue to work on other documents of a technical nature which express the approach of the pharmaceutical industry to questions related to the evaluation procedures for medicines and medical products.

Medical Visits Functional Group. The aim of this FG is to carry out monitoring of the regulatory projects at national and autonomous region levels which could affect medical visits and prepare sectoral positions in this area.

In this sense, during 2008 contacts intensified with diverse Autonomous Regions to agree upon legislative proposals in the area of the regulation of medical visits as a medical and scientific information activity.

Special mention should be made of the meeting held with officials from the Madrid Health Department to raise and cooperate on diverse themes, among them the organisation of medical visits. Following the judgment by the Supreme Court on 11 June 2008, confirming the judgment of the Madrid Supreme Court of 8 June 2005, which declaring sections of the Medical Visits Circular 1/2002 null and void, FARMAINDUSTRIA noted the will of the Region to arrive at an agreement to regulate this activity with all the actors involved in this field. At the close of this Report, the passage of the Order, establishing the organisation and control of medical visits in centres of Madrid Region's public health care network, continued.

Elsewhere, the group's work also focused on analysing the draft Bill to create a professional college of medical visitors in the Valencian Region, which is passing before the Department of Justice and Public Administration of the Region. Following an exhaustive study of the legislation currently in force in the area of professional colleges (Act 2/1974, regulating medical visits in Valencia (Order of 27 January 2004), FARMAINDUSTRIA, through the group, presented its arguments concerning the draft bill.

Hospital Debt Functional Group. The former Hospital Supplies Section changed its name in 2008, becoming this FG in which it has continued to carry out a constant monitoring of the evolution of the Hospital Supplies Debt, electronic billing initiatives and regulatory development of the Act 30'2007, of 30 October, on public sector contracts.

Latest available data for the sector as a whole indicates that, at the end of 2008, the National Health System (SNS) owed pharmaceutical companies 2,708 billion euros for supplies of medicines and medical products to its hospitals and that the average payment time was 282 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 increase in debt for the SNS as a whole in 2008 (+15%) was very similar to that recorded in the previous fiscal year (+14.4%), demonstrating there had been no improvement in the situation, complicating greatly the financial viability of small and medium-sized pharmaceutical companies.

The Hospital Debt FG of FARMAINDUSTRIA has thus carried out a constant monitoring of the various Autonomous Region initiatives aimed at solving the problem of debt for hospital pharmaceutical supplies, the highest of which belongs to Andalucía and the Valencian Region.

Only four Autonomous Regions managed to reduce their hospital debts in 2008 and the first months of 2009: Andalucía, the Canary Islands, Cataluña and the Valencian Region. Special mention should go to Andalucía, whose Health Service made large payments in January 2009 (almost 600 million euros) with which it has succeeded in amortise over 70% of its debt which, at the end of January 2009, stood at 212.4 million euros with an average payment period of 132 days.

Elsewhere, the FG has monitored various electronic billing initiatives both at the autonomous and national levels. For the latter, FARMAINDUSTRIA has channeled before the Secretary of State for Telecommunications and the Information Society and the Secretary of State for Taxation and Budgets a document signed by the main multisectoral associations expressly asking for the UN/EDIFACT INVOIC format and its policy of electronic signatures associated for its application in electronic billing with Central Government.

In the same way, the group continued with the task of analysing the specifications of various hospital tenders, watching that they adapt to the legislation applied in the area of public contracts.

To this effect, letters have been sent to various management bodies in hospital centres indicating the existence of errors in the specifications and pressing for their modification to adapt them to Act 30/2007, of 30 October, on public sector contracts and the Report 17/2008, of 28 July, issued by the Consultative Board for Administrative Procurement in the area of prices, rebates and non-replaceable products.

It should be recalled that satisfactory replies were received to many of the letters sent. The hospital centres in question have proceeded to eliminate the errors contained in the reference specifications.

At the close of 2008, the SNS owed pharmaceutical companies 2,708 billion euros, with payment taking place on average in 282 days

Vaccines Functional Group. The health importance and regulatory singularity of vaccines enjoy full recognition. The FARMAINDUSTRIA Vaccines FG, aligned with the position of the *European Vaccine Manufacturers* (EVM) of EFPIA, in this sense handles the different themes relevant to this area and their application at national level.

The appropriate course of the annual flu vaccination campaigns, the importance of highlighting the value of vaccines for society and the activities carried out in favour of patients and professionals, increasing their knowledge in this field, take up the main activities of this FG. At the same time, the recent appearance of the new A/H1N1 influenza will constitute one of the main areas of work for the FG during 2009.

International Relations Functional Group. International Relations is a newly created group which began its work in 2009, given the international dimension of the pharmaceutical industry is a key vector within

the strategy of FARMAINDUSTRIA. The aim of this FG is to inform upon and monitor the developments in the area of pharmaceutical policy both at European level and in other international areas, and to analyse their possible repercussions at the Spanish level.

Barcelona Office. During 2008, and in close coordination with the different departments in the Association, the FARMAINDUSTRIA office in Barcelona worked intensely responding to inquiries from member laboratories. Although the subjects handled were of a varied nature, they mainly focused upon questions related to legislative and regulatory developments concerning the Guarantees and Rational Use of Medicinal Products and Medical Devices (29/2006), taxation, market and hospital debt, electronic billing and public sector contract legislation (hospital supplies), among others.

The office thus monitored on a daily basis the provisions published in the various Official Bulletins of the Autonomous Regions to pass on to members the Autonomous Regions' legislation related to the pharmaceutical sector.

Physical and video conference meetings involving the different WGs and FGs of the Association were held weekly in the Barcelona office. This stimulated participation and knowledge exchange on the part of the laboratories located in Cataluña. At the same time, the office served as a meeting point for diverse organisations (COASHIQ and ANEFP, among others) and the Association's statutory groups.

Throughout the year, the office collaborated actively with Catalan universities, the Catalan Government, the Catalan Water Agency, Employment Promotion and other bodies, with the aim of knowing all the Autonomous Region's new developments of interest to the sector.

The Barcelona office is also a member of the FEDEQUIM Socio-Labour Committee and took part actively in the Catalan Mixed Delegated Committee of the federation above with the aim of interpreting the Chemical Industry Collective Agreement jointly with the Mixed Central Committee of FEIQUE.

All these activities had the final objective of offering better service and advice to member laboratories in general and to those located in the Catalan region in particular.

3.3.3. SPANISH TECHNOLOGICAL PLATFORM OF INNOVATIVE MEDICINES (PTEMI)

The Spanish Technological Platform of Innovative Medicines (PTEMI) has been running for more than three years and represents 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 Spain. The PTEMI is the Spanish arm of the *Innovative Medicines Initiative* (IMI), a programme of EFPIA and the European Commission to promote research in new medicines in order to strengthen the position of Europe in pharmaceutical research, increase the attractiveness of Europe to research investment and, over the long term, provide European citizens with quicker access to medicines of greater quality. The IMI forms part of the European Union's 7th R&D Framework Programme (2007-2013) in which, for the first time, the pharmaceutical industry is one of the strategic sectors that the European Commission has prioritised in its R&D policy, alongside others such as energy, aeronautics and telecommunications.

The PTEMI is the Spanish body promoting pharmaceutical research

The IMI annually calls for pre-competitive research projects to be carried out by consortia formed by research groups from pharmaceutical companies, research centres and SMEs. The first call for projects was put out on 30 April 2008. Eighteen themes were selected and the Spanish participation was very positive, since eight proposals were classified first in their respective subject areas, with a total budget of 6.5 million euros. The proposal for predicting *in silico* toxicity will be led from Spain and the consortium management office will be installed in Barcelona.

Within the IMI's governing bodies, the significant Spanish participation should be emphasized. There are two Spaniards on the Scientific Committee (the consultative body made up of 15 experts): Cristina Avendaño, pharmacology doctor and current Director of AEMPS, and Ferrán Sanz, doctor in chemistry and academic coordinator of the PTEMI, as well as researcher for GRIB-IMIM.

The activities carried out by PTEMI during 2008 were:

- In the area of clinical research, the BEST Project established itself as a Platform of Excellence in Clinical Research of Medicines in Spain.

- An inventory has been carried out of the offer of teaching activities in R&D in Spain through direct searches and dissemination to all those registered in the Education and Training Committee of PTEMI. The access to the catalogue of teaching offers and registration of new teaching activities is already available on the Platform's website.

- In the section on seminars and conferences, the 2nd *Innovative Medicines Initiative Information Day* should be mentioned, held on 11 March in Madrid and co-organised by FARMAINDUSTRIA together with the Carlos III Health Institute, the Industrial Technological Development Centre (CDTI) and the Ministry of Education and Science, with the idea of mobilising all the actors involved in medicines R&D in the first call for projects.

- PTEMI also coordinated and organised in Madrid its annual conference with the Spanish Nanomedicine Technologica Platform, entitled *Annual Conference on Biomedical Research Technological Platforms,* which attracted 250 participants from public and private institutions. The progress of these platforms allows the presentation of a wide range of initiatives and projects. The current panorama of biomedical research in Spain was presented at the conference.

PTEMI organised its 2008 annual conference in Madrid, attracting more than 250 participants

Elsewhere in 2008, PTEMI set up its International Innovation Unit with financing from the Ministry of Science and Innovation through CDTI, which has allowed it to carry out a diagnosis of the industrial sector dedicated to pharmaceutical R&D to know better its strengths and weaknesses with the aim of fostering the participation of Spanish companies and other national institutions in European programmes. The unit has been conceived as an instrument of promotion and support to companies and Spanish entities active in the biomedical sector and seeks to maximize the economic and scientific returns through the participation of Spanish organisations in European programmes.

PTEMI's communications vehicle is its web portal (www.medicamentos-innovadores.org), which is the reference for biomedical pharmaceutical research at the national level and serves as a meeting point and also for coordinating activities, information and communications between all the participants. There is a monthly newsletter which is sent to more than 1,000 people interested in PTEMI's activities. The website is available in Spanish and English, and is updated every week.

3.3.4. CODE OF GOOD PRACTICE

Approval of a new version of the Code of Promotion and a new Code aimed at the relations between the pharmaceutical industry and patients' organisations took place at the end of June 2008.

The self-regulation system for the Spanish pharmaceutical industry, since 1 July 2008, is thus made up of two Codes:

- **The Spanish Code of Practice for the Promotion of Medicines and Interaction with Healthcare Professionals** (later, the Code of Healthcare Professionals).

- **The Spanish Code of Practice on Relationship between the Pharmaceutical Industry and Patient Organisations** (later, the Code of Organisations of Patients).

As far as the new version of the Code of Healthcare Professionals is concerned, it is important to point out that the motives conducive to the approval of a new version (the last one dated from June 2005) are mainly two: i) the entry into force in October 2007 of a new version of the *EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with Healthcare Professionals,* and; ii) the continuous improvement of our self-regulation system, adapted to the legislation in force, strengthening its efficiency and transparency, handing additional powers to the control bodies and publishing mediation accords reached before the Code of Practice Committee and incorporating technical and writing improvements.

SUMMARY OF DEVELOPMENTS IN THE CODE AND REGULATION

DEVELOPMENTS IN THE EFPIA CODE	CONTINUOUS IMPROVEMENT
▪ **Name change:** Applies not only to marketing but any type of relationship between the laboratories and health professionals. ▪ **New Articles:** ▪ **Art. 15. Donations and subsidies.** ▪ **Art. 16. Services offered by bodies made up of health professionals.** ▪ **Art. 17. Services offered by health professionals.**	▪ **Art. 7.1. Distribution of promotional material:** Expressly forbiddening the promotion of prescription medicines for the general public. ▪ **Art. 10. Incentives**: Adaptation to LGURMPS 29/2006. Definition of market price. ▪ **Art. 11. Hospitality and meetings:** Definition of "event". Prior authorisation by the USD for events abroad. ▪ **Art. 14. Studies:** Adaptation of content. Implementation of a new communications system prior to studies similar to events. ▪ **Art. 18. Rules for applying the Code:** Responsibility for non-compliance for third parties. ▪ **Art. 23. Communication and archiving of decisions.** Mediation agreements reached by the Code of Practice Committee. ▪ **Regulations. Art. 4. Code of Practice Surveillance Unit.** New powers: investigation procedure; appeals to health care authorities; good practice certificate. ▪ **Regulations. Art. 10. Studies communication process.** ▪ **Regulations. Art. 12. Investigation procedure.**

The new Code for relations with patients' organisations is a transposition of the new Code approved by EFPIA in relation to this area in October 2007 (*EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations*). This Code recognises the common interests existing between patients' organisations and the pharmaceutical industry and establishes standards and guidelines for action which guarantee that the relations develop in an ethical and transparent manner, respecting in each case the principles upon which this Code is based, which are as follows:

- Independence of patients' organisations.
- Mutual respect.
- Prescription of specific medicines should neither be requested nor assumed.
- Transparency.
- Plurality of finance sources.

This Code came into force on 1 July 2008 and with the aim of guaranteeing its fulfilment and effectiveness, the pharmaceutical industry located in Spain agreed to incorporate the device in its organisation that those articles of the Code for Relations with Health Professionals that are applicable and subject itself to compliance control by the control bodies: the self-control panel; the Code of Practice Committee and the Code of Practice Surveillance Unit.

Both Codes share a common Regulation applicable to their control bodies, except as foreseen in their Article 9, on procedures for the communication of events and scientific meetings, and in Article 10 on the procedure for communication of studies.

CODE OF ORGANISATIONS OF PATIENTS "INDEPENDENCE, MUTUAL RESPECT, NO PROMOTION, TRANSPARENCY AND PLURALITY OF FINANCING"	
SPECIFIC ARTICLES	GENERAL ARTICLES
▪ **Art. 1. Prohibition of medicine promotion.** ▪ **Art. 2. Formalising agreements.** ▪ **Art. 3. Use of logos and registered materials.** ▪ **Art. 4. Editorial control.** ▪ **Art. 5. Transparency.** ▪ **Art. 6. Collaboration with one party.**	▪ **Art. 7. Hospitality and meetings.** ▪ **Art. 8. Rules and application of the Code.** ▪ **Art. 9. Consultation applications.** ▪ **Art. 10. Compliance control.** ▪ **Art. 11. Infractions and fines.** ▪ **Art. 12. Operational guides and cooperation agreements.** ▪ **Art. 13. Communicating and archiving decisions.** ▪ **Art. 14. Entry into force of the Code.**

Code of Practice Committee actions. Looking back, we must make a special mention of Juan Manuel Reol Tejada, who died in September 2008 and was member of the Code of Practice Committee since its creation in 2001. We would like to hereby pay tribute to him as a person of great professional worth and extraordinary human quality, who was dedicated to his work and gave personal commitment for many years, at any moment, to this Committee.

The Steering Committee of FARMAINDUSTRIA, in its meeting of December 2008, appointed a new member of the Committee, Dra África Mediavilla, to replace Dr Reol. She is a pharmacological doctor and since 1974 carries out her professional health care activity and teaching in the Clinical Pharmacological Service of the Marqués de Valdecilla University Hospital in Santander and in the Faculty of Medicine at the University of Cantabria. She was President of the Spanish Clinical Pharmacological Society and is currently also member of CODEM.

The self-regulation system for the Spanish pharmaceutical industry is made up of two Codes: Relations with Healthcare Professionals and with Organisations of Patients

As far as the Code of Practice Committee is concerned, it should be emphasised that during 2008 a slight fall in complaints was observed before the Committee with respect to 2007. As reflected in the figures which are shown below, 56% of the complaints presented were resolved through agreement between the parties as a result of the mediation work of the Code of Practice Committee, with only 35% of documents transferred to the self-control panel and 9% filed following a previous agreement at the Code of Practice Committee.

The number of complaints presented to the Code of Practice Committee for alleged breach of the Code was 23, mainly relating to the scientific content of promotional material and other promotional activities, one of them for violating the Spanish Code of Practice on Relationships between the Pharmaceutical Indus-

try and Patient Organisations. The following schematic brings together all the complaints recorded in 2008, grouped for different classification criteria:

COMPLAINTS PRESENTED TO THE CODE OF PRACTICE COMMITTEE	
Presented	23
COMPLAINANTS	
Member laboratories	14
Non-member laboratories	1
Code of Practice Surveillance Committee (USD)	8
COMPLAINED AGAINST	
Member laboratories	21
Non-member laboratories	2
RESULTS OF COMMITTEE MEDIATION	
Agreements	13
Remittance to Self-Regulating body	8
Pre-mediation agreement	2

Actions by the Code of Practice Surveillance Unit. The activities carried out by the Code of Practice Surveillance Unit (USD) during 2008 can be encompassed in three large areas:

1. Dissemination of the Spanish Code of Practice for the Promotion of Medicines;
2. Advice and cooperation;
3. Compliance control and application of the rules of the Code through preventive action and officially lodged complaints.

In relation to the dissemination of the rules of the Code, the following should be mentioned: i) active participation in national and international conferences with the aim of promoting the new Code for relations with patients' organisations; ii) organisation of conferences in Madrid and Barcelona on the self-regulations system for the pharmaceutical industry in Spain, as well as the joint organisation of the Pharmaceutical Marketing and Research Group (AIMFA) monographic seminars related to Article 14 studies on the Code of Healthcare Professionals; iii) the holding of bilateral meetings with the heads of department for promotion of medicines in the Autonomous Regions; iv) expansion of the practical case tests.

In-company training sessions have also continued to be held. These were started in 2007 and focused upon satisfying the training needs requested by the companies.

As far as advice is concerned and collaboration, the recognition at international level of our self-regulation system for the pharmaceutical industry in Spain was recognised with the holding in December of the *Sixth Code Compliance Network Conference of the IFPMA* made up of professionals from laboratories and associations belonging to IFPMA, with experience in applying codes in the sector. The meeting took place with the active participation of representatives of the World Health Organization, World

Self-Medication Industry, the Association for the Self-Regulation of Commercial Communications in Spain, and representatives of the pharmaceutical industry from Japan, South Korea, South Africa, India, Mexico, the United States, Turkey, Sweden, Portugal, Switzerland, the United Kingdom, France and Spain.

Also in 2008, the renewal took place of the FARMAINDUSTRIA Code of Practice Surveillance Unit as: i) member of the *EFPIA Code Steering Group,* the body responsible for monitoring the implementation and compliance of the EFPIA Code; ii) President of the Court of First Instance of IFPMA and Chairman of the Adjudication Group, the group of experts belonging to member associations and created by IFPMA given their experience in applying national codes to settle claims connected to the promotion of medicines.

At the same time, the USD has taken part in meetings and forums organised by FARMAINDUSTRIA with Autonomous Regions and communications media and has participated in the review, adaptation and improvement of internal procedures introduced by laboratories to guarantee compliance with the Code and legislation in the area of marketing of medicines.

Elsewhere, USD has given continual advice to pharmaceutical companies and involved third parties, mainly scientific companies, technical secretariats and service providers in general. During this year, it has processed seven binding consultations and published seven Circulars.

As far as control and prevention activities are concerned, the growing trend for preventive actions has continued with a notable reduction in the number of complaints placed before the USD (eight in 2008, compared to 18 in 2007).

And finally, in relation to communications, the analysis and checking of events and scientific meetings communicated in 2008 reached 3,388 (462 more than in 2007), an increase of over 13%.

CODE OF PRACTICE SURVEILLANCE UNIT						
	2004	2005	2006	2007	2008	ACUMULATIVE
	Apr.-Dec.	Jan.-Dec.	Jan.-Dec.	Jan.-Dec.	Jan.-Dec.	Apr. 04-Dec. 08
Events checked and analysed	945	1,747	2,199	2,926	3,388	11,205
Events studied without incidents	718	1,390	1,909	2,616	3,087	9,720
COMPLAINTS	**18**	**11**	**9**	**18**	**8**	**64 ***

* 11 concrete decisions by the Self-Regulating body in favour of the USD.
* 48 mediation agreements by the Code of Practice Committee recognising infractions and accepting corrective measures.
* 2 complaints filed on USD request.
* 1 not upheld by the Self-Regulating body.
* 2 awaiting review by the Code of Practice Committee.

Judicial processes. Three of the eight processes initiated by FARMAINDUSTRIA in 2006, reclaiming registration fees unpaid by some laboratories were following decisions by the Self-Regulating Body, was completed by a judgment in the interests of FARMAINDUSTRIA ordering the payment of outstanding amounts. The rest of the processes are still awaiting decisions by the courts.

Note: This table brings together data from the USD (annual and cumulative) from the start of its activity to 31 December 2008.

3.4. International Relations

3.4.1. EUROPEAN CONTEXT

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. EFPIA represents the voice of 32 national associations and 44 pharmaceutical companies in Europe.

AIMS Programme. During 2008, the activities of FARMAINDUSTRIA have concentrated on the development of the strategy defined in 2007 by the 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 this area EFPIA's priorities are directed towards reducing the inequalities in the access to medicine in Europe and encouraging good practices in Health Technology Assessment (HTA) procedures, limiting their improper use. With regard to this point, EFPIA actively participated in the completion of the work of the High Level Pharmaceutical Forum through its priority action group, of which FARMAINDUSTRIA forms a part, developing a group of basic principles amongst which stands out the clear distinction between the pricing and reimbursement processes and the HTA processes applied nationally. At the same time, the creation of a joint platform is noteworthy between the HTA and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and The Pharmaceutical Research and Manufacturers of America (PhRMA), with the aim of co-ordinating the actions of all the associations in this field.

Regarding the inequalities in the access to medicines, EFPIA has continued with the work of public awareness of existing inequalities amongst European Union citizens in the access to new medicines, evaluated with analysis tools such as the W.A.I.T. indicator or the Karolinska study on the differences in the access to oncologic medicines of European citizens, and which will be widened to other pathologies (osteoporosis, rheumatoid arthritis and multiple sclerosis).

Innovation

The priorities to act on in this area refer to strengthening the scientific base in Europe and improving the conditions for R&D on European soil, concentrating its efforts on the Innovative Medicines Initiative (IMI), whose first meeting was launched in 2008. Furthermore, the developments of the revision of Directive 609/86 on the protection of species of animals used in laboratories has been carefully followed, carrying out different meetings with members of the European Parliament and Commission, as well as communication acts intended to guarantee that the Directive balances, once implemented, animal welfare, the real needs of the research and the needs of the patients.

Mobilisation

The actions carried in this area refer mainly to information aimed at patients, encouraging them and all European citizens to adopt a more active role in managing their health, through better access to non-promotional, high quality information. In this sense, EFPIA has monitored and managed the process of public consultation and the later publication of the proposal of the Directive of the European Parliament and Commission that modifies, referring to public information in general on medicines requiring a prescription, Directive 2001/83/CE, which established a common code on medicines for human use, including those in what is called the Pharmaceutical Package.

The activities of FARMAINDUSTRIA in Europe have been principally channelled through EFPIA

Security

This strategic pillar has as a fundamental aim guaranteeing the integrity and security of the medicine supply chain in Europe, increasing the traceability of the medicines at a highly sensitive political time

The High Level Pharmaceutical Forum has as an objective increasing the competitiveness of the European pharmaceutical industry

and of that of public opinion with respect to the battle against counterfeit medicines. In this case, the participation of EFPIA was decisive in the public consultation launched in May by the Commission, prior to the publication of the proposal of a Directive of the European Parliament and Commission which modifies Directive 2001/83/CE relating to the prevention of counterfeit medicines entering the supply chain regarding their identity, history or origin. With the aim of guaranteeing that the objectives of this strategic pillar are reached, EFPIA has developed a medicine identification and codification pilot project which will start up throughout 2009 in Sweden.

Furthermore, the thirtieth annual reunion of EFPIA had as its main theme the growing threat that the entry of counterfeit medicines in the legitimate European supply chain supposes. In its final conclusions, EFPIA called on the European authorities to include measures such as the prohibition of repackaging medicines, or the implementation of a single identification system that will allow total traceability in future legislation relating to counterfeit medicines.

High Level Pharmaceutical Forum. The third and latest meeting of the High Level Pharmaceutical Forum took place on 2 October, 2008. This forum is a high level political platform created by The European Commission in the light of the G10 recommendations, whose aim is to increase the competitiveness of the pharmaceutical industry and its contribution to social objectives and public health, in which FARMAINDUSTRIA participates actively and directly through EFPIA.

After the presentation of these conclusions, EFPIA publically called on the institutions of the EU and the member states to guarantee that the recommendations made by the three groups that make up this platform be implemented rapidly. In this manner the limitation of the implementation of the Good Practices Principles in the pricing and reimbursement processes are considered to be vital steps, the limitation of the set prices of the medicines effectively sold in national territory (the principle of extraterritoriality in price control regimes), and a more flexible definition of the concept of added value in the pricing and reimbursement policies, that guarantees compensation for innovation. Resulting to be equally important is the implementation of the Principle of Good Practices in the evaluations of the relative effectiveness of the medicines, assigned to increase the quality and consistency of the Health Technology Assessments, carried out in Europe, as well as the Quality Principles on Information on Health, which advocate the right of the European citizens to receive non-promotional and high quality information on health and medicines, recognising the pharmaceutical industry as a legitimate source and establishing a series of requirements to evaluate the quality of the information. All these principles were, in fact, gathered together in the proposal of the Commission Directive on the Informed Patient.

In this area the decision of the European Court is noteworthy which reinforces the recommendation on the non-extraterritoriality of the prices of the medicines that have set prices. In this manner, on 16 September 2008 the Court of Justice of the European Communities pronounced judgment on the gathered matters C-468/06 to C-478/06 regarding the legitimacy of the pharmaceutical company GSK to provide local distributors in a member State (Greece) only with the necessary quantities to supply the national market, thus avoiding shortages produced by parallel trade. The Court declared that a pharmaceutical company, even when having a dominant position in the medicine market, can restrict the supply to certain wholesalers, providing them with normal quantities that they require to satisfy the needs of the Market of the member state concerned. This way, the Court confirmed that the company "should adopt reasonable and adequate measures in the need to preserve its own commercial interests" and at the time of evaluating if these measures are reasonable and adequate, it should be established if the orders of the distributors have a normal nature with respect to the needs of the market of the member state concerned and the commercial relationships previously held.

The remitting National Court will determine if the orders are of a normal nature. This sentence takes into account the specific characteristics that affect competition in the pharmaceutical sector in Europe, an area in which pricing and reimbursement processes are controlled in a large part by the Member States,

as well as the fact that parallel trade benefits only a few intermediaries and not the consumers of the healthcare systems of the member states.

'Pharmaceutical Package'. In December 2008 the European Commission launched a group of legislative initiatives known as the *Pharmaceutical Package,* comprising a Communication from the European Commission and three Directive proposals. In the communication, the Commission analysed the current state of the European pharmaceutical industry and proposed various alternatives with the aim of improving the access to new medicines by EU patients, through better transparency in the pricing and reimbursement processes and to give incentives to investments for new therapies, R&D, strengthening the cooperation with other countries such as the USA, Japan or emerging countries.

The proposals for directives include three types of initiatives:

1. The battle against the growing counterfeiting and illegal distribution of medicines in Europe through the various security systems that allows the identification, authentication and traceability of the medicines.

2. Patient access to high quality information on prescription medicine, recognising the role of the pharmaceutical industry as a legitimate source of information.

3. Strengthening and improving the transparency of the pharmacovigilence systems as well as intensifying the level of patient protection in Europe.

The European pharmaceutical industry favourably received that these initiatives expressly recognise their value and contribution as an industrial sector and as a guarantor of patient security. However, the industry regrets that the proposal on counterfeiting medicines does not include a total prohibition on their repackaging or manipulation, at the same time stating its will to work with the European institutions to guarantee that the security of the patients is not compromised. The legislative proposals will be submitted to be adopted to the co-decision procedure between the European Parliament and Commission, whose work will be predictably affected by the renewal of both institutions in June and November 2009, respectively. FARMAINDUSTRIA participates actively in following of these legislative proposals, forming part of the priority action team constituted in the heart of EFPIA, and conveying at the same time to the competent Spanish Authorities the position of the pharmaceutical industry in this area.

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. The preliminary report questioned the commercial practices of the innovating companies by understanding that these delay the entry of generics onto the market and block, through complex strategies of patenting, the entry of innovative competitor products.

In a press release, EFPIA refuted the reasons alleged by the Directorate General for Competition affirming forcefully and with empirical evidence: i) that the delays of the generics coming onto the market are not attributable neither to the abusive use of the system of patents/litigation nor to the incremental innovations –in fact, the entry of generics occurs almost immediately on the original product patent expiring, especially for the highest selling products in the main European markets– and ii) that the decline in the number of innovations is due to reasons very different from those alleged by the Directorate General for Competition.

From the date of the publication of the preliminary report, a consultation period of two months until 31 January, 2009 was opened, so that all the implicated parties could forward their allegations.

FARMAINDUSTRIA coordinated the different actions with EFPIA to guarantee that the interests of the associated companies were duly contemplated in the final report, whose publication is expected in June or July 2009.

Proposal of the "Cross Border Health" Directive. This legislative proposal is a consequence of the various sentences of the European Court of Justice in which the right of the patient to be reimbursed for healthcare they receive from any member State is recognised. The Directive has as an aim to provide a clear legal framework to exercise such rights, although its reach is today greater than initially intended. Amongst others, the proposal brings together aspects such as:

- A new decision body, called the Safe, Efficient and High Quality Healthcare Assistance Committee.
- A legislative framework for a European HTA network.
- New competences in the area of health for the Commission, under the umbrella of improving cooperation between member states.
- Electronic health and European prescription.
- Obligations on transparency and equality of health services available in National Health Systems.

The proposal of the Directive includes two sections that have a direct impact on the pharmaceutical industry:

1. Article 14, which refers to the incorporation of measures that guarantee the correct identification of the prescriptions in any of the member States, could give place to the introduction of the INN prescription in a generalised manner. The pharmaceutical industry has stated that the establishment of this system will require an evaluation from a medical, logistical, technical and legal point of view which will allow patients to assure their right to obtain the medicines prescribed by their doctor in any member State. For example, the problems that could arise from the prescription of medicines after leaving hospital or continuing treatment when the products are not available, cannot be reimbursed or are not included in clinical practice guides in other member states, make an exhaustive evaluation of the impact of this measure advisable.

2. Article 17 requires that the member States apply a set of good practices in the area of cooperation in the management of Health Technology Assessment (HTA), as well as the exchange of information between Member States. In this case, the European pharmaceutical industry supports the creation of a European HTA network in which all the interested parties will participate, including the pharmaceutical industry, whenever open, transparent parameters adjusting to internationally recognised Good Practices are guaranteed.

Revision of Directive 86/609 on Animal Protection. On 5 November, 2008, 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 homogenising 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, which actively participated in the developing of this proposal, highlighted in a press release the need to balance animal welfare, the realties of research and the needs of patients, underlining that Europe currently gives the highest standards of protection for laboratory animals in the world, and likewise recalling that 90% of the research carried out currently occurs without animals being involved, their use continuing to be essential for research and development for therapies destined to fight against pathologies such as Alzheimer's disease, cancer, Parkinson's disease, hepatitis, malaria, or multiple sclerosis. The work relating to this Directive will continue throughout 2009.

FARMAINDUSTRIA channels its participation in the international non-European context through IFPMA

European Biopharmaceutical Enterprises (EBE). During 2008 the activities of the European Biopharmaceutical Enterprises (EBE) Group of Companies focused on the actions of an *ad hoc* group of the High Level Pharmaceutical Forum with the aim of improving the access to Orphan Drugs, as well as its collaboration with the European Medicines Agency (EMEA) and the WHO in the development of an accelerated protocol for the authorisation of biological medicines.

In May 2008, FARMAINDUSTRIA brought about a meeting between the then Biotechnology Section of FARMAINDUSTRIA and the European Biotechnology Group, with the participation of their Executive Director and their President, where an exchange of opinions on identifying possible areas of mutual interest in the biotechnology field, and possible formulas of future collaboration were explored.

3.4.2. INTERNATIONAL CONTEXT

FARMAINDUSTRIA channels its participation in this context through its participation in the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), with which it held a bilateral meeting in September 2008. During this meeting the Spanish pharmaceutical industry, the activities and organisation of FARMAINDUSTRIA, the activities of the Unit for Deontological Supervision and the new Good Practices Code were analysed. In parallel, FARMAINDUSTRIA and IFPMA agreed to strengthen ways of collaboration through multilateral meetings with the representatives of Spanish Diplomacy in Geneva (where important international organisations have their headquarters, such as WHO, WTO and WIPO), or the organisation of conferences and seminars that group together the associations and representatives of the pharmaceutical industry of the Spanish speaking countries of IFPMA and health authorities of the Latin American countries.

FARMAINDUSTRIA actively participates in all the IFPMA committees, whose work was carried out throughout 2008 essentially in a double direction: the closure and follow up of the IGWG process and the battle against counterfeiting medicines world wide.

IGWG. 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 illnesses 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) has as a mandate to elaborate a strategy and an action plan, that were presented at the 61st General Assembly of the WHO held in May 2008.

The work of the IGWG concluded with the publication of a global strategy adopted by resolution 61.21 (passed unanimously at the 61st WHO Assembly), and the publication of a proposal of an action plan, which is still pending consolidation due to the lack of consensus between member States. Resolution 61.21 asked the WHO for a short-term continuation of the IGWG process that will consider the following elements:

- Prepare a "quick start programme", detailing budget needs and the immediate implementation of the global strategy elements that could be included in it.
- Finalising the most important elements of the action plan, including a cost estimate.
- Establish an Expert Working Group that will examine the current financing and coordination of the R&D as well as possible proposals to look for new sources of financing that could give incentives to research and development in low and medium income countries, reporting on the results of the work at the WHO Assembly in 2010. The Group was constituted in November 2008 and consists of 24 members (11 belonging to developed countries and 13 to developing ones) all of them from distinct fields (civil servants,

academics, NGOs and think tanks), with politically neutral positions, thus forming a balanced group which has been positively received by the majority of the players. The pharmaceutical industry, through IFPMA, has made available to the Expert Group, and is already providing them with continuous information on the projects of the pharmaceutical industry in developing countries, for which a close and fluid collaboration is expected during 2009 in the development of its work.

The battle against counterfeit medicines worldwide. The battle against counterfeit medicines was the central theme of the Assembly of the WHO held in May 2008. The Director General of this organisation, Margaret Chan, in her inaugural speech made clear that the counterfeiting of medicines is a first grade public health problem, at the same time damaging the credibility of health systems. The number of incidents detected in 2007, according to this body was 1,500, ten times more than in the year 2000.

During this Assembly, the Nigerian delegation presented a resolution for approval that demanded greater support from the member States to maintain the continued leadership of the WHO in the battle against the counterfeiting of medicines. However, this resolution was not passed and the debates on this area were postponed for the Executive Committee and the General assembly of the body in 2009.

Furthermore, IMPACT (a multi-sector group coordinated by the WHO whose aim is to combat counterfeiting worldwide) held its third annual assembly in December 2008 in Tunisia, agreeing to a new definition of "counterfeited medicine" that separates this concept from the conflicts with patents, for its future presentation to the WHO Executive Committee in 2009.

Bilateral meetings. As in previous years, FARMAINDUSTRIA has organised diverse bilateral meetings with the Italian (Farmindustria), Portuguese (Apifarma), Swiss (Interpharma), British(ABPI) and French (LEEM) Industry Associations. In all cases, the respective delegations had the opportunity to exchange points of view on the development and evolution of their respective markets and other common themes of interest, such as the measures to hold down costs, multi-sector agreements, or recommendation number 6 from the G10 Group and Article 90 of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, as a model to consolidate the concept of the non extraterritoriality of the pricing control systems of the European Union.

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4. Farmaindustria Foundation

The Farmaindustria Foundation has kept to its line of actions focused on developing, in accordance with its aim, 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 health education for the population.

IV Award for the Best Initiatives for Patient Service. The meeting for these IV awards had an extraordinary reception as more than 230 candidates were presented and evaluated by a multidisciplinary jury, made up of representatives of all the sectors relating to the world of the patient, health and medicine.

As usual, the Real Fábrica de Tapices in Madrid was the scene for the handing out of awards, held on 16 December, an event that gathered together authorities and institutional representatives of the academic world and of the pharmaceutical industry.

'Patients' Magazine (*Pacientes*). During 2008 the publication of the *Patients* magazine continued as a main communication channel in patient service and of patient associations. In 2008 three editions came out. The first centred on the Biomedical Research Law passed in 2007. The second centred its attention on the television series whose plot revolves around healthcare themes, and through patients, doctors and television professionals, carrying out a check on these type of programmes and especially the influence they have on the public. The third of the issues edited in 2008 revolved around health on the web and how the irruption of Internet in health areas has meant a real revolution.

Other activities. Finally, on another note, throughout 2008 the Farmaindustria Foundation has continued to sponsor courses and seminars, amongst which should be pointed out the V Meeting of the Pharmaceutical Industry, organised by the Menéndez Pelayo International University, as well as the collaboration on the 3rd International Meeting of Translational research and Individual Medicine, organised by the Fundación Jiménez Díaz.

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5. Sigre MEDICINE AND THE ENVIRONMENT

Sigre Medicine and Environment is a selective collection system for medicines started up by the pharmaceutical laboratories to help citizens dispose of containers and left over medicines that they have in their homes, guaranteeing that this waste receives the right environmental treatment.

In this sense AEMPS, through the Resolution of 5 March, 2008 confirmed that the inclusion of the Sigre symbol on the labelling of medicines dispensed through the pharmacy office, allows the pharmaceutical laboratories to comply with the health regulations (Article 15.6 of Law 29/2006 and Article 62.6 of R.D. 1345/2007), relating to the obligation of participating in systems than guarantee the collection of waste medicines generated in households.

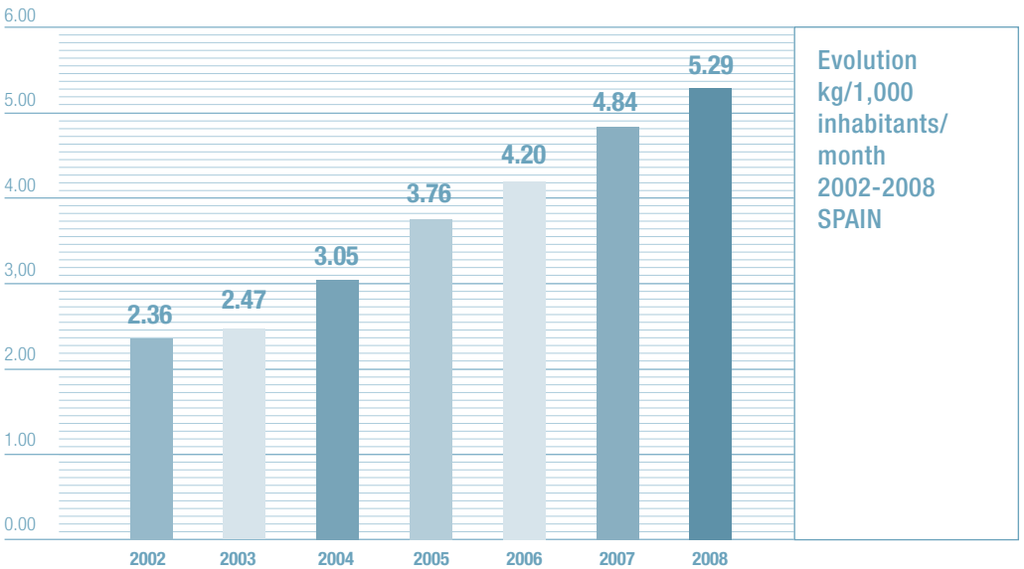
This way, through its participation in Sigre, the pharmaceutical laboratories fully comply with environmental regulations as well as health regulations.

SIGRE
Medicamento y Medio Ambiente

Environmental Declaration 2008. As in each year, SIGRE presented in March 2008 its Environmental Declaration to all the Environmental Ministries.

This declaration includes the information corresponding to more than 15,500 different commercialised presentations last year by adhered laboratories, the amount of waste collected in the more than 20,500 SIGRE points and the environmental treatment applied to each one of the fractions that are obtained in the waste Medicines classification Plant.

According to that arising from this declaration, the citizen collaboration with medicine recycling continues to increase, given that in 2008 a monthly average of 5.29 kilos of containers and left over medicine was deposited in SIGRE Points in pharmacies for each thousand inhabitants, 9.30% more than the previous year.

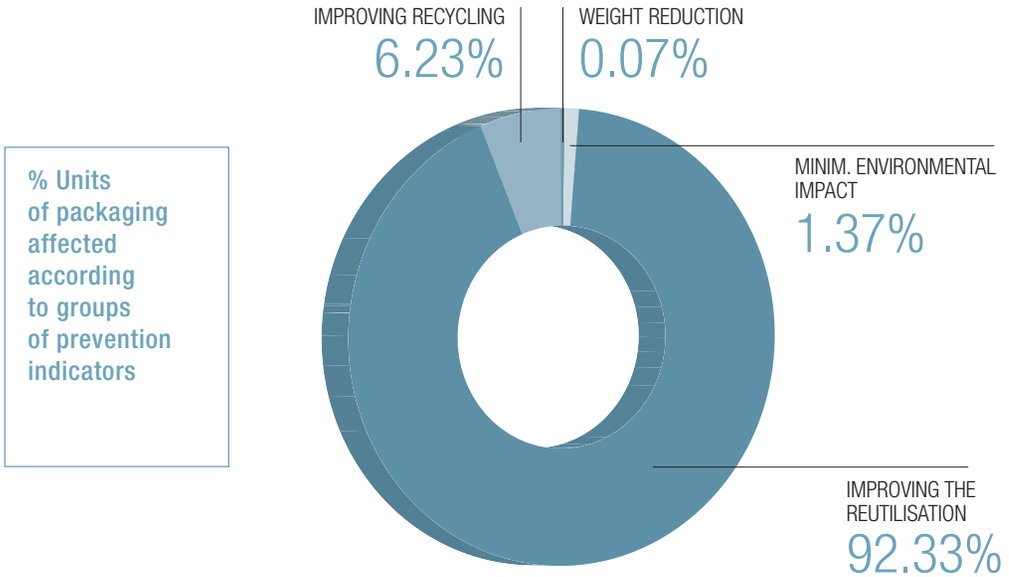


The prevention work of the pharmaceutical industry through SIGRE. The pharmaceutical industry has maintained its commitment to reduce the environmental impact of its packaging during 2008. According to that arising from the Third Report of the Monitoring of the Business Prevention Plan (PEP) 2006-2008, the laboratories have applied a total of 94 prevention measures incinerating more than 26.4 million containers, making these presentations more respectful of the environment by reducing their weight and volume or using more ecological materials.

The strict technical and security conditions that have to be complied with, as well as the health regulations, have made the application of these prevention measures more difficult in medicine packaging. In spite of that, the results obtained in the three year period 2006-2008 places the percentage reduction of the Kr/Kp indicator (weight of container/weight of product) at 0.51%, which has allowed it to meet the objective of a global reduction anticipated in the plan approved by environmental administrations.

PERCENTAGE OF GLOBAL REDUCTION (PEP 2006-2008)	
Objective proposed (PEP 2006-2008)	Objective achieved Years 2006-2008
≥ - 1.50% and ≤ 0.75%	0.51%

The involvement of the pharmaceutical industry in this field continues to grow as time goes on, even if the measures to be applied in the future should be evermore innovative to be able to continue to advance in the commercialisation of more ecological products.



Communication campaigns. In 2008 and using Nature, like it has always been, SIGRE began a new information campaign with the aim of making public opinion aware of the importance of the responsible use of medicine, from the environmental point of view as well as from the point of view of health. The new campaign transmits the effort that the pharmaceutical industry is making in the environmental area, an effort than should carry on into the actions of the citizens to finish, between all of us, the life cycle of the medicine in a correct manner. Thanks to this joint work, the intention is to alleviate the effects of climate change. This campaign is another initiative from the pharmaceutical industry showing its concerns for the environment, from research to recycling.

The involvement of the pharmaceutical industry in improving the environment continues to increase

Also in 2008 SIGRE, with the Castilla & León government, developed in this region a campaign called *Medical prescription + environmental prescription,* aimed at informing and involving doctors and nursing personnel in the recycling of medicines. As a consequence of the campaign, these professionals have been giving out to their patients along with the prescription, a card with health and environmental advice on the correct use of the medicines, as well as simple indications about how to keep them properly, their correct use and correct disposal.

The campaign, which will spread progressively through other regions, has obtained an excellent reception in Castilla & León. It thus confirms the fact that 92 % of doctors and nursing personnel in health centres have classed the information received on SIGRE, its operation and its aims as adequate or complete, thus being able to later advise their patients.

Laboratory Workshops. Madrid and Barcelona held in June 2008 the VIII SIGRE Information Workshops. This event has become one of the essential environmental events of the sector, this edition again having the presence of important representatives of the pharmaceutical industry. The results obtained in 2007, the main new legislation on the environment, as well as the prevention measures, the environmental impact of medicines or the importance of communication were some of the themes dealt with on this occasion.

Forums and congresses. Last year, SIGRE participated in the ninth edition of the National Environmental Congress (CONAMA), Summit on Sustainable Development.

Besides their presence through a stand, on this occasion SIGRE signed a cooperation agreement with the CONAMA Foundation, actively collaborating in the organisation of this congress through Technical Working Groups on health and the environment, environmental education and corporate social responsibility.

The presence in this professional forum, the most important environmental event held in our country, allows disseminating to all the visitors the social commitment of the pharmaceutical industry in the environmental area and the advances made in the field of prevention and in the environmental treatment of medicines and their containers.

Likewise, SIGRE participated in the XVI National Pharmaceutical Congress, carrying out a pioneering initiative consisting of obtaining for this congress the AENOR certification as a Compensated Emissions Event.

For the first time in our country, this certification was granted to a national congress for the compensation of greenhouse gases deriving from the event itself, in line with the Kyoto Protocol directives.

On this occasion, the emission rights acquired by SIGRE were assigned to an energy generation project from biomass in Thailand, thus strengthening the pharmaceutical sector's commitment to sustainable development.


Certificado AENOR Medio Ambiente
CO_2 Compensado

16 CONGRESO NACIONAL FARMACÉUTICO

AENOR

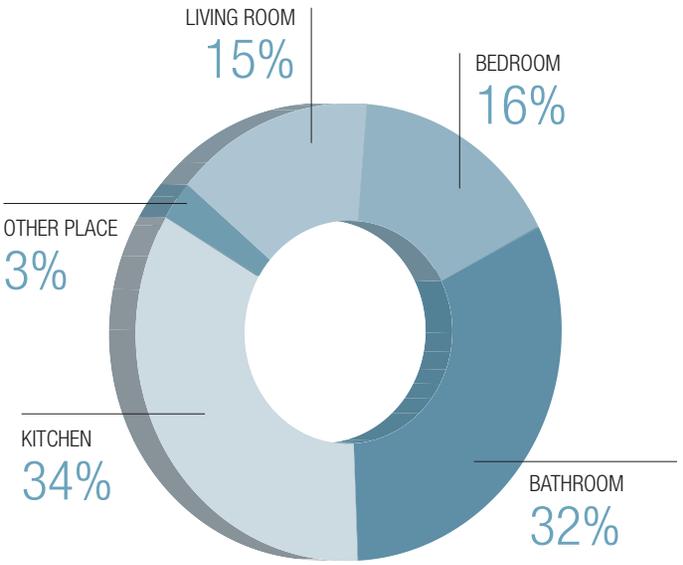
SIGRE has headed various campaigns and information sessions in Spain in the area of environmental protection

Collaboration agreement. SIGRE has become a reference point for those countries who want to implement a waste management system for medicines of domestic origin. Amongst the contacts developed in 2008 a highlight is the agreement signed with the Chamber of the Pharmaceutical Industry of the Association of Columbian Businessmen (ANDI), where SIGRE has agreed to collaborate in the development and implantation of a system of collection and management or waste medicine in that country. For that, SIGRE will lend its experience and knowledge in the management of these types of waste, and will advise ANDI on aspects relating to the logistical system, the awareness and whatever other elements that helps to implement a specific system for Columbia.

Opinion polls. 29% of Spanish households keep some medicine in an incorrect manner, principally without its box or patient information leaflet. This and other data come from the study carried out by SIGRE in 2008 to analyse the sanitary habits of Spanish society and the way they conserve medicines in their own homes.

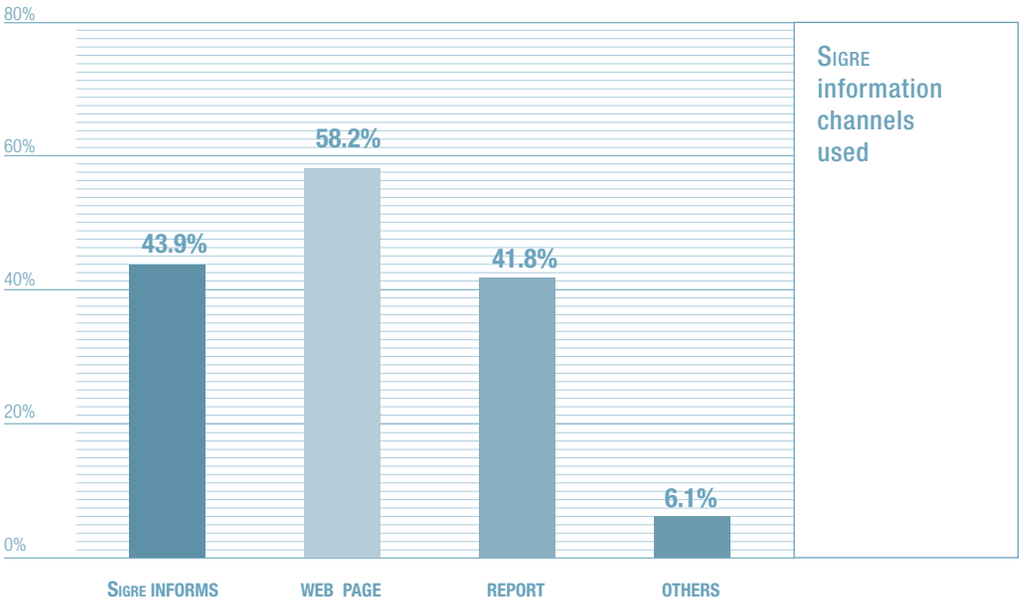
Among the results obtained highlights are the average number of medicines that make up the household medicine cupboard in a Spanish home is 12, of which 5 or 6 are regularly used by the members of that family. The study also signalled out that 3 out of 4 questioned consider that self-treatment with remains of medicines from finalised treatments that have been kept in the cupboard, could bring about some health risk.

Place where medicines are normally kept



SIGRE is an international point of reference in the management of waste medicines

Likewise, in the past year SIGRE carried out a third opinion poll amongst those responsible for the environment in the pharmaceutical industry. Among the results obtained in the survey, in which 101 pharmaceutical groups or companies participated, are highlighted: i) that the activities of SIGRE continue contributing to improving the image of the pharmaceutical industry, ii) that the www.sigre.es website has become one of the main sources of information and iii) that the awareness of the effort that the pharmaceutical industry is carrying out in this area continues to be valued positively.



02

THE PHARMACEUTICAL INDUSTRY IN SPAIN AND WORLDWIDE

02.

1. THE PHARMACEUTICAL INDUSTRY IN EUROPE

As was expected, 2008 has been a very difficult year for the main global economies especially for the most developed ones, and the European economy has not been an exception. To be precise, in 2008 the GDP of the EU-27 grew by 0.9% in real terms (2 percentage points less than the previous year) and that of the Eurozone 0.8%, compared to the 2.6% that was recorded in 2007.

At the time of producing this report, countries such as Germany, the United Kingdom, Italy, Spain, Holland, Portugal, Denmark, Finland or Sweden have already entered into recession, after recording at least two quarters of negative growth, whilst others such as France are on the brink of recession.

The economic difficulties have also been reflected in the most important structural indicators: in 2008 the unemployment rate in the EU-27 went from 6.8% to 7.4%, its evolution being worse in the Eurozone, where it went from 7.2% to 8%. In absolute terms, the increase in the number of unemployed in the Euopean Union throughout the year is estimated at 1,665,000 people.

With regard to the trade deficit, this increased in the EU-27 by 25.4% whilst the Eurozone went from a position of surplus in 2007 (15,800 million euros) to that of a deficit in 2008 (32,100 million euros), as a consequence, among other factors, of the strong appreciation of the Euro[1] against currencies like the Dollar or Pound Sterling, which notably affected the export trends of the Euro Zone.

In accordance with the known macroeconomic data and what is becoming known from the first months of 2009, it is without doubt that the financial and credit crisis originating from the subprime mortgages in the United States in the second half of 2007 has had a much wider reach than that initially expected and has ended up infecting the whole international financial system. This has had serious repercussions for credit, which has provoked a considerable contraction in consumption and investment. Added to all this has been the severe fall in the value of real estate assets, which have ended up putting financial institutions in serious difficulties and with that the whole financial system as well. If all sectors have been affected, probably the automobile and construction sectors have been, together with the financial sector, those most damaged by these economic difficulties.

All these company problems have had the following impact on their annual accounts, which inevitably, has been reflected in the market valuation of these companies. To be precise, through 2008 the Eurostoxx 50 index has fallen by 44.3%. By sector, the valuations of the companies that make up Eurostoxx financial fell by an average of 65%, while the construction and automobile sectors went down by 48% and 45% respectively.

At the date of this report been finalised, and despite the general situation of deterioration previously described, there seems to be unanimity in that the worst phase is yet to arrive. In fact, the principle international bodies (IMF, World Bank, OECD, CEB) expect a considerable contraction in the European economy in 2009, that they estimate to be between -3.2% and -4.1% for the Eurozone, with growth around 0% and -0.3 in 2010, meaning that the recovery will not arrive, in the best scenario, until well into 2011.

However, sight must not be lost that the pessimism about the future economy is not restricted only to Europe, but in 2009 a contraction of the world economy is expected of between -1% and -2%, with GDP falls forecast of between -2.6% and -4.0% for the USA and -5.8% and -6.6% in Japan.

Concentrating on the European case, it has to be sated that against this critical global situation a series of concerted measures between the different members of the EU to support the most sensitive sectors of the economy have been taken, especially the financial sector, and very expansive fiscal and monetary policies have been carried out.

1 The appreciation, throughout 2008, was, in terms of the average annual exchange rate, of 7.3% against the US Dollar and 16.4% against Pound Sterling.

The pharmaceutical industry is facing up to the crisis better than other sectors more dependent on the economic cycle

In the fiscal area, each country has adopted its own battery of stimulation measures directed fundamentally at protecting the banking sector and reactivating the concession of loans to manage to get the normal functioning of the economy to pick up. Without doubt, all these measures have a very high cost for the state treasuries, which have contributed to these public deficit levels again increasing in 2008 after four consecutive years of falls in Europe. More precisely, the latest predictions from the European Commission put the public deficit in the Eurozone at -1.7%% in 2008 and -4.0% in 2009, compared to -0.6% in 2007. As can be seen, the present events, budgetary discipline and the Stability Pact have been pushed into the background, and, as a consequence, considerable increases in public debt are beginning to be seen after some years of being relatively controlled.

In the monetary area, due to the seriousness of the situation some very expansive policies have been adopted to try to reactivate the economy and cheapen access to financing. Within the European context, the most aggressive in this sense has been the Bank of England, which reduced in 2008 the official interest rate by 350 base points to leave it at 2%. Concerning the CEB, although in a more moderate way, it also reduced official interest rates in 2008 from 4.00% to 2.50%. These reductions have continued in the first quarter of 2009, which has led to, at its closure, the interbank interest rate (Euribor) being at the lowest levels in its history.

Besides the fall in the Euribor, the continuing fall in inflation which in 2008 in the Eurozone went from 3.1% to 1.6%, has not only given a bigger margin for manoeuvres in the monetary policies of the central European banks, but also that it is a second factor which is contributing to alleviate the financial situation of consumers. However, lately, the general increase in prices in the Eurozone has reached levels that are too low (only 0.6% in the first quarter of 2009) and the phantom of deflation is now another of the threats that hangs over economic recovery.

Summarising, 2008 and more exactly the second half, has begun to feel the intensity of the effects of the economic crisis, whose full implications are still unknown, although a truly difficult two years are expected (2009-2010).

Despite no economic sector being untouched by the situation described, it is no less certain that sectors such as the pharmaceutical sector are less dependent on the economic situation and its development, and is affected more by other factors such as the implications of the social protection policies in each country and the measures adopted by the distinct States to make such policies financially sustainable.

This has caused that the industry to bear up to the crisis better than others, as is reflected in the fact that it has not had to ask for state help to assure its viability and that the market has punished the valuation of its companies less. It serves as an example that in 2008 the Eurostoxx pharmaceutical index, which brings together the 20 main traded companies of this sector in the European Union, has fallen 19%, which constitutes a relatively moderate figure if it is compared with the 44% by which the general index fell.

However, the fact should not be ignored that the sector is facing considerable difficulties such as the public budgetary restrictions and the imminent ending of the industrial protection period of high consumption products that will be difficult to replace, which will no doubt affect the future growth of the market. Proof of these difficulties are the workforce cuts that various pharmaceutical companies have announced and the concentration process that the sector is experiencing –which has seen some of the most important mergers and takeovers in the business world in recent months– in search of optimising the respective cost structures and product portfolio of the different companies to face up to in better conditions the difficulties that the market presents.

The market data below confirms what has been exposed before. Effectively, in the following diagram it can be seen how the growth of the main European pharmaceutical markets in 2008 has been fairly modest placing it on average at 2.2 % which means 1.4 points less than the previous year.

EVOLUTION OF THE PHARMACEUTICAL MARKET IN THE MAIN EUROPEAN COUNTRIES

Countries	Variation on previous year (%)		% Sales of total 5 countries
	2007	2008*	2008
Germany	4	4	30.8
France	5	0	26.8
United Kingdom	3	2	14.0
Italy	-3	1	15.0
Spain	8	4	13.4
TOTAL 5 COUNTRIES	**3.6**	**2.2**	**100.0**

(*) Data 12 months to November 2008 vs. data 12 months to November 2007.
Source: FARMAINDUSTRIA from IMS Retail Drug Monitor.

According to the data that IMS presents it can be seen how France and Spain have recorded a clear moderation in their rate of growth, whilst Germany remains stable at 4%, the United Kingdom reducing slightly and Italy improves its performance, although the Transalpine country only showed growth of 1%, despite starting off from a 3% fall in its market in 2007.

The pharmaceutical market in France and Spain has registered a sharp moderation in its rhythm of growth in 2008

In Spain, the industrial pharmaceutical sector does not have much weight in the national GDP, but its peculiarities (a strongly innovative sector, R+D intensive and highly productive) translates into sustained increases of added value that contributes to the economy of the country, contrary to what will happen (in fact, it is already happening in the current situation) with some sectors of low productivity and a lot of weight in GDP which are going to be greatly affected by the economic crisis. For that reason, and excepting currently unforeseen reasons, the growth in the pharmaceutical industry will be, in percentage terms, higher than the Spanish economy in 2009, which is already talking about a fall that could reach -3.0%.

This fact, linked to fulfilling the intentions and commitments recently expressed by FARMAINDUSTRIA to the Government and to Spanish society in the way to intensify R+D efforts, internationalisation and qualified employment, which will mean in 2 or 3 years a notable increase in the weight of this industry in the Spanish economy.

02. 2. THE PHARMACEUTICAL INDUSTRY IN SPAIN

2.1. R&D&i

R&D&i constitutes a fundamental factor in the competitiveness of an economy and is one of the determinants of future growth. In times like the present, marked by economic difficulties, it is more necessary than ever to advocate a sustainable growth model based on high productivity and R&D intensive sectors.

The conclusions of the recent study of the Centre for Industrial Technological Development (CDTI), *Impact of R&D&i in the Spanish productive sector*[2] supports this assumption: the study assures that the companies that invest in R&D&i achieve as a return, amongst other competitive advantages, higher productivity (+16 percentage points compared to non-innovating companies), a higher grade of internationalisation (their export capacity will improve by 18 p.p.), a higher capacity to create employment (+2p.p) and besides has a significantly higher probability (+15 p.p.) of increasing its product portfolio.

2 The full text of this report can be consulted at http://www.cdti.es/index.asp?MP=35&MS=0&MN=1&TR=C&IDR=34&idCategoria=6&accion=si

The pharmaceutical industry is the leader in expenditure and investment in R&D in Spain

For that reason it is nor surprising that the more developed countries give great importance to policies that contribute to encouraging investment in research activities. In this sense, the European Union, through the Lisbon strategy, proposes to reach in 2010 two fundamental objectives in the area of R&D:

- Increase expenditure on R&D until it reaches 3% of the European Union GDP.
- Achieve that at least two thirds of this expenditure comes from the private sector.

However, the said objectives will not be easy to meet. At the close of 2007 the EU-27 countries invested in R&D the equivalent of 1.83% of their GDP, with a business financing percentage of 54.5%.

Regarding our country, the situation in the area of R&D effort is far from what is desired and constitutes one of the main weaknesses of our economy. At the end of 2007, Spain invested in R&D the equivalent of 1.27% of its GDP, which places us not only significantly below the European average, but also below countries such as Slovenia or the Czech Republic which have less developed economies than ours.

It has to be remembered however, that in recent years a considerable effort is being made to increase our R&D investment and that this has been reflected in the fall in the difference in the area of research with the EU-27 average which, measured as a percentage of research expenditure over GDP has gone from 0.98 points in 1997 to 0.56 points in 2007.

However, a lot remains to be done. Our technological deficit is also evident from many other indicators. For example, our high technology export quota (4.9%) does not even reach a third of the average export quota for this type of product in the EU-27 (16.7%), which is a good demonstration of the scarce competitiveness of our technological sector.

Parallel to this, the latest data on the national technological balance published by the Bank of Spain can only affirm our high dependency on imported technology, having recorded a deficit of 1,646 Million Euros. Thus the balance of royalties reflects an annual flow of income for the use of Spanish patents of 539 million euros, whilst the payments of our country for the use of patents from the rest of the world amounted to 2,185 million euros, resulting in a coverage rate of only 25%.

The world ranking of innovation that the World Economic Forum produces annually also shows the deficiencies of our country in this field. In this ranking Spain occupies the 39th position in the area of innovation, an inappropriate position for a country that is the eight economy in the world.

To alleviate the highlighted deficiencies, to accelerate our technological convergence with Europe and collaborate in reaching the Lisbon objectives, the Government adopted in July 2005 the Programa Ingenio 2010, which constitutes one of the fundamental axis of the National Reform Plan and assumes two fundamental commitments:

- Increase public and private investment in R&D until it reaches 2% of the GDP in 2010.
- Increase the business participation until it finances 55% of total R&D investment in 2010.

Both objectives are closely linked, as for reaching the objective of 2% it is necessary that the private sector acts as motor and main financier of research, especially in a context such as the present in which policies to encourage spending have the margin for manoeuvre of the public sector almost exhausted.

In this sense, observing the financing structure of R&D expenditure in the three big worldwide economic blocks, a clear correlation between research effort and the level of prominence of the private sector in financing these activities can be clearly observed.

EXPENDITURE IN R+D ACCORDING TO THE SOURCE OF THE FUNDS

Countries	Expenditure in R&D (% /GDP)	Origin of the funds (*)		
		% contrib. Priv. S.	% contrib.Pub. S.	% >Foreign and others
Japan	3.32%	76.1	16.8	7.1
USA	2.61%	64.9	29.3	5.8
EU-27	1.84%	54.5	34.2	11.3
SPAIN	**1.20%**	**47.1**	**42.5**	**10.4**

(*) The breakdown of the funds according to their origin in Japan correspond to 2005 (latest published data).
Source: Eurostat.

Compared to the three big economic blocks, private R&D investment in Spain is much more modest, representing only 47% of the total, compared to 76% in Japan, 65% in the USA or 55% in the EU-27. Furthermore, far from improving or achieving advances in this aspect, the percentage of R&D investment financed by the private sector in our country is at the moment the lowest that it has been since 1997. It is therefore essential to encourage and carry out policies for incentives for private R&D investment, which will without doubt contribute to achieving the strategic objectives of the Plan Ingenio 2010. For that reason, the contribution of the pharmaceutical industry is hankered after, which is the industrial sector leader in R&D, as was seen in the latest results of the *Statistics on R&D activities* published by the INE and referring to 2007, amongst which are highlighted:

- The pharmaceutical sector is, by a big difference, the industrial sector that invests most in research in Spain and the second sector in importance in the whole Spanish business fabric (after the R&D Services branch). In 2007 the pharmaceutical companies set aside for research more than 884 million euros, way ahead of the rest of the more innovative industrial sectors, in such a way that the pharmaceutical sector represents 18.5% of the total R&D expenditure carried out in the whole of Spanish industry. This percentage is particularly significant if we take into consideration that the sales of the pharmaceutical industry only represents 2.2% of the industry total. Seen from another angle, the pharmaceutical industry dedicates 6.5% of its sales volume to R&D, whilst industry as a whole sets aside on average 0.8%.

- The pharmaceutical sector heads the industrial ranking in intramural expenditure (research carried out internally in the company) as well as extramural expenditure (research contracted to third parties), this last area where it is the absolute leader among the business sectors (industrial as well as the rest of the economic activity branches).

- The pharmaceutical industry heads, together with machinery, the creation of employment in research[3] with 4,521 professionals dedicated to these tasks full time, which represents 11.4% of the total for the whole of the industry. In the same manner, the biomedical industry also heads, along with machinery and mechanical equipment, the contracting of researchers, having on the workforce 2,153 professionals exclusively dedicated to R&D tasks, 575 of which are women. In this sense, the pharmaceutical industry is, by a big margin, the industrial sector that employs the highest number of women in research, 2,890 or in the same manner, 26.1% of total female employment in research generated by the whole of the industrial sectors.

3 Data on employment
Full Day Equivalent (FDE).

R&D ACTIVITY OF SPANISH COMPANIES (2007)					
Sector	Personnel in R&D*	Expenditure on R+D (mill. €)			
		Internal	External	Totals	% incr. s / 2006
Total industry	39,748	3,586.08	1,198.65	4,784.73	6.8%
Aerospace		266.69	223.20	489.88	-24.7%
Automobile	2,654	253.96	197.01	450.97	-0.1%
Pharmaceutical industry	4,521	616.67	267.67	884.34	4.8%
Radio, TV, communications	1,622	120.42	7.66	128.08	-4.3%

(*) Personal Full Day Equivalent (FDE).

Source: FARMAINDUSTRIA from INE (Statistics on R&D activities 2006 and 2007).

It is fundamental not only that research is carried out, but also that it gives results and contributes to the economic development of the country. One of the indicators of efficiency of a research sector is the percentage of companies that request a patent in a set period of time, over the total of companies that carry out R&D tasks in that sector. This indicator is of great relevance given that Spain is notably behind in this area with respect to the rest of the European Union. So, on the basis of this indicator, the pharmaceutical sector would be the second most efficient industrial (and business) sector (behind the Other Transport equipment sector), given that 29.5% of the pharmaceutical companies that carried out R+D in 2007 registered a patent in the period 2005-2007.

Another interesting reflection is to study the relationship between the growth in sales of a sector and the increase in its R&D investment over long periods of time. In this sense, it has to be pointed out that the average growth of investment in research of the pharmaceutical industry throughout the last ten years is, within the more traditional research investigation sectors, that which presents the greatest positive differential with respect to the average growth in sales in the same period, which demonstrates the clear advocating of R&D in the pharmaceutical industry. Pharmaceutical research is, furthermore, constant and sustained in time, which contrasts with other also intensive research sectors but which are more cyclical in this aspect.

ANNUAL AVERAGE RATE OF CHANGE (AARC IN %) (1997-2007)		
Sector	Net Revenue	Expenditure on R&D
Total industry	6.8	7.8
Aerospace	12.8	13.3
Automobile	4.6	3.0
Pharmaceutical industry	6.6	10.2
Radio, TV, communications	2.3	-3.9

Source: FARMAINDUSTRIA from INE (Industrial Survey of Companies, Survey on Innovation Technology and Statistics on R&D Activities).

Finally, the data earlier pointed out shows the extraordinary strategic importance of the pharmaceutical sector in the area of research in our country, not only for the magnitude of the resources assigned to these activities, but also for its high and sustained rate of growth, the efficiency in the management of resources and the capacity of the sector to generate highly qualified employment.

At the same time, the recent commitment expressed by the pharmaceutical industry with the Government and Spanish society constitutes, without doubt, an important milestone that will contribute to the pharmaceutical industry increasing its R&D investments in Spain. In this area, the pharmaceutical sector has taken on the commitment to increase its investment in research by at least 15% on average annually through the 2009-2011 three year period, which will mean an investment in three years of 3,600 million euros in our country.

However, a high risk business model as is the pharmaceutical sector, characterised by a process of long research cycles, which are evermore expensive and which are submitted to growing demands from the regulatory bodies, needs a stable regulatory framework that will allow the companies to adequately plan their investments.

In this sense a recent milestone has to be highlighted which can help to create this environment of stability and predictability that the pharmaceutical sector needs to exploit all its research potential, as has been the repealing of the temporary limit of the deduction of Corporation Tax for R&D&i investment whose total abolition was anticipated for 1st February 2012. Thus, the Royal-Decree-Law 3/2009 of 27th March, for urgent measures in tax, financial and insolvency matters faced with the development of the economic situation, published in the BOE of 31 March, suppresses this temporary limit and establishes the continuity of those deductions.

To sum up, and in accordance with that expressed, the pharmaceutical industry is configured, given its condition of an industrial sector leader in R&D, as a key sector, of enormous strategic importance for the growth and economic recuperation of our country.

2.2. Internal market

The sales of specialised pharmaceuticals in Spain during 2008 recorded an increase of 5.6%, reaching a figure of 13,948.9 million euros at ex-factory price (EFP). 75% of these sales were carried out in pharmacies and the rest through hospitals.

INTERNAL MEDICINE MARKET (EFP, MILLIONS OF €)

	Pharmacies [1]	Incr. (%)	Hospitals [e]	Incr. (%)	Total	Incr. (%)
2006	9,258.97	6.2%	2,894.74	10.5%	12,153.71	7.3%
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%

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

The total pharmaceutical market in Spain grew by 5.6% in 2008

Regarding sales through pharmacies, the prescription medicines have increased their market share, reaching 96.7% of the total, the remaining 3.3% corresponding to over the counter medicines, whose sales have witnessed a notable fall of 13.1% in units and 9.9% in value, resulting from the relative loss of weight of these medicines in the national pharmaceutical market.

In 2008, the prescription market was affected by a new reference price order

MEDICINE MARKET IN PHARMACIES (EFP)

	Units (thou.)	Incr. (%)	Value (thou. €)	Incr. (%)	Av EFP	Incr. (%)
Prescription	1,169,591	1.7%	10,109,666	5.0%	8.64	3.2%
OTCs	106,377	-13.1%	348,995	-9.9%	3.28	3.7%
TOTAL	**1,275,967**	**0.3%**	**10,458,661**	**4.4%**	**8.20**	**4.1%**

Source: FARMAINDUSTRIA from IMS.

As far as the prescription market is concerned, in 2008 this has been affected by the coming into force of a new reference price order (Order SCO/3867/2007), which has added 14 new groups to the Reference Price System (RPS).

The impact of this new order was less than that which was enacted in 2006, which affected the prices of 136 groups. Still, this measure, together with the fact that in the last year the increase in the number of units in IMS terms has been the lowest in recent years (1.7%), has led to a resulting increase in the prescription market of only 5%, the lowest in recent years. The increase in average price was 3.2%.

Besides the coming into force of the said reference price order (Order SCO/3867/2007), in December 2008 another order was enacted (SCO/3803/2008), which came into force on 1 February 2009, and by virtue of which 13 new groups were added to the system and the corresponding prices of the groups created by the orders of 2006 and 2007 were revised.

This new order eliminates groups C105 (Pergolida oral) and C113 (Salbutamol -pulmonary), created by Order SCO/3997/2006 applying that set out in Order SCO/2874/2007, by which medicines that constitute an exception to the possible substitution by the pharmacist are established. Also disappearing is the C90 group (Metotrexato), in this case because it includes insufficient doses, so that at present there 160 groups included in the RPS, corresponding to 143 molecules or associations.

GROUPS CREATED BY ORDER SCO / 3997 / 2006

	Active Ingredient	Method of adminstr.
C1	Aceclofenac	Oral
C2	Acetylcysteine	Oral
C3	Acyclovir	Oral
C4	Acyclovir	Paediatric Oral
C5	Alendronic Acid	Oral
C6	Alfuzosin	Oral
C7	Allopurinol	Oral
C8	Alprazolam	Oral
C9	Ambroxol	Oral
C10	Amikacin	Parenteral
C11	Amlodipine	Oral
C12	Amoxicilin	Oral
C13	Amoxicilin	Paediatric Oral
C14	Amoxicilia/Clavulanic Acid	Oral
C15	Amoxicilin/Clavulanic Acid	Paediatric Oral
C16	Atenolol	Oral
C17	Azithromycin	Oral
C18	Azithromycin	Paediatric Oral
C19	Bisoprolol	Oral
C20	Budesonide	Nasal
C21	Captopril	Oral
C22	Carboplatin	Parenteral
C23	Carvedilol	Oral
C24	Cefaclor	Oral
C25	Cefaclor	Paediatric Oral
C26	Cefazolin	Parenteral
C27	Cefixime	Oral
C28	Cefixime	Paediatric Oral
C29	Cefonicide	Parenteral
C30	Cefotaxime	Parenteral
C31	Cefotaxime	Paediatric parenteral
C32	Ceftazidime	Parenteral
C33	Ceftriaxone	Parenteral
C34	Ceftriaxone	Paediatric parenteral
C35	Cefuroxime	Parenteral
C36	Cetirizine	Oral
C37	Cetirizine	Paediatric Oral
C38	Ciprofloxacin	Oral
C39	Ciprofloxacin	Paediatric Oral
C40	Cyproterone/Ethilnylestradiol	Oral
C41	Citalopram	Oral
C42	Clarithromycin	Oral
C43	Clarithromycin	Paediatric Oral
C44	Clindamicyn	Parenteral
C45	Clotrimazole	Vaginal
C46	Dacarbazine	Parenteral
C47	Deflazacort	Oral
C48	Desmopresine	Nasal
C49	Dexamethasone	Parenteral
C50	Diclofenac	Oral
C51	Diclofenac	Rectal
C52	Dilthiazem	Oral
C53	Doxazosin	Oral
C54	Doxorubycin	Parenteral
C55	Ebastine	Oral
C56	Enalapril	Oral
C57	Spironolactone	Oral
C58	Etoposide	Parenteral
C59	Famotidine	Oral
C60	Finasteride	Oral
C61	Fluconazole	Oral
C62	Fluorouracil	Parenteral
C63	Fluoxetine	Oral
C64	Flutamide	Oral
C65	Fluvoxamine	Oral
C66	Folinic Acid	Parenteral
C67	Fosinopril	Oral
C68	Gabapentin	Oral
C69	Gemfibrozil	Oral
C70	Glimepiride	Oral
C71	Hydrochlorothiazide/Captopril	Oral
C72	Hydrochlorothiazide/Enalapril	Oral
C73	Hydrochlorothiazide/Lisinopril	Oral
C74	Ibuprofen	Oral
C75	Ibuprofen	Paediatric Oral
C76	Indapamide	Oral
C77	Isosorbide mononitrate	Oral
C78	Itraconazole	Oral
C79	Lamotrigine	Oral
C80	Lansoprazole	Oral
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 *
C91	Mirtazapine	Oral
C92	Moclobemide	Oral
C93	Naproxen	Oral
C94	Naproxen sodium	Oral
C95	Nifedipine	Oral
C96	Nimodipine	Oral
C97	Nitrendipine	Oral
C98	Norfloxacin	Oral
C99	Ofloxacin	Oral
C100	Omeprazole	Oral
C101	Ondansetron	Oral
C102	Paracetamol	Oral
C103	Paroxetine	Oral
C104	Pentoxifiline	Oral
C105	Pergolide	Oral *
C106	Piroxicam	Oral
C107	Pravastatin	Oral
C108	Quinapril	Oral
C109	Ramipril	Oral
C110	Ranitidine	Oral
C111	Risperidone	Oral
C112	Roxithromycin	Oral
C113	Salbutamol	Pulmonary *
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
C126	Torasemide	Oral
C127	Tramadol	Oral
C128	Tramadol	Paediatric Oral
C129	Tramadol	Parenteral
C130	Tramadol	Rectal
C131	Triflusal	Oral
C132	Trimetazidine	Oral
C133	Vancomycin	Parenteral
C134	Venlafaxine	Oral
C135	Vincristine	Parenteral
C136	Zolpidem	Oral

(*) Withdrawn by order SCO/3803/2008.

GROUPS CREATED BY ORDER SCO / 3867 / 2007

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

GROUPS CREATED BY ORDER SCO / 3803 / 2008		
	Active Ingredient	Method of adminstr.
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 (**)
C160	Paracetamol	Pediatric Oral
C161	Perindopril	Oral
C162	Quetiapine	Oral
C163	Ropinirole	Oral

(**) Suspended until final judgement on industrial property.

With the said order coming into force, the structure of the prescription market on 1 January 2009 according to the data corresponding to 2008 will end up as follows:

STRUCTURE OF THE PRESCRIPTION MARKET (1)		
	Units (%)	Value (%)
Doses included in RPS	**34.4**	**21.0**
Generics	42.5	30.8
Rest	57.5	69.2
Doses not included in RPS	**65.6**	**79.0**
Generics	1.7	0.3
Rest	98.3	99.7
Total doses	**100.0**	**100.0**
Generics	15.7	6.7
Rest	84.3	93.3

(1) According to 2008 sales data.
Source: FARMAINDUSTRIA from IMS.

With regard to generic medicines, during 2008, 184 million units have been commercialised with a value of 679.8 million euros at EFP and its average price has been 3.69 euros. The market share of these medicines has reached 6.7% by value and 15.7% by units. In 2008 12 new molecules of generics were commercialised, which means that there are now 151 molecules or associations where some generic is commercialised. At the end of 2008, the market at reference prices represented 34.4% of the total prescription market by units, and 21% by value. That is, one in three prescription medicines dispensed in Spain in 2008 was a medicine subject to RPS.

Therapeutic groups. From the market analysis differences arise in the evolution of the different therapeutic groups, depending on what the impact of the introduction of products in the RPS has been, of the therapeutic advances that have been carried out on pathologies that increasingly affect more population groups (cardiovascular, rheumatic, oncologic), etc.

Thus, the major part of the sales are concentrated in four therapeutic groups: Central Nervous System, Cardiovascular, Digestive and Respiratory Systems which together represent 64.6% of the total market by value and 67.1% by units.

PHARMACEUTICALS SALES THROUGH PHARMACIES BY THERAPEUTIC GROUP (2008)

	Units (thousands)	Share (%)	Incr. (%)	Value PVL (thousands)	Share (%)	Incr. (%)	EFP Av. (€)	Incr. (%)
A Digestive and Metabol. System	195,814.2	15.3	2.8	1,279,343.5	12.2	2.8	6.53	0.0
B Blood and Hematop. Organs	55,720.6	4.4	6.2	444,177.0	4.2	5.6	7.97	-0.6
C Cardiovascular System	224,725.3	17.6	3.8	2,188,185.4	20.9	6.0	9.74	2.1
D Dermatology	63,776.1	5.0	-1.7	328,089.4	3.1	1.8	5.14	3.6
G Genito-Urinary Products	55,366.6	4.3	2.5	695,506.8	6.7	7.2	12.56	4.6
H Hormones	18,410.8	1.4	-0.4	202,697.3	1.9	14.4	11.01	15.0
J Anti-infectious	57,278.7	4.5	-4.3	460,979.5	4.4	3.7	8.05	8.3
K Hospital solutions	2,736.0	0.2	1.1	3,171.0	0.0	0.0	1.16	-1.1
L Antineoplastics / Inmun.	6,466.1	0.5	1.6	625,709.0	6.0	6.1	96.77	4.4
M Locomotor System	102,992.3	8.1	2.7	639,324.4	6.1	5.8	6.21	3.0
N Nervous System	293,379.3	23.0	-0.6	2,234,077.1	21.4	3.9	7.61	4.6
P Anti-parasitics	1,081.6	0.1	1.4	6,370.7	0.1	-2.2	5.89	-3.5
R Respiratory System	142,937.3	11.2	-8.1	1,061,134.8	10.1	-1.1	7.42	7.6
S Sensory Organs	53,290.2	4.2	2.9	248,427.0	2.4	5.5	4.66	2.5
T Diagnostic Agents	94.7	0.0	-32.2	1,464.7	0.0	-36.5	15.47	-6.3
V Various	1,897.4	0.1	-3.9	40,002.4	0.4	23.4	21.08	28.4
TOTAL	**1,275,967.2**	**100.0**	**0.3**	**10,458,660.2**	**100.0**	**4.4**	**8.20**	**4.1**

Souuce: FARMAINDUSTRIA from IMS.

The Central Nervous System is again the group with the largest market share by units and by value

As in recent years, the Central Nervous System is again the group with the biggest market share, by units as well as value, although in both cases growth lower than the market average was recorded. In fact, the increase in units has been negative (-0.6%), brought about, largely, by the 4% fall of the analgesics sub-group, which represents practically 50% of the total units of the said group. In this sub-group there has been a displacement of units consumed towards higher dosage products and towards products formed by analgesic associations, at the same time as the market share of non-publically financed products has increased, whose average price is higher than the rest of the market. All of this has had an influence on the average price of the medicines in this group having slightly surpassed that of the market as a whole.

The following group by sales, Cardiovascular Systems shows above average increases, by units as well as value. On the other hand, the average price of the group has increased less than the market average, given that, despite the majority of the units corresponding to new therapies being concentrated in this group, the percentage of units included in the Reference Price System is higher than 40%.

Regarding the Digestive System, the increase in units is practically the same as that of the other values, which produced the maintenance of the average price of the group with respect to the previous year, slightly decreasing(-1.3%) if we only take into account the prescription market. In fact, 90% of the sub-group units with higher market share (the anti-ulcers) are included in the RPS, which has led to a fall in the price of the said sub-group of 16%.

With regard to the Respiratory System, we should point out the fall in sales of this group's medicines, more marked in units than in value. An important part of this fall is explained by the reduction of 16% in the sales of advertised medicines in this group, with a 25.6% share. At the same time, the commercialised units of low LSP sub-groups has also fallen, with a high private market share, such as antitussives, and that corresponding to sub-groups such as anti-asthmatics, with a higher price and in which new therapies have also been introduced, amongst others, for an easier administration of the medicine. In fact, 30% of the units of new molecules commercialised in 2008 correspond to the respiratory system.

The sales of the Locomotor System grew above average, by units and by value, keeping its average price below the average.

The Anti-infectious group saw a fall in units of -4.3%, whilst the value rose by 3.7%. 90% of the units of this group correspond to antibiotics, a sub-group that recorded a fall in units and value of -5.55% and-8.8% respectively, resulting in a fall in the average price of -3.5%. This is the group that has the largest share of products included in the RPS (67.3% in units and 40.8% in value). The reason for this increase in the average price of the anti-infectious medicines is found in the vaccines sub-group, where in recent years important therapeutic advances have been included that have spread to the greater part of the target population.

In the Antineoplastics group the increase in units is below the average, whilst the value increases above the average. Given the pathologies that these medicines are aimed at (principally for the hospital approach), it gives a unit share of little relevance in the patient area, but is one of the groups where more new therapies are being introduced, being the reason why it records the highest average price.

Finally, the Hormones group has to be mentioned, where the fall in units of 1.4% has been accompanied by an increase of those by value of 14.4%, a fact explained by the higher consumption of more innovative and efficient products in the treatment of some pathologies.

New launches. During 2008 261 new medicines have been commercialised, whose sales have amounted to 106.3 million euros. Of these products, 170 are generic medicines and 31 correspond to new molecules or associations. The new products have focused principally on two therapeutic areas: the Central Nervous System, with 65 products, of which 49 are generic, and the Cardiovascular System, with 51 products, 43 of which are generic.

The sales distribution by therapeutic group of the newly commercialised products in 2008 has been as follows:

SALES OF NEW PRODUCTS BY THERAPEUTIC GROUPS (STRUCTURE %)

Therapeutic Group	Total		New molecules		Generics	
	Units	Value	Units	Value	Units	Value
LO Antineoplastics	0.4	17.3	0.2	27.1	0.8	5.9
RO Respiratory System	23.6	15.4	30.6	15.8	0.5	0.2
NO Nervous System	22.3	14.9	6.6	7.1	46.6	56.0
CO Cardiovascular System	13.8	11.7	32	16.7	17.2	10.6
AO Digestive System	13.1	10.0	13.7	12.8	14.5	10.6
MO Locomotor System	13.5	10.0	-	-	17.0	13.7
JO Anti-infectious	2.5	6.4	2.6	7.4	0.8	1.4
VO Various	0.6	5.9	2.8	10	-	-
GO Genito-Urinary Products	1.1	5.4	0.5	0.4	1.0	1.3
DO Dermatology	5.3	2.0	10.9	2.5	1.6	0.4
SO Sensory Organs	3.7	0.9	-	-	-	-
BO Blood and Hematop. Organs	0.0	0.0	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[4]

The trade deficit has traditionally constituted one of the most important imbalances of the Spanish economy. In recent years this problem has worsened and the balance of trade has progressively deteriorated up to positioning Spain in 2007 as the nation, amongst the main developed economies, with the highest trade deficit in relative terms and the third in absolute terms after the USA and United Kingdom.

In 2008, however, it can be observed how, for the first time since 2002, the tendency has been reversed, recording a fall of 4.9% in the trade deficit, that reached 94,067 million euros and which represents 8.6% of national GDP.

This decrease in the trade deficit has been due, principally, to the stagnation of imports which only grew 0.6% with respect to the previous year. With regard to exports, they have notably slowed down as well, but not as intensely as imports and closed the year with an increase of 3.7%. This varying intensity of external purchases and sales has resulted in an improvement of the coverage rate of almost two percentage points to close the year on 66.7%.

Focusing on the pharmaceutical sector, it is important to point out that, in general, the trade exchanges in this sector have relatively autonomous behaviour patterns. Thus, in 2005 and 2006, in a general context of growing trade deficit, the pharmaceutical balance of trade witnessed a notable recovery that finished up with the deficit at its lowest levels since 1999. This progression, was however, cut short in 2007 and has not recovered in 2008.

4 The data that appears in this section is restricted to external merchandise trade in general and pharmaceutical products in particular. In both cases, the data relating to 2008 is provisional, being susceptible to a posterior revision.

In 2008 the exports of pharmaceutical products exceeded 6,800 million euros

In this way, the coverage rate of the pharmaceutical balance of trade was reduced by 1.3 points in 2008 to 73.6%, although its level continues to be considerably higher than the coverage rate for the Spanish economy as a whole.

In 2008, pharmaceutical imports were for 10,008 million euros (3.5% of the total external purchases of our economy), while exports reached a value if 7,368 million euros (3.9 % of the total external sales of our country).

By parts, it can be seen how, after two years of surpluses, a slight deficit is again recorded in the trade balance of pharmaceutical raw materials. On another note, a new increase in the deficit recorded in the international trade of pharmaceutical products can be noticed, although it must be pointed out that independently of that and within a global context of Spanish external trade, pharmaceutical exports continue to be the relatively most important (3.9% of the total exports compared to 3.5% of total imports).

TOTAL EXTERNAL PHARMACEUTICAL TRADE 2008 (MILLIONS OF €)

	Imports	Δ 08/07 (%)	Exports	Δ 08/07 (%)	Balance
Raw materials	562.14	6.1%	544.17	1.8%	-17.97
Pharmaceutical products	9,445.55	12.0%	6,824.17	2.4%	-2,621.38
*Medicines	7,354.40	12.6%	5,844.48	1.5%	-1,509.92
TOTAL	**10,007.69**	**11.6%**	**7,368.34**	**2.4%**	**-2,639.35**

Note: The data for 2008 is provisional and corresponds to aggregating monthly data from D.G.A.I.E. However, the increases take as a basis the consolidated data from 2007, so the resulting variations should be treated with caution.

Source: Ministry of Industry, Tourism and Trade. Statistics for Spanish External Trade.

With respect to the geographical distribution of external pharmaceutical trade, the European Union continues to be our principle trading partner: more than 70% of Spanish external purchases come from our European partners, and likewise, we destine more than 60% of our exports to them. However, in relation to 2007 a certain change of pattern was observed in our trade exchanges –which, however will have to be confirmed in the coming years– in that the group of non-European countries is gaining importance, which has increased its share by between 5 and 6 points in exports as well as imports, largely in detriment to the EU.

In this sense, the increase in our external trade with the USA should be pointed out, based above all on a considerable increase (+65%) in our pharmaceutical purchases from this country, which has converted the American giant into our number one supplier of pharmaceutical products ahead of Germany and France.

It is also worth pointing out the strong increase in exports to Japan, which has gone from counting for 2.1% of the total of our pharmaceutical exports in 2007 to representing 3.5%.

With regard to the European Union, it should be pointed out that, despite the moderation in the rate of growth of imports coming from this zone with respect to previous years (+6.2%), the trade gap has increased, as in 2008 a fall in Spanish pharmaceutical exports to the European Union (-6.5%) was recorded, an aspect where the heavy fall in sales in Italy was notable.

Finally, it is important to note, that that in absolute terms, Germany, France and the United Kingdom are, in that order, the European countries where the largest part of our trade exchanges have taken place.

STRUCTURE OF SPANISH EXTERNAL PHARMACEUTICAL TRADE BY COUNTRY

	2007		2008	
	Import (%)	Export (%)	Import (%)	Export (%)
GLOBAL TOTAL	**100.00**	**100.00**	**100.00**	**100.00**
European Union (UE-27)	74.6	65.9	71.0	60.2
· France	13.1	9.6	11.9	11.3
· Germany	15.7	13.6	14.8	13.1
· Italy	6.6	15.4	6.0	8.8
· United Kingdom	12.4	8.8	11.6	8.4
Rest of Europe	9.6	12.5	7.9	13.3
· Switzerland	9.3	10.7	7.6	11.1
Rest of world	15.7	21.6	21.1	26.5
· United States	11.0	9.6	16.3	9.2

Source: Ministry of Industry, Tourism and Trade. Statistics for Spanish External Trade. Consolidated report 2007 and monthly summaries 2008.

2.4. Social Security pharmaceutical expenditure

According to data from the Ministry of Health (summaries of billing of medical prescriptions), during 2008 889.5 million prescriptions charged to Social Security were dispensed, which means an increase of 5.5% compared to the previous year. The said prescriptions have given rise to public expenditure of 11,960.5 million euros, increasing by 6.9% over the previous year. As has already been commented upon, the impact of the reference price order that came into force in 2008 has been less than that of 2007, by affecting 14 groups, compared to 136 the previous year. Even so, the increase in the average cost per prescription has been of a moderate 1.3%, which, together with those recorded in 2006 and 2007 (1.7% and -0.7%, respectively, both influenced by each of the reference prices) are the lowest in the last 20 years.

PUBLIC EXPENDITURE BY PRESCRIPTIONS DISPENSED IN PHARMACIES

Year	Expn (Mill. € PVP IVA)	Incr. (%)	Nº presc. (Mill.)	Incr. (%)	Expn./presc. (€)	Incr. (%)
2006	10,636.2	5.8%	796.0	4.1%	13.36	1.7%
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%

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

Distribution of average consumption *per capita* by autonomous regions. In 2008, the average pharmaceutical expenditure *per capita* was 259.1 euros, 4.7% more than the previous year. By autonomous regions there are big differences, going from 197.1 euros *per capita* of the Baleares to the 313.4 euros of Asturias, maintaining the same relative positions as the previous year. The regions that have a higher *per capita* expenditure are Asturias (€ 313.4), Galicia (€ 312.3) and the Valencian Region (€ 308.8). Conversely, the regions with the least *per capita* expenditure continue to be Baleares (€ 197.1), Madrid (€ 198.8) y Andalucía (€ 238.5).

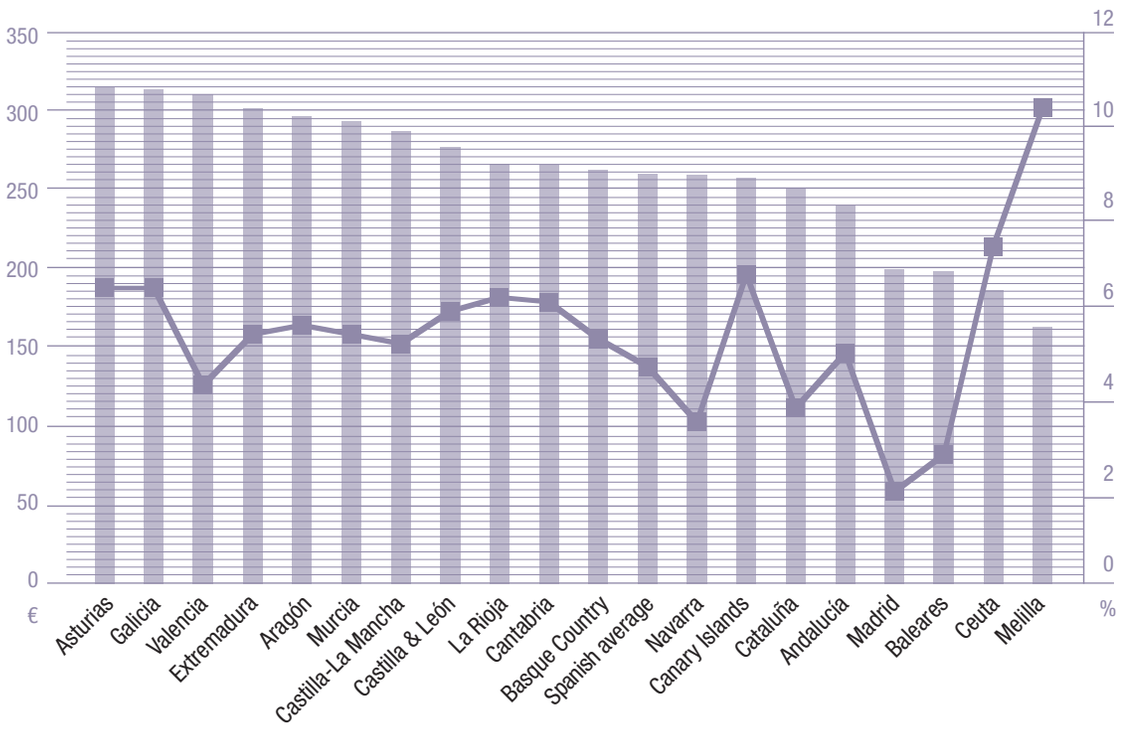
In 2008 public pharmaceutical expenditure *per capita* in Spain was 259.1 euros

In terms of growth rates, The Canary Islands is the region that has the highest growth in expenditure *per capita* (6.7%), followed by Asturias and Galicia (both with 6.4%). Conversely, the region with the lowest *per capita* growth in expenditure was Madrid (2%), followed by Baleares (2.8%).

PHARMACEUTICAL EXPENDITURE PER CAPITA BY AUTONOMOUS REGION 2008

Autonomous Region	Expenditure share (%)	Expenditure *per cápita*	
		Euros	Incr. on/2007 (%)
Asturias	2.8	313.4	6.4
Galicia	7.3	312.3	6.4
Valencia	12.9	308.8	4.3
Extremadura	2.8	300.1	5.4
Aragón	3.2	294.9	5.6
Murcia	3.4	291.8	5.4
Castilla-La Mancha	4.8	285.8	5.2
Castilla & León	5.9	275.5	5.9
La Rioja	0.7	265.3	6.2
Cantabria	1.3	264.3	6.1
Basque Country	4.7	261.0	5.3
SPANISH AVERAGE		**259.1**	**4.7**
Navarra	1.4	258.1	3.5
Canary Islands	4.3	256.1	6.7
Cataluña	15.5	250.0	3.8
Andalucía	16.4	238.5	5.0
Madrid	10.6	198.8	2.0
Baleares	1.8	197.1	2.8
Ceuta	0.1	185.4	7.3
Melilla	0.1	162.2	10.3

EXPENDITURE *PER CAPITA* AND INCREASE BY AUTONOMOUS REGION



Source: Farmaindustria from Ministry of Health and Consumption. (Summaries of billing of prescriptions) and INE (Official population figures as of 1/1/08).

2.5. Medicine prices

As has been occurring since the new Reference Price System was implemented in 2006, the RPI Medicine and other pharmaceutical products heading recorded a fall in its index, specifically -5.8% on this occasion.

INFLATION AND MEDICINE PRICES 2008

Expenditure group or heading	Annual CPI variation (%) 2008
General (inflation)	1.4%
Medicine	0.3%
Medicines & other pharm. products	-5.8%
Therapeutic material	3.0%
Medical & non-hospital paramedical services	4.3%
Dental services	3.4%
Hospital services	3.5%

Source: INE.

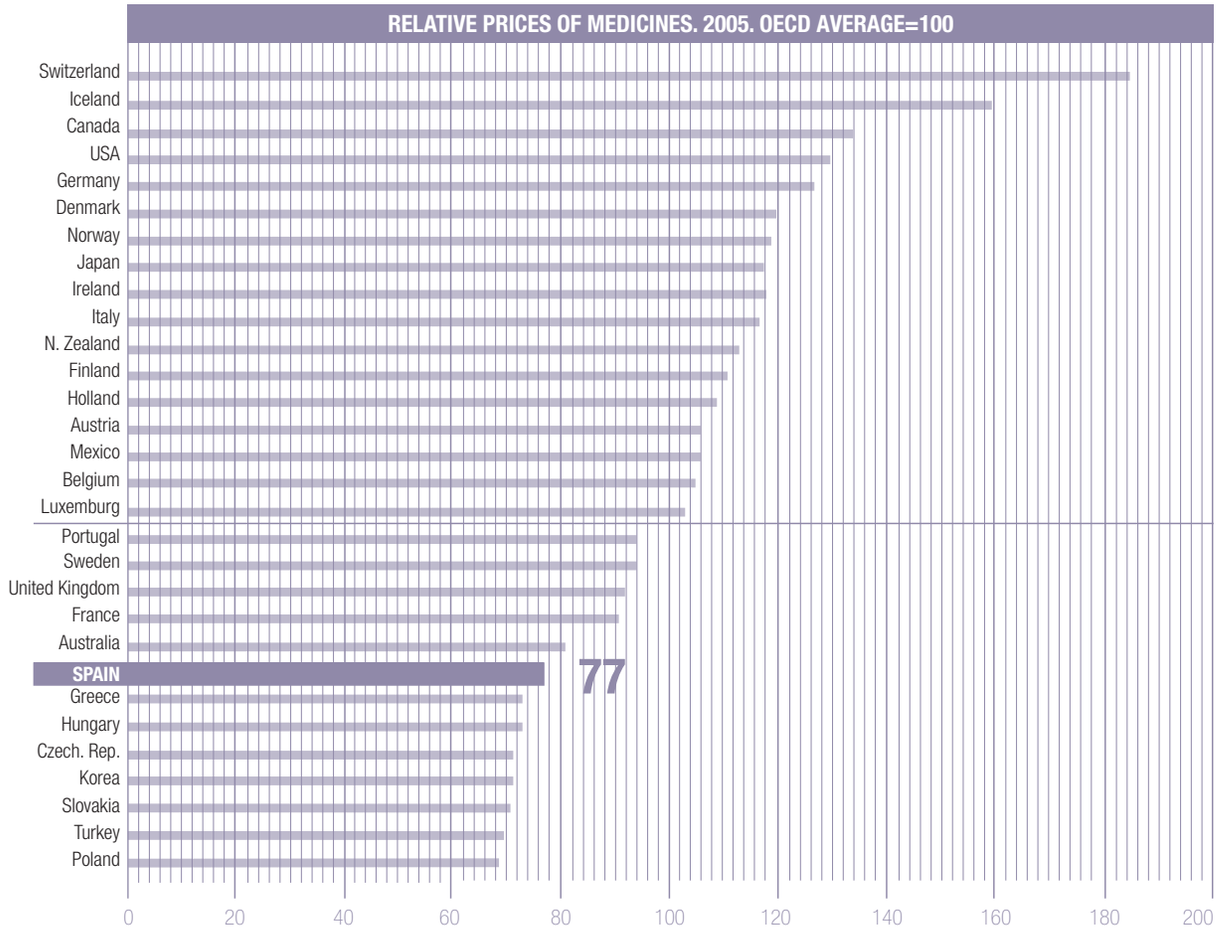
It should be taken into account that this data from INE is not incompatible with the positive increase in the average weighted price of the market (IMS), to which we have referred in previous pages of this Report, given that the reach and objective of both sources, from a conceptual point of view, as well as the methodology used (definition, measurement and verification, tracking etc.) are clearly different, so the results of each one (INE, IMS), do not detract, by themselves, from each other.

In whatever case, it seems unarguable that the pharmaceutical prices in Spain continue to be among the lowest in Europe, as has been stated in the different comparisons that have been made, from public as well as private institutions.

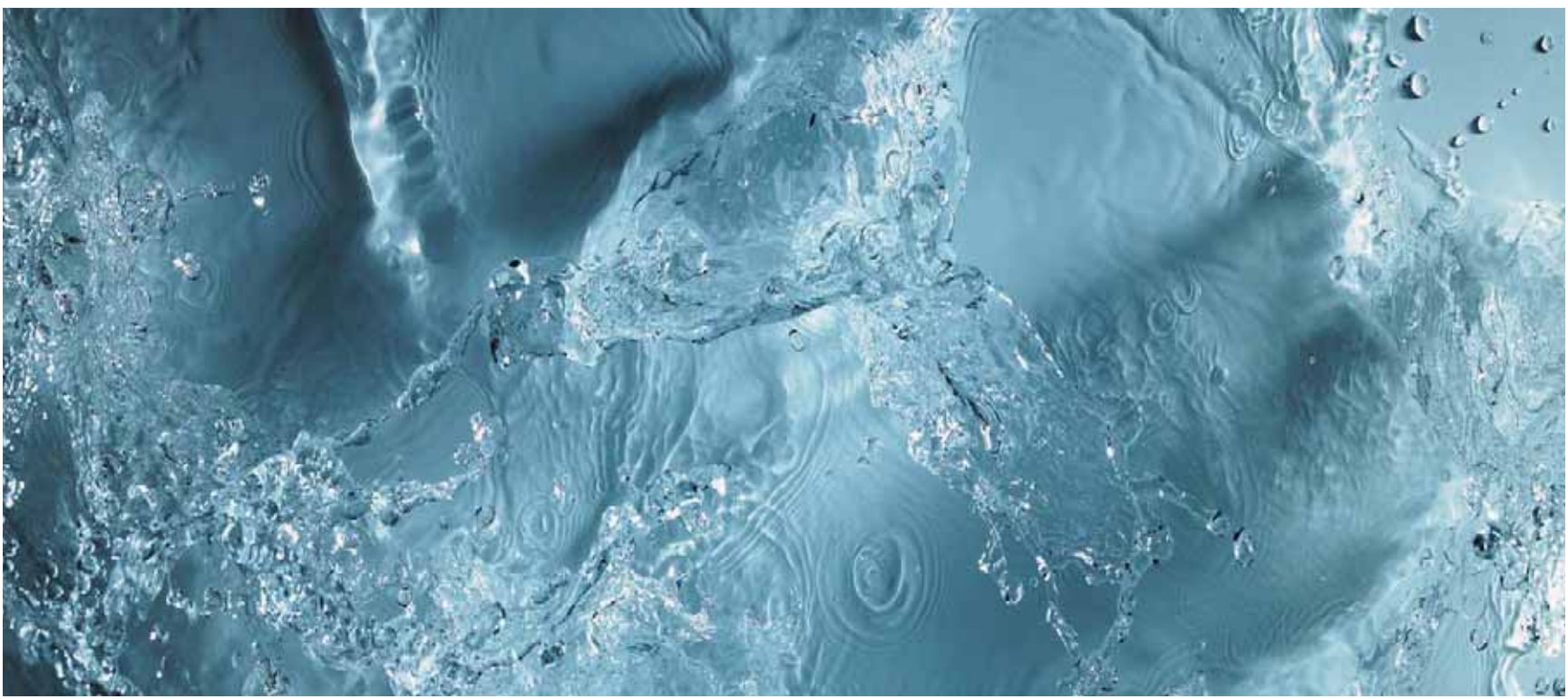
PRICES OF MEDICINES IN THE MAIN EU COUNTRIES (AVERAGE MARKET PRICE EFP, 2007)

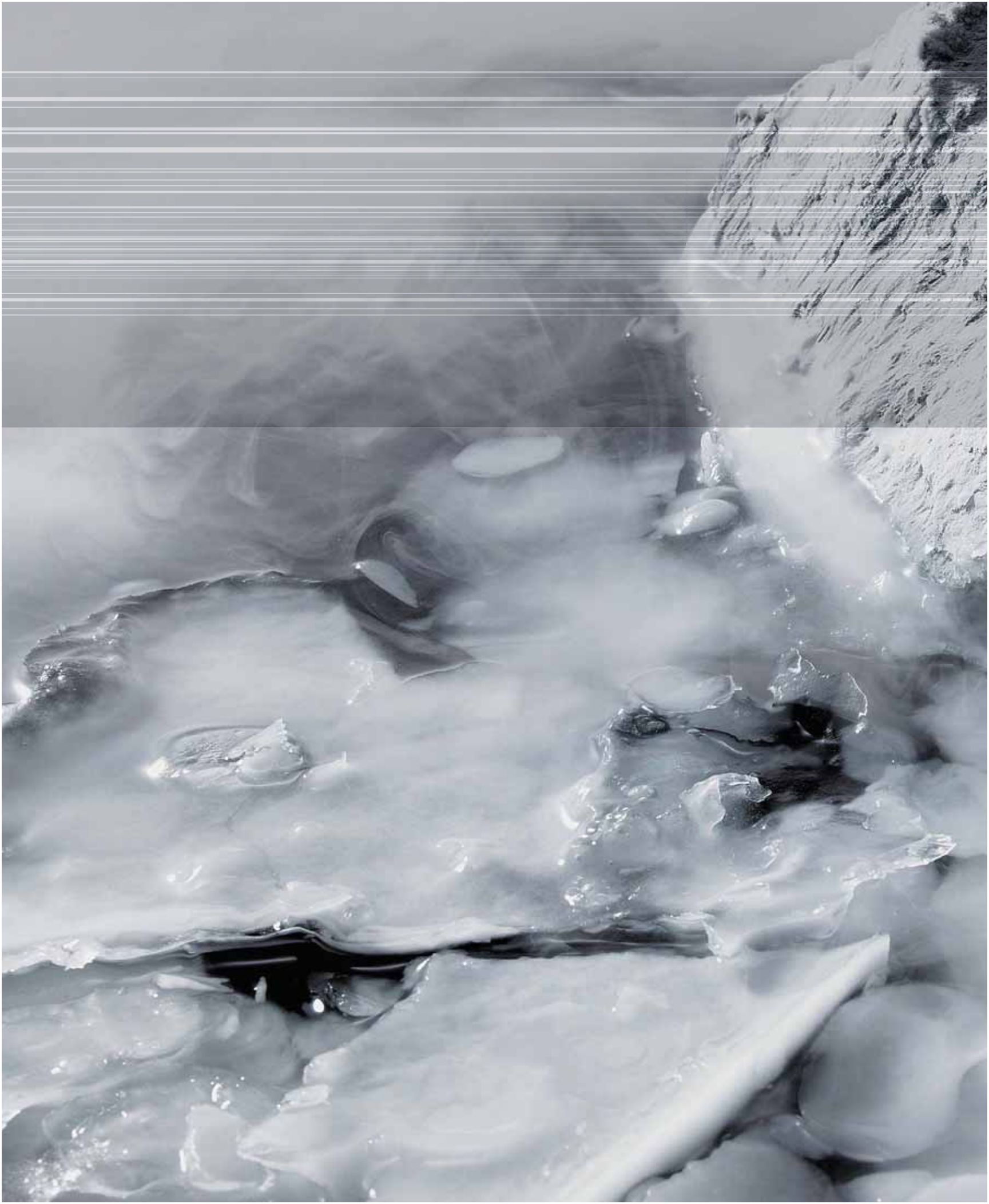
	Average EFP (Euros)	Index (Spain=100)
Germany	14.43	188
Holland	11.94	155
Belgium	11.54	150
United Kingdom	10.00	130
Spain	7.69	100
France	7.10	92
Italy	6.48	84

Source: Own elaboration from Farmindustria (Indicatori Farmaceutici 08) and EFPIA.



Source: OCDE (2008). *Pharmaceutical pricing policies in a global market.*





03

NEW LEGISLATION

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ELECTRONIC ADMINISTRATION

Decree 232/2007, of 18th December, of the Vice-presidency of the Basque Government, which regulates the use of electronic, computing and telematic means in administrative procedures.

Order, of 25th January 2008, of the Galician Health Ministry, which regulates the services provided in electronic, computing and telematic means in the Galician Health Ministry and Galician Health Service.

CONTRACEPTIVES

Decree 96/2008, of 19th September, of the Baleares Health & Consumer Affairs Ministry, which regulates the prescription and dispensing of post-coital intervention medicines in Baleares Health Service Centres.

AUTHORISATION OF PHARMACEUTICAL LABORATORIES

Informative Note, of 14th January 2008, from the Spanish Medicine & Healthcare Products Agency on the procedure on the modification of the authorisation of a pharmaceutical laboratory.

Guide of the Spanish Medicine & Healthcare Products Agency on the contents of the Technical Report on Pharmaceutical Laboratories.

AUTHORISATION AND REGISTERING OF MEDICINES

Instruction, of 10th July 2008, from the Spanish Medicine & Healthcare Products Agency, for renewing the authorisation of commercialisation of medicines.

BIOETHICS

Decree 226/2008, of 18th November, of the Health Department of the Catalan Government, modifying Decree 166/2005, of 26th July, which regulates the Catalan Consultative Bioethics Committee.

ANATOMICAL CLASSIFICATION OF MEDICINES

Order SCO/78/2008, of 17th January, which updates Annex I of Royal Decree 1348/2003, of 31st October, which adapts the anatomical classification of medicines to the ATC classification system.

EXTERNAL TRADE

Resolution, of 15th September 2008, of the department of customs and special taxes of the State Agency for Tax Administration (AEAT), where the instructions are gathered for the formalisation of the Single Administrative Document (DUA).

Circular 1/2008, of 1st February, of the Spanish Medicine & Healthcare Products Agency, on external trade of medicines.

Informative Note, of 16th July, 2008, of the Spanish Medicine & Healthcare Products Agency, on exporting registered medicines by a producing laboratory which is not the bearer of the commercialisation authorisation.

Clarifications of the Spanish Medicine & Healthcare Products Agency, of 15th July, 2008, on export certificates without excipients.

ETHICS COMMITTEES OF CLINICAL RESEARCH

Decree 139/2008, of 3rd July, of the Ministry of Health and Dependency of the Government of Extremadura, which establishes the regulation of Clinical Research Ethics Committees in Extremadura.

AUTONOMOUS REGION OF ANDALUCÍA

Decree 32/2008, of 5th February, of the Ministry of Justice and Public Administration of the Government of Andalucía, which approved the Regulations of Foundations of the Autonomous Region of Andalucía.

Decree 193/2008, of 6th May, of the Ministry of Health of the Government of Andalucía, which establishes an organic structure of the Ministry of Health and the Andalucian Health Service.

Decree 517/2008, of 2nd December, of the Interior Ministry of the Government of Andalucía, which approved the Regulations of the Organisation and Operation of the Andalucian Board of Consumer Affairs and the Provincial Consumer Affairs Boards.

AUTONOMOUS REGION OF ARAGÓN

Decree 6/2008, of 30th January, of the Department of Health and Consumer Affairs of the Aragón Government, which passed the organic structure of the Department of Health and Consumer Affairs and of the Aragón Health Service.

AUTONOMOUS REGION OF CANTABRIA

Law of Cantabria 7/2008, of 26th December, on the creation of the Cantabrian Consumer Affairs Agency.

AUTONOMOUS REGION OF CASTILLA-LA MANCHA

Decree 72/2008, of 3rd June, of the Ministry of Health of the Government of the Castilla-La Mancha Region, which creates the Board of Consumers and Users of Castilla-La Mancha.

Decree 76/2008, of 10th June, of the Ministry of Health of the Government of the Castilla-La Mancha Region, on the creation of the Defence of Competition organs of Castilla-La Mancha.

Decree 104/2008, of 22nd July, of the Ministry of Industry and Information Society of the Government of the Castilla-La Mancha Region, on the protection of data of a personal nature in the Region of Castilla-La Mancha Government.

Decree 139/2008, of 9th September, of the Ministry of Health and Social Welfare of the Government of the Castilla-La Mancha Region, which establishes the organic structure and competencies of the Ministry of Health and Social Welfare.

AUTONOMOUS REGION OF EXTREMADURA

Decree 220/2008, of 24th October, of the Ministry of Public Administration and Taxation of the Government of Extremadura, which establishes the organic structure of the Ministry of Health and Dependency of the Government of Extremadura.

Decree 221/2008, of 24th October, of the Ministry of Public Administration and Taxation of the Government of Extremadura, which approved the Statutes of the Autonomous Health Service Body of Extremadura.

AUTONOMOUS REGION OF GALICIA

Law 8/2008, of 10th July, of the Presidency of the Government of Galicia, on Galician Health.

Decree 195/2008, of 28th August, of the Ministry of Health of the Government of Galicia, which modifies Decree 45/2006, of 23rd February, which establishes the organic structure of the Ministry of Health.

AUTONOMOUS REGION OF MURCIA

Decree 327/2008, of 3rd October, of the Board of Government of the Murcia Region, which establishes the Managing Bodies of the Ministry of Health and Consumer Affairs.

AUTONOMOUS REGION OF LA RIOJA

Decree 65/2008, of 26th December, of the Ministry of Public Administration and Local Policy of the Government of La Rioja, which modifies Decree 84/2007, of 20th July, which establishes the organic structure of the Ministry of Health and its functions following Law 3/2003, of 3rd March, of the Organisation of the Public Sector of the Autonomous Region of La Rioja.

AUTONOMOUS REGION OF THE BASQUE COUNTRY

Decree 36/2008, of 4th March, of the Department of Taxation and Public Administration and of the Department of Industry, Trade and Tourism of the Basque Country, of modifying the Decree of the creation of the Basque Court of Defence of Competition and of assigning functions of the Defence of Competition Service in the Basque Autonomous Region.

AUTONOMOUS REGION OF THE PRINCIPALITY OF ASTURIAS

Decree 125/2008, of 27th November, of the Ministry of Health and Health Services of the Principality of Asturias, of a basic organic structure of the Ministry of Health and Health Services.

MADRID REGION

Decree 22/2008, of 3rd April, of the Board of Government of the Madrid Region, which establishes the organic structure of the Ministry of Health.

Decree 23/2008, of 3rd April, of the Board of Government of the Madrid Region, which establishes the organic structure of the Madrid Health Service.

Decree 24/2008, of 3rd April, of the Board of Government of the Madrid Region which establishes the legal basis and operation of the Madrid Health Service.

FORAL REGION OF NAVARRA

Foral Law 10/2008, of 30th May, which modifies Article 5 of Foral Law 10/1990, of 23rd November, on Health.

Foral Decree 120/2008, of 1st December, which modifies Foral Decree 45/2006, of 3rd July, which approved the Statutes of the Navarran Health Service-Osasunbidea.

VALENCIA REGION

Law 6/2008, of 2nd June, of the Valencian Government, on Health Insurance of the Public Health System of the Valencia Region.

Order of 13th October 2008, of the Ministry of Health of Valencian Government, which approved the Regulation on the Operation of the Board of Health of the Valencia Region.

CONSUMERS AND USERS

Royal Decree 231/2008, of 15th February, which regulates the Consumer Arbitration System.

Order SCO/453/2008, of 14th February, which modifies Royal Decree 1507/2000, of 1st September, which updates the catalogues of products and services of common, ordinary and general use and durable goods.

PUBLIC CONTRACTING

Order EHA/1220/2008, of 30th April, which approved the instructions for operating in the State Contracting Platform.

Order 15/2008, of 14th January, of the Regional Minister of Health and Consumer Affairs of the Madrid Region, which agreed on the uniformity of certain medicines and declared centralised management for its contracting.

Order, of 11th June 2008, of the President's Department of the Government of Aragón, which established the computerised Contactor Profile of the Portal of the Government of Aragón.

Order, of 16th June 2008, of the Ministry of Economy and Taxation of the Government of Andalucía, which regulates the contractor profile of contracting bodies of the Administration of the Government of Andalucía and the entities which carry it out.

Order ECF/313/2008, of 23rd June, of the Department of Economy and Finance of the Catalan Government, which approved the application of a public contracting services platform.

Order, of 17th September 2008, of the Ministry of Economy, Taxation and Employment of the Valencian Government which approved the application of the Government Contracting Platform.

DEFENCE OF COMPETITION

Royal Decree 261/2008, of 22nd February, which approved the Regulations on the Defence of Competition.

Royal Decree 331/2008, of 29th February, which approved the Statute of the National Competition Commission.

Resolution, of 23rd April 2008, of the Presidency of the National Competition Commission, which regulates the procedures for the presentation of self-settlement for payment by telematic means of taxes anticipated in article 23 of Law 15/2007, of 3rd of July, on Defence of Competition.

RIGHTS AND OBLIGATIONS OF THE PATIENT

Decree 4/2008, of 23rd January, of the Ministry of Health and Healthcare Services of the Principality of Asturias, on Organisation and Operation of the Registry of the Principality of Asturias of Previous Instructions in the field of health.

Decree 55/2008, of 10th October, of the Ministry of Health of the Government of La Rioja, on second medical opinions.

Order SAN/359/2008, of 28th February, of the Ministry of Health of the Government of Castilla & León, expands upon Decree 121/2007, of 20th December, which regulates the right to a second medical opinion in the Castilla & León Health System.

Order, of 21st November 2008, of the Ministry of Health Social Welfare of the Government of the Region of Castilla-La Mancha, which widens the processes with guarantees of a second medical opinion gathered in Article 4 of the Decree 180/2005, of 2nd November, of the right to a second medical opinion.

Resolution, of 29th April 2008, of the Ministry of Health and Healthcare Services of the Principality

of Asturias, on the development and execution of Decree 4/2008, of 23rd January, on Organisation and Operation of the Registry of the Principality of Asturias of Previous Instructions in the field of health.

DISTRIBUTION OF MEDICINES

Law 1/2008, of 17 April, of the Valencian Government, on the Medicine Supply Guarantees in the Valencia Region.

HUMANITARIAN DONATIONS

Instructions, of 25th October 2008, of the Spanish Medicine and Healthcare Products Agency, on exports of medicines as humanitarian donations.

DOPING IN SPORT

Royal Decree 185/2008, of 8th February, which approved the Statute of the State Anti-Doping Agency.

CLINICAL TRIALS

Order SCO/362/2008, of 4th February, which Modified Order SCO/256/2007, of 5th February, which established the principles and directives of Good Clinical Practice and the requirements to authorise production or importing of medicines for research for human use.

Resolution of the Management Board of the Murcian Health Service, of 14th May 2008, which established the procedure and requirements for the carrying out of clinical trials with medicines in Murcian Health Service centres and approved the type-model of contract to sign.

Single contract model for the carrying out of clinical trials with medicines in the Madrid Region.

POST AUTHORISATION STUDIES

Order, of 30th July 2008, of the Regional Minister of Health and Consumer Affairs of the Government of Aragón, which regulates post authorisation studies of an observational type with medicines in the Autonomous Region of Aragón.

STUPEFACIENTS & PSYCHOTROPIC SUBSTANCES

Order SCO/1870/2008, of 17th June, which includes the substance oripavina in the list I annex of the 1961 Single Convention on Narcotic Drugs.

EXCIPIENTS

Circular 2/2008, of 5th March, of the Spanish Medicine and Healthcare Products Agency, Instruction on Excipients.

ANIMAL EXPERIMENTATION

Decree 296/2008, of 30th December, of the Countryside Ministry of the Government of Galicia, on the protection of animals used for experimentation and other scientific ends, including teaching, and which creates a register of breeding centres, suppliers and users and the Galician Commission of Welfare in Animal Experimentation.

PHARMACOVIGILANCE

Clarifications of the Spanish Medicine and Healthcare Products Agency, on the need to include in the notifications of suspected adverse reactions (SAR) the commercial name of the medicine implicated. (May 2008).

HEALTH COHESION FUND

Order SCO/3773/2008, of 15th December, which updated annexes I and II and incorporated annexe III to Royal Decree 1207/2006, of 20th October, which regulates the management of the Health Cohesion Fund.

FOUNDATIONS

Royal Decree 1611/2007, of 7th December, which approved the Regulation of the Registry of foundations of state competence.

Law 9/2008, of 3rd July, of the Valencian Government, on modifying Law 8/1998, of 9th December 1998, on Foundations in the Valencia Region.

MANAGEMENT OF HEALTH RISKS

Foral Order 127/2008, of 28th October, of the Ministry of Health of the Government of Navarra, which constitutes the Observatory for the Security of Patients in the Foral Community of Navarra.

Order 775/2008, of 4th November, of the Ministry of Health of the Madrid Region, which modified the composition of the Regional Observatory of Health Risks of the Madrid Region.

Foral Order 148/2008, of 28th November, of the Regional Minister of Health of the Government of

Navarra, which modified Foral Order 127/2008, of 28th October, of Regional Minister of Health, which constitutes the Observatory for the Security of Patients in the Foral Region of Navarra.

GROWTH HORMONES

Decree 200/2008, of 30th September, of the Ministry of Health of the Government of Canarias, which modifies Decree 61/1997, of 30th April, which creates the Assessment Committee for the Therapeutic Use of Growth Hormone and Related Substances.

PHARMACEUTICAL INSPECTION

Decree 15/2008, of 25th January, of the Board of Government of the Murcia Region, which approved the Regulation of the Arrangement of the Health Inspection Services of the Autonomous Region of Murcia.

CARLOS III INSTITUTE OF HEALTH

Royal Decree 1183/2008, of 11th July, which develops the basic organic structure of the Ministry of Science and Innovation.

BIOMEDICAL RESEARCH

Decree 143/2008, of 3rd October, of the Ministry of the Valencian Government, which regulates the biobanks in the Valencia Region.

SCIENTIFIC RESEARCH

Order SCO/523/2008, of 27th February, which establishes the regulatory bases for the concession of grants for the strategic research initiative in health in the framework of Law 14/2007, of 3rd July, on biomedical research, and of the National R&D&i plan 2008-2011.

Order SCO/562/2008, of 3rd March, on the delegation of competencies to carry out the announcement and verification of the grants contemplated in the sub-programme of actions to invigorate the research and technological area of the National Health System of Order SCO/523/2008, of 27th February.

Order PRE/621/2008, of 7th March, which regulates the bases, the type of grants and the management of the clear line of R&D&I project actuation in the framework of the National Plan for Scientific Investigation, Development and Technological Innovation, 2008-2011.

PROFESSIONAL MARGINS

Royal Decree 823/2008, of 16th May, which establishes the margins, deductions and corresponding discounts in the dispensing of medicines for human use.

Informative Note, of 17th June 2008, of the Directorate General of Pharmacy and Health Products, on guideline information on the factos for conversion of the EFP to RSP and RSP VAT, applicable from 1st August 2008.

CONDITIONING MATERIAL

Resolution, of 5th March 2008, of the Spanish Medicine and Healthcare Products Agency, which authorises the inclusion of the SIGRE symbol on the labelling of medicines.

PAEDIATRIC MEDICINES

Procedure relating to dosage in the Spanish Medicine and Healthcare Products Agency on studies of medicines for paediatric use (January 2008).

ADVERTISED MEDICINES

Informative Note, of 21st November 2008, of the Spanish Medicine and Healthcare Products Agency, conditions for authorising medicines not subject to prescriptions or advertised medicines.

TRADITIONAL MEDICINES BASED ON PLANTS

Instructions, of 10th July of 2008, of the Spanish Medicine and Healthcare Products Agency, to complete the application for registering traditional medicines based on plants.

ENVIRONMENT

Royal Decree 9/2008, of 11th January, which regulates the Public Hydraulic Domain, approved by Royal Decree 849/1986, of 11th April.

Royal Decree 2090/2008, of 22nd December, which approved the Regulation of the partial development of Law 26/2007, of 23rd October, on Environmental Responsibility.

Order MAM/85/2008, of 16th January, which established the technical criteria for evaluating the damage the Public Hydraulic Domain and the rules on taking samples and analysis of waste water spillages.

Law 9/2008, of 10th July, of the Presidency Department of the Catalan Government, on modification of Law 6/1993, of 15th July, regulating waste.

Law 10/2008, of 3rd November, of the Presidency of the Government of Galicia, on waste in Galicia.

Decree 70/2008, of 2nd October, of the Ministry of the Environment of the Government of Castilla & León, which modifies Annexes II and V and widens Annexe IV of Law 11/2003, of 8th April, on Environmental Prevention in Castilla & León.

Order, of 18th of December 2007, of the Department of the Environment of the Government of Aragón, which approved the normalised model for the notification of the E-PRTR register (European Pollutants Release and Transfer Register) in the Autonomous Region of Aragón.

Order, of 14th March 2008, of the Ministry of Industry, Energy and the Environment of the Government of Extremadura, which regulated the prior notification and created the Register of Emitting Installations of Volatile Organic Compounds in the Autonomous Region of Extremadura.

Order, of 5th May 2008, of the Department of the Environment of the Government of Aragón, which proceeded to the establishment of generic reference levels for the protection of human health from heavy metals and other trace elements in the ground soil of the Autonomous Region of Aragón.

Resolution, of 23rd May 2008, of the Directorate General of Quality and Environmental Evaluation of the Sustainable Environmental of the Government of Galicia, which regulates the procedure for the telematic presentation of the documentation that controls the transfer of dangerous waste in the territorial ambit of the Autonomous Region of Galicia and the setting up of the registration book in an electronic format.

MINISTRY OF HEALTH AND CONSUMER AFFAIRS

Royal Decree 1133/2008, of 4th July, of the development of the basic organic structure of the Ministry of Health and Consumer Affairs.

Order SCO/3194/2008, of 4th November which constitutes the Commission of co-ordination of the activities in the international relations area of the Ministry of Health and Consumer Affairs.

Order SCO/3597/2008, of 24th November, which modifies the Order, of 21st July 1994, which regulates the files with data of a personal nature managed by the Ministry of Health and Consumer Affairs.

REFERENCE PRICES

Order SCO/3803/2008, of 23rd December, which determines the new groups of medicines, their reference prices, and revises the reference prices set by Order SCO/3997/2006, of 28th December, and by Order SCO/3867/2007, of 27th December.

Resolution, of 28th December 2007, of the Subsecretary of Health and Consumer Affairs, which authorises the presentation of the papers for voluntary reductions in the price of medicine presentations, without changing the national code, in the framework of the reference price system through the Telematic Register of the Department.

PRESCRIPTION BY ACTIVE INGREDIENT

Resolution, of 12th November 2008, of the Spanish Medicine and Healthcare Products Agency, which updated Annexe I of Order SCO/2874/2007, of 28th September, which established the medicines that constitute an exception to the possible substitution by the pharmacist in accordance with article 86.4 of Law 29/2006, of 26th July, on Guarantees and Rational Use of Medicinal Products and Medical Devices.

Clarifications on Order SCO/2874/2007, of 28th September, which established the medicines that constitute an exception to the possible substitution by the pharmacist in accordance with article 86.4 of Law 29/2006, of 26th July. (April 2008).

PHARMACEUTICAL SERVICES

Order PRE/1797/2008, of 18th June, on accreditation of the status of pensioners for Social Security for the purposes of recognising the right to pharmaceutical services.

DIETETIC PRODUCTS

Order SCO/1730/2008, of 6th June, which modified the annexe of Royal Decree 1091/2000, of 9th June, which approved specific technical-health Regulations of dietary foods for special medical use.

HEALTH PRODUCTS

Order SLT/373/2008, of 24th July, of the Department of Health of the Catalan Government, on modification of Order SSS/143/2002, of 30th April, which created the Assessment Commission on publicity of health products aimed at the public.

HEALTHCARE PROFESSIONS

Royal Decree 183/2008, of 8th February, which determines and classifies the specialities in health sciences and develops certain aspects of the specialised health training system.

PROMOTION AND PUBLICITY

Order, of 26th March 2008, of the Ministry of Health and Dependency of the Government of Extremadura, which regulated the recognition of health interest acts of a scientific and technical nature held in the Autonomous Region of Extremadura.

Instructions of the Spanish Medicine and Healthcare Products Agency, on the inclusion of the 'yellow triangle' in the promotional material of medicines.

INDUSTRIAL AND INTELLECTUAL PROPERTY

Modifications to the Regulations of the Cooperation Treaty in the area of PCT Patents (Official State Bulletin, of 7th November 1989), adopted at the 32nd session of the assembly of the International Patents Cooperation Union, Geneva, 1st October 2003.

Law 3/2008, of 23rd December, relating to the right of an author of an original work of art to participate in the profits.

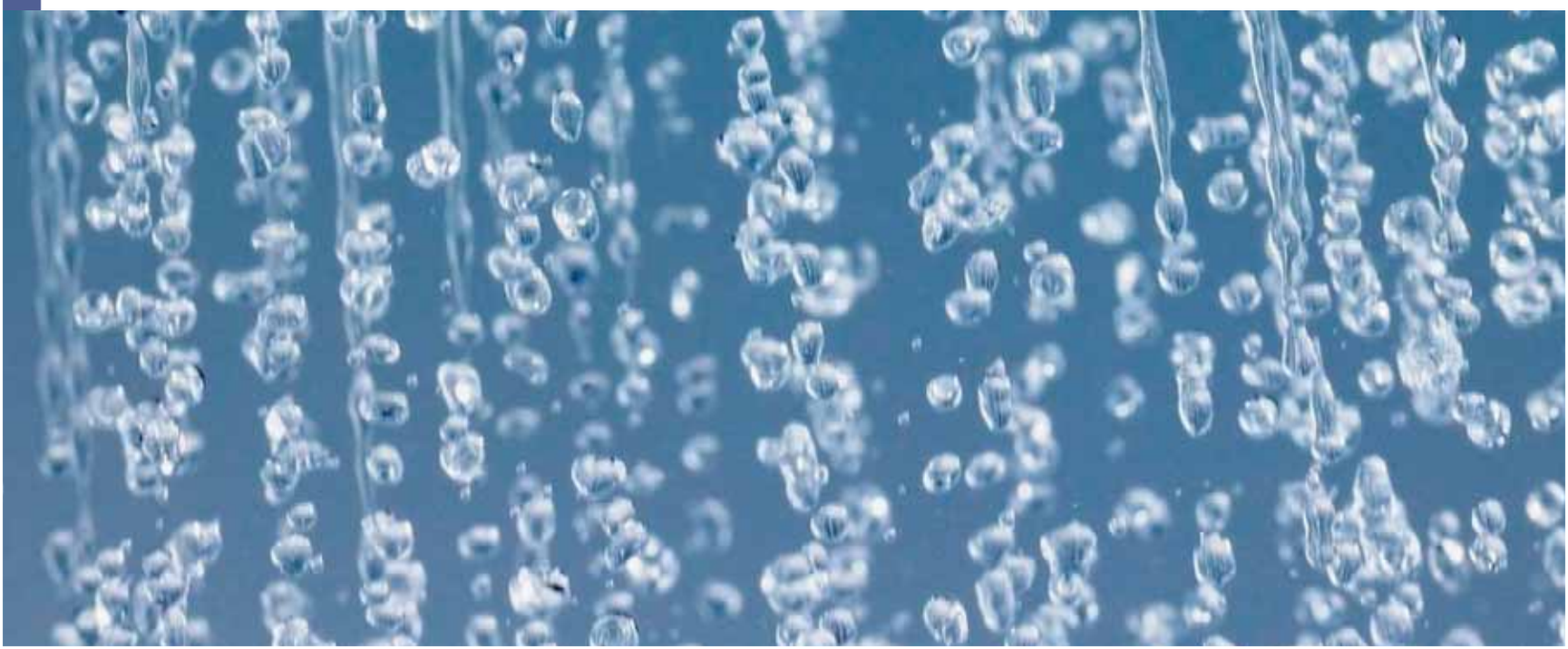
Royal Decree 1431/2008, of 29th August, which modifies certain regulatory stipulations in the area of industrial property.

PERSONAL DATA PROTECTION

Royal Decree 1720/2007, of 21st December, which approved the Regulations of the developing of the Organic Law 15/1999, of 13th December, on data protection of a personal nature.

Resolution, of 3rd November 2008, of the Spanish Data protection Agency, which modified that of 1st September 2006, which determines the information contained in the File Catalogue recorded in the General Registry of Data Protection.

Decree 104/2008, of 22nd July, of the Ministry of Industry and Information Society of the Government of the Castilla-La Mancha Region, on data protection of a personal nature in the Government of the Government of the Castilla-La Mancha Region.



Order, of 4th February 2008, of the Ministry of Health of the Valencian Government, which creates electronic Fotofinder files, pharmacokinetic database data reports, SIP database, Health Ministry and Gaia pharmaceutical management help.

Order SLT/465/2008, of 27th October, of the Department of Health of the Catalan Government, which regulates the Information Security Programme of the Department of Health.

MEDICAL PRESCRIPTION

Decree 206/2008, of 28th August, of the Ministry of Health of the Government of Galicia, on electronic prescriptions.

Order SLT/72/2008, of 12th February, of the Department of Health of the Catalan Government, which develops Decree 159/2007, of 24th July, which regulates electronic prescriptions and telematic handling of pharmaceutical services by the Catalan Health Service.

Resolution, of 18th March of 2008, of the Directorate General of Pharmacy of the Canarias Health Service, which dictates instructions for the unification of criteria relative to the emission of official medical prescriptions and their billing by the Canarias Health Service.

CORPORATE SOCIAL RESPONSIBILITY

Royal Decree 221/2008, of 15th February, which creates and regulates the State Board of Social Responsibility of Companies.

Royal Decree 1469/2008, of 5th September, which modifies Royal Decree 221/2008, of 15th February, which creates and regulates the State Board of Social Responsibility of Companies.

INDIVIDUAL HEALTH CARD

Decree 9/2008, of 25th January, of the Ministry of Health and Dependency of the Government of Extremadura, which regulates the Single Health Card, the Autonomous Personal identification Code and the System of Health Information 'Population management and the Health Resources CIVITAS' in the ambit of the Autonomous Region of Extremadura.

TAXES

Resolution, of 20th November 2008, of the Spanish Medicine and Healthcare Products Agency, which established the application of a procedure for presentation and self-settlement and the conditions for payment by telematic means of the tax anticipated by article 107 Law 29/2006, of 26th July, on guarantees and rational use of medicines and healthcare products.

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