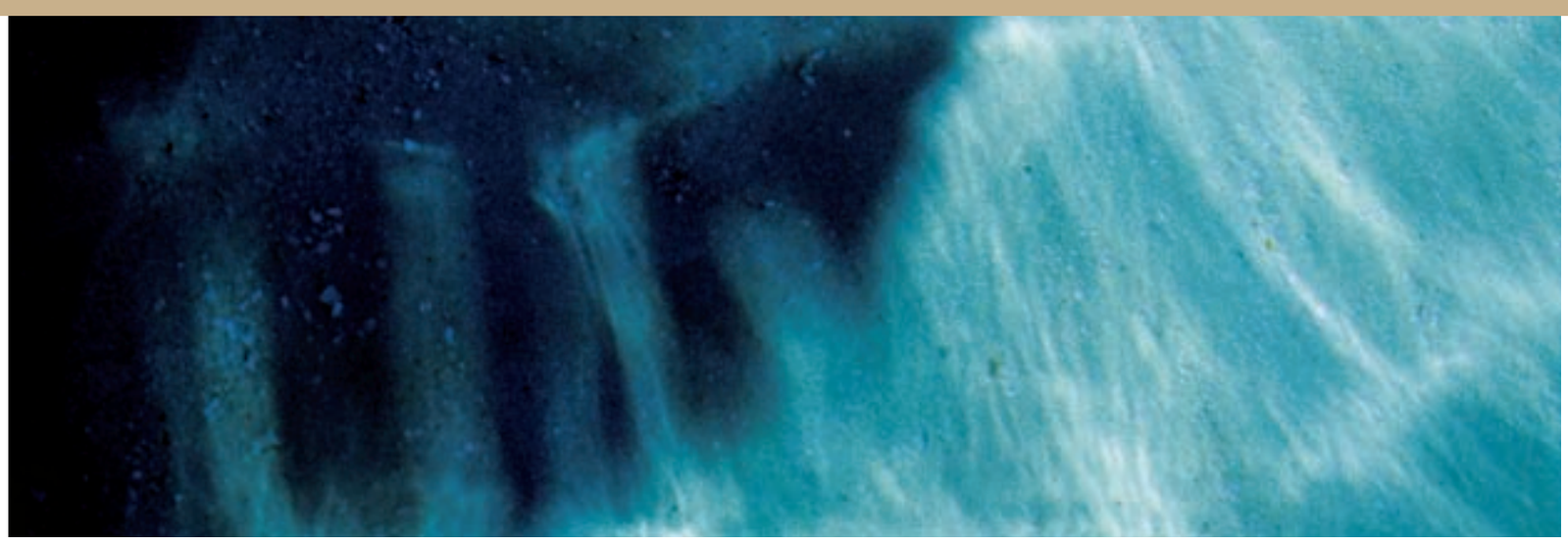
farmaindustria

Annual Report 2005

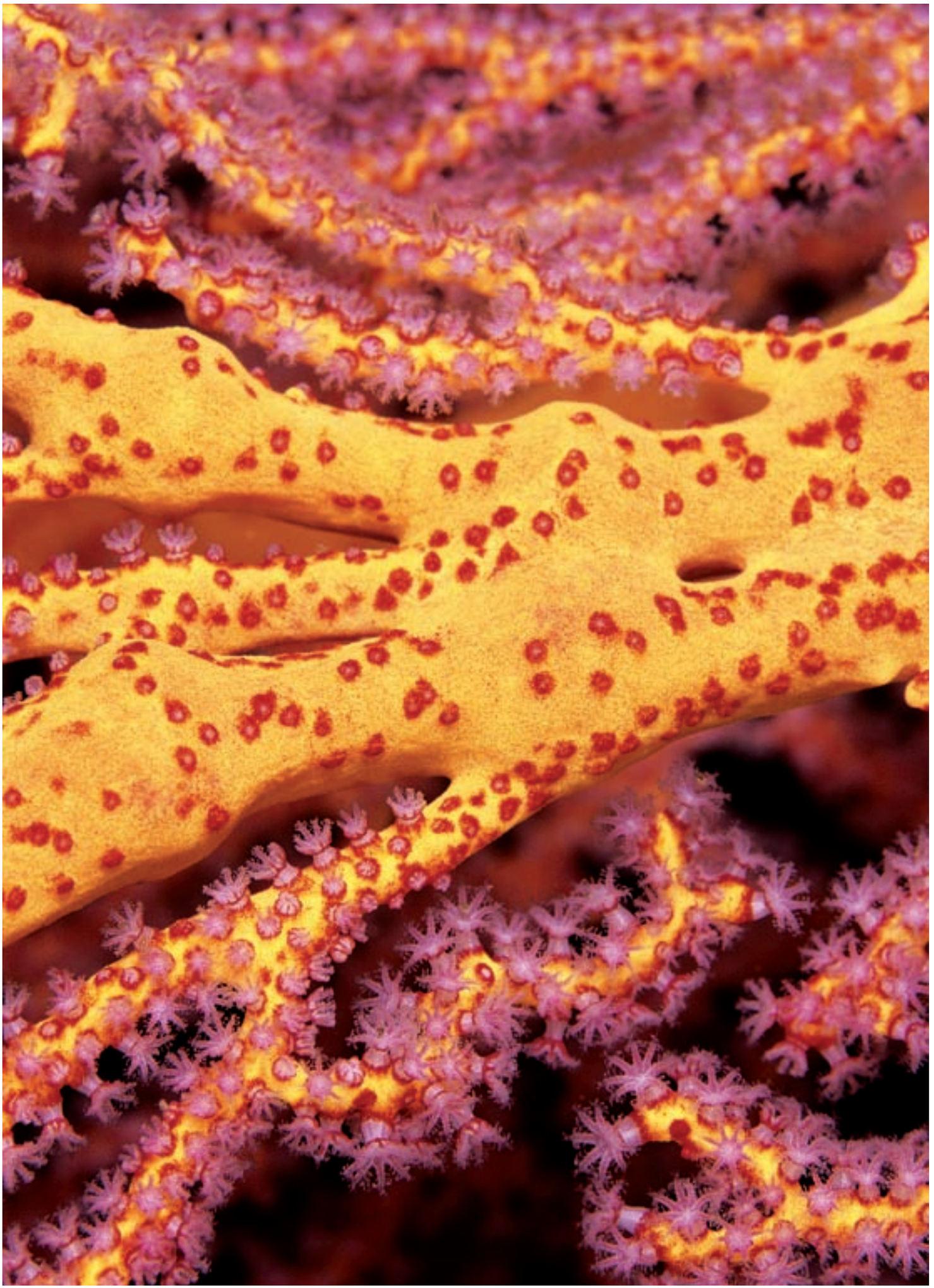
Annual Report 2005



FARMAINDUSTRIA

farmaindustria

Annual Report 2005



INDEX

MESSAGE FROM THE PRESIDENT

Emilio Moraleda
PRESIDENT OF FARMAINDUSTRIA

When it comes to summing up a year in the biomedical pharmaceutical industry, it's almost inevitable to start off by saying that it's been a highly challenging twelve months, involving many changes and situations that were difficult to tackle. One needs only look, for example, at how often the cautionary expression "at the time this report was written" crops up in this document, to realize just how changeable the scenario is.

The year 2005 was marked by the discussion and processing of the new Medicine Act, which at the time that this Report was written, was being debated in the Senate.

The Safeguards and Rational Use of Medicinal Products and Medical Devices Act was initially drafted in the first quarter of 2005, so we have been debating its contents for over a year now. Over that time, the pharmaceutical industry had to face the situation with a united front. Despite all the work and the progress we have made, we are left with a bittersweet taste: while we were able to improve on the content of the Act, the onus for pharmaceutical spending restrictions is still on the industry. This has a direct effect on the prices of medicinal products and imposes mandatory contributions on the part of the laboratories.

It should also be remembered that in March 2005 and March 2006 two consecutive and linear price cuts of 4.2 and 2 percent were imposed, respectively. Accordingly, it comes as no surprise to learn that expectations for market growth have dropped. Likewise, total market turnover in retail sales for 2005 came to 11.3 billion Euros (according to IMS figures), a 6% increase over 2004 and slightly below GDP growth. Of these sales, 76.9% were made through pharmacies and the rest in hospitals. Growth was recorded at 5.7% in the pharmacies and 8% in the hospitals.

In any event, the pharmaceutical industry in Spain has more than proven its ability to energise the economy, and has made its commitment to R&D and its intention for permanence in our country clear. Annual production of medicinal products running at well above 10 billion Euros, 40,000 highly qualified employees and more than 700 million Euros per annum invested in research and

development (almost 20% of the total R&D investment in the Spanish industry), endorse this commitment.

It is a fact, however, that R&D investments are extremely sensitive to regulatory change. This is demonstrated by the results of a FARMAINDUSTRIA survey, which show that our R&D expenditure grew by a mere 5.5% in 2005 (706 million Euros), compared with average annual growth rates of 18.9% between 2000 and 2004. Corresponding government bodies should be aware of this contribution by the pharmaceutical industry, which is crucial to the country's economy, and they need to carefully weigh expenditure restriction measures, considering their impact on these variables. Autonomous Communities, which have an ever increasing role of importance in the regulation and management of this sector, should also be well aware of these considerations. In short, all players in this sector (ourselves included) should share the responsibility of striking a balance between sustainable pharmaceutical services and the development of the industry itself.

In terms of international trade, the pharmaceutical industry has been a major contributor to the Spanish economy. While 2005 was a year of serious decline in the balance of global trade, the pharmaceutical sector did not follow that trend. To the contrary, it reduced its trade deficit by 13.7%, thanks to a spectacular 21.2% growth in exports of medicinal products, totalling 4.8 billion Euros at the year end.

THE PHARMACEUTICAL INDUSTRY IN SPAIN HAS MORE THAN PROVEN ITS ABILITY TO ENERGISE THE ECONOMY, AND HAS MADE ITS COMMITMENT TO R&D AND ITS INTENTION FOR PERMANENCE IN OUR COUNTRY CLEAR

Our intense work on many fronts over the past year will be described in detail throughout this Report. Nevertheless, and without attempting to be exhaustive, I would like to point out some of our most important efforts.

One of the priorities that I set myself when I became President was to enhance the industry's image and prestige. I am proud to say that the increase in the communications budget and the fine work by the Association have achieved a considerable increase, not only in public awareness of FARMAINDUSTRIA, but also in our ability to influence. This, in turn, had a decisive positive influence on the Association's dialogue and negotiation processes with the Government.

The Association's activity was particularly relevant in the assessing of pharmaceutical research, relating with the different medical groups and developing a closer relationship with patients. Examples of this strategy include the following initiatives: the magazines *Redes* y *Pacientes* (*Networks* and *Patients*), the launch of the Spanish Technological Platform for Innovative Medicines, the update of the Code of Practice and the first edition of the Patient Service Awards, are examples of this strategy.

Member participation in the life of the association through our many Working Groups —whose activities are described in this Report— continues to be a cornerstone. Our information services have improved thanks to a daily information bulletin and a weekly news flash, all delivered electronically.

Many challenges lie ahead (patent harmonisation, regional pharmaceutical policies, traceability, INN (International Non-Propietary Name) prescribing, development of regulations implementing the new Law...) on which we have all been working for some time and which are key elements on the current and future FARMAINDUSTRIA agenda. Of all of these points, the most important one is the fight for a complete patent legislation harmonisation, which will finally set Spain among the most advanced countries in terms of industrial property protection.

I would like to end this message by thanking all FARMAINDUSTRIA member companies for their support, and the Management and personnel of FARMAINDUSTRIA for their dedication and skill throughout this year.

FARMAINDUSTRIA IN 2005

FARMAINDUSTRIA IN 2005

1. MEMBERS

On the 31st of December 2005 FARMAINDUSTRIA had 219 member-laboratories.
Geographically, they are distributed as follows:

LABORATORIES DISTRIBUTION

FARMAINDUSTRIA'S member-laboratories represent 52.6% of the holders of some pharmaceutical proprietary drug registration, regardless of whether or not they are being manufactured and/or marketed. In terms of sales, they represent 86% of the total market.

LABORATORIES PER GROUP

NATIONAL		**98**
Large	10	
Medium	6	
Small	82	
INTERNATIONAL		**121**
Large	28	
Medium	27	
Small	66	
TOTAL		**219**

2. ORGANISATION

2.1. Governing Bodies

The General Assembly made up of all association members 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 and 27 representatives of member companies; and the Executive Board, made up of the President, six Vice-Presidents and 10 Directors appointed by the Steering Committee from among its own members.

The composition of these two governing bodies at the closing of this Report was as follows:

EXECUTIVE BOARD

President

Mr. Emilio Moraleda Martínez PFIZER, S.A.

Vice-presidents

Mr. Jesús Acebillo Marín NOVARTIS FARMACEUTICA, S.A.	**Mr. Antoni Esteve Cruella** DR. ESTEVE, S.A., LABORATORIOS*
Mr. Jorge Gallardo Ballart ALMIRALL PRODESFARMA, S.A.	**Mr. Manuel García Garrido** BOEHRINGER INGELHEIM, S.A.**
Mr. Rafael Juste Sesé JUSTE, S.A. QCO. FCA.	**Mr. José Luis Sotoca Santos** JANSSEN CILAG, S.A.

Directors

Mr. Javier Ellena Aramburu DISTA, S.A.	**Mr. Pierre Faraldo** LABORATORIOS SERVIER, S.L.
Ms. Belén Garijo López SANOFI-AVENTIS, S.A. Unipersonal***	**Mr. Germano Natali** BAMA-GEVE, S.L.
Mr. Antonio Pérez Mosquera MERCK SHARP & DOHME DE ESPAÑA, S.A.	**Mr. Javier Peris Musso** S.A.L.V.A.T., S.A., LABORATORIO
Mr. Juan Puig Corcoy MENARINI, S.A., LABORATORIOS	**Mr.Jorge Ramentol Massana** FERRER INTERNACIONAL, S.A.
Ms. Philippa Rodríguez ASTRAZENECA FCA. SPAIN, S.A.****	**Mr. Juan Uriach Torelló** J. URIACH & CIA., S.A.

* Appointment made at the Board Meeting on the 21st of June 2005, to replace Mr. Albert Esteve Cruella.
**Appointed Vice-president at the Board Meeting on the 18th of October 2005, to replace Mr. Carlos Trías Vidal de Llobatera, due to his leaving the company.
***Appointment made at the Board Meeting on the 13th of December 2005, to replace Mr. John Keeler, following his retirement.
**** Appointment approved at the Board Meeting on the 13th of December 2005, to replace D. Carlos Trías Vidal de Llobatera, due to his leaving the company.

STEERING COMMITTEE

President

Mr. Emilio Moraleda Martínez PFIZER, S.A.

Vice-presidents

ALMIRALL PRODESFARMA, S.A. **Mr. Jorge Gallardo Ballart**	BOEHRINGER INGELHEIM, S.A. **Mr. Manuel García Garrido***
DR. ESTEVE, S.A., LABORATORIOS **Mr. Antoni Esteve Cruella****	JANSSEN CILAG, S.A. **Mr. José Luis Sotoca Santos**
JUSTE, S.A. QCO. FCA. **Mr. Rafael Juste Sesé**	NOVARTIS FARMACEUTICA, S.A. **Mr. Jesús Acebillo Marín**

Directors

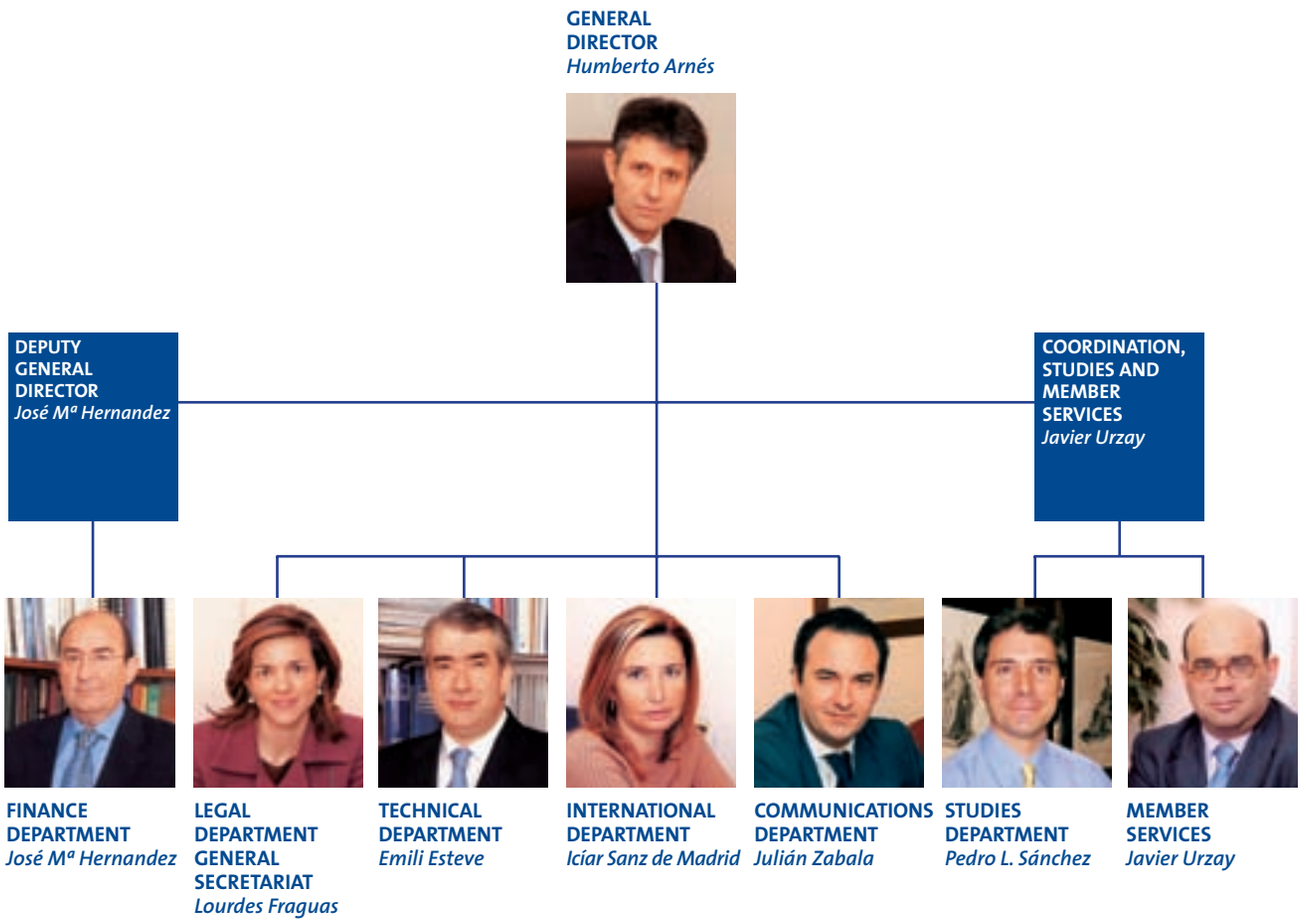
ASTRAZENECA FCA. SPAIN, S.A. **Ms. Philippa Rodríguez****	BAMA-GEVE, S.L. **Mr. Germano Natali**
CEPA SCHWARZ PHARMA, S.L. **Mr. Antonio Martín García**	DISTA, S.A. **Mr. Javier Ellena Aramburu**
FAES FARMA, S.A. **Mr. Eduardo Fernández de Valderrama**	FARDI, Lbo. De Aplic. Farmacodinámicas, S.A. **Mr. Javier Font Salgado**
FARMA LEPORI, S.A. **Mr. Claudio Lepori**	FERRER INTERNACIONAL, S.A. **Mr. Jorge Ramentol Massana**
J. URIACH & CIA, S.A. **Mr. Juan Uriach Torelló**	MENARINI, S.A., LABORATORIOS **Mr. Juan Puig Corcoy**
MERCK SHARP & DOHME DE ESPAÑA, S.A. **Mr. Antonio Pérez Mosquera**	NORMON, S.A., LABORATORIOS **Mr. Jesús Govantes Esteso**
ROCHE FARMA, S.A. **Mr. Luc Dirckx**	LABORATORIOS FCOS. ROVI, S.A. **Mr. Juan López-Belmonte López**
S.A.L.V.A.T., S.A., LABORATORIO **Mr. Javier Peris Musso**	SANOFI-AVENTIS, S.A. Unipersonal **Ms. Belén Garijo López****
SHERING-PLOUGH, S.A. **Mr. Angel Fernández García**	LABORATORIOS SERVIER, S.L. **Mr. Pierre Faraldo**
UPSA MEDICAS, S.L. **Mr. Tomás Vilarroya Ponsirenas**	LABORATORIOS VIÑAS, S.A. **Mr. Antonio Buxadé Viñas**
WYETH FARMA, S.A. **Ms. Elvira Sanz Urgoiti**	

* Appointed Vice-president at the Meeting of the Committee on the 18th of October 2005, to replace Mr. Carlos Trías Vidal de Llobatera, due to his leaving the company.
** Appointment made at the Meeting of the Committee on the 21st of June 2005, previously held by Mr. Albert Esteve Cruella.
***Became part of the Steering Comittee as of December 2005 to replace Mr. Carlos Trías Vidal de Llobatera.
**** Became part of the Steering Comittee as of January 2006, to replace Mr. John A. Keeler.

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 organisational chart follows:



3. AREAS OF ACTIVITY

3.1. Government Relations

3.1.1. The Safeguards and Rational Use of Medicinal Products and Medical Devices Act

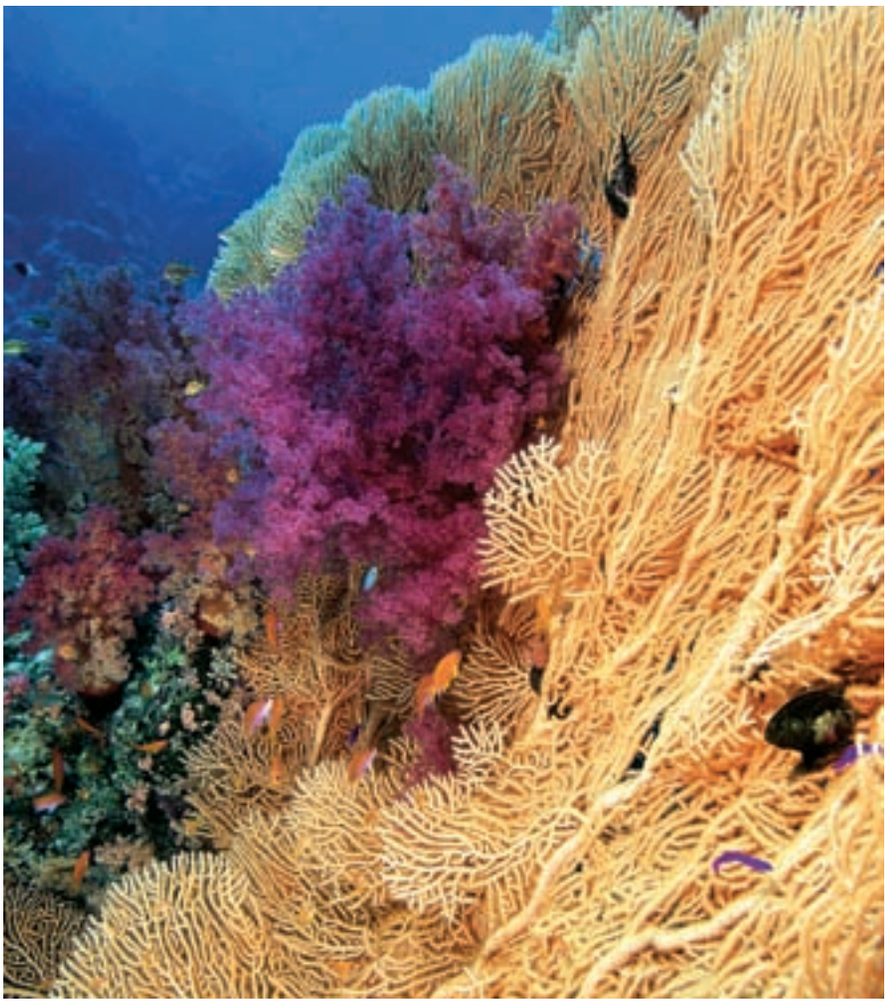
As a result of the revision of the European pharmaceutical legislation which took place in 2004, Spain has had to adapt its national legislation to the European Union Law. In our country, the adaptation of national legislation to the European Law has been carried out in the context of the preparation of a new Law regulating the pharmaceutical sector, which will replace the current law, dating back to 1990.

The Safeguards and Rational Use of Medicinal Products and Medical Devices Act will replace the Medicine Act 25/1990, 20th of December. Through this new Act, Directive 2004/27/CE from the European Council and Parliament on the 31st of March 2004, which modifies Directive 2001/83/CE that established a EU code of medicines for human use, as well as the European Council and Parliament Directive 2004/28/CE, 31st of March, which modifies the Directive 2001/82/CE establishing a EU code for veterinary medicines, will be introduced into Spanish law. Furthermore, the harmonisation of our legislation to (EC) Law No. 726/2004, establishing the EU wide procedures for the authorisation and control of medicines for human and veterinary use for which the European Medicines Agency was created, is assured. This law broadens the European Medicines Agency's responsibilities, as well as the scope of centralised procedures for the authorisation of medicines.

Halfway through 2005, the Government drew up a Draft Law which was presented to Farmaindustria. The draft was analysed by several Association working groups —AEMPS, Legal Council, Market Access, Clinical Research and Pharmacovigilance— and finally a report was prepared, ratified by the Association's governing bodies, which included arguments, comments and alternative proposals for all the areas regulated in the Draft, economic, technical and legal.

As a whole, the Draft Law was very harmful to the activities of pharmaceutical companies located in Spain, with estimated income losses for laboratories exceeding 1.1 billion euros in the first year of implementation of the Law. Such a strong impact could seriously jeopardise both the financial feasibility of many companies and the investment in R&D activities by Spain's leading industry. One out of five Euros invested in industrial R&D activities in Spain comes from pharmaceutical companies.

The Draft Law not only received criticism from Farmaindustria, but from practically the entire sector. In this respect, it is worth mentioning the Council of State's report, which was highly critical



THE NEW SAFEGUARDS AND RATIONAL USE OF MEDICINAL PRODUCTS AND MEDICAL DEVICES ACT WILL REPLACE THE CURRENT LAW, WHICH GOES BACK TO 1990

of the Draft Law and agreed on several issues with the arguments presented by FARMAINDUSTRIA.

Following approval by the Cabinet on the 16th of December 2005, the Bill was published in the Parliament's Official Bulletin, as the first step in its parliamentary processing which will continue in 2006.

At the time this Report was closed in April 2006, the Bill had concluded its processing in the Chamber of Deputies and had been sent to the Upper Chamber to continue its parliamentary proceedings. The Bill that will be studied in the Senate is a document that has undergone significant modification compared to the report sent by the Cabinet to Congress in December 2005, as many of the measures most detrimental to the pharmaceutical industry included in the original report have been either completely removed or at least softened. The contribution of up to 5% of sales volume, lack of recognition for pharmaceutical innovation, price cuts of up to 20% on medicines marketed previously for over a decade and with no generic in Spain, price displayed on packaging, etcetera.

THE DRAFT LAW NOT ONLY RECEIVED CRITICISM FROM FARMAINDUSTRIA, BUT FROM PRACTICALLY THE ENTIRE SECTOR. THE MOST RECENT TEXT CONTAINS A NUMBER OF WEAKNESSES, PARTICULARLY WITH REGARD TO THE RECOGNITION OF PHARMACEUTICAL R&D

However, even the most recent text contains a number of weaknesses, particularly with regard to the lack of recognition of pharmaceutical R&D which will have a strong financial impact on pharmaceutical companies located in Spain. Almost more importantly, the Bill does not take advantage of a unique opportunity to harmonise Spain's pharmaceutical product patents law with the EU standards.

The Adhesion Treaty of Spain to the European Community in 1986 established a provisional period with regards to patent law, accepting the product patent for medicines only since 1992. As a consequence, and until 2012, some medicines have product patent protection in the EU, but not in Spain. This allows generics to be produced in Spain, but not in other EU countries.

To put Spain on the same level of industrial protection as the European standard is not only a political matter, but a legal need, as the Trade Related Aspects of the Intellectual Property Rights Agreement (TRIPS), signed by Spain in 1995, requires that the rights granted by the patenting process be extended to those medicines with patents prior to that date, providing them with a product patent recognition, as has been recently acknowledged in a sentence ruled by the Court of Summary Jurisdiction In Madrid.

Accordingly, and bearing in mind that the Law currently being processed in Parliament defines in great detail the authorisation regime, prices and public funding of medicines —including the reference pricing system—, this would be an ideal moment to finally harmonise the situation of pharmaceutical sector industrial property regulation in Spain with the rest of Europe.

FARMAINDUSTRIA is confident that throughout the parliamentary proceedings of the Bill, the demands of the Spanish pharmaceutical industry will be incorporated, especially those related to the recognition of the pharmaceutical innovation and industrial property rights protection regarding pharmaceutical products.

3.1.2. The Autonomous Communities

The undeniable influence of the autonomous communities in the pharmaceutical sector can be seen in the considerable increase of rules and regulations affecting the areas of responsibility transferred from the central government, especially those related to the organisation of clinical research and pharmacovigilance.

The autonomous communities constitute a clear and varied interlocutor for the pharmaceutical industry, which needs to establish an ongoing dialogue with the autonomous delegates who are responsible for providing pharmaceutical services. In this sense,

FARMAINDUSTRIA has been regularly organising a debate forum with the sector's regional decision-makers and in which the most current and relevant industry issues are discussed. In the last year, there have been forums in Valencia, Toledo and Segovia, which have dealt with therapeutic value of medicines, biomedical research promotion and providing health professionals with training and information on medicines.

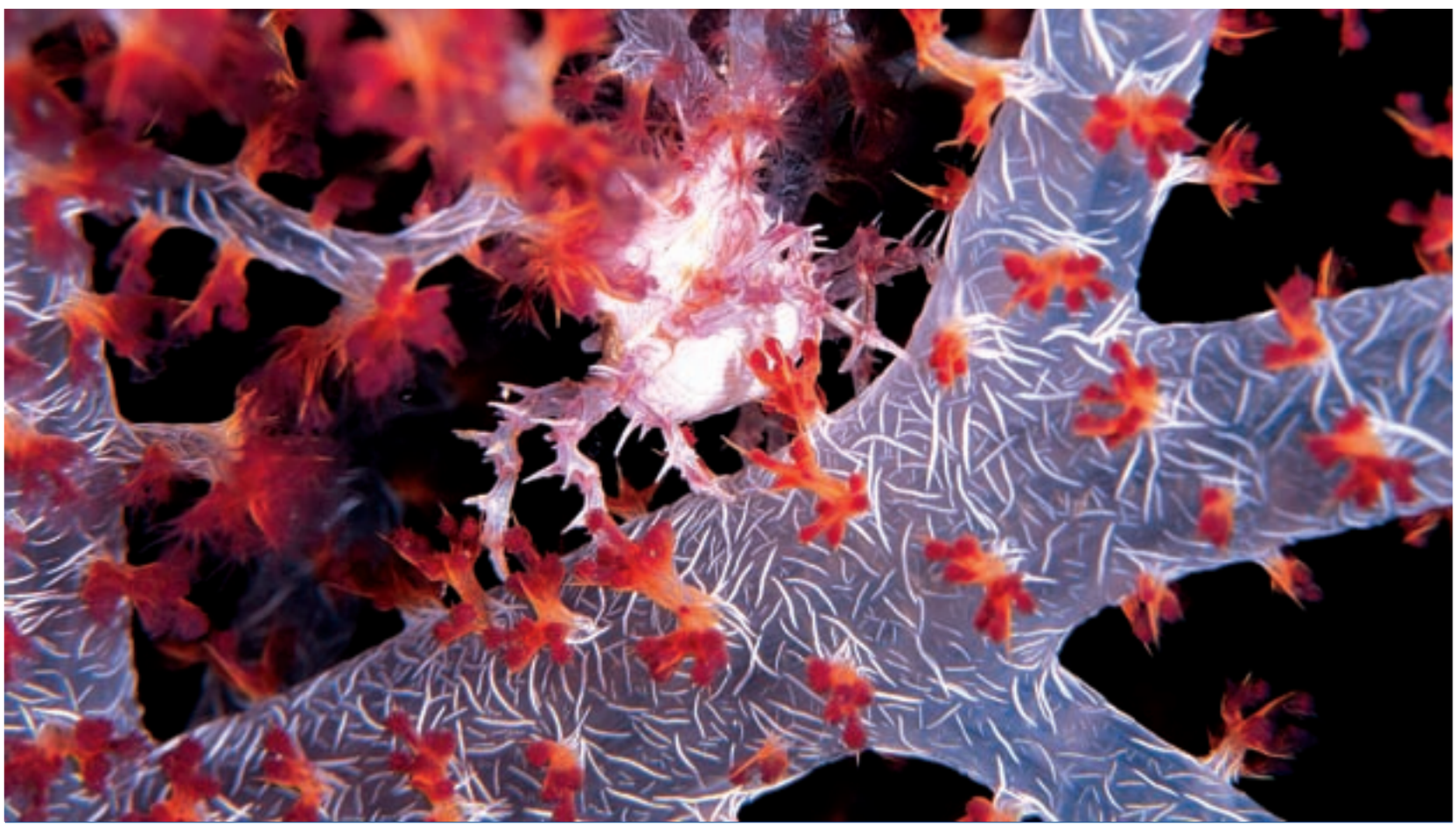
Furthermore, some of the practices that had been systematically carried out in some autonomous communities —such as prescription by active ingredient (International Non-Propietary Name -INN- Prescribing) or the organisation of clinical research— have been extended to other regions, although different models continue to be followed by different autonomous communities.

INN prescribing

In Spain, INN prescribing is a widespread practice. For example, the Andalusian system does not establish any limits to this practice and actively encourages its systematic application as it understands that all authorised medicines with the same active ingredient should have the same therapeutic benefit. On the other hand, the Castilla-Leon model limits INN prescribing to those medicines that have a generic, thus excluding from this practice those medicines with strict therapeutic ranges, and tries to avoid that patients (particularly chronic or poly medicated ones) have to continually change medication for this reason.

If the Government encourages INN prescribing it is for purely financial reasons, and this practice has strongly emerged in some autonomous communities, as their management decision makers understand that the financial profits that the practice generates are well worth the inconveniences and health risks deriving from continuous changes in patient´s medication appearance as well as the limits established on doctors' freedom of prescription.

FARMAINDUSTRIA has pointed out the weaknesses of this type of policy which offers no advantages to the



prescriber, increases the risk of patient confusion and produces no saving in the case of medicines without a generic and very little saving in a context where a fully operative reference price system exists.

Draft Andalusian Pharmacy Law

The Draft Andalusian Pharmacy Law , which started proceedings this year, practically deals with all the aspects related to pharmacy and medicines for human and veterinary use. This text not only establishes the main rules for the regulation of pharmacies and pharmacy services, but also regulates the rational use of medicines, their distribution, promotion and communication, professional incompatibilities and defines violations as well as penalties.

The industry assessment of this Draft Law could not be more negative, particularly with regard to Chapter III, which refers to the rational use of medicines. This Chapter grants the Andalusian public health system extremely wide powers to control doctors' prescriptions and to evaluate and assess the compared therapeutic use of new medicines, insisting on the generalised use of INN prescribing and maintaining the regional certification. Furthermore, the rules establish an overall ban on any type of medicine promotion (including visits to doctors) unless expressly authorised.

Farmaindustria presented the relevant arguments regarding the text and has established contacts at a number of levels to put forward its points of view, which coincide with those of other important groups that have also expressed their concern about this Draft Law.

Clinical Research

The promotion of clinical research is one of the aspects that developed most throughout last year. Spanish legislation requires that, before starting a clinical trial in a specific centre, the promoter should take into account three crucial elements: (i) the report from the Ethical Committee, (ii) the authorisation from the Spanish Medicines Agency and (iii) the contract with the centre itself.

Some autonomous communities are developing contract models which can be applied in all public centres in their territory. Even if this procedure is a progress in itself, there is still a lot to be done to improve the practice of clinical research in Spain. Through the Medical Directors Functional Group, Farmaindustria is currently analysing some relevant parameters, especially those concerning the different time periods required for the processing of clinical trials.

3.1.3. Regulatory Framework

The processing of the Safeguards and Rational Use of Medicinal Products and Medical Devices Act has led to less regulatory activity throughout last year, possibly as a precaution until the final text of the future Act is known.

3.1.4. Technical Committees

Farmaindustria participates in several technical committees set up by the appropiate authorities, presenting the pharmaceutical industry's point of view and maintaining the necessary link with Government decision makers.

The National Health System Inter-regional Council Consultative Committee

The National Health System (NHS) Cohesion and Quality Act 16/2003, from the 28th of May, establishes that the social participation in the NHS should be conducted through the Consultative Committee, among others. This Committee is the body through which unions make their institutional presence in the NHS.

The functions of the Consultative Committee are to report, advise and formulate proposals on issues of special interest for the functioning of the National Health System. Among these proposals is draft legislation concerning health services, funding and pharmaceutical spending.

Throughout last year, the Committee met on a regular basis and debated on pharmaceutical issues focused on the Safeguards and Rational Use of Medicinal Products and Medical Devices Act and on several lines of development of the Pharmaceutical Policy Strategic Plan developed by the Ministry of Health and Consumer Affairs at the end of 2004.

CODEM

The Committee for the Evaluation of Medicinal Products for Human Use (Comité de Evaluación de Medicamentos de Uso Humano–CODEM) is the associate body of the Spanish Medicinal Products Agency (AEMPS) responsible for advising on the technical and scientific issues involved in the authorisation of new pharmaceutical products. The membership of this Committee was renewed by Ministerial Order SCO/932/2005, issued on the 14th of March. One of the members of CODEM is appointed at the proposal of the Pharmaceutical Industry Association, providing FARMAINDUSTRIA with a permanent presence on the Committee.

Catalonia Regional Advisory Board for Medication Errors

The main task of the Advisory Board for Medication Errors —created at the initiative of the Catalan Directorate General of Health Resources— is to examine the most common causes of medication errors and to propose possible preventive measures aimed at minimising such errors.

The Board has developed a document on the errors that could occur in the life-span of medicine, from the moment of manufacture to the moment that it is taken by the patient, passing through the prescription and supply phases. This document, which publication was pending at the time this Report was closed, examines the possible causes of errors in each of these areas and proposes possible preventive measures, taking into account the points of view of experts from Universities, public institutions from the pharmaceutical sphere, health, nursing and pharmaceutical professionals and FARMAINDUSTRIA.

ISSUES HANDLED BY CODEM IN 2005

Meetings held:	9
Issues raised:	1.327
- New applications accepted:	774
* Mutual Recognition:	168
* Domestic:	116
* Generic:	421
* Medicinal Plants:	1
* OTC:	68
* Homeopathic products:	0
- New applications turned down:	387
* Mutual Recognition:	28
* Domestic:	58
* Generics:	254
* Medicinal Plants:	1
* OTC:	46
* Homeopathic products:	0
- Modifications accepted:	66
- Modifications turned down:	24
- Reports on centralized product applications:	76

Source: Spanish Medicines Agency.

Committee on the inclusion of active ingredients in OTC products

The listed active ingredients used in OTC medicines are updated on a regular basis via Ministerial Orders.

Integrated in the Spanish Medicinal Products Agency, this multidisciplinary committee carries out proposals for the inclusion of new active ingredients, as well as modifications to the information included in the technical specifications templates and information leaflets for patients taking OTCs.

During 2005 the list of active ingredients allowed in OTC products was updated by a Ministerial Order which will be published during 2006.

Advertising control and OTC self-regulatory committees

Royal Decree 1416/1994, regulating advertising of medicines for human use, distinguishes two types of advertising: one directed specifically at health professionals on prescription products, which needs to be communicated to the competent health authorities, and another aimed at the general public, requiring prior approval, either from the Directorate General for Pharmacy and Health Products when the campaign has a national scope, or from the respective autonomous community when the campaign is regional.

Public advertising is only allowed in the case of proprietary drugs that have been specifically rated as advertisable, that is, those that have been developed and meant for the treatment of symptoms or minor ailments.

Farmaindustria, representing its member laboratories, participates with the representatives of the Directorate General for Pharmacy and Health Products, as well as the Spanish Medicinal Products Agency, in the Advertising Control and OTC Self-Regulatory Committee, Committee where OTC advertising campaigns are analysed.

3.2. Communication

In June 2005, the Farmaindustria General Assembly approved the launch of a Communication Plan aimed at improving not only the public's perception of the biomedical industry in Spain, but also the presence, access and influence of Farmaindustria in different areas. The new Communication Plan has led to the opening of new lines of work, and has enhanced, both in quality and quantity, all of Farmaindustria's activity with regard to the public presence of the Association, with the aim of transmitting effectively and on daily basis, the strategic messages of our Sector.

In the first year of implementation of this Plan, the laying of foundations to achieve the aforementioned objectives was initiated, maintaining a high activity level and converting Farmaindustria into an unquestionable source of information about the sector.

3.2.1. Farmaindustria in the media

Wide Presence in the Media

2005 turned out to be a turning point in Farmaindustria's information policy. After a period of steady growth, Farmaindustria's media presence increased substantially in 2005. Specialised, general and economic media have systematically dealt with subjects of interest to the pharmaceutical industry on a daily basis, with different approaches and issues, but always with a positive outcome.

THE NEW COMMUNICATION PLAN HAS LED TO THE OPENING OF NEW LINES OF WORK, AND HAS ENHANCED, BOTH IN QUALITY AND QUANTITY, ALL OF Farmaindustria's activity

This is all the more remarkable if we consider the political situation that the pharmaceutical sector has gone through from June 2005 on, as the proceedings of the Safeguards and Rational Use of Medicinal Products and Medical Devices Act have demanded additional effort in this area.

Increased Information Activity

The increase in the number of activities and the aforementioned political situation have required a proportional increase of FARMAINDUSTRIA information activity. During 2005, over 3 press releases a month were published —40 all together last year—, the media were called to 15 press conferences; more than 40 interviews appeared in different media, and 15 opinion columns were published on relevant topics.

All these figures as well as the achieved media repercussions exceed the 2004 rates by far while a large variety of subjects were also dealt with.

Along with traditional information tools —press releases, press conferences, etc.— the systematisation of other types of PR tools with opinion leaders were initiated in 2005. In this area, a series of encounters were organised between prestigious political and business journalists and opinion leaders and different representatives of FARMAINDUSTRIA's member companies. This activity proved to be an important communication tool in both directions, as well as an effective means of passing messages on to a very important and influential opinion group.

Professional Training for Journalists

For the third year in a row, FARMAINDUSTRIA organised its Pharmaceutical Industry and Media Seminar in November 2005, in collaboration with the National Association of Health Journalists (ANIS) and, for the first time, with the Federation of Spanish Press Associations (FAPE).

This year's Seminar, held in Granada, brought together almost forty media professionals and carried forward the principles of previous years, creating a framework for discussion, exchange of opinions and mutual training on the current situation of the pharmaceutical industry in Spain and its relationship with the media.

As on previous occasions, the directors of the different Association Departments analysed the current situation of the pharmaceutical sector in Spain, described some of the most relevant of FARMAINDUSTRIA's activities from last year and explained how the recent changes on the regulatory scene have affected and may affect the Spanish pharmaceutical industry.

During 2005, a new training activity was introduced that will be part of those planned for 2006: FARMAINDUSTRIA's participation in the I National Convention of Health Journalism, organized jointly with the Spanish National Association of Health Journalists (ANIS) and the Autonomous Community of Madrid.

This Convention was created with two aims in mind: (i) to discuss the different aspects of health information, its special sensitivity and complexity, and (ii) to give the recognition deserved to this activity of such high social relevance.

The Convention was attended by over 400 participants and more than thirty speakers.

Top: Humberto Arnés and Emilio Moraleda (left to right). Bottom: Together with other speakers at the Seminar held in Granada).

New logo

FARMAINDUSTRIA and the FARMAINDUSTRIA Foundation created a new logo and corporate image during 2005 to update the look of their respective symbols and to bring their image in line with current aesthetic trends.

farmaindustria

fundación farmaindustria

With the new logo —designed by the Alberto Corazón Studio—, FARMAINDUSTRIA attempts to stress the priority given to innovation and, using simple and clear forms, expresses its commitment to the transparency and strength of the Association's messages, representing a modern and dynamic sector.

FARMAINDUSTRIA took part in the I National Congress of Health Journalism.

New advertising

The updating of FARMAINDUSTRIA's communication policy with a high component of social rapprochement, public presence and message simplification, demanded a new way of understanding advertising creativity. So, FARMAINDUSTRIA opted in 2005 for an innovative way of sending out the Sector's strategic messages, with previously unused elements.

FARMAINDUSTRIA opted for simple and direct messages, along with an illustration in flat and friendly colours —the work of the renowned illustrator Iván Solbes— to launch a new form of visual

Farmaindustria has turned to simple messages for its new advertising.

communication intended to give the Association's advertising a unique and unmistakable appearance.

I Annual Farmaindustria Foundation Patient Service Awards

The Farmaindustria Foundation announced its first Annual Patient Service Awards. The awards ceremony was held at the Royal Tapestry Factory in Madrid, with the attendance of Ms. Elena Salgado, Minister of Health and Consumer Affairs.

These prizes were created to stress the patient as the real reference for our activity and for the activities of all agents in the Health System. The Award rules identify three categories: (i) patient associations, (ii) information and service entities and (iii) other entities, with different sections for each of the three categories.

More than one hundred candidates were present for the first Awards ceremony. The panel of judges organised in June was composed of prestigious representatives from the Patients and Disabled People Associative Movement and from the medical, scientific, social, media and political arenas. It awarded the following winners:

Elena Salgado, Minister of Health and Consumer Affairs, attended the ceremony organised by Farmaindustria Foundation

CATEGORY	AWARD WINNERS
PATIENT ASSOCIATIONS	
Best Health Education Initiative	Association for the Support and Help in the treatment of cancer and other serious illnesses (Carena)
Best Presence in Society	Spanish Cancer Fighting Association
Quality in Service to the Members	Madrid Multiple Sclerosis Association
INFORMATION AND SERVICE ENTITIES	
Scientific and Professional Societies	Cardioalert (Spanish Cardiology Association, Spanish Heart Foundation, Spanish Society of Community Pharmacy, Spanish Society of Family and Community Healthcare, Bayer Healthcare, Manistry of Health and Consumer Affairs
Media	Radio Nacional de España, Radio 5
Healthcare Centres	La Paz University Hospital Support Group
RECOGNITION	Rafael Matesanz

'Pacientes' ('Patients') Magazine

A new FARMAINDUSTRIA publication made its first appearance in 2005, aimed at Patient Associations and all those institutions, organisations, and individuals interested in this subject.

This new quarterly magazine —prepared and designed by Servimedia—, currently has a circulation of 20,000 copies, which shows the sector's growing demand for the publication. The magazine's contents give priority to the different activities, interests, innovations, services and messages of the Patient Associations.

'Redes' ('Network') Magazine

The *Medicine Research Networks* magazine was first published in 2005 with the aim of disseminating and valuing the reality of current Spanish research within the framework of this network. Each issue has a central monographic section devoted to analysing the activities of each of the Group Networks and, after only three issues, the magazine has become the reference publication in this area.

With the same aim of spreading the knowledge about researchers in our Country, *Redes* magazine

includes a comprehensive review of the activities of the Centre Networks. Some 10,000 copies of this quarterly magazine are read by professionals in the different Administrations, Institutions and Organisations related to biomedical R&D in Spain.

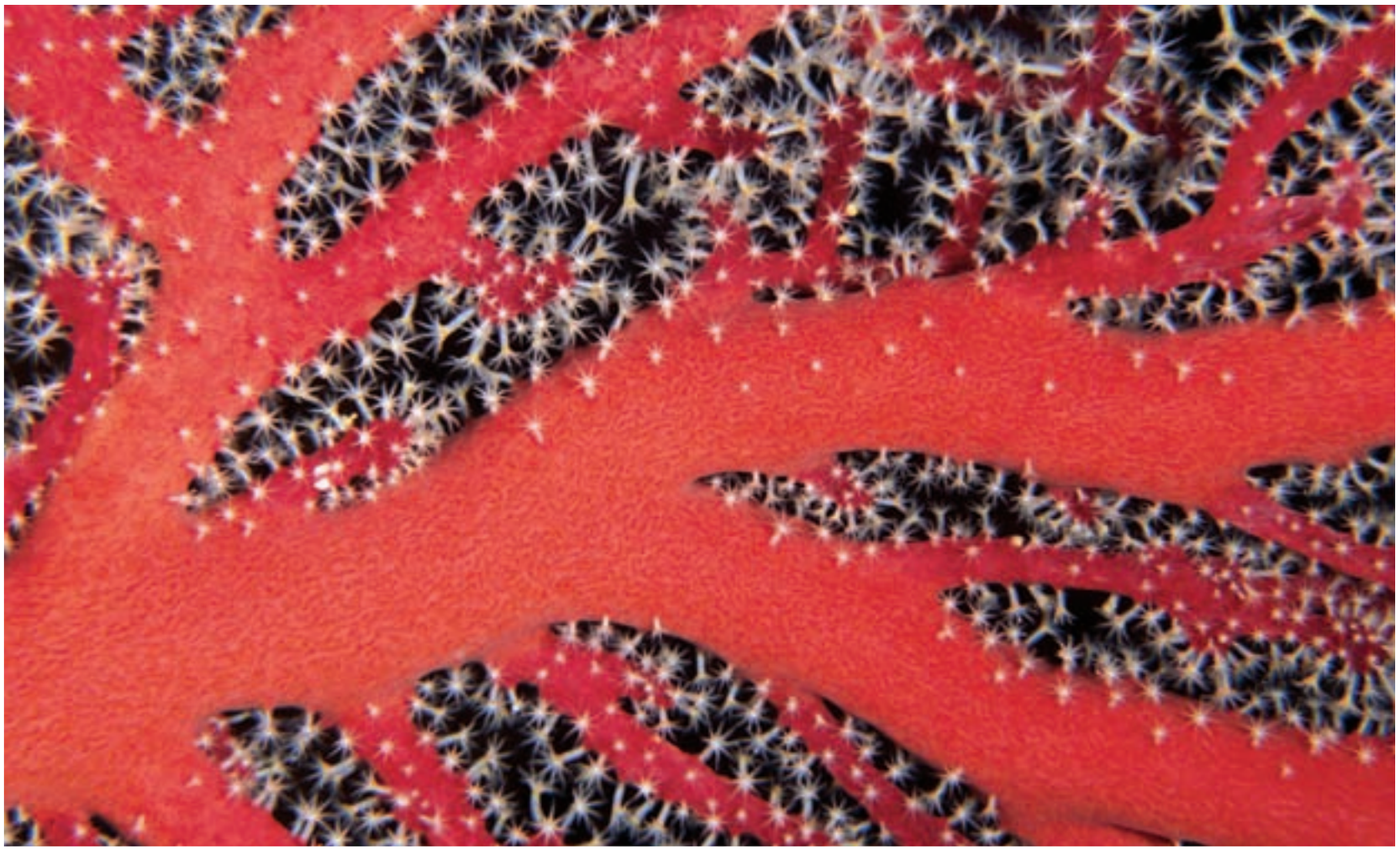
Each issue of the magazine is presented at a press conference that is followed by an encounter with the most important researchers in the specific field covered in that issue. This encounter allows two-way discussion of the current situation of research in Spain and helps to advance in the necessary relationships between researchers and the pharmaceutical industry that is the main promoting and financing agent for these activities in Spain.

Press Website

FARMAINDUSTRIA's press website (www.prensa.farmaindustria.es) evolved along the same positive lines as the rest of the Association's information activity in 2005. Along with daily press clippings, summaries and real time coverage of the most relevant news for the Sector, the site contains FARMAINDUSTRIA press releases and announcements, as well as a complete graphic file of people and events, all the publications of the Association and a wide variety of information related to FARMAINDUSTRIA and the FARMAINDUSTRIA Foundation.
The number of journalists registered on this website grew considerably in 2004, as did the number of visits, particularly during the last quarter of 2005.

Collaborations with ANIS and APIE

Besides the abovementioned Pharmaceutical Industry and Media Seminar, FARMAINDUSTRIA extended its collaboration with the National Association of Health Journalists (ANIS) and the Association of Financial Journalists (APIE) one more year for the preparation of two communication guidebooks: the Health Communication Guide and the Financial Communication Diary.



3.2.2. Studies and Publications
STUDY SERIES

The Many Faces of Innovation

In June 2005 FARMAINDUSTRIA published the Spanish translation of the study carried out by the Office of Health Economics entitled *The Many Faces of Innovation*. This report stresses the fact that pharmaceutical innovation is both complex and multidimensional and that it has to be evaluated from a broad perspective, or run the risk of some or all of the advantages to be obtained from new medicines going unnoticed.

The report highlights that where medicines are concerned, innovation has many faces: they can provide beneficial effects with respect to health, a greater degree of comfort for patients or positive effects for society, such as the freeing up of economic and human resources whenever new medicines enable a change in the way medical care is administered to a group of patients, or an improvement in the productivity associated with the consumption of new medicines.

Speakers at the public presentation of the report included the Under Secretary of the Ministry of Health and Consumer Affairs, Mr Fernando Puig de la Bellacasa, the Chairman of the Spanish National Research Council (CSIC), Mr Carlos Martínez Alonso and the Director General of the Centre for the Industrial and Technological Development (CDTI), Mr Maurici Lucena.

'FARMAINDUSTRIA' Magazine

The year of 2005 saw the publication of issues 6 and 7 of the FARMAINDUSTRIA Magazine. Among the articles featured in both issues it is worth mentioning: an article on the pharmaceutical R&D carried out in Spain using the data provided by the yearly R&D survey undertaken by FARMAINDUSTRIA; an international comparison of prices and penetration indices with respect to innovative medicines; the analysis of an opinion poll targeting Spanish doctors promoted by the Council of Phisicians Proffessional Associations (OMC) regarding the factors involved in the quality of prescription in Spain; an article on the debt of the Spanish National Health System for the supply of medicines to hospitals and an article in which the results of a survey on INN prescribing carried out in Andalusia are analysed.

Status Report. The Pharmaceutical Market in Spain

In May 2005, FARMAINDUSTRIA began the monthly publication of its bulletin, *The Pharmaceutical Market in Spain*. The bulletin describes the development of Spanish public pharmaceutical consumption and analyses current, relevant and useful data and information in order to better understand the way in which the pharmaceutical market works. The bulletin is the object of intense scrutiny by both the economic press and specialist media.

3.3.Services provided to Associated Laboratories

3.3.1. Online Services

www.farmaindustria.es

FARMAINDUSTRIA has a website on which all the documentation it generates is posted on a daily basis. The website is made up of two parts that are differentiated by access type —public or private— and it is accessed by over 1,300 different visitors every day.

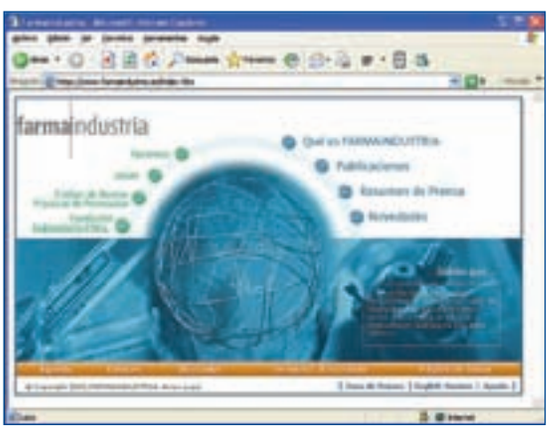
The number of visits continues to grow and it reached 3.5 million in 2005, with over 2 million downloads, representing a total volume of information of 281 million Kb. By geographical area, 54% of visits come from Western European countries, followed by North America (22%) and Latin America (20%).

Improvements and New Information

During 2005, a number of important new features have been incorporated, some of which are intended to improve the management of the website itself and reduce its download times —by equipping it with a greater bandwidth and redesigning the routines used to access it— and others designed to provide spaces in which to store new information or to complete that which already exists.

A new section has been created within the eight main sections that appear in the private area, which is made up of the News Flash, the Daily Information Bulletin for Associates and the new Communications Flash, which includes news and activities linked with the Association's communications division.

The two new series of FARMAINDUSTRIA publications have also been added; the magazine *Pacientes* (*Patients*) and the monthly bulletin, *The Pharmaceutical Market in Spain*. Both publications have their own sections within the website and also form part of the Association's history archive.



Within the open work environment set aside for the Code of Practice Surveillance Unit (CPSU), tools have been developed that speed up and improve its management capacity, together with modules that intensify its relations with laboratories, as is the case of the new *Events Communications* formula - *Eventos de Terceros* (Third-Party Events).

New Support for FARMAINDUSTRIA Publications

At the end of 2005 a new service came into operation that will improve the systems that FARMAINDUSTRIA uses to send information to its associates. Each year's documentation will now be copied onto two CD-ROMs: one containing information intended for associates —including, among others, Circulars and News Flashes— and the other with information of a public nature, including publications, notes, etcetera.

Documental Management System

Two years have passed since FARMAINDUSTRIA's Document Management System first came into operation. The system currently manages 9,000 files of managers in charge of the different areas of interest of the sector, with these being grouped into 500 homogenous environments in accordance with FARMAINDUSTRIA's communication criteria. At least 1,600 people are contacted on a daily basis from the System, thereby covering 100% of the documentation sent out by the Association and representing a monthly volume of over 50,000 messages.

3.3.2. Working Groups, Sections and Functional Groups

Working Groups, Sections and Functional Groups play a fundamental role in the way FARMAINDUSTRIA works.

Although the objectives and the functioning of each of these differ in accordance with their type, the element that they all have in common is that of strengthening the active participation of the associate laboratories with respect to all matters of interest to the sector.

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

- **Working Groups:** these are established on the initiative of the Association's Governmental Bodies in order to tackle specific problems. They have a predetermined lifespan and work towards the conformation of stances within the industry and on the analysis of proposed high-impact legislation.
- **Sections:** these are made up of groups of laboratories that share a common problem who meet on a periodical basis to analyse certain themes and subjects and make proposals. Essentially, these are permanent bodies, as long as matters to discuss and reasons to work together exist.
- **Functional Groups:** these bring together the managers of different laboratories by functional area in order to study specialist matters and they play a supportive role in helping FARMAINDUSTRIA's departments to prepare proposals and evaluate the stances of the sector with respect to its competence. Occasionally these groups contain ad hoc subgroups or commissions set up to analyse on specific themes.

2005 saw a renewal of the Working Groups, Sections and Functional Groups concept, with both their composition and work plans being updated. While some groups have been incorporated into others due to the nature of the functions assigned to them, new groups with specific objectives have been created in response to the mandate issued by FARMAINDUSTRIA's governmental bodies.

The purpose of this updating process was none other than to encourage the active participation of the associates whilst at the same time ensuring that the different business groups are suitably represented. To illustrate this, it is worth pointing out the intensive work carried out by the groups with respect

to providing a coherent stance for the industry regarding various matters, all of which are extremely relevant for the pharmaceutical companies.

There follows a summary of the activities of the different groups and sections in 2005.

Working Group on the Development of Article 100

Throughout 2005, this Group focused its work on monitoring both the legislative development and the practical implementation of Article 100.2 of Spanish Law 25/1990 governing Medicines via that established in Royal Decree 725/2003 of June 13.

In July 2005, the Spanish Ministry of Health and Consumer Affairs commissioned the General Council of Official Pharmaceutical Associations (COF) to manage the information contained in Royal Decree 725/2003. This represented a significant change in the target of the information supplied by the laboratories, which switched from being the General Directorate for Pharmacy and Health Products to being the General Council of COF itself.

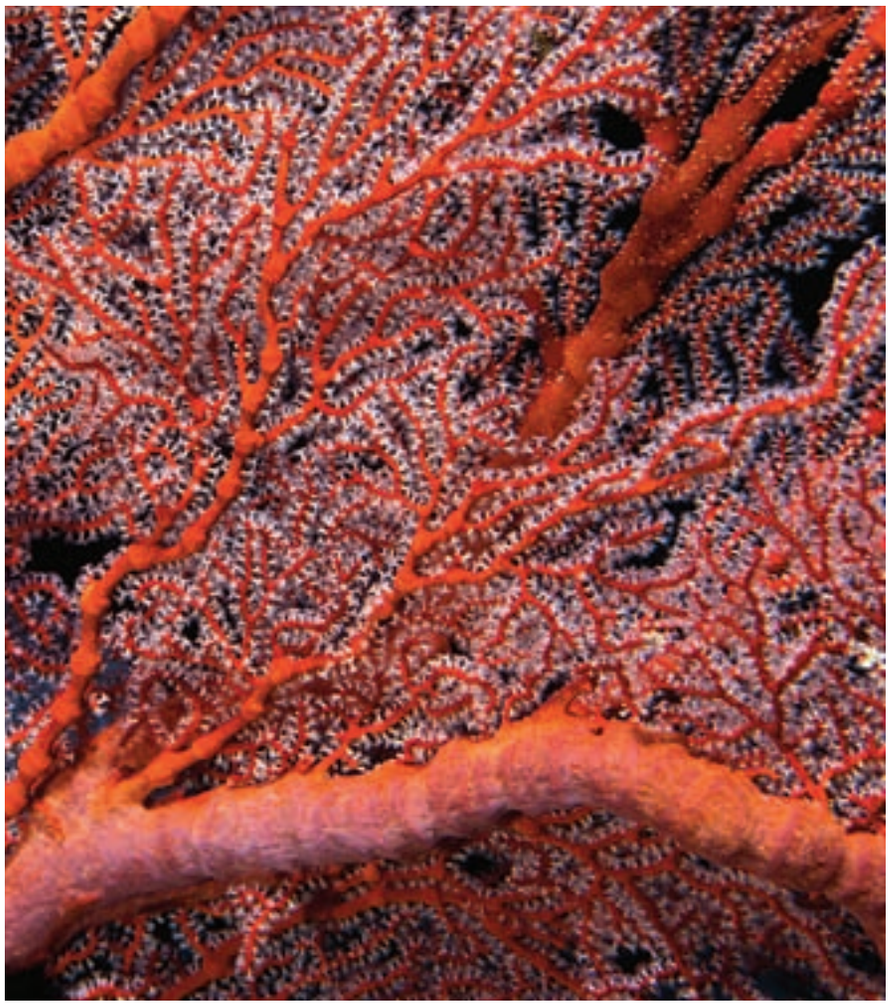
With the aim of progressing in this new direction, the Group held several meetings with representatives of the General Council of COF and with the General Directorate for Pharmacy and Health Products, with the upshot being the formation of a Group made up of ten laboratories who will carry out a pilot test to enable the validity of the application submitted by the General Council of COF to manage the information and eventually improve its performance to be verified.

In the second quarter of 2005 Farmaindustria took on the Royal Decree project to set about modifying the aforementioned Royal Decree 725/2003, of June 13, and granting the mandatory audience process to the Association. In compliance with this process, the Working Group carried out an exhaustive analysis into the Royal Decree project and added its corresponding observations in the definitive ground document presented by Farmaindustria to the Ministry of Health and Consumer Affairs.

As has been stated by the appointed Government ministers, the intention behind this new legislation is to make progress in the area of total traceability by broadening the framework of the currently in force Royal Decree 725/2003.

This objective is also being pursued by the pharmaceutical industry. It is worth pointing out here that EFPIA is also developing an initiative that will mean the inclusion of a Data Matrix on all medicine packaging, with the aim being to contribute towards the detection and prevention of forgeries, avoid errors in the identification of units and improve the traceability and integrity of the medicines distribution chain in the European Union.

IN 2005 THE WORKING GROUPS, SECTIONS AND FUNCTIONAL GROUPS WERE RENEWED, WITH THE AIM BEING TO ENCOURAGE THE ACTIVE PARTICIPATION OF THE ASSOCIATES



Working Group on the Regulation of Promotion and Advertising

During the first half of 2005, and following the approval of the new EFPIA's Code of Practice for the Promotion of Medicines at the end of 2004, this Group —made up of the representatives of 17 laboratories and via a series of meetings between FARMAINDUSTRIA and the OMC, scientific societies and the Self-Monitoring Board— continued with the work of updating the Spanish Code in order to adapt it to the new European text and at the same time modifying other points contained not only in the Code, but also in the Development Regulations and Guidelines.

At the same time —and making the most of the working experience of the Code of Practice Surveillance Unit, the Code of Practice Committee and the Self-Monitoring Board— the revisions have enabled the efficienc a y of the process to be improved and advances to be made in the permanent self-regulation system under the slogan "zero tolerance", whilst at the same time strengthening its credibility with respect to third parties —health professionals and public administration bodies—.

The aforementioned work gave rise to the publication of a new version of the texts referred to above, which were approved and ratified by the Annual Assembly of the Association of the Association on June 21, 2005.

Elsewhere, among the primary objectives of this Working Group and in conjunction with the tasks already set in motion at the end of 2004, a strict monitoring process was implemented of the different initiatives taken by Spain's Autonomous Regions to regulate doctors' visits starting with the updating of the document: "Moving towards a standard model for the organisation of doctors' visits". Along the same lines, the group has been concentrating its efforts upon analysing the status of the electronic prescription on both the state and regional level, with a further document being drawn up stating their position on the subject.

Both documents have been submitted to the Ministry of Health and Consumer Affairs with the aim of communicating the standpoint of the industry on these matters.

Market Access Working Group

Created with the aim of monitoring the market access conditions with respect to pharmaceutical innovations —price, reimbursement and entry barriers—, the Market Access Working Group has made a significant contribution towards the wording of the arguments presented by FARMAINDUSTRIA regarding the Safeguards and Rational Use of Medicinal Products and Medical Devices Act.

The Group also prepared an extensive Innovation Support Programme based on the analysis of various publications and studies produced by the Association for this purpose, focusing its efforts on establishing the foundations for developing —in conjunction with the Functional Group for Health Outcomes Research— FARMAINDUSTRIA's stance with respect to the Selective Financing of Medicines.

The Group is currently working on a review of regional pharmaceutical policy with the aim of exploring the viability of new lines of action that the Association might follow in this field.

THE WORKING GROUP ON INDUSTRIAL PROPERTY WAS CREATED WITH THE OBJECTIVE OF ANALYSING THE LACK OF HARMONISATION OF THE SPANISH LEGISLATION REGARDING PATENTS WITH RESPECT TO THAT CURRENTLY IN FORCE WITHIN THE EU

Working Group on Personal Information Protection

In response to the mandate of FARMAINDUSTRIA's government liaison bodies, the Working Group on Personal Information Protection was set up with the aim of studying those aspects related to the legislation passed to protect information of a personal nature and the way in which this is applied in the fields of clinical research and Pharmaco-vigilance with respect to medicines for human use.

Initially, the Group concentrated its analysis on the field of clinical testing, with the aim of ensuring the confidentiality of those taking part in the trials, thereby preventing drug developers from being able to identify the patient at any time.

Currently, the Group is working on the preparation of a Standardised Working Procedure or Sectorial Code in which the details of the way in which personal information of a health-related nature is handled both in the field of Clinical Research and the area of Pharmaco-vigilance. The aim is to present the aforementioned Code to the Data Protection Agency for registration in compliance with the Personal Information Protection Act, Organic Law 15/1999 of December 13. Once officially registered, it will be the voluntary decision of each laboratory whether to adhere to it or not.

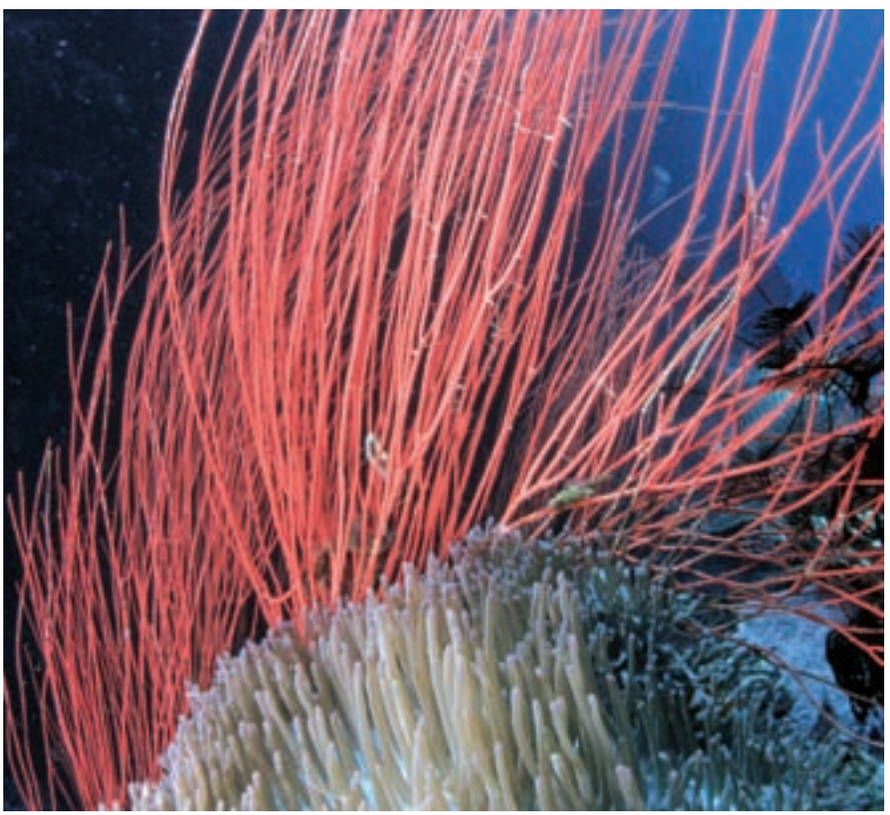
Working Group on Industrial Property

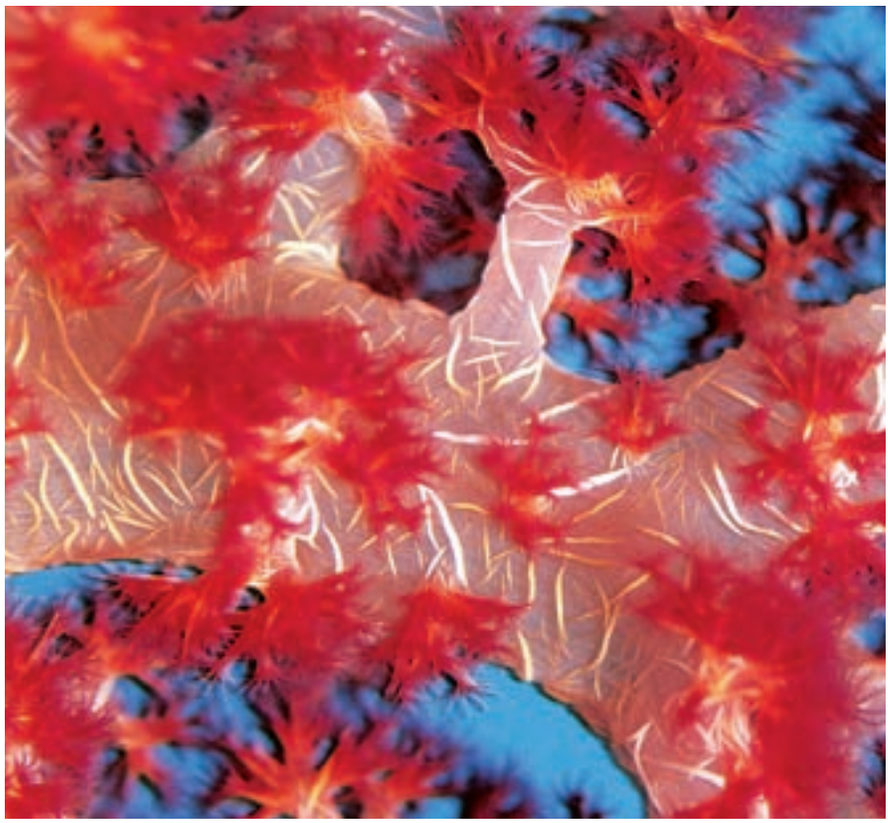
This Group was created with the aim of analysing the lack of harmonisation of the Spanish legislation regarding patents with respect to that currently in force within the European Union.

This lack of coherence can be traced back to the period of transition established in the Membership Treaty that marked Spain's entry into the European Economic Community in 1986. As a result of that transition period, a number of medicines that have now been on the market for over 10 years enjoy product patent protection in the EU but not in Spain —where they are only protected by a patent of procedure—, meaning that a generic version can be marketed in Spain but not throughout the rest of the EU.

Although this is a temporary situation —valid until 2012— and currently affects a reasonably small volume of the Spanish market, its repercussions both on multinational companies and on Spanish laboratories are extremely negative.

The TRIPS international trade agreements, undersigned by Spain, allow the rights garanted by a patent of procedure to be extended in the case of medicines for which said patent was applied for prior to





1995, changing it into a product patent. This would mark the end of a period during which innovative companies have been filing suits against a decision taken 20 years ago —and which then responded to a specific situation— that has little to do with current reality, a fact corroborated by the WTO's interpretation of Article 70 of TRIPS.

Via FARMAINDUSTRIA, the Group has been in contact with the Ministry of Industry, Tourism and Trade and has initiated actions to introduce an amendment to the Proposed *Anti-Piracy* Law—a Proposed Law that sets out to expand legal powers with regard to the protection of intellectual property rights to establish procedural legislation to make it easier to apply a number of EU regulations— or, if not with this law, in the Safeguards and Rational Use of Medicinal Products and Medical Devices Act— with the aim of modifying the Patents Law and adapting the protection granted by Spanish legislation to pharmaceutical products, to the international commitments entered into by Spain and to the demands of the domestic market.

Working Group on Profarma and Public R&D Policy

This Group was set up at the beginning of 2005 with a broad representation of associated laboratories. Its objectives include pushing through those actions intended to promote R&D within the pharmaceutical industry, especially in the field of public policy.

Throughout last year, the Group analysed and presented observations with respect to the proposed Resolution made by the General Secretariat for Industry that establishes the legislative foundations of the Profarma Plan. Along similar lines, the Group has looked into the different initiatives that have been set up to promote R&D, which include the development of the CENIT (National Technological Research Consortium) Programmes and the European Innovative Medicines Technological Platform Project that forms part of the 7th European Union Research Framework Programme.

Working Group on Communication

Throughout 2005, the Working Group on Communication has focused its efforts upon the development and implementation of FARMAINDUSTRIA's new Communication Plan, which aims to strategically inform the wider community about R&D activities, the values of medicine and the social responsibility of the pharmaceutical industry, among other relevant aspects.

In order to achieve this objective, the Communication Plan focuses on a number of different areas: improving the social perception of the pharmaceutical industry; networking; the media; Research, Development and Innovation; patients, and health professionals.

With respect to these areas, it is worth pointing out the design of a new public image and the updating of the Association's logo, as well as the active encouragement of meetings and an exchange of opinions and ideas between participants from different backgrounds regarding a diverse range of subjects.

The framework of the Communication Plan also encompasses the launch of the magazine *Pacientes* (*Patients*); the preparation of diverse informative reports on R&D activities; the promotion of those publications dealing with subjects of interest to the pharmaceutical sector and the Awards of the FARMAINDUSTRIA Foundation.

Along the same lines, it is worth mentioning that the Group has actively encouraged meetings with representatives of EFPIA to exchange experiences, with the aim being to know more about communication strategies and practices on both an EU and international level.

The Vaccines Section

Throughout 2005, this Section has continued to analyse all those matters for which it is responsible and that require constant dialogue with the relevant health agencies and departments.

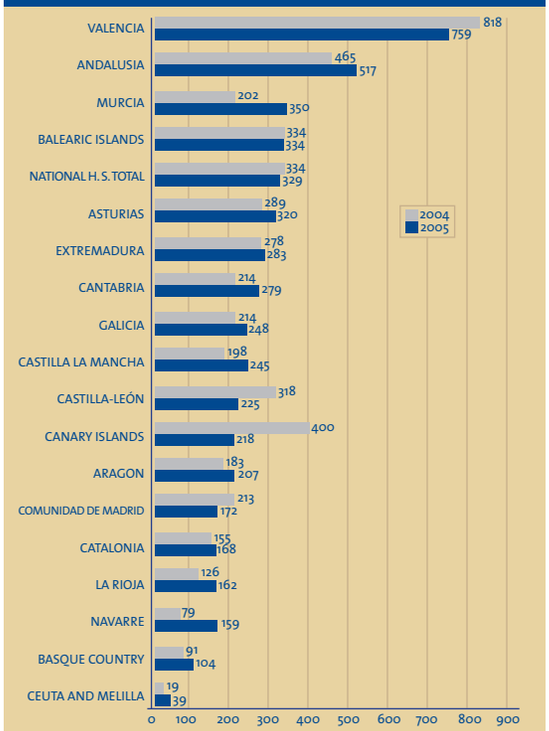
This has led to the establishment of a periodical mechanism of cooperation between the industry supplying the vaccines and the health authorities, the aim of which is to coordinate actions with respect to all issues involving vaccines, with special emphasis being placed on those aspects concerning public bidding and tendering processes.

To this effect, and following a proposal put forward by the Group, FARMAINDUSTRIA has notified, on a number of occasions, not only the Health Advisors of Spain's Autonomous Regions, but also the Directorate General for Public Health about the possible storage problems that might occur if the bidding and tendering process with respect to flu vaccines is not made more efficient. Due to the unique problems inherent to this type of vaccine, the different laboratories that market it will experience increasing difficulties in supplying the Spanish market sufficiently if the announcement and allocation of the bids and tenders is not successfully completed before the end of the first quarter of every year.

At the same time, an attempt has been made to modify a number of clauses of the public bidding and tendering documentation with respect to the supply of vaccines in order to reduce the uncertainty that the companies have to endure as regards returns, reservations and distribution terms and conditions concerning the product in question.

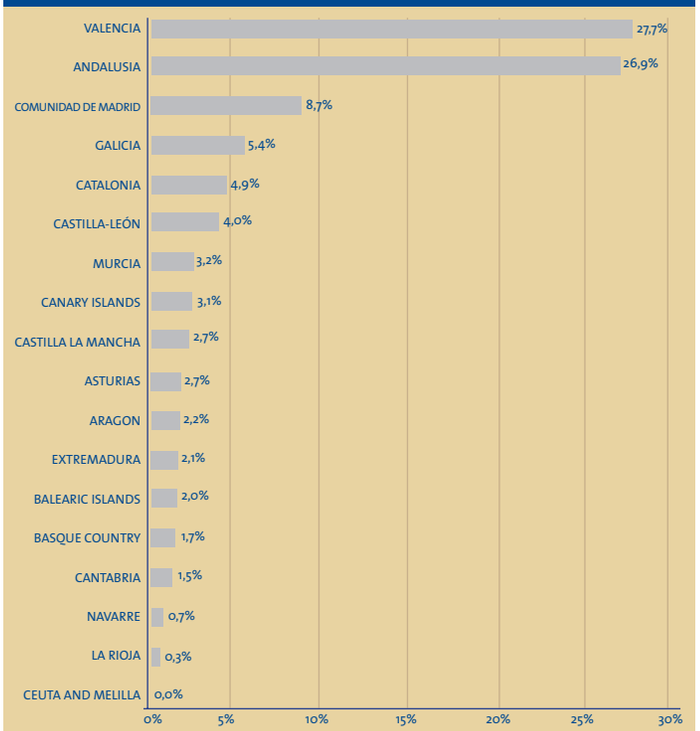
Other subjects tackled by the Group have been the projects for implementing bar code systems to make it easier to trace the distribution of vaccines, the contingency plans in the event of a flu pandemic in Europe and the question of pharmaco-vigilance.

AVERAGE PAYMENT PERIOD UP TO 31-12-2005



Source: FARMAINDUSTRIA hospital debt survey (2005)

COMPOSITION OF THE DEBT UP TO 31-12-2005



Small- and Medium-Sized Companies Section

The Small and Medium-Sized Companies Section is formed by members of FARMAINDUSTRIA's Statutory Group of Spanish Small and Medium-Sized Companies, who meet on a regular basis following the periodical sessions of the Steering Committee, with the aim of bringing their representatives up to date with the subjects under discussion at Governmental Body level.

The Hospital Supplies Section

During 2005, this section continued to analyse those questions of a legal and financial nature related to hospital supplies.

The latest available data shows that, at the end of 2005, the Spanish National Health System owed the pharmaceutical companies 2,192 million euros for the supply of medicines to public hospitals, with the average payment period (APP) being 329 days, and with a worrying level of debt concentration in two Autonomous Regions: Andalusia and Valencia, who between them account for more than half of the total debt.

AT THE END OF 2005, THE SPANISH NATIONAL HEALTH SYSTEM OWED PHARMACEUTICAL COMPANIES 2,192 MILLION EUROS FOR THE SUPPLY OF MEDICINES TO PUBLIC HOSPITALS

This situation is causing serious financial problems for the companies, especially those of small- or medium-size, and could well result in many of them closing.

Likewise, these figures show it to be glaringly obvious that the implementation of Law 3/2004 of December 29, which establishes measures to combat bad debt in commercial operations, has not contributed towards improving the situation. Both the internal and external controls set up to ensure that the Law is correctly applied, have proved to be alarmingly ineffective.

In turn, the increasingly judicial nature of the problem is beginning to result in a significant increase in financial costs for the regional governments. To this effect, the Section is running a permanent monitoring process focused on the different initiatives being implemented by the regions that are far removed from the spirit of the Law, whilst at the same time trying to ensure that the current legislation is respected by the different public administrations.

Elsewhere, the Hospital Supplies Section analysed other regional initiatives of interest to this sector, such as the centralised management process with respect to the contracting of certain medicines in the hospitals of the Comunidad de Madrid (Order 429/2006 of March 3 passed by the Health Advisory Counsel of the Comunidad de Madrid) and the electronic invoicing project set up by the Andalusian Health Service —an ad hoc group has been created to take part in a pilot test of this scheme—, among other matters.

The Generics Section

FARMAINDUSTRIA's Generics Section met on several occasions during 2005, with the aim being to analyse the true market situation of generic products in Spain and the degree to which this has developed.

Particular attention was paid to certain measures adopted in the regional sphere, such as INN prescribing, the generalised use of which might involve potential risks of a diverse nature, not only on the health status of the population, but also of a legal and industrial type.

In relation to this, issue number 7 of the FARMAINDUSTRIA Magazine featured an article summarising a survey Committeed by FARMAINDUSTRIA regarding the practice of INN prescribing in Andalusia that highlights the risks involved in the generalised and indiscriminate use of this method.

This Section reiterated its support for the quality of generic products and for the establishment of the conditions that the companies of this subsector require to enable them to make a return on their investments, with the aim of developing the generic medicines market.

The Taxation Functional Group

The Taxation Functional Group once again held its traditional yearly seminar on new aspects of taxation, during which information was provided regarding the new tax measures being introduced during 2005, judicial statements and all other taxation matters that might be of interest to the pharmaceutical sector.

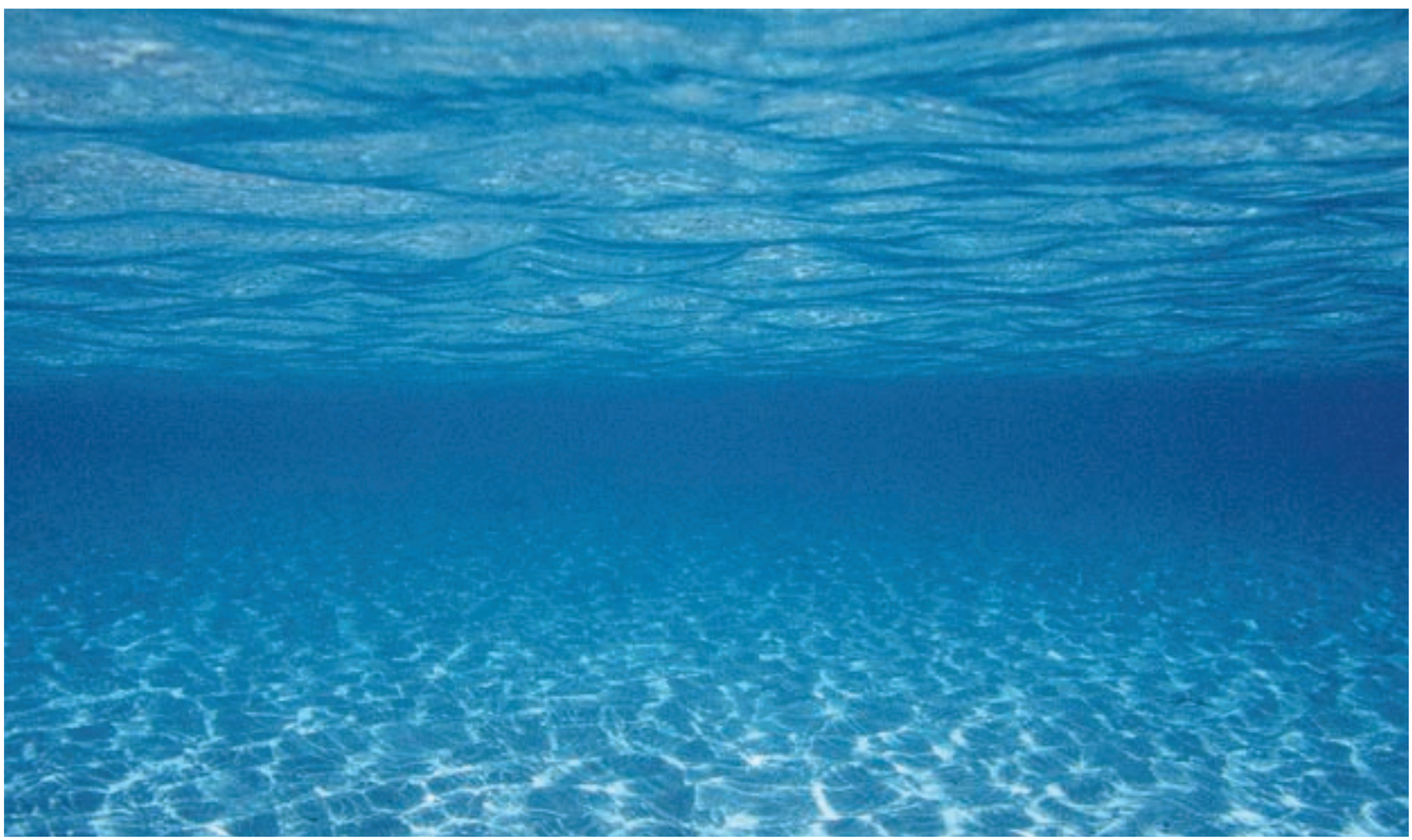
In this sense, it is important to highlight the efforts made by the Group via FARMAINDUSTRIA to make Central Government and all the other bodies and authorities with a say in the matter, aware of the damage that could be caused to the pharmaceutical industry by the proposal to do away with current tax relief for R&D that the Proposed Law on Income Tax, and the partial modification of Corporate Tax, Non-Residents Income Tax and Property Tax —which was going through Parliament at the time of writing this Report— intends to introduce, given that the alternative measures included in the aforementioned Proposed Law are totally inadequate.

At the same time, the ad hoc Group created to analyse the unconventional nature of the pharmaceutical sector when it comes to invoicing continued its work throughout 2005, focusing its attention on a study of the modifications imposed by Royal Decree 87/2005 of January 31, with respect to invoicing obligations.

The Group also analysed different fiscal questions: the disparity of criteria shown by the Chambers of Commerce in the application of a permanent appeals process; a study into the way VAT is processed where clinical tests are concerned, etc.

The Legal Services Functional Group

Made up of the heads of the legal departments of the laboratories associated with FARMAINDUSTRIA, this Functional Group continued to act as a forum in which know-how and opinions regarding the diverse subjects of a legal nature affecting the pharmaceutical sector could be discussed and exchanged.



During 2005, the Group held two meetings, one in each half of the year, and tackled different questions of interest and relevance to the sector. Of these, it is worth highlighting the follow-up of The Code of practices for the Promotion and Advertising of Medicines and the actions carried out by the corresponding control bodies; the study of the Safeguards and Rational Use of Medicinal Products and Medical Devices Act; the analysis and proposal to adopt actions in relation with the volume discounts by sales volume regulated in the 9th Additional Regulation of Law 25/1990 governing Medicines; the analysis of administrative contracting; the study into the regional legislation affecting the pharmaceutical sector, as well as the measures adopted by the Central Government and Parliament —lineal decreases in the prices foreseen in Royal Decree 2402/2004; the aforementioned volume discount, etc.—.

During these forums, the Group received the latest information regarding, the recent jurisprudence concerning matters of a pharmaceutical nature —in particular that involving the European Court of Justice— and regarding the activities carried out by the Association's different working groups —personal information protection, patent legislation, hospital supplies, traceability, etcetera—.

Likewise, it is worth mentioning that FARMAINDUSTRIA channelled all the sectoral claims to the different legislative projects that affect the pharmaceutical sector.

The Human Resources Functional Group

Made up of the managers of the Human Resources Departments of the laboratories associated with FARMAINDUSTRIA, this Functional Group continued to act as a know-how exchange forum with respect to the diverse subjects of a legal-occupational nature that affect the pharmaceutical sector.

During 2005, the Group held a meeting at which the main new legislative developments were considered along with other relevant occupational matters that affected the pharmaceutical companies.

Likewise, FARMAINDUSTRIA participated in the monthly meetings held by the Spanish Chemical Industry Federation's (FEIQUE) Joint Committee at their 14th Chemical Industries Convention. It also took part in the Labour Relations Committee meetings organised by the Confederation of Employers and Industries of Spain (CEOE).

The Group's participation in the processing of legal projects of an occupational nature, Committeeed either by the employers' organisation CEOE or by the chemical industry federation FEIQUE, increased in 2005. Highpoints of the year include (i) the passing of Law 14/2005, of July 1, in relation to the clauses of the collective bargaining agreements referring to reaching ordinary retirement age, which re-established the legal obligation that authorises mandatory retirement ages to be agreed upon as a part of Collective Bargaining Agreements, and (ii) Law 28/2005, of December 26, regarding the health measures affecting smoking and the regulations governing the sale, supply, consumption and advertising of tobacco products, which came into force on January 1, 2006, forcing companies to quickly change their smoking policies.

Finally, the end of 2005 saw negotiations commence in preparation for the 15th Spanish Chemical Industries Convention, which will take place in 2006.

The Registrations Functional Group

The mission of the Registrations Functional Group is that of contributing towards establishing the industry's stance with respect to the regulations and instructions drawn up by the Spanish Medicines Agency dealing with the procedures involved in the authorisation and modification of medicines.

In spite of this, the legislative initiatives generated by the Agency in this field during 2005 were few what was unexpected considering the implementation of the EU legislation during 2005. However, the restructuring of the Agency and the processing of the Safeguards and Rational Use of Medicinal Products and Medical Devices Act were key factors when it comes to explaining the lack of legislative initiatives taken in this regard.

PRACTICALLY ALL OF FARMAINDUSTRIA'S WORKING GROUPS HAVE BEEN PAYING SPECIAL ATTENTION TO ANALYSING THE PROPOSED LAW

As a result, the activities of this Functional Group were limited to analysing a number of proposed changes in the medicine registration process.

The Functional Group for the Reform of Pharmaceutical Legislation

One of the main tasks of this Group involved the drawing up and preparation of a significant number of technical amendments to the Safeguards and Rational Use of Medicinal Products and Medical Devices Act procedure.

The Technical Operations Functional Group

Since it was created in 2001, this Group has regularly met on a quarterly basis to tackle, from a technical point of view, subjects of current interest relevant to the sector, especially those involving manufacture and logistics.

The Group continued to provide logistical information with respect to traceability and regarding the need to modify the medicine encoding systems. The Group played an especially relevant role in the discussions regarding the manner to proceed with the re-labelling process, a requirement that arose as a result of the price reductions imposed by Royal Decree 2402/2004, embodied in an informative note issued by the Spanish Medicines Agency on December 12, 2005.

The Environmental Functional Group

Throughout 2005, the Environmental Functional Group monitored and followed up the different legislative and environmental developments —waste, waste disposal sites and emissions— affecting the pharmaceutical industry.

Given the complexity of government regulations with respect to the environment, this Group represents a platform for ideas to be discussed and shared on a regular basis. Furthermore, its collaboration with SIGRE (the Integrated Packaging Management and Collection System) kept FARMAINDUSTRIA actively involved in the Environmental Committees of different corporate organisations and resulted in an even closer collaboration with the Spanish Ministry for the Environment in matters directly affecting the sector.

The Pharmacovigilance Functional Group

The relevance that pharmacovigilance related matters have for patients and health professionals alike justifies the additional efforts being made by the European Medicines Agency in this field and the convenience of the pharmaceutical industry's close monitoring of the subject.

The Pharmacovigilance Functional Group keeps abreast of the main matters of interest, which include the electronic communication of adverse reactions to medicines, the promotion of the MedDRA language, which enables medical terminology to be encoded and the personal details of process servers from outside the health professions to be protected.

This Group also reviews legislative documents issued by the Spanish Medicines Agency in order to

discuss them, with the aim being to provide the maximum legal guarantees to consumers, academic research institutions and laboratories and to ensure that EU regulations are incorporated into Spain's legislative system. Along these lines, it is worth highlighting the work put in by the Group in reviewing the diverse regulations included in the Safeguards and Rational Use of Medicinal Products and Medical Devices Act.

Likewise, the Group collaborates with the European Federation of Pharmaceutical Industries and Associations (EFPIA) in reviewing all current matters related to EU pharmacovigilance legislation.

The Clinical Trials Functional Group

Following the entry into force of Royal Decree 223/2004, of February 6, which governs the clinical trials of medicines, the Spanish Medicines Agency has published a series of guidelines regarding clinical trials procedures. These regulations can be found in the document entitled 'Clarifications regarding the application of clinical trials regulations with medicines for human use as of May 1, 2004 (version No. 3, September 2005)'.

IN 2005, ASPECTS PERTAINING TO CLINICAL RESEARCH WERE ANALYSED, SUCH AS THE CLINICAL TRIALS CONTRACT MODELS TO BE USED BY THE AUTONOMOUS REGIONS

These clarifications, which describe the Agency's interpretation of how to act with respect to certain aspects involved in clinical trials, have been reviewed by the Group on two occasions, resulting in comments and suggestions being sent to the Agency. It is essential that this clarification document be raised to legislative level in order to ensure that all parties involved comply with a single set of instructions for the carrying out of clinical trials in Spain.

In the legislative field, the Group also reviewed the Safeguards and Rational Use of Medicinal Products and Medical Devices Act and presented its own arguments for the adequate incorporation of European legislation with respect to clinical research into the new law.

During 2005, working sub-groups were created to analyse relevant aspects with respect to clinical research, such as the clinical trials contract models to be used in the Autonomous Regions of Andalusia, Catalonia and the Basque Country, and to fix standpoints regarding the registration of clinical trials and the publication of the results thereof.

The Autonomous Regions Functional Group

In the same way as the other functional groups, the Autonomous Regions Functional Group meets on a regular basis to review those matters that, in the field of Spain's autonomous regions, represent a new development or present new demands upon the existing framework.

Many of the aspects regulated by the autonomous regions are dealt with in a number of more specific forums, but this does not mean that we can forget the importance of a functional group that is horizontal in nature, that possesses in-depth knowledge about institutional relations and about the pharmaceutical contribution across Spain's autonomous regions.

Given its importance, it is well worth mentioning the detailed analysis that this Group has carried out in relation with the Proposed Andalusian Pharmacy Law, thereby contributing towards the preparation of the corresponding arguments and claims to the Law presented by FARMAINDUSTRIA. The work done by the Group with respect to this matter has helped greatly towards putting a number of precepts in their due place that, by ensuring modifications in the proposed legislation, will significantly limit the free prescription of medicines in this autonomous region.

The Functional Group for Health Outcomes Research

The basic mission of this newly set up Functional Group is the specific analysis and development of the technical questions and elements that would lead to the eventual creation of a system for evaluating the therapeutic contribution made by new medicines, as stated in the Strategic Pharmaceutical Policy Plan developed by the Ministry of Health and Consumer Affairs. In some cases, the subjects analysed by this Group are similar to those dealt with by the Market Access Working Group. However, the latter's profile is more focused upon the planning and implementation of initiatives of a more strategic nature and upon solving matters that are less technical than those to be analysed by this new functional group. Having said this, close collaboration between the two Groups will be necessary to avoid any possible overlaps.

The parliamentary proceedings of the new Safeguards and Rational Use of Medicinal Products and Medical Devices Act has put much of this Group's activity on hold, but this is likely to change in the second half of 2006, as this will mark the beginning of actions carried out by the different authorities involving finding a way to evaluate the therapeutic value of new medicines in Spain.

The Medical Directors Functional Group (BEST Project)

This new Group has been created in order to promote an initiative in the field of clinical research (the BEST Project). Its aim is to improve both the efficiency and quality of clinical research processes.

The BEST Project forms part of the Innovative Medicines Technological Platform, which is an ambitious joint project involving the pharmaceutical industry, clinical researchers, Public Administration Agencies —the Ministry of Health and Consumer Affairs and the Autonomous Regions— and patients' association, and sets out to make Spain one of the reference countries of the European Union as regards the carrying out of clinical trials.

The Group has commenced work on a benchmark study, the first step of which has been the development of an initial times module for evaluating the efficiency and quality of the processes. Over the next few months the Group will work on analysing other

key factors involved in making clinical research more competitive in Spain: documentation, hospital pharmacy, etcetera.

The Barcelona Office

In 2005, Farmaindustria's Barcelona Office continued performing technical secretarial tasks on behalf of several of the Association's working groups, sections and functional groups as well as coordinating their meetings.

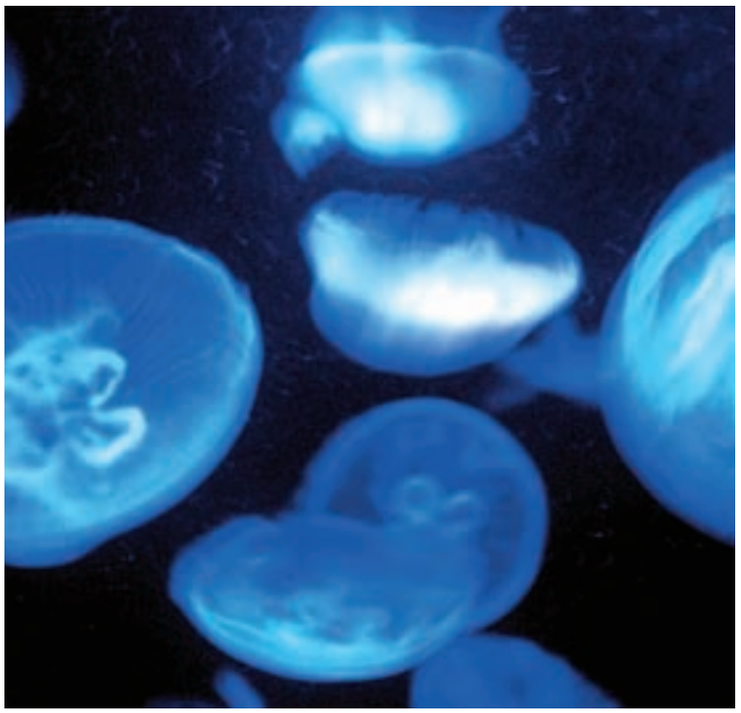
The Office has also been working hard to resolve the technical queries submitted by the associate laboratories based in Catalonia and has been in contact with a diverse range of entities, taking an active part in different groups and Commissions.

Another of the Barcelona Office's activities has been to collaborate in the organisation of events and meetings held in the Catalonian capital and it has provided logistical and administrative support services to the laboratories associated with Farmaindustria.

3.3.3. The Innovative Medicines Technological Platform

The European Technological Platforms are instruments developed by the European Committee to tackle large-scale economic, technological and social challenges by way of research and development activities. Their purpose is to stimulate cooperation between the public and private sectors in Europe by setting up and financing Strategic Research Agendas that are agreed upon by all the agents involved. The Platforms will receive a significant boost with the implementation of the 7th European Union Research Framework Programme (2007-2013), and they should make a significant contribution towards achieving the Lisbon objectives of attaining an R&D budget amounting to 3% of European GDP.

This has resulted in the European pharmaceutical industry setting up the European Technology Platform of Innovative Medicines a project that aims to revitalise biomedical research in Europe in order to attain safer and more effective medicines over shorter periods of time. In order to do this, the first objective set is that of identifying, with the collaboration



of all the agents involved, the obstacles that hamper the development of new medicines.

July 2005 saw Barcelona host the meeting to launch the Spanish Innovative Medicines Technological Platform, that will mirror its European counterpart and stimulate biomedical research via the cooperation of all those participating in the system (industry, the regulators of the different Public Administration Bodies, basic and clinical researchers, scientific societies and patients). The Spanish Platform is organised around four fundamental areas: safety, efficiency, know-how management, and education and training.

Farmaindustria, just as EFPIA on a European level, has played an extremely active role in the launch of this initiative, given that the involvement of the laboratories is essential in order to ensure that the Platform provides new approaches and solutions for research into new medicines. The development and implementation of the BEST Project is, currently, the main strategic objective of the Spanish Platform.

For further information about the Platform, please visit the following website:
www.medicamentos-innovadores.org.

3.3.4. The Spanish Code of Practice for the Promotion and Advertising of Medicines

2005 was an important year for the system of self-regulation with respect to the promotion and advertising of medicines, a year that saw the consolidation of the system and the adaptation and updating of its operational rules.

As a result of the modification of the EFPIA Code, it was necessary to adapt the Spanish Code accordingly, and advantage was taken of this process to introduce a number of improvements both in the text and in the Regulations of the Control Bodies.

FARMAINDUSTRIA's Annual General Assembly approved the new version of the Code and at the end of 2005 FARMAINDUSTRIA signed a new Agreement with the Self-Regulation Body that replaces the one in force to date.

The Actions of the Code of Practice Committee

In 2005, the Steering Committee of FARMAINDUSTRIA, at their meeting of February 15, extended the appoint ments of the members of the Code of Practice Committee, namely Dr Juan Manuel Reol Tejada, Dr Josep Torrent i Farnell and Dr Miquel Vilardell Tarrés, by a further three years.

Among the new elements introduced by the new texts that go to make up the rules of the self-regulation system, as far as the Code of Practice Committee is concerned, it is worth highlighting the possibility that in the case files forwarded to the Self-Regulation Body, the Committee —and not only the component parts thereof— can request of said Body the holding of an oral trial, as well as the intervention of experts if the complexity of the case so requires.

In 2005, the fourth year in which the Code was applicable, the Code of Practice Committee held ten mediation meetings spaced approximately one month apart.

With respect to the actions of the Committee, the statistics pertaining to previous years reflect the efficiency of the self-regulation system regarding the promotion and advertising of medicines. As reflected in the figures shown below, 60% of the complaints received by the Code of Practice Committee were resolved due to the mediation thereof, with 26% of the case files being forwarded to the Self-Regulation Body, while the remaining 13% were filed at the request of the complainant following reception of the arguments of the accused.

In 2005, 30 complaints were presented to the Code of Practice Committee for presumed infringement of the Code. These complaints can be classified as follows:

- 18 complaints in relation with the content of the promotional material of pharmaceutical specialities.
- 5 complaints regarding promotional activities related to hospitality during meetings.
- 4 complaints regarding incentives.
- 1 complaint about advertising targeting the public.
- 2 complaints with respect to rules governing the application of the code.

The following chart summarises the total number of complaints, the condition of the parties involved, and the actions taken by the Code Control Bodies, the Code of Practice Surveillance Unit, the Code of Practice Committee and the Self-Regulation Body.

COMPLAINTS

TOTAL COMPLAINTS	**30**
Estimated	29
Rejected	1
COMPLAINANTS	**30**
Associated Laboratories	15
Attached, non-associated laboratories	3
Code of Practice Surveillance Unit (USD)[1]	11
Others	1
ACCUSED	**30**
Associated laboratories	27
Attached laboratories	1
Non-associated, unattached laboratories	2
CODE OF PRACTICE COMMITTEE	**18**
Agreements	13
Filed following mediation	5
ACTION OF THE SELF-REGULATION BODY	**8**
Sanctions imposed	7
Rejected	1
CASED FILED	**4**

[1] Filed at request of the Unit: 3. Resolved during mediation phase, with express recognition and acceptance of the infraction and of the corrective measures proposed, respectively: 18. Sanctions imposed by the Self-Regulation Body: 7.

Actions taken by the Code of Practice Surveillance Unit

2005 was an extremely busy year for the Code of Practice Surveillance Unit. The work carried out by the Unit can be divided up into three major areas: spreading awareness about the Spanish Code of Practice for the Promotion and Advertising of Medicines; consultancy and collaboration and controlling the compliance with and the application of the precepts of the Code that materialised via preventive actions and complaints dealt with out of court.

With respect to **spreading awareness about the precepts of the Code**, it is worth highlighting: the participation in 13 conferences; the organisation of two press conferences targeting both the sectorial and general media; the holding of three bilateral meetings with health managers of the autonomous regions of Cantabria, Murcia and Navarre; the active participation at Informative Open Days organised by FARMAINDUSTRIA with the aim of making the main new elements of the new Code approved in June 2005 known; the preparation and distribution of the document entitled *Useful Key Points for Health Professionals*, the aim of which is to show the main precepts of the Code to this particular group in a summarised and accessible manner, and finally, the expansion and improvement of the Code's Practical Cases Test.

THE CODE OF PRACTICE SURVEILLANCE UNIT CHANNELS ITS EFFORTS INTO THREE MAIN AREAS: SPREADING AWARENESS ABOUT THE CODE OF PRACTICE, CONSULTANCY AND COLLABORATION, AND CONTROLLING THE WAY IN WHICH THE CODE IS APPLIED

Where consultancy and collaboration are concerned, it is worth mentioning the continuous consultancy services provided by the Unit, both to pharmaceutical companies and to third-party entities —scientific societies, technical secretariats, service providers, etc—; the implementation and start-up of the website featuring events organised by third parties; the notable reduction in the number of queries received regarding the Code —four, compared with the 18 formulated in 2004—; participating in the Marketing Code Task Force, the body set up by the IFPMA to review and draw up the Code; the continued collaboration with EFPIA; the signing of the collaboration agreement with the Mexican National Pharmaceutical Industry Chamber (CANIFARMA and its Ethics and Transparency Counsel CETIFARMA), and its active intervention in the different meetings and forums organised by FARMAINDUSTRIA in conjunction with the autonomous regions and with the communication media.

As regards its control and prevention activities, mention must be made of the notable efforts made during 2005 aimed at avoiding promotional activities and/or practices that could infringe upon the precepts of the Code. Here we must highlight the number of preventive actions carried out in 2005, which exceeded 1,800 —compared with the 814 carried out in 2004—, and which involved a total of 142 laboratories. The result of all this preventive work, the number of complaints filed in 2005 —11 complaints— fell in comparison with those filed in 2004 —18 complaints—. Finally, it must be pointed out that with respect to events, the number of in-situ inspections carried out in 2005 was more than three times that registered in 2004.

3.4. International Relations

Throughout 2005, Farmaindustria's activities on a European level focused on consolidating the three priorities identified by the General Assembly of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in June 2004:

- **Strengthening the EU's scientific base** by tailoring research projects to the needs of the pharmaceutical industry whilst at the same time maintaining the highest possible levels of protection with respect to industrial property both in Europe and worldwide.
- **Improving the market access conditions** for new

medicines by finding a fair balance between the objectives of the EU's industrial and health policies and those of the Member States. (The "Post-G10" Process).

- **Adapting the European legislative framework** to the needs of the research-based pharmaceutical industry. At the end of 2005, some of the initiatives taken to achieve the three aforementioned objectives had been successfully implemented.

1. Strengthening the EU's Scientific Base

The Innovative Medicines Initiative (IMI). Within its 7th Framework Programme, the European Commission has established a Public-Private Partnership (PPP) with the aim of overcoming the bottlenecks that occur during the pre-competitive phases of the research process. FARMAINDUSTRIA has been keeping a close eye on the activities that EFPIA's Research Working Group has been carrying out in order to identify the main obstacles inherent to the different areas, such as safety, efficacy, know-how management and education. The IMI, which could well be operational as early as 2007, will require an estimated annual investment of 440 million euros. The pharmaceutical industry will provide experts, data and infrastructure, while the public funds will be used to finance research, university and academic partnerships.

Regulatory/industrial property matters. Paediatric Trials. In September 2004, FARMAINDUSTRIA favourably received the European Commission's proposed Ruling with respect to medicines for paediatric use and put all its support behind the introduction of incentives for the promotion and fostering of the development and authorisation of this type of medicines, as well as the creation of a European Paediatric R&D Infrastructure. On September 7, 2005, and by way of the co-decision procedure, the European Parliament adopted, after the first reading, the aforementioned proposed Ruling calling for the mandatory carrying out of paediatric tests, which shall be compensated with the extension of the patent's complementary certificate of protection (CCP) for an additional six months.

The contacts maintained by FARMAINDUSTRIA with Spanish Euro MPs has contributed towards the European Parliament's rejection of the amendments proposed for limiting the extension of the CCP or for the establishment of a variable incentives mechanism. The European Parliament's vote had important repercussions for the pharmaceutical industry, as it was the first time that the new and expanded Parliament had voted on a pharmaceutical matter and, furthermore, one that was related with industrial property rights and was strongly opposed by the manufacturers of generic medicines.

The Ruling will now be debated by the Member States, with a definitive decision not expected until the end of 2006.

Register data protection. Half way through 2005, the European Commission officially rejected the requests of the new Member States to obtain a repeal of between 2 and 15 years of the "8+2+1" Regulation established in the new European pharmaceutical legislation.

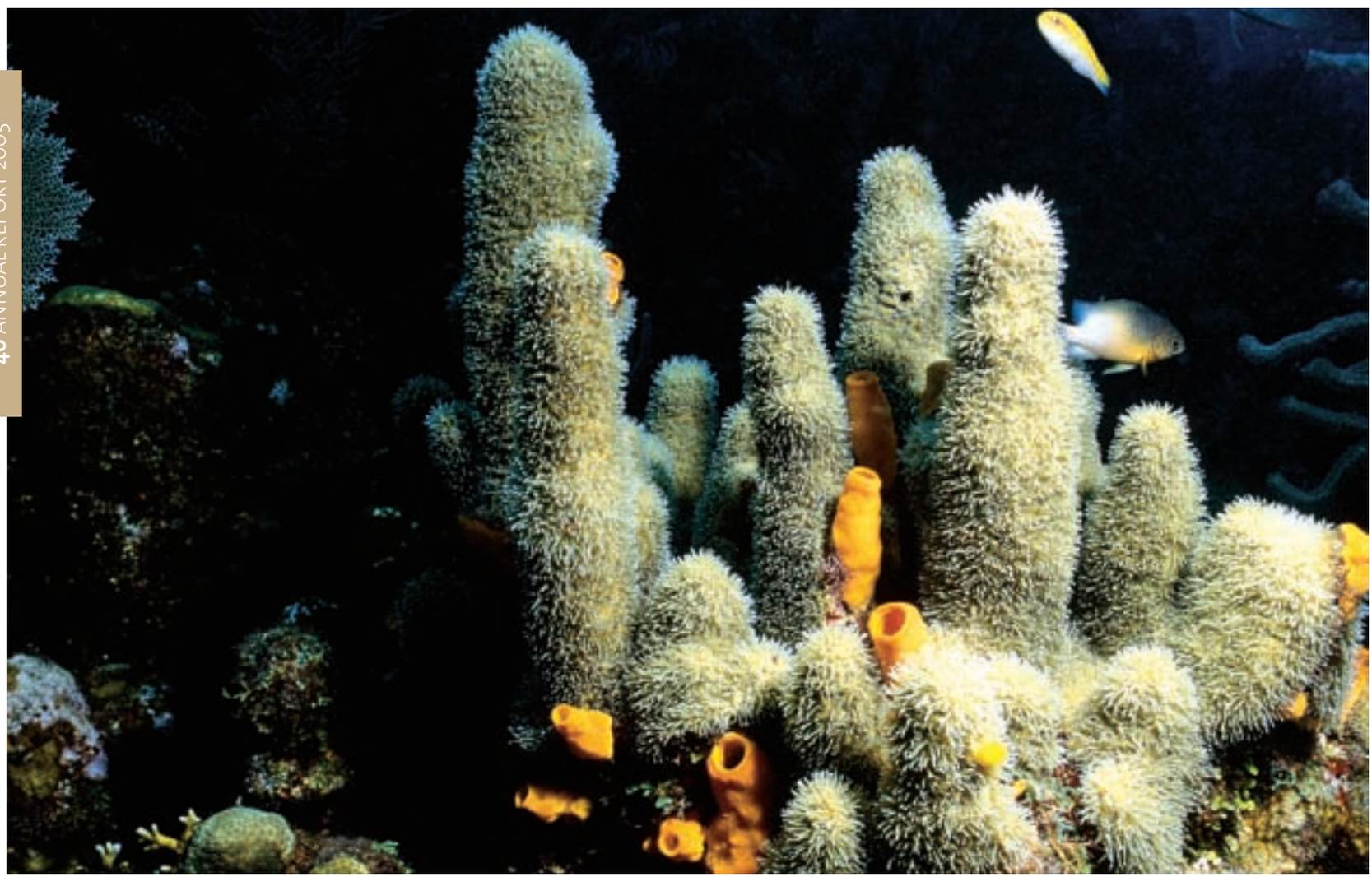
2. Improving the Market Access Conditions for New Medicines

FARMAINDUSTRIA, in coordination with EFPIA and the rest of the national associations, has continued applying the market access working programme, both at EU and Member States level, by way of different initiatives such as those described below.

The "Post G-10" Process

In October 2005, Commissioner Verheugen announced the main features of the European Commission's new Industrial Policy, which is based on two core areas:

- Seven inter-sectoral initiatives, including the protection of industrial property rights; the promotion of competition and market access in non-EU countries; the simplification of current legislation, and the design of an integrated European approach directed towards industrial research and innovation.
- Seven specific initiatives for each sector, including the creation of a new pharmaceutical forum, which is set to hold its first meeting in 2006, and a commitment to review the strategic policy with respect to biotechnology in the two-year period 2006-2007.



IN COORDINATION WITH EFPIA AND THE REST OF THE NATIONAL ASSOCIATIONS, FARMAINDUSTRIA CONTINUES APPLYING ITS MARKET ACCESS PROGRAMME

This new pharmaceutical forum, which will carry out an in-depth review of some of the 14 recommendations made by the G-10 (An Expert Group on the Innovation and Supply of Medicines), will be made up of government representatives from all the Member States as well as from all other interested parties. Although the industry, represented by EFPIA, wanted a smaller structure that would include representatives from the European Commission, the European Parliament, some Member States and the research-based pharmaceutical industry, the Commission finally deemed it necessary for all of the Member States to participate, with the aim being to ensure everybody's commitment to those G-10 recommendations that fall within the States' own spheres of competence —pricing and reimbursement—.

The first initiative engendered by the new pharmaceutical forum took place in December 2005, when the British Presidency of the EU organised a round table in London to discuss the access available to the European patient to new medicines and the need to explore the benefits and added value that a strong and competitive pharmaceutical industry can provide European citizens with, as regards health and wellbeing.

Market Access Delays

During 2005, FARMAINDUSTRIA monitored the database known as Patients W.A.I.T Indicator, which was created by EFPIA. This database, which is updated every six months, records the time it takes for a medicine to become available on the 25 EU markets after it has been authorised for commercialization. The last report published states that over the past five years, market access time has been reduced.

This reduction in market access time for new medicines is the result, in part, of the efforts made by EFPIA's Market Access Delays Working Group, of which FARMAINDUSTRIA forms part. The W.A.I.T. Indicator enables Member States with excessive delays or those undergoing a deterioration of the situation in comparison with previous years to be identified. Once identified, the Market Access Delays Group programmes a working line with the relevant national authorities in order to ensure that they comply with the delay periods established in the Transparency Directive with regard to prices and reimbursement.

Liberalisation of prices for Non-Reimbursed medicines (Recommendation VI of the G-10)

Article 100 of Law 25/1990 governing Medicines —that justifies Government intervention with respect to fixing the price of medicines only when they are subject to reimbursement and they are dispensed in Spain— is the most significant progress that has been made as regards the implementation of recommendation VI of the G-10 process and EFPIA consider this as the most significant advance made towards the principle of free pricing for medicines non-reimbursed by the national health systems.

Even when stating the difficulties involved in applying the Royal Decree that imposes the principle that is the inspiration for Article 100 —evidence of dispensation in Spain—, at the same time it is recognised that the law also makes it possible for private contractual agreements to exist. For this reason, Article 100 is seen in Europe as being a legally accepted, viable and operational formula in practice, and one that provides the industry with the flexibility it needs in its relations with the distribution chain.

Prices

FARMAINDUSTRIA, by way of its participation on EFPIA's Economic and Social Policy Committee (ESPC) continues working on the design of proposals that might be accepted by all the interested parties

within the context of the European Commission's reflective exercise with respect to the prices of medicines; a reflection and debate that will begin in 2006 with the new team of DG Enterprise.

Health Technologies Assessment (HTA)

The work done by FARMAINDUSTRIA in 2004 as part of the EFPIA Working Group culminated with the adoption this year of a guide to the global recommendations and principles that must govern this type of assessment with the aim of providing a greater degree of transparency to the Spanish assessment procedures that form part of the decision making process with regard to price and reimbursement.

In 2006, the new pharmaceutical forum will begin a multilateral dialogue —European Commission, Member States and interested parties— in order to identify and analyse different practices and approaches, and propose common principles with respect to the methodology and transparency of national procedures.

The Informed Patient

FARMAINDUSTRIA also forms part of EFPIA's Informed Patient Working Group, which in 2005 drew up a collection of principles that encourage the pharmaceutical industry to make a proactive, constructive and responsible contribution as regards keeping patients informed.

These principles will act as the basis and standpoint of the research-based industry with a view to the debate planned for 2006 under the new pharmaceutical forum promoted by Commissioner Verheugen.

3. Improving the European Medicines Regulatory Framework

Many of the studies and actions carried out by FARMAINDUSTRIA and the rest of the national Associations have focused on the implementation of the new European pharmaceutical legislation, which was published a day before the expansion of the EU that took place on May 1, 2004.

The 25 Member States had until October 30, 2005 to incorporate the Directives on Medicines for Human Use (2004/27/CE) and Veterinary and Medicinal Plants (2004/24/CE) into their legal systems. In fact, although Regulation 726/2004/CE came into force on October 30, 2005, some aspects thereof (Heading IV relating to the new changes and structures of the EMEA Committees) were to be applied immediately as of May 1, 2004.

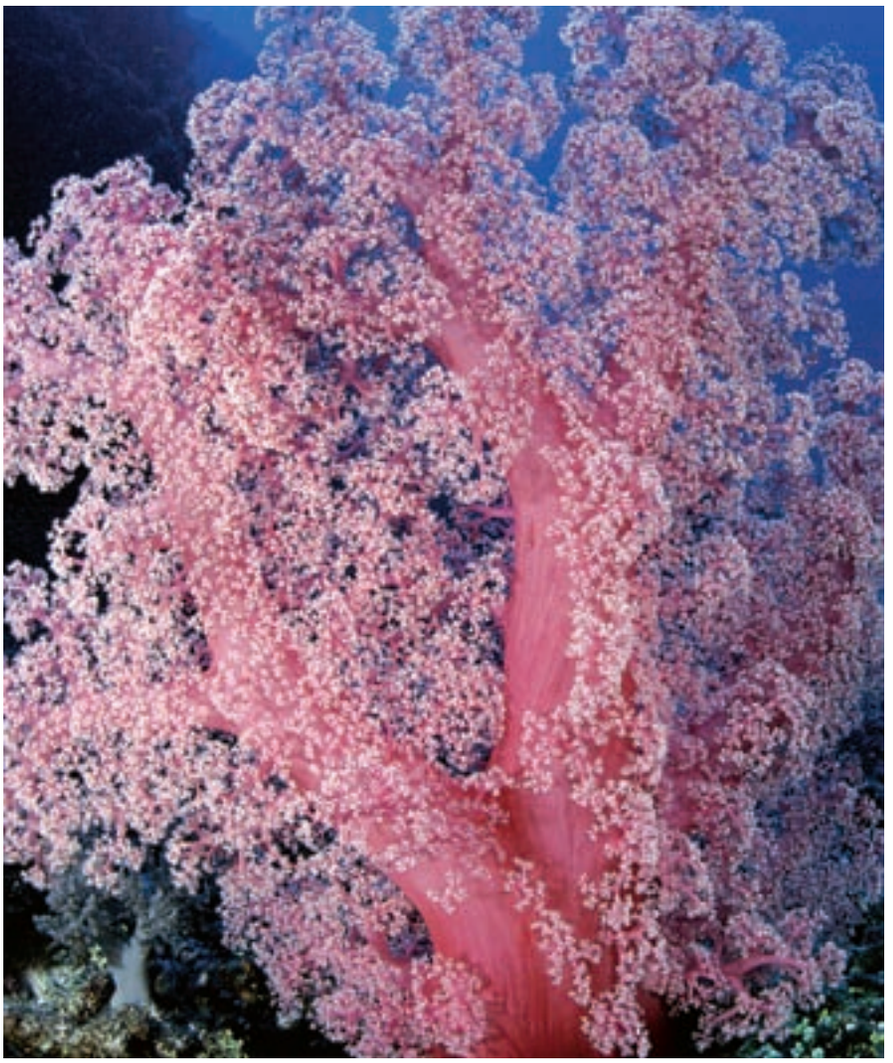
However, at the end of 2005, these were still pending publication due to the querying of a number of legislative development measures and directives of the European Commission, EMEA and National Agencies. Therefore, it is no wonder that, once the final deadline for incorporation had passed, the majority of Member States —including Spain— had not included the regulations that make up the new European legislative body with respect to medicines in their respective legal systems.

In December 2005, FARMAINDUSTRIA held a meeting in Brussels with the Head of the Medicines Unit of the EC´s DG Entreprise with the aim of conveying some of the concerns and unease felt by the pharmaceutical industry about the European legislation´s transposition process. In particular, FARMAINDUSTRIA tackled:

EFPIA HAS DRAWN UP A COLLECTION OF PRINCIPLES THAT ENCOURAGE A PROACTIVE, CONSTRUCTIVE AND RESPONSIBLE CONTRIBUTION WITH RESPECT TO KEEPING THE PATIENT INFORMED

- The proposed Ruling on the economic solutions applicable in the event of an infraction of pharmaceutical legislation, requesting a reduction in the amount of the fine —the Commission's proposal is for fines of up to 10% of the company's overall earnings— as this is completely disproportionate with respect to the nature of the categories.

- The need to treat the application of the Bolar clause in a more fair manner, on the one hand, and the 8+2+1 formula pertaining to register data protec-



tion on the other. The fact that the additional year of data protection that can be granted to a company —if and when the new therapeutic indication was obtained during the first eight years following the date on which the product was first marketed—, is applied only to new products as of the entry into force of the law that transposes the European legislation, whereas the manufacturers of generics can apply the Bolar clause retroactively —in other words, for all of the original products that are already on the market— represents a discrimination that favours the manufacturers of generics and punishes the innovative companies.

The 2005 EFPIA Annual Meeting

As a result of the elections to the European Parliament and the new appointments within the European Commission, the political environment of the EU experienced significant changes that have a direct impact on all of the questions related with the pharmaceutical industry.

EFPIA Annual Meeting, which was held in Brussels from June 1 to 3, 2005, offered all those taking part the chance to meet with the new representatives of the European institutions, governments of the Member States and patients' organisations, thereby stimulating an open and fluid dialogue on the three priorities defined by EFPIA's Governing Bodies. The conference organised within the framework of the Annual Meeting, concentrated on a variety of subjects, with the conclusion being that the success of innovation, sustained by a solid scientific basis and research, represents an important promotional and dynamic element of economic competitiveness in Europe.

Relations with the International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

FARMAINDUSTRIA also plays an active and participative role in the International Federation of Pharmaceutical Manufacturers Associations, IFPMA, an entity that brings together more than 55 pharmaceutical industry Associations from all over the world.

Since it was restructured in 2004, and following a budgetary increase, IFPMA's areas of action have broadened with respect to different international organisations, principally the World Health Organisation, the World Trade Organisation, the World Bank, the World Industrial Property Organisation and Patients' Associations with worldwide representation.
As well as having representatives on the Directors Committee of IFPMA's National Associations and Governing Bodies, Farmaindustria is represented on the Committees of the PPHA (Partnership, Public Health Advocacy), HCSC (Health Care Systems Committee) and IIPT (Innovation IP Trade).

In May 2005, the Spanish Health Minister, Ms Elena Salgado, was elected President of the 58th World Health Assembly, the top decision making body of the WHO, thereby becoming the first Spanish Health Minister to preside over the aforementioned Assembly.

The central theme of the Assembly in 2005 was maternal and child health, although in its extensive agenda the 58th Assembly on Health also tackled subjects related with the control of tuberculosis, actions to combat malaria, poliomyelitis, smallpox and AIDS; the control and prevention of cancer; violence and health; the prevention, treatment and rehabili-

tation of the handicapped, the rational use of medicines, and the mobility of health professionals in order to increase the level of collaboration within the WHO and other international bodies.

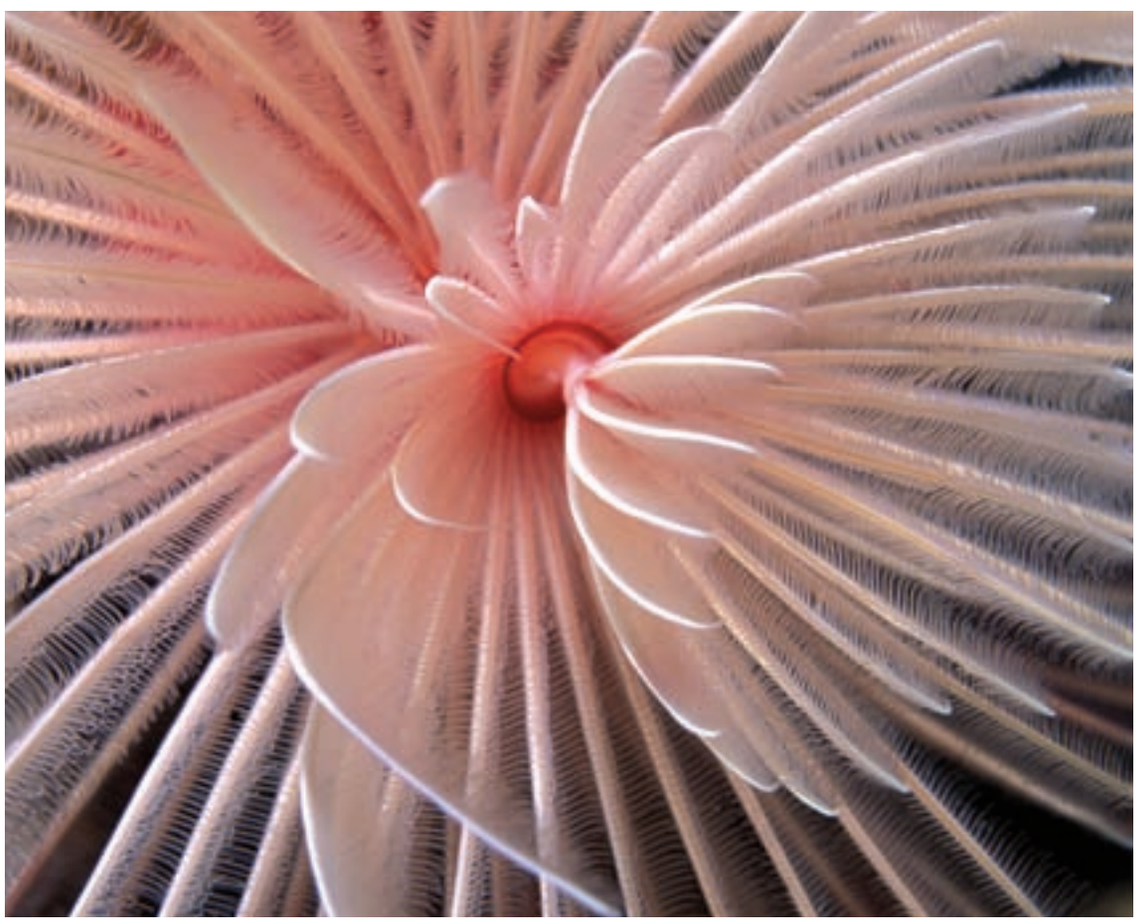
On May 15, the eve of the opening session of the 58th World Assembly, FARMAINDUSTRIA organised a tripartite meeting between the Spanish Minister for Health and Consumer Affairs and the IFPMA during which Mr Harvey Bale (Director General of IFPMA) and Mr Humberto Arnés (Director General of Farmaindustria) brought the Health Minister up to date with the most relevant aspects of the R&D-based pharmaceutical industry, such as the platform for the promotion of innovation, the growing concern for finding joint solutions for combating counterfeiting of medicines and the possible collaboration channels for making closer contact with Latin American countries.

4. THE FARMAINDUSTRIA FOUNDATION

The activities carried out by the FARMAINDUSTRIA Foundation during the fourth year of its existence were, in accordance with its purpose, focused on promoting those actions that favour scientific research and contribute towards improving the Spanish healthcare sector as a whole by fostering, in particular, biomedical and pharmaceutical research, training health professionals and educating the population in health-related matters.

Activities implemented using the financial contributions made to the Carlos III Health Institute

The FARMAINDUSTRIA Foundation continued channelling the funds contributed by the pharmaceutical industry in line with the Agreement signed with the Ministry for Health and Consumer Affairs regarding the financing of the projects managed by the Carlos III Health Institute.



By virtue of the aforementioned Agreement, it was established that the projects would be financed via the Carlos III Health Institute, namely the body chosen to provide scientific and technical support to Spain's Ministry of Health and Consumer Affairs and to the Health Services of the Autonomous Regions, and that the Institute would manage and, where appropriate, monitor and follow-up said projects.

In 2005, the contribution made by the industry within the framework of the aforementioned Agreement was replaced by a mandatory contribution related to the the volume of sales of medicines to the National Health System, as established by Law 2/2004 of December 27 governing General State Budgets for the year 2005.

The 'Redes' (Networks) Magazine

Continuing on with the initiative started in 2004 and with the aim of providing society in general and health professionals in particular with information regarding the main research activities being carried out in Spain and about the activities of the networks of centres and groups registered with the Carlos III Health Institute, last year the Farmaindustria Foundation published three issues of its Medical Research magazine *Redes* (Networks).

The first issue was exclusively dedicated to neuroscientific research and went into the reasons for creating a network research model in this field. This issue included a number of editorial articles and in-depth reports on the main challenges facing neuro-scientific research and the key factors for the future.

The central section of the second issue of this publication was dedicated to the rise of tropical diseases —up to now infrequent in the developed world— as a result of the increased international mobility of the population, the sharp increase of immigration and tourist trips to exotic countries, among other reasons. As an upshot of this, and thanks, to a great extent, to the financial contributions made by the pharmaceutical industry to the Carlos III Health Institute, the Tropical Disease Centres Research Network (RICET) was created. In the two and a half years since it was founded, 18 cooperative research projects have been implemented in fields such as malaria, leishmaniasis, trypanosomiasis, helminthiasis and arthropods, among others.

THE MAGAZINE 'PACIENTES' (PATIENTS) WAS CONCEIVED AS A COMMUNICATIONS CHANNEL SERVING BOTH PATIENTS AND THE ASSOCIATIONS THAT REPRESENT THEM

The third issue focused on the research being carried out in Spain in the field of clinical and molecular genetics via the Network of Clinical and Molecular Genetics Centres (RECGEN), that is also dependent on the Carlos III Health Institute and receives financial support from the pharmaceutical industry. This network was set up to act as a multidisciplinary organisation made up of entities working in the field of hereditary diseases. Another theme tackled in this issue was the contribution made by vaccines towards the eradication of diseases, with especial attention being paid to the work being carried out by the different Networks of Groups who depend upon the Carlos III Health Institute in fields such as neurology, geriatrics, biochemistry and transplants.

The 'Pacientes' (Patients) Magazine

2005 saw the presentation of a new Farmaindustria Foundation publication, namely the magazine *Pacientes* (Patients) that, on a quarterly basis, was conceived as a communications channel serving both patients and the associations that represent them.

Two issues were published in 2005. The first issue focused its attention on the sharp rise in the number of patients' associations in Spain, a phenomenon that has mirrored the increased awareness of this collective that disease and illness is more effectively combated if patients play a more active role in the healing and curing process.

The second issue of the magazine concentrated on the importance of volunteers with respect to the activities carried out by the patients' associations —in Spain more than a million people form part of this social movement—, and where Spanish patients stand in light of the future Safeguards and Rational Use of Medicinal Products and Medical Devices Act.

1st Edition of Awards for the Best Patient Service Initiatives

Among all the activities carried out by the Farmaindustria Foundation during 2005, a special mention must be made of the holding of the 1st Edition of Awards for the Best Patient Service Initiatives, a series of awards that are the result of the commitment of the pharmaceutical industry to the rational use of medicines and which aim is recognising the best actions carried out in favour of patients in different fields.

The Awards ceremony was held on November 13, 2005 at the Real Fábrica de Tapices (Royal Tapestries Workshop) in Madrid. The event was presided over by the Spanish Minister for Health and Consumer Affairs, Ms Elena Salgado, and brought together leading lights and institutional representatives from both the academic world and the pharmaceutical industry.

Other Activities

One of the permanent activities carried out by the Farmaindustria Foundation is that of sponsoring courses and seminars, which include: the V Pharmaceutical Industry Congress, which was organised in conjunction with the Universidad Internacional Menéndez Pelayo; the Severo Ochoa Open Day, which was held to celebrate the centenary of the Nobel Prize-winner's birth and organised by the Fundación Escuela Asturiana de Estudios Hispánicos de La Granda; and the I National Congress of Health Journalism, which was jointly organised with the Health and Consumer Affairs Counsel of the Madrid Autonomous Region, the Spanish Federation of Press Associations (FAPE) and the National Association of Health Journalists (ANIS).

Finally, mention must be made of the Farmaindustria Foundation's support for the Fundación Reina Sofía (Queen Sofía Foundation) with respect to its work in spreading awareness about the Alzhei-mer Project, given in recognition of the high degree of social interest of this project, as well as for the Spanish Pharmacological Foundation, to name only a few institutions.

5. THE INTEGRATED WASTE MANAGEMENT AND COLLECTION SYSTEM (SIGRE)

Sigre was created on the initiative of the pharmaceutical industry, with the collaboration of the pharmacy distribution and outlets network, in order to provide citizens with a comfortable and safe system via which they could dispose of medicines that are either out of date or no longer required whilst at the same time guaranteeing the correct environmental handling thereof. 2005 saw a significant increase in the amount of waste medicines disposed of in the Sigre Deposit Points, which fully vindicates all the effort being made by the industry to ensure that medicines are used responsibly, even when they are being disposed of.

Legal Framework

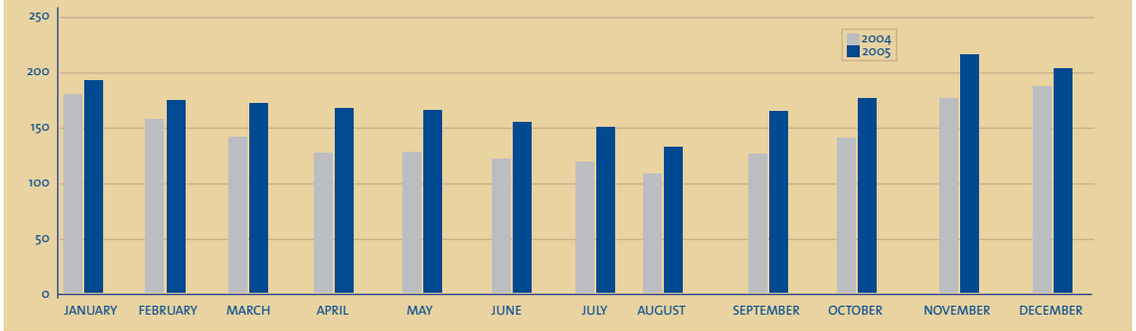
Directive 2004/27/CE, which establishes a community-wide code with respect to medicines for human use and the Safeguards and Rational Use of Medicinal Products and Medical Devices Act, endorse the activities being carried out by the Spanish pharmaceutical industry via its SIGRE initiative by reiterating the obligation to create adequate systems for the collection of unused or expired medicines that have accumulated in people's homes.

This new legislation will not lead to significant variations in the model implemented by SIGRE, which has, for the first time in Europe, built a Medicines Classification Plant especially designed to provide the most suitable environmental processing for this type of product.

Medicines and Corporate Social Responsibility

Despite society having been aware of the significant value that medicines provide for many years now, over the last few years the pharmaceutical sector has faced a new set of challenges as society's expectations have become increasingly higher. It now demands that products not only be of the highest quality, but that they are also environmentally friendly. In this sense, the pharmaceutical industry has been a pioneer in the introduction of environmental responsibility criteria into its corporate policies, with SIGRE being a good example of this. The positive way in which this initiative has been received by citizens and administrative bodies alike, and the influence that it is having on the image of the pharmaceutical industry, confirm the importance that the manifestations of corporate social responsibility have when it comes to evaluating the behaviour and performance of companies.

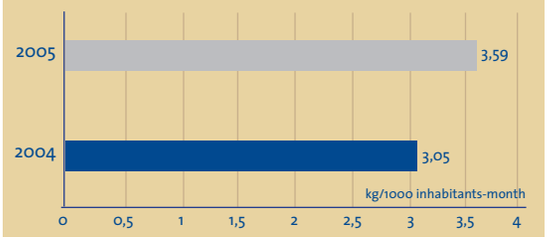
WEIGHT OF WASTE PACKAGING COLLECTED NATIONWIDE (TONNES) 2004-2005



In 2005, Spaniards disposed of 1,990 tonnes of packaging and unwanted medicines via the SIGRE Deposit Points located in pharmacies, representing an increase of 20% with respect to the previous year.

In light of the results obtained, we can safely say that the degree of environmental sensitivity being shown by the population is on the up in Spain, a claim reiterated by the rise in the monthly collection rate per 1,000 inhabitants, which in 2005 reached 3.59 kg, 18% above the rate recorded in 2004.

MONTHLY COLLECTION RATE



SIGRE and the prevention of waste packaging at source

In order to guarantee that medicines are conserved in optimum conditions as regards quality, safety and efficiency, the Health Administrations have established an authorisation procedure that includes an assessment of the packaging that must provide protection against external agents, be they mechanical, environmental or biological, enable the product to be identified, provide the information necessary for ensuring correct usage by patients and avoid any possible tampering.

IN 2005, SPANIARDS DISPOSED OF 1,990 TONNES OF PACKAGING AND UNWANTED MEDICINES VIA THE SIGRE DEPOSIT POINTS LOCATED IN PHARMACIES: 20% MORE THAN IN 2004

As a result of the strict legislation and the increasing amount of information that must appear on the labelling of medicines in order to ensure they are correctly used, these products encounter greater difficulties than others when it comes to applying prevention measures on their packaging.

However, the pharmaceutical industry has for years been making significant efforts to reduce the environmental impact of its products, including their packaging.

One of SIGRE's missions involves the preparation of the pharmaceutical sector's Corporate Prevention Plans (PEPs), which have to be approved and monitored by the environmental authorities and which include quantified prevention objectives, the measures planned for achieving these and the control mechanisms for ensuring they are fulfilled.

2005 saw the end of the PEP covering the period 2003-2005, during which an overall reduction of 3.2% was achieved in the existing ratio between the weight of the packaging and that of the medici-

nes they contain, thereby exceeding the objectives initially set by the pharmaceutical industry, (namely a reduction of 3%).

This reduction was possible thanks to the application by 96 pharmaceutical companies of more than 373 different prevention measures that have affected over 160 million items of packaging.

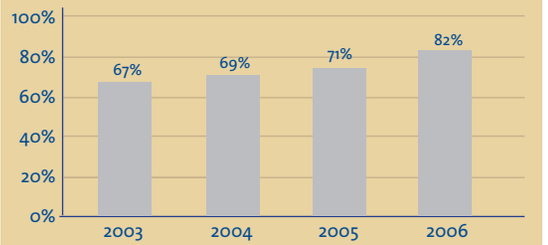
Public Awareness

Aware that the collaboration of the public would play an essential role in the success of this initiative, SIGRE has run a series of strong campaigns from the outset aimed at making the public aware of and sensitive to the environmental and socio-health issues related with medicines.

In 2005, the SIGRE Communications Plan once again gave priority to its publicity campaign entitled *Cuida tu salud, Cuida la Naturaleza* (Take care of your Health, Take care of Nature), in which it invites members of the public to review their medicine cabinets and take any packaging items and/or surplus medicines that have not been taken or have reached their expiry date down to the SIGRE Deposit Point located in their local pharmacy.

Once again, in 2005 the SIGRE campaign was able to count on the supervision and collaboration of the Environmental Counsels and the support of the Health Counsels of the different Autonomous Regions.

PERCENTAGE OF CITIZENS WHO ARE AWARE OF THE SIGRE DISPOSAL POINTS



Although the general public continues to be the number one target of SIGRE's communication activities, in the knowledge that the task of environmental protection and the responsible management of waste medicines implicates the whole of society, in 2005 SIGRE initiated an approach to the medical community. Given the role that these professionals play in the prescribing of medicines, their contribution towards improving the environment by advising the public and spreading the messages prepared by SIGRE is essential.

THE PHARMACEUTICAL INDUSTRY HAS BEEN A PIONEER IN THE INTRODUCTION OF ENVIRONMENTAL RESPONSIBILITY CRITERIA INTO ITS CORPORATE POLICIES; SIGRE IS A GOOD EXAMPLE OF THIS

In this context, and in collaboration with the Organisation of Physicians Professional Associations (OMC) and FARMAINDUSTRIA, in 2005 SIGRE organised an Open Day on Medicines and the Environment aimed at the medical community in which representatives of the Ministries for the Environment and for Health and Consumer Affairs participated.

THE PHARMACEUTICAL INDUSTRY IN SPAIN AND WORLDWIDE

1. THE PHARMACEUTICAL INDUSTRY IN EUROPE

2005 has not been a particularly good year for the European economy. The recovery that appeared to be on the horizon in 2004, with growth rates of 2.3% in the EU-15, failed to materialize. Growth in EU-15 in 2005 ran at 1.4% (1.6% for the EU-25), while GDP for the Eurozone registered a 1.3% increase, 0,8 percentage points less than the previous year. Of the five main European economies, four saw growth decelerate and only Spain consolidated its growth from the previous year.

The future looks uncertain, as structural imbalances in the European economy persist: high unemployment levels budget deficits over the 3% ceiling set by the EU's Stability and Growth Agreement (Germany, France, Italy, UK...) and national debt running high.

Moreover, inflation has not yet been tamed, partly because of the upward trend in oil prices (the barrel of Brent went up 42% in 2005[2]). As a result, the European Central Bank (ECB) adopted a more restrictive monetary policy and in December 2005 decided to raise interest rates (which had been at 2% since June 2003 and which had not risen since October 2000).

But there are positive aspects. In Germany, the IFO Business Confidence Index is at a 15-year high. Similarly, in Italy, businessmen are increasingly more optimistic about the prospects for the economy. Investors also appear to be confident with regard to the future of the EU's economy and are backing European companies, as the 21% increase in Eurostoxx 500 Index in 2005 (Europe's main stock exchange) would appear to indicate.

SPAIN HAS CONSOLIDATED ITS POSITION AS THE FIFTH EUROPEAN PHARMACEUTICAL MARKET IN TERMS OF SALES AND EMPLOYMENT

All this means that although the macroeconomic data could be better, there appears to be a certain optimism regarding Europe's economic prospects. Europe's economic progress next year will depend largely on future interest rate increases by the ECB and on economic growth in the USA and Japan, which will determine the future of the EU's trade balance (it should be remembered that Germany is the EU's main exporter worldwide and that German economic growth is heavily dependent on overseas sales).

Owing to the sector's special characteristics, the evolution of the pharmaceutical market is frequently out of step with the general progress of the economy,

EVOLUTION OF THE PHARMACEUTICAL MARKET IN MAIN EUROPEAN COUNTRIES

	Variation (%) 2005/04	% of total sales of 5 countries, 2004
Germany	8	29.9
France	5	25.0
Italy	0	16.2
United Kingdom	3	16.7
Spain	6	12.1
TOTAL 5 COUNTRIES	3.9	100.0

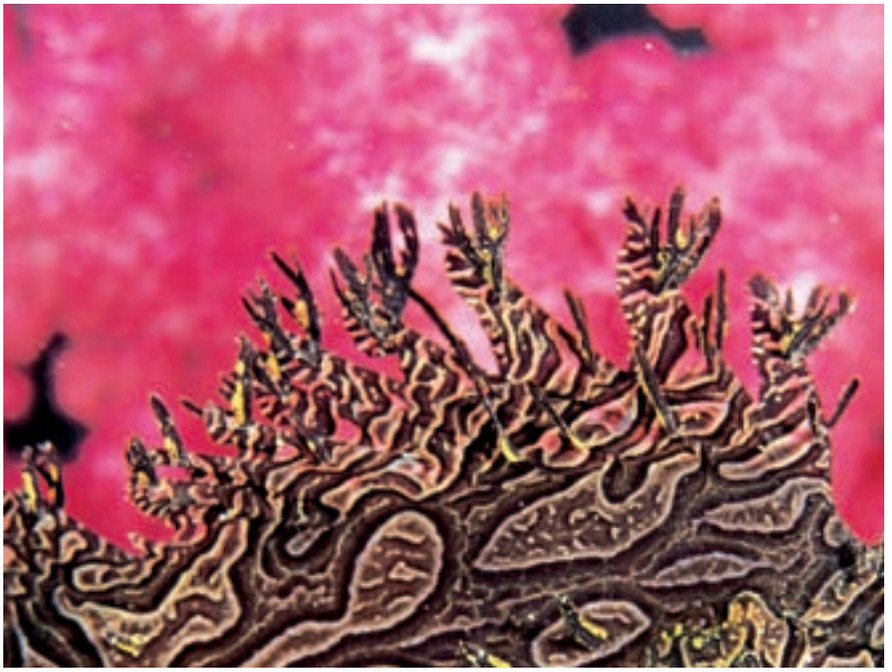
Source: FARMAINDUSTRIA based on data of IMS Retail Drug Monitor.

[2] Average annual price of a barrel of Brent Dated crude (Ministry of Industry, Tourism and Trade).

however because it depends on factors such as social welfare policies applied in different countries and measures introduced by governments to keep pharmaceutical costs under control. However, on this occasion, the downturn registered by the European economies in 2005 has taken its toll on the pharmaceutical sector. The average growth rate of total sales in the top five European markets dropped from 4.2% to 3.9%.

Of the top five European pharmaceutical markets, four (UK, Italy, Spain and France) registered the same growth or lower than the previous year, and only Germany registered stronger growth than in 2004, owing mainly to the end of the price freeze introduced in 2002.

The Spanish market suffered another downturn and registered growth below GDP for the second year running —the growth rate in 2005 was the lowest in 12 years—. The main reason was the generalised 4.2 % price cut established by the RD 2402/2004; 30 december, which came into effect in March 2005.



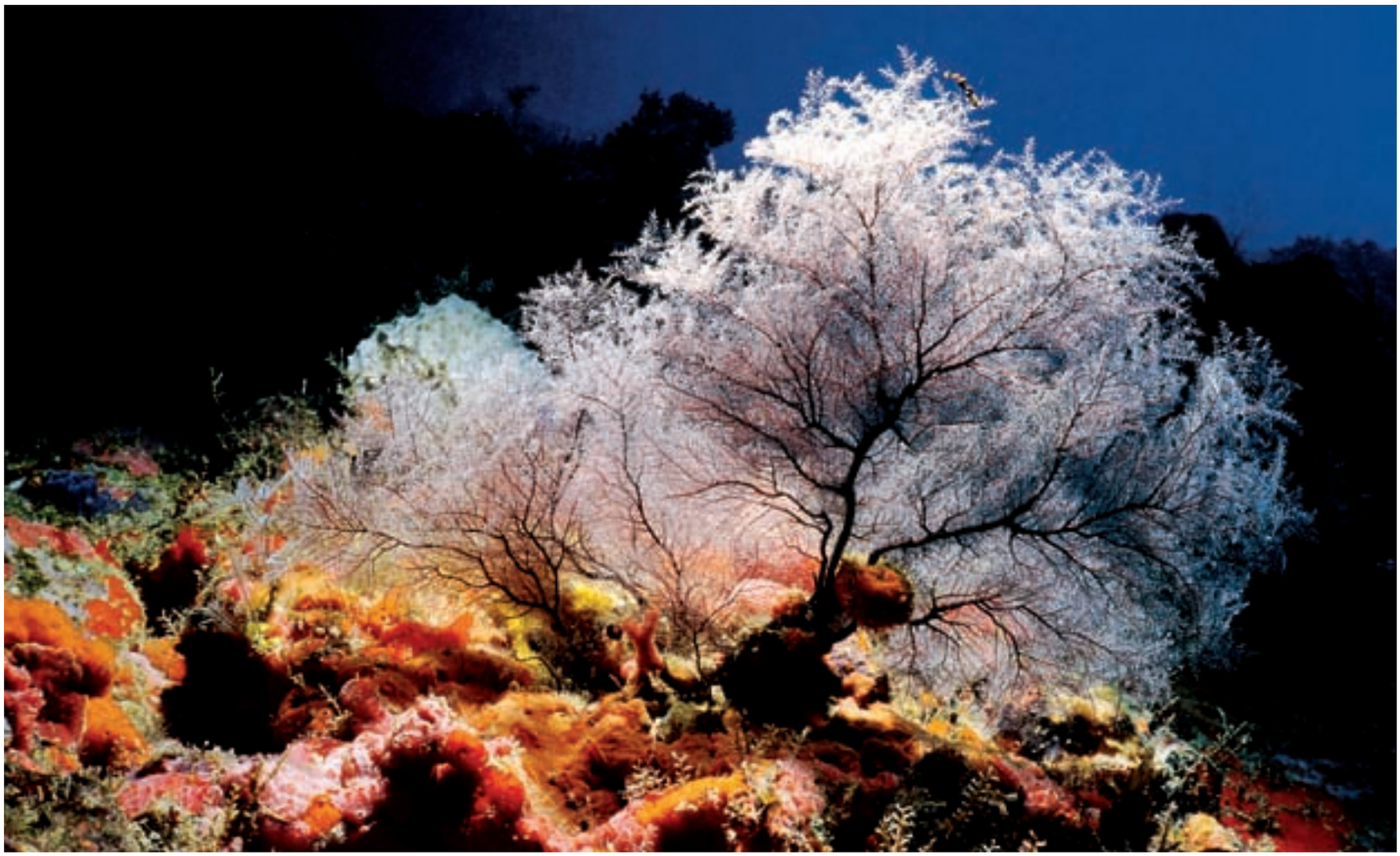
The following table shows the growing relevance of the Spanish pharmaceuticals industry within Europe. Spain is now Europe's fifth largest market by sales and employment (after Germany, France, Italy and the UK), and the sixth in terms of production (after the *Big Four* and Ireland).

THE EU PHARMACEUTICAL INDUSTRY IN FIGURES (2004)

Country	Nº of labs (*)	Production €m (**)	Jobs	Domestic Sales (€m)	Foreign Trade (Ex-Lab prices) (€m)	
					Imports.	Exports.
Germany	310	20,893	114,200	21,551	21,991	27,333
Austria	105	1,597	9,523	2,312	2,996	2,875
Belgium	140	4,799	27,185	3,539	26,316	24,599
Denmark	41	4,593	16,759	1,410	1,734	4,525
Spain	239	9,656	39,000	10,671	6,716	3,999
Finland	64	724	6,648	1,689	1,283	490
France	257	33,141	99,400	22,760	12,963	17,196
Greece	65	449	11,300	3,468	2,254	677
Holland	48	5,660	16,000	3,579	8,421	8,989
Ireland	56	15,866	22,500	1,306	1,988	15,156
Italy	213	17,742	73,266	15,195	10,448	9,060
Portugal	141	1,590	10,717	2,879	1,597	308
UK	74	22,555	73,000	16,110	12,742	18,207
Sweden	62	5,565	20,100	2,608	1,999	5,791
Total UE-15	**1,815**	**144,830**	**539,598**	**109,077**	**113,448**	**139,205**

Source: FARMAINDUSTRIA based on data of EFPIA and the Pharmaceutical industry association of each country.

NB. Luxembourg not included.
*Member Laboratories of the EFPIA associations.
**Figures refer to production activities of pharmaceutical specialities and raw materials for veterinary and human use, except in Spain where they refer solely to activity for human use.



2. THE PHARMACEUTICAL INDUSTRY IN SPAIN

2.1. R&D

Investment in R&D is essential to ensure the future economic growth and competitiveness of any country. While the USA and Japan apply around 3% of GDP to R&D, investment in the EU as a whole is around 2% of GDP and Spain barely scrapes 1%.

The data also show that the role of the State is very limited in all three of these economic blocks (especially in the USA and Japan) and that it is private enterprise that acts as the main driver of innovation. By contrast in Spain, the share of the public sector remains very large, while the level of research is still very low.

This means that in order for Spain to be competitive in R&D and raise its level to EU average, it is essential to promote research in the private sector, which is what ultimately makes an economy dynamic and competitive. In particular, it is important to stimulate investment in the most R&D intensive sectors.

R&D SPENDINGS ACCORDING TO FUNDS ORIGIN (2003)

	R&D spendings (% GDP)	ORIGIN OF FUNDS % Contribution Priv. Sector	% Contribution Public Sector	% Foreign and other
Japan	3.12%	74.5	17.7	7.8
USA	2.65%	63.1	31.2	5.7
EU-25	1.92%	54.3	34.9	10.8
Japan	3.12%	74.5	17.7	7.8

Sources: Eurosat

IN 2004 PHARMACEUTICAL COMPANIES SPENT MORE THAN 681€ MILLION ON R&D RESEARCH, EQUIVALENT TO 17.4% OF TOTAL EXPENDITURE ON R&D OF ALL THE INDUSTRIAL SECTORS PUT TOGETHER

Of these sectors, the pharmaceutical industry, is without a doubt the most important one. This is evidenced by results taken from the Technological Innovation Study, recently published by the National Institute of Statistics, and which state that:

- In Spain, the pharmaceutical sector, along with automotive, is the sector which invests most on research, though it is significant to point out that the automotive sector's global sales volume is three times that of the pharmaceutical sector's. In 2004, pharmaceutical companies spent more than €681 million on research, equivalent to 17.4% of total expenditure on R&D from all the industrial sectors put together. This percentage is significant bearing in mind that the turnover of the pharmaceutical companies represents just 2.3% of the industry's total sales. In other words, the pharmaceutical sector spends 6% of its sales volume on research, while industry as a whole spends an average 0.8%.
- The pharmaceutical industry leads the way, along with machine manufacture, in job creation in the area of re-search, with 3,850 full-time employees, a figure which represents over 10% of total employment in R&D in the whole industrial sector, and a 6.5% growth compared with 2004 figures.
- The pharmaceutical sector is also at the top of the industrial sectors in terms of companies engaged in innovative activity (64%) and those conducting R&D (54%).
- Pharmaceutical R&D differs from other more cyclical sectors in that it is sustained over time. Over the past ten years, the sector's pharmaceutical, investments in R&D have grown at an average annual rate of 12%, higher than other R&D intensive sectors.
- Another interesting conclusion can be reached by studying the relationship between the growth of a sector's turnover and the increase in its R&D investments. In this respect, it should be noted that the average increase of the pharmaceutical sector's investments in R&D over recent years is double the average growth of the sector's turnover over the same period.

The above data highlights the strategic importan-

SPANISH COMPANIES R&D ACTIVITY (2004)

SECTOR	R&D Employees *	R&D Spendings (million €)			
		Internal	External	Total	%^s/2003
Total industry	37,567	2.788.54	1.128.84	3.917.38	13.8
Aerospace	2,481	269.53	138.12	407.65	33.7
Automotive	3,407	225,00	511.49	736.49	8.4
Pharmaceutical industry	3,850	479.22	202.09	681.31	7.6
Radio, TV, communications	1,822	107.38	24.72	132.10	3.4

(*) Personnel in EJC (full time employees).
Sources: FARMAINDUSTRIA FORM INE "Statistics National Institute" (Statistics on R&D activities 2003 and 2004).

Source: Farmaindustria from INE "Statistics National Institute" (Industrial Companies Survey and R&D activities statistics)

AVERAGE ANNUAL VARIATION (CAGR) (1995-2004)

SECTOR	Turnover	R&D Costs
Total Industry	**6.7**	**9.2**
Aerospace	**12.7**	**9.7**
Automobile	**6.7**	**11.6**
Pharmaceutical Industry	**6.3**	**12.2**
Radio, TV, Communications	**3.2**	**-3.9**

ce of the pharmaceutical sector for Spanish research, not only in terms of investment but also because of its high and sustained growth and its ability to create highly-qualified jobs.

However, it is important to point out that over recent years the conditions for investment in pharmaceutical R&D in Spain have worsened. It is plain to see that a high-risk investment model, as it is the case of the pharmaceutical sector where the research cycle is long, increasingly expensive and subject to increasing demands from the regulators, requires a stable legal framework allowing companies to plan their investments adequately.

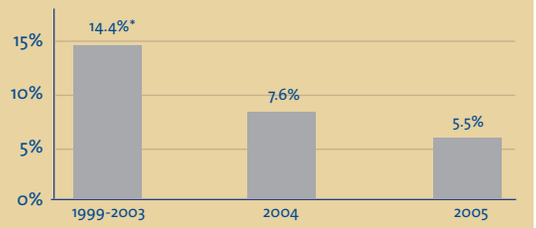
However, budgetary considerations often mean that the pharmaceutical industry is affected by unforeseen administrative measures. Last year was no exception and saw a number of public policy measures having an effect upon the sector:

- Central government decreed an across-the-board 4.2% drop in prices, followed by a further 2% cut in 2006 for all products on the market for over one year and not subject to the reference price system, what affected all innovative patented products, which are still recouping their investment costs. This measure also reduced the prices of products which were already significantly lower than the EU average, which tends to worsen the problem of parallel sales which is so harmful to innovative companies.
- Also, in 2005 a law came into effect (Law 2/2004, 27 December, National Budget 2005) requiring companies to make a contribution of between 1.5% and 4.5% of their sales to the NHS (National Health System), according to each Corporate's sales to the latter. This measure, will inevitably affect research conducted by pharmaceutical companies, and will further widen the gap between Spain and the EU, USA and Japan.

THE PHARMACEUTICAL SECTOR IS IMPORTANT FOR SPANISH RESEARCH BOTH IN TERMS OF INVESTMENT AND BECAUSE OF ITS SUSTAINED GROWTH AND ITS ABILITY TO CREATE HIGHLY-QUALIFIED EMPLOYMENT

The above-mentioned difficulties show up in tangible and quantifiable results. If we look again at the data provided by the National Institute of Statistics, we can see that average annual growth of pharmaceutical R&D over the past twelve years reached 12.2%. If we look at a shorter and more recent period (1999 -2003) , this growth rises to 14.4%. However 2004 showed only a 7.6% increase. In other words, pharmaceutical industry investment in R&D slowed considerably. This slowdown continued into 2005, according to provisional data from an R&D survey conducted by

PHARMACEUTICAL R&D GROWTH RATE (1999-2005)



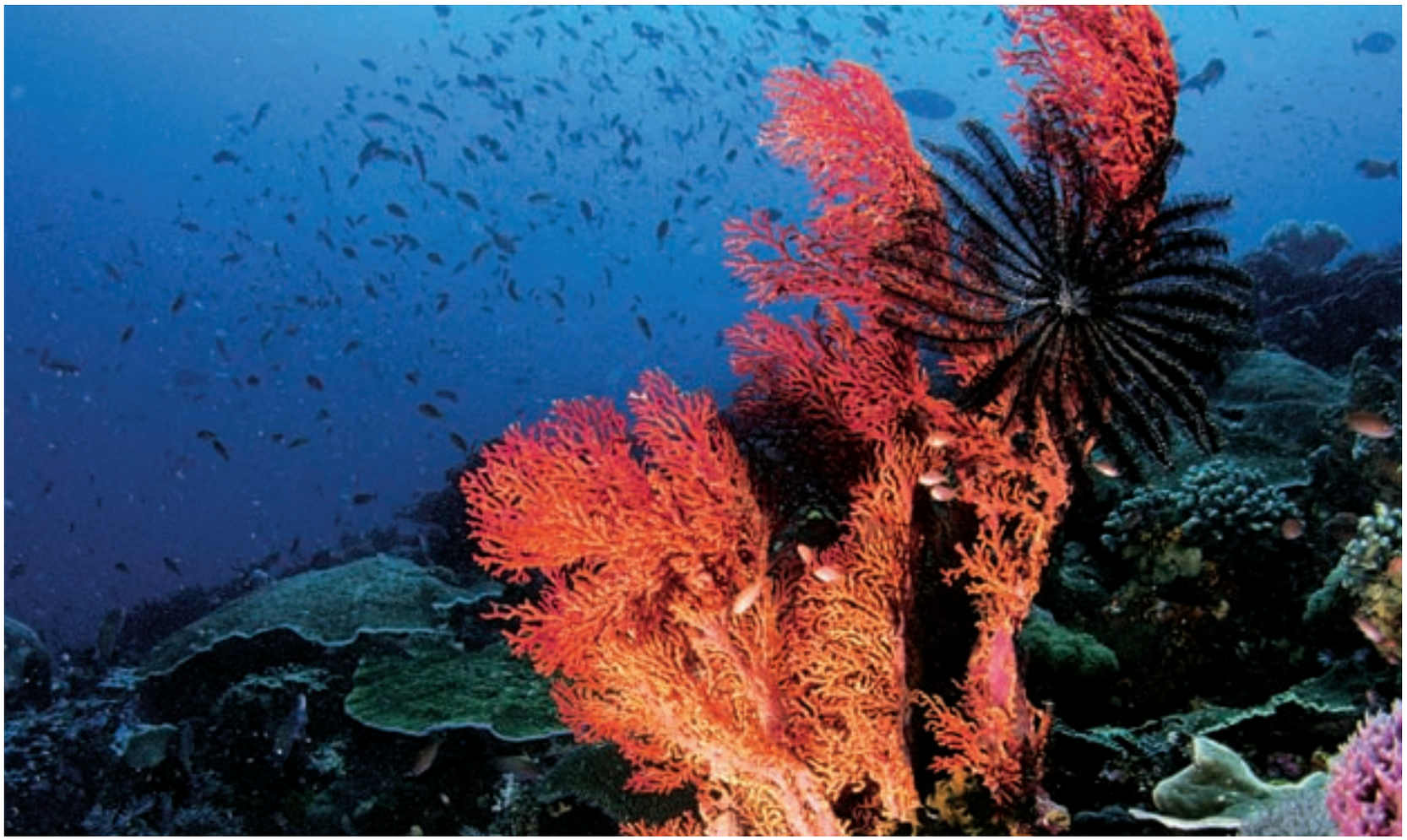
FARMAINDUSTRIA among its members. R&D expenditure in 2005 grew by only 5.5%, no doubt as a result of the above-mentioned government measures.

A more stable regulatory framework would have meant that the pharmaceutical industry's contribution to national R&D investment would have been greater over the past two years.

The future raises several doubts and uncertainties, stemming from the different regulations that are being debated in Parliament at the time of writing this annual report:

- The Safeguards and Rational Use of Medicinal Products and Medical Devices Act. In the version sent to the Congress by the Government, the bill, which, once passed, will lay down the basic legal framework for the pharmaceutical industry for the next few years- includes a number of economically-slanted measures which are hard to justify and that will cause considerable harm to pharmaceutical companies and pharmaceutical R&D in Spain.
- Personal Income Tax Bill and the Partial Amendment of the Corporate Tax Laws, Tax for Non-Residents and Wealth Tax. This Bill establishes the gradual reduction of tax relief for R&D in Corporate Tax, leading to their complete elimination in 2012. The lowering of the tax rate to 30% in 2012 will not make up for the elimination of these relief: given the magnitude of the resources that pharmaceutical companies set aside for R&D and Innovation, these companies were taxed at approximately 22%[3]. Also, the discounts on Social Security payments for research personnel is a measure that not only fails to make up for the elimination of deductions, but also was due to come into effect prior to the introduction of the National Reform Plan, within the framework of the Programme for the Promotion of Employment.
- The Bill which broadens the means for the supervision of Intellectual and Industrial Property Rights and establishes procedural norms for the application of several EU Regulations. This legislative initiative, awaiting debate in the Senate, provides an opportunity to harmonise the protection of patents in Spain and the rest of the EU and to include in Spain's legal framework the agreements signed by Spain in 1995 (TRIPS) in the framework of the World Trade Organization. This would avoid the foreseeable judicial slant in this area and would highlight Spain's role as an advocate for respect for industrial property rights as an agent for stimulating innovation, all of which would

[3] Association of Economists of Catalonia estimate.



enhance the confidence of foreign investors. In Spain, at the moment, the lack of complete harmonisation in this area has a doubly-negative effect on innovative companies: on the one hand, because of the anticipated loss of market share in Spain —because of the early appearance of generic drugs— as opposed to what is happening in the rest of EU-15, and the increase of parallel trade.

We are therefore at a crucial point, on the threshold of very important events that will shape the pharmaceutical industry's context for action over the coming years. The final outcome of the legislative procedures currently under way will, to a significant extent, shape the future of pharmaceutical investment in Research, Development and Innovation in Spain, which, as we have already pointed out, is vital to the competitiveness of our economy.

2.2. Domestic Market

Market Structure

Total pharmaceutical sales in Spain reached 11.328 million euros in 2005, a 6% rise on the previous year's figure. Of these sales, 76.9% were made through retail pharmacies (up 5.7% on 2004) and the rest through hospitals (up by 8.0%).

DOMESTIC MARKET FOR PHARMACEUTICAL PRODUCTS (EX-LABORATORY PRICES € MILLION)

	Retail Pharmacies	% Increase	Hospitals (%)	% Increase	Total	% Increase
2003	7,744.40	11.7	2,162.57	13.2	9,906.98	12.0
2004	8,267.46	6.8	2,422.08	12.0	10,689.54	7.9
2005	8.712.07	5.7	2,615.85	8.0	11,327.92	6.0

(e) Estimate.
Source: Farmaindustria based on IMS data and own estimations.

According to IMS figures, Spain's prescription market, which accounts for 96% of sales through retail pharmacies, has registered its lowest increase in recent years, at 5.7%. To a great extent, this moderate rise is due to the 4.2% reduction in the ex-laboratory prices applied to specialities financed by the Social Security, with over a year on the market and not subject to the Reference Price System.

SALES OF MEDICINAL PRODUCTS THROUGH RETAIL PHARMACIES (EX-LABORATORY PRICES)

	Total	Incr. (%)	Prescription	Incr. (%)	OTC	Incr. (%)
Units (million)	1,163.21	1.8	1,040.80	2.2	122.41	-2.1
Value at ex-lab. prices (€ million)	8,712.07	5.7	8,365.07	5.8	347.00	3.4

Fuente: FARMAINDUSTRIA based on IMS.

Despite a drop in unit sales (-2.1%), OTC sales grew by 3.4%, retaining a hold on its 4% market share. The sale of generic pharmaceutical specialities reached €474.6 million, with a 5.7% share of the prescription market. In unit terms, market share stands at 10.5%. If we consider the whole group of molecules that use generic drugs, the market share stands at 16% in value terms and 23% in units.

PHARMACY SALES OF MEDICINAL PRODUCTS BY THERAPEUTIC CLASS THROUGH PHARMACIES (EX-LAB. PRICES) (2005)

THERAPEUTIC CLASS	UNITS			VALUE			Av. Price (Ex-Lab Prices)
	Thousand	Struct. %	% Change	€ mill	Struct. %	% Change	
A Alimentary Tract and Metabolism	169,860	14.6	1.3	1,084.04	12.4	6.2	6.38
B Blood and blood forming organs	46,471	4.0	4.9	346.87	4.0	6.2	7.46
C Cardiovascular system	190,345	16.4	2.7	1,875.44	21.5	3.8	9.85
D Dermatologicals	63,933	5.5	-2.2	287.99	3.3	2.0	4.50
G GU systems and sex hormones	50,467	4.3	1.8	571.24	6.6	8.5	11.32
H Systemic hormonal preparations	16,253	1.4	3.7	175.41	2.0	-7.0	10.79
J Systemic anti-infectives	61,682	5.3	-2.2	443.56	5.1	2.8	7.19
K Hospital solutions	2,524	0.2	2.8	3.00	0.0	4.9	1.19
L Antineoplasic and immunological products	5,558	0.5	3.2	439.34	5.0	11.7	79.05
M Musculoskeletal system	87,115	7.5	3.4	503.19	5.8	3.4	5.78
N Central nervous system	275,533	23.7	0.8	1,835.72	21.1	7.8	6.66
P Parasitology	1,100	0.1	-1.4	6.20	0.1	12.3	5.64
R Respiratory system	143,707	12.4	4.1	914.00	10.5	7.1	6.36
S Sensory organs	47,902	4.1	2.7	205.16	2.4	4.5	4.28
T Diagnostic products	147	0.0	0.7	1.49	0.0	25.9	10.13
V Other products	614	0.1	1.0	19.42	0.2	12.5	31.62
TOTAL	1,163.213	100.0	1.8	8,712.07	100.0	5.7	7.49

Note: PVL= Ex-Laboratory prices 2004.
Source: IMS

LAST YEAR 261 NEW PRODUCTS CAME ONTO THE SPANISH MARKET: OF THESE, 145 WERE GENERICS AND 19 WERE NEW MOLECULES

By therapeutic class, sales are concentrated in four groups: Alimentary Tract and Metabolism, Cardiovascular System, Central Nervous System and Respiratory system –which together make up two-thirds of total sales.

The group with the largest market share in unit terms is Central Nervous System, whose average price is below the market average, despite being one of the most innovative groups.

In 2005, the Cardiovascular System group, which has the largest market share in value terms, registered a value increase below the market average. In this group the penetration of generic pharmaceutical specialities is important, and its market share in unit terms is 13.5%.

The Alimentary Tract and Metabolism group registered an increase above the average in value terms, though below average in unit terms. One of the reasons for this situation is the appearance, in one of the most relevant subgroups, of molecules or presentations incorporating innovations which improve treatment by offering new alternatives, or by making therapy easier, and whose price is, logically, slightly higher than that of existing products.

Systemic-Anti-infectives and Dermatologicals fell significantly in unit terms, though both registered increased sales. In the case of Systemic Anti-infectives this is due to the new presentations with increased dosage that have come onto the market. In the case of Dermatologicals, apart from the appearance of new specialities with improved therapeutics, this group has the largest proportion of OTCs and non-financed specialities, both with free prices.

Sales of hormones dropped by 7% despite a 3,7% rise in units, owing mainly to Growth Hormone being considered officially a medicinal product for hospital use only. By contrast, last year saw Growth Hormones as the subgroup of Hormones with the highest sales in pharmacies. The new directive has therefore resulted in a loss of almost half of its market share.

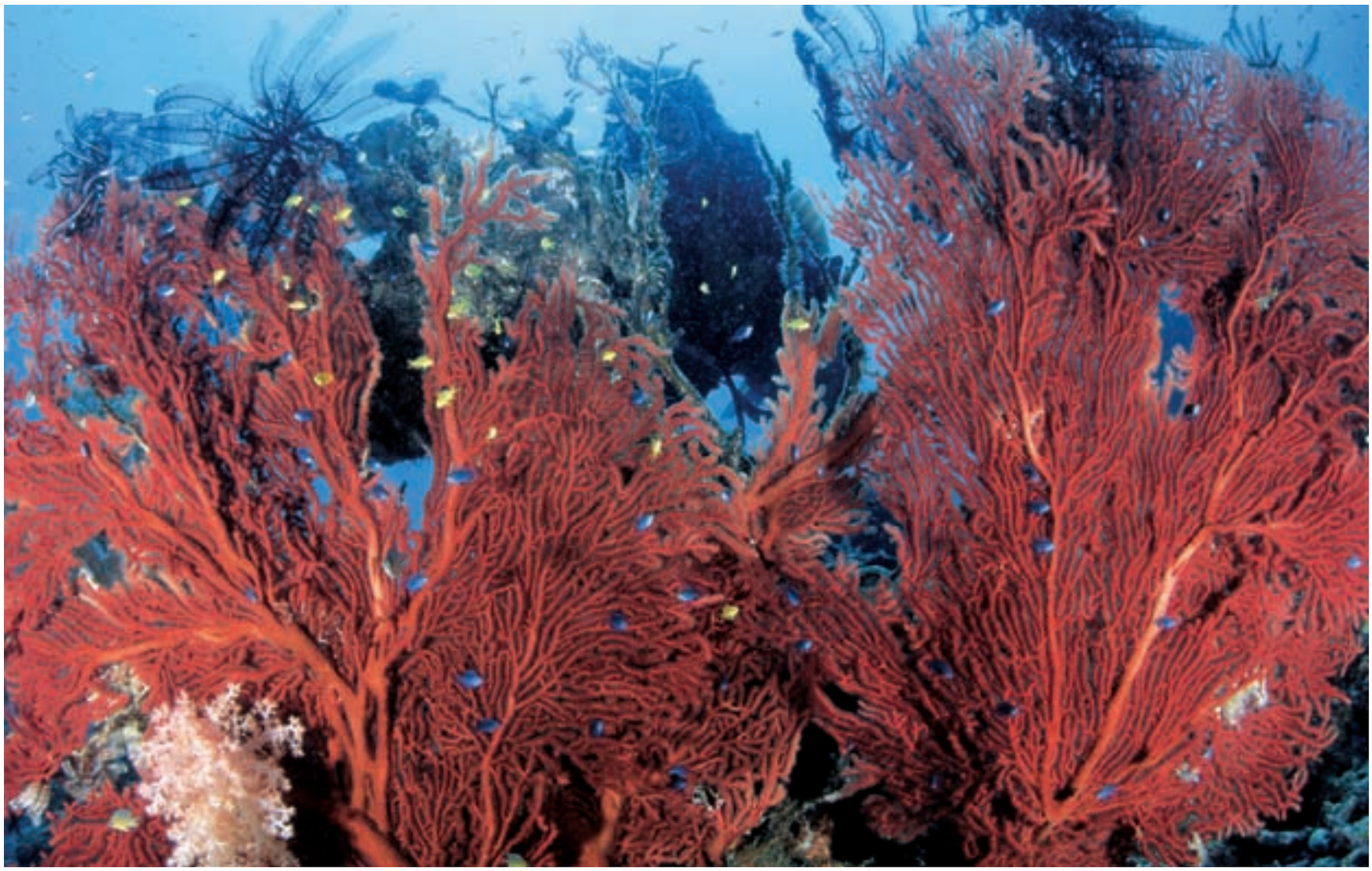
New Launches

2005 saw the launch of 261 new products, of which 145 were generic pharmaceutical specialities and 19 were new molecules. Sales of these products reached €105.2 million, 16% of which were generic pharmaceutical specialities and 56% were new molecules. The new launches were mainly in two classes: Central Nervous System, with 79 new products (58 generic pharmaceutical specialities), and Cardiovascular System, with 59 new products (49 generic pharmaceutical specialities). In terms of sales, these same therapeutic classes make up 51%, a similar percentage to the total sales of new products.

2.3. International Trade

Spain's solid economic progress over the past few years cannot and should not be used to mask a number of imbalances and threats to future growth. One of these negative areas is the country's trade deficit, which grew 28.3% in 2005, and stood at 77.800 million euros, equivalent to 8.6% of GDP. Spain, in relative terms, has the worst trade gap of the developed nations, even higher than the USA (5.8% of GDP).

The considerable worsening of Spain's balance of trade is the result of a small rise in exports (4.8%) and a strong rise in imports (11,7%). This thrust in imports —three points of which are made up of increases in oil prices— caused trade coverage to drop from 70.7% to 66.4%.



Regarding the pharmaceutical sector, as in previous years the sector's trade is barely dependent on the general state of the economy, and tends largely to go its own way, as can be seen quite clearly if we look, for example, at the way in which, in a year of deterioration of the balance of trade at the aggregate level, the pharmaceutical sector displayed the opposite trend and managed to reduce its trade deficit by 13.7%, going from a total €2.582 million in 2004 to €2.461 million in 2005.

This reduction of the sector's trade imbalance can be attributed to very strong (21.2%) growth in exports of medical products, reaching €4.819 million at the end of 2005, a figure equivalent to 3.1% of total Spanish exports. On the other hand, imports of pharmaceutical products, registered a 6.6% increase in 2005, reaching €7.280 million, equivalent to 3.1% of total Spanish imports.

Broken down into its component parts, the trade balance of the raw materials has deteriorated slightly, going into a slight deficit after running a surplus for two successive years. Medicinal products have seen a great improvement, with a 14.9% reduction of the trade balance. The fact that these products represent over 90% of all trade exchanges has been responsible for the positive evolution of the total trade balance.

TOTAL INTERNATIONAL TRADE IN PHARMACEUTICAL PRODUCTS, 2005 (€ MILLION)

	IMPORTS.	05/04 (%)	EXPORTS.	05/04 (%)	BALANCE
Raw materials	452.83	11.9	447.98	2.1	-4.85
Pharmaceutical Products	6,827.54	6.3	4,371.07	23.5	-2,456.47
* Medicinal	5.733.19	5.8	3,667.26	26.6	-2,065.93
TOTAL	7,280.37	6.6	4,819.05	21.2	-2,461.32

Source: Directorate General of Customs and Special Taxes (monthly summaries)

As a result of this, pharmaceutical trade cover improved considerably, reaching 66.2% at the end of 2005, compared with 58.2% in 2004.

Regarding the geographical distribution of the trade exchanges, 79.4% of our imports and 64.4% of our exports come from and go to EU-25 countries. If we compare the last two years, it becomes clear that the EU has continued to gain strength and now represents 80% of our pharmaceutical purchases. By contrast, exports have varied considerably and there is a clear shift towards Switzerland, which has become the principal buyer of our pharmaceutical products, ahead of EU countries such as the UK or Germany.

INTERNATIONAL TRADE IN PHARMACEUTICAL PRODUCTS BY REGION

Region	YEAR 2004		YEAR 2005	
	% IMP	% EXP	% IMP	% EXP
EUROPEAN UNION	76.6	77.0	79.4	64.4
Germany	15.6	13.4	16.1	12.7
France	15.3	10.0	15.3	8.2
Italy	7.3	6.9	7.8	6.6
UK	15.2	19.8	15.1	13.5
REST OF EUROPE	8.5	5.0	7.7	15.7
Switzerland	8.2	2.8	7.5	13.6
REST OF WORLD	14.9	18.0	12.9	19.9
TOTAL	100.0	100.0	100.0	100.0

Source: Directorate General of Customs and Special taxes (monthly summaries)

2.4. Public Pharmaceutical Expenditure

In 2005 764.6 million Social Security prescriptions were filled out, 4.9% more than in the previous year. The total value of these prescriptions was €10,051 million, 5.6% more than in 2004. At the end of 2005 the average cost per prescription was €13.5, just 0.67% more than in the previous year.

The reason for this moderate and contained growth was a package of measures introduced by the Central Government last year, involving a 4.2% cut in ex-laboratory prices of publicity financed pharmaceutical products, a 1% cut in the distribution margin and a cut in the retail pharmacy margin for generics, as well as restrictive policies applied by regional governments with regard to pharmaceutical assistance.

AVERAGE COST PER PRESCRIPTION REACHED 13.5 EUROS BY THE END OF 2005, THUS REACHING A MERE 0.67% INCREASE COMPARED TO 2004

Of total pharmaceutical spending, 77% was accounted for by population groups free from co-payment, mainly pensioners. Total spending by the active population, account for 23% of spending.

As regards the distribution of pharmaceutical

Source: Ministery of Health and Consumer.
(Summaries of invoicing of Medical Recipes)

PUBLIC PHARMACEUTICAL EXPENDITURE (1)

	COST (mill. at Retail Price VAT)		Nº PRESCRIPTIONS (Mill.)		COST/PRESCRIPTION (Euros)	
		Incr. (%)		Incr. (%)		Incr. (%)
2003	8,940.96	12.2	706.3	6.8	12.66	5.0
2004	9,513.00	6.4	728.7	3.2	13.00	3.1
2005	10,051.33	5.6	764.63	4.9	13.15	0.7

(1) Includes all invoicing contingencies per prescription: specialties, master formulas and therapeutical accessory effects.
(2) Final Cost, once the discounts established in R.D. Law 5/2000 have been deducted.

spending by regions, the greatest per capita spending was in the Valencia region (€270.6), followed by Galicia (€266.1) and Asturias (€265.1). By contrast, the regions with the lowest spending were Madrid (€167.4), the Balearic Islands (€173.6) and Andalusia (€208.6).

The greatest increases in per capita pharmaceutical spending were in the Basque Country, Galicia and the Canary Islands, while the lowest, and the only ones below the national average, were in Andalusia (0.6%) and Catalonia (1.6%).

2.5. Medicine Prices

In 2005 the average price of medicines sold in Spain was €7.49 (ex-laboratory prices), with significant differences according to market segments, going from €4.34 in the case of generics, to €14.78 in the case of pharmaceutical specialities for chronic conditions.

Similarly, prices vary considerably according to how long the products have been on the market: 5 or more years, €11.99, on average; more than 20 years, €2.66.

In 2005 the Consumer Price Index rose by 3.7%, 0,5% more than in 2004. However, an analysis of the movement of prices in the Medicine class reveals that the group of medicinal products (the group with the greatest weight for calculating the index for this class), dropped by 2.9%, keeping the price rise in the Medicine class at 0.7%.

One of the reasons behind the drop in the medicinal products price index is the above-mentioned 4.2% cut in laboratory prices and margin reductions. The following table shows the evolution of the CPI for the different components of the Medicine class compared to the general CPI.

In Europe, just as in Spain, there are two clearly distinguishable product segments with very different characteristics and trends. On the one hand there are the innovative products protected by patents; while the price differences among these products are decreasing among the EU countries, in Spain this type of product is among the cheapest to be found anywhere in the Europe. And on the other hand, there exists a growing market for generics, the development of which is a major priority for most European governments; in Spain it has given rise to the Price Reference System and drastic price cuts in a number of products, which has helped to keep prices down in the market and to keep inflation in check.

The latest figures available for the major European countries reveal that France is the country with the lowest average prices —the comparison takes ex-laboratory prices as average prices, in order to avoid distortion caused by the differences in distribution margins—, followed closely by Italy and Spain. On the contrary, the highest prices are to be found in Germany, The Netherlands and the United Kingdom.

Over recent years there has been a gradual harmonisation of the registration procedures for new

INFLATION AND MEDICINE PRICES (2005)

Group or Class	Increase in CPI (%)
General (Inflation)	3.7
Medicine	0.7
* Medicines and other pharmaceutical products	-2.9
* Therapeutic products	1.5
* Non-hospital medical and paramedical services	3.8
* Dental services	3.1
* Hospital services	5.3

Source: National Institute of Statistic.

OVER RECENT YEARS THERE HAS BEEN A GRADUAL HARMONISATION OF THE REGISTRATION PROCEDURES FOR NEW PRODUCTS WITHIN THE EU

AVERAGE PRICE OF MEDICINES IN THE MAIN EU MARKETS (AVERAGE MARKET PRICE, EX-LABORATORY PRICE)

COUNTRY	AVERAGE PRICE (€)	(Spain=100)
Germany	14.22	196
Belgium	11.28	155
Spain	7.26	100
France	6.27	86
Netherlands	11.68	161
Italy	6.62	91
United Kingdom	12.38	170

Source: FARMAINDUSTRIA based on it´s own information. (Indicatori Farmaceutici´OS) and Eurostat.

products within the EU. In this respect, international price comparisons are being used more and more. In Spain, just as in other countries like Austria, Belgium, Finland or Sweden, companies are required by law to state the price at which the product is sold abroad, and this information is used increasingly to set prices. For their part, countries such as Denmark, The Netherlands, Italy, Ireland, Norway and Switzerland set their prices according to a product's average price in a given group of countries, while Portugal adapts its prices to the lowest prices in certain reference countries, i.e. France, Italy and Spain.

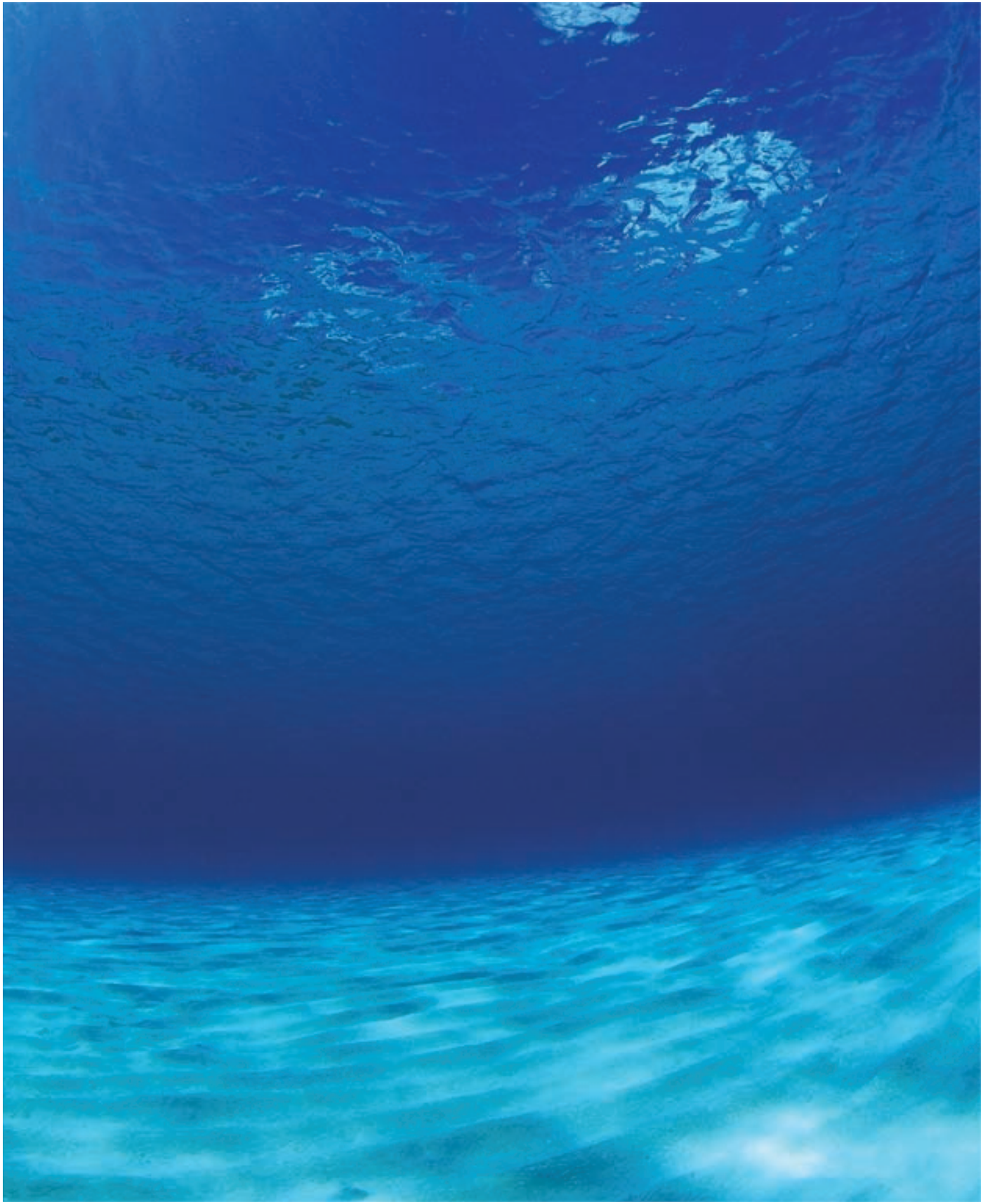
However, this process of bringing prices closer together is not enough to dispel one of the main problems facing the pharmaceutical industry: parallel trade of medicines which, as can be seen in the following table, represents an increasingly large percentage of sales in some of the major European markets.

PARALLEL TRADE AND PHARMACEUTICAL SALES IN 2004

Country	Parallel Imports/Domestic Sales
United Kingdom	17.0%
Netherlands	12.8%
Denmark	14.8%
Sweden	12.1%
Norway	7.4%
Germany	5.3%

Source: EFPIA.

NEW LEGISLATION



NEW LEGISLATION

Spanish Medicines and Health Products Agency

- Resolution of the Spanish Medicinal and Health Products Agency dated 6 September 2005 agreeing the publication of a summary of annual accounts for 2004.

Valencian Health Agency

- Valencia Regional Government Council Decree 25/2005, 4 February, agreeing the Regulatory Statuts of the Valencian Health Agency.
- Valencia Regional Government Council Decree 77/2005, 15 April, amending the Statutes of the Valencian Health Agency, approved by Valencia Regional Government Council Decree 25/2005, 4 February.
- Valencia Regional Government Council Decree 164/2005, 4 November, amending the Statutes of the Valencian Health Agency.

Contraceptives

- Aragon Regional Government Health and Consumer Affairs Department Order, 3 October 2005, regulating the free prescription and administration of the Post-coital Pill in the Public Health Centres of the Aragon Health System.

Centres – Services and Healthcare Establishments

- Extremadura Regional Government Health and Consumer Affairs Department Decree 227/2005, 27 September, regulating the procedure and facilities required for the application of the quality model and the accreditation of health quality of the centres, services and health establishments of the Extremadura Autonomous Community.

Parallel Trade

- Royal Decree 11/2005, 14 January, amending Royal Decree 1785/2000, 27 October, concerning the circulation within the EU of medicines for human use.

Commissions

- Royal Decree 1224/2005, 13 October, creating and regulating the Intersectoral Commission responsible for acting against activities which violate industrial property rights.

Committees

- Valencia Regional Government Council Decree 99/2005, 20 May, amending Valencia Regional Government Council Decree 99/2004, 11 June, regulating the creation and accreditation of Bioethics Care Committees.
- Catalonia Regional Government Health Department Decree 166/2005, 26 July, regulating the Catalonian Consultative Committee on Bioethics.
- Asturias Regional Government Health and Health Services Department Decree 109/2005, 27 October, establishing a legal regime for the creation and accreditation of committees of ethics for Health Care.
- Murcia Regional Government Council Health Department Order, creating the Regional Advisory Committee on Pharmaceutical Distribution.

Clinical Research Ethics Committees

- 3/2005 Decreee, from the 11th January, from the Vasque Government Health Department, establishing the Clinical Research Ethics Committee for the Autonomous Community of the Vasque Country.
- 84/2005 Decree, from the 21st of july, from the Cantabria Government, regulating the Clinical Research Ethics Committee of Cantabria.
- 71/2005 Decree, from the 2nd of December, from the La Rioja Governement Health Depart-ment, creating the Clinical Research Ethics Committee of La Rioja.
- 292/2005 Decree, from the 13th of December, from the Aragon Government, which modifies the 26/2003 Decree, from the 14th of February, which created the Clinical Research Ethics Committee for Aragón.

Regional Health Department

- Canary Islands Regional Government Council Decree 5/2005, 25 January, agreeing the

Organic Regulations of the Regional Health Department.

- Valencia Regional Government Council Decree 26/2005, 4 February, agreeing the Organic and Functional Regulations of the Regional Health Department.
- La Rioja Regional Government Department of Public Administration and Local Policy Decree 6/2005, 16 February, establishing the Organic Structure of the Regional Health Department.
- Extremadura Regional Government Presidential Department Decree 152/2005, 21 June, amending Regional Decree 80/2003, 15 July, establishing the Organic Structure of the Department of Health and Consumer Affairs.
- Madrid Regional Government Council Decree 100/2005, 29 September, establishing the Organic Structure of the Regional Department of Health and Consumer Affairs.
- Catalonia Regional Government Health Department Decree 219/2005, 11 October, remodelling the Regional Health Department.
- Navarre Regional Government Health Department Decree 45/2005, 24 February, establishing the Organic Structure of the Regional Health Department.
- Valencia Regional Government Health Councillor's Order, 27 May 2005, developing Decree 26/2005, 4 February, agreeing the Organic and Functional Regulations of the Regional Health Department.

Regional Government Advisory Committees

- Basque Regional Government Health Department Decree 121/2005, 24 May, regarding the regime of the Advisory Committees of the Regional Health department.
- Galicia Regional Government Health Department Order, 25 May 2005, regulating the composition, organisation and functioning of the Advisory Committee of the Regional Health System.

Regional Health Councils

- Castilla-La Mancha Regional Government Health Department Decree 13/2005, 1 February, regarding the Participatory Organs of the Regional Health System.
- Galicia Regional Government Health Department Decree 74/2005, 14 April, establishing the composition of the Regional Health Council.
- Galicia Regional Government Health Department Order, 20 May 2005, establishing the General Rules of Organisation and Functioning of the Regional Health Council.

Consumers and Users

- Royal Decree 894/, 22 July, regulating the Council of Consumers and Users.
- La Rioja Regional Government Health Department Decree 1/2005, 7 January, regulating the Legal Statute and the functioning of the Regional Health System Ombudsman.

Competition

- Extremadura Regional Government Presidency Law 2/2005, 24 June, creating the Jury for Competition in the Region.
- Galicia Regional Government Economy and Treasury Department , developing Law 6/2004, 12 July, regulating the organs for the defence of competition in the Region.
- Madrid Regional Government Economy and Technological Innovation Department, establishing certain provisions related to Law 6/2004, 28 December, creating the Tribunal for the Defence of Competition in the Region.
- Extremadura Regional Government Economy and Labour Department Decree 218/2005, 27 September, agreeing the Rules of the Organisation and Functioning of the Jury for the Defence of Competition in the Region.

Patients' Rights and Obligations

- Galicia Regional Government Presidency Department Law 3/2005, 7 March, amending Law 3/2001, regulating the informed consent and the medical records of patients.
- Madrid Regional Government Presidency Department Law 3/2005, 23 May, regulating the exercise of the right to formulate prior

instructions in the health sphere, and creating the corresponding official register.

- Castilla-La Mancha Regional Government Presidency Department Law 6/2005, 7 July, regarding the Declaration of Prior Wishes with regard to the patient's own health.
- Extremadura Regional Government Presidency Department Law 3/2005, 8 July, regarding health information and the autonomy of the patient.
- La Rioja Regional Government Presidency Department Law 9/2005, 30 September, regulating the Document of Prior Instructions in the sphere of health.
- Murcia Regional Government Council Decree 80/2005, 8 July, agreeing the Rules of Prior Instructions and the corresponding official register.
- Canary Islands Regional Government Health Department Decree 178/2005, 26 July, agreeing the Rules governing the medical records in hospitals and establishing the content, conservation and modification of these records.
- Castilla-La Mancha Regional Government Health Department Decree 180/2005, 2 November, regarding the right to a second opinion.
- Castilla y León Regional Government Health Department Decree 101/2005, 22 December, regulating patients' medical records.
- Valencia Regional Government Health Councillor's Order, 25 February 2005, developing Valencia Regional Government Council Decree 168/2004, 10 September, regulating the Document of Prior Wishes and creating the Central Register of Prior Wishes.
- Canary Islands Regional Government Health Department Order, 28 February 2005, agreeing the Health System Patients' and Users' Rights and Obligations Charter and regulating the communication of the Charter.
- Castilla y León Regional Government Health Department Order SAN/279/2005, 5 April, developing the procedure for presenting complaints and suggestions within the health system and regulating the processing and analysis of information obtained using this procedure.
- Cantabria Regional Government Department of Health and Social Services Order SAN/27/2005, 16 September, establishing the model of the document for communicating Prior Wishes in the Region.

Regional Autonomy Basic Orders

- Aragon Regional Government Presidency Department Law 2/2005, 24 February, amending certain articles of the Aragon Health Law (6/2002, 15 April).
- Valencia Regional Government Public Health Law (4/2005, 17 June).

Drug Testing

- National Sports Council Presidency Resolution, 21 December 2005, agreeing the list of substances and methods prohibited in sports.

Creutzfeld-Jakob Disease

- Spanish Medicinal and Health Products Agency Circular 3/2005, 27 July, regarding the reduction of the risk of transmission of the variant of Creutzfeld-Jakob Disease in medicines that include derivatives of blood or human plasma as an active ingredient or excipient or during the period of fabrication.

Clinical Trials

- Andalusia regional Government General Secretariat of Quality and Modernisation (Regional Health Council) Resolution, 9 December 2005, agreeing the model for the economic contract for the carrying out of clinical test of medicines within the Regional Health System.

Post-Authorisation Studies

- Basque Regional Government Health Department Decree 102/2005, 26 April, regulating the carrying out of observational-type post-authorisation studies with medicinal products.
- Application form for post-authorisation stu-

dies with medicinal products, within the Region of Aragon (February 2005).
- Requirements for conducting post-authorisation studies in the Region of Extremadura. (Merida, 11 April 2005).

Experimenting on Animals

- Royal Decree 1201/2005, 10 October, concerning the protection of animals used in experiments and other scientific purposes.

Spanish Pharmacopeia

- Order SCO/3129/2005, 30 September, agreeing the third issue of the Real Farmacopea Española.

European Pharmacopeia

- Spanish Medicinal and Health Products Agency Circular 5/2005. Information on Resolutions of the Public Health Committee (Partial Agreement), the European Council, regarding European Pharmacopeia.
- Spanish Medicinal and Health Products Agency Circular 6/2005, 29 September. Information on Resolutions of the Public Health Committee (Partial Agreement), the European Council, regarding European Pharmacopeia.

Pharmacovigilance

- Balearic Islands Regional Government department of Health and Consumer Affairs Decree 71/2005, 24 June, creating the Regional Alerts Network for the detection of health risks derived from medicines or other pharmaceutical products.

Foundations

- Andalusia Regional Government Presidency Department Law 10/2005, 31 May, concerning Foundations within the Region.
- Royal Decree 1337/2005, 11 November, agreeing the Rules for state-run foundations.
- Castilla y León Regional Government Presidency department and territorial Administration Council Decree 63/2005, 25 August, agreeing the Rules for Foundations in the Region.

Haemoderivatives

- Aragon Regional Government Law 3/2005, 12 May, creating the regional public body Blood and Tissue Bank.
- Galicia Regional Government Health Department Decree 100/2005, 21 April, regulating blood donation and hemotherapy in the Region.
- Spanish Medicinal and Health Products Agency Circular 4/2005, 27 July, concerning the second stage of the use of the principal archive certificate for plasma.

Pharmaceutical Inspection

- Canary Islands Regional Government General Direction of Pharmacy Resolution 22 December 2005, agreeing the Inspection Plan for Pharmaceutical Administration 2006.

Health Inspection

- Andalusia Regional Government Health Department Decree 224/2005, 18 October, agreeing the Administration Rules for the Inspection of Health Services of the Andalusia Regional Government.
- Madrid Regional Government department of Health and Consumer Affairs, agreeing the Health and Consumer Affairs Inspection Plan for the Region, 2005.

Carlos III Institute of Health

- Royal Decree 590/2005 amending the Statute of the "Carlos III" Institute of Health, agreed by Royal Decree 375/2001, 6 April.

Scientific Research

- Canary Islands Regional Government Health Department Order, 4 October 2005, partially amending Order 4 July 1997, regulating the recognition of scientific interest for events of a scientific nature.

Legionnaire's Disease

- Aragon Regional Government Decree 136/2005, 5 July, establishing special measures for the prevention and control of Legionnaire's Disease.

Narcotics and Psychotropic Substances

- Asturias Regional Government Department of Health and Healthcare Services Decree 90/2005, 30 August, establishing the procedure for the use of narcotics in the Region's hospitals.

Foreign Medicinal Products

- Aragon Regional Government Department of Health and Consumer Affairs, establishing the system of acquisition and dispensation of foreign medicinal products in the Region.

Environment

- Instrument for Ratifying the Kyoto Protocol to the United Nations Framework Convention on Climate Change, created in Kyoto, 11 December 1997.
- Law 1/2005, 9 March, regulating the regime of trading with the rights of the emission gases contributing to the *greenhouse effect*.
- Law 1/2005, 4 February, Basque Regional Government Presidency Department, concerning the prevention and correction of land pollution.
- Navarre Regional Government Law 4/2005, 22 March, concerning the intervention in the protection of the environment.
- Castilla y León Regional Government Presidency Department Law 3/2005, 23 May, amending Law 11/2003, 8 April, for the Protection of the Environment in the Region.
- Royal Decree 9/2005, 14 January, establishing the list of potential land-polluting activities and the criteria and standards for declaring land polluted.
- Royal Decree 60/2005, 21 January, amending Royal Decree 1866/2004, 6 September, agreeing the national Plan for Assigning Emission Rights, 2005-2007.
- Royal Decree 208/2005, 25 February, concerning electrical and electronic appliances and devices and the management of their waste.
- Royal Decree 1264/2005, 21 October, regulating the organisation and functioning of the National Register of Emission Rights.
- Royal Decree 1315/2005, 4 November, establishing the basic rules for the systems of monitoring and verification of emissions of *greenhouse effect* gases in installations covered by Law 1/2005, 9 March, regulating the regime of trading with the rights of the emission gases contributing to the *greenhouse effect*.
- Castilla y León Regional Government Environment Department Decree 18/2005, 17 February, agreeing the Regional Sectoral Plan for Urban Waste and Packaging Waste (Castilla y León Law 4/2004, 1 July).
- Catalonia Regional Government Presidency Department Decree 50/2005, 29 March, developing Law 4/2004, 1 July, regulating the process of adapting existing activities to Law 3/1998, 27 February, and amending Decree 220/2001, concerning the management of livestock waste.
- Aragon Regional Government Decree 58/2005, 29 March, creating the Committee for the Monitoring of the Aragon Regional Plan for Integral Waste Management.
- Cantabria Regional Government Decree 53/2005, 21 April, providing the design of the body responsible for matters concerning the emission of *greenhouse* gases in the Region.
- Galicia Regional Government Environment Department Decree 174/2005, 9 June, regulating the legal regime of waste production and management, and the Regional General Register of Waste Producers and Managers.
- Cantabria Regional Government Decree 127/2005, 14 October, naming the official body responsible for giving integral environmental authorisation, and creating the Commission for the Integral Prevention and Control of Pollution.
- Aragon Regional Government Decree 236/2005, 22 November, agreeing the Rules for the production, possession and management of dangerous waste, and the legal regime for the Public Service of Dangerous Waste Elimination in the Region.
- Andalusia Regional Government Environment Department Order, 7 February 2005, establishing the models of annual notification

of polluting emissions by companies covered by Law 16/2002 regarding the integral prevention and control of pollution.

- Galicia Regional Government Departments of the Environment and Innovation, Industry and Trade Order 31 March 2005, amending Order 14 September 2004, regulating the procedure for obtaining authorisation for the emission of *greenhouse effect* gases.
- Galicia Regional Government Department of the Environment and Sustainable Development Order 2 November 2005, creating a personal database making up the Regional General Register of Waste Producers and Managers.
- Aragon Regional Government Agreement 11 January 2005, agreeing the Regional Integral Plan for Waste Management (2005-2008).

Genetic Modification

- Order PRE/3834/2005, 9 December, agreeing the payment of the tax on services and actions carried out by Central Administration in the carrying out of activities involving genetically modified organisms.

Integral Health Plans

- Extremadura Regional Government Department of Health and Consumer Affairs Order 10 October 2005, regulating the drawing up, monitoring and evaluation of the Regional Integral Plan for the Fight Against Cancer.

Prices

- General Directorate for Pharmacy and Healthcare Products Resolution 15 February 2005, amending the annexe to Royal Decree 2402/2004, 30 December, developing article 104 of Law 25/1990, 20 December, for seasonal revisions of pharmaceutical specialities, and adopting additional measures to keep pharmaceutical spending under check.
- General Directorate for Pharmacy and Health care Products Resolution 7 December 2005, amending the annexe of Royal Decree 2402/2004, 30 December, developing article 104 of Law 25/1990, 20 December, for seasonal revisions of pharmaceutical specialities, and adopting additional measures to keep pharmaceutical spending under check.
- Spanish Medicinal and Health Products Agency Informative Note, explaining conditions and requirements for the re-labelling of prices of medicinal products, in accordance with the single transitory disposition of Royal Decree 2402/2004.

Pharmaceutical Users in the National Health System

- Basque Regional Government Health Department Decree 251/2005, 20 September, regulating the identification of persons wishing to receive pharmaceutical assistance from the National Health Service.

Healthcare Products

- La Rioja Regional Government Health Department Decree 66/2005, 4 November, establishing the legal regime and the procedure for the authorisation and registration of licenses for the manufacture of personalised healthcare products, and the licenses for distribution of healthcare products; and creating the official regional register of authorised healthcare products establishments.
- Extremadura Regional Government Department of Health and Consumer Affairs Decree 247/2005, 23 November, regulating the distribution of healthcare products in the Region.
- Valencia Regional Government Health Department Order 14 November 2005, creating and regulating the Register of licenses granted by the Health Department to establishments of made-to-measure products and distributors of healthcare products.

Profarma

- General Secretariat of Industry Resolution 26 July 2005, establishing basic rules regulating the PROFARMA Plan: the Promotion of scientific research, development and technological innovation in the pharmaceutical industry.

Industrial property

- Order ITC/2043/2005, 4 April, creating a telematic register in the Spanish Patent and Trade Mark Office.
- Order ITC/2043/2005, 28 June, including the electronic request for brands and trademarks from the Telematic Register of the Spanish Patent and Trade Mark Office.

Data protection

- Basque Regional Government Vice-President's Office Decree 308/2005, 18 October, developing Law 2/2004, 25 February, concerning publicly-owned personal information databases, and creating the Basque Data Protection Agency.
- Basque Regional Government Vice-President's Office Decree 309/2005, 18 October, agreeing the Statute of the Basque Data Protection Agency.
- Cantabria Regional Government Department of Health and Social Services Order SAN/28/2005, 16 September, creating the automated personal database of the Regional Register of Prior Wishes.
- Director of the Basque Data Protection Agency Resolution 28 November 2005, developing the Agency's organic structure.

Advertising

- Catalonia Guide Advertising of Medicines for Human Use (April 2005; 2nd edition).

Prescriptions

- Valencia Regional Government Health Department Resolution, updating requirements for using the Department's official medical prescription, with recognised digital signature.

Register of Pharmaceutical Specialities

- Spanish Medicinal and Health Products Agency Circular 01/2005, 10 March, outlining the information required of companies and organisations requesting the temporary suspension of sale, and the cancellation requested by the company, organisation or person to whom the authorisation of sale has been granted.

Return of Expenses

- Castilla y León Regional Government Health Department Order SAN/1479/2005, 2 November, amending Order SAN/415/2004, 27 February, regulating the return of expenses on purchases of pharmaceutical products.

Penalties

- Andalusia Regional Government Health Department Decree 20/2005, 25 January, breaking up the concentration of powers to sanction, and regulating certain procedural aspects of penalisation in the area of Health.
- Valencia Regional Government Decree 57/2005, 11 March, amending Decree 44/1992, 16 march, concerning the procedure, sanctions and sanctioning power with regard to healthcare and food hygiene violations.

Aragon Regional Health Department

- Aragon Regional Government Decree 41/2005, 22 February, concerning the Organisation and Functioning of the Healthcare Sector in the Regional Health System.

Canary Islands Regional Health Department

- Canary Islands Regional Government Health Department Order 23 September 2005, regulating the Regional Information System.

Catalonian Institute of Health

- 292/2005 Decree, from the 13th of December, from the Aragon Governement, which modifies the 26/2003 Decree, from the 14th of February, which created the Clinical Research Ethics Committee for Aragón.

La Rioja Regional Health Department

- La Rioja Regional Government Health Department Law 1/2005, partially amending (Health) Law 2/2002, 17 April, in order to adapt the La Rioja health Service to Law 3/2003, 3 March,

concerning the Organisation of the Regional Public Sector.

- La Rioja Regional Government Department of Public Administration and Local Policy Decree 7/2005, 16 February, establishing the organic structure and functions of the La Rioja Direction of Health.

Hospital Pharmacy Services and Medicinal Product Deposits

- Asturias Regional Government Department of Health and Healthcare Services Decree 44/2005, 19 May, regulating the pharmaceutical services and the deposits for medicines and healthcare products at the primary attention level of the Regional Health System.
- Asturias Regional Government Department of Health and Healthcare Services Decree 90/2005, 3 August, establishing the procedure for use and control of narcotics in the Region's hospitals.

Official Pharmaceutical Services

- Castilla y León Regional Government Health Department Decree 23/2005, 22 March, establishing the radius of action and the functions of the Region's Official Pharmaceutical Services; and adopting measures within the framework of the restructuring process of those services.

Health Service Card

- Murcia Regional Government Decree 92/2005, 22 July, regulating the Regional Health Service User's Card and its usage.

Fees

- Valencia Regional Government Council Legislative Decree 1/2005, 25 February, agreeing the rewritten regional Fees Law.
- Murcia Regional Government Treasury Department Order 20 January 2005, publishing the public fees and prices applicable in 2005.
- Extremadura Regional Government Treasury and Budget Department Order 21 January 2005, publishing the new public fees and prices applicable in the Region, in accordance with the 2005 regional budget.
- Catalonia Regional Government Health Department Order SLT/95/2005, 28 February, linking existing Health Department fees to the identification of services and their corresponding quotas.
- Canary Islands Regional Government Economic and Treasury Department (General Tax Directorate) Resolution 24 January 2005, providing information on the updated total of the fixed amounts of fees in the Region for 2005.

Transference of Responsibilities

- Royal Decree 1515/2005, 16 December, concerning the transference of Health functions and services to the City of Melilla Authorities.

Transplants

- Andalusia Regional Government Health Department Order 27 September 2005, creating the Region's Coordination of Transplants Information System.

Traceability

- Under-Secretariat of Health and Consumer Affairs Resolution, 17 June 2005, publicising the Agreement by which the management of the information included in Royal Decree 725/2003, 13 June (developing certain aspects of Article 100 of Law 25/1990, 20 December, the Medicine Law) becomes the responsibility of The Council General of Official Pharmaceutical Associations.
- Agreement 12 July 2005 between the Ministry of Health and Consumer Affairs and the Council General of Official Pharmaceutical Associations of Spain, creating the publicly owned database of the Council General of Official Pharmaceutical Associations regarding the control of supply and distribution of pharmaceutical specialities nationwide.