ANNUAL REPORT 06

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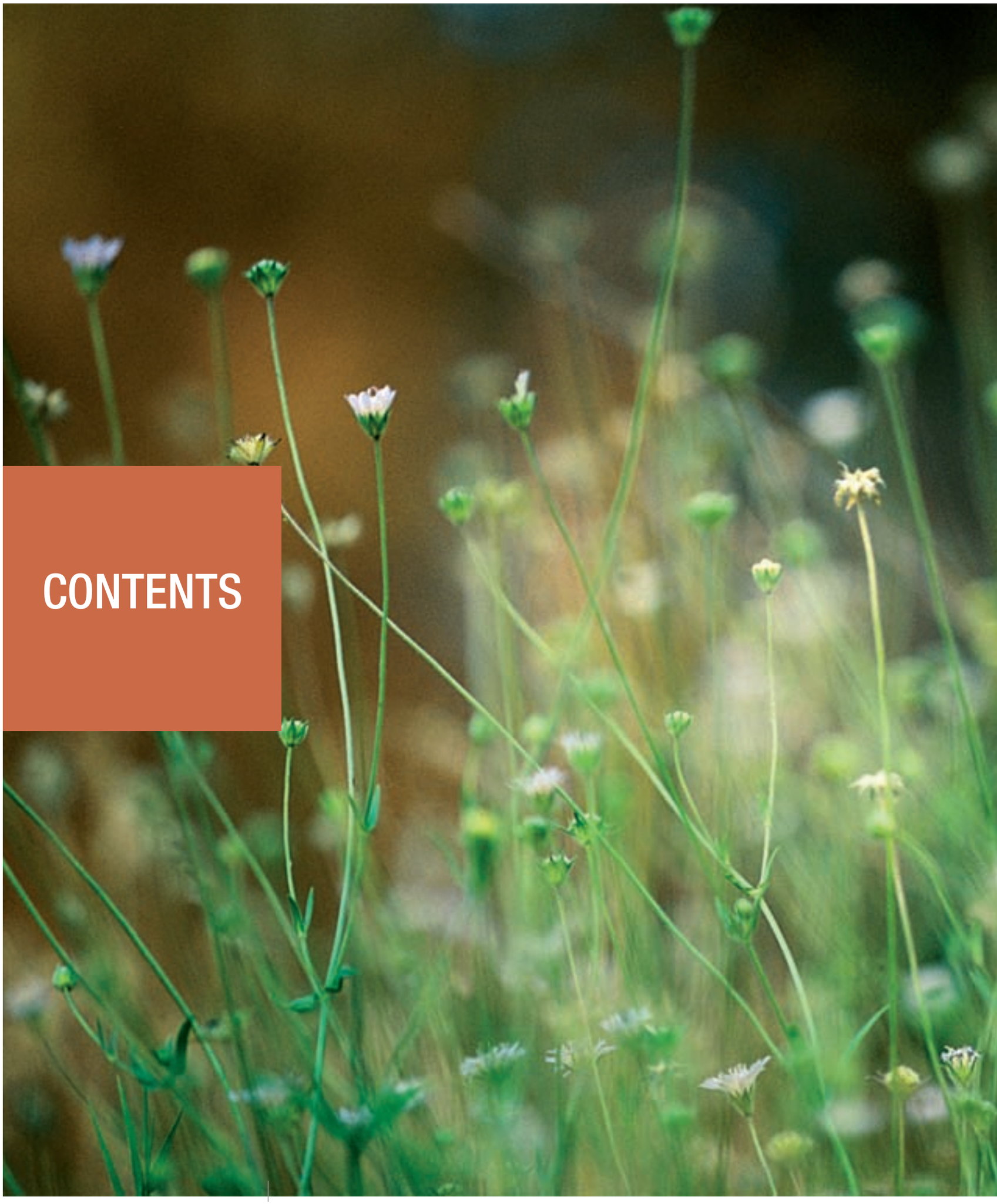
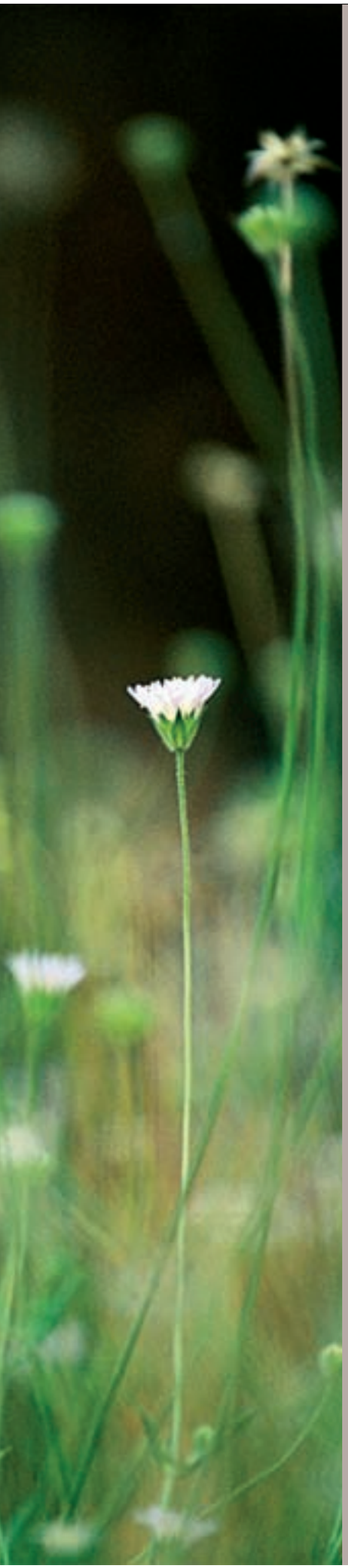


CONTENTS



LETTER FROM THE PRESIDENT

ANTONI ESTEVE I CRUELLA
FARMAINDUSTRIA President

IN MY FIRST YEAR as President of FARMAINDUSTRIA, it gives me great satisfaction to present the Annual Report of the activities of the Association in 2006. In this sense, I would like to use this opportunity to thank the previous President, Emilio Moraleda, for his fine leadership of the Association during a particularly complex period in which the basic legislation regulating the pharmaceutical industry in our country has been changed.

2005 revolved around the debate and passage of the Safeguards and Rational Use of Medicines and Medical Devices Act, 2006, and the first few months of 2007 have been marked by the law entering into force and by the enactment of its first regulatory developments.

The text of the new Act, although it adequately adopts the technical aspects of the revision of European pharmaceutical legislation which occurred in 2004, also incorporates structural measures aimed at containing public pharmaceutical expenditure that are especially negative for the industry. It is estimated that the impact of the new law on pharmaceutical companies will be over 650 million euros in the first year of application.

At the moment of writing these lines, there have been various Royal Decrees, Regulations and Ministerial Orders that develop a number of norms set out by the Act that is now in force in Spain. Among them the regulations developing the new Reference Price System, fully operative in Spain since the 1st of March 2007 and which, according to sector analysts, will have a strong effect upon the evolution of public pharmaceutical expenditure during this year; pharmaceutical expenditure which, for the third consecutive year, grew below the rate of increase of Spanish GDP, accumulating since 2004 a negative differential in growth with respect to GDP of six percentage points.

Although an important part of FARMAINDUSTRIA's effort during 2006 has focused on the procedural passage of the new law and its regulatory developments, this has not prevented FARMAINDUSTRIA from working on many other fronts of great relevance for the interests of all its members. In this sense, I would like to stress the great

value to FARMAINDUSTRIA of the participation of the laboratories via the different Working Groups of the Association and whose work has been decisive in elaborating the submissions to legislative projects and papers, reports and documents stating the position of the pharmaceutical industry in Spain on a wide range of subjects.

The future priorities for the Association necessarily involve defending pharmaceutical innovation in all its different aspects: protection of industrial property rights, generation of an adequate return on R&D investment and guaranteeing fair access to innovative medicines for Spanish patients. In this sense, it is especially important to achieve the definitive harmonization of Spain with our main European neighbours in the area of pharmaceutical patent legislation, as required by the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), signed by Spain in 1995.

The defence of pharmaceutical innovation is a priority for FARMAINDUSTRIA

Another critical aspect that will guide the future work of FARMAINDUSTRIA is the defence of the single pharmaceutical market in Spain, a key component for increasing the efficiency and functioning of the sector. In this respect, and due to the large diversity of policies regulating the demand of medicines put into practice by the Spanish regions, there exists today a high risk of fragmentation of the Spanish pharmaceutical market, with potentially serious consequences for pharmaceutical companies and also for Spanish patients.

The Association has also embarked upon important projects for the future involving the reaffirmation of our commitment to research with patients and health professionals. It is sufficient to mention initiatives such as the Technological Platform for Innovative Medicines, the Awards for the Best Patient Service Initiatives and the functioning of the self-regulatory system that is the Code of Practice – described in depth in this annual report – to give an idea of the seriousness and commitment with which the industry will confront these future challenges.

I would not like to finish this letter without thanking all the associated laboratories, especially the members of the Steering Committee and the General Assembly of FARMAINDUSTRIA, for their understanding and support for my tasks as the Association's President, and the FARMAINDUSTRIA personnel for their great commitment and the dedication they have demonstrated to me in the few months that have passed since I assumed FARMAINDUSTRIA's Presidency.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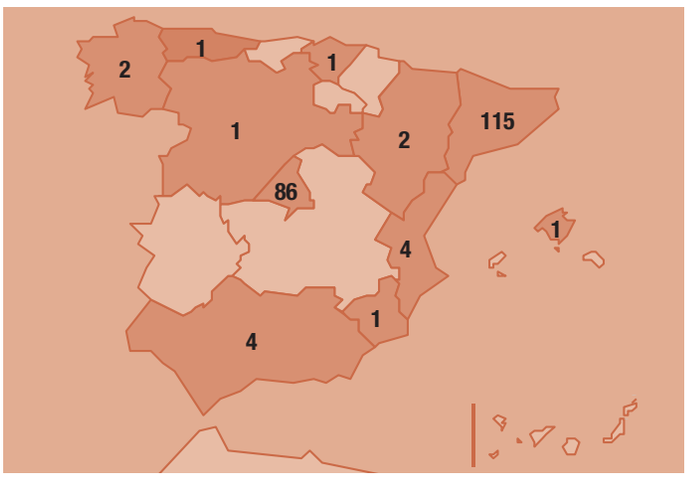
FARMAINDUSTRIA IN 2006

1. Members

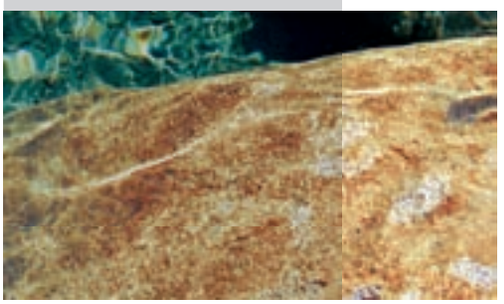
At 31 December 2006, 218 laboratories were associated to FARMAINDUSTRIA. They were distributed geographically in the following way:



Laboratories associated to FARMAINDUSTRIA make up 85.1% of the market, measured by sales volume

The laboratories associated to FARMAINDUSTRIA represent, by number, 51.5% of all holders of authorisations for marketing of medicines, having, or not, production and/or marketing activity. In sales terms, they represent 85.1% of the market.

LABORATORIES BY GROUP			
National	**100**	International	**118**
Large	10		27
Medium-sized	5		27
Small	85		64
TOTAL 218			



2. Organisation

2.1. Governing bodies

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

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

In October 2006, elections were held to renew the governing bodies of the Association. Fulfilling the statutory provision that establishes the rotation of the Presidency every two years, Antoni Esteve i Cruella was designated

President, as representative of the National Group, replacing Emilio Moraleda Martínez, who was until this date President representing the International Group.

Likewise, and according to the provision in the Statutes, in these elections the Steering Committee increased by three new members, passing from 27 to 30, all of the new members belonging to the sector of companies with foreign capital. At the same time, the Executive Board reduced by one member, passing from 16 to 15, with the post eliminated belonging to the sector of companies with national capital.

The composition of these two governing bodies at the close of this report was as follows:

EXECUTIVE BOARD

PRESIDENT

Antoni Esteve i Cruella LABORATORIOS DR. ESTEVE S.A.	

VICE-PRESIDENTS

Jesús Acebillo Marín NOVARTIS CONSUMER HEALTH, S.A.	Jorge Gallardo Ballart LABORATORIOS ALMIRALL, S.A.
Belén Garijo López SANOFI-AVENTIS, S.A.	Rafael Juste Sesé JUSTE, S.A. QCO. FCA.
Emilio Moraleda Martínez PFIZER, S.A.	Juan Puig Corcoy LABORATORIOS MENARINI, S.A.

DIRECTORS

Javier Ellena Aramburu DISTA, S.A.	Javier Font Salgado FARDI, Lbo.de Aplic.Farcodinámicas, S.A.
Manuel García Garrido BOEHRINGER INGELHEIM, S.A.	Claudio Lepori FARMA LEPORI, S.A.
Juan López-Belmonte López LABORATORIOS FCOS. ROVI, S.A.	Antonio Martín García SCHWARZ PHARMA, S.L.
Jorge Ramentol Massana FERRER INTERNACIONAL, S.A.	Philippa Rodríguez ASTRAZENECA FCA. SPAIN, S.A,
José Luis Sotoca Santos JANSSEN CILAG, S.A.	

STEERING COMMITTEE

PRESIDENT

Antoni Esteve i Cruella LABORATORIOS DR. ESTEVE S.A.	

VICE-PRESIDENTS

LABORATORIOS ALMIRALL, S.A. Jorge Gallardo Ballart	JUSTE, S.A. QCO. FCA. Rafael Juste Sesé
LABORATORIOS MENARINI, S.A. Juan Puig Corcoy	NOVARTIS CONSUMER HEALTH, S.A. Jesús Acebillo Marin
PFIZER S.A. Emilio Moraleda Martínez	SANOFI-AVENTIS, S.A. Belén Garijo López

DIRECTORS

AMGEN, S.A. Jordi Martí Pi Figueras	LABORATORIOS ANDROMACO, S.A. Evert J. G. Van Oosterum
ASTRAZENECA FCA. SPAIN, S.A. Philipa Anne Rodríguez	BOEHRINGER INGELHEIM, S.A. Manuel García Garrido
BRISTOL-MYERS SQUIBB, S.L. Manuel Cobo Delgado	DISTA, S.A. Javier Ellena Aramburu
FAES FARMA, S.A. Eduardo Fernández de Valderrama	FARDI, Lbo. de Aplic. Farmacodinámicas, S.A. Javier Font Salgado
FARMA LEPORI, S.A. Claudio Lepori	FERRER INTERNACIONAL, S.A. Jorge Ramentol Massana
JANSSEN CILAG, S.A. José Luis Sotoca Santos	J. URIACH & CIA., S.A. Enrique Trías Vidal de Llobatera*
LACER, S.A. Helmut Andress	MERCK SHARP & DOHME DE ESP., S.A. Antonio Pérez Mosquera
LABORATORIOS NORMON, S.A. Jesús Govantes Esteso	NOVO NORDISK PHARMA, S.A. Felipe Gómez Pérez
ORFI FARMA, S.A. Elvira Sanz Urgoiti	ROCHE FARMA, S.A. Luc Dirckx
LABORATORIOS FCOS. ROVI, S.A. Juan López-Belmonte López	LABORATORIOS S.A.L.V.A.T. Jordi Julve Rubio**
SCHERING-PLOUGH, S.A. Ángel Fernández García	SCHWARZ PHARMA, S.L. Antonio Martín García
LABORATORIOS SERVIER, S.L. Pierre Faraldo	LABORATORIOS VIÑAS, S.A. Antonio Buxadé Viñas

* New representative since the General Assembly of 19.12.06; before it was Juan Uriach Torelló.
** New representative since the General Assembly of 24.04.07; before it was Javier Peris Musso.

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. In January 2007, José Ramón Luis-Yagüe joined the FARMAINDUSTRIA staff as director of the Department for Relations with the Autonomous Regions.

The organisational chart follows:

GENERAL DIRECTOR
Humberto Arnés

DEPUTY GENERAL DIRECTOR
José Mª. Hernández

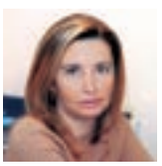
GENERAL SECRETARIAT
Lourdes Fraguas

COORDINATION, STUDIES AND MEMBER SERVICES
Javier Urzay

FINANCE DEPARTMENT
José Mª. Hernández

LEGAL & HUMAN RESOURCES DEPARTMENT
Lourdes Fraguas

TECHNICAL DEPARTMENT
Emili Esteve



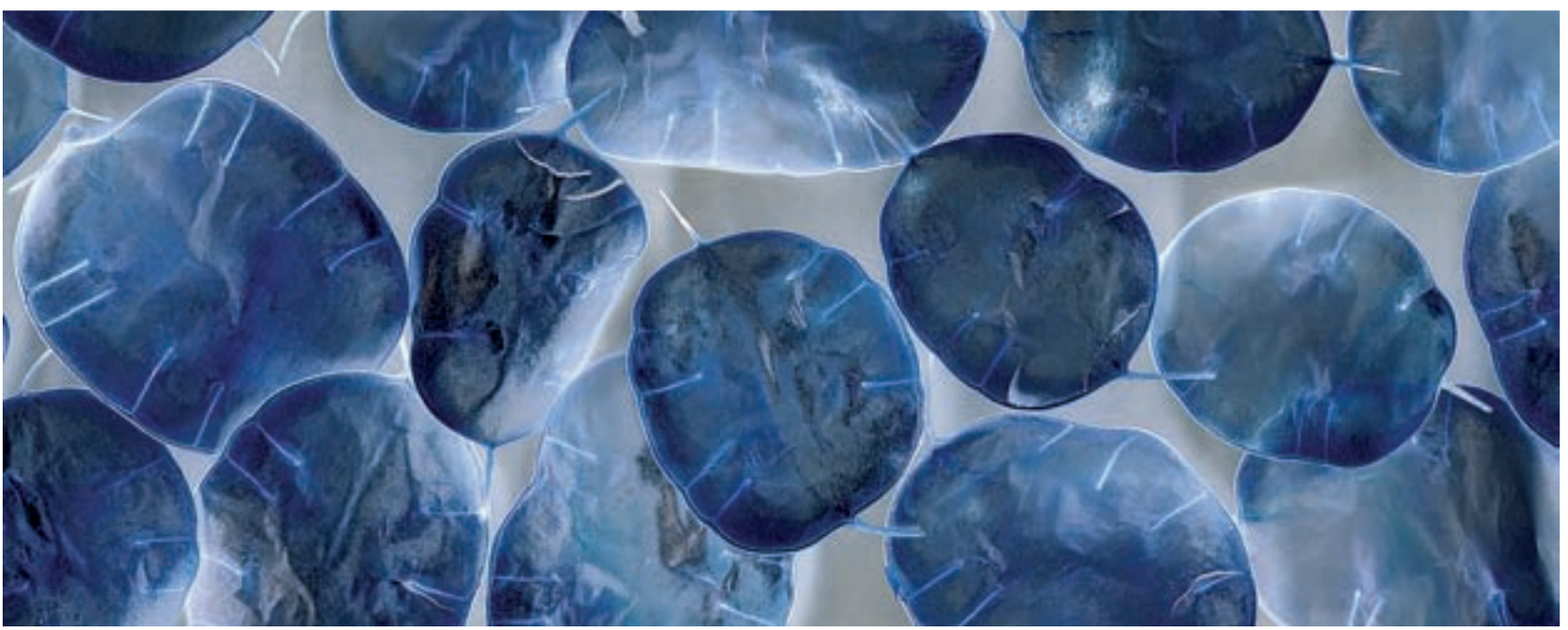
INTERNATIONAL DEPARTMENT
Icíar Sanz de Madrid

COMMUNICATIONS DEPARTMENT
Julián Zabala

RELATIONS WITH AUTONOMOUS REGIONS DEPARTMENT
José R. Luis-Yagüe

STUDIES DEPARTMENT
Pedro L. Sánchez

MEMBERS SERVICES
Javier Urzay



3. Areas of activity

3.1. Government relations

3.1.1. Safeguards and Rational Use of Medicines and Medical Devices Act (29/2006, of 26 July)

The overhaul of European pharmaceutical legislation that occurred in 2004 has been progressively integrated into the national legislations of the different Member States. In Spain, the Safeguards and Rational Use of Medicines and Medical Devices Act 29/2006, of 26 July (from now on Act 29/2006) fulfils this task, incorporating the new EU precepts in our legal system with what is predominately technical content. Yet as well as the incorporation of European legislation of technical character, Act 29/2006 regulates other, economic, aspects of the pharmaceutical sector. This regulation also repeals the Medicines Act, 25/1990, of 20 December, although it incorporates much of its precepts, which have continued to remain in full force as the years have gone by.

With respect to the technical aspects, it is correct to say that Act 29/2006 is adapted in a quite faithful way to the EU provisions. In a general way, the legislator has intended to comply with European obligations in the area of the marketing authorisations and pharmacovigilance so that pharmaceutical laboratories dispose of a common framework throughout the European Union. The text, however, contains some imperfections with regard to the one set out by the EU regulations, such as the obligation to market a medicine in Spain contrary to the will of its owner if the Spanish Agency of Medicines and Medical Devices (AEMPS) considers it necessary, or the apparent duplication of obligations by owners (for example the obligation to supply information on clinical trials to a national database as well as a EU one).

It is the economic elements of the regulation that have caused the most polemic, however. Act 29/2006 forms a tough Reference Price System (RPS) through the formation of groups that comprise, for a certain channel of administration, the totality of the authorised formats containing a determined active ingredient, among which at least one generic must be included, with the exception of those for paediatrics, which form a group apart. This new dimension of groupings affects, in some manner or other, all the formats of an innovative medicine, as well as those that include a generic and for which, for them to continue to be financed, the reference price must be lowered. This is also the case for those formats that do not have a generic form and have to reduce their price to reach the reference price. During the passage of the law, Farmaindustria has opposed this approximation because it alters the market dynamic by imposing a forced reduction in the prices of formats without a generic.

The new Act has shaped a strict economic regulatory framework for the pharmaceutical industry

The finally-approved text of the Act took into account these arguments, in a way that some formats can be integrated in the RPS groupings a certain time after their configuration. In this way, the formats declared by the AEMPS as medical innovations of therapeutic interest will remain excluded from the RPS for five years from the configuration of the corresponding group. Separately, laboratories who own formats whose price is affected by more than 30% with respect to the resulting application of the RPS, can opt, in this case, to assume all the reduction in one year or do it in minima of 30% a year until they reach the reference price. This allows, at least in theory, to reduce the impact of the legislation in this area.

Other precepts of an economic character provided for in Act 29/2006 will have practical effects when development regulations are published or from the interpretation the competent administration places with regard to the law's text. Such is the case with the level of innovation of a medicine or the consideration of the average European price, two criteria to take into account at the moment the prices of new medicines are fixed.

Finally, it is also important to assess what Act 29/2006 could have regulated and did not.

In this sense, it is common knowledge that protection of innovative medicines in Spain is lower than in the rest of the advanced countries of the EU, given the lateness of the incorporation of product patents into our legislation. This means that an original medicine, patented before 7 October 1992, has a product patent in EU states without provisional regimes in the area of industrial property, while in Spain such a medicine enjoys only a process patent. The effects of this difference are very important for innovative laboratories since the lower protection of industrial property rights on their medicines means that generics of their products can appear in Spain before other European countries, with the consequent expected loss of market share and reduction of prices in Spain. This lower price generates greater incentives for parallel trade of these medicines from Spain, which has been shown to be the cause of supply problems on the Spanish market.

To put industrial protection on the same level as the European standard is possible from a legal point of view, as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), signed by Spain in 1995, obliges the extension of process patent rights for certain medicines patented before this date, recognising them as product patents. But the 29/2006 law – which modifies the Patents Act in other areas – does not recognise this. In these circumstances, an intricate judicial process is underway, the results of which do not look encouraging for the moment.

3.1.2. The Autonomous Regions

The contribution of the Autonomous Regions to the pharmaceutical legislative framework is increasing. The internal politics of each region, far from finding rapprochement, are becoming models of differentiated action, which might fragment the market through the specific demands of each region. Also, the predominant role the National Health System Interterritorial Council and its Pharmacy Committee should have, has suffered several reversals and, on occasions, is used more as a platform to stage political disagreements than as a real body for coordination of the National Health System (NHS).

Whatever, it is fundamental for the pharmaceutical industry to dispose of an efficient channel of permanent dialogue with the autonomous partners in the health domain generally, and on pharmaceutical provision in particular. In this sense, Farmaindustria regularly organises a forum of debate with the autonomous decision-makers in the sector, on themes of great importance and relevance for the industry today. Over the past year, Farmaindustria held two fora. The first, at the international level, was held under the auspices of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in Prague, to coincide with its Annual Meeting. Problems of the European regions were analysed and it counted upon the participation of Spanish autonomous health executives as well as regional health authorities from other Member States. The second forum, at the national level, was held in La Rioja and dealt with medicine shortages.

The Autonomous Regions, in the areas of their competence, also intervened in various aspects which affect the sector. We consider the most relevant below.

INN prescribing

In Spain, there coexist different INN prescription models. The Andalusian system, for example, does not provide for limits to this practice and actively promotes its systematic application to the point at which all authorised medicines with the same active ingredient are deemed to have the same therapeutic behaviour. The Castille-León model, for its part, approximates INN prescribing to the medicines that have a generic counterpart, excluding from this practice medicines with a narrow therapeutic range and trying to avoid that patients – especially the chronically ill and polymedicated – continually have to change their medication as a consequence. Yet, in other regions, INN prescribing has little impact.

The promotion of INN prescribing by public administrations, although it has a recent legal basis in Act 29/2006, has purely economic motives. The practice continues to hold for some Autonomous Regions an attraction derived from price differentials between medicines authorised with the same active ingredient. However, the strong homogenisation of prices due to the application of the new RPS should make regional decision-makers in the area of pharmaceutical policy reconsider the convenience of developing an indiscriminate practice of INN prescribing, whose hoped-for economic benefits cannot compensate for the health inconveniences due to continuous changes in the medicine dispensed to patients and the restriction of doctors' freedom of prescription.

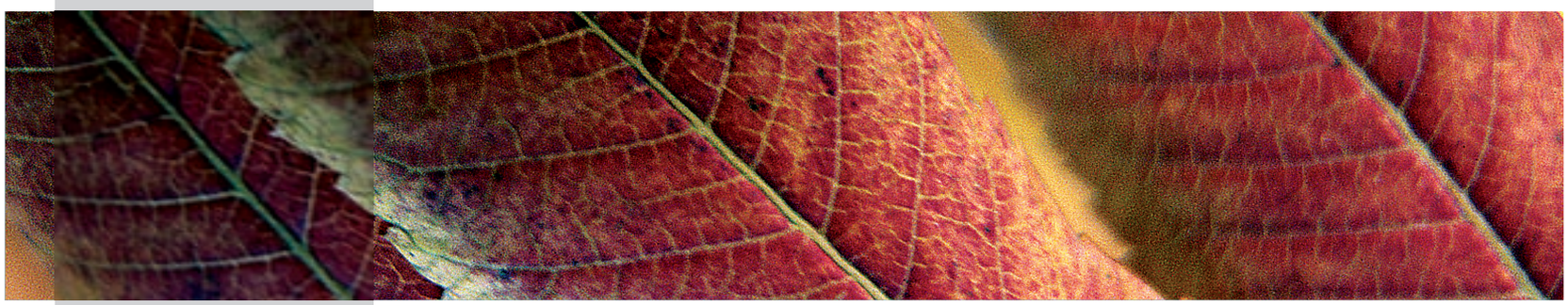
Farmaindustria has made clear on numerous occasions the weakness of such policies, especially considering that, once the RPS is set, the differences in the price of medicines that share the same active ingredient and pharmaceutical form become minimal.

The Valencian Region's Bill on Safeguards in the Supply of Medicines

Farmaindustria submitted a document containing arguments against the Valencian Region's Bill on Safeguards in the Supply of Medicines, alerting the legislator to the existence of errors and incompatibilities in the legal text, as much in reference to the State legislation as to that of the Region.

For the Valencian Region to establish provisions that interfere with regulations which are the competence of central government to prepare, and which central government is currently processing, might add unnecessary confusion between them and limit the final objective they intend to attain. This is why Farmaindustria proposed the withdrawal of this Bill.

To bring the level of industrial protection up to the European standard is essential for the future of pharmaceutical R&D in Spain



3.1.3. Legal framework

Since Act 29/2006 came into force, several regulations developing it further have been published, while others are currently in the processing phase.

Royal Decree on innovative pharmaceutical forms of therapeutic interest[1]

Royal Decree 1338/2006 establishes criteria and procedures for qualification of innovative pharmaceutical forms of therapeutic interest, developing Article 93 of Act 29/2006.

The final draft of the text incorporates the arguments presented by FARMAINDUSTRIA on the date from which the exclusion period of the RPS should be calculated for medicines declared "innovative pharmaceutical forms of therapeutic interest". In this way, these medicines will enjoy a period of exclusion from the RPS of five years, calculated from the date the order comes into force determining the corresponding group and its reference price and, if the qualification as an innovative pharmaceutical form of therapeutic interest is later than the creation of the group, the period is to be calculated from the date on which the qualification took place.

There are two annexes in the Royal Decree. The first brings together the formats of medicines declared innovative pharmaceutical forms of therapeutic interest before Act 29/2006 came into force and which remain subject to the 6th transitional provision of the Act. The second annex is related to the formats of medicines authorised before Act 29/2006 came into force and which are declared in the Royal Decree to be innovative pharmaceutical forms of therapeutic interest that are to stay outside the RPS for five years since the Royal Decree came into force.

Ministerial Order for determining the medicine groupings and their reference prices[2]

The Order establishes the general framework that must operate in Spain in the area of reference prices and includes various annexes that will be updated according to the determination of the reference prices of new groupings and as new reductions in the reference prices of already existing groups occur.

The content of this Order is not substantially different from the Draft Order, published during the hearing process, except for some advances which were achieved in meetings with the Ministry of Health and Consumer Affairs at the end of 2006. In this way, certain changes contributed to reduce the impact of the 20% price reduction for medicines with more than 10 years, now that the reductions will only apply to formats that have a generic in the same format in another European country not subject to special or provisional industrial property regimes. Likewise, to form a grouping, three costs/treatment/day will have to exist (not one, or two, as established by the Draft Order).

Draft Biomedical Research Bill

The main arguments on the Draft Biomedical Research Bill, which finally were considered, focused on: the need to exclude clinical trials and post-authorisation studies of the type where observations are made with medicines; the obligations provided for in the draft bill and the recommendation that maximum periods are established for the evaluation of a research project; and, mechanisms for the mutual recognition of research projects by the competent health authorities.

FARMAINDUSTRIA advocates maintaining the single pharmaceutical market on all national territory

[1] Royal Decree 1338/2006, of 21 November, for the development of certain aspects of Article 93 of Act 29/2006, of 26 July, on Safeguards and Rational Use of Medicines and Medical Devices in the framework of the Reference Price System (BOE No. 279, of 22 November 2006).
[2] Order SCO/3997/2006, of 28 December, for the determination of groupings of medicines and their reference prices and for the regulation of certain aspects for the application of that set out in Act 29/2006, of 26 July, on Safeguards and Rational Use of Medicines and Medical Devices (BOE No. 312, of 30 December 2006).

Draft Royal Decree on the regulation of the procedure for the establishment, through inspection visa, of special exceptions to the conditions for prescription and dispensing of medicines

FARMAINDUSTRIA presented arguments on the Draft Royal Decree, basically referring to the need that the visa be the same for all the national territory, and be used exclusively for health motives, avoiding the proliferation of regional forms that, under another name, suppose in practice the imposition of special requirements for the prescription or dispensing of medicines.

Draft Royal Decree for the regulation of the traceability of medicines for human use

The principal observations of the Association on this draft Royal Decree focus on: technical aspects (the Data Matrix Code) in the periods necessary for its implementation; associated costs; and, above all, in the access of companies to relevant information in order to be able to apply Article 90 of Act 29/2006, as is established in Royal Decree 725/2003, of 13 June, currently in force, for the development of certain aspects of Article 100 of the Medicines Act 25/1990, of 20 December, which was repealed after the approval of the new Royal Decree.

Draft Royal Decree for the regulation of the procedure of authorisation, registry and dispensing conditions concerning industrially-manufactured medicines for human use

FARMAINDUSTRIA presented arguments to the Ministry of Health and Consumer Affairs, drawing attention to the advisability of substituting precepts which reproduce EU regulations for references to them and, in this way, permit that the modifications introduced in such EU regulations enter in force without the need to realise new modifications of the Royal Decree.

The Association considered very worthy the adaptation of national procedures to EU procedures, avoiding on many occasions aggravated situations whose origin lies in a temporary lack of consistency in the procedures of authorisation. Otherwise, the draft should establish a greater flexibility for adaptation to the new requirements; for example, modifications in labelling should be able to be incorporated in a gradual way.

Draft Royal Decree for the regulation of pharmacoviligance of medicines for human use

In the framework of the hearing process, FARMAINDUSTRIA asked for the modification of this draft so the text was harmonized completely with the EU directives in this subject, eliminating requirements of an exclusively local nature. Otherwise common criteria were requested for carrying out post-authorisation studies, since, as the draft is now, the procedure of authorisation would only have flexibility for studies included in a risk management plan, developed by the regulatory authority or financed with public funds.

Draft Order for establishing the list of prescribed medicines that cannot be substituted at pharmacy outlets

The arguments on the Draft Order on medicines that cannot be substituted in dispensing have reflected upon the exceptional character of the substitution, as provided for in Article 86 of Act 29/2006, and have justified the advisability of adding to the draft new groupings of medicines that should not be substituted without medical authorisation, for reasons of usual medical practice and beyond that of a mere formal interchangeability. Furthermore, the arguments contemplate other assumptions - medicines holding incentives legally limiting interchangeability (paediatric use, orphan drugs and patent-protected indications) – whereby the legislator prevents the substitution and for legal, technical reasons should be included in the Order.

3.1.4. Technical Committees

FARMAINDUSTRIA participates in various technical committees created by the competent authorities, contributing points of view from the pharmaceutical industry and maintaining the necessary link with government decision-makers.

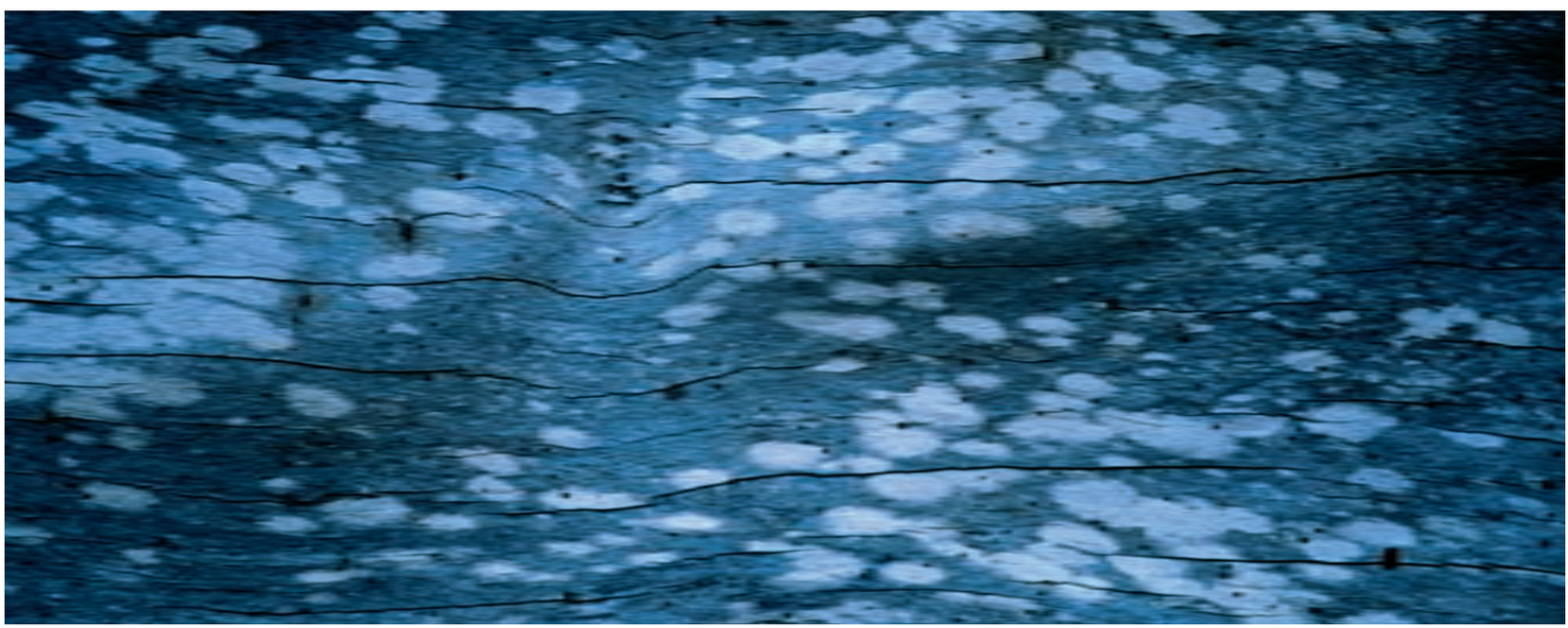
National Health System Interterritorial Council Consultative Committee

The National Health System (NHS) Cohesion and Quality Act 16/2003, of 28 May, establishes that the social participation in the NHS should be conducted, among others, through the Consultative Committee. This Committee is the body through which unions and employers have institutional presence in the NHS. FARMAINDUSTRIA participates as a member attached to the Confederation of Employers and Industries of Spain (CEOE).

The functions of the Consultative Committee are to report, advise and formulate proposals on issues of special interest for the functioning of the NHS. Among these proposals is draft legislation concerning health services, funding and pharmaceutical spending. Over the past year, the Committee's debates in the pharmaceutical field focused on the development regulations of Act 29/2006.

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, of 14 March. One of the members of CODEM is appointed at the proposal of FARMAINDUSTRIA allowing it a permanent presence on the Committee.



FARMAINDUSTRIA has a permanent presence on CODEM

ISSUES TREATED IN CODEM IN 2006 [3]	
Meetings held	**11**
New applications	**1.267**
Applications authorised	857
• Mutual recognition	171
• National	686
• Decentralised procedures	0
Applications refused	449
• Mutual recognition	0
• National	449
• Decentralised procedures	0
Type IA modifications	
• Applied for	5.927
• Authorised	5.090
• Refused	698
Type IB modifications	
• Applied for	2.875
• Authorised	2.841
• Refused	413
Type II Modifications	
• Applied for	3.852
• Authorised	3.247
• Refused	262

Source: Spanish Medicines Agency (AEMPS)

[3] CODEM passes judgment on new applications for registration and some Type II variations, particularly new indications. Nethertheless, data from the Spanish Medicines Agency (AEMPS) is included here referring also to Type I & II variations.

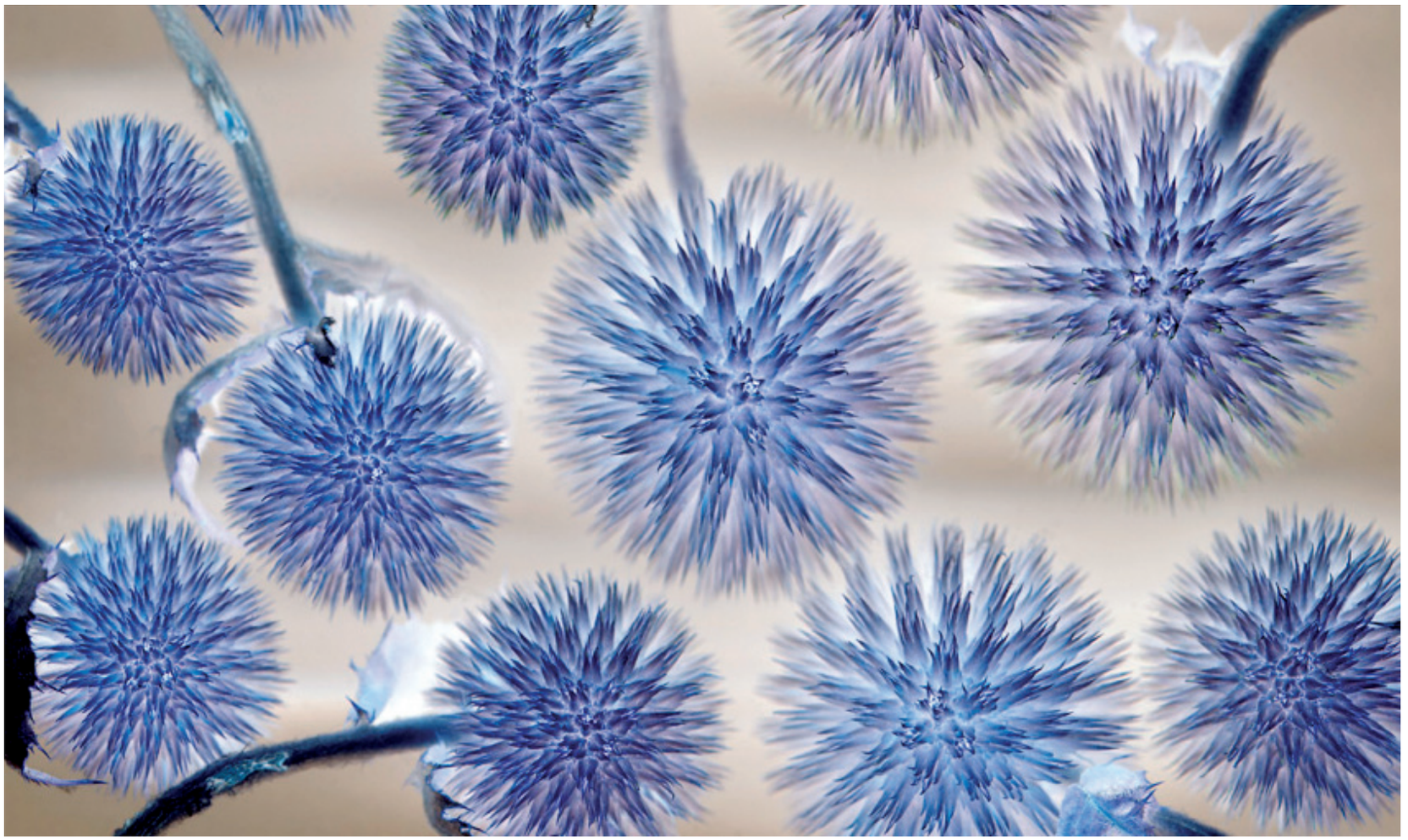
Catalonia Regional Advisory Board for Medication Errors

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, made up of experts from the University, public institutions in the pharmaceutical field, medical doctors, pharmacists and nurses, and FARMAINDUSTRIA, has developed a document on the errors that could occur in the life-span of medicines, from manufacturing to administration to the patient, passing through the prescription and supply phases, analysing the causes of the errors in each one of these areas and proposing solutions to them.

Committee for the inclusion of active ingredients as over-the-counter (OTC) medicines

The listed active ingredients used in OTC medicines are updated on a regular basis via Ministerial Order. Meeting monthly in the Spanish Medicines Agency, this multidisciplinary committee studies the proposals for the inclusion of new active ingredients and new dosages in the Order, as well as evaluating new indications and modifications to the information included in the technical specifications and information leaflets for patients taking OTCs.



During 2006, the draft Ministerial Order was revised. It was published on 3 February 2007 and it gathers together the active ingredients evaluated up to October 2005 that are to be listed as OTCs.

Advertising control and OTC self-regulation committees

Royal Decree 1416/1994, regulating advertising of medicines for human use, distinguishes two types of advertising: one on prescription products directed specifically at health professionals, 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 Region 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 are meant, for the treatment of symptoms or minor ailments.

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

3.2. Social communications

During 2006, Farmaindustria went more deeply into the development of the Communications Plan approved by the Association's General Assembly for the 2005-2006 biennial. The aim was to continue to improve the social perception of the biomedical industry in Spain, making progress in the presence, access and influence of Farmaindustria in different fields and to support, through communications, the general strategy of the Association.

Thanks to the development of the Communications Plan, Farmaindustria has consolidated its position as the reference for communications media (specialised and generalists) when it is necessary to evaluate information in the pharmaceutical field, corresponding with the Association's role as the representative of a complete economic sector.

The Association has made a huge effort on communications tasks, carrying out dozens of press conferences and press releases, hundreds of appearances in the communications media, organisation of events with different publics (communications professionals, patients' associations, researchers, public opinion in general, etc.), editing of publications, sponsorships, etc.

3.2.1. FARMAINDUSTRIA in the media

Wide presence in the media

As a consequence of the work carried out in 2006, the messages transmitted from FARMAINDUSTRIA were widely diffused by the communications media at a particularly sensitive time, with the passage and later approval of the Safeguards and Rational Use of Medicines and Medical Products Act.

In this way, in 2006, the number of times FARMAINDUSTRIA featured in communications media increased notably, and, of most relevance, the pharmaceutical industry positioned itself to put forward its arguments before public opinion and communicate its demands to the Public Administrations and diverse institutions.

Increased information activity

If 2005 represented a qualitative and quantitative leap in the information activity of FARMAINDUSTRIA, with an important growth in the number of press conferences organised, press releases distributed, interviews granted and opinion articles published, during 2006 the trend was maintained: the communications media was invited to 20 press conferences, some 40 interviews were managed in different communications media with members of the Association and personal meetings were carried out with almost 20 prestigious opinion leaders (with communications media directors, columnists and directors of the information services of radio and television stations).

The growing activity carried out by FARMAINDUSTRIA has consolidated the Association as the reference for communications media

The growing number of information activities carried out by FARMAINDUSTRIA and the multiple formats employed has allowed the communications media to tackle numerous issues of interest for the sector (patents, R&D, promotion of medicines, etc.) and, often, from new points of view, such as the defence of industrial property rights in the pharmaceutical field, the positive assessment of the role of the biomedical industry as top private investor in R&D in Spain or the success of the Code of Practice in the promotion of medicines, driven by FARMAINDUSTRIA and which has become an international reference.

As well as direct communications actions, the Association has carried out an important effort for promoting, developing and supporting greater involvement from the communications media in the diffusion of information about health and R&D, as much in daily newspapers and magazines as in radio channels, and online media, with the objective that the whole of public opinion can receive truthful and constant information on the pharmaceutical industry in its various fields (economic, health, etc.).

Training for professional journalists

For the fourth consecutive year, FARMAINDUSTRIA organised in November 2006 the 4th annual Pharmaceutical Industry and Communications Media Seminar in collaboration with the National Association of Health Journalists (ANIS), the Association of Economic Information Journalists (APIE) and the Federation of Spanish Press Associations (FAPE).

FARMAINDUSTRIA in 2006 organised the 4th annual Pharmaceutical Industry and Communications Media Seminar in collaboration with various professional information organisations and associations.

The latest seminar, held in Bilbao, brought together almost 40 professionals from the communications media with the double objective of widening the journalists' knowledge about the activity of the pharmaceutical industry and maintaining a framework of dialogue, exchange of views and mutual apprenticeship about the sector and its relationship with the media.

As on past occasions, the directors of the various FARMAINDUSTRIA departments carried out an analysis of the situation of the sector, describing some of the most important actions implemented by the Association in the past year and putting forward the principal challenges of the future for the industry.

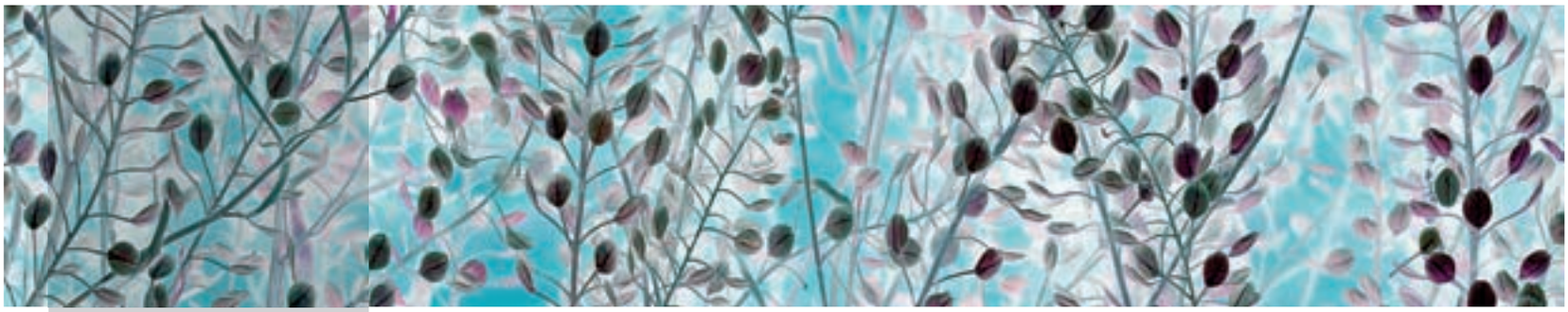
On another note, the FARMAINDUSTRIA FOUNDATION collaborated in the organisation of the 2nd National Health Journalism Congress, together with the National Association of Health Journalists (ANIS), the Spanish Federation of Press Associations and the Health Ministries of the Regions of Madrid and Castille-La Mancha. With this event, held in Toledo in November 2006, it was intended to contribute to the professional debate about health information.

Humberto Arnés (first on the left), General Director of FARMAINDUSTRIA, at the inauguration of the 2nd National Health Journalism Congress.

Advertising

Advertising support continued in 2006 when it was necessary to transmit the strategic messages of the sector, as a reinforcement to the rest of the communication activities. Designs approved at the end of 2005 were kept, based on the importance of the research that the pharmaceutical industry carries out and the value of medicines.

Images of the original advertising designs.



The Awards for the Best Patient Service Initiatives have become a model in the area of patients' associations

2nd Annual FARMAINDUSTRIA FOUNDATION Patient Service Awards

The Farmaindustria Foundation held a ceremony for its 2nd annual Awards for the Best Patient Service Initiatives in December 2006 at the Royal Tapestry Factory in Madrid, in the presence of Elena Salgado, the Minister for Health and Consumer Affairs.

In just two years, these Awards have become a model in the area of patients' associations. There are three categories to date: patients' associations, service and information entities, which include scientific and professional societies, communications media and health care centres, and people who at an individual level stand out for their careers in the health field. The value of the prizes, which include recognitions and cash prizes, amounts to 100,000 euros.

The Awards for the Best Patient Service Initiatives ceremony, given by the Farmaindustria Foundation, took place at the Royal Tapestry Factory, in the presence of Elena Salgado, Minister for Health and Consumer Affairs.

Over 150 candidates were present at the event, with six finalists selected for each category and section. The Awards Jury, appointed in October and including relevant personalities from the patient and disabled associations' movement and the medical, scientific, social, media, political and institutional fields, awarded the following winners:

CATEGORY	PRIZEWINNERS
PATIENTS' ASSOCIATIONS	
Best health education initiative	Spanish Federation of Associations to Help & Fight Against Anorexia Nervosa and Bulimia Nervosa (FEACAB)
Greatest presence in society	Spanish Federation of Fragile X Syndrome
Quality of service to associate patient	Fundación Menudos Corazones (Children's Heart Foundation)
SERVICE & INFORMATION ENTITIES	
Scientific & professional societies	Spanish Society for General Medicine
Communications media	El Periódico de Aragón
Care centres	Adolescent Psychiatry Hospitalisation Unit of the Gregorio Marañón Hospital in Madrid
INDIVIDUAL RECOGNITION	Doctor Luis Mª Escribano Mora

Sponsorships

FARMAINDUSTRIA's presence and visibility has increased in various areas (sectoral or not) through the selection of sponsored activities and events. In this way, the industry has been present in numerous meetings organised by academic institutions (the Universities of Madrid Complutense, Internacional Menéndez Pelayo, Navarra and Barcelona), business institutions (Madrid Chamber of Commerce and Plataforma de Cultura Empresarial Factores de Progreso), political institutions (Madrid Region), sectoral (the Spanish medical doctors' professional Association, the Spanish Society of Industrial & Medical Pharmacy, Spanish Society of Family & Community Medicine, Foundation for Health Research, Association of Health Economics and Spanish Federation of Rare Diseases) and the field of communications (Recoletos, the Association of Economic Information Journalists-APIE, National Association of Health Journalists-ANIS, and the Intereconomia Group).

Just in the health field, thanks to collaboration agreements signed by FARMAINDUSTRIA, the Association has participated, among others, in events such as the Global Patients' Congress, the 1st International Meeting on Translational Research and Individualised Medicine, the 7th European Platform for Patients' Organisations, Science and Industry congress, the Inesme Forum on INN Prescription, the Day on the Medical Profession in the European Union, the 7th Madrid Science Fair or the Rare Diseases Week.

FARMAINDUSTRIA has increased its social visibility by participating in selected events

The Seminar on patents and innovation promoted by FARMAINDUSTRIA was held at the Lázaro Galdiano Foundation and attracted more than 100 participants.

Patents and Innovation Seminar

In May 2006, FARMAINDUSTRIA, in collaboration with the Instituto de Empresa and Pricewaterhouse-Coopers, organized the "Medicine Patents & Innovation" Seminar with the aim of increasing public and political sensitivity on the need to harmonize the legislative framework for industrial property rights protection in Spain with the rest of Europe. Over 100 participants attended the event, held at the Lázaro Galdiano Foundation.

The 'Pacientes' (Patients) and 'Redes' (Networks) Magazines

During 2006, the magazines *Pacientes* (Patients) and *Redes* (Medicine Research Networks), launched in 2005, became publications of great use and dissemination among their respectives audiences, i.e. the patients' associations collective and all those institutions, organisations and people interested in this field on the one hand, and, on the other, the biomedical research context.

The magazine published by the FARMAINDUSTRIA FOUNDATION is for the patients' collective and has a print run of 20,000.

With a print run of 20,000 each quarterly issue, *Pacientes* deals with themes of special interest for the patients' collective, with reporting related to health and health care, in all their wide-ranging scope, and information on the patients' associations movement.

Redes is distributed in all research centres and institutions and organisations connected with biomedical research.

Redes magazine maintains the FOUNDATION's objective to spread and assess the reality of Spanish biomedical research. With a central monographic section in each issue to analyse the research activity in a specific area, the magazine has attracted great interest from researchers.

With a quarterly periodicity, 10,000 copies of this magazine are distributed in all research centres, as well as different Administrations, institutions and organisations connected with biomedical R&D.

FARMAINDUSTRIA has also organised meetings with the main researchers in the concrete field on which each issue of the magazines focuses. These meetings serve for bidirectional debate on the current research panorama in Spain and to make progress in the necessary relationship between the researchers' collective and the pharmaceutical industry, main promotional actor and finance provider of these activities in Spain.

Press Website

The press zone on the FARMAINDUSTRIA website (http://prensa.farmaindustria.es) has experienced an important increase in both the information included, due to the association's own activity and its public presence, and the number of visits.

Last year, the number of journalists registered on the website increased 50% with respect to 2005 and number of visits was over 350,000.

The report "Perspectives on pharmaceutical spending in Spain", published by FARMAINDUSTRIA in 2006.

3.2.2. Studies and publications

STUDY SERIES

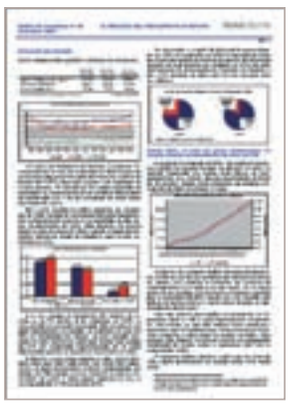
'Perspectives on pharmaceutical spending in Spain'

The report 'Perspectives on pharmaceutical spending in Spain', prepared by Nera Economic Consulting, was presented in October 2006. It consists of an analysis of the evolution of pharmaceutical spending in Spain, particularly as far as the impact of the Safeguards and Rational Use of Medicines and Medical Devices Act is concerned. According to the report, as a result of the application of measures provided for in the Act, pharmaceutical spending in Spain between 2006 and 2008 will increase at a lower rate than Spanish Gross Domestic Product.

Issue 8 of the FARMAINDUSTRIA magazine published a large report on patent harmonization.

'FARMAINDUSTRIA' magazine

Issue 8 of the 'FARMAINDUSTRIA' magazine was published during 2006. Among the articles included in this publication, a wide-ranging report on the lack of harmonization in pharmaceutical patents in Spain might be highlighted. Also, an analysis of the relationship between economic regulation and pharmaceutical R&D; a study on the Public Administration debt for hospital supplies; pharmaceutical R&D investment data in Spain for 2005; and a report on the basic principles of EFPIA, the European Federation

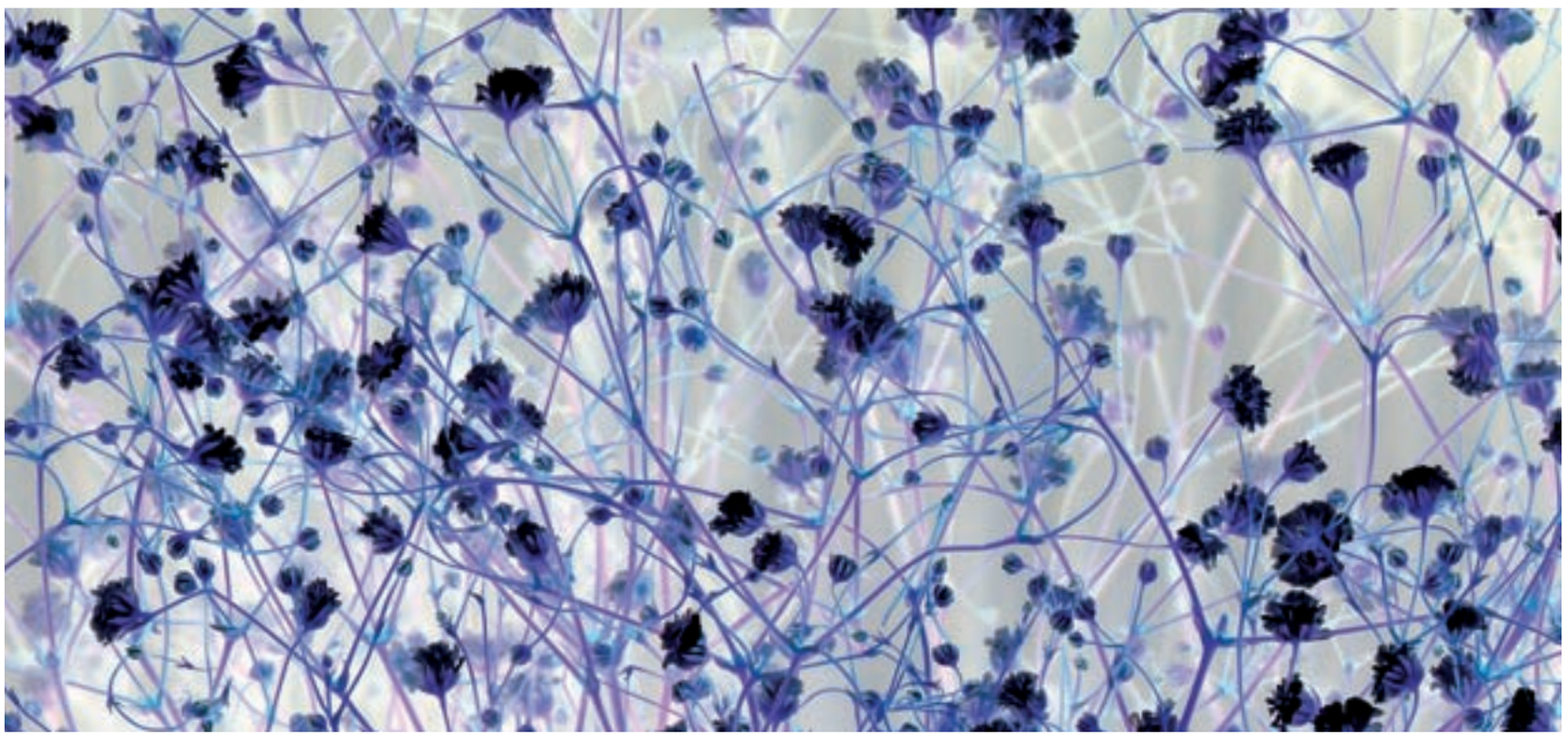


The status report on the pharmaceutical market is published monthly with daily newspaper Expansión.

of Pharmaceutical Industries and Associations, for the assessment of health care technologies.

Status Report. The pharmaceutical market In Spain

Published every month, the Status Report. The pharmaceutical market In Spain describes the evolution of public pharmaceutical consumption in our country and includes analysis of data and current information, relevant and useful to understand better how the pharmaceutical market works. As well as its internal dissemination to members, the economic daily newspaper Expansión publishes it every month, raising awareness of other communications media who frequently reproduce the information it includes.



3.3. Services to Associated Laboratories

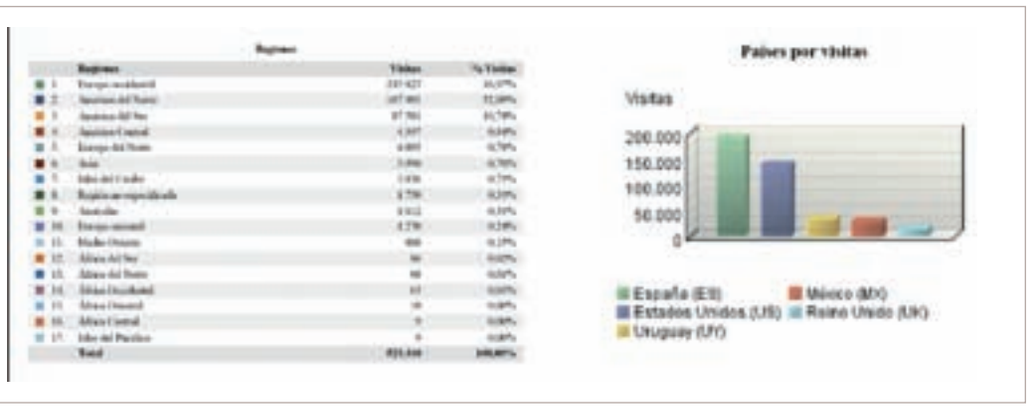
3.3.1. Online Services

www.farmaindustria.es

During 2006, the FARMAINDUSTRIA portal grew as much in number of visitors and downloads as in content and new information lines. Over the past few years, the FAR-

www.farmaindustria.es receives an average of 1,433 visits a day, more than half of which come from outside Spain.

FARMAINDUSTRIA'S website is the reference in terms of sectoral pharmaceutical information in Spain and third countries



MAINDUSTRIA portal has become the sectoral information service concerning the Spanish pharmaceutical industry and currently it is becoming recognised as a reference portal for third countries: some 1,433 visits a day are received on average, more than half due to access from terminals outside Spain.

Improvements and New Information

Important progress was made during 2006, oriented particularly at improving the accessibility and immediacy of the content flow and to complete the information fields. In this sense, information loading time has been shortened considerably to being available on the portal.

Code of Practice Surveillance Unit (USD) and Code of Practice Committee dossiers on the website also continue to be managed better and a new portal has been developed inside the Spanish Technological Platform Innovative Medicines, which will centralise the information flows that support the project.

During 2005, a new service was commissioned that allows all the Association's publications to be put on a single CD, including historical ones.

In 2006, a second CD brought together all the more restricted circulars and documents, aimed exclusively at the associated laboratories.

All the FARMAINDUSTRIA document management and information sending is done through a tool which was implemented in 2004 and has allowed associated laboratories to receive punctually all the documents sent out institutionally.

This service sends out more than 500,000 messages a year, tracking the distribution and controlling its maintenance.

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 associated 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 Governing Bodies in order to tackle specific problems, make proposals, elaborate industry positions and monitor

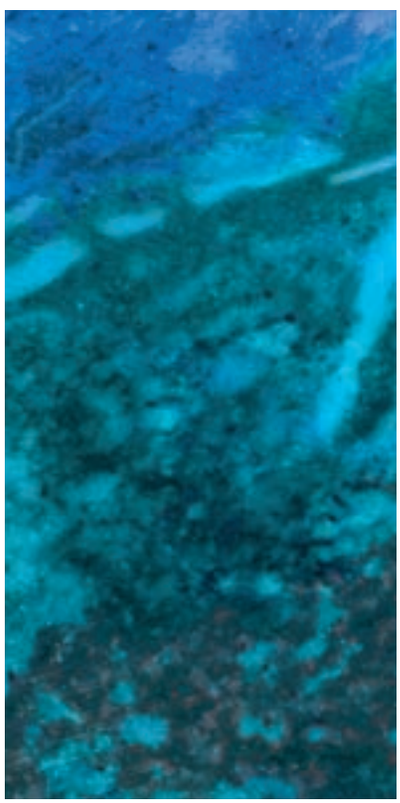
specific action plans (objectives, means, indicators) on strategic themes. The composition of the Working Groups are approved by the Governing Bodies following criteria of representativeness, suitability and operability.

- **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 committees set up to analyse specific themes. When the subject requires the preparation of a relevant sectoral position, it is channelled through the Executive Board.

In 2006, the Working Groups, Sections and Functional Groups were overhauled, with the updating of their composition and work plan. Some of the groups were integrated into others by virtue of the functions assigned to them and new groups were created with specific objectives, responding to the instructions of the Governing Bodies of FARMAINDUSTRIA.

The aim of this updating was to promote the active participation of the members, ensuring at the same time adequate reform of the different groups. To such effect, it is essential to highlight the intense work carried out by different groups to shape, in a coherent form, the position of the industry in various areas, all of them very relevant to pharmaceutical companies.

Presently, FARMAINDUSTRIA can count upon:



Working Groups:

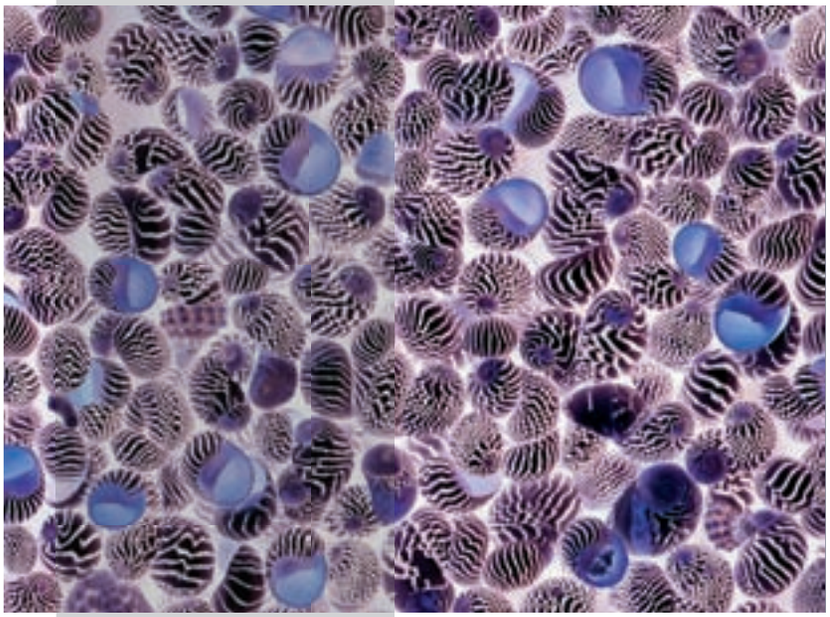
1. Regulatory developments of economic scope.
2. Regulatory developments of technical scope.
3. Industrial property: patents and trade marks.
4. Traceability, shortages and parallel trade.
5. INN prescribing and defence of the brand.
6. Relations with the Autonomous Regions.
7. Code of Practice.
8. Scientific information: Medical visits.

Sections:

1. Hospital supplies.
2. Vaccines.
3. Biotechnology.

Functional Groups

1. Clinical research.
2. Medical and research directors (BEST Project).
3. Environment.
4. Pharmacovigilance.
5. Technical operations.
6. Registry.
7. Human resources.
8. Personal data protection.
9. Legal services.
10. Taxation.
11. Health Technologies Assessment.
12. Communications.



FARMAINDUSTRIA'S Working Groups were particularly active during 2006

Here follows a summary of the activities of the different groups and Sections in 2006:

WORKING GROUPS

Working Group on regulatory developments of economic scope concerning the Safeguards and Rational Use of Medicines and Medical Devices Act

This Working Group, heir in part to the former Market Access Working Group, has as its main aim to carry out a close monitoring, with maximum involvement, of all the regulatory proposals and administrative actions for development in the economic area of the Safeguards and Rational Use of Medicines and Medical Devices Act.

Approval of the new law has brought with it the introduction of important changes in aspects of economic regulation of the pharmaceutical industry, some of which were introduced automatically (the new contribution based on sales of medicines to the NHS) and others which have demanded and will demand the development of specific legislation in the field (new Reference Pricing System, consideration of the average European price in the new price and reimbursement process, etc.).

In the Working Group meetings (usually monthly), the following objectives, among others, are pursued: preparation of position papers on economic aspects resulting from legislative development; uniting positions so as to disseminate consistent and well-argued messages promptly, following up procedures and results of the policies of medicine prices and reimbursement in Spain and Europe, searching for an adequate treatment for pharmaceutical innovation, etc.

Over the past year, the Group has met on numerous occasions and it is thanks to its work that submissions have been prepared for different legal texts presented by the Government. It has also prepared position papers and proposed actions to the Association's Governing Bodies.

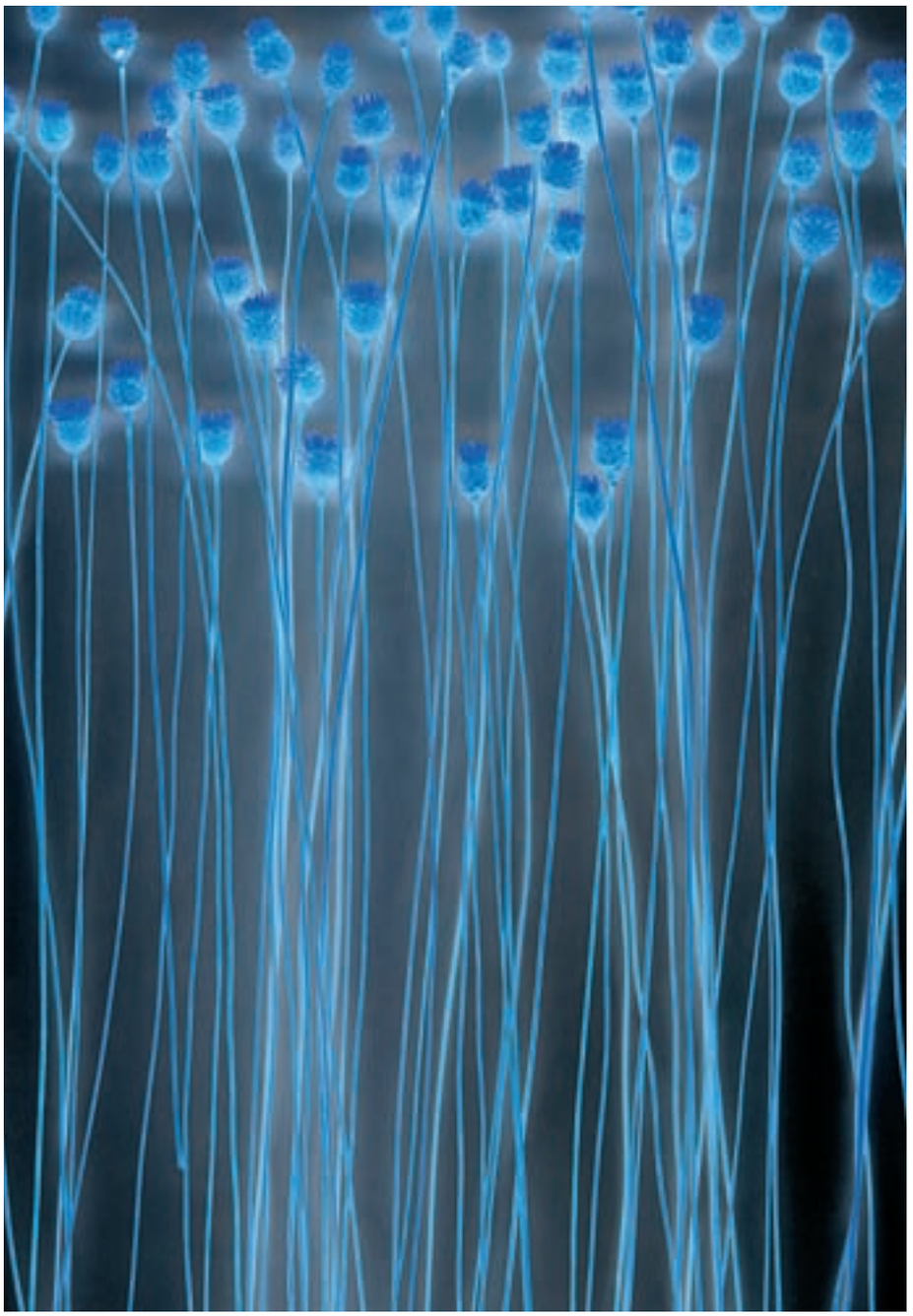
Working Group on the technical development of the Safeguards and Rational Use of Medicines and Medical Devices Act

As well as the provisions in the economic area that were elaborated in the development of Act 29/2006, approval of the law has brought with it important changes in aspects of technical nature, whose development competence corresponds to the Spanish Medicines Agency (AEMPS).

With the aim of specifying positions on these technical areas and passing them on to the Association's Governing Bodies, this Working Group held a series of meetings in which issues relevant to the laboratories were dealt with, such as: modifications to authorisation procedures; modification and renewal of registrations; typology of laboratories following the approval of Act 29/2006; the progressive modification of labelling; and non-substitution of medicines.

Working Group on Industrial Property

In 2006, the activity of this Working Group has been intense. The Group has been dedicating its time to analysing the situation and preparing actions designed to promote the definitive harmonization with the EU of Spanish legislation on pharmaceutical product patents, which has been one of the strategic priorities of the Association. In fact, in 2006, it has carried out important institutional activities as much in the national as the international arena. Numerous legal expert reports, dealing with the theme, giving a full view of the problems and offering possible solutions, have been prepared. Such reports have been passed on to the Ministry of Industry and other competent authorities.



In the national arena, it has held meetings with the Spanish Patent and Trade Mark Office (OEPM), Congress and Senate MPs, the Ministries of Industry, Education, Health and Consumer Affairs, the Attorney General and the Economic Office of the President of the Government, to inform them of the problems.

In the international arena, it has maintained contacts with the European Commission (representatives of the Industrial Property Unit and Trade Directorate-General), with the European Patent Office, the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), with the aim of setting out to them directly the Spanish situation so that from now on there will be carried out some type of activity designed to ensure the full applicability of the WTO agreement and its agreed annexes, specifically TRIPS.

Working Group on Traceability

Act 29/2006 incorporates traceability of medicines as one the elements in need of regulation in order to achieve a series of objectives, among those the guarantee of supply of medicines throughout the country.

FARMAINDUSTRIA, conscious of the importance of keeping the Spanish market properly supplied, has analysed the situation in detail through the Working Group on Traceability and according to the data studied has found there to be shortages in a certain group of medicines. This shortage exists despite the continual and excess supply, in relation to the Spanish market's needs, by the pharmaceutical industry in Spain. In these circumstances, FARMAINDUSTRIA, has called on the health authorities to bring about greater transparency in information relating to medicines commerce and also an exchange of the information supplied by the pharmaceutical laboratories in order to avoid such shortages.

For its part, the Ministry of Health and Consumer Affairs has put into operation a pilot project, called SEGUIMED, which replaces the previous so-called *Encomienda de Gestion* (a type of special management force), which is no longer operative. SEGUIMED needs full collaboration from the industry, distributors, the Autonomous Regions and the Ministry of Health and Consumer Affairs and it is to be hoped that, on this occasion, the process of furnishing data on the part of pharmaceutical distributors will culminate satisfactorily.

Finally, the new consciousness with regard to the importance of avoiding medicines shortages has opened a debate over the current and future role of pharmaceutical distribution, especially in light of the alternatives offered by EU legislation and Act 29/2006 being incorporated into our legal system. In this sense, the obligation of producers to supply permanently the national market and the possibility of the direct application of Article 90 of Act 29/2006 is, to conclude, changing the traditional distribution model for medicines in Spain.

Working Group on INN prescribing and defence of the brand

INN prescribing is a practice that has extended to various Autonomous Regions and which, as well as not achieving large economic savings in the framework of a Reference Price System that functions appropriately, can give rise to important health risks for certain types of patients, especially the elderly, polymedicated patients or those with chronic diseases.

This Working Group has as its main objective to reduce as much as possible the practice of INN prescribing, defending the doctor's freedom of prescription and promoting the exclusion of its application to medicines without generics (since there would be no savings whatsoever associated with INN prescribing in this category of medicines), to special medicines (narrow therapeutic range, biological medicines, medical formulations) and to patients liable to suffer more because of this practice (the elderly, chronically ill and polymedicated patients).

This Working Group has been particularly active during 2006 and carried out a whole series of activities (publications, meetings, legal reports, communications activities, statistics, etc.) in the different areas affected by the practice of INN prescribing: scientific/health, legal, economic and communications, as much in the national as international arena.

Finally, at the time of writing, the Group is finalising an action plan in defence of the pharmaceutical brand as a valuable asset for companies, professionals and patients.

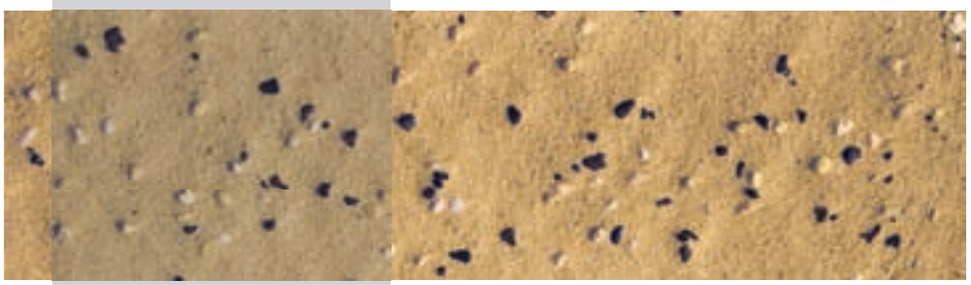
Working Group on Autonomous Regions (ARs)

This Working Group substitutes the former Autonomous Regions Functional Group.

The objective of this Working Group is to revise, analyse and monitor pharmaceutical policies in the Autonomous Regions of Spain, as well as promoting areas of collaboration with the ARs, professional organisations and scientific societies that help to shape a favourable environment for pharmaceutical innovation and preserve the single pharmaceutical market in Spain.

Pharmaceutical brands generate value for companies, professionals and patients

Although many of the regulated aspects in the AR arena are dealt with in diverse Working and Functional Groups and Sections of FARMAINDUSTRIA, which have more specific scope, the horizontal nature of the AR Working Group will serve to provide the Association with a flexible instrument that allows it to carry out a proactive and early monitoring of the regulatory initiatives that are tackled by ARs in the area of pharmaceutical legislation, medicines and medical devices. In another initiative, the Working Group is also seeking to create a favourable atmosphere for a relationship of mutual understanding and confidence with the ARs in order to facilitate industrial stability and sustainability of public pharmaceutical spending.



Working Group on the Code of Practice

The fundamental objective of this Working Group is to analyse the proposals that the control bodies of the Spanish Code of Practice for the Promotion of Medicines come up with, in order to improve its efficiency, to go deeper into aspects considered crucial and align it with international standards.

In this sense, the Working Group is mainly focused upon achieving the effective application of the Spanish Code, strengthening the mechanisms necessary to making it fully operative and improving upon the progress already made.

In the international arena, the Working Group will analyse changes made to international codes to make sure the Spanish Code is in line with international standards.

Working Group on Scientific Information: Medical Visits

The main aim of this Working Group is to analyse and follow up the national or regional regulatory projects that could affect medical visits in whatever scientific information activity.

In what is a more practical area, the Working Group will be responsible for monitoring regulatory developments of the Safeguards and Rational Use of Medicines and Medical Devices Act and to study the situation of the medical visit in Autonomous Regions in order to provide it with the highest quality levels.

SECTIONS

Hospital Supplies Section

During 2006, this section continued to analyse those questions of a legal and financial nature related to hospital supplies and the debt of the different regional health services with their pharmaceutical products providers.

Although the data of a reduced sample of companies at March 2007 appears to signal a certain improvement in terms of the size of debt as well as the average payment period in most Autonomous Regions (ARs), the latest available data for the pharmaceutical sector as a whole shows that, at the end of 2006, the Spanish National Health System owed the pharmaceutical companies 2,060 million euros for the supply of medicines to its hospitals, with the average payment period of this organisation being 277 days, way above the 60 days established by Act 3/2004, of 29 December, establishing measures to combat slow payment in commercial operations.

Although the size of the debt has reduced by 6% compared to 2005, with 14 ARs presenting a lower debtor balance than the previous year, the situation continues to be very worrying, especially in two regions (the Valencian Community and Andalusia) that account for over half the total debt.

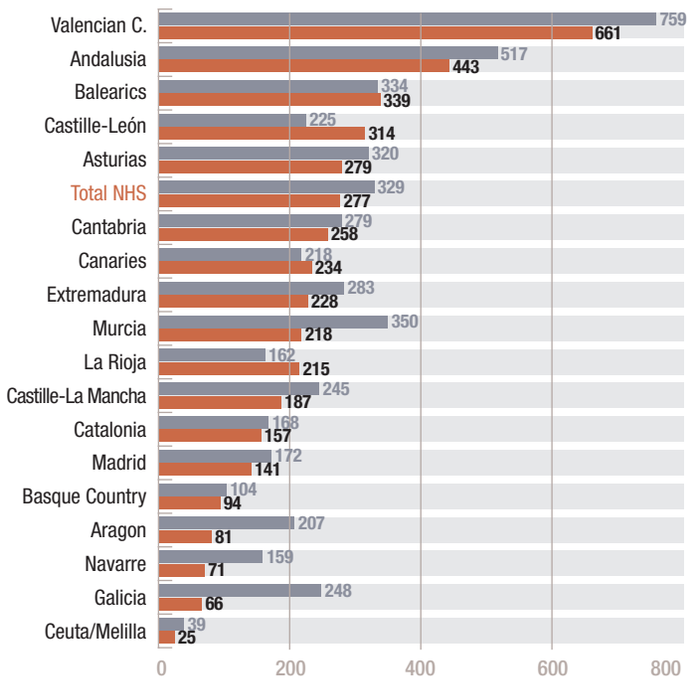
HOSPITAL DEBT TO PHARMACEUTICAL COMPANIES IN AUTONOMOUS REGIONS

Health service	Payments owed at 31.12.06 (€m)	Variation 06/05
Andalusia	569.2	-3.6%
Aragon	21.1	-55.3%
Asturias	55.5	-6.3%
Balearics	55.1	25.4%
Castille-La Mancha	56.2	-6.6%
Castille-León	138.3	58.1%
Canaries	79.0	14.4%
Cantabria	34.9	3.7%
Catalonia	99.8	-7.9%
Valencian Community	590.1	-2.8%
Extremadura	42.8	-5.6%
Galicia	35.9	-69.7%
La Rioja	10.1	45.0%
Madrid	176.7	-7.3%
Murcia	50.2	-28.5%
Navarre	7.9	-46.2%
Basque Country	36.6	-2.9%
Ceuta and Melilla	0.4	-68.0%
TOTAL NHS	**2,059.8**	**-6.0%**

Source: FARMAINDUSTRIA estimates, from "Survey of Hospital Supplies Debt" (2006).

These delays in payments are provoking serious financial problems for companies, particularly SMEs and could cause many of them to disappear. The seriousness of the situation was denounced by FARMAINDUSTRIA through its General Director when he made a presentation[4] before the Senate's Economic and Treasury Committee in a session dedicated to studying the problem of payment delays in commercial operations in Spain.

AVERAGE PAYMENT PERIOD BY HEALTH SERVICE (DAYS)



Source: "Survey of Hospital Supplies Debt", FARMAINDUSTRIA (2006).

[4] On 24 March 2006.

It is necessary that the different regional administrations look for solutions to this problem and find the necessary resources to meet their financial obligations, especially after the 3/2004 Act came into force, which makes the situation ever worse for them. In this sense, the Section has carried out a constant monitoring of the different regional initiatives under way to solve the problem of debt for pharmaceutical supplies to hospitals.

Elsewhere, the Hospitals Section has also analysed other questions relevant to the sector, such as the centralised management for contract purchasing of certain medicines in hospital centres in the ARs of Madrid and Galicia, or the Andalusian Health Service's electronic billing project.

Vaccines Section

Throughout 2006, this Section continued to analyse all the matters that require dialogue with the competent health administrations. It has continued cooperating in this way with the health authorities with the aim of coordinating activities in all those areas related to vaccination. Of special importance are those aspects relative to Autonomous Region calls for tenders for vaccines, and the study of administrative clauses included in the tender specifications, with the intention of reducing the uncertainty that companies face in terms of returns, extensions and substitution of vaccines.

Other themes dealt with at the heart of the Group were the Draft Royal Decree regulating the traceability of medicines for human use, contingency plans in the event of a bird flu pandemic in Europe, transport, the vaccination calendar and pharmacology.

Biotechnology Section

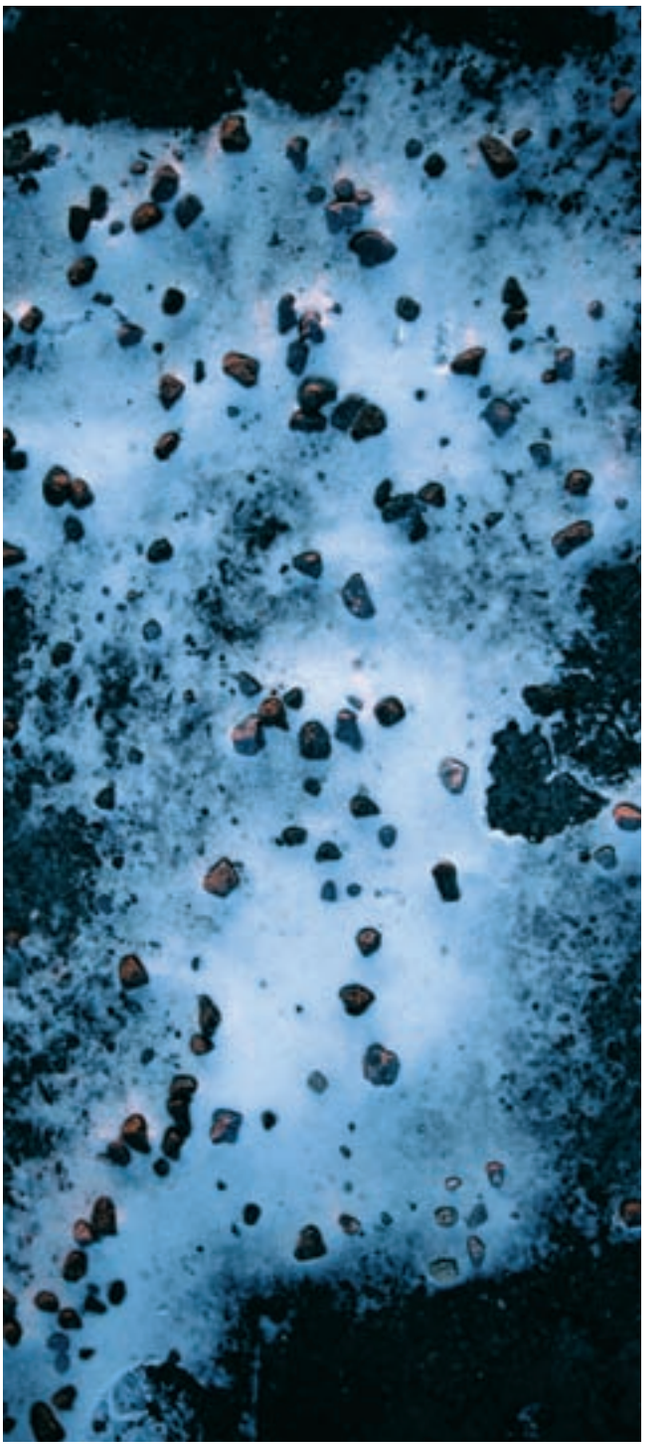
The Biotechnology Section recently created in FARMAINDUSTRIA held its first meeting in April 2007. The new Section will work in three main fields of activity: communications, transmitting the importance of biotechnology and its impact on therapies; cooperation between biotechnological SMEs and pharmaceutical companies in the area of R&D, as well as with other associations and agents in the research arena; and regulatory aspects of biotechnological medicines, with a pilot, and complementary, approach to the tasks already dealt with in other Working Groups in FARMAINDUSTRIA.

At the end of 2006, the situation of hospital debt continued to be very worrying in some Autonomous Regions

FUNCTIONAL GROUPS

Clinical Research Functional Group

Following the entry into force of Royal Decree 223/2004, of 6 February, 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 1 May, 2004 (version No. 4, November 2006)'. 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, resulting in com-



ments 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.

During 2006, Subgroups were created for specific work to analyse the relevant aspects in the area of clinical research, such as: clinical research and post-authorisation contract models in certain Autonomous Regions; the introduction of a new European clinical trials database (Eudra-CT); the editing of an explanatory procedure on necessary data; and steps to take when applying for authorisation in the importers'/exporters' register for biological samples from clinical trials, etc.

Medical Directors Functional Group (BEST Project)

This Group, constituted at the end of 2005, forms part of the Spanish Technological Platform Innovative Medicines. During the past year, it has set into motion a series of initiatives with the aim of improving the efficiency and quality of clinical research processes in Spain, such as the creation of the BD Metrics database.

BD Metrics, updated in July 2006, contains 306 clinical trials from 24 pharmaceutical companies. 87% are international clinical trials. The main therapeutic areas in which clinical trials are carried out are oncology, cardiovascular, neurosciences and anti-infectious drugs and are concerned preferably with Phase II and III clinical trials.

Due to the urgency and importance of the problem, the first BD Metrics module was that of the durations of the different phases prior to the start of clinical trial in earnest. For this, it was necessary to define a series of indicators that would allow the evaluation of the efficiency of the processes and quality of clinical research.

The most important result is that, on average, 216 days are spent between the reception of the protocol in the laboratory and the inclusion of the first patient in the clinical trial in Spain. This is 78 days more than in the best of the countries participating in the same clinical trial for the inclusion of the first patient.

At present, the Group is working to promote clinical research in primary care, for which it has established contacts with scientific societies and involved networks. Also it is foreseen to establish a series of bilateral meetings with the Autonomous Regions.

Environment Functional Group

Throughout 2006, the Environment 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.

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 new guidelines relative to the carrying out of pharmacovigilance plans, of risk management programmes and the continued evaluation of the risk-benefit of a medicine when an application is made for its marketing authorisation and during the whole life cycle of the product. Other current themes are the electronic communication of adverse reactions to medicines, personal data protection and the applicable criteria in our country to the rate of periodical safety reports.

This Group also reviews legislative documents issued by the Spanish Medicines Agency and the EMEA for discussion, 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 *Volumen 9A* project on pharmacovigilance guidelines for medicines for human use and the draft Royal Decree on the regulation of pharmacovigilance of medicines for human use.

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 manufacturing and logistics.

The Group met twice in 2006, mainly to inform upon the logistical aspects of traceability and on the pertinence of modifying the coding systems for medicines. In the first meeting, the EFPIA technical report was analysed on Data Matrix (2D) as the most appropriate solution for improving the coding system. In the second meeting, Group members were required to analyse and give their opinion on the application of the future Royal Decree on traceability in order to form arguments that FARMAINDUSTRIA would submit to the Spanish government.

Registry Functional Group

The Registry Functional Group made a periodical revision of the main regulatory issues relative to the authorisation procedures and medicines' registration. This Group is composed of experts from a large number of companies who contribute on concrete themes as a function of the specific needs raised at

any moment: export certificates, limits to the substitution of medicines, registration variations, IT applications, etc.

Human Resources Functional Group

During 2006, this Group held two meetings, at the first one, the Group made an inventory of the latest main legislative developments in the labour sphere that could affect companies in the sector, and a second one at the 14th Chemical Industries Convention, which expired on 31 December 2006.

Halfway through the year, the first day of pre-negotiation of the 15th Convention took place and Farmaindustria took part through two representatives of the Human Resources Group, who continued as members of the Negotiating Committee throughout the whole process.

Elsewhere, Farmaindustria continued to take part in monthly meetings of the Joint Committee for Interpreting the Collective Bargaining Agreement, the Socio-Labour Committee and, in particular in the Working Group on the Code of Practice Guideline "Processes of externalization of services in companies" and the Pension Plans Working Group, created under the auspices of the Spanish Chemical Industry Federation (FEIQUE). It also took part in the Labour Relations Committee of the Confederation of Employers and Industries of Spain (CEOE), which meets about every two months.

Among new legislative developments approved in the labour sphere during the year was the start of the passage of the draft Organic Bill for Equality Between Men and Women and the approval of Royal Decree/Act 5/2006, of 9 June, aimed at improving growth and employment through three basic objectives: promoting the use of indefinite contracts by creating a new Employment Development Programme; limiting the successive use of temporary contracts; and, finally, introducing improvements to the services for unemployment in specific collectives.

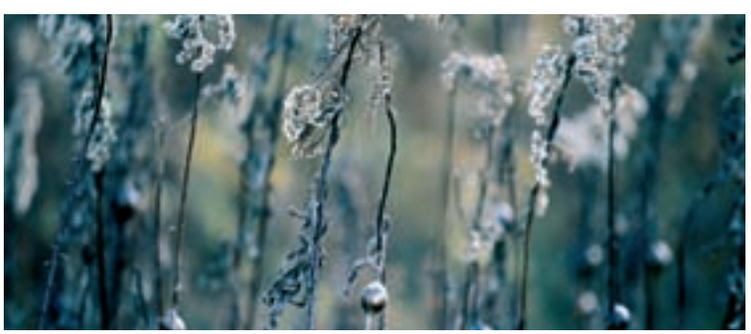
Personal Data Protection Functional Group

Following the mandate of the Governing Bodies of Farmaindustria, the Personal Data Protection Functional Group was created with the objective of studying aspects related with personal data protection legislation and its application in areas of clinical research and pharmacoviligance.

In a first phase, the Group has focused its analysis in the area of clinical research. The Group is presently working on preparing a Standardized Working Procedure or Sectoral Code, in which it will describe the particularities of treatment of personal health data, as much in the area of clinical research as in the area of pharmacovigilance. The aim is to present such a Code to the Data Protection Agency to register it, in accordance with the Personal Data Protection Act 15/1999 of 13 December. Joining the code will be a voluntary decision on the part of each laboratory.

Legal Services Functional Group

Composed of the legal managers of the laboratories associated to Farmaindustria, this Group has continued to act as a forum for the exchange of knowledge and opinions on the various themes of a legal nature that affect the pharmaceutical sector.



During the year, the Group analysed, among others, the Safeguards and Rational Use of Medicines and Medical Devices Act, amendments and final text of the law, as well as the later developed regulations. Another aspect of great significance was the passage of the Draft Public Sector Contracts Bill, establishing the regulations for calls for tender of public contracts, in particular supplies contracts affecting hospitals. The Group also monitored and studied regulations dictated by the Autonomous Regions.

In the half-year fora, the Group has received timely information on the state of appeals lodged by FARMAINDUSTRIA against various provisions of state and regional legislation, as well as the most relevant sentences passed by the European Court of Justice. The Legal Services Functional Group has also taken part indirectly in other Groups and Sections of the Association, in those where the legal nature of matters being dealt with required intervention by lawyers, such as, for example, Human Resources, Registry, Traceability, Hospital Supplies, Economic Development of the Safeguards Act, INN Prescribing, Patents, Taxation, etc.

Taxation Functional Group

The Taxation Group continued to hold its traditional annual seminar on new fiscal developments, during which information was provided relative to new developments in the year in course, legal sentences passed in this area and all those other fiscal aspects that could be of interest for the pharmaceutical sector.

An important issue arose in November 2006 when FARMAINDUSTRIA presented before the Tax Directorate-General (DGT) a binding review with the objective of the DGT confirming definitively the recent change in criteria in VAT applicable to clinical trials. The reply of the DGT in January 2007 stated that the carrying out of clinical trials with the aim of testing medicines on physical persons could not be included in the exemption of tax foreseen in Article 20.One.III of the 37/1992 Act, of 28 December, on Value Added Tax. Thus, the carrying out of the referred-to clinical trials will be taxed at 7%.

Health Technologies Assessment (HTA) Functional Group

This Functional Group, heir of the former Health Outcomes Research Group, returned to its activities during 2006 with the aim of developing documents of a technical character referring to the main problems that would be caused by the development of a system for the evaluation of therapeutic usefulness and grade of innovation of new medicines in Spain, as included in the Safeguards and Rational Use of Medicines and Medical Devices Act.

Over the past year, the Functional Group met on various occasions and began the development of technical position documents for a variety of subjects such as the therapeutic utility of innovative pharmaceutical forms, the use of comparators in the HTA of new medicines, the use of variables to measure results, etc.

The legislative development of the Safeguards and Rational Use of Medicines and Medical Devices Act implies a strong workload for this Functional Group during the years to come.

FARMAINDUSTRIA'S Barcelona Office worked intensively throughout 2006

Barcelona Office

The FARMAINDUSTRIA Office in Barcelona has continued performing technical secretariat functions for various Working Groups, Sections and Functional Groups of the Association and coordinating their meetings. In the same way, it has worked intensively to provide technical replies to the enquiries from the associated laboratories established in Catalonia and has maintained contacts with entities of a diverse nature, taking part in various technical, academic and social groups and committees.

The Spanish Technological Platform Innovative Medicines has, as its mission, the promotion of pharmaceutical R&D in Spain

At the same time, the Barcelona Office has collaborated in the organisation of acts and meetings in Barcelona and provided services of logistical and administrative support to the associated laboratories to FARMAINDUSTRIA.

3.3.3. Spanish Technological Platform Innovative Medicines

The Spanish Technological Platform Innovative Medicines (PTEMI) is an initiative promoted by the pharmaceutical industry in collaboration with academic institutions, clinical researchers and public administrations to promote R&D in innovative medicines in our country. There are three coordinating organisations in PTEMI: FARMAINDUSTRIA (Madrid), the Leia Foundation (Vitoria) and the Biomedical Research Park in Barcelona. PTEMI would like to be seen as the Spanish reference for the European Platform Innovative Medicines Initiative (IMI), responding to the priorities and needs of Spanish partners, facilitating dialogue between them and with their European counterparts and making possible the genesis of research projects, at both national level and in the European arena.

The Spanish initiative was presented in Barcelona in July 2005. Since then, it has been working in three horizontal areas: clinical research, knowledge management and education and training.

There were many activities that took place during 2006 in three main areas:

- Clinical Research: The BEST project has been started as a Platform of Excellence in Clinical Research of Medicines in Spain.
- Education and Training: On the first day of training in R&D of medicines in Spain (June 2006), there was a large turnout from all the stakeholders involved. This area has a multidisciplinary and translational character, covering the gaps between industry, academia and suppliers.
- The challenge in Knowledge Management is to organise the data to generate knowledge with the purpose of predicting the safety and efficiency of new medicines. Already a series of workshops have been held with an important participation from public and private sectors.

The PTEMI coordinated and organized its 2nd Annual Conference held in Madrid in July 2006 with more than 250 participants, representing public and private institutions. In turn, the PTEMI has participated in various Congresses, Seminars and Courses in the national and international arenas in which it has presented its organisation and activities.

A proposal to constitute an Office of Support in the Creation of Consortia and Research Projects in the PTEMI has been presented to the Centre for Technological and Industrial Development (CDTI). This Office would promote the format of proposals to different programmes, principally the EU's 7th Framework Programme for R&D and more specifically for the IMI's calls for tender. The PTEMI communications vehicle is its website: www.medicamentos-innovadores.org which presents itself as the reference for biomedical pharmaceutical research at the national level and serves as a meeting point and a place for coordinating activities, information and communications between all the participants. A newsletter is published monthly and sent to more than 200 registered readers. The website is available in Spanish and English and is updated weekly.

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

After the reform introduced in the Code in 2005, work undertaken in 2006 has focused on the application and consolidation of these modifications.

The Farmaindustria-Autocontrol Monitoring Committee has held various meetings in accordance with and as foreseen in the Agreement signed by both bodies with the aim of dealing with general and specific matters that can have a bearing on the self-regulation of medicines.

Despite the recent modification of the Code, another modification was made necessary to adapt it to Act 29/2006 and a development regulation which will repeal the Royal Decree 1416/2004 in force until now. For this, the Executive Board of Farmaindustria agreed to call upon the Code of Practice Working Group to meet and initiate the study of the changes that would be necessary to adapt it to these regulations and to the reality of the most recent experiences.

The self-regulation system for the promotion of medicines has notably increased its efficiency during 2006

Actions of the Code of Practice Committee

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, 65% of the complaints received by the Code of Practice Committee were resolved due to an agreement prior to the mediation meeting or as a consequence of the Committee's mediating work, meaning only 25% of the case dossiers had to be forwarded to the Self-Regulation Body, while the remaining 10% were archived at the request of the complainant following acceptance of the arguments of the accused.

In 2006, 20 complaints were presented to the Code of Practice Committee for presumed infringement of the Code. These complaints can be classified as follows:

- 9 complaints in relation to the content of the promotional material of proprietary medicinal products.
- 6 complaints regarding promotional activities related to hospitality during meetings.
- 3 complaints regarding incentives.
- 1 complaint about promotion through the Internet.
- 1 complaint with respect to rules governing the application of the code.

The following chart summarises the total number of complaints, the status 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.

Total complaints	**20**
Accepted	17
Rejected or inadmissible	3
Complainants	**20**
Associated laboratories	11
USD	9
Accused	**20**
Associated laboratories	18
Attached laboratories	2
Action by Code of Practice Committee	**13**
Agreements	13
Action by Self-Regulation Body	**5**
Sanctions imposed	2
Rejected or inadmissible	3
Cases filed	**2**

Actions of the Code of Practice Surveillance Unit

The level of interrelation between the Code of Practice Surveillance Unit (USD) and pharmaceutical companies increased notably in 2006.

The version of the Code currently in force – approved on 22 June 2005 – establishes in Article 12.11 the obligation of each pharmaceutical company to name at least one employee or manager responsible for supervising internal compliance with the Code, that person being named the "Internal Supervisor".

During 2006, the USD held bilateral meetings in the offices of the laboratories, where aspects such as the work of disseminating the Code were analysed, as well as relations with the different agents involved – Government, scientific associations, health professionals, general public, etc.. Other items on the agenda were: the repercussions of the new Safeguards and Rational Use of Medicines and Medical Devices Act in the area of the promotion of medicines; the need to increase the interrelation and collaboration of the companies with the Unit, making key the Internal Supervisor's role; the evaluation of the functioning and usefulness of the electronic system for the notification of events; possible areas of improvement in the self-regulation system, etc.

Most laboratories gave the USD a copy of their current internal procedures, in which they apply different promotional activities or practices. This initiative, apart from endorsing and demonstrating the commitment of the laboratories to collaborate, has helped the Unit contrast the individually, internally implemented measures so as to watch over and guarantee the compliance of the terms and conditions of the Code, as well as driving forward the creation of a Certificate of Good Practices. The purpose of this certificate is to accredit the conformity of a promotional activity, or practice, with the rules of the Code. In an initial phase, scientific events and meetings will be those activities able to obtain this certificate. The objective of the USD is that the certificate is implemented effectively before the end of 2007.

The activities carried out by the Unit in 2006 were in three main areas:

1. Dissemination of the Spanish Code of Practice for the Promotion of Medicines.
2. Advice and collaboration.
3. Control of the compliance and application of the rules of the Code through preventive actions and officially lodged complaints.

In relation to the **dissemination of the rules of the Code,** the following activities can be highlighted: active participation in more than 15 conferences at a national and international level; organisation of 2 press conferences aimed at general and specialist media; holding of bilateral meetings with people in charge in the area of promotion of medicines in the Autonomous Regions; organisation in Madrid and Barcelona of the 1st Pharmaceutical Industry Internal Supervisors' Meeting, as well as the 1st Code of Practice Basic Seminar; participation in Information Days organised by FARMAINDUSTRIA in Madrid and Barcelona with the aim of spreading awareness about the main new features of the Safeguards and Rational Use of Medicines and Medical Devices Act; organisation of Code training seminars for laboratories as well as their service suppliers; and publication of press releases, opinion pieces and letters-to-the-Editor in diverse general and specialised press and media.

In the area of **advice and collaboration,** attention needs to be drawn to the greater presence in, and support of the Unit to, international institutions and organisations with self-regulation systems, as an active member of their working groups. In this sense, USD collaborated actively during 2006 in the process of adapting and modifying the EFPIA Code, the approval of its new version being foreseen for June 2007. Likewise, the Unit actively took part in the editing and review of the new IFPMA Code, which entered into force on 1 Janaury 2007. In recognition of such work, Madrid was selected to host the First Annual IFPMA Compliance Network Conference held in June and the USD director was designated Chairman of the IFPMA Adjudication Group, the group of experts belonging to member associations, created by IFPMA to settle any complaints that could arise by virtue of its terms and conditions.

Other activities carried out by the USD were: collaboration in the preparation of amendments for the Safeguards and Rational Use of Medicines and Medical Devices Act, in those aspects related to promotion, especially in the matter of discounts and bonuses; active participation in meetings and fora organised by FARMAINDUSTRIA with the Autonomous Regions and communications media; the revision, adaptation and improvement of internal procedures implemented by the laboratories for guaranteeing compliance with the Code as well as the applicable legislation in the area of promotion of medicines; continual advice to pharmaceutical companies and involved third parties, mainly scientific associations, technical secretariats and suppliers of services in general.

As far as **control and prevention** activities are concerned, the commitment of the laboratories to fulfilling the terms and conditions of the Code should be mentioned. This commitment has been endorsed by the increasing demand for services of early advice, as well as by preventive mechanisms implemented by the USD to avoid whatever kind of activity, practice or situation that, far from safeguarding the image of the pharmaceutical industry, could mean infringement of the Code's rules. This commitment has contributed very positively to the fact that the number of actions carried out by the Unit – in relation to the activities connected to this control and prevention function – have decreased. To this effect, it needs to be pointed out that the number of preventive actions carried out during 2006 was 1,376 - compared to 1,801 in 2005.

The fruits of this preventive work can be seen by the number of complaints lodged directly at the Unit falling for the second consecutive year: 9 in 2006, compared to 11 in 2005 and 18 in 2004.

Finally, the notable increase in the total number of events verified and analysed by the USD in 2006 should be highlighted. This figure reached 2,199 – an increase of 25% on the 1,747 in 2005.

Legal action

During 2006, FARMAINDUSTRIA, following the instructions of its Governing Bodies, proceeded to initiate different legal procedures against various pharmaceutical laboratories that, having been fined by the Self-Regulation Body, asked to leave the Association. In particular, 8 legal actions were lodged with the aim of reclaiming quantities these laboratories owe. It is to be hoped that these processes are concluded during 2007.

3.4. International Relations

EUROPEAN CONTEXT

High-Level Pharmaceutical Forum

The Pharmaceutical Forum has its origins in the Lisbon Agenda, and during the so-called G-10, where the EU Heads of Government agreed an economic reform programme designed to achieve the strategic objective of building a more competitive and dynamic European economy, based on knowledge and capable of bringing about sustainable economic development and better social cohesion.

In this context, the pharmaceutical industry was considered as one of the sectors with most potential to contribute to achieving these objectives, although certain reasons for concern were detected as to the loss of competitiveness in the pharmaceutical industry: a risk of the European market fragmenting, the inexistence of free market prices, delays in bringing medicines to market, etc.. To deal with these challenges, the European Commission created the High-Level Group on Innovation and the Provision of Medicines, also known as the G-10.

After the constitution of this Group, a report was published with 14 recommendations for improving the competitiveness of the European pharmaceutical industry. The EU Council of Ministers responded to these recommendations by issuing a series of conclusions that reaffirmed the need to balance industrial policy and public health services.

The 2004 reform of European pharmaceutical legislation was done so on the basis of the G-10 recommendations. With this reform, time periods were made more flexible and a more rapid process was designed for the approval of innovative medicines, the period for data protection was extended to 10 years throughout the

EU and the European Medicines Agency (EMEA) was given greater competences and a more relevant role in scientifically advising companies.

During 2006 FARMAINDUSTRIA was highly active in the international arena

Unlike the G-10, the Pharmaceutical Forum is made up of all the actors in the pharmaceutical sector: Member States, Parliament, European Commission, patients' organisations, doctors, pharmacists, wholesalers, insurance companies, the generic industry, the medical supplies industry and the innovative pharmaceutical industry.

Debate in the Pharmaceutical Forum, which began in June 2005, centred on some of the most critical of the G-10 recommendations: prices, relative effectiveness (health technologies assessment) and patient information.

Throughout 2006, the activities of FARMAINDUSTRIA in the European arena fundamentally focused on contributing to shaping the position of EFPIA in the three above-mentioned areas. This position was presented at the first Pharmaceutical Forum meeting on 29 September 2006. The Pharmaceutical Forum working groups are to continue their work and inform of the progress in these areas in the second forum meeting scheduled for 2007.

FARMAINDUSTRIA, in coordination with rest of the national pharmaceutical industry associations that are members of EFPIA, advocates that the Pharmaceutical Forum should: facilitate patients access to the highest-quality information from all sources, including those of the pharmaceutical industry itself; ensure that health technologies assessment is not converted into a tool for the containment of pharmaceutical spending, nor for delaying the entry of innovative medicines to the market; and ensure that the value of innovation is recognised in the prices of medicines, thus incentivizing pharmaceutical R&D investment for the development of new and better medicines.

THE EUROPEAN COMMISSION'S INDUSTRIAL STRATEGY FOR THE PHARMACEUTICAL SECTOR

Increase innovative activity

- Participate in the 7th Framework Programme (FP7) to support R&D projects relevant to the pharmaceutical industry.
- Allocate 2,600 million euros to the Enterprise & Innovation Programme in support of SMEs and new entrepreneurs.
- Develop technological platforms to promote public-private associations at the European level.

Increase competitiveness

- Reduce delays in the access of innovative medicines to the market.
- Promote price freedom for medicines not financed with public resources.
- Assess the impact of parallel trade.
- Promote compliance with the Transparency Directive (price regulation and public reimbursement of medicines).

Improve patient information and safety

- Establish a public-private partnership to improve access to high-quality information.

Paediatric medicines in the EU

On 1 July 2006, the European Parliament, in plenary session, voted through the draft Regulation on medicines for paediatric use, which was adopted formally a few days later by EU Health Council. The objective of the Regulation is simply to improve the quality of research and development, and the authorisation of paediatric medicines.

During the process of the passage of the Regulation, FARMAINDUSTRIA took part in work coordinated by EFPIA, with the aim of ensuring that the EU provided an adequate framework for paediatric research to satisfy the needs of patients. Among the incentives for paediatric research were: a six-month extension in the duration of the complementary patent protection certificate; an increase of two years in the market exclusivity period for orphan medicines; and a new marketing authorisation for paediatric use that allows 10 years' data protection in the innovation (new studies) of medicines outside patent

The future of EU patent policy

In the area of European patents, the position of FARMAINDUSTRIA, represented by EFPIA, is reflected in the response to the questionnaire that was submitted to the European Commission halfway through 2006 and whose results Commissioner McCreevy made public on 12 July 2006, making clear the need to develop a less expensive patents system with greater guarantees.

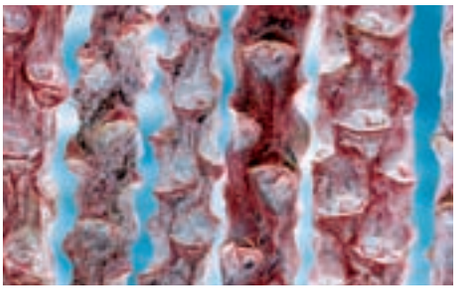
It is proposed to simplify the structure and procedure for the concession of patents, reduce the cost of obtaining a patent and improve its quality. FARMAINDUSTRIA trusts that the response of the Commission and the Council satisfies the needs of the interested parties in improving the patents system.

Counterfeit medicines

Medicines counterfeiting is a serious and growing global problem which has been on the agendas of all the meetings of the EFPIA Board during 2006 and will continue to be so in the future. In fact, the seriousness of this problem has motivated the constitution of a new working group involving the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Commission, the Council of Europe and World Health Organization.

Although it is difficult to quantify this phenomenon in Europe, what is certain is that cases of counterfeiting have been detected in practically all EU Member States. For this reason, sharing experiences with other geographical areas is of great use in coordinating strategies.

In November 2006, FARMAINDUSTRIA held a bilateral meeting with FIFARMA, the Latin American Pharmaceutical Industry Federation, to understand in more depth the problems of counterfeits as well as the initiatives taken in Latin American countries.



At a European level, the EFPIA working group has identified three objectives necessary to deal with this problem efficiently:

- **Ensure** the integrity of the product in legitimate distribution channels through the use of suitable technologies. To this effect, the EFPIA Board, in November 2005, unanimously adopted the Recommendation to use the 2D (Data Matrix) system as a single barcode system for medicines throughout the EU.
- **Strengthen** legislation and compliance with it to dissuade counterfeiters, establishing criminal sentences with fines.
- **Carry out** public awareness campaigns, without creating social alarm but informing of the importance of only obtaining medicines from authorised sources.

A single EU medicines coding system will help combat counterfeiting

EFPIA General Assembly: Strengthening the scientific base in Europe and improving competitiveness

EFPIA's 2006 Annual Meeting reviewed the progress of the EFPIA priorities defined for the period 2006-2008, reiterating the need to strengthen the European scientific base and improve competitiveness.

In a hostile context, in which national policies penalise innovation in favour of obtaining short-term financial savings, the EFPIA General Assembly stated four key principles that should guide EU policies in the pharmaceutical sector: focus on value, not cost; deliver sustainable funding mechanisms; support a stronger science base; and maintain an open and constructive dialogue for the common purpose of ensuring that European patients receive the health care that they deserve and expect.

In order to accomplish these principles, EFPIA's priorities for the next years focus on:

1. Improving the understanding of patients and society in general on the value of pharmaceutical innovation.
2. Delivering sustainable funding mechanisms for innovative medicines.
3. Improving the access of patients to new medicines, reducing delays in national price and reimbursement procedures.
4. Focusing the debate on the added value of the research-based pharmaceutical industry and its benefits for the European society and economy.

The EFPIA General Assembly also named the General Director of FARMAINDUSTRIA as the representative of the European national pharmaceutical industry associations in the Bureau, EFPIA's top governing body.

FARMAINDUSTRIA also counts upon permanent representation on EFPIA's Board as well as on three main committees which form the basic structure of the Federation: the Economic and Social Policy Committee (ESPC), the Intellectual Property Policy Committee (IPPC) and the Scientific, Technical and Regulatory Policy Committee (STRPC).

Also in the context of the EFPIA Annual Meeting, the Autonomous Regions of Madrid, Catalonia and the Canaries, and the Valencian Community, took part, together with FARMAINDUSTRIA, in a working day also attended by

regional representatives from Italy, Germany and Belgium, as well as the national industry associations of France (LEEM), Belgium (pharma.be), Italy (Farmindustria) and Sweden (LIF).

The workday showed the opportunities that a decentralisation of health services can offer in promoting R&D through public-private partnerships, although the challenges presented by the phenomenon of regionalisation were also discussed (market fragmentation, inequities between citizens of different regions, etc.).

After different points of view were expressed, a debate began in which it was stated that the phenomenon of decentralisation was highly complex, and that there was a risk when trying to achieve an equitable distribution of resources and access to therapies that can influence the health of citizens. All participants in the workday agreed to continue the debate with the aim of improving mutual understanding and arriving at constructive solutions.

Delays in market access

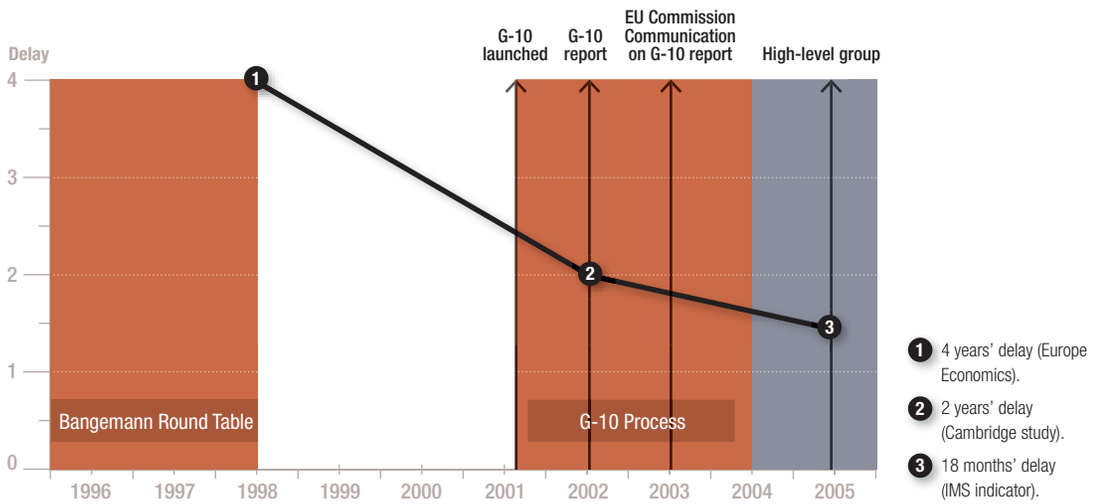
The delays patients suffer accessing new medicines is a problem FARMAINDUSTRIA and EFPIA have been analysin for several years.

In the mid-1990s, the time taken from when a medicine had gained marketing authorisation up until its launch on to the market was as long as four years in some Member States. These delays caused the EFPIA Board to set up a Working Group, in which FARMAINDUSTRIA took part, with the purpose of identifying the countries with the greatest delays and organising meetings with their competent authorities to analyse the causes and urge them to reduce the delays to the maximum legally-allowed time periods.

That study was a powerful tool for demonstrating the delays in each country and comparing them with the rest of the Member States. In fact, the four-year delay in 1996 has been reduced to 18 months in 2006.

Now the Working Group has initiated the creation of a database to monitor the 27 EU Member States plus Croatia, Turkey, Norway, Switzerland and the United States. The study allows confirmation of the progressive worsening of the average delay in Spain over the past two years, such that not only is it above the limits established in European legislation, but Spain is among the Member States of the former EU-15 with the longest delays.

PUBLIC PERCEPTION OF THE MARKET ACCESS DELAYS FOR INNOVATIONS SINCE 1996



Market access delay has reduced by 1,000 days

More than 500 million people have benefited from health programmes developed by the pharmaceutical industry

INTERNATIONAL CONTEXT

Relations with IFPMA

As well as relations with EFPIA in the European context, FARMAINDUSTRIA operates at an international level mainly through the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), which represents pharmaceutical associations and companies (R&D-based, biotechnology and vaccines) in developed and developing countries.

The 23rd IFPMA General Assembly, which counted upon the participation of FARMAINDUSTRIA, gathered together more than 100 participants representing Governments, patients' groups, medical professionals, NGOs, as well as representatives from the World Bank, the World Intellectual Property Organisation, UNAIDS, the Red Cross, the Director-General of the World Trade Organization (Pascal Lamy) and the Acting Director-General of the World Health Organization (Anders Nordstrom).

Participation of FARMAINDUSTRIA in the different IFPMA working groups in 2006 centred on the following areas:

- Revision of the Code of Practice for the marketing of medicines, establishing minimum requirements for national Codes and more transparent regulations for self-regulation mechanisms at the international level.
- Creation of a clinical trials portal, which was publicly launched at FARMAINDUSTRIA's headquarters in Madrid with wide media coverage. Through this portal, online access is provided - in English, French and Spanish - to data on clinical trials carried out by the pharmaceutical industry in any country in the world.
- Analysis of the contribution of the research-based pharmaceutical industry in achieving development objectives in the area of health in the Third World population. The results revealed that between the years 2000 and 2005, pharmaceutical companies intervened with different initiatives that had reached over 500 million people and with contributions that are estimated to be worth around 4,400 million dollars.

Relations with international organisations

The need to harmonize pharmaceutical patents in Spain to European standards was stated by FARMAINDUSTRIA before various international organisations: the European Patents Office (EPO), World Trade Organization (WTO), World Intellectual Property Organisation (WIPO), European Commission's Internal Market Directorate-General and the European Life Science Circle (ELSC) group in the European Parliament.

At the EU institutional level, FARMAINDUSTRIA has had various meetings during 2006 with the European Commission's Internal Market Directorate-General and the Spanish Permanent Representative to communicate to them the concern caused by the impact of the new Medicines Act on the Spanish pharmaceutical industry.

Finally, FARMAINDUSTRIA went to the Headquarters of the European Parliament in Strasbourg in order to attend meetings with the Spanish Euro MPs whose main area of work was directly or indirectly related to the pharmaceutical industry (Industry Committee, Environment Committee, etc.), to get across the need to develop policies at a European level which promote the competitiveness of the pharmaceutical industry and to express the concern for the impact of the measures of pharmaceutical expenditure control implemented in Spain and other European countries.

4. The Farmaindustria Foundation

The activities developed by the Farmaindustria Foundation, in its 5th year of existence, have centred, in line with its purpose, on the promotion of actions that contribute to scientific research and to the better development of Spanish healthcare, promoting in particular biomedical and pharmaceutical research, the training of health professionals and the health education of the population.

2nd Awards for the Best Patient Service Initiatives

Among the activities developed by the Farmaindustria Foundation in 2006, one of the highlights was undoubtedly the ceremony for the 2nd Awards for the Best Patient Service Initiatives, prizes that show the pharmaceutical industry's commitment to patients and whose purpose is to recognise the best actions carried out in this field.

The awards-giving ceremony was held on 11 December 2006 at Madrid's Royal Tapestry Factory and was attended by representatives of the Spanish Government, institutions, the academic world and the pharmaceutical industry.

'Pacientes' magazine

During 2006, the magazine *Pacientes* (Patients) continued to appear as the main communication channel at the service of patients and their associations.

There were three issues of *Pacientes* in 2006. The first focuses its content on the right of patients to have free access to their clinical history and analyses patients' rights, included in Act 41/2002, of 14 November, which regulates the rights and obligations of patients in terms of information and clinical documentation. At the same time, the magazine sets out the opinions of different patients' associations on this theme.

The second issue of the *Pacientes* magazine revolves around health on the Web and how the explosion in Internet use has been a true revolution for patients, who have access to an unprecedented volume of

information on pathologies that affect them. But, in spite of this and other advantages, health professionals warn about the risks this presents and that must be taken into account.
In the last issue of *Pacientes*, the magazine dedicates its central pages to analysing the General Health Act and the 20 years it has been in force, and does so from the perspective of politicians, health professionals and patients' associations.

'Redes' magazine

Last year the Farmaindustria Foundation published three issues of the magazine *Redes de Investigación en Medicamentos* (Pharmaceutical Research Networks). This magazine has the purpose of facilitating information to society and health professionals on the main biomedical research activities currently undertaken in Spain.

The first of the issues published in 2006 (*Redes No. 4*) dedicates one of its principal features to the European Union's 7th Framework Programme, which aims to give importance to, and boost European competitiveness in, R&D. In this issue, the importance of R&D is set out and the opportunity this represents for the economy of all countries, at the same time warning about a certain decrease in the rate of R&D investment in the Spanish business sector in general and in the pharmaceutical sector especially.

The Farmaindustria Foundation's mission is to develop actions that contribute to scientific research

The central section of Issue 5 of the *Redes* magazine, analyses the research being carried out in Spain in the field of Oncology through the RTICC (Thematic Network for Cooperative Research in Cancer), part of the Carlos III Health Institute and which works to develop more effective diagnostic and treatment methods to treat one of the pathologies with greatest social impact in Spain. The magazine also analyses the work by the Spanish AIDS Research Network (RIS), a group network that works through the cooperation of 39 institutions spread across Spain.

Finally, the *Redes* magazine dedicated its sixth issue to analysing the work being carried out by RCESP, the Epidemiological and Public Health Research Centres Network, part of the Carlos III Health Institute since it was created in 2003. RCESP bases its work on public health research and in the development of knowledge transfer strategies which allow the health administrations to combat the most relevant health problems in Spain with better tools.

Other Activities

During 2006, the Farmaindustria Foundation continued to sponsor courses and seminars, among which might be mentioned the "6th Pharmaceutical Industry Meeting", organised jointly with the International Menéndez Pelayo University; "The Medical Profession in the EU", by the Aranzadi Health Training Forum; "INN Prescribing: Problems and Challenges", by INESME. It also supported the 7th Madrid Science Fair, organised by the Madrid Region, and collaborated in the 1st International Meeting on Translational Research and Individual Medicine, organised by the Jiménez Díaz Foundation.

5. Integrated Packaging Management and Collection System (SIGRE)

2006 saw a series of highly important events for SIGRE, the non-profit-making entity created by the pharmaceutical industry to offer citizens a convenient and safe system by which they can dispose of the packaging and remains of non-used or out-of-date medicines.

Last year, SIGRE celebrated its 5th anniversary, five years in which this environmental initiative has become part and parcel of the daily life of citizens, administrations and social partners.

Triple Certification for Management Systems

Also in 2006, SIGRE obtained triple certification from AENOR for its Quality, Environmental and Health and Safety at Work Management Systems, so becoming the leading Integrated Management System and one of the 20 top Spanish companies to obtain this triple certification in all its activities.

These certificates reflect conformity of SIGRE's operations with the requirements established in the UNE-EN ISO 9001:2000 and UNE-EN ISO 14001:2004 standards, and the OHSAS 18001:1999 specification.

SIGRE has obtained certification for its quality, environmental and health and safety at work systems.

2006 Annual Packaging Declaration

With the object of fulfilling the legal requirements as stipulated by packaging legislation, SIGRE presented the annual packaging and waste declaration for 2006 to the environmental authorities.

In its preparation, the 257 laboratories associated to SIGRE contributed detailed information about the more than 13,000 formats of medicines marketed through pharmacies: name, weight of product and packaging, packaging material(s), type of format, pharmaceutical form, returns, etc.

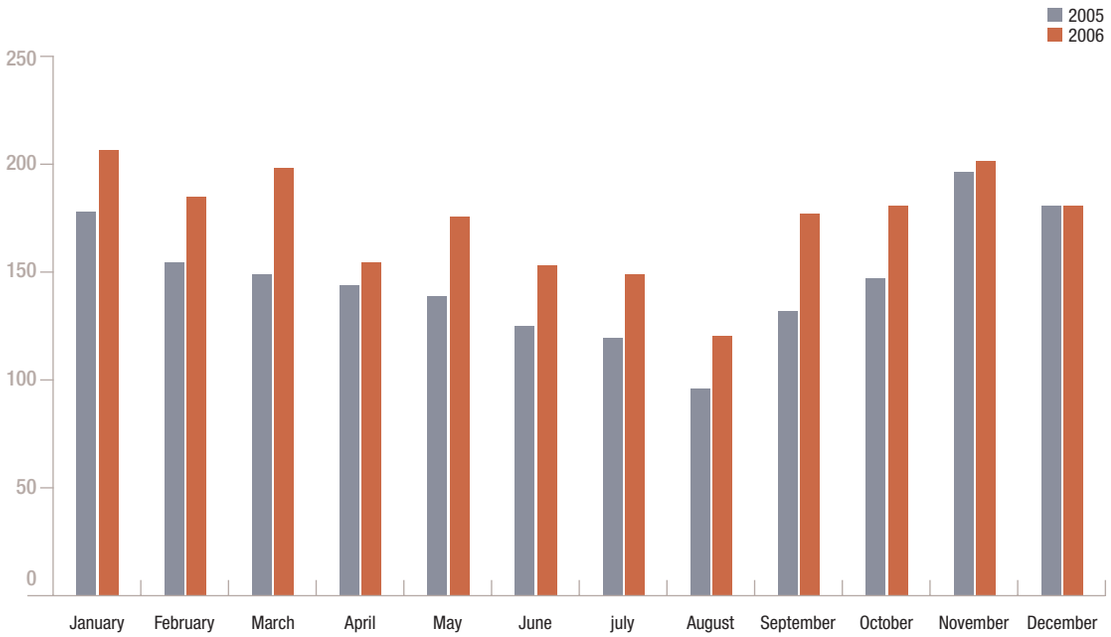
The annual declaration also includes information corresponding to the SIGRE points at pharmacies in all of Spain (20,306), pharmaceutical distribution warehouses which collaborate (145), the collected packaging waste, its classification and its final treatment.

The indicator for citizen cooperation improved by 11.7% compared to 2005 and the average monthly collection per 1,000 inhabitants has reached 4.2kg.

This figure, when considered with the 3.7% increase produced in the quantity of packaging materials which were able to be recycled, endorses the efforts made by the pharmaceutical industry to minimise the environmental impact of its products.

The greater response from citizens and the increase in recycled packaging reduces the environmental impact of the pharmaceutical industry

WEIGHT OF WASTE PACKAGING COLLECTED NATIONWIDE (TONNES), 2005-2006



The pharmaceutical industry's prevention work through SIGRE

The pharmaceutical industry put into action its 3rd Business Prevention Plan (Plan Empresarial de Prevención, PEP) for the sector in 2006, to last till 2008.

This 2006-2008 PEP includes new objectives and prevention measures which the pharmaceutical laboratories should apply to reduce the environmental impact of packaging through the full life cycle.

The first year of the 2006-2008 PEP has produced positive results that reflect the effort made by the industry to achieve the minimisation of the different types of packaging, having applied 97 different prevention measures that have reached over 21 million packages.

OVERALL REDUCTION OBTAINED IN 2006

	2005	2006	Percentage of overall reduction
Kr: total quantity (t) of packaging waste generated in a year	57,852,711	57,430,853	2.4%
Kp: total quantity (t) of packaged products consumed in same year	100,423,929	102,168,862	
(Kr/Kp) overall	**0.576**	**0.562**	

Meanwhile, SIGRE also published in 2006 the document, "Pharmaceutical Sector Initiatives in Preventing Packaging Waste", which describes, in the style of a guide, a selection of the measures adopted for pharmaceutical laboratories to reduce the environmental impact of their packaging, without it supposing a reduction of the levels of quality, safety or effectiveness.

Communications campaigns

The citizen is a key component in SIGRE's operations. For this reason, the development of communications campaigns and citizen awareness-raising to sensitize citizens over the necessity to collaborate with this pharmaceutical industry environmental initiative is one of SIGRE's priorities. These campaigns also count with the collaboration and support of the Regional Ministries of Environment and Health in all the Autonomous Regions.

The new campaign produced by SIGRE in 2006, with the title "A gesture for the Environment", was designed so as to seek the involvement in, and commitment of, citizens, so that they are encouraged and invited to deposit the packaging and remains of medicines in the SIGRE Point at the pharmacies.

Proof of the effectiveness of these communications campaigns, that periodically take place, is the important drop in the percentage of those who said that they continued to throw the remains of medicines in their bin at home: from 43% in 2001 down to 8% in 2006.

The number of visits to the SIGRE website (www.sigre.es) receives has increased more than 30,000 since it was updated.

During 2006, SIGRE has participated in a series of Congresses and Symposia, such as the 15th National Pharmaceutical Congress, and the biennial National Environmental Congress, CONAMA 8, the most important event in the environmental field in Spain.

The percentage of citizens who say they throw medicine waste away at home has dropped from 43% in 2001 to 8% in 2006

The document "Pharmaceutical Sector Initiatives in Preventing Packaging Waste" describes measures adopted by laboratories to reduce the environmental impact of their packaging.

The 2006 campaign titled "A gesture for the Environment", seeks the involvement of citizens.

Workshops

For the 5th Anniversary of SIGRE's launch, the traditional *Workshop for the Affiliated Laboratories* took place in Santiago de Compostela, organised such that the participants could visit the Medicines Selection and Classification Plant at Cerceda (La Coruña).

During the visit, representatives of the laboratories were able to appreciate the different activities that take place in selecting medicine packaging that can be recycled from those which need another environmental treatment for controlled elimination.

Information days organised by SIGRE during 2006.

Legislative framework

The approval of the Safeguards and Rational Use of Medicines and Medical Devices Act, 29/2006, meant the incorporation into Spanish health law of various new measures related to the environment.

Among these there is the obligation to include on the packaging "the symbol authorised by the Spanish Medicines Agency to facilitate the application and development of the system of collection of medicine wastes and contribute to environmental protection".

This fact confirms the commitment made by the Spanish pharmaceutical industry when it designed the SIGRE system and decided to assume the management of unused or out-of-date medicines generated at home, although the legislation at the time did not demand it. In this sense, it is the SIGRE Symbol that has for years been a proof of the pharmaceutical industry's environmental commitment.

Medicines and corporate social responsibility

Although society has known, for years now, the high value of medicines, the sector is facing new challenges, since society's expectations are growing and demand is not only about product quality but also about the environment. In this sense, the pharmaceutical industry has been pioneer in introducing criteria of environmental responsibility as part of corporate policy, with SIGRE being a clear example of that. The warm welcome this environmental initiative has had from citizens and administrations, and the influence that it is having on the image of the pharmaceutical industry, confirm the importance of corporate social responsibility when it comes to assessing the behaviour of businesses.

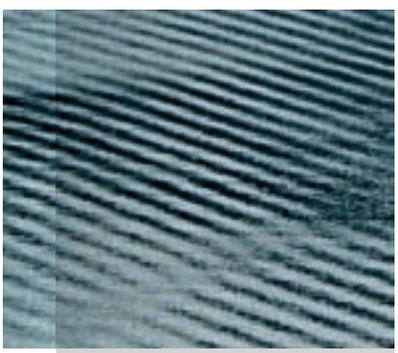
02 THE PHARMACEUTICAL INDUSTRY IN SPAIN AND WORLDWIDE

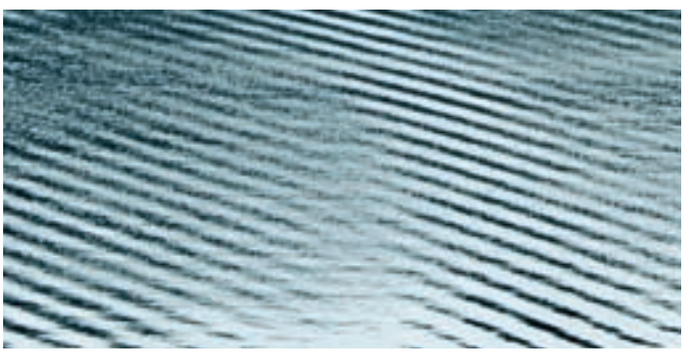
1. The pharmaceutical industry in Europe

The European pharmaceutical industry worked in 2006 in an economic climate that, judging from its main indicators, evolved favourably. GDP growth in the EU-25 was 2.9%, while in the Eurozone it was 2.6%, in both cases 1.2% above the growth registered in 2005. These are the highest growth rates recorded since 2000, with 20 of the 25 states that make up the EU[5] growing at a higher rate than in 2005.

The main highlight of the year was the awakening of the two main economies of the EU: Germany turned in its best growth since 2000 (2.7%), while French GDP grew at a rate of 2.2%, one percentage point above its 2005 performance. It was also notable that Italy recovered from the stagnation in which it has been immersed in the past few years.

This economic prosperity is also resulting in a substantial improvement of the imbalances which were dogging the main European economies: unemployment, public deficit, and high level of debt. Nevertheless, there is one indicator that did not improve and that continues to be the cause of uncertainty and concern: inflation. In 2006, the price index stayed stable at around 2.2%, somewhat above the level considered acceptable by the European Central Bank (ECB), which is 2%. This has obliged the Bank to adopt a restrictive monetary policy, with successive increases in the price of money, which has seen interest rates rise from 2.25% at the end of 2005 to 3.5% at the end of 2006.





For 2007, the main international organisations (IMF, World Bank and European Commission) foresee a slight deceleration in the European economy of around four to five tenths of a point below the growth rates registered in 2006. The actual rate of the deceleration, however, will depend, among others, on the following factors:

- The increase in VAT in Germany: the general rate for VAT in Germany increased from 16% to 19% on 1 January 2007. Although its effects on the German economy are as yet uncertain, it could provoke a reduction in consumption and investment levels in Germany.

- The euro being favourable against the dollar: the euro rose against the dollar in 2006 for the fifth year in succession. The situation was exacerbated in the first quarter of 2007 due to the North American crisis in the high-risk mortgage sector and the cooling of its property market. If the euro-dollar trend continues in this way, pernicious effects on the European trade balance will be inevitable.

- The rate rises applied by the ECB during 2006 will very probably continue in 2007, which, while it will help control inflation, could weigh down EU growth.

Spain is the fifth European market in terms of sales volumes and job creation in the pharmaceutical industry

All things considered, 2006 was a rather positive year for the European economies, but the factors cited above, together with others just as important (such as geopolitical tensions in the Middle East which could unleash a rise in energy prices, with the consequent negative effect on inflation and interest rates) support the forecast of a slowdown in growth for 2007.

[5] The composition of the EU at 31 December 2006 is taken as the reference here. The values for Romania and Bulgaria (EU) have not been incorporated, nor have those for Slovenia (Eurozone).

Due to its special characteristics, the evolution of the pharmaceutical market is not always closely related to the general course of the economy; it is influenced by other factors such as the scope of social protection policies applied in each country and measures adopted by different States to slow down growth in pharmaceutical expenditure. For this reason, there is nothing new about the fact that the higher growth in the European economies has not been reflected in the pharmaceutical sector. Proof of this is that, while real GDP growth (at market prices) for the five largest EU economies rose from 3.1% in 2005 to 4.5% in 2006, the weighted average growth rate for the pharmaceutical sector in these five countries fell from 3.9% to 3.3%.

EVOLUTION OF THE PHARMACEUTICAL MARKET IN THE MAIN EUROPEAN COUNTRIES

	Variation (%) 2006/05	% Sales/Total for 5 countries 2006
Germany	2	29
France	4	26.8
Italy	2	15.6
United Kingdom	3	16.4
Spain	6	12.2
TOTAL 5 COUNTRIES	**3.3**	**100**

Source: FARMAINDUSTRIA/IMS Retail Drug Monitor

In the following table, the position Spain occupies in the European pharmaceutical arena can be observed, where it is the fifth most important market in volume of sales and generation of employment – behind Germany, France, Italy and the United Kingdom – and the sixth largest producer, after these four countries and Ireland.

GENERAL DATA ON THE EU PHARMACEUTICAL INDUSTRY (2005)

Country	Nº Labs*	Production (€m)**	Employment	Int. sales (€m)	Ext. trade (EFP) (€m) Imports	Exports
Germany	310	22,653	113,100	24,846	24,643	30,696
Austria	119	1,799	10,002	2,410	3,382	3,630
Belgium	140	4,812	28,605	3,657	28,779	28,164
Denmark	43	4,593	16,933	1,536	1,884	5,146
Spain	219	11,114	39,285	11,332	7,230	5,430
Finland	64	753	6,097	1,742	1,418	624
France	256	34,316	101,500	23,838	13,817	18,457
Greece	65	525	11,350	3,821	2,730	928
Netherlands	47	5,664	16,200	3,795	9,396	9,548
Ireland	56	15,146	24,000	1,514	1,993	14,531
Italy	219	19,300	74,000	15,749	11,201	10,573
Portugal	139	1,745	10,953	3,105	1,646	297
United Kingdom	75	22,935	68,000	15,569	12,834	18,077
Sweden	61	5,720	20,974	2,673	2,202	5,783
TOTAL EU-15	**1,813**	**151,075**	**540,999**	**115,587**	**123,154**	**151,884**

Source: FARMAINDUSTRIA, from EFPIA, national pharmaceutical industry associations & Eurostat.

Note: It does not include Luxembourg since it is barely representative *Members of EFPIA associations. **Data refers to proprietary medicinal production activities and raw materials for human and veterinary use, except in Spain, where it corresponds only to activities destined for human use.

2. The pharmaceutical industry in Spain

2.1. R&D

Investment in R&D plays a key role when the goal is to increase productivity and competitiveness of an economy and in the same way to set up the basis for its future growth. For this reason, every developed country places great importance on policies that contribute to encouraging this type of investment.

The most used indicator to measure research effort (R&D spend/GDP) shows that Spain has important deficiencies in this area. In Spain, only the equivalent of 1.06% of GDP goes to R&D activities, which situates the country behind all its European partners in the old EU-15, with the exception of Greece and Portugal. Likewise, some of the countries which have recently acceded to the EU also beat us in this indicator. Slovenia and the Czech Republic are clear examples of this.

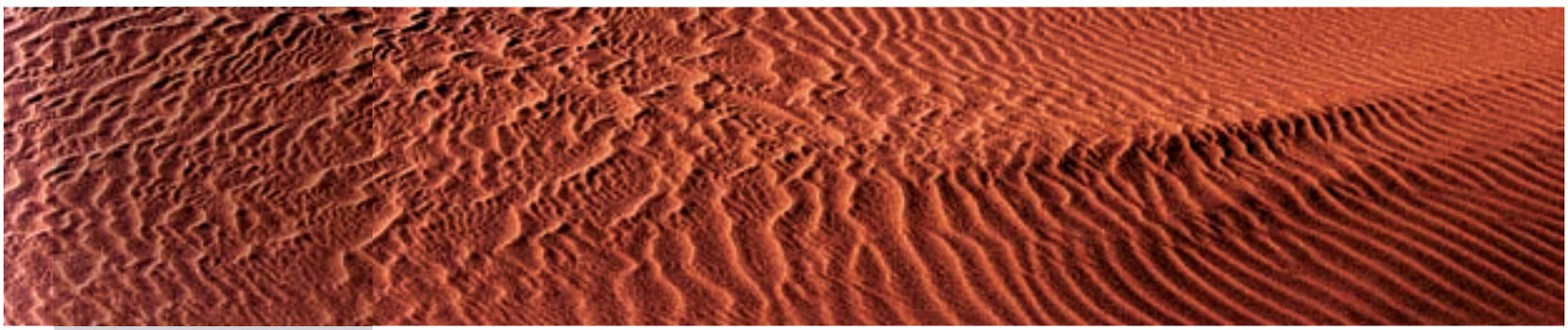
A low rate of investment in R&D also results in a heavy technological dependence abroad. The latest data published by the Bank of Spain are a reliable reflection of this: the balance of royalties (which measures the annual flow of receipts and payments between Spain and the rest of the world for the use of patents) reveals a large deficit for 2006 (-1,247 million euros), with a very low coverage rate, just 37%, which only goes to show our shortcomings in this sense.

It would be an interesting and instructive exercise to study how the main developed economies finance their R&D. According to figures published by Eurostat, which we summarise in the following table, it can be seen how, in the main capitalist economies, the highest rates of R&D investment occur when the private sector is the motor of research. In these cases (Japan and the US principally), public investment plays a complementary role to private research. Albeit in a lesser sense, the EU also exhibits this relationship.

R&D SPENDING ACCORDING TO SOURCE OF FUNDS (2004)

	R&D spending (% of GDP)	SOURCE OF FUNDS		
		% Private	% Public	% Foreign/others
Japan	3.20%	74.5	17.7	7.8
US	2.67%	61.4	30.4	8.2
EU-25	1.85%	54.9	34.6	10.5
Spain	1.06%	48.0	41.0	11.0

Source: Eurostat.



The pharmaceutical industry leads job creation in R&D in Spain

In Spain, however, private investment in R&D is much more modest. Additionally, far from improving in this sense, the percentage of investment in R&D financed by the private sector is at the lowest since 2001, having fallen in the last two years. It is necessary to promote and implement policies that incentivize R&D carried out by the private sector, stimulating investment decisions in the most intense R&D sectors, such that private capital can perform a clear leadership role in the area of research and development.

Of the most intensive R&D sectors, pharmaceuticals is, without any doubt, the most important one, as it becomes evident after analysing the figures published by INE, the Spanish National Statistics Institute, on R&D activities and its survey on technological innovation:

- Pharmaceuticals is, after automobile, the industrial sector that invests more resources in research in Spain, although it has to be taken into account that the automobile industry sales are three times higher than pharmaceuticals. As INE states, the pharmaceuticals companies dedicated more than 763 million euros to research in 2005, which represents 17% of the total R&D spending made by all of the industrial sectors put together. This percentage is especially significant if it is taken into consideration that the sales of pharmaceuticals companies only amount to 2.2% of the industry total. Therefore, the pharmaceutical industry dedicates 6.5% of its sales volume to R&D activities, while industry as a whole only dedicates 0.8% on average.

- The pharmaceutical industry leads, alongside machinery, employment creation in research, with 4,365 professionals dedicated full-time to this task, which represents more than 11% of the total employment in research across the whole of industry. The pharmaceutical sector also leads in contracting researchers, able to count on 2,094 professionals dedicated exclusively to R&D tasks.

R&D ACTIVITY IN SPANISH COMPANIES (2005)

Sector	R&D personnel*	R&D spending (€m)			
		Internal	External	Total	% Δ up on 2004
Total industry	38,952	2,995.04	1,518.25	4,513.29	9.9
Aerospace	2,702	296.82	144.82	441.64	8.4
Automobile	3,474	268.10	644.68	912.78	17.6
Pharmaceutical	4,365	544.11	219.74	763.84	11.7
Radio, TV, comms.	1,754	121.65	22.25	143.89	10.3

* Personnel, FDE (Full Day Equivalent).

Source: FARMAINDUSTRIA, from National Statistics Institute (INE Survey on Technological Innovation 2004 & 2005 and Statistics on R&D activities 2005).

›› Another interesting reflection can be obtained from studying the relationship between sales growth in a sector and the increase in its R&D investment over long periods of time. It must be pointed out here that the average growth in R&D investment in the pharmaceutical industry over the past 10 years is double its average revenue growth during the same period, which proves the whole-hearted commitment of the pharmaceutical industry to research activities. Pharmaceutical research is also constant and sustained in time, which contrasts with other sectors that are also intensive in R&D investment but much more cyclical in this respect.

COMPOUND ANNUAL GROWTH RATE (CAGR) (1995-2005)

Sector	Revenues (%)	R&D spending (%)
Total industry	6.9	9.8
Aerospace	13.2	9.5
Automobile	5.6	12.8
Pharmaceutical	6.1	12.2
Radio, TV, comms.	3.9	-2.7

Source: FARMAINDUSTRIA/Spanish National Statistics Institute (INE), "Industrial Survey of Companies", "Statistics on R&D Activities".

The data show the extraordinary strategic importance of the pharmaceutical sector in the area of research in Spain, not only in terms of the amount of resources it dedicates to these activities, but also for its high and sustained rhythm of growth, as well as its capacity to generate highly-qualified employment.

It should not be forgotten, however, that a high-risk business model such as pharmaceuticals production, characterised by a long-cycle research process ever more costly and already subject to increasing requirements by regulatory bodies, needs a stable legislative framework that allows companies to plan for their investments appropriately. However, a series of events have happened recently in Spain that penalise seriously pharmaceutical R&D activities by taking resources out of the sector with the purpose of containing growth in public pharmaceutical spending, without respect for the necessary balance that has to exist between the sustainability of public budgets and the maintenance and development of Spain's industrial sector.

The principal events that have lead to this situation are as follows:

›› The Government decreed a widespread 2% reduction in prices of pharmaceutical products that aggravated the effects of the 4.2% cut undertaken in 2005. It has to be taken into account that these mandatory price reductions have affected all medicines on the market for more than one year and which are not subject to the Reference Price System, affecting especially innovative drugs with a patent in force and which are in the period of R&D investment recovery. Additionally, these measures will have reduced the prices of medicines which were already much lower than the European average, which will aggravate the problem of parallel trade that so affects R&D-based pharmaceutical companies.

›› On 28 July 2006 the Safeguards and Rational Use of Medicines and Medical Devices Act, 29/2006, came into force. This law constitutes the basic reference framework for the Spanish pharmaceutical industry. Far from favouring development of the sector, this Act contains a series of economic measures such as: legislative consolidation of the discount for volumes of sales to the NHS; the ob-

ligatory 20% reduction in prices for those products with over 10 years of public financing in Spain that do not have a generic in Spain, but do have a generic in Europe[6] with a price lower than the original's; and an aggressive reference price system, whose entry into force took place in March 2007, which discriminates against the trade mark in favour of the generic and which takes away substantial resources from the pharmaceutical industry.

The difficulties arising from this are now translating themselves into concrete data. The R&D survey that Farmaindustria carries out every year among its member companies shows a 3.6% increase in pharmaceutical R&D spending in 2006, which means a stagnation, due, without doubt, to the application of the above-mentioned measures and the uncertainty that has surrounded the whole process of drafting of the new Medicines Act.

There are two other obstacles that make growth in pharmaceutical R&D spending difficult, and which make Spain less attractive for foreign companies when choosing a location for their research activities:

- *Progressive elimination of tax deductions for R&D in the Companies Tax:* The Act, 35/2006 of 28 November, on Tax on Personal Income and partially amending the Companies Tax laws, Tax on the Income of Non-Residents and on Capital Resources, which came into effect on 1 January 2007, establishes the progressive reduction of fiscal deductions for R&D in the Companies Tax until its complete elimination in 2012. Although it also provides for a lowering of the general tax rate to 30%, this will not compensate for the elimination of these deductions. Pharmaceutical companies, given the volume of resources they invest in R&D, are currently paying taxes at an average effective rate of approximately 22%[7]. Meanwhile, the discounts in Social Security contributions for research personnel constitute a measure that not only does not compensate for the elimination of these tax deductions, but also, additionally, its adoption was foreseen previously in the National Reform Plan, in the framework of the Employment Promotion Programme.

- *Lack of harmonization of Spain with other EU countries in the area of pharmaceutical patents:* Spain is not harmonized with the rest of Europe in the subject of industrial property protection, since it has not incorporated into the Spanish legal system the agreements signed by Spain in 1995 (TRIPS) in the framework of the World Trade Organization. It would appear, then, indispensable to adopt the necessary measures in order to resolve this anomaly; that would avoid the foreseeable legal recourse to resolve this matter and, at the same time, would send a clear message to foreign investors about Spain's commitment regarding protection of industrial property rights and commitment to innovation. The lack of full harmonization in this field is currently impacting very negatively on research-based companies, for two reasons: the expected loss of market share in Spain – due to the earlier launches of generics – compared to the rest of the EU, and the increase in parallel trade.

[6] Only considers those EU members which, without being subject to exceptional or temporary regimes in the area of industrial property, would have incorporated the corresponding Community legislation into their legal systems. In practice, these are all the EU-15 countries, except Greece, Portugal and Finland and, as already recounted, Spain.
[7] Estimates by the Catalonian Professional Association of Economists.

The R&D left undone is as important as the research that has been carried out. In this sense, it is obvious that, in a more stable regulatory environment, the contribution of the pharmaceutical sector to national R&D in the past would have been more than it has been. Recent estimates[8] calculate at more than 1,500 million euros the pharmaceutical R&D investment that will not be undertaken in Spain as a consequence of the application of the economic measures established in the Safeguards and Rational Use of Medicines and Medical Devices Act.

In summary, the pharmaceutical industry is a sector of enormous strategic importance for Spain's future economic growth, since it consists of the industrial sector where R&D is most intensive. However, as we have seen, the many hindrances that are being imposed upon it have been felt in its investment growth rate in the past and will especially be felt in the future. It is of critical importance that the government understands the situation and adopts the necessary measures to make our country an attractive environment for R&D investors, which will eventually reduce our technological dependence and will be key to ensuring the future competitiveness of the Spanish economy and bring it closer to European standards.

2.2. National market

Sales of proprietary medicinal products grew by 7.3% in 2006, reaching a total of 12,153.7 million euros at ex-factory prices (EFP). From this total, 76.2% was sold through pharmacies (+6.2%) and the rest, through hospitals (+10.5%).

INTERNAL PHARMACEUTICAL MARKET (EFP, €M)

	Pharmacies	Increase (%)	Hospitals [e]	Increase (%)	Total	Increase (%)
2004	8,267.46	6.8	2,422.08	12	10,689.54	7.9
2005	8,712.07	5.7	2,619.67[1]	8.2	11,331.74	6
2006	9,258.97	6.2	2,894.74	10.5	12,153.71	7.3

(e) Estimate
(1) Revised

Source: FARMAINDUSTRIA/IMS/own estimates.

Looking at the pharmacies' market, 96.4% of sales correspond to prescription medicines, according to IMS data for 2006. The 2% price reduction imposed by the government in March 2006 resulted in a total increase of 6.7%, which, with the exception of 2005, when there was another general price reduction of 4.2%, is the lowest growth in recent years.

[8] NERA (2006), "Impact of economic regulation on R&D in the Spanish pharmaceutical industry". Available at: www.farmaindustria.es

The fall in Over-the-counter (OTC) medicines continued both in terms of units and value, with a 1% market share reduction in units and a 0.4% market share reduction in value, compared to 2005.

PHARMACEUTICAL MARKET THROUGH PHARMACIES, 2006 (EFP, €M)

	Units (Th.)	Increase (%)	Share (%)	Value	Increase (%)	Share (%)
Prescription	1,060,550	1.9	90.5	8,923.85	6.7	96.4
• *Generics*	*125,180*	*13.9*	*11.8*	*544.99*	*14.6*	*6.1*
OTC	110,710	-9.8	9.5	335.13	-4.1	3.6
Total	**1,171,260**	**0.7**	**100**	**9,258.97**	**6.2**	**100**

Source: IMS, December 2006.

As far as generic medicines are concerned, their sales rose in Spain by 14.6% reaching 545 million euros in 2006. This sales volume represents a share of the prescription market of 6.1%. In terms of units, after growing by 14% in 2006, generic medicines have an 11.8 % market share.

Therapeutic groups

Four groups – Digestive, Cardiovascular, Nervous System and Respiratory – together captured 65% of pharmaceutical market sales in terms of value and 67% in units.

PHARMACEUTICAL SALES THROUGH PHARMACIES BY THERAPEUTIC GROUP IN 2006

Therapeutic Group	Units			Value (EFP)			Average EFP (€)
	Th.	Share (%)	Increase (%)	€,000	Share (%)	Increase (%)	
A Digestive	174,534	14.9	2.8	1,168,139	12.6	7.9	6.69
B Haemotology	48,796	4.2	5.0	377,754	4.1	8.8	7.74
C Cardiovascular	198,131	16.9	4.1	1,971,728	21.3	5.1	9.95
D Dermatology	63,053	5.4	-1.7	302,443	3.3	4.9	4.8
G Genito-urinary	51,810	4.4	2.4	606,007	6.5	5.6	11.7
H Hormones	17,217	1.5	5.9	164,243	1.8	-6.1	9.54
J Anti-infectious	57,274	4.9	-7.1	428,598	4.6	-3.4	7.48
K Hospital solutions	2,545	0.2	0.8	3,053	0.0	1.9	1.20
L Antineoplastics	5,893	0.5	6.0	508,385	5.5	16.1	86.27
M Locomotor	88,697	7.6	2.5	536,658	5.8	6.4	6.05
N Central nervous system	275,673	23.5	0.3	1,996,149	21.6	9.1	7.24
P Antiparasitics	1,165	0.1	5.8	7,215	0.1	16.4	6.19
R Respiratory	135,303	11.6	-5.9	941,958	10.2	3.1	6.96
S Sensory organs	49,022	4.2	2.3	217,882	2.4	6.2	4.44
T Diagnostic agents	137	0.0	-7.1	1,896	0.0	16.9	13.84
V Miscellaneous	2,012	0.2	-1.6	26,867	0.3	6.3	13.35
Total	**1,171,262**	**100**	**0.7**	**9,258,975**	**100**	**6.2**	**7.91**

The Spanish trade deficit in the pharmaceutical sector is at its lowest since 1999

Central nervous system is the group with the largest market share both in terms of units and value. Following the trend of recent years, this group maintains a moderate growth of 0.3% in terms of units and although the increase by value is higher than the market average, the average price is lower in spite of being the group where most innovations are marketed.

The next group by market share is Cardiovascular System, which, like the year before, showed an increase by units higher than the market average. The average price of medicines in this group rose by just 1%, which means that this group remains below the market average in terms of value.

Digestive System registered above-average growth in sales, as much by value as by number of units. In this group, anti-ulcer treatments represent 37% and their average price fell by 0.5% during 2006, which has contributed to the average price of medicines in this group remaining below the average price for the whole market.

Elsewhere, the fall in units sold in the Respiratory System and Dermatology groups was in both cases accompanied by an increase in revenues. In the Dermatology group, the explanation is found in the appearance of a pharmacological innovation that improves the treatment of certain pathologies. In the Respiratory System group, there was a drop in the number of units sold in several therapeutic subgroups of high private consumption, with low prices, and so the fall could be related to the advertising campaigns on rational use of medicines.

Anti-infectious drugs decreased both in terms of units and by value. Although the fall in units sold has been observed in years before, this year it was more pronounced, possibly due to a better use of antibiotics because of the advertising campaigns mentioned above.

New launches

2006 saw sales of new products on the prescription market at 75.1 million euros, a fall of 27% compared to the sales registered for products launched in 2005. Market share of these products has been falling in recent years and they represented 0.4% of all units sold and 0.8% of total sales by value, compared to figures of 1% and 1.8%, respectively, recorded in 2003.

Of the 189 new products introduced in the prescription market in 2006 (47 less than the year before), 141 are generic medicines and their sales represent 53% of total sales of new products by units. Only 15 products correspond to new molecules.

The new products were centred mainly on two therapeutic areas: Central Nervous System, with 46 new products, 36 of which were generics, and Cardiovascular System with 31 new products, 27 of them generics.

In terms of revenues, 49% of the sales of new products correspond to the Central Nervous System category, which is followed by Antineoplastics on 18%. It is in these two groups that product sales corresponding to new molecules are concentrated, 64.5% and 27.5%, respectively.

2.3. International trade

The foreign trade deficit grows in Spain year after year. At the close of 2006 it was 89,687 million euros, equivalent to 9.2% of GDP. Currently Spain is, among the developed countries, the one that has the highest foreign trade deficit in relative terms and the third, behind the United States and the United Kingdom, in absolute terms.

However, it is important to point out that the rate of growth of Spain's foreign deficit slowed over the past year. If in 2004 the trade deficit grew 31% compared to the year before and in 2005 grew by 28%, the rate of growth of the deficit in 2006 was 15.3%.

This slowdown in the deficit growth rate was possible thanks to an increase in exports, which grew in 2006 by 10.6% in nominal terms, 5.8 points above the growth recorded in 2005. Imports, on the other hand, grew at a rate similar to in 2005 (12.2% in 2006 compared to 11.7% in 2005). Coverage rate had fallen to 65.4% by the end of 2006 from 66.4% at the start of the year.

Focusing on the pharmaceutical sector, it was noticeable in 2006, as in other years, that trade did not keep in step with the overall economic situation, maintaining relatively independent behaviour patterns. In 2006, then, within a general context of growing trade deficit as described, the pharmaceutical trade balance experienced a notable recovery. In fact, during 2006, the trade deficit fell by 32%, from -2,461 million euros in 2005 to -1,674 million in 2006, which translates into an important increase in the coverage rate of the pharmaceutical trade balance, from 66.2% in 2005 to 78.2% in 2006. This was the second consecutive year where the pharmaceutical trade deficit came down and is now at its lowest level since 1999.

The main architect of this recovery has been the way exports have evolved. While pharmaceutical imports maintained a rhythm of growth of 5.3% (similar to in 2005), the sales of pharmaceutical products abroad rose by 24.3%. By value, imports were 7,666 million euros (3% of all Spain's foreign purchases), whereas exports reached 5,992 million euros (3.5% of all Spain's foreign sales).

Breaking this down further, a fall in raw pharmaceutical material imports allowed the raw materials trade balance to show a trade surplus, after the small deficit registered the year before. However, it is in pharmaceutical products where the most marked recovery has happened, with a 29.5% drop in deficit during 2006.

TOTAL EXTERNAL PHARMACEUTICAL TRADE, 2006 (€M)

	Imports	Δ 2006/05 (%)	Exports	Δ 2006/05 (%)	Balance
Raw materials	408.88	-9.7	466.28	4.1	57.4
Pharmaceutical products	7,256.81	6,3	5,525.70	26.4	-1,731.12
• *Medicines*	*5,929.21*	*3.4*	*4,761.56*	*29.8*	*-1,168.35*
Total	**7,665.69**	**5.3**	**5,991.97**	**24.3**	**-1,673.72**

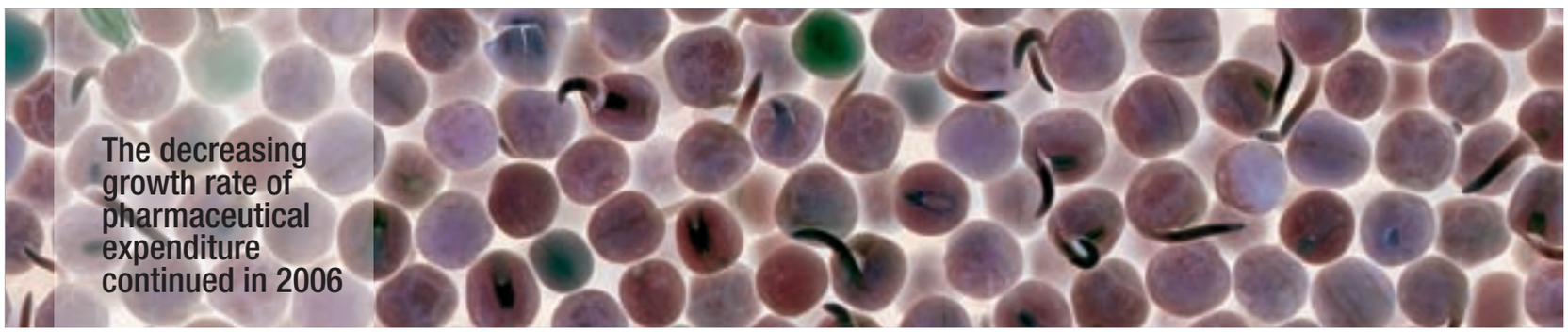
Source: Customs & Special Taxes Office (monthly breakdowns).

As far as the geographical distribution of trade is concerned, the EU-25 continues to be Spain's main commercial partner with 77% of Spanish pharmaceutical imports and 61% of exports. In the past two years, however, Switzerland has attained a special relevance in the subject of pharmaceutical external trade. In fact, Switzerland has become the main destination for Spanish pharmaceutical exports, ahead of countries such as Germany, the United Kingdom, France and the United States.

STRUCTURE OF SPANISH EXTERNAL TRADE IN PHARMACEUTICALS

Geographical Area	2005		2006	
	% Imports	% Exports	% Imports	% Exports
European Union	79.4	64.4	77.0	61.0
Germany	16.1	12.7	15.3	12.3
France	15.3	8.2	15.7	10.1
Italy	7.8	6.6	7.3	5.7
United Kingdom	15.1	13.5	13.8	11.5
Rest of Europe	7.7	15.7	9.1	18.8
Switzerland	7.5	13.6	8.8	16.9
Rest of World	12.9	19.9	13.9	20.2
United States	7.8	7.6	8.6	8.2
Total	**100**	**100**	**100**	**100**

Source: Customs & Special Taxes Office (monthly breakdowns).



2.4. Public pharmaceutical expenditure

Some 796 million prescriptions were issued and charged to Social Security in 2006, 4.1% more than in the year before. These prescriptions have resulted in public spending of 10,636 million euros, 5.8% up on 2005. In 2006, the average cost per prescription reached 13.36 euros, 1.7% up on the average cost in 2005.

PUBLIC EXPENDITURE BY PRESCRIPTIONS DISPENSED IN PHARMACIES

	Public expenditure (€m, Retail price +VAT)	Increase (%)	No. of prscrpns. (millions)	Increase (%)	Spend/prscrpn. (€)	Increase (%)
2004	9,513.0	6.4	728.7	3.2	13.00	3.1
2005	10,051.3	5.6	764.6	4.9	13.15	0.7
2006	10,636.2	5.8	796.0	4.1	13.36	1.7

Source: Ministry of Health & Consumer Affairs (Breakdowns of medical prescription bills)

The trend of recent years to moderate the growth rate in pharmaceutical expenditure was thus maintained. The mandatory 2% reduction in the ex-factory prices of most medicines contributed significantly, as did the 1% cut in the wholesale distribution margin. Also, diverse practices by Autonomous Regions to contain pharmaceutical spending and the growing presence of low-cost medicines on the market have contributed to contain growth of public pharmaceutical expenditure in Spain.

Distribution of public pharmaceutical expenditure by Autonomous Regions

If the distribution per capita expenditure is analysed in the Autonomous Regions, the highest levels corresponded, as in previous years, to Galicia (282.2 euros per capita), the Valencian Region (281.8 euros) and Asturias (280.8). The regions with the lowest pharmaceutical expenditure per capita were, as in previous years, Madrid (184.7 euros), the Balearics (186.2) and Andalusia (218.1).

As far as increases in per capita expenditure in 2006 are concerned, the Madrid region stood out with the highest rise (6.5%), which was accompanied by a sizeable increase in number of prescriptions per head (4.5%). The lowest increases in per capita expenditure in 2006 were recorded in Catalonia (+2.6%), followed by Andalusia (2.9%) and the Balearics (3%).

PER CAPITA PHARMACEUTICAL EXPENDITURE BY AUTONOMOUS REGIONS (2006)

	Expenditure share (%)	Per capita expenditure	
		(euros)	Increase on 2005 (%)
Galicia	7.3	282.2	6.1
Valencian Community	12.7	281.8	4.2
Asturias	2.8	280.8	5.9
Extremadura	2.8	271.8	5.6
Aragon	3.2	267.5	5.7
Castilla-La Mancha	4.8	261.7	4.5
Murcia	3.3	259.9	5.0
Castilla-León	5.9	247.8	4.3
Navarre	1.4	239.6	4.9
Basque Country	4.8	238.9	5.3
La Rioja	0.7	238.4	5.0
Catalonia	15.9	237.2	2.6
Cantabria	1.3	236.7	5.2
Canaries	4.3	231.7	5.3
Andalusia	16.4	218.1	2.9
Balearics	1.8	186.2	3.0
Madrid	10.4	184.7	6.5
Ceuta	0.1	166.4	4.7
Melilla	0.1	145.7	4.9
Total	**100**	**237.9**	**4.4**

Source: FARMAINDUSTRIA, from Min. Health/Cons. Affrs. (Breakdowns of Prescrptn. Billing) & INE (Offl. Popn. Figs. at 1.1.2006).

2.5. Prices of pharmaceutical products

The weighted average price of medicines marketed in Spain in 2006 was 7.91 euros (ex-factory), with significant differences depending upon the segment of the market considered. The average price of medicines that were on the market for five years or less was 13.60 euros, whereas in the case of products marketed for over 20 years the average price was 2.90 euros.

Growth in the general Consumer Price Index (CPI) in 2006 was 2.7%, one point lower than in 2005. Contrary to the general CPI, the "Medicines Group" showed a growth rate of one point above the previous year's rate (1.7% in 2006 compared to 0.7% in 2005).

However, if we analyse the behaviour of price indexes of the different components of the Medicines Group, it can be seen that the sub-group, "Medicines and Other Pharmaceutical Products" decreased by 1.2% in 2006, as the following table illustrates:

INFLATION AND PRICES OF 'MEDICINE GROUP', 2006

Group or sub-group	Annual CPI variation (%)
	2006
General (inflation)	2.7
Medicines	1.7
• Medicines & Other Pharmaceutical Products	-1.2
• Therapeutic Material	2.7
• Non-Hospital Medical & Paramedical Services	4.0
• Dental Services	3.2
• Hospital Services	5.7

Source: Spanish National Statistics Institute (INE).

One explanation for the fall in the medicines CPI in 2006 is the 2% reduction in the prices of most medicines which came into force on 1 March.

On the subject of prices, there are two clearly distinct product segments with very different characteristics and developments. On the one hand, there are the innovative medicines protected by patent and for which, although the difference in prices between EU Member States is gradually narrowing, the price of these products in Spain continues to be one of the lowest in Europe. On the other hand, there is a growing generics market whose development is a priority for most European governments and that in Spain, through the Reference Price System, has brought drastic reductions in the prices of numerous products, which has contributed to reduce the growth rate of the average market price and CPI.

Focusing on the analysis of average prices in the main European countries, the latest data available shows France and Italy as the countries with the lowest average price (measured ex-factory to avoid possible distortions caused by differences in distribution margins), followed closely by Spain. In contrast, Germany, the Netherlands and Belgium are the countries with the highest price levels.

MEDICINE PRICES IN MAIN EU MARKETS (AVERAGE EX-FACTORY PRICE, 2005)

	Average EFP (euros)	Index (Spain = 100)
Germany	14.91	194
Netherlands	12.06	157
Belgium	11.60	151
United Kingdom	11.38	148
Spain	7.70	100
Italy	6.44	84
France	6.44	84

Source: Farmindustria (indicatori Farmaceutici 06) & EFPIA.

In recent years, there has been a progressive harmonization in the procedures for registering new products in EU countries. In Spain, as in other countries such as Austria, Belgium, Finland or Sweden, it is required to notify the price at which the medicine is being sold in other countries, with this information influencing more and more the final decision over price. At the same time, countries such as Denmark, the Netherlands, Italy, Ireland, Norway and Switzerland set prices on the basis of the average prices of different groupings of countries, whereas Portugal adapts its prices to the lowest in the three countries it takes as a reference: France, Italy and Spain.

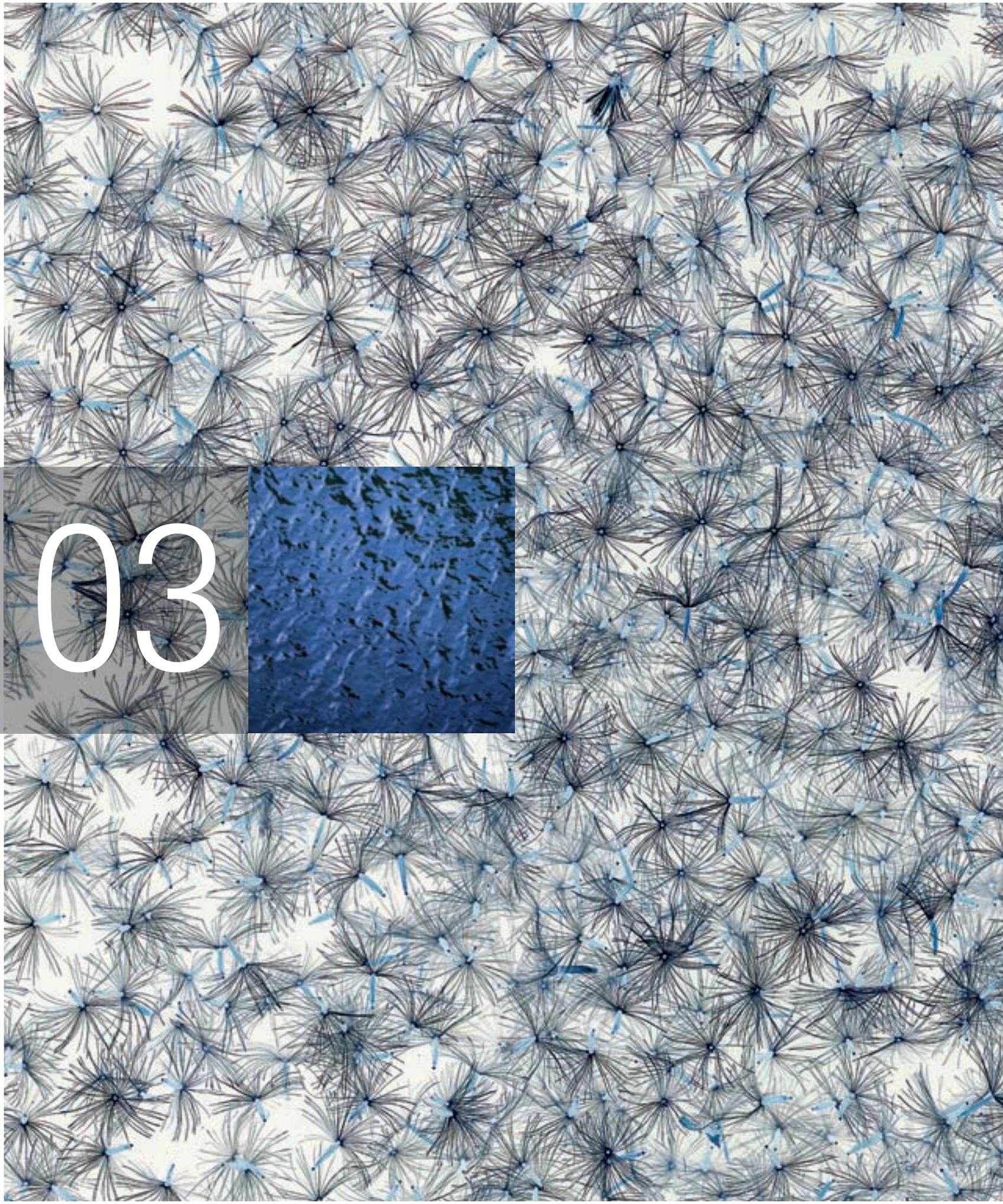
This narrowing process, however, is insufficient to discourage one of the pharmaceutical industry's main problems: parallel trade in medicines, which, as can be observed in the following table, forms a very high percentage of sales in some of the principal European markets.

Medicine prices in Spain are among the lowest in the EU

PARALLEL IMPORTS AS % OF PHARMACEUTICAL SALES (2005)

	Parallel imports/Internal sales
Denmark	15.7%
United Kingdom	14.5%
Sweden	13.9%
Netherlands	11.5%
Norway	8.2%
Germany	5.9%

Source: EFPIA.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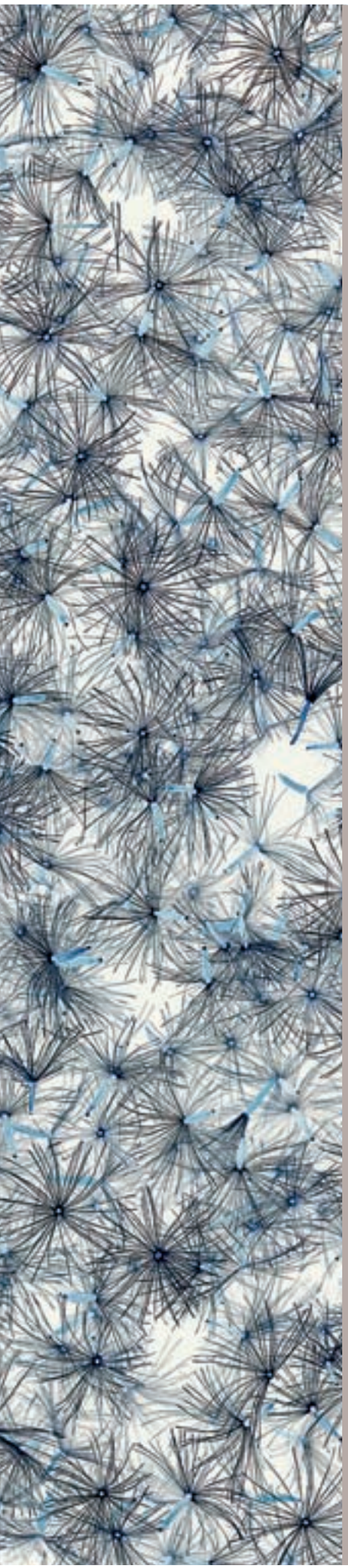

NEW LEGISLATION

Regional Advisory Boards

Order of 22 February 2006, of the Health Ministry of the Galician Government, amending the other of 25 May 2005 regulating the composition, organisation and functioning of the Galician Health Service Advisory Board.

Anatomical Classification of Medicines

Order SCO/114/2006, of 20 January, updating Annex 1 of Royal Decree 1348/2003, of 31 October, to adapt the anatomical classification of medicines to the ATC classification system.

Order SCO/2147/2006, of 26 June, updating Annex 1 of Royal Decree 1348/2003, of 31 October, to adapt the anatomical classification of medicines to the ATC classification system.

Assisted Reproduction

Act 14/2006, of 26 May, on assisted human reproduction techniques.

Order SCO/393/2006, of 8 February, establishing the organisation and functioning of the National Bank for Cell Lines.

Autonomous Regions Statutes

Organic Law 1/2006, of 10 April, Reform of the Organic Law 5/1982, 1 July, of the Statute of Autonomy of the Valencian Region.

Organic Law 6/2006, of 19 July, of Reform of the Statute of Autonomy of Catalonia.

Basic Regional Laws

Act 3/2006, of 20 March, of the Presidency of the Canaries Government, modifying Article 33 of Act 4/2005, of 13 July, on Canaries Pharmaceutical Planning.

Act 7/2006, of 18 October, of the Presidency of the La Rioja Government, modifying Act 8/1998, of 16 June, on La Rioja Autonomous Region Pharmaceutical Planning.

Act 6/2006, of 9 November, of the Presidency of the Extremadura Government, on Pharmacy in Extremadura.

Basic National Laws

Act 29/2006, of 26 July, on Safeguards and Rational Use of Medicines and Medical Devices.

Royal Decree 1030/2006, of 15 September, establishing the portfolio of common National Health System services and the procedure for their update.

Bioethics

Decree 95/2006, of 17 July, of the Health Ministry of the Government of the Regions of Castille-La Mancha, on the Welfare Ethics Committees in the scope of the Castille-La Mancha Health Service.

Order of 13 July 2006, of the Health Ministry of the Galician Government, amending that of 13 February 2001, creating the Galician Bioethics Committee.

Biological Samples

Royal Decree 65/2006, of 30 January, establishing requirements for the import and export of biological samples.

Blood & Haemoderivatives

Decree 13/2006, of 3 February, of the Health Ministry of the La Rioja Government, regulating the donation of blood and haemotherapy of the Autonomous Region of La Rioja.

Decree 28/2006, of 23 March, of the Council of the Government of the Region of Madrid, regulating the constitution of, and functioning of, the system for storing blood from umbilical cords.

Decree 298/2006, of 18 July, of the Health Department of the Catalonian Government, regulating the Haemotherapy Network and creation of the Haemovigilance System in Catalonia.

Order 837/2006, of 6 April, regulating the necessary requirements for the authorisation and accreditation of deposits of blood from umbilical cords in the territorial area of the Region of Madrid.

Clinical Research Ethics Committees

Decree 406/2006, of 24 October, of the Health Department of the Catalonian Government, on the regulation of the requirements and procedures for accreditation of clinical research ethics committees.

Order of 22 February 2006, of the Health Ministry of the Galician Government, to renew the accreditation of the Galician Clinical Research Ethics Committee.

Clinical Trials

Order of 27 December 2006, of the Health and Consumer Affairs Department of the Aragon Government, approving the Tax 35 self-assessment models for clinical trials and other activities relating to medicines and medical devices, and issuing instructions for their Management and Settlement.

Resolution of 23 May 2006, of the General Secretariat of Quality and Modernisation of the Health Ministry of the Andalusian Government, for the approval of the new economic contract model for the carrying out of clinical trials with medicines in the Andalusian Public Health System.

Instruction 3/2006, of 13 June, of the Directorate-General of Health Resources of the Health Department of the Catalonian Government, requirements of the contracts between instigators and health centres of the Catalonian public use health network for the carrying out of clinical trials with medicines.

Compassive Use of Medicine

Order 13 February 2006, of the Health and Consumer Affairs Ministry of the Extremadura Government, creating and regulating the Compassive Use of Medicine Committee in the area of the Autonomous Region of Extremadura.

Defence of competition

Royal Decree 602/2006, of 19 May, approving the Regulation of exemption from certain categories of agreements for interchange of information on arrears.

Decree 29/2006, of 24 January, of the Aragon Government, creating and regulating the Aragon Competition Defence bodies.

Decree 36/2006, of 25 May, of the Economics and Employment Ministry of the Castilla-León Government, attributing competence in the area of competition defence and creating the Competition Defence Court of the Region of Castille-León.

Decree 169/2006, of 10 November, of the Council of the Valencian Government, approving the Statute of the Valencian Region Competition Defence Court.

Conditioning Material

Information Note, of 29 November 2006, of the Spanish Medicines & Medical Devices Agency, relating to the requirements for the information in Braille on the outside of packaging of medicines for human use.

Consumers & Users

Act 44/2006, of 29 December, improving consumer and user protection.

Act 1/2006, of 7 March, of the Cantabrian Parliament, for the Defence of Consumers and Users.

Regional Act 7/2006, of 20 June, for the Defence of Consumers and Users.

Act 16/2006, of 28 December, of the Presidency of the Aragon Government, on the Protection and Defence of Aragon Consumers and Users.

Dietetic Products

Order SCO/3858/ 2006, of 5 December, regulating certain aspects related to the supply of dietetic products by the National Health System.

Distribution of Medicines

Information Note of 5 October 2006, of the Spanish Medicines & Medical Devices Agency, relating to the temporary Provision of the Safeguards and Rational Use of Medicines and Medical Devices Act, 29/2006 of 26 July.

Information Note of 18 October 2006, Directorate-General for Pharmacy and Medical Devices, on application of Article 3.6, Safeguards and Rational Use of Medicines and Medical Devices Act, 29/2006 of 26 July.

Doping in Sport

Ratification instrument, of 26 September 2006, for the International Convention Against Doping In Sport, made in Paris on 18 November 2005.

Organic Act 7/2006, of 21 November, on health protection and the fight against doping in sport.

Resolution of 21 December 2006, of the Presidency of the High Council for Sport, for the approval of the list of banned substances and methods in sport.

Early Stage Researchers

Royal Decree 63/2006, of 27 January, approving the Statute of early stage researcher.

Order ECI/2441/ 2006, of 17 July, for the regulation of the grants registration procedure in the General Registry of programmes of research grants, created by virtue of Royal Decree 63/2006, of 27 January, approving the Statute of early stage researcher.

Electronic Signature

Decree 94/2006, of 8 November, of the Council of the Government of the Region of Madrid, on use of the electronic signature in relations with the Region of Madrid Administration by electronic, computer or telematics means.

Order of 11 October 2006, of the Justice and Public Administration Ministry of the Andalusian Government, regulating use of the port@firma system for the electronic signature of documents in electronic form.

Environment

Act 9/2006, of 28 April, on the assessment of the effects of certain environmental plans and programmes.

Act 27/2006, of 18 July, regulating rights of access to information, public participation and access to justice in the area of the environment (incorporates Directives 2003/4/EC and 2003/35/EC).

Royal Decree 252/2006, of 3 March, revising the recycling and assessment objectives established in the Packaging and Packaging Waste Act 11/1997, of 24 April, amending the Regulation for its development and execution, approved by Royal Decree 782/1998, of 30 April.

Correction of errors in the Royal Decree 252/2006, of 3 March, revising the recycling and assessment objectives established in the Packaging and Packaging Waste Act 11/1997, of 24 April, amending the Regulation for its development and execution, approved by Royal Decree 782/1998, of 30 April.

Royal Decree 777/2006, of 23 June, amending Royal Decree 1866/2004, of 6 September, approving the National Allocation Plan for greenhouse gas emission allowances, 2008-2012.

Royal Decree 1370/2006, of 24 November, approving the National Allocation Plan for greenhouse gas emission allowances, 2008-2012.

Order MAM/1444/2006, of 9 May, designating the Directorate-General of Quality and Environmental Assessment of the Environmental Ministry as National Authority for the National Atmospheric Contaminant Emissions Inventory System.

Order MAM/1445/2006, of 9 May, on tariffs of the National Registry of Emission Allowances.

Order MAM/3624/2006, of 17 November, amending Appendix 1 of the Regulation for the development and execution of the Packaging and Packaging Waste Act, 11/1997 of 24 April, approved by Royal Decree 782/1998, of 30 April, and the Order of 12 June 2001, establishing conditions for

the non-application of the levels of concentration of heavy metals established in Article 13 of the Packaging and Packaging Waste Act, 11/1997 of 24 April, to glass containers.

Act 2/2006, of 5 May, of the Presidency of the Valencian Government, on Prevention of Contamination and Environmental Quality.

Act 7/2006, of 22 June, of the Presidency of the Aragon Government, on environmental protection in Aragon.

Act 1/2006, of 23 June, of the Presidency of the Basque Government, on Waters.

Act 12/2006, of 27 July, of the Department of the Presidency of the Catalonian Government, on measures in the area of the environment and amendment of Acts 3/1998 and 22/2003 relative to animal protection, of Act 12/1985 on open spaces, of Act 9/1995 on motorised access to natural areas, and of Act 4/2004 relative to the process of adapting activities with an environmental impact.

Act 11/2006, of 14 September, of the Presidency of the Balearic Islands, on assessments of environmental impact and strategic environmental assessments in the Balearic Islands.

Cantabrian Act 17/2006, of 11 December, on Integrated Environmental Control.

Decree 2/2006, of 10 January, of the Aragon Government, approving the Regulation for the production, possession and management of non-hazardous industrial waste and the legal system of the public service for the elimination of non-hazardous industrial waste which is not liable for assessment in the Aragon Autonomous Region.

Decree 4/2006, of 13 January, of the Ministry of Tourism, Environment and Regional Policy of La Rioja Government, regulating the waste production and management activities.

Decree 127/2006, of 15 September, of the Valencian Government, developing Act 2/2006, of 5 May, of the Valencian Government, on Prevention of Contamination and Environmental Quality.

Decree 397/2006, of 17 October, of the Department of Environment and Housing of the Catalonian Government, on the application of the system of greenhouse gas emission trading allowances and the regulation of the system of accreditation of inspectors of greenhouse gas emission reports.

Decree 182/2006, of 12 December, of the Ministry of Environment and Town and Country Planning of the Canaries Government, determining the competent environmental body and integrated environmental authorisation procedure.

Regional Decree 93/2006, of 28 December, approving the Regulation developing the Regional Intervention for Environmental Protection Act 4/2005, of 22 March.

Order of 24 March 2006, of the Department of Environment of the Aragon Government, developing the registration procedure for the Registry of producers of non-hazardous industrial waste.

Order MAH/294/ 2006, of 31 May, of the Department of Environment and Housing of the Catalonian Government, publicising taxes in force and managed by the Catalonian Waste Agency.

Order of 15 June 2006, of the Department of Environment and Sustainable Development of the Galician Government, developing the Decree 174/2005, of 9 June, regulating the legal system for the production and management of waste and the General Registry of Producers and Managers of Waste of Galicia.

Order of 9 October 2006, of the Ministry of Environment of the Andalusian Government, designating the National Accreditation Body as the accreditation organisation for inspectors of greenhouse gas emissions in Andalusia.

Order MAH/491/ 2006, of 18 October, of the Department of Environment and Housing of the Catalonian Government, on the computing format and medium for the basic project and other documentation that has to accompany the application for environmental authorisation of the activities in Annex 1 and environmental licence of the activities in Annex 2.1 of the Integral Intervention of Environmental Administration Act, 3/1998 of 27 February.

Resolution of 29 November 2006, Ministry of the Environment of the Cantabrian Government, to appoint the National Accreditation Body (ENAC) as accreditation organisation for the Community of Cantabria in agreement with that regulated by Royal Decree 1315/2005, of 4 November, to establish the basis of the monitoring and verification systems for greenhouse gas emissions.

European Pharmacopoeia

Circular 2/2006, of 22 January, of the Spanish Medicines & Medical Devices Agency, information on Resolutions of the European Council's Public Health Committee (Mid-Term Agreement), on the subject of the European Pharmacopoeia.

External Health

Resolution of 15 March 2006, of the Undersecretaryship of the Ministry of the Presidency, to publicise the Council of Ministers Agreement of 17 February 2006, to establish a Plan of Measures for the Improvement of External Health Services.

External Trade

Circular 1/2006, of 1 June, of the Spanish Medicines & Medical Devices Agency, on external trade of medicines between Spain and the Swiss Confederation.

Fees

Order SLT/240/2006, of 2 May, of the Department of Health of the Catalonian Government, relating to current Health Department fees, with identification of the services and corresponding charges.

Foundations

Act 12/2006, 1 December, Presidency of the Galician Government, foundations of Galician interest.

Genetically Modified Organisms

Decree 65/2006, of 7 March, of the Aragon Government, determining the competent bodies of the Administration of the Autonomous Region of Aragon and establishing the rules of procedure, in the area of activities of confined use, voluntary release and marketing of Genetically Modified Organisms.

Decree 69/2006, of 19 May, of the Council of the Valencian Government, creating the Valencian Committee for the Control of Genetically Modified Organisms.

Health Centres, Services & Establishments

Order SCO/1741/2006, of 29 May, amending the annexes of Royal Decree 1277/2003, of 10 October, establishing the general basis for the authorisation of health centres, services and establishments.

Decree 31/2006, of 21 February, of the Department of Health of the Basque Government, on authorisation of health centres, services and establishments.

Health Cohesion Fund

Royal Decree 1207/2006, 20 October, re management of the Health Cohesion Fund.

Royal Decree 1302/2006, of 10 November, establishing the basis for the procedure for the designation and accreditation of the centres, services and units of reference of National Health System.

Health Inspection

Decree 56/2006, of 28 April, of the Council of the Valencian Government, approving the Regulation for the Organisation and Functioning of the Inspection of Health Ministry Health Services.

Health Ministries

Decree 1/2006, of 13 January, of the Council of the Valencian Government, amending Decree 26/2005, of 4 February, approving

the Organic and Functional Regulation of the Health Ministry.

Decree 15/2006, of 14 February, of the Health Department of the Catalonian Government, on the creation of the Strategy and Coordination Secretariat of the Health Department.

Decree 45/2006, of 23 February, of the Health Ministry of the Galician Government, to establish the organic structure of the Health Ministry.

Decree 47/2006, of 19 May, of the Balearic Islands Health and Consumer Affairs Ministry, amending Decree 14/2002, of 1 February, on the Ordering of Competences in the area of Health and Health Services.

Decree 103/2006, of 13 October, of the Council of the Cantabrian Government, amending the basic structure of the Ministry of Health and Social Services.

Decree 221/2006, of 7 November, of the Aragon Government, amending Decree 267/2003, of 21 October, approving the organic structure of the Health and Consumer Affairs Department.

Decree 97/2006, of 8 November, of the Council of the Region of Madrid Government, amending the organic structure of the Health and Consumer Affairs Ministry.

Order SAN/972/2006, of 9 June, of the Health Ministry of the Castilla-León Government, amending the organic structure of the Central Services of the Health Ministry.

Health Protection Agencies

Decree 128/2006, of 9 May, of the Health Department of the Catalonian Government, approving the Health Protection Agency Statute.

Order of 7 June 2006, of the Health Ministry of the Valencian Government, for the constitution of the Valencian Health Agency's Abucasis Management Office.

Order of 4 September 2006, of the Valencian Health Ministry, amending the Order of 7 June 2006 constituting the Valencian Health Agency's Abucasis Management Office.

Health Services

Decree 39/2006, of 21 April, of the Health and Consumer Affairs Ministry of the Balearic Islands Government, approving the Statutes of the Health Services public corporation of the Balearic Islands.

Decree 46/2006, of 23 February, of the Health Ministry of the Galician Government, establishing the organic structure of the Galician Health Service.

Decree 45/2006, of 21 April, approving the Statutes of the Navarre Health Service/Osasunbidea.

Health Research

Order of 21 April 2006, of the Department of Health and Consumer Affairs of the Aragon Government, regulating health declarations of interest for certain activities.

Order of 16 May 2006, of the Health Ministry of the Basque Government, regulating the recognition of health interest for scientific activities taking place in the Autonomous Region of the Basque Country.

Health Research Institutes

Order SCO/1245/2006, of 18 April, developing Royal Decree 339/2004, of 27 February, on accreditation of health research institutions.

Human Tissues

Royal Decree 1301/2006, of 10 November, establishing the rules of quality and safety for the donation, obtaining, assessment, processing, preservation, storing and distribution of human tissues and cells and approving the rules of coordination and functioning for human use.

Intellectual & Industrial Property

Act 19/2006, of 5 June, widening the protective means of intellectual and industrial property and establishing procedural

rules to facilitate application of various Community regulations.

Act 23/2006, of 7 July, modifying the revised text of the Intellectual Property Act, approved by Legislative Royal Decree 1/1996, of 12 April.

Royal Decree 397/2006, of 31 March, amending Royal Decree 1270/1997, of 24 July, regulating the Spanish Patent & Trade Mark Office.

Magistral Formulations & Compounding in Pharmacies

Decree 14/2006, of 20 January, of the Council of the Valencian Government, establishing the legislation for the application in the Community of Valencia of Royal Decree 175/2001, of 23 February, which approved the rules for the correct preparation and quality control of magistral formulations and pharmacy compounds.

Medical Devices

Resolution of 20 March 2006, of the Directorate-General of Pharmacy and Medical Devices for the Valencian Health Agency, to create the Medical Devices Cataloguing Committee for the purposes of the Valencian Region Medical Devices Safety System.

Medical Visit

Order 3/2006, of 31 January, of the Health Ministry of La Rioja Government, repealing Order 6/2004, of 19 July, of the Health Ministry, regulating the visit of Technical Health Representatives of Laboratories to the Health Centres of the Public Health System of La Rioja.

Narcotics & Psychotropic Substances

Order SCO/2004/2006, 19 June, amending Order SCO/469/2006, of 19 February, to include certain active ingredients in Annex 1 of Royal Decree 2829/1977, 6 October, regulating psychotropic substances and products.

Order of 22 August 2006, of the Health Ministry of the Galician Government, regulating the distribution and control of official prescriptions for narcotics.

National Formulary

Order SCO/3123/2006, of 29 September, updating the National Formulary.

NHS Health Services

Decree 6/2006, of 10 January, of the Health and Consumer Affairs Ministry of the Extremadura Government, regulating the procedure and requirements for the refund of the costs of pharmaceutical, orthoprosthesis and health care products, as well as the aids for travel and overnight stay.

Decree 68/2006, of 4 April, of the Health and Consumer Affairs Ministry of the Extremadura Government, regulating the right of large families, and disabled and chronically sick children, to obtain pharmaceutical products for paediatric use free of charge.

Personal Data Protection

Order SCO/1070/ 2006, of 24 March, extending the Order of 21 July 1994, regulating the personal datafiles managed by the Ministry of Health and Consumer Affairs.

Order SCO/1655/2006, of 12 May, extending the Order of 21 July 1994, regulating the personal datafiles managed by the Ministry of Health and Consumer Affairs.

Resolution of 28 April 2006, of the Spanish Data Protection Agency, to create and amend datafiles for Agency personnel.

Resolution of 12 July 2006, of the Spanish Data Protection Agency, to approve electronic forms by which applications to register files in the General Data Protection Registry shall be made, as well as the formats and requirements that notifications must comply with when sent in computer or telematic form.

Resolution of 12 July 2006, of the Spanish Data Protection Agency, to create the Spanish Data Protection Agency's Telematics Registry.

Resolution of 1 September 2006, of the Spanish Data Protection Agency, to determine the information that shall be contained in the Catalogue of registered files in the General Data Protection Registry.

Order SLT/88/2006, of 6 March, of the Department of Health of the Catalonian Government, creating the Security of Information Programme in the Health Department.

Personal Health Cards

Order 1285/2006, of 22 June, of the Health and Consumer Affairs Ministry of the Region of Madrid, regulating the personal health card in the area of the Madrid Region.

Pharmaceutical Service

Decree 6/2006, of 19 January, of the Council of the Government of the Region of Madrid, approving measures to improve the pharmaceutical service to chronically sick patients.

Post-Authorisation Studies

Resolution of 15 March 2006, of the Deputy Minister of Health and the Director-General of the Basque Health Service, for the approval of the contract model to be signed between the Management, Instigator, Researchers and the BIO Foundation, for the carrying out of observational post-authorisation studies with medicines in the Basque Health Service/Osakidetza health care organisations.

Prescriptions

Decree 225/2006, of 23 November, of the Health Ministry of the Galician Government, amending Decree 244/2003, of 24 April, on the approval of official prescriptions for the pharmaceutical service.

Resolution of 8 November 2006, of the Valencian Health Agency, on the billing for prescriptions coming from other Autonomous Regions.

Instruction 5/2006, of 24 April, of the General Secretariat of the Galician Health Service, on management of renewable dispensing.

Public Contracts

Order 429/2006, of 3 March, of the Health and Consumer Affairs Ministry of the Region of Madrid, agreeing the uniformity of certain medicines and announcing the centralised management of their procurement.

Public Financing of Medicines & Medical Devices

Order of 29 June 2006, of the Health Ministry of the Valencian Government, establishing the financing of certain medicines for the treatment of erectile dysfunction in people with spinal injuries.

Public Participation

Decree 29/2006, of 25 May, of the Ministry of Health of La Rioja, regulating the public participation bodies in the La Rioja Public Health System.

Reference Prices

Royal Decree 1338/2006, of 21 November, developing certain aspects of Article 93 of the Safeguards and Rational Use of Medicines and Medical Devices Act, 29/2006, of 26 July, in the framework of the reference price system.

Order SCO/3997/ 2006, of 28 December, determining the groups of medicines and their reference prices and regulating certain aspects for the application of that provided for by Act 29/2006, of 26 July, on Safeguards and Rational Use of Medicines and Medical Devices.

Regional Advisory Boards

Order of 22 February 2006, of the Health Ministry of the Galician Government, amending the other of 25 May 2005 regulating the composition, organisation and functioning of the Galician Health Service Advisory Board.

Registry of Advance Decision-Making

Act 1/2006, of 3 March, of the Presidency of the Balearic Islands, on advanced decision-making.

Decree 13/2006, of 8 February, of the Health Ministry of the Canaries Government, regulating declarations of advanced decision-

making in the health care field and the creation of a corresponding Registry.

Decree 15/2006, of 21 February, of the Health Ministry of the Castille-La Mancha Government, on the Castille-La Mancha Registry of Advanced Decision-Making.

Decree 30/2006, of 19 May, of the Health Ministry of the La Rioja Government, regulating the La Rioja Registry of Prior Instructions.

Decree 101/2006, of 16 November, of the Council of the Government of the Region of Madrid, regulating the Region of Madrid Registry of Prior Instructions.

Order 8/2006, of 26 July, of the Health Ministry of La Rioja Government, on how to make the document of prior instructions before administration personnel.

Order 2191/2006, of 18 December, of the Ministry of Health and Consumer Affairs of the Community of Madrid, developing Decree 101/2006, of 28 November, regulating the Registry of Prior Instructions of the Community of Madrid and establishing the official models of the documents of application for registration of Prior Instructions and their revocation, amendment or substitution.

R&D

Order ITC/570/2006, of 22 February, creating the registry of bodies carrying out research and development (R&D) activities in the Ministry of Industry, Tourism and Trade.

Order SCO/806/2006, of 13 March, approving the regulatory basis for the award of grants for financing stable cooperative research structures in the area of biomedicine and health sciences, in the framework of CIBER Actions, in the Consolider Programme of the 2010 Ingenio initiative.

Resolution of 4 October 2005, of the State Secretariat for Universities and Research, for the award of grants in relation to the 2002 Torres Quevedo Programme official announcement, corresponding to the third year of the awards by Resolution of 3 April 2003.

Resolution of 31 March 2006, of the General Secretariat of Political Science and Technology, for the publication of the grants awarded in the Torres Quevedo Programme, corresponding to the third year of the awards by Resolution of 3 April 2003.

Resolution of 3 April 2006, of the General Secretariat of Political Science and Technology, for the publication of the grants awarded in the Torres Quevedo Programme, corresponding to the second year of the awards by Resolution of 27 February 2004.

Resolution of 4 April 2006, of the General Secretariat of Political Science and Technology, for the publication of the grants awarded in the 2004 Torres Quevedo Programme official announcement, corresponding to the first year of the first assessment.

Resolution of 5 April 2006, of the General Secretariat of Political Science and Technology, for the publication of the grants awarded in the Torres Quevedo Programme, corresponding to the second year of the awards by Resolution of 3 April 2003.

Resolution of 6 April 2006, of the General Secretariat of Political Science and Technology, for the publication of the grants awarded in the Torres Quevedo Programme, corresponding to the second year of the awards by Resolution of 21 May 2003.

Resolution of 16 October 2006, of the State Secretariat for Universities and Research, that the official announcement is made, for 2006, of the Torres Quevedo Programme for the recruitment of R&D personnel (doctors and technologists) in companies, technological centres and business associations, in the framework of the National Programme for Strengthening Human Resources of the National Scientific Research, Development and Innovation Plan, 2004-2007.

Decree 314/2006, of 25 July, of the Department of Education and Universities of the Catalonian Government, creating the designation R&D&I Reference Network.

Spanish Medicines & Medical Devices Agency (AEMPS)

Resolution of 7 August 2006, of the Spanish Medicines & Medical Devices Agency, to publicise the 2005 annual accounts summary.

Telematics Registry

Order SCO/2751/2006, of 31 August, creating the Telematics Registry of the Ministry of Health and Consumer Affairs for the presentation of documents, applications and communications and establishing the general requirements for the telematic processing of certain procedures.

Traceability of Medicines

Resolution of 12 December 2006, of the Undersecretaryship of Health and Consumer Affairs, to publicise the resolution of the agreement to entrust the management of the information foreseen in Royal Decree 725/2003, of 13 June, to the General Council of Official Pharmacists' Associations (Consejo General de Colegios Oficiales Farmacéuticos).

Transfer of Authority

Royal Decree 1419/2006, of 1 December, on the transfer of functions and services from the State Administration to the Autonomous Community of Cantabria, in the subject of the execution of the State legislation of pharmaceutical products.

Transplants

Order of 13 January 2006, of the Health Ministry of the Valencian Government, on accreditation of Valencian Health Agency health centres for the practice of extraction and transplant of organs, tissues and cells.

Visas

Order 852/2006, of 7 April, of the Ministry of Health and Consumer Affairs of the Region of Madrid, approving the procedure of prescription visa for second generation antipsychotics for chronically sick patients over 75 years of age.

farmaindustria

Serrano, 116
28006 Madrid
Tel: +34 91 515 93 50
www.farmaindustria.es