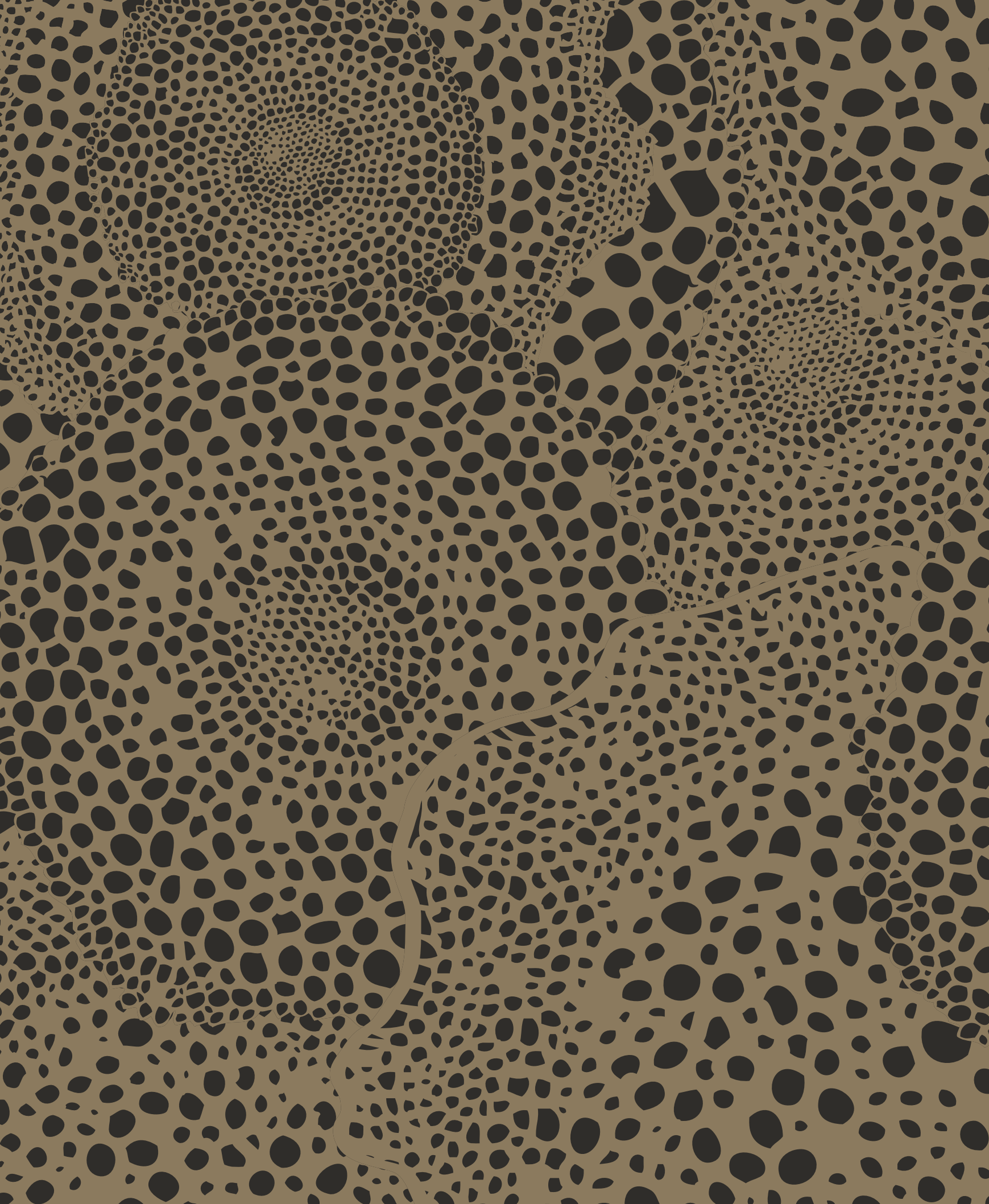
2011
ANNUAL REPORT

farmaindustria



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ANNUAL REPORT

farmaindustria


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LETTER FROM THE CHAIRMAN

It is impossible to come up with a positive balance of the twelve-year period that ends just as this 2011 FARMAINDUSTRIA Annual Report is published. Overall, it has not been a prosperous period, neither for the Spanish economy on the whole nor for the country's pharmaceutical industry, which invests resources and creates wealth across the nation.

In fact, in the year 2011, and in 2012 so far, the Spanish economy went through and is currently contending with one of the most difficult periods of the last decades. Spain has returned, technically, to recession following a 0.3% fall in GDP in the fourth quarter of 2011 and an additional 0.3% dip in the first quarter of 2012, and faces the prospect of ending 2012 with an overall fall in economic activity of 1.7%. The unemployment rate climbed to 23.7% in 1Q2012 and may end the year somewhere around the 25% mark. Moreover, following recent reviews, the public deficit closed at 8.9% of GDP in 2011 and, by force of the Government's current commitments, cannot exceed 5.3% in 2012, which will call for colossal public spending cuts in Spain. For yet another year, the only positive contribution to the economy comes from exports; but, even, so, the forecasts all point to a dip in export growth in 2012.

Right now, the efforts of our political and economic authorities are aimed squarely at reining in the public deficit. In actual fact, since the change of government in Spain following the general elections held in November 2011, in which the Partido Popular (Popular Party) came to power, cutting the deficit has become the top priority not only for central government but also for the country's regional governments, which have taken on the responsibility of making sizeable public spending cuts in sensitive areas such as education, public health and social services.

Jordi Ramentol Massana
Chairman of FARMAINDUSTRIA

But the outlook for 2013 is equally somber. In the current economic climate, marked by instability, forecasts that go beyond four or five months entail a certain risk; even so, few analysts see 2013 as a year of economic growth in Spain—at best, the third or fourth quarter may bring a degree of GDP growth in Spain, though not enough to generate economic growth for the whole year.

Even so, and regardless of in which quarter it takes place, the year 2013 should see Spain return to the path towards economic growth. What is important is that the reforms carried out so far contribute to the ultimate goal of laying the foundations for more solidly-based growth, helping to give our most promising and competitive sectors and industries the necessary thrust in international markets.

Last year was a tough one for Spain's pharmaceutical industry. The results speak for themselves: pharmaceutical spending in Spain fell by an unprecedented 8.8% in 2011, which follows on from the 2.4% dip registered in 2010.In terms of the overall Spanish pharmaceutical market (i.e. state, private, hospitals and pharmacies) the fall registered in 2011 came to more than -5%.

One of the main factors behind these results was the industry's lack of regulatory stability. The past twelve months have seen the introduction of two new Royal Decree Laws which have had (and will have in the future) a considerable impact on Spain's pharmaceutical market and, subsequently, on the companies that operate in it.

August 2011 saw the introduction of Royal Decree Law 9/2011, which brought with it major changes to the Industry's regulatory framework by introducing a raft of measures aimed at bringing about spending cuts, with an annualized impact of more than 2.4 billion euros on pharmaceutical spending.

Similarly, Royal Decree Law 16/2012 came into effect in April 2012, bringing with it a number of far-reaching regulatory provisions such as the public de-financing of pharmaceutical products, the introduction of a new selective pricing system, and changes to pharmaceutical provision for

users, introducing a new "co-payment" of 10% of the retail price, applicable to Spain's Social Security pensioners, with monthly limits depending on the amount spent by each user. Depending on how they will finally be implemented, the provisions of this Royal Decree Law may lead to a potential annualized reduction of more than three billion euros. Moreover, this Royal Decree Law will have a structural effect on Spain's public pharmaceutical market and its effects will be felt year after year, not only in terms of market volume but also in terms of its growth rate.

As a result of the combined impact of these two Royal Decree Laws and the cuts In pharmaceutical costs at the regional level, 2012 may well close with a fall in public pharmaceutical spending in pharmacies in Spain of anywhere between -15% and -20% less than the final figure for 2011, which would take public pharmaceutical spending in Spain back to end-2004 levels.

But there has also been a bright side to the pharmaceutical sector over the past twelve months. 2011 ended with a record volume of debt generated by state hospitals with pharmaceutical laboratories through medical products purchases (nearly 6.37 billion euros) and in terms of the average payment period (525 days); however, in the first quarter of 2012, the government announced a number of measures aimed at enabling public administrations to meet their commitments to suppliers, including, of course, the debt arising from the supply of medicines to the Spanish National Health System's hospitals. At the time of going to print, it is scheduled that all such suppliers will receive all outstanding payments from 2011 by late June-early July 2012.

SPAIN'S PHARMACEUTICAL INDUSTRY IS A PRIME EXAMPLE OF A MODERN, DYNAMIC AND HIGHLY PRODUCTIVE INDUSTRY, CAPABLE OF TAKING ON THE BEST IN INTERNATIONAL MARKETS, R&D INTENSIVE AND, FUTHERMORE, WITH TREMENDOUS PULLING POWER

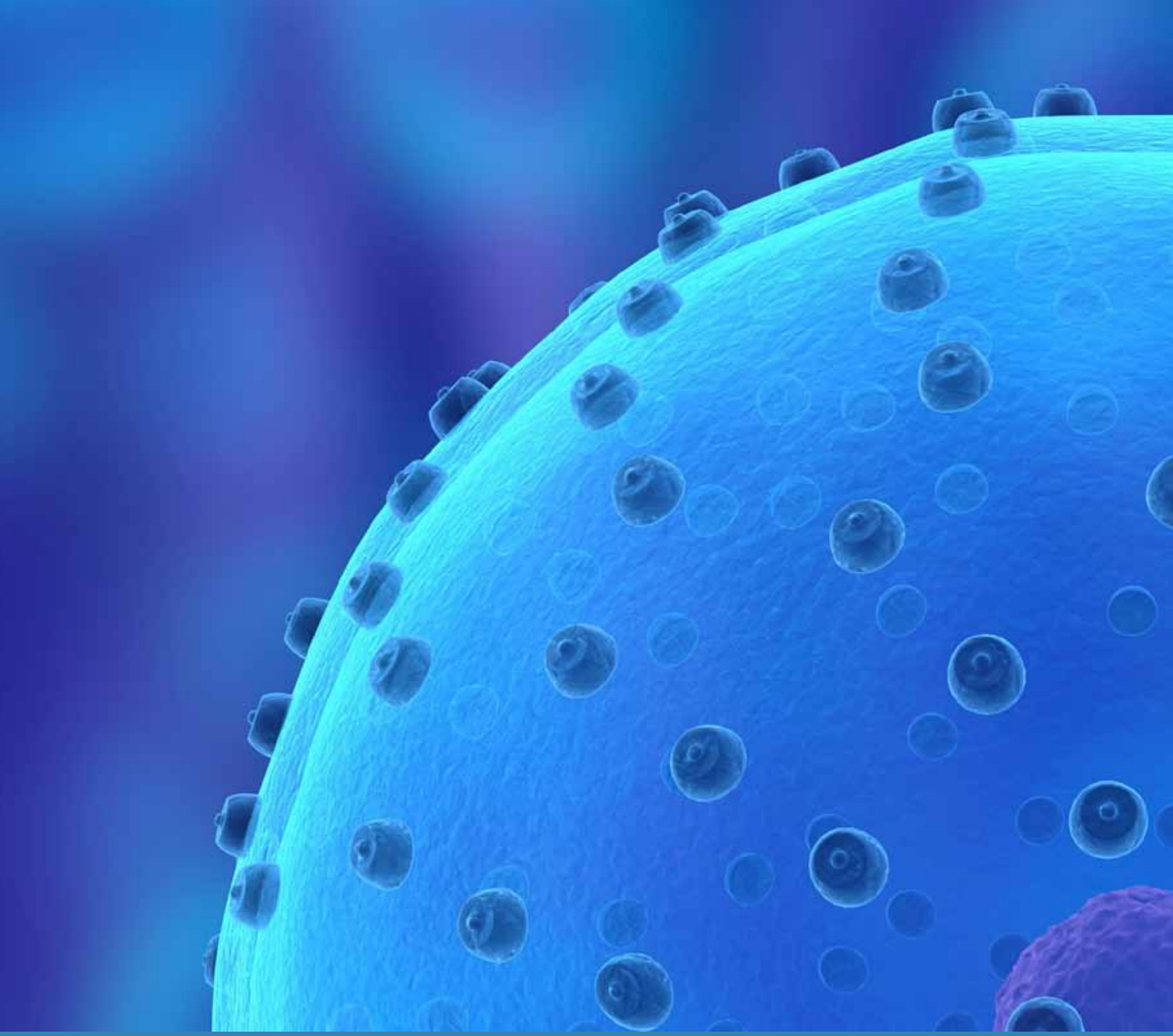
FARMAINDUSTRIA's communication and institutional activities—and those of other institutions and member companies—complaining to the authorities about the enormous extent of this problem and putting forward feasible solutions, has been a fundamental tool for articulating this payments plan which comes as a solution to a situation that is not only unfair but also extremely harmful for many pharmaceutical companies.

Having touched on the subject of this payments plan for suppliers, I should like to bring this Letter to a close on a positive note, because I am truly convinced that, if we all move forward intelligently, then Spain's pharmaceutical Industry is in for a very bright future.

Spain's pharmaceutical industry is a prime example of a modern, dynamic, extremely productive and highly active industrial sector, R&D intensive, capable of taking on the best in international markets, and with tremendous pulling power.

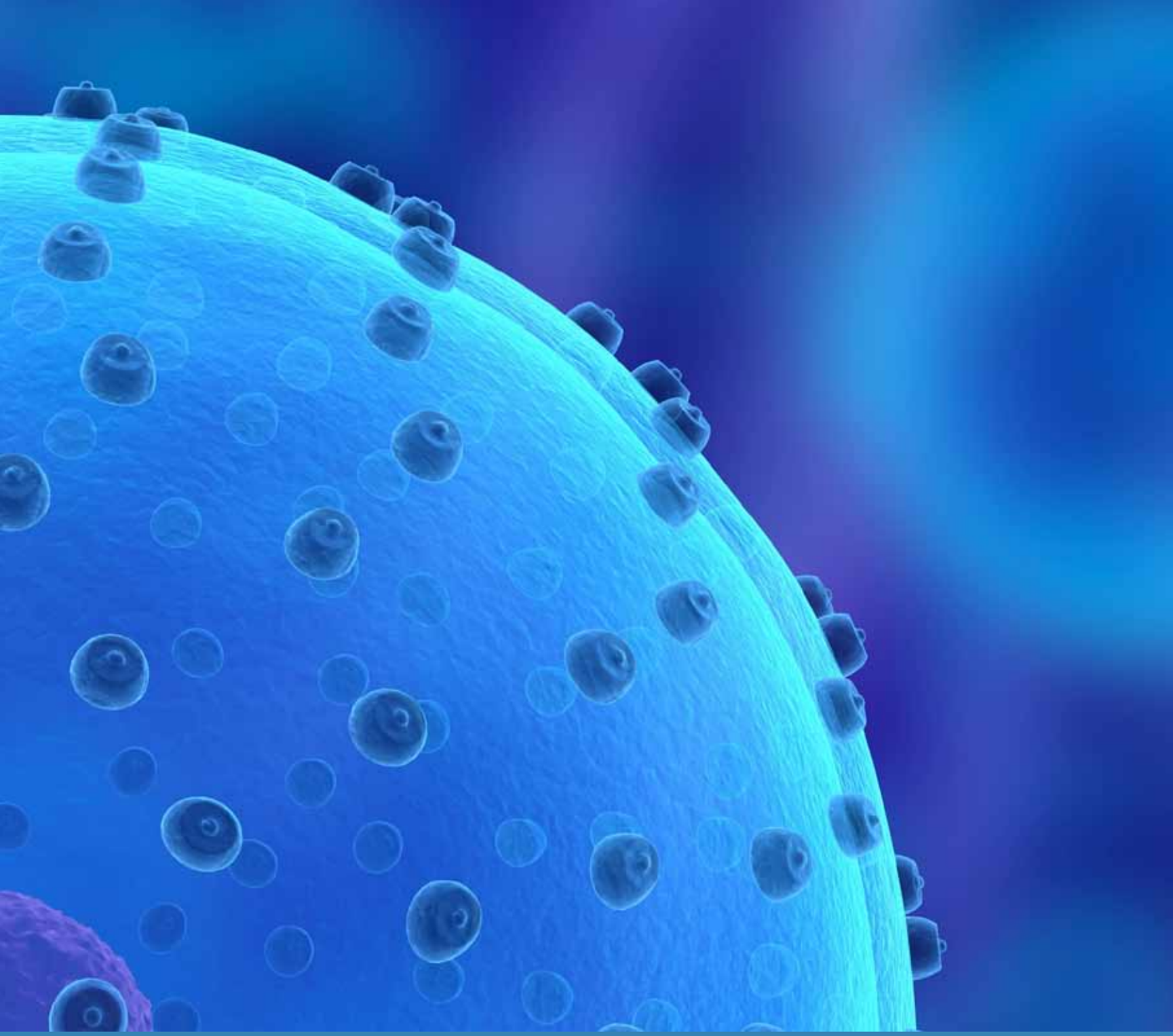
However, in Spain the pharmaceutical industry is highly regulated (to an extreme) and with a sizeable volume of pubic purchases. In fact, in the past two years, changes in the regulatory framework have been the main cause behind the fall in pharmaceutical companies' revenues. Subsequently, as things stand, with public pharmaceutical spending under control, a stable, predictable and innovation-friendly regulatory framework would go a long way towards helping Spain's pharmaceutical industry to fulfill its growth potential while, naturally, upholding its commitment to the country's National Health System and in a manner consistent with the System's financing.

In order to achieve this, I hope that Royal Decree Law 16/2012 and the rest of the Spanish pharmaceutical industry's existing legal and regulatory requirements finally come together, once and for all, to make up the stable and predictable framework that FARMAINDUSTRIA has been calling for repeatedly for many years now, and which would help the main industry players to advance in the long term. If this eventually becomes a reality, and despite the high economic impacts already suffered by pharmaceutical companies, it might well lay the foundations for the sustainable development of Spain's pharmaceutical industry.



01.

FARMAINDUSTRIA in 2011



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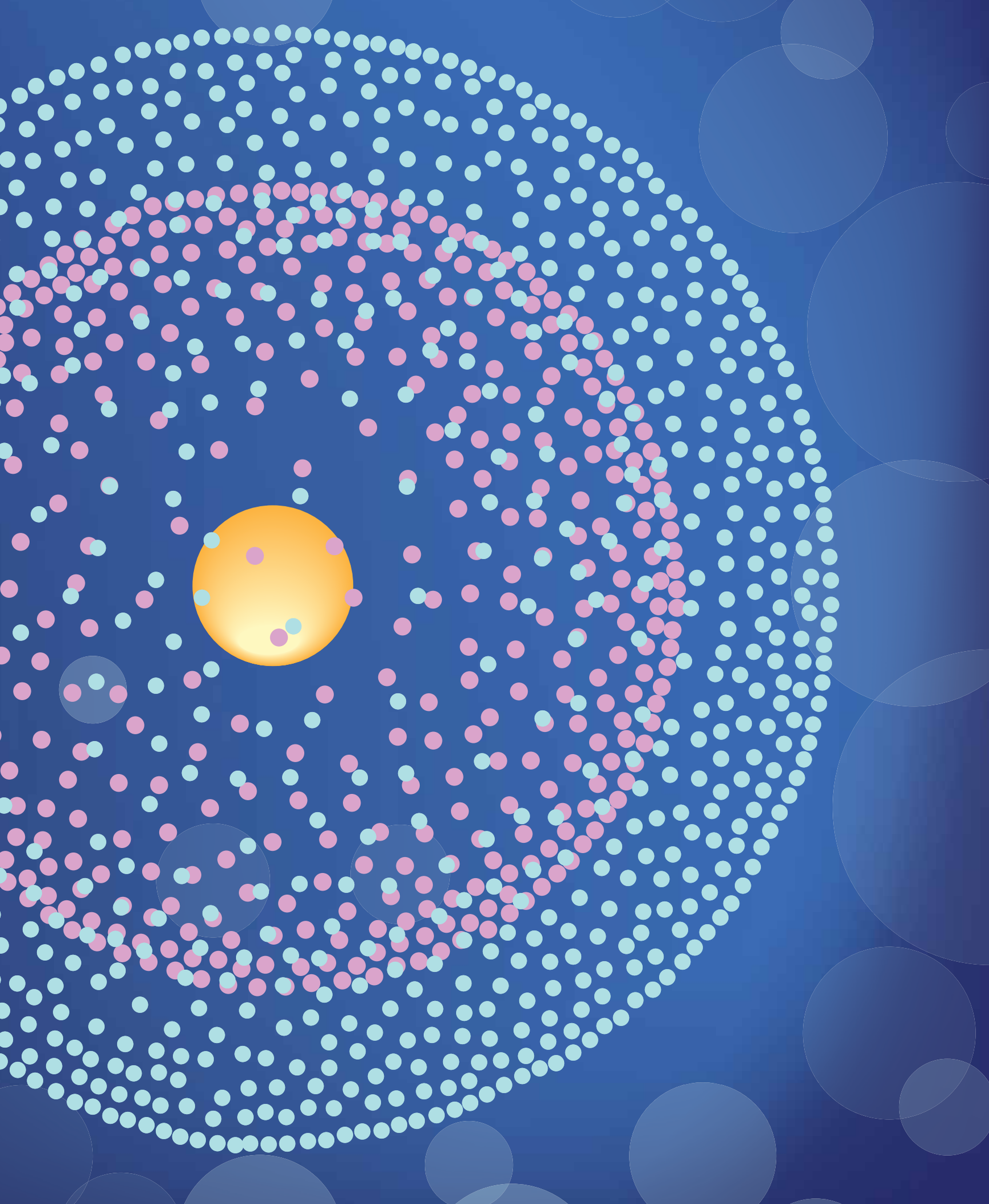
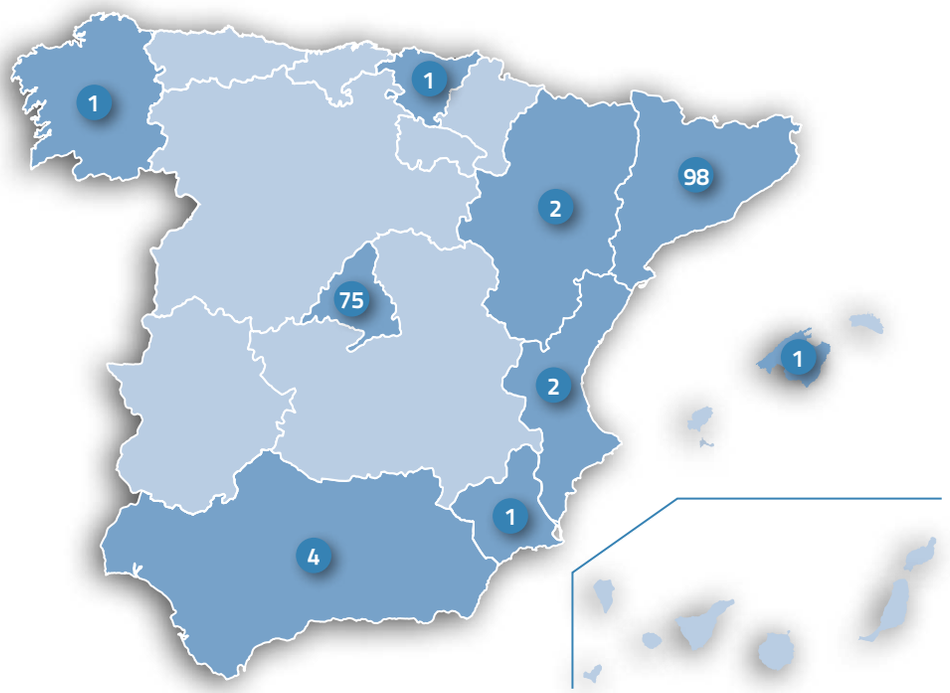


01. MEMBER COMPANIES

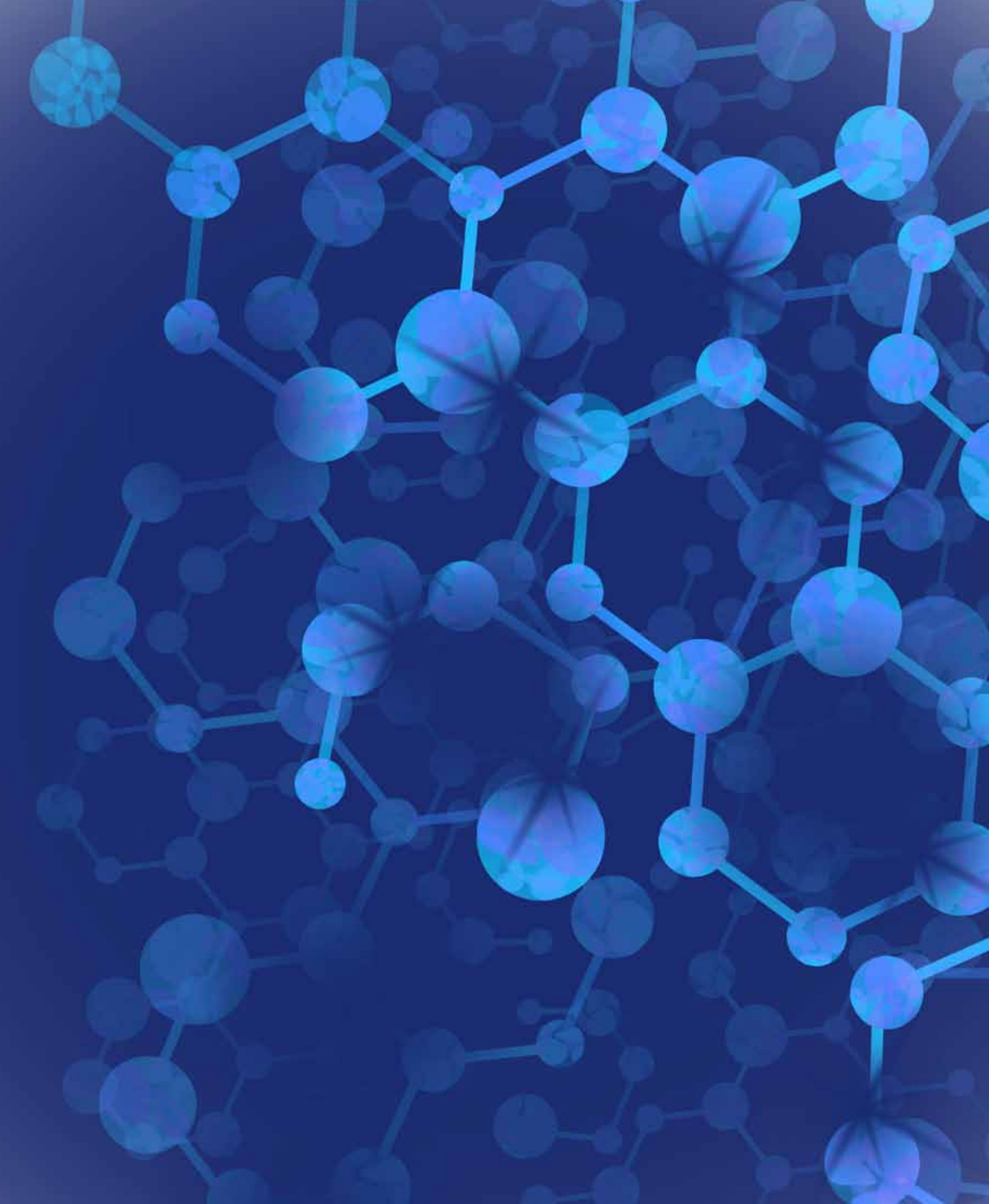
At 31 December 2011, FARMAINDUSTRIA had 185 member companies, whose geographic distribution is as follows:



FARMAINDUSTRIA's member companies represent, in number, 42% of the holders of a permit to sell pharmaceutical products, or their local representatives In the case of those permit-holders authorized using the centralized procedure, regardless of whether or not they are engaged in trade activity In terms of sales, they represent 82% of the prescription market.

PHARMACEUTICAL COMPANIES BY GROUPS

National		International			
		USA	European		
Total	82	21	82		
Large	7		Germany	17	
Medium	7		France	15	
Small	68		Mixed	23	
			United Kingdom	15	
			Switzerland	12	



02. ORGANIZATION

2.1.

GOVERNING BODIES

The General Assembly, comprising all of the Association's Member Companies, is the supreme governing bodies and expresses the collective will of the member companies.

The Association's governance resides in its Steering Committee which is made up of the Chairman of the Association and 30 representatives of Member Companies (11 Spanish-capital companies, 8 USA-capital companies and 11 European-capital companies) and a Board of Governors made up of the Chairman and 17 Member Companies, seven of which hold a vice-chairmanship (2 Spanish-capital companies, 2 USA-capital companies and 4 European-capital countries) and 10 board members designated by the Board of Directors from among its members (4 Spanish-capital companies, 2 USA-capital companies and 4 European-capital companies).

In February 2012, in accordance with the Additional Provision of the FARMAINDUSTRIA Bylaws, the appointment of a vice-chairman of the European group was brought forward from October 2012, as occurred last year with another statutory group.

At the time of going to press, the composition of both governing bodies stands as follows:

EXECUTIVE BOARD

CHAIRMAN	
Mr. Jorge Ramentol Massana FERRER INTERNACIONAL. S.A.	
VICE-CHAIRS	
Mr. Jesús Acebillo Marín NOVARTIS FARMACÉUTICA. S.A.	**Mr. Jordi Martí Pi-Figueras** AMGEN. S.A.
Mr. Antoni Esteve Cruella ESTEVE	**Ms. Elvira Sanz Urgoiti** PFIZER. S.A.
Mr. Jorge Gallardo Ballart ALMIRALL. S.A.	**Ms. Lide Isabel Verdugo Martínez** NYCOMED PHARMA. S.A.
Ms. Camilla H. Hartvig ASTRAZENECA FARMACEUTICA SPAIN. S.A.	
MEMBERS	
Mr. Andreas Patrick Abt ROCHE FARMA. S.A.	**Mr. Marc-Antoine Lucchini** SANOFI-AVENTIS. S.A.
Mr. Sergi Aulinas Guillaumes LABORATORIOS GEBRO PHARMA. S.A.	**Dr. Germano Natali** BAMA-GEVE. S.L.
Mr. Javier Font Salgado LABORATORIO DE APLICACIONES FARMACODINÁMICAS. S.A. "FARDI"	**Mr. Eric Jean François Patrouillard** LILLY. S.A.
Ms. Inés Juste Bellosillo JUSTE. S.A. QCO. FCA.	**Mr. Francisco Quintanilla Guerra** FAES FARMA. S.A.
Mr. Juan López-Belmonte López LABORATORIOS FCOS. ROVI. S.A.	**Mr. Martín Sellés Fort** JANSSEN CILAG. S.A.

STEERING COMMITTEE

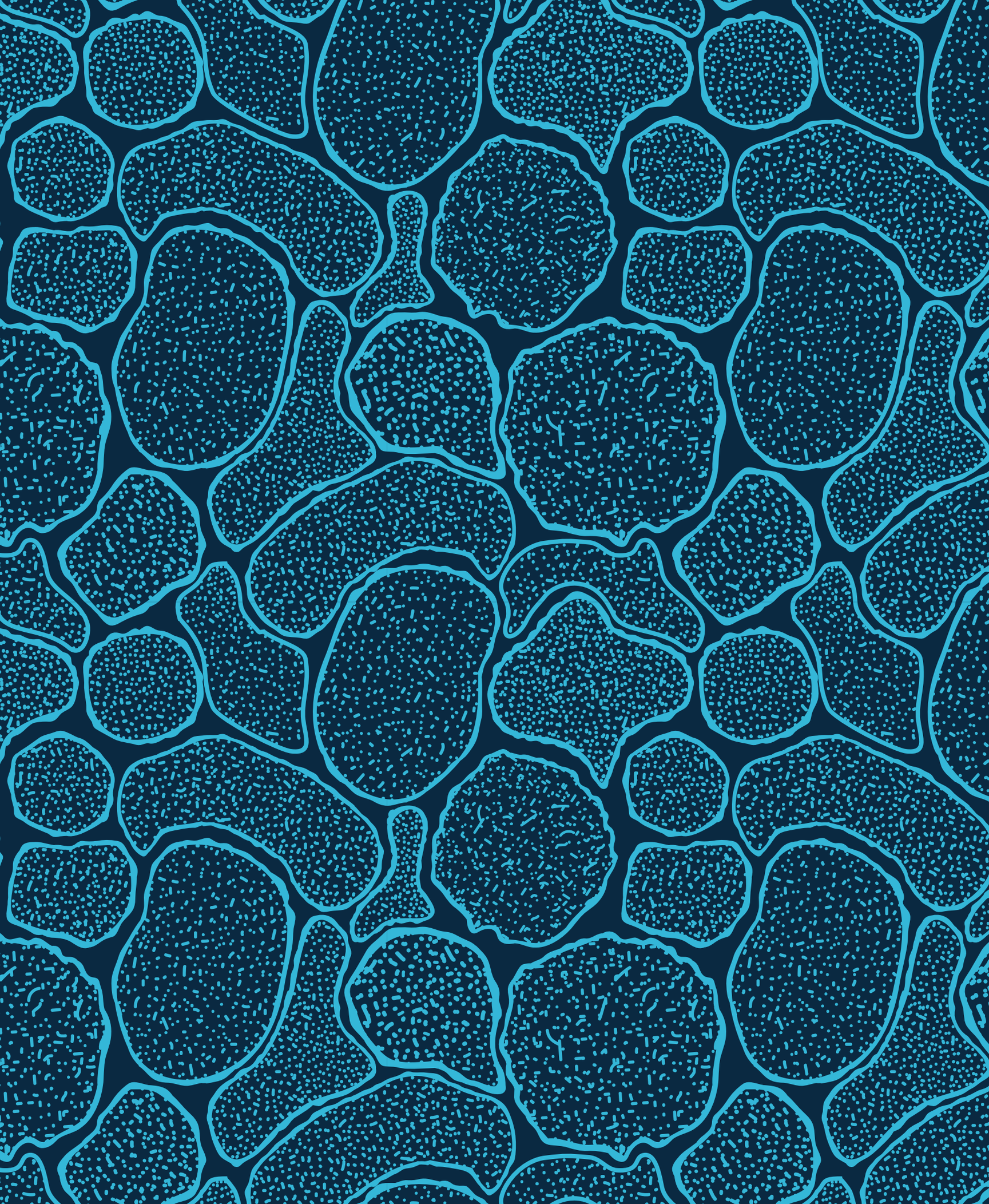
CHAIRMAN	
FERRER INTERNACIONAL. S.A. **Mr. Jorge Ramentol Massana**	
VICE-CHAIRS	
ALMIRALL. S.A. **Mr. Jorge Gallardo Ballart**	NOVARTIS FARMACÉUTICA. S.A. **Mr. Jesús Acebillo Marín**
AMGEN. S.A. **Mr. Jordi Martí Pi-Figueras**	NYCOMED PHARMA. S.A. **Ms. Lide Isabel Verdugo Martínez**
ASTRAZENECA FARMACÉUTICA SPAIN. S.A. **Ms. Camilla H. Hartvig**	PFIZER. S.A. **Ms. Elvira Sanz Urgoiti**
ESTEVE **Mr. Antoni Esteve Cruella**	
MEMBERS	
ABBOTT LABORATORIES. S.A. **Mr. Esteban Plata González**	LACER. S.A. **Mr. Helmut Andress**
BAMA-GEVE. S.L. **Dr. Germano Natali**	LABORATORIOS LETI. S.L. UNIPERSONAL **Mr. Jaime Grego Sabaté**
LABORATORIOS BETA. S.A. **Mr. Federico Plaza Piñol**	LILLY. S.A. **Mr. Eric Jean François Patrouillard**
BRISTOL MYERS SQUIBB. S.A. **Ms. Aurora Cayetana Berra de Unamuno**	MERCK SHARP & DOHME DE ESPAÑA. S.A. **Mr. Antonio Pérez Mosquera**
LABORATORIOS ERN. S.A. **Mr. David Solanes López**	NOVARTIS CONSUMER HEALTH. S.A. **Mr. Francisco Ballester Cañizares**
FAES FARMA. S.A. **Mr. Francisco Quintanilla Guerra**	ROCHE FARMA. S.A. **Mr. Andreas Patrick Abt**
LBO.DE APLICACIONES FARMACODINÁMICAS. S.A. "FARDI" **Mr. Javier Font Salgado**	LABORATORIOS FCOS. ROVI. S.A. **Mr. Juan López-Belmonte López**
GRUPO FARMASIERRA. S.L. **Mr. Tomás Olleros Izard**	SANOFI-AVENTIS. S.A. **Mr. Marc-Antoine Lucchini**
LABORATORIOS GEBRO PHARMA. S.A. **Mr. Sergi Aulinas Guillaumes**	LABORATORIOS SERVIER. S.L. **Mr. Pierre Faraldo**
GILEAD SCIENCES. S.L. **Mr. Roberto J. Urbez Plasencia**	LABORATORIOS VIÑAS. S.A. **Mr. Antonio Buxadé Viñas**
JANSSEN CILAG. S.A. **Mr. Martín Sellés Fort**	ZAMBON. S.A.U. **Mr. Jaime Pey Sanahuja**
JUSTE. S.A. QCO. FCA. **Ms. Inés Juste Bellosillo**	

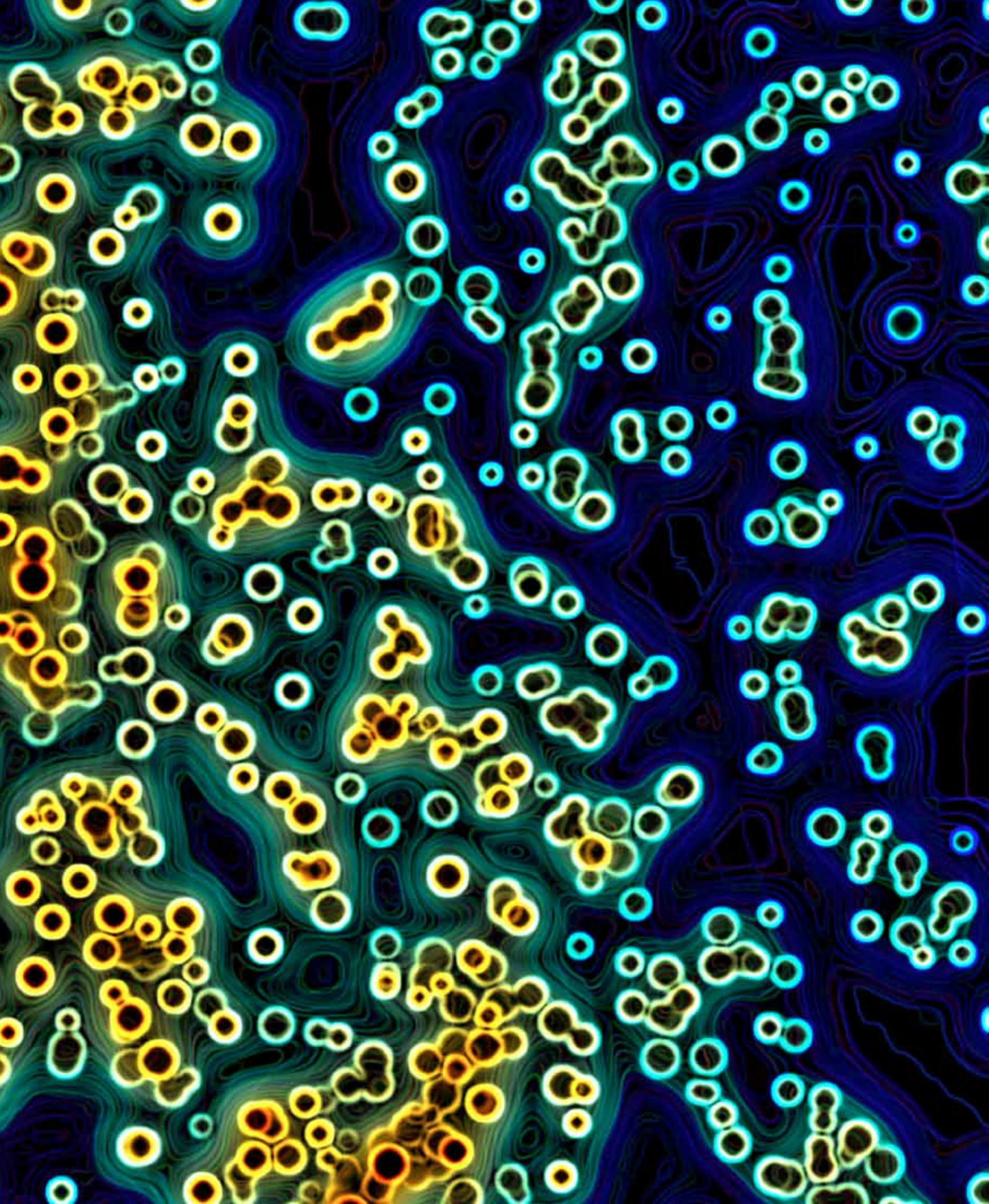
2.2.

EXECUTIVE COMMITTEE

FARMAINDUSTRIA has a Managing Director who heads the executive committee which is structured in functional departments. The Association has its headquarters in Madrid (Spain) and offices in Barcelona.

The functional organization chart is as follows:





03. ENVIRONMENTS IN WHICH FARMAINDUSTRIA OPERATES

3.1.

MARKET REGULATION AND ENGAGEMENT WITH PUBLIC ADMINISTRATIONS

The 12-month period spanned by this Report began in June 2011, just two months after Spain's Pharmaceutical Industry Sector Plan was announced by the then Minster of Health, Social Policy and Equal Opportunities, Ms. Leire Pajín and the then Minister of Science and Innovation Ms, Cristina Garmendia, accompanied by the Chairman of FARMAINDUSTRIA, Mr. Jordi Ramentol. The plan arose from a commitment undertaken by Spain's Prime Minister at the time, Mr. José Luis Rodriguez Zapatero, in an effort to stimulate Spain's pharmaceutical industry and sought to provide a boost for the clinical research, production and internationalization of the industry. One of the Plan's basic premises, and an irrevocable condition for its success, was to make the sector's regulatory framework more stable and predictable, in line with Spanish National Health System's health policy objectives and sustainability requirements.

However, the announcement in Boletín Oficial del Estado (Official Spanish Gazette), or BOE for short, on 20 August 2011, of Royal Decree Law 9/2011-August 19, which introduced measures aimed at improving the quality and cohesion of the National Health System, contributing to fiscal consolidation and raising the amount of State guarantees for 2011, brought substantial changes to the regulatory framework for Spain's pharmaceutical industry, invalidating to all intents and purposes the content of the abovementioned Pharmaceutical Industry Sector Plan.

This Decree Law introduced a raft of new measures, the most important of which are as follows:

- It introduced extensively the practice of prescription of active ingredients (with a few exceptions) and made it mandatory to dispense, in any event, the cheapest medical product;

- It made the existing reference pricing system stricter, eliminating the option of gradually lowering prices and doing away with the protection of pharmaceutical innovations as soon as the first generic appears, and so on;

IN 2011 THE COMBINED EFFECTS OF RDL 4/2010 AND RDL 8/2010 LED TO 1.071 BILLION EUROS' WORTH OF CUTS IN PUBLIC PHARMACEUTICAL SPENDING

▪ It raised to 15% (previously 7.5%) of the retail price the deduction applicable to non-generic medicines In Spain, but which have been financed for more than ten years and whose patent is no longer protected.

With the introduction of this Royal Decree Law, the Ministry of Health expects to obtain 2.4 billion euros' worth of savings annually, of which, according to FARMAINDUSTRIA calculations, 1.85 billion euros will come as a result of lower revenues for pharmaceutical companies operating in Spain.

This impact on companies comes on top of the 2.1 billion euro impact on pharmaceutical companies as a result of the introduction of Royal Decree Laws 4/2010 and 8/2010.

In fact, the combined effects of these Royal Decree laws were felt widely throughout 2011, when public pharmaceutical spending in pharmacies fell 8.8% (-1.071 billion euros) compared with end 2010, an unprecedented fall for the Spanish public pharmaceutical market.

However, even more important than the immediate impact of Royal Decree Law 9/2011 was the structural change that this norm has imposed upon Spain's pharmaceutical market by introducing changes that modified not only the market's operational dynamic, but also the incentives and relations between the players in the medicine chain. FARMAINDUSTRIA had already warned that RDL 9/2011's provisions were so far reaching that their introduction would mark a watershed for Spain's pharmaceutical industry.

But if there is any single event for which 2011 will be remembered in the Spanish pharmaceutical market (other than the historic fall in public pharmaceutical spending), it is the fact that it was the year that saw the explosion of the Public Administrations" debt crisis caused by the supply of medicines to Spain's National Health System, and also the year that marked the beginning of the solution to this problem.

In 2011 the problem of the debt arising from the supply of medicines to state hospitals worsened considerably, reaching unsustainable levels for many pharmaceutical companies. At end-2011, hospital debt came to more than 6.369 million euros (1.685 billion euros more than in 2010), with an average payment period of 525 days for the whole Spanish National Health System (135 days more than at end-2010).

Faced with this problem, FARMAINDUSTRIA stepped up its media and institutional activity considerably, reporting the scale of the problem to the corresponding authorities and putting forward feasible solutions, and, more importantly, making every effort to ensure that a similar situation was unlikely to occur in the future.

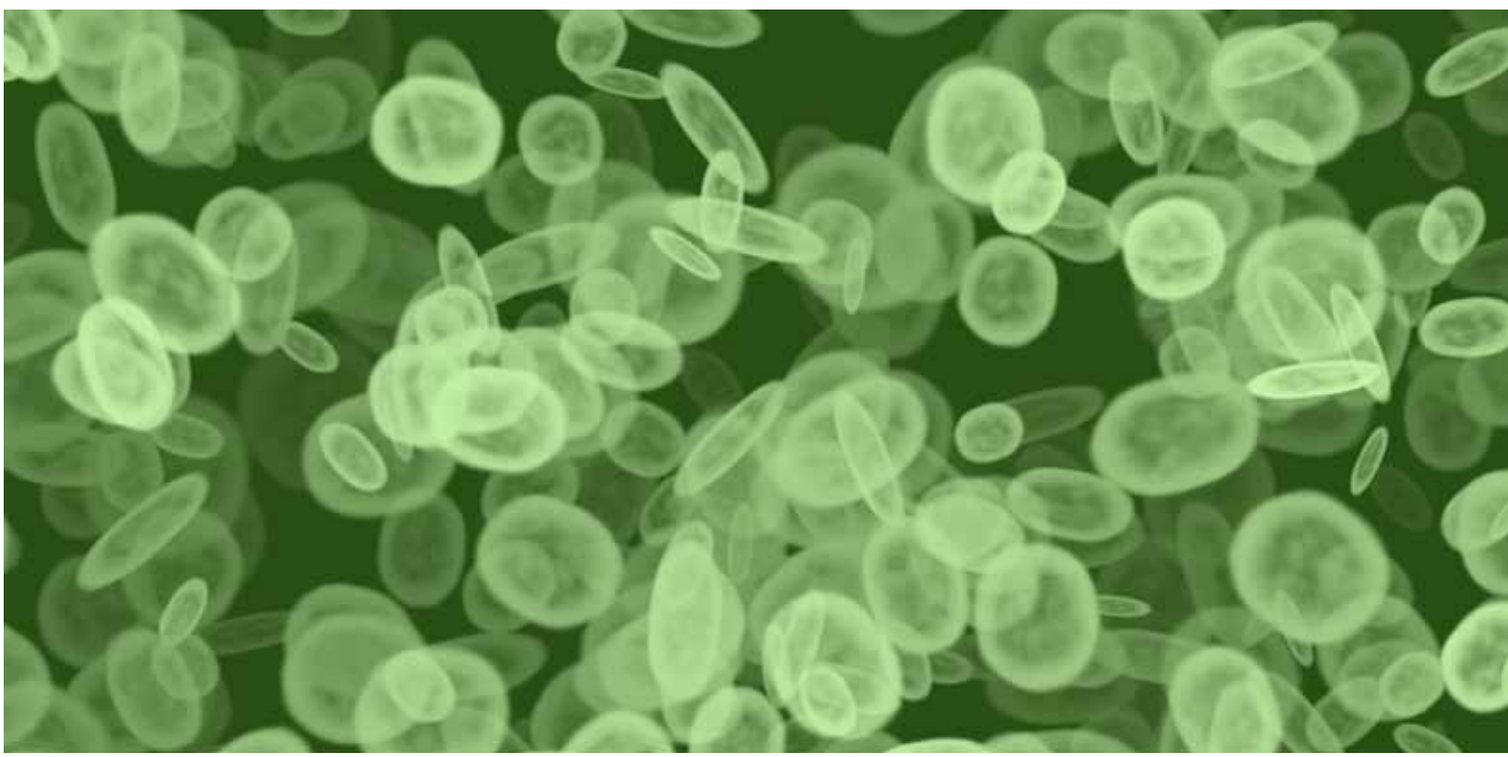
Finally, the institutional efforts carried out by FARMAINDUSTRIA and other business organizations bore fruits in the first quarter of 2012 when the Spanish government came up with measures designed to pay the Public Administrations' debt with Its suppliers, including, of course, the debt for supplying medicines to National Health System hospitals. In other sections of this Report, we weigh up more accurately the solutions that were applied to this

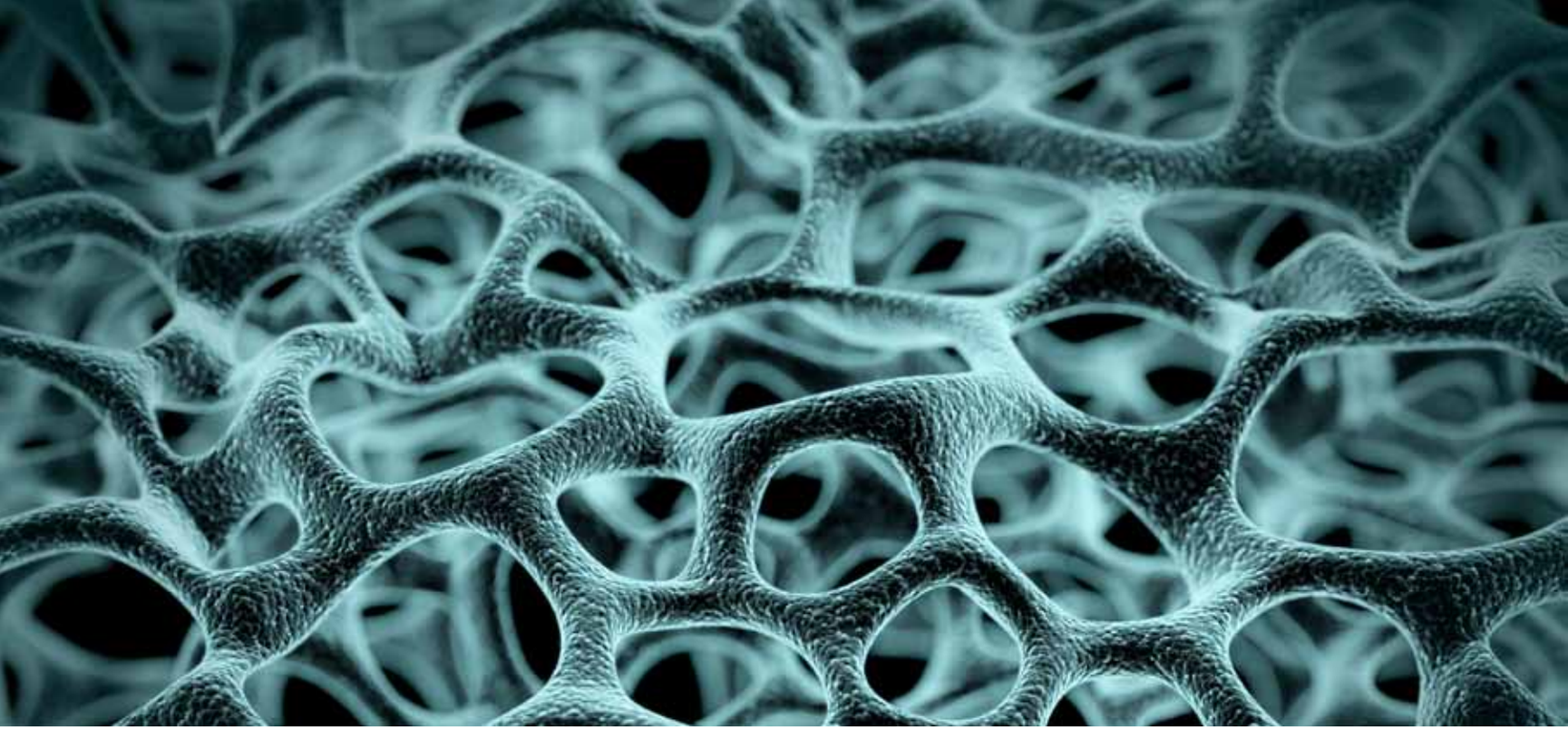
problem; suffice to say that the Minister of Finance and Public Administrations, Mr. Cristóbal Montoro, has given his guarantee, in recent statements, that all suppliers will receive payment before the end of June 2012.

In addition, Spain's new Government, led by the Partido Popular, has made cutting the public deficit and controlling public spending its top priority for 2012. Its commitment to bringing down the deficit from 8.9% of GDP at end-2011 to 5.3% of GDP at end-2012, in the midst of a severe economic downturn (2012 is forecast to end with a real fall in GDP of -1.7%), calls for public spending cuts on an unprecedented scale in Spain and this, inevitably, affects such an important part of public spending as public health spending.

In this respect, Royal Decree Law 16/2012 of April 20th, introducing urgent measures aimed at guaranteeing the sustainability of Spain's National Health System and improving the quality and assurance of its services, takes steps towards reducing public health spending by 7.267 billion euros, as specified in the Regulatory Impact Analysis Memorandum which accompanied this Royal Decree Law during the corresponding parliamentary debate.

Pharmaceutical spending is one of the budgetary areas most affected by the measures introduced by this Royal Decree Law. Although we will look at this issue in greater detail a little further on in this Report, it should be said that some of the measures of this Royal Decree Law have far-reaching effects on Spain's pharmaceutical market. They include the following:





- Yet again, generic medicines take priority when they come at a lower price and when the prescription is for the active ingredient (this preference had been eliminated by Royal Decree Law 9/2011)

- The new law opens the door to de-financing medicines that are meant for minor syndromes

- A selected pricing system is set up for medicines included in the Reference Price System, with the aim of bringing down the cost of acquisition of the medicines that fall within the scope of the system

The Royal Decree Law also introduces a new system enabling users to participate in medicine prices for outpatient dispensing which, in turn, introduces a variable co-payment according to income, in the case of members of the working population and a fixed co-payment of 10% of the retail price for pensioners, with ceilings depending on income. This article also introduces co-payment for outpatient dispensing, by prescription, in pharmacy services and updates the current highest reduced contribution, which will be automatically updated in January 2013 in line with the Consumer Price Index.

Although many of the new measures have yet to be implemented, their eventual application is likely to make the Spanish pharmaceutical market shrink at an unprecedented rate.

In fact, even before Royal Decree Law 16/2012 was Introduced, many pharmaceutical industry analysts predicted the Spanish market would contract by anywhere between 10% and 13.5% by end-2012. However, If the Law's pharmaceutical spending measures come Into effect on 1 July 2012, it would not be unreasonable to say that public pharmaceutical spending in Spain will fall by anywhere between 15% and 20% on 2011, which would take public pharmaceutical spending back to 2004 levels.

Finally, it should be said that over the past year, and despite the sharp fall in pharmaceutical spending registered in all of Spain's autonomous regions, the regional authorities have taken more and more steps to further reduce their pharmaceutical spending, with their sights firmly set on bringing down spending as part of their efforts to meet their public deficit target for 2012 of 1.5% of GDP, compared with 3.2& of GDP at end 2011).

Many Spanish regional governments are limiting doctors' prescriptions and are eliminating certain medicines from their electronic prescriptions systems; swapping branded medicines for active ingredient prescriptions, ending public financing for branded medicines, and even in some more extreme cases, promoting programmes involving the exchange of other medicines with different active.

Many of these measures have led to a number of legal appeals by FARMAINDUSTRIA given that the Association understands that they alter substantially the competition conditions of Spain's pharmaceutical market and are clearly damaging to companies that trade in medicines whose prescription has been seriously hampered, or even made impossible, by these measures. As FARMAINDUSTRIA sees it, Spain's regional governments have no legal power to introduce these regulations because they not only imply the covert exclusion of certain medicines from the public financing system (only Spain's central government is empowered to do so), but also violate the principle of equal access to medicines.

Having made all the adjustments in this sector, the moment has now come to see medicines as part of the solution and not the cause of the Spanish National Health System's problems. What's more, economic data show that Spain's pharmaceutical Industry is a prime example of a modern, dynamic, extremely productive and highly active industrial sector, R&D intensive, capable of taking on the best in international markets, and with tremendous pulling power for other sectors. These characteristics make it a highly attractive industry, whose local development helps to improve the outlook for Spain's economic growth for the next few decades.

At difficult times such as these, there is a particular and vital need for a regulatory framework capable of developing this sector in a coordinated and balanced way, yet without turning public spending austerity and fiscal consolidations (both necessary for Spain) into lower level, secondary Issues.

THE PAST TWELVE MONTHS HAVE SEEN IMPORTANT CHANGES IN THE ECONOMIC REGULATION OF SPAIN'S PHARMACEUTICAL INDUSTRY

3.1.1. THE REGULATORY FRAMEWORK

Provisions concerning Administrative Contracts

The past twelve months have seen important changes in the regulations concerning administrative contracts. In the framework of Spain's Government Strategy on Innovation, special mention should be made of Cabinet Agreement of 8 July 2011 which gave the go-ahead to the Compra Pública Innovadora [literally, Public Innovation Purchases], an administrative tool designed to foster innovation initiatives aimed at opening and developing new innovation markets from the demand side by means of an administrative contract instrument.

This Agreement was supplemented, in November 2011, by the "Guide to Public Innovation Purchases", a publication intended to facilitate and improve administrative contract procedures and public procurement tenders and to encourage businesses to take part in administrative calls for tender In the field of public innovation purchases.

In addition, by virtue of the mandate established in Final Provision No. 32 of Law 2/2011, 4 March , on the Sustainable Economy, it Is worth mentioning that the revised text of Spain's Public Sector Contracts Law, by means of Royal Legislative Decree 3/2011, 14 November, was given the green light. This Royal Legislative Decree brought together in a single text not only the modifications introduced in law 30/2007, 30 October, but also the current provisions on the capturing of private finance for the execution of public contracts.

The year 2011 also saw the introduction of Law 7/2011, 11 April, which modified Law 41/1999, 12 November, on payments systems and assets liquidation, and Royal Decree Law 5/2005, 11 March, which introduced urgent reforms aimed at driving productivity and improving the administrative contracts process.

Similarly, the Order EHA/3479/2011, 19 December specified the limits to the different types of public sector contracts as of 1 January 2012.

Finally, at the European level, mention should be made of a number of provisions, resolutions and rulings concerning administrative contracts:

- An EU Parliament Resolution on new aspects of administrative contracts policy (DOUE 31 May 2011)
- Rulings by the EU's Committee of the Regions and the European Court of Auditors on the European Commission's Green paper on the EU's administrative contracts policy (DOUE 1 and 2 July 2011, respectively)
- The European Commission's Implementing Regulation (UE) n° 842/2011, 19 August 2011, establishing the standardized forms for the publication of administrative contract advertisements/announcements and annulling CE Regulation No. 1564/2005
- The Commission's Decision, 3 September 2011, to create a Group of Experts on Administrative Contracts
- European Parliament Resolution, 25 October 2011, on the modernization of administrative contracts
- EESC Rulings on how to make the most in Europe of the advantages offered by electronic billing (e-billing), on the Green Paper on the general use of electronic administrative contracts in the EU and on the modernization of the EU's administrative contracts policy (DOUE 29 October 2011)
- European Commission Regulation 1251/2011 establishing new thresholds for the application of contract awarding procedures (DOUE 2 December 2011).

SOME VERY IMPORTANT ARREARAGE PROVISIONS WERE PUBLISHED OVER THE PAST FEW MONTHS

Provisions on arrearage

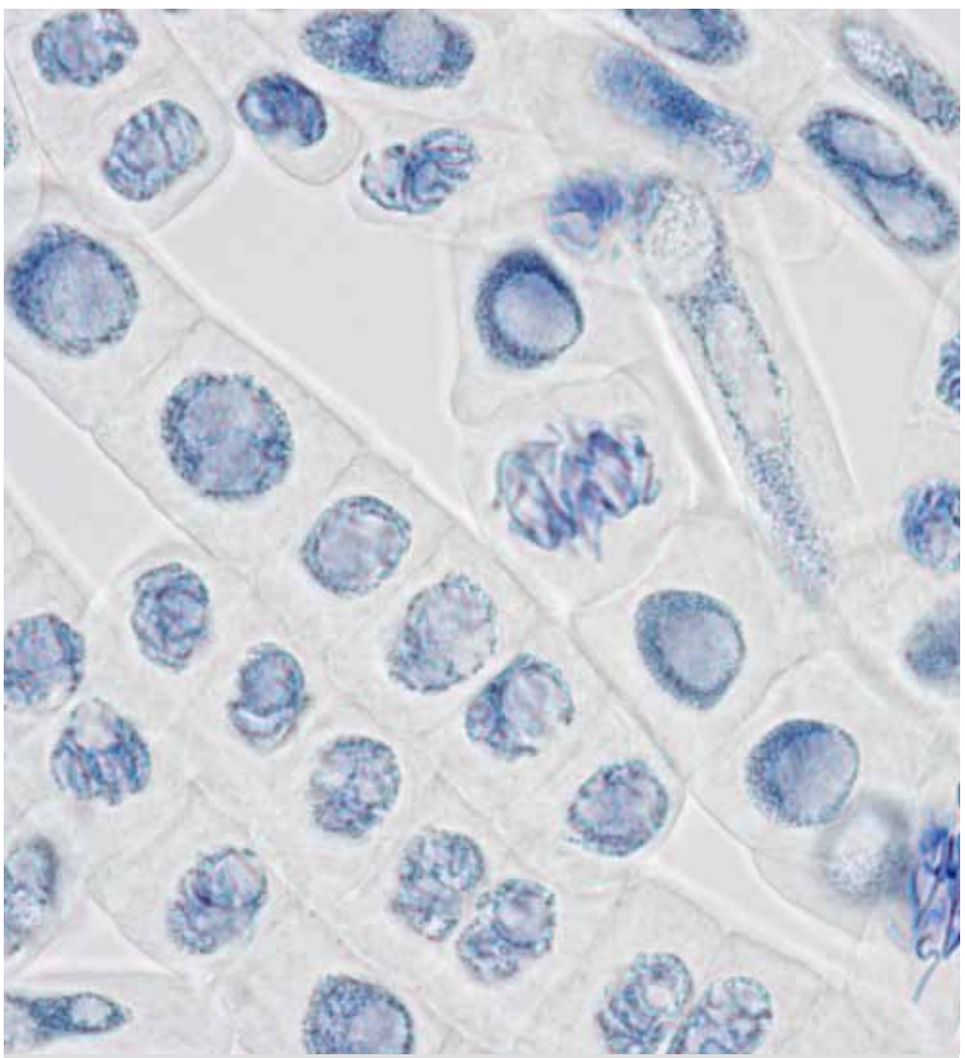
On the matter of arrearage, the past few months have seen the Introduction of a number of highly relevant provisions, all of them aimed at coming up with a solution to the serious problem posed by local and regional authorities' accumulated debt with suppliers.

Firstly, mention should be made of Resolution 23 February 2012, issued by Spain's Directorate General of the Treasury and Financial Policy, defining the principle of Financial Prudence applicable to all of the borrowing and lending operations carried out by common-regime Autonomous Regions and those cities holding a Statute of Regional Autonomy and which obtain direct financing through ICO-CCAA 2012.

Secondly, Royal Decree Law 4/2012, 24 February, specifying information requirements, and the necessary procedures for setting up a financing mechanism enabling local authorities to settle outstanding debts with suppliers.

For its part, Agreement 6/2012, 6 March 2012, issued by Spain's Fiscal and Financial Council, set out the general lines for an extraordinary mechanism enabling regional authorities to

RDL 4/2012 LAYS OUT OBLIGATIONS ON INFORMATION AND PROCEDURES FOR SETTING UP FINANCING MECHANISMS TO ENABLE LOCAL AUTHORITIES TO SETTLE OUTSTANDING PAYMENTS WITH THEIR SUPPLIERS



settle outstanding debt with suppliers, published through Resolutions 10 and 13 April 2012 by the Directorate-General of Local and Regional Coordination.

Similarly, the abovementioned Agreement took the final shape of Royal Decree Law 7/2012, 9 March, which set up a fund for the coordination in capital and credit markets of all kinds of borrowing and lending operations, as well as the coordination with local and regional authorities of credit operations for the payment of outstanding debt with suppliers. This legal text was modified by Royal Decree Law 1072012, 23 March, which modified a number of financial regulations concerning the EU authorities' powers of supervision.

Another relevant provision was Order HAP/537/2012, 9 March, which gave the go ahead for the model of the individual certificate, the model for applying for it and the model of the Adjustment Plan, as envisaged by Royal Decree Law 4/2012, 24 February, specifying information requirements, and the necessary procedures for setting up a financing mechanism enabling local authorities to settle outstanding debts with suppliers.

The introduction of Organic Law 1/2012, 3 April, excluded a number of financing mechanism from the scope of application of the Additional Provision of Organic Law 3/2006, 28 May, and the reform of Organic Law 5/2011, 13 September, which supplemented the Budget Stability General Law. This provision enabled the State to stand surety for the new mechanism for

payment to suppliers by local and regional authorities while being excluded, occasionally and as an extraordinary measure, from the existing limitations.

Similarly, Order PRE/774/2012, 16 April, published Delegate Commission of the Government for Economic Affairs' Agreement (22 March 2012) on the putting into operation of the financing mechanism enabling regional authorities to settle outstanding debts with suppliers.

Finally, at the time of going to print, Spain's parliament continues to debate the draft Organic Law on Budget Stability with the following three-fold goal:
1. Guarantee budgetary sustainability for Public Administrations;
2. Increase confidence in the Spanish economy;
3. Strengthen Spain's commitments to the European Union.

RDL 9/2011, 19 AUGUST, IS ONE OF THE MOST IMPORTANT LEGAL MEASURES EVER TAKEN IN THE FIELD OF PHARMACEUTICAL PROVISION

Royal Decree Law 9/2011

As mentioned in other sections of this Report, Royal Decree Law 9/2011-August 19, which introduced measures aimed at improving the quality and cohesion of the National Health System, contributing to fiscal consolidation and raising the amount of State guarantees for 2011, published in the Boletín Oficial del Estado (Official Spanish Gazette), or BOE for short, on 20 August 2011, is one of most relevant legal provisions adopted thus far regarding pharmaceutical provision.

The impact of this rule come in the wake of that of Royal Decree Laws 4/2010 and 8/2010, introduced just a year earlier, and which were also adopted with the aim of reinforcing fiscal and budgetary measures in an effort to meet pubic deficit reduction targets.

Royal Decree Law (henceforth 'RDL') 9/2011 introduces measures in both spheres. The following are some of the most relevant ones as regards pharmaceutical provision:

- RDL 9/2011 made changes to RDL 8/2010 by introducing a new 15% education on medicines which have been available for more than ten years after the authorisation date to finance them, which do not have a generic or an authorized biosimilar product and which are not included in the Reference Price System. Exception is made of those products that hold a product patent in all of EU member states which, or those countries which without being subject to special or transitory regimes regarding Industrial Property, have adopted EU law in their own legal systems. This exception must be duly accredited with the corresponding declaration which must be presented annually to the country's Department of Pharmacies.

- RDL 9/2011 made substantial changes to the former article 85 of Law 29/2006 in order to achieve the greatest savings for Spain's National Health System, establishing a set of rules aimed at guaranteeing at all times the dispensation of medicines at the lowest price when filling a given prescription. This RDL extends generally the prescription per active ingredient, while introducing Important nuances by allowing prescriptions per branded product in the following cases:
  - o when there are specific therapeutic needs;
  - o when the medicine is part of a grouping made up of a sole medicine and Its licenses;

o and when the branded medicine is available at a lower price.
At a later date, RDL 16/2012, which will be explained briefly a little further on in this Report, changed the regulations regarding pharmaceutical prescriptions.

▪ In turn, by leveling the discounts on generic and non-generic medicines (10% of RRP), the market took on a new configuration in which the dispensation of medicines at the lowest price became the norm. In practice, this means that brands always have to be in line with the lowest prices in order to be dispensed within the National health System.

▪ To enable the application of the stipulated cases of dispensation and substitution in the case of prescription of active ingredients, a new additional Provision 14 was introduced in Law 29/2006, the so-called "Homogeneous Groupings", which includes the financed medicines that are interchangeable regarding dispensation in the event of the prescription of an active ingredient medicine, for another medicine of equal content, pharmaceutical form or grouping of pharmaceutical forms and route of administration.

▪ RDL 9/2011 also made changes to Article 90.3 of Law 29/2006 of Guarantees, and establishes that Spain's Inter-Ministry Commission on Medicine Prices will take into consideration all reports issued by the "Cost Effectiveness Committee", which will be chaired by the Director-General of Pharmacies and will be made up of experts designated by the Spanish National Health System's Inter-Territorial Council. The Committee's organizational and working rules will be established by the National Health System's Inter-Territorial Council. Later on, RDL 16/2012, which will be summed up later, made further changes to the Committee's name, its representativity and its functions.

▪ RDL 9/2011 also envisages the total adaptation of Law 11/2007, 22 June, on public electronic access to public services and introduces the obligation, in Article 93.8 of Law 29/2006, to ensure that all notifications regarding Reference Prices are conveyed via telematic means by the electronic head office of Spain's Ministry of Health.

▪ A series of new measures were introduced designed to avoid possible shortages of medicines and enabling health authorities to carry out control and inspection operations. Thus, three new violations were introduced in Article 101:

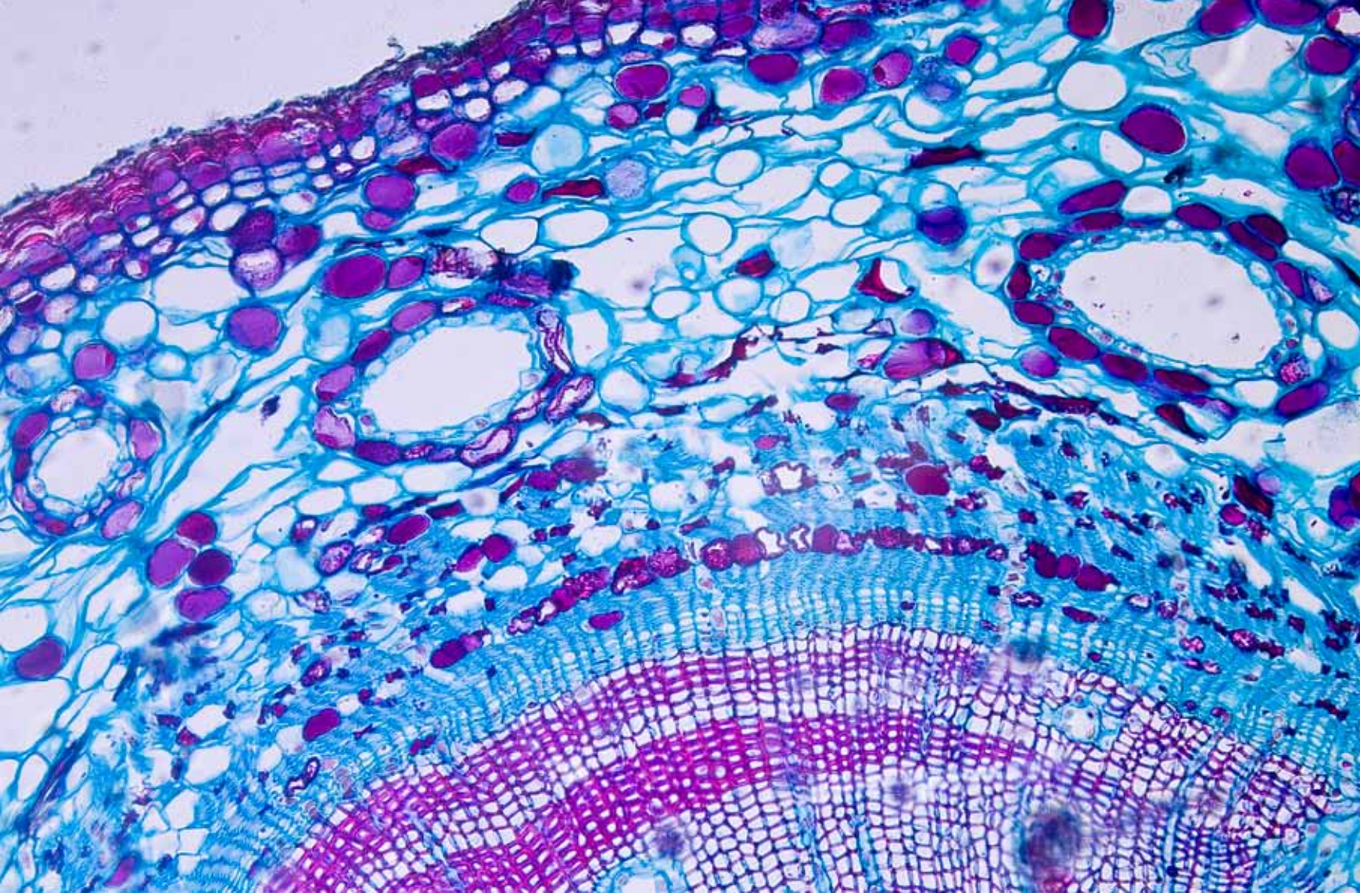
RDL 9/2011 ENVISAGES TOTAL ADAPTATION TO LAW 11/2007, 22 JUNE, ON ELECTRONIC ACCESS BY CITIZENS TO PUBLIC SERVICES

o shortages caused by the holder of the trading permit;

o cross-border distribution of medicines that are in short supply and which is leading to health care assistance problems;

o and distribution of medicines by pharmacies to other pharmacies or wholesalers, or to third parties outside of Spain.

▪ Finally, the 10th Transitional Provision includes a transitional regime for traceability (awaiting the development of Article 87 of Law 29/2006) through a medicines follow-up system by which pharmaceutical and wholesalers are under obligation to notify to the Ministry of



Health the lot number and the number of units sold, supplied or returned in Spanish territory, specifying the recipient, be it a pharmacy, pharmaceutical services or wholesalers.

Royal Decree Law 16/2012

At the time of going to print, the Spanish Official Gazette (in its 24 April issue), published a new RDL introducing sustainability measures for Spain's National Health Service: RDL 16/2012, 20 April, introducing a raft of urgent measures aimed at ensuring the sustainability of the National Health Service and improving the quality and safety of its assistance, as well as bringing major changes to the healthcare legal framework.

The new measures will cause public pharmaceutical spending to fall substantially and will have a considerable impact industry-wide. The main modifications introduced by this RDL affecting Law 29/2006 are as follows:

- Article 85. Prescription per branded product is fully accepted and it will not be replaced by another cheaper product, even when one is available. However, the preference for generic products at the same price is re-established when the prescription is per active Ingredinet. This preference had been eliminated by RDL 9/2011.

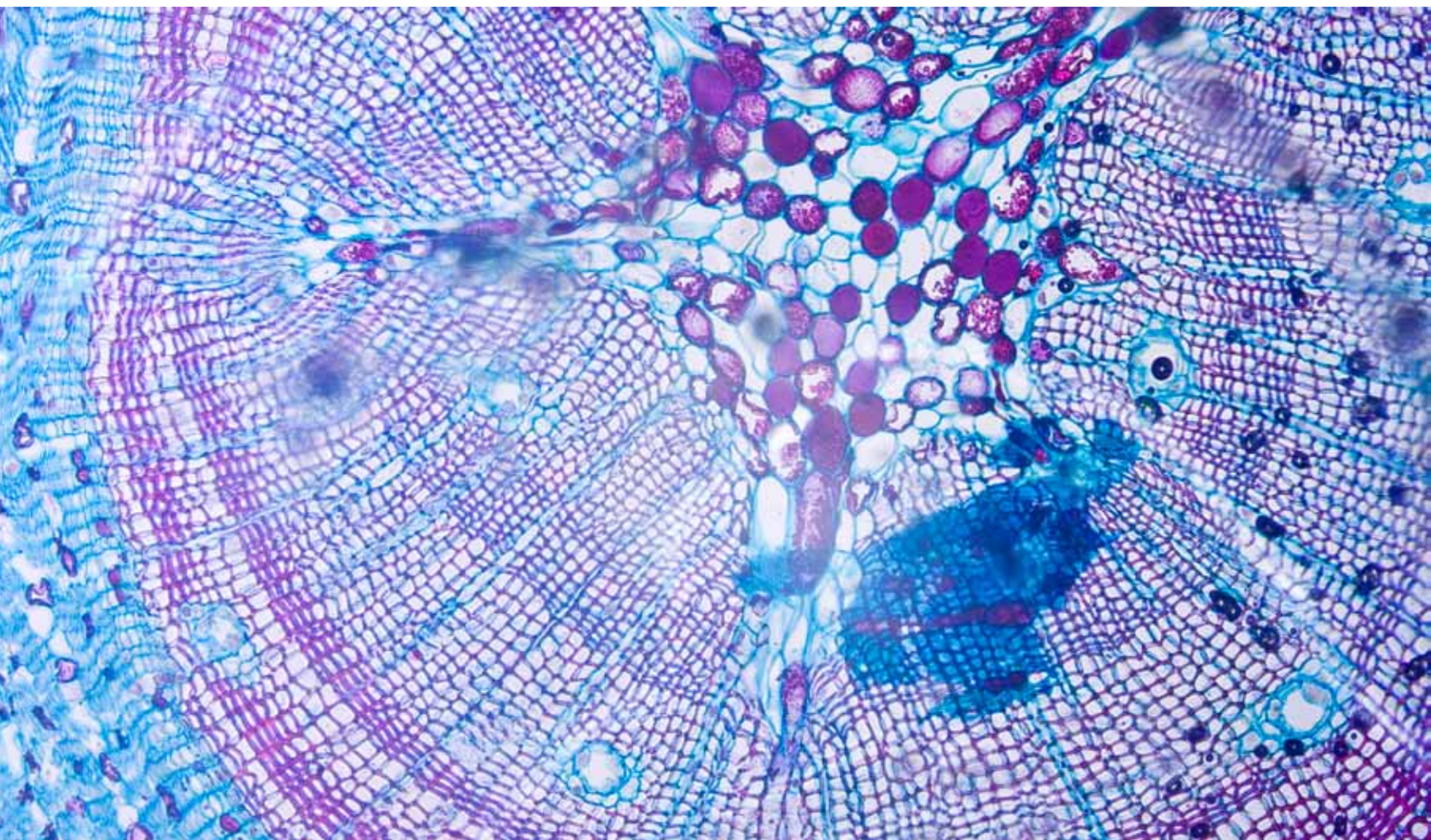
▪ Art. 85.3. Envisages the possibility of not financing medicines when they are suitable for minor symptoms, and when a financed medicine exists alongside a non-prescription medicine with the same active Ingredient and dosage. Those medicines will be charged for.

▪ Art. 89.1. Autonomous Regions are not allowed to place unilaterally special conditions on the prescription, dispensation and financing of medicines.

▪ Art. 89.2. Establishes the government's authority for reviewing medicine groups the financing of which it deems unnecessary. In any event, public pharmaceutical assistance will not include non-prescription medicines, or those suitable for minor syndromes or which are negative in terms of risk-benefit.

▪ Art. 89a. This article lays down the financing criteria for new medicines, as well as their cost effectiveness and budgetary impact, therapeutic advances and contribution to GDP. It also provides return mechanisms on innovative medicines (linear discounts, price reviews, etc.) and does away with all other references to medicine prices in other EU countries.

▪ Art. 90. Maintains the freedom to set prices for prescription medicines Included In public financing when they not dispensed other than by the National Health System. In addition,



this article lays down the obligation to notify non-financed and non-prescription medicine prices, and enables the Administration to lodge an objection when it considers the case to be one of public interest.

- Art 90a. Sets up a National Health Service Advisory Committee on Pharmaceutical Assistance comprising 7 reputed and experienced members appointed by the Minister (takes the place of the Cost Effectiveness Committee created by Royal Decree Law 9/2011)

- Art 91.6. In price reviews in which prices are lowered by pharmaceutical companies, only those which come down less that 10% of RRP are taken into account.

- Art 93. Enables the creation of reference prices ten years after the start of trading of the active ingredient in any EU member country, even if there is no corresponding generic available in Spain. Supply at a lower price must be guaranteed. The new sets and the price review of existing ones will be carried out annually. The new homogeneous groupings will be created automatically in each month's Nomenclature and prices will be reviewed on a quarterly basis.

- Art 93a. Sets up a "Selected Prices System" applicable only to medicines included In the Reference Prices. This system will be made up of different sets of reference prices.

- Art 94a. Sets up a new system through which users participate in medicine prices dispensed in pharmacies. The changes include a variable co-payment depending on the income of users: pay 40% of RRP if their income is lower than 18,000 euros per annum, 50% if their annual income falls between 18,000 and 100,000 euros, and 60% If their income exceeds 100,000 euros a year. Exceptions to these cases are users who are receiving state social integration benefits, the unemployed who do not receive benefits, people receiving treatment for workplace accidents and professional illness, people affected by the so-called Toxic Syndrome, and differently-abled people, according to specific rules. Pensioners are now required to pay 10% of RRP, with a ceiling of 8 to 18 euros a month depending on whether their income is lower than 18,000 euros a year or if it is between 18,000 and 100,000 per annum. Pensioners with an Income in excess of 100,000 euros p.a. are required to pay 60% of RRP with a ceiling of 60 euros a month. Those with non-contributory pensions are not required to pay. This article introduces co-payment in pharmacies and updates the existing maximum contribution and which will be updated annually in January according to the CPI.

- Art 97a. Each month, regional authorities will inform the Ministry of Health, Social Services and Equal Opportunities on turnover figures for medicines dispensed in pharmacies and acquisitions of hospital medicines, making a clear distinction on medicines dispensed in the pharmacy regime.

The expected subsequent fall in public pharmaceutical spending is without precedent in Spain.

Finally, this rule is pending regulatory development and, given its urgency, a number of doubts of interpretation have arisen that may lead to the issuing of explanatory circulars in the second half of 2012.

THE FALL IN PUBLIC PHARMACEUTICAL SPENDING RESULTING FROM THE APPLICATION OF MEASURES INCLUDED IN RDL 16/2012, IS WITHOUT PRECEDENT IN SPAIN

Resolutions concerning the Reference Price System

The Reference Price System (RPS) was reformed with the coming into effect of RDL 9/2011, which modifies Law 29/2006 on Guarantees and was further reformed by RDL 16/2012. There follows a summary of the changes introduced by both RDLs and the final configuration of the RPS at the time of going to print (May 2012).

RDL 9/2011 established that the creation of new sets and their corresponding reference prices, as well as the review of the existing ones be carried out by means of a Resolution by the Directorate-General of Pharmacy instead of through the usual procedure of a Ministry Order. Subsequently, the Official Gazette, issue 30 December 2011 published Resolution 28 December 2011 by the Directorate-General of Pharmacy and Medical Products on reference prices.

Nonetheless. RDL 16/2012, summed up previously in this Report, brought new changes to this legislation, with a return to the obligation to publish a Ministry Order to establish new sets and prices, or to modify existing ones.

A Resolution has been introduced for the first time regulating reference prices for hospital medicines. This Resolution has been criticized in a number of spheres because It does not lead to savings for Spain's National Health System because it regulates a market in which competition has already led to a substantial fall in the effective prices of the medicines concerned.

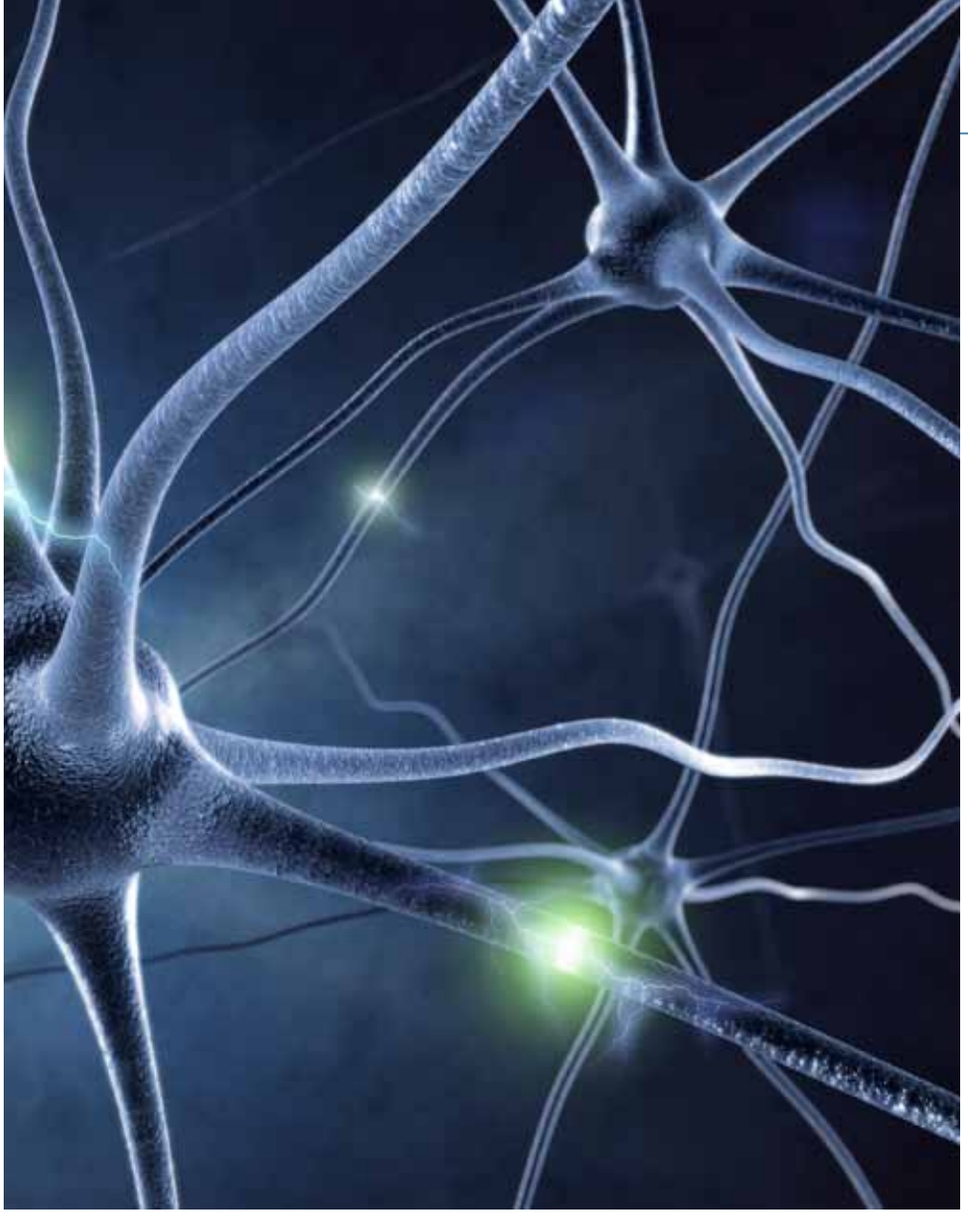
The system keeps as the reference price the lowest cost/treatment/day of the medicines that make up the group of medicines the same active ingredient and route of administration and which must include—as part of the National Health System's pharmaceutical assistance—at least one generic medicine or biosimilar medicine. But the new wording of Article 93 leaves out of the PRS the regulation of substitution, applicable to the homogeneous groupings by virtue of the conditions laid down in the new wording of Article 85. For this reason, all medicines eligible for one of the sets, regardless of whether or not they can be substituted mutually, are now affected by the PRS.

Finally, it should be noted that the reduction in price imposed by the reference prices have an impact on a number of homogeneous groups; as a result, prices in those groups are aligned downwards and there is even a possibility of further voluntary price reductions without changes to the National Code. These modifications are envisaged in the Resolution on reference prices and have been carried out, also for the first time, through a telematic procedure operated by the Ministry of Health's e-office.

FOR THE FIRST TIME EVER, A RESOLUTION HAS BEEN DRAWN UP TO REGULATE REFERENCE PRICES FOR HOSPITAL MEDICINES

3.I.2. THE AUTONOMOUS REGIONS

Over the past year, FARMAINDUSTRIA has stepped up its institutional activities in the sphere relations with Spain's Autonomous Regions, regional health authorities, scientific bodies, professional and political bodies, institutions and social organizations. The lynchpin of the Association's strategic policy in 2011 was to strengthen engagement and commu-



nication with all these stakeholders in an effort to represent and defend interest of our member companies.

In this respect, the Association has carried out close monitoring of the different regional initiatives regarding healthcare policy and access to pharmaceutical services, and has given its members information regularly on all the most relevant aspects.

Boletín Informativo de Comunidades Autónomas (BICCAA)
[The Autonomous Regions Official Gazette]
This space, available on the Association's website, brings together and analyzes the different healthcare and pharmaceutical activities carried out by Spain's Autonomous Regions. It is based on reports drawn up In conjunction with members of FARMAINDUSTRIA's autonomous region working groups.

This line of work arose in response to the need for coordinated information on the different healthcare initiatives at the regional health service level. The Observatory's overall objectives include the following:

EVERY TWO WEEKS, THE REGIONAL GOVERNMENTS' GAZETTES PUBLISH THE MOST IMPORTANT INFORMATION ON HEALTHCARE POLICY OF INTEREST TO THE PHARMACEUTICAL INDUSTRY

▪ Analysis and follow-up of regional actions on health policies and pharmaceutical provision.

▪ Coordination and joint compilation of reports.

▪ Dissemination of up-to-date and timely information that helps the decision-making process.

Similarly, throughout 2011, the Association has continued to draw up situational and theme-based reports on current major issues for the sector. Some of the main reports (available on the FARMAINDUSTRIA website) are as follows:

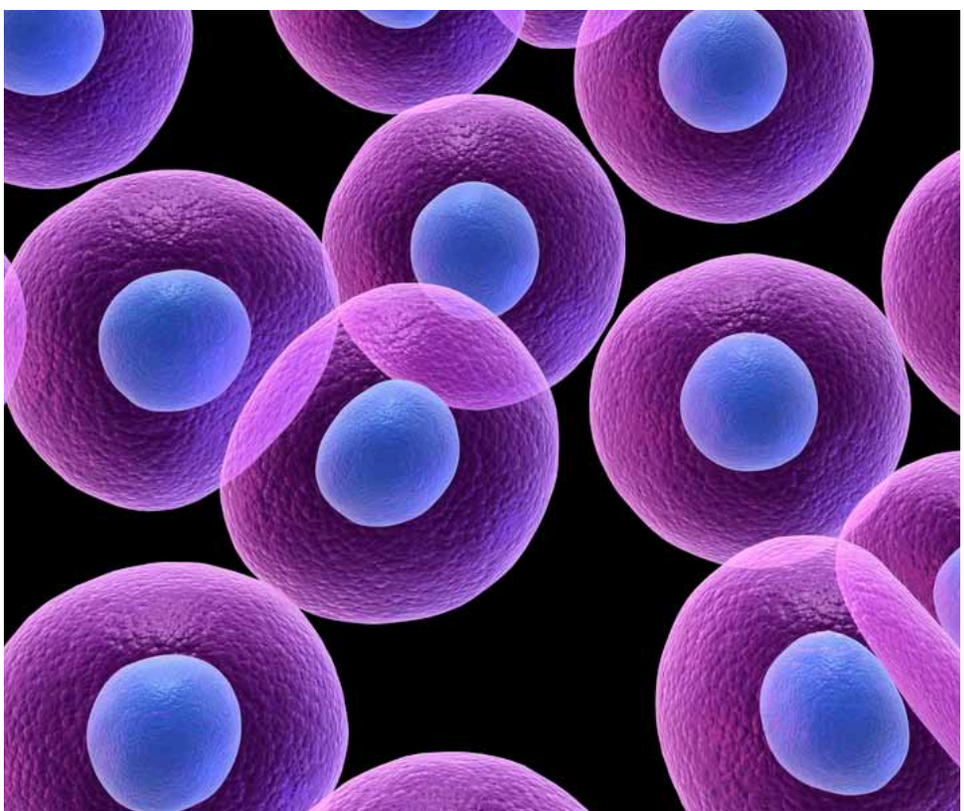
▪ Situational reports and basic data tables including regional healthcare information.

▪ Implementation of Royal Decree Law 9/2011 in each region.

▪ Active Ingredient Prescriptions. This report looks at the situation in each region, and offers, among other things, all the latest information on the percentages of Active Ingredient Prescriptions in relation to the total number of prescriptions.

▪ e-Prescriptions. Offers region-by-region information on the implementation of e-prescriptions and the support activity for e-prescriptions in each region.

▪ Medicines restricted to Hospital Dispensing. Current situation in each region.



- Health Services Budget 2011 —Budget and Health Spending 2010— Spanish National Health System.

- Budgets 2011: Regional, health services and pharmaceutical.

- Progress of the healthcare budget 2008–2011 per region.

- Progress of pharmaceutical spending 2008–2010 and the pharmaceutical budget (2011 total and per capita) for each region.

- Inequalities in the regional financing of medicines.

FARMAINDUSTRIA-Autonomous Regions Forums

FARMAINDUSTRIA organizes regular forums with healthcare representatives from central government and regional authorities which have become a major meeting point aimed at looking very closely at a broad range of current issues related to medicines and pharmaceutical provision in the Spanish national health system and to which the pharmaceutical industry, with its commitment to innovation, wishes to contribute and share its vision.

Over the past twelve months, the Association has organized two events dealing with innovation, sustainability and Spain's National Health System and the various initiatives that are being carried out in each region to control pharmaceutical spending.

- 14th FARMAINDUSTRIA-Autonomous Regions Forum; "Innovation and Sustainability in the National Health System" (Pamplona, Spain. February 17-18, 2011). Representatives from fifteen Spanish regions took part in the event which was opened by the Regional Health Department of Navarre and closed by the Director-General of Pharmacy and Healthcare Products of Spain's Ministry of Health, Social Policy and Equality.

- 15th FARMAINDUSTRIA-Autonomous Regions Forum; Medicines: A basic provision In the National Health System (Valladolid, Spain. March 8-9, 2012). The event was attended by representatives of 13 autonomous regions. The opening address was made by the Regional Health Minister of Castile-Leon and was closed by the Director-General of the Basic Portfolio of Services of the Spanish National Health Service and Pharmacy (Ministry of Health, Social Policy and Equality).

Institutional Contacts

FARMAINDUSTRIA has stepped up the communication and engagement efforts that it set up in previous years with regional health authorities. The Association has kept up its institutional contacts with regional health ministers and Pharmacy directors, informing them of the industry's priorities and addressing specific issues in each region.

Mention should be made also of the intense round of institutional meetings held ion the last quarter of 2011 and the first of 2012 to address the management, follow-up and

THE FORUMS WITH REGIONAL AUTHORITIES ORGANIZED BY FARMAINDUSTRIA HAVE CONSOLIDATED THEIR STANDING AS A MEETING POINT WHERE THE PHARMACEUTICAL INDUSTRY CAN ANALYZE DIFFERENT ASPECTS OF PHARMACEUTICAL CURRENT AFFAIRS

evaluation of the "+i" Program on Clinical and Translational Research Cooperation (dealt with in greater detail later in this Report). During these meetings, FARMAINDUSTRIA representatives seized the opportunity to explain to the representatives of regional authorities the industry's current situation as well as addressing regional authorities' debt for hospital supplies.

Regulatory initiatives within the scope of the Autonomous Regions

There follows a brief review of the year's main policies, regulations and initiatives at the regional level, and FARMAINDUSTRIA's activities in this respect:

Royal Decree Law 9/2011 and its implementation in the Autonomous Regions

Royal Decree Law (RDL) 9/2011-August 19, introducing measures aimed at improving the quality and cohesion of the National Health System, contributing to fiscal consolidation and raising the amount of State guarantees for 2011, brought with it a number of changes to Law 29/2006 on guarantees and the rational use of medicines and healthcare products. Among other aspects, it changed the wording of Article 85 establishing as a general rule Active Ingredient Prescriptions in Spain's National Health Service and requiring pharmacies to dispense the lowest-priced medicines, in accordance with the homogeneous groupings established by Spain's Ministry of Health.

Nonetheless, the provision envisaged the prescription of branded medicines and the dispensing of the prescribed medicine when the price of the medicine was not higher than the lowest price in the corresponding homogeneous grouping, in the following cases:

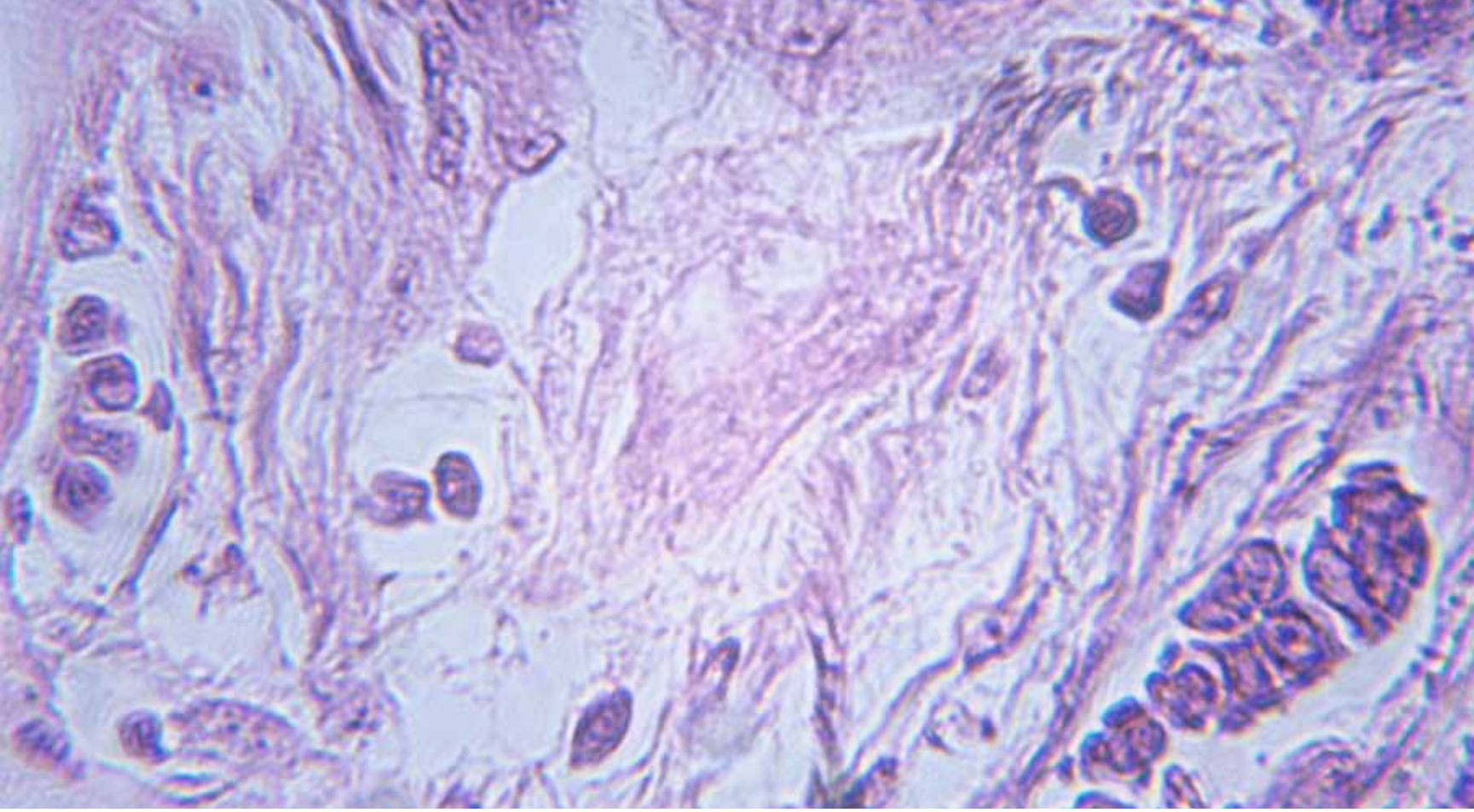
- As an exception to the overall rule.
- Owing to the therapeutic needs of the patient.
- When the medicines form part of single-medicine groupings and their licenses, with the same price as the medicine of reference.

Similarly, although no specific reference is made, the branded-medicine prescription is allowed when no substitute medicines are available (according to Article 86.4 of Law 29/2006 and Order SCO/2874/2007).

RDL 9/2011 LAYS DOWN AS A GENERAL RULE THE USE OF ACTIVE INGREDIENT PRESCRIPTIONS IN SPAIN'S NATIONAL HEALTH SYSTEM AND THE DIPSENSATION OF THE LOWEST-PRICED MEDICINE

In order to clearly define the scope of this rule, FARMAINDUSTRIA submitted an official query to the Director-General of the Health Ministry's Pharmacy and Healthcare Products Department. The Department's reply stated that medicines that are not part of homogeneous groupings may be prescribed per brand.

In this context, regional health authorities have drawn up a variety of rules or instructions addressed to healthcare professionals on how to apply RDL 9/2011 in their respective regions.



Accordingly, in the autonomous regions of Andalusia, the Canary Islands, Castile-Leon, Madrid and Navarre Active Ingredient Prescriptions (Spanish abbreviation PPA) are compulsory; in the Balearic Islands however, even though PPAs are compulsory, the regional health authorities announced a number of changes in the IT system to allow for branded-medicine prescriptions.

Galicia continues to have its own catalog which, for the time being at least, coincides essentially with the homogeneous grouping; this means that, in practice, the prevailing criterion is the prescription of branded medicines at the lowest available price.

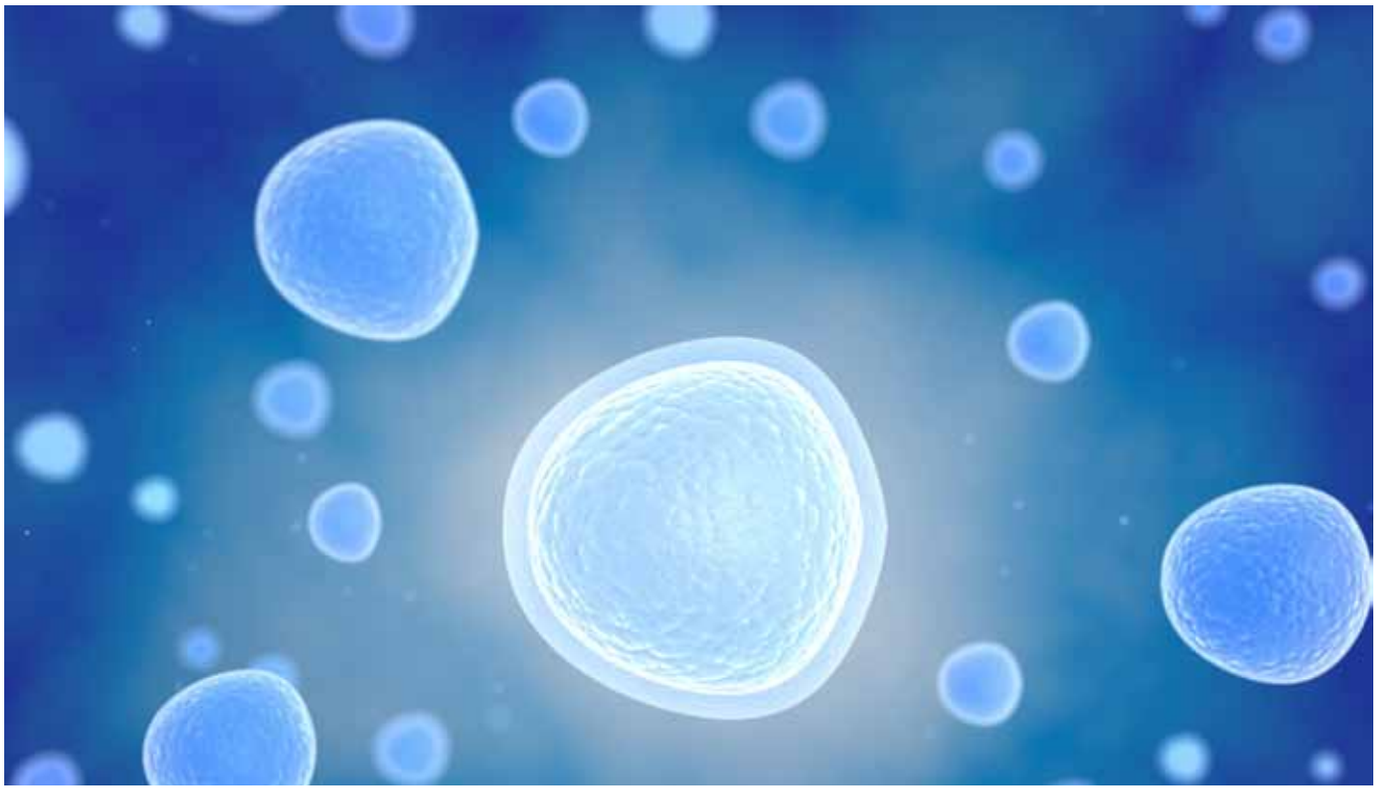
In the Valencia region, the authorities allow each so-called "health district" to choose between PPAs or branded medicines at the lowest price.

In other Spanish regions, PPAs are optional and there are no limitations on branded medicine prescription, providing the prescribed medicine is at the lowest available price.

Despite the abovementioned, it should be pointed out that all autonomous regions allow for branded-medicine prescriptions in accordance with existing regulations.

e-prescriptions and online medical patient records

e-prescriptions and online medical patient records continue to be implemented In Spain's regions. The regions of Andalusia, the Balearics, the Canaries, Cantabria, Catalonia, Extremadura, Galicia and the Basque Country have completed the implementation of e-prescriptions in their respective territories. At the time of going to print, the regions of



Andalusia, Catalonia Extremadura and Galicia already have their own particular e-prescriptions regulations.

Regarding online channels and resources, RDL 9/2011 foresees the full implementation and interoperability of e-prescriptions and online medical patient records before 1 January 2013.

Active Ingredient Prescriptions and Generics

As indicated in the previous section, several prescription models continue to co-exist in Spain's National Health System. However, the regions' desire to obtain savings in the pharmaceutical provision using PPAs has abated somewhat as a number of the branded medicines included in the homogeneous groupings have come down in price to become the lowest-price medicine, settling at a price comparable to the retail price of generics.

Exclusion of medicines from the e-prescriptions database: Castile-La Mancha and Extremadura

FARMAINDUSTRIA upholds its legal appeals against these regional health authorities to avoid the exclusion of certain branded medicines (mentioned in the Association's 2010 Annual Report) from the regional e-prescriptions system. However, it should be mentioned that at the time of going to press of the 2011 Report, the Extremadura health authorities have re-introduced nearly all of those previously excluded medicines into their regional prescriptions system.

Automatic substitution of medicines in prescriptions: The Basque Country, Cantabria and Aragon

Similarly, FARMAINDUSTRIA continues to pursue its appeals against the Basque Country, Cantabria and Aragon in an effort to reverse a number of changes made to the e-prescriptions system and which involved replacing branded medicines with active ingredient ones.

Regional catalog of medicines financed by public health authorities: Galicia

This initiative (likewise addressed by the FARMAINDUSTRIA 2010 Annual Report) is currently pending appeal in Spain's Constitutional Court, at the proposal of the Council of State, because it considers that Articles 1, 2, 3 and 4 and the first and second Provisions of Law 12/2010-22 December, aimed at rationalizing pharmaceutical provision expenditure in the autonomous region of Galicia, and Resolution 30 December 2010, which establishes the regional catalog of medicines financed in Galicia, encroach on State competences. The courts initially ruled a precautionary suspension which was later lifted on 3 March 2011.

FARMAINDUSTRIA has lodged an appeal (currently pending) against Resolution 30 December 2010.

However, it should be noted that the regional catalog of medicines financed In Galicia is practically In line with the homogeneous groupings and the reference prices established by Spain's Ministry of Health, Social Services and Equality as a result of RDL 9/2011.

Finally, it is important to point out that on 27 October 2011, the regional government In Galicia passed an amendment to this catalog to accommodate the review of the homogenous groupings of medicines, in order to adapt it to the new reference prices that came Into effect on 12 April 2012. In addition, 26 new homogeneous groupings of medicines and 32healthcare product groupings have been included.

Auctions of medicines dispensed in pharmacies: Andalusia

As a result of Decree Law 3/2011-13 December, introducing urgent measures on the pharmaceutical provision of the regional public health system in Andalusia, an auctions system has been set up to select the medicine that the region's pharmacies will be required to dispense in the event of an active ingredient prescription.

Pursuant to this Decree Law, the Andalusia Regional Health Authority, in accordance with Resolution 25 January, issued a call for tender in order to select the medicines of choice for active ingredient prescriptions for statins, proton pump inhibitors and antiplatelet agents, among others.

This initiative led to the Spanish Government appealing to the Constitutional Court alleging a positive conflict of competences, because it considers that the regional authorities are encroaching on competences of the State.

DIFFERENT AND VARIED PRESCRIPTION MODELS CONTINUE TO EXIST SIDE-BY-SIDE IN SPAIN'S NATIONAL HEALTH SYSTEM

THE REGIONS CONTINUE TO DRIVE PROJECTS AIMED AT ESTABLISHING CENTRALIZED PROCUREMENT OF MEDICINES FOR THEIR HOSPITALS AND CLINICS

FARMAINDUSTRIA has lodged a similar appeal against this Resolution passed by the Andalusia Regional Health Authority.

Regional committees for the evaluation of medicines

FARMAINDUSTRIA has carried out exhaustive follow-up work on the different regional initiatives aimed at setting up committees, commissions or advisory boards on the evaluation of medicines, directed, according to each case, at regional authorities and with the intention of clearing up existing doubts and issues that are likely to affect the industry. Up until now, seven Spanish regions have adopted provisions, namely Andalusia, Aragon, Catalonia, Galicia, Madrid, Navarre and Valencia. Legal appeals have been filed against Aragon and Madrid and the courts have ruled in favor of FARMAINDUSTRIA in the case of the latter.

As a result of the abovementioned ruling, the Madrid autonomous region has started proceedings to issue a new order to set up the so-called Rational Use of Medicines Committee which led to FARMAINDUSTRIA presenting allegations during the proceedings' public information phase.

Central Purchasing Bodies for Medicines

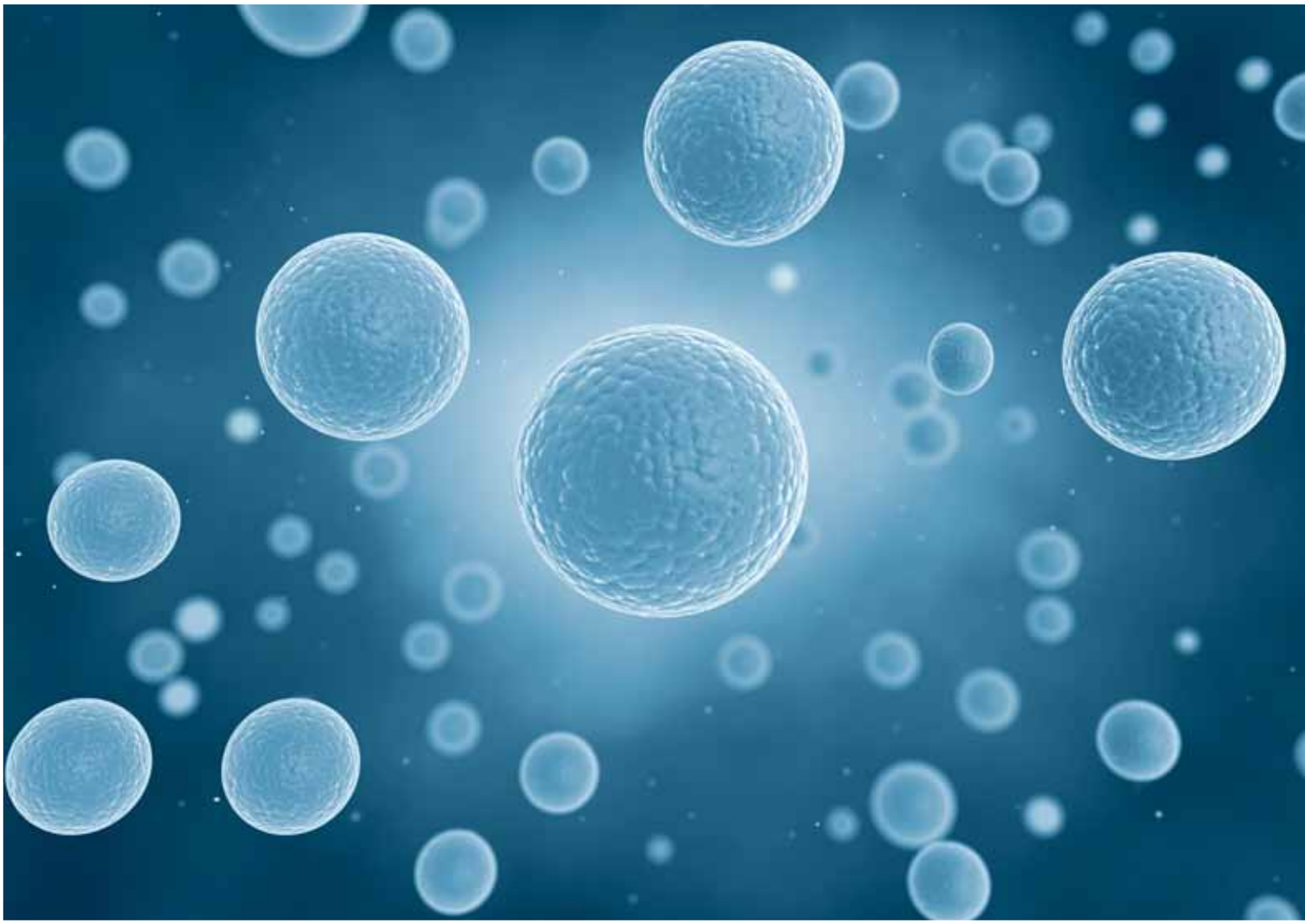
Spain's regions continue to launch projects intended to promote the centralized acquisition of medicines for their respective healthcare centers and hospital services via central purchasing bodies or aggregated purchase arrangements. In this respect, the Castile-Leon regional authorities have passed Order SAN/19/2012-13 January, to set up the region's Central Purchasing Body, joining similar existing initiatives in other regions, such as the Basque Country, Valencia, Murcia, Catalonia, Andalusia, Madrid and Galicia.

In this respect, special mention should be made of the Agreements set up by Spain's National Health System's Inter-Territorial Council on 18 March 2012; among other initiatives, these Agreements envisage the setting-up of an Aggregate Purchases Proceeding for the National Health System overall, open to other regions on a voluntary basis.

Conversion of Hospital Diagnosis Medicines to Hospital-Dispensed Medicines/Hospital Medicines

The 2010 FARMAINDUSTRIA Annual Report highlighted the different initiatives being adopted region by region to ensure that certain Hospital Diagnosis Medicines (HDM) are converted to Hospital-Dispensed Medicines. This covers mainly medicines for cancer processes, rheumatoid arthritis, psoriasis, ovarian stimulation and acromegaly.

In this respect, the Directorate-General of the Basic Portfolio of Services of Spain's National Health System approved, by Resolution, a list of medicines that are now dispensed in hospital dispensaries and which, consequently, no longer carry the medication labels required previously. The list features 79 medicines (52 came into effect on 1 March 2012 and the remaining 27 on 1 April 2012).



This list is not legally binding for the regions and these are allowed to choose freely and unilaterally which medicines may be acquired solely in hospital dispensaries and financed by the public health system covering the region. FARMAINDUSTRIA has been following-up these initiatives and has made their findings and conclusions available to member companies on the Association's website.

Castile-La Mancha. Implementation of the Therapeutic Equivalents Program

The Castile-La Mancha regional public health service's e-prescription program (known as "Turriano") was supplemented in April 2012 with a new IT tool which facilitates the interchangeability of active ingredients.

IN 2011 THE 84 PROJECTS THAT MAKE UP THE "+I" PROGRAM, IN ACCORDANCE WITH THE AGREEMENTS ESTABLISHED BETWEEN FARMAINDUSTRIA AND THE REGIONS, CONTINUED TO MOVE FORWARDS

At the moment this program includes the following active ingredients:

i) Omeprazole, as the most efficient IBP;

ii) Simvastatin, as the most efficient statin in cases of dislipidemia, and

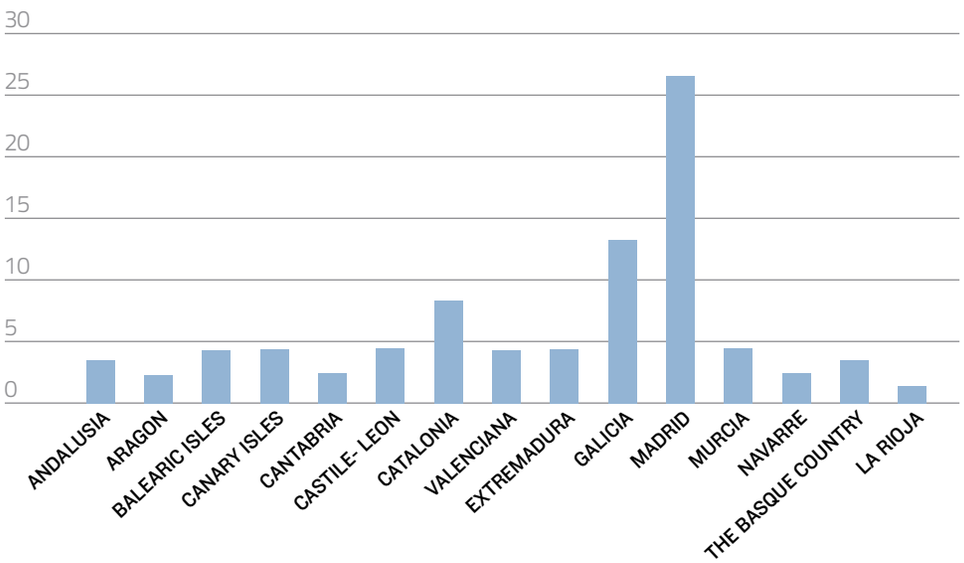
iii) Losartan, Valsartan and Irbesartan, alone or in conjunction with hydrochlorothiazide, as the most efficient angiotensin II receptor antagonists (ARA II).

Among other measures, FARMAINDUSTRIA has called for an injunction against this initiative (with the leave to appeal) because the Association considers it to a covert exclusion from the public financing of medicines affected in this particular region as well as a violation of the existing regulatory framework.

The "i+" Program. Program for Cooperation in Translational Clinical Research

2011 saw continued efforts to develop the 84 projects that make up the "+i" Program, according to to the agreements reached by FARMAINDUSTRIA and the autonomous regions:

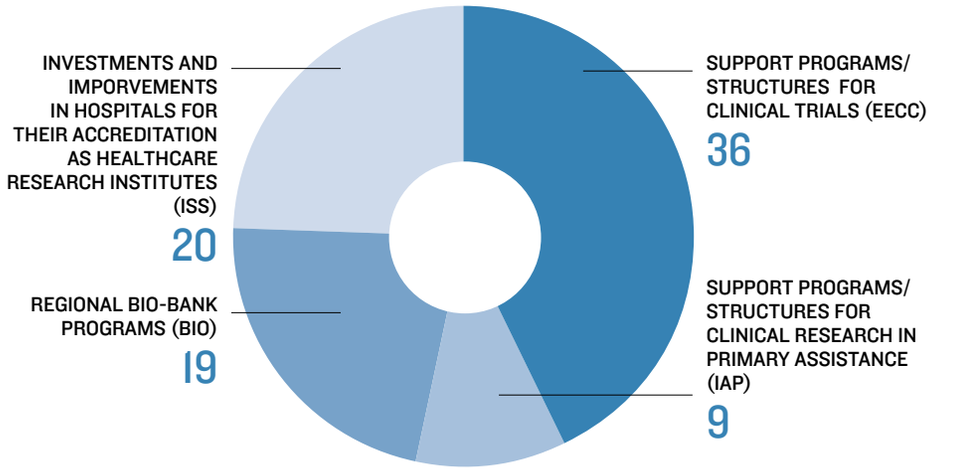
NUMBER OF PROJECTS



The regions with the greatest number of projects financed are Madrid (26), Galicia (13) and Catalonia (8). Between them, these three regions account for more than half of the total projects.

The figure below shows the distribution of projects according to areas of cooperation:

TYPE OF PROJECT



TOTAL: 84

The different projects that comprise the "+i" Program are financed jointly by FARMAINDUSTRIA and the corresponding autonomous region. The table below shows the participation of both bodies and the total budget for each project.

	Contribution by FARMAINDUSTRIA	Contribution per region	Total	Number of projects
Andalusia	8,000,000 €	9,766,000 €	17,765,000 €	3
Aragon	1,500,000 €	1,500,000 €	3,000,000 €	2
Balearic Isles	1,20,000 €	1,380,000 €	2,580,000 €	4
Canary Isles	1,998,000 €	1,932,000 €	3,930,000 €	4
Cantabria	600,000 €	600,000 €	1,200,000 €	2
Castile-Leon	2,483,500 €	2,848,000 €	5,331,500 €	4
Catalonia	7,000,000 €	18,394,370 €	25,394,370 €	8
Valencia	5,000,000 €	5,712,054 €	10,712,054 €	4
Extremadura	1,200,000 €	906,846 €	2,106,846 €	4
Galicia	2,454,126 €	2,644,505 €	5,098,631 €	13
Madrid	6,000,000 €	5,998,682 €	11,998,682 €	26
Murcia	1,500,000 €	1,551,500 €	3,051,500 €	4
Navarre	600,000 €	560,000 €	1,160,000 €	2
The Basque Country	2,000,000 €	2,214,000 €	4,214,000 €	3
La Rioja	300,000 €	495,000 €	795,000 €	1
Total	41,835,626 €	56,501,957 €	98,337,583 €	84

In compliance with the agreements, in September 2011the regions forwarded to FARMAINDUSTRIA the performance reports for the first half of 2011. After being analyzed by the Project Support Office (Deloitte), these reports were examined by the Follow-Up Committees of the "i+" Program; they found no deviations on the targets set for each project.

In this respect it should be recalled that the Follow-Up Committees for the "i+" Program are regional bodies set up jointly by the each region and Farmaindustria and with a collaboration agreement. Their basic aim is to oversee the "+i" Program's development and, in particular, to ensure the coordinated follow-up of the projects that make up the Program, as well as ensuring their correct management and assessment.

The following table lists the meetings held by the different Follow-Up Committees during 2011.

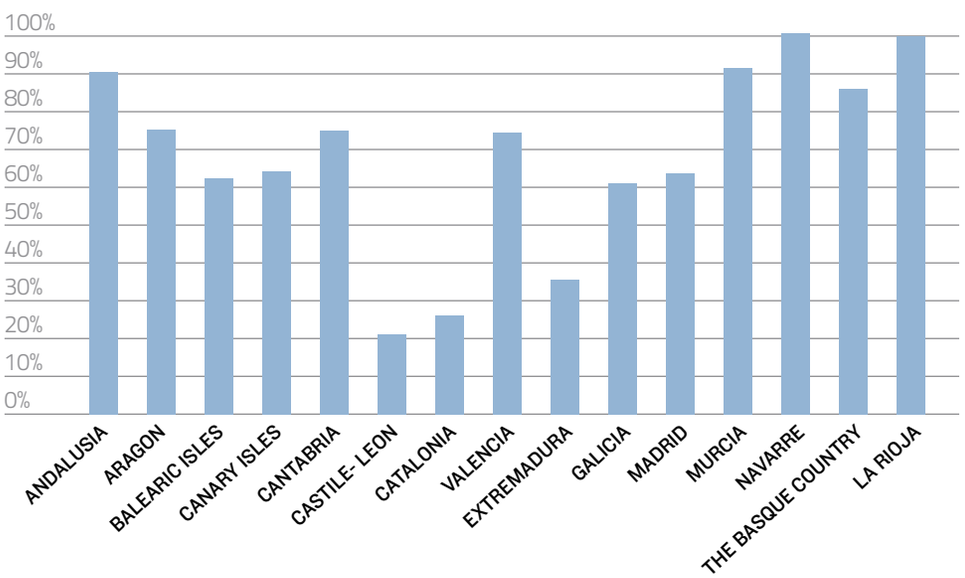
	Date that the Follow-Up Committees met
Andalusia	10/11/2011
Aragon	21/12/2011
Balearic Isles	20/10/2011
Canary Isles	22/11/2011
Cantabria	21/09/2011 10/12/2011
Castile- Leon	29/11/2011
Catalonia	13/12/2011
Valencia	18/10/2011
Extremadura	15/11/2011
Galicia	20/01/2012
Madrid	29/09/2011
Murcia	26/01/2011
Navarre	30/11/2011
The Basque Country	26/10/2011
La Rioja	15/12/2011

FARMAINDUSTRIA SITS ON A VARIETY OF HEALTH MINISTRY ADVISORY COMMITTEES, WHICH HELPS TO CONVEY THE INDUSTRY'S POSTION TO THE HEALTH AUTHORITIES

In order to measure the progress of the Program a number of targets were set for each project.

The table below shows in percentages to what extent each region met its targets from the outset of the Program until the first half of 2011.

% OF TARGETS ACHIEVED



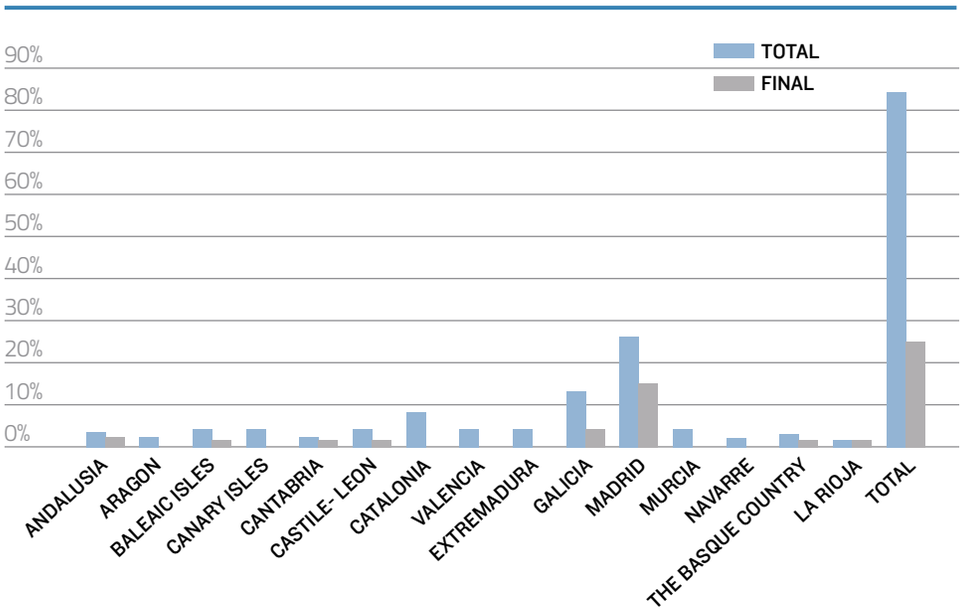
Quite clearly, the leaders are Navarre and La Rioja, with a score of 100%, with Murcia and the Basque Country slightly behind with around 90%.

At the time of going to press, a new round of meetings is being held by the regional Follow-Up Committees, In which they are analyzing the performance reports of the projects for the second half and full-year of 2011, as well as the audit reports on the costs funded by FARMAINDUSTRIA. All the regions have sent FARMAINDUSTRIA the performance and audit reports for the abovementioned period and the Project Support Office (Deloitte) has detected no irregularities worthy of note.

While still at a preliminary stage (the Follow-Up Commissions have yet to formalize the data), the information thus far appears to indicate that the year 2011 will see the completion of 26 projects in all:

- Andalusia, 3 projects. The project involving the construction of the Malaga Research Institute has been cancelled and the contribution made by FARMAINDUSTRIA has been refunded.
- Baleares, 1 project.
- Cantabria, 1 project.
- Galicia, 4 projects.
- Madrid, 15 projects.
- Basque Country, 1 project.
- La Rioja, 1 project.

The table below shows the completion dates forecast for the projects of each region.



IN 2011 AN AMBITIOUS MEDIA RELATIONS CAMPAIGN (INCLUDINGTHE REGIONAL MEDIA) WAS PUT INTO PLACE IN AN EFFORT TO CONSOLIDATE THE INDUSTRY'S COVERAGE BY, ACCESS TO AND INFLUENCE ON THE MEDIA

3.I.3.
CONSULTATIVE AND ADVISORY COMMITTEES

FARMAINDUSTRIA's institutional presence in a range of the Ministry of Health, Social Services and Equality's consultative and advisory committees comes as an opportunity to convey to the health authorities the industry's position in a greater framework of participation and transparency. FARMAINDUSTRIA's inclusion in this kind of committees helps to normalize institutional relations and this is particularly necessary given the current situation.

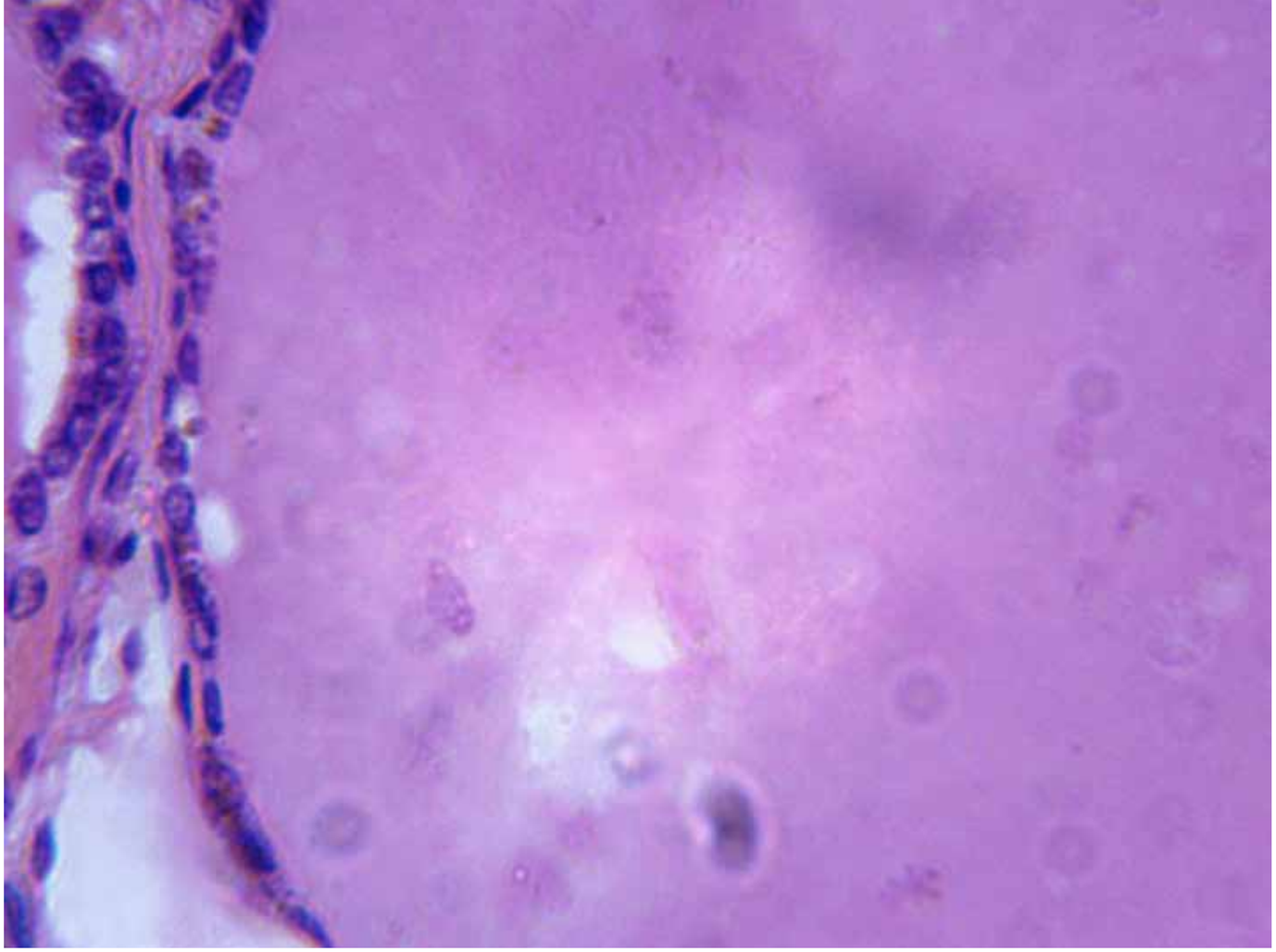
Advisory Committee of the Inter-Territorial Council of the National Health System

Chaired by the Secretary-General of Health, this advisory committee sets out to debate and inform on the regulatory projects presented to the Inter-Territorial Council of the National Health System. The Committee is made up of representatives of the different administrations (local, regional and central), labor unions and business organizations (including FARMAINDUSTRIA).

In the current legislative period, the Committee held its first meeting with the presence of the Minister of Health, Ms. Ana Mato, and is likely to be among the participatory bodies of the social representatives of the future State Compact for Health and Social Services, which will culminate in the Basic Services Law.

Medicines for Human Consumption Committee

The transformation of the Spanish Medicines and Healthcare Products Agency (Spanish acronym AEMPS) into the State Agency changed the role and relevance of the Medicines for Human Consumption Committee (acronym CMH). The CMH represents the interest of society



and ensures the transparency, objectivity and scientific rigor in the Agency's decisions regarding the trading of medicines.

The 22-member CMH (6 more than the former CODEM, thanks to the incorporation of the AEMPS representative in the European Agency for the Evaluation of Medicinal Products and the 5 heads of the AEMPS's different Medicines for Human Consumption divisions) has 4 members appointed on the basis of their posts (the Director of the AEMPS, the head of the Medicines for Human Consumption Department, a representative of the Directorate-General of the Services and Pharmacies Portfolio and a representative of the Directorate-General of Industry) as well as 12 members appointed by the AEMPS's Steering Committee, chosen among reputed and dedicated members of the scientific community and fields related to medicines and therapeutics, one of whom is appointed at the proposal of FARMAINDUSTRIA.

The CMH's overriding mission is to ensure the efficiency and transparency of the authorization procedures for medicines, to inform in a prescriptive but non-binding manner on authorization procedures, relevant changes, suspension or revocation of Medicines for Human Consumption and also, when called upon by the Steering Committee, to compile reports on procedures related to Medicines for Human Consumption.

The standout feature this year, as far as the CMH is concerned, is that the CMH is now in charge of coordinating the Committees and Working Groups involved in the procedures of evaluation and therapeutic utility of Medicines for Human Consumption.

3.2.

SOCIAL COMMUNICATION

In 2011, as in recent years, FARMAINDUSTRIA continued to carry out its important work in social communication in an effort to raise the pharmaceutical sector's public profile and make it better known to society at large.

FARMAINDUSTRIA's communication campaigns in 2011 revolved mainly around achieving the Association's strategic goals. Subsequently, it set about, first and foremost, increasing its influence in the major public debates on healthcare and the pharmaceutical sector, as well as raising the Association's public profile and its capacity to influence through the media.

It also worked hard to position the pharmaceutical industry as a strategic sector from an economic and social point of view, in order to enhance its image in the media, in the public arena, among patients and healthcare professionals, institutions, public and private bodies, not-for-profit organizations and other collectives and in society in general.

In 2011 is communication efforts targeted three main stakeholders: the media, society overall and patients in particular and the new information and relational mechanisms and channels such as the social media.

3.2.1.
THE MEDIA

FARMAINDUSTRIA's three main lines of engagement with the media in 2011, as in previous years, aimed primarily at gaining the trust of the media and its professionals in order to move closer to society, make the pharmaceutical sector better-known and raise its social standing.

With its sights set on this goal, the Association drew up an ambitious media engagement policy, including the regional media, as a way of consolidating the pharmaceutical sector's presence in, access to and influence over the media.

As well as continuing to develop its more traditional communication activities and increase its standing as a yardstick in high-level public debate on healthcare, in 2011 FARMAINDUSTRIA made a special effort to adapt to the new media and information mechanisms that have erupted on the Spanish media scene.

Similarly, it looked more closely at how to elicit media interest in pharmaceutical sector issues helping to create specific coverage in a variety of formats, and particularly in the regional media. At the same time, FARMAINDUSTRIA continued to provide background for media professionals and honed assessment and follow-up tools to ensure greater efficiency and to be able to delve deeper into their various working areas.

IN 2011 AN AMBITIOUS MEDIA RELATIONS CAMPAIGN (INCLUDINGTHE REGIONAL MEDIA) WAS PUT INTO PLACE IN AN EFFORT TO CONSOLIDATE THE INDUSTRY'S COVERAGE BY, ACCESS TO AND INFLUENCE ON THE MEDIA

2011 stood out for a number of media milestones for Spain's pharmaceutical sector which garnered extensive and nationwide media coverage and which led the Association to step up its communication activity compared to previous years.

The most important media action carried out by FARMAINDUSTRIA, not only In terms of impacts but also overall efficiency, was the Action Plan (press releases, interviews, opinion, etc.) which was carried out throughout the year to raise public awareness on the public health authorities' debt outstanding with the pharmaceutical industry as a result of medicines supplied to Spain's state hospitals.

Another important moment in terms of repercussion and impact came in February 2011 with the public announcement of the "Manifesto for the Sustainability and Cohesion of Pharmaceutical Provision" subscribed by FARMAINDUSTRIA, the General Council for Professional Associations of Pharmacists, the Federation of Pharmaceutical Distribution Companies and the Spanish Association of Manufacturers of Generic Substances and Specialties to express their rejection of the restrictions on pharmaceutical provision either adopted or announced by a number of Spain's autonomous regions.

The defense of the integrity of the pharmaceutical market in the face of measures adopted by some regional governments and which violated the principle of Spanish patient's equal access to treatments available was yet another major media event in 2011.Cosniderable media attention centered on initiatives such as Galicia's Priority Medicines Catalog; Castile-La Mancha's decision to pull out of the "Turriano" prescriptions program, 133 medicines withdrawn from prescription, or the Decree passed in Andalusia establishing an auctions mechanism to select the medicines to be dispensed by pharmacies when a prescription is for an active ingredient.

In each case, every effort was made to convey the pharmaceutical industry's position (and the social and economic consequences of the decisions adopted) to the local media in the regions affected.

In addition, when RDL 9/2011 was passed, with its enormous economic impact, FARMAINDUSTRIA rolled out an intense media campaign to put the spotlight on the measures' grave consequences for Spain's pharmaceutical sector. Similarly, the Association drew on an impressive array of communication resources (interviews, opinion articles, press releases, etc.) to defend the pharmaceutical brand stressing the fact that with the new regulations original medicines lead to maximum savings for the National Health System because in order to be dispensed they had to first align themselves with the lowest available retail price, which puts them on an equal footing with generics in terms of savings.

The media spotlight also fell on FARMAINDUSTRIA on a number of other occasions in 2011 as a result of various industry issues. A case in point was the announcement of the Pharmaceutical industry Sector Plan, with the participation of Leire Pajin and Cristina Garmendia, the ministers of Health and Science & Innovation at the time, and the Secretaries-General

of Health and Innovation. Similarly, a meeting with the erstwhile leader of the Opposition, Mariano Rajoy, and the report on Spain's National Health System titled "Is healthcare no longer a social priority?" commissioned by FARMAINDUSTRIA and compiled by AT Kearney, also prompted considerable media attention.

IN 2011 FARMAINDUSTRIA's role in current affairs, making its presence felt in major economic sectors, also came in the shape of a monthly section ~~ec~~onomic bulletins under the heading "The Medicine Market in Spain", compiled by FARMAINDUSTRIA ~~pu~~blished in the business daily "Expansión" and which have earned themselves a reputation as an accurate snapshot of Spain's pharmaceutical market and its attendant factors and players.

In 2011 FARMAINDUSTRIA took another step forward towards its goal of consolidating its position as an opinion leader in industry current affairs and set up, in conjunction with Spain's Europa Press news agency, a number of forums for debate and thought on issues of interest and current debate for the healthcare sector overall and for the pharmaceutical industry in particular. Under the name "Ideas & Dialog on Healthcare Forums" four events were held in Madrid featuring guest speakers such as the Health Minister at the time, Leire Pajín; Catalonia's regional minister of Health, Boi Ruiz; the former Spanish Prime Minister, Felipe Gonzalez, and the Partido Popular's Participation Secretary at the time, Ana Pastor. The forums were extremely successful in terms of the number of attendees, media coverage and the exchange of ideas, positions and proposals on healthcare in Spain.

As in previous years, FARMAINDUSTRIA also stepped up its presence in the print media with creative advertising.

On the one hand, it sought to emphasize its role as an R&D leader in the pharmaceutical industry and to underscore how the sector's notable investment efforts help to improve not only Spain's productive model but also the quality of life of the man and woman on the street. Ultimately, its intention was to showcase not only the industry's contribution to healthcare overall, but also its importance as a strategic sector in the current economic clime which urgently needs sectors based on innovation and knowledge.

On the other hand, it drew on advertising to highlight its engagement with Patient Associations, in an effort to encourage them to take part in the FARMAINDUSTRIA Foundation's 2011 Awards.

3.2.2. SOCIAL ENGAGEMENT

As part of its efforts to get closer to society, in 2011 FARMAINDUSTRIA organized a range of activities aimed at highlighting the sector's commitment and contribution to public health and society overall.

On the one hand, the Association took on a highly active role in events such as debates, conferences, round tables, etc. organized by various collectives and aimed at a broad range of audiences. A prime example is the Association's participation in the long-standing summer courses organized by Santander's Menendez Pelayo International University which, on this occasion, looked at public policy priorities during times of crisis.

The Association continues to collaborate with and take part In events organized by NGOs such as Pharmacists Without Borders Spain who informed FARMAINDUSTRIA on the medicine and healthcare product needs of the people of Haiti and the Dominican Republic who are faced with a cholera outbreak; the "Fundación Corresponsables", or the 2nd "Farmacriticxs" Seminars, which addressed a range of issues such as access to essential medicines, medicine assessment or the pharmaceutical industry's engagement with doctors, and advertising and information for patients.

Similarly, FARMAINDUSTRIA and the Spanish Platform for Clinical Trials (CAIBER) organized an awareness campaign highlighting the importance of promoting clinical trials and taking part in them.

FARMAINDUSTRIA HAS COLLABORATED WITH A SPANISH PLATFORM FOR CLINICAL TRIALS AIMED AT RAISING SOCIAL AWARENESS OF THE IMPORTANCE OF PROMOTING AND PARTICPATING IN CLINICAL TRIALS

2011 also saw the publication of a new edition of the "Study on how the Pharmaceutical Industry is perceived", which was commissioned to market analysts Sigma Dos. The conclusions indicate that the pharmaceutical industry is seen in a better light than other industrial sectors as far as factors such as contribution to quality of life, availability of advanced technology and R&D investment are concerned. It also reveals that in recent years more than 60% of the Spanish population has improved its perception of the sector, and that medicines continue to be one of society's most highly-valued items: 84% of society shows great trust in medicines, although the public is relatively unaware of the long and expensive research activities involved in coming up with a new medicinal product.

2011 saw further work by FARMAINDUSTRIA's Social Council, a deliberative body which brings an outside vision on issues of Interest to the pharmaceutical Industry and proposes possible courses of action. This consultative organ was joined recently by former Spanish Prime Minister, Felipe Gonzalez, bringing the total number of members to eight. The other members are Guillermo de la Dehesa, Vice Chairman Goldman Sachs and Chairman of the European Central Bank Observatory; Joaquín Moya-Angeler, Chairman of the Andalusia Technological Corporation; Pedro Nueno, Senior Lecturer in Business Initative at the IESE Business school;

Isabel Aguilera, Independent Director; Federico Mayor Zaragoza, Chairman of "Fundación por una Cultura de Paz"; Joan Mulet, Managing Director of COTEC and Joan Rodés, General Manager of the Barcelona Clinical Hospital.

FARMAINDUSTRIA continues to participate in a variety of forums aimed at addressing social communication challenges faced by businesses and institutions, including events organized by the communication heads of CEOE [Spanish Confederation of Employers' Organizations] member organizations, or the CEOE's Social Responsibility Committee, of which the Association is an active member.

External communication is important, but for FARMAINDUSTRIA internal engagement with its member companies is equally important, and a range of well-established channels is in place to ensure a regular flow of communication, fresh information, exchange of ideas and, in short, a communication marked by sound coordination and transparency.

The Association's "Weekly Communication Briefing", of which 43 issues were distributed by e-mail in 2011, is a prime example of how highly FARMAINDUSTRIA values internal communication.

Similarly, member companies receive regular reports on not only the Communication Department's activities, but also on media coverage and impact, which analyze media activity and assess campaign efficiency.

Finally, four meetings of the Communication Working Group were convened in 2011, attended by a large number of representatives from pharmaceutical companies. The meetings addressed a variety of industry-related issues and helped to give greater coherence to outgoing messages and improved coordination between members.

3.2.3. HEALTHCARE PLAYERS: PATIENTS

INTERNAL COMMUNICATION WITH MEMBER COMPANIES IS JUST AS IMPORTANT AS EXTERNAL COMMUNICATION

Last year FARMAINDUSTRIA stepped up activities with patients and, in particular, the organizations that represent them. Long-standing activities, such as the Association's "Pacientes" magazine and the Best Patient Initiatives Awards, were joined by a range of initiatives including the "Pharmaceutical Industry and Patients Associations Seminars" or the setting up of an internet-based platform aimed at providing information and service to patients and Patients Organizations, their families, carers and healthcare professionals. The Patients ad hoc group continued to function, with a busy agenda of visits and meetings with over 70 Patients Organizations.

The "Best Patient Initiatives Awards"

In 2011, the annual ceremony of FARMAINDUSTRIA Foundation's "Best Patient Initiatives Awards"—now a major event on the Patients Organization calendar—was held on December 13th. Last year, there were more than 300 entries.

By pathologies, the Patients Organizations with the most representatives in last year's Awards were Alzheimer's sufferers and their families, patients with mental disorders, cancer patients, patients with heart disease, sufferers of rare diseases, diabetes sufferers, patients with Parkinson's disease and those with multiple sclerosis, among others.

The award winners were decided by the following multidisciplinary panel of judges: Iván Ballesteros, Vice Chairman of the Seve Ballesteros Foundation; Luis Cayo, Chairman of the Spanish Committee of Representatives of the Differently-Abled; Pilar Cernuda, journalist; Dr. Manuel Díaz-Rubio, Chairman of Spain's Royal Academy of Medicine; María Antonia Gimón, Chair of the Spanish Breast Cancer Federation; Elsa González, Chair of the federation of Associations of Spanish Journalists; José Ramón Hidalgo, Director of the Office of the Extremadura Regional Health Services Ombudsman; Albert Jovell, Chairman of the Spanish Patients' Forum; Javier Nadal, Chairman of the Spanish Association of Foundations;. Eduardo Punset, editor of the Spanish national TV program "Redes" [Networks]; Ramón Sánchez Ocaña, journalist; Paloma Segrelles, Honorary Chair of Club Siglo XXI [a cultural association]; Juan Manuel Suarez del Toro, Chairman of the Spanish Red Cross; Marta Valencia Beltrán, Secretary-General of COCEMFE ARAGÓN; and Pasqual Maragall and his wife Diana Garrigosa), who were awarded the "Best Patient Initiatives Awards"

THE FARMAINDUSTRIA FOUNDATION'S AWARDS FOR THE BEST INITIATIVES FOR SERVICES TO PATIENTS ARE NOW ROOTED FIRMLY AND STAND AS AN INDUSTRY YARDSTICK FOR PATIENT ORGANIZATIONS

in 2010, In the "Personality" category. In addition, FUNDACIÓN FARMAINDUSTRIA was represented on the Panel of Judges by its Chairman, Jordi Ramentol; Director Humberto Arnés, and patrons Jordi Martí, Francisco Quintanilla and Martín Selles.

Following tradition, the 2011 awards ceremony was held In Madrid's Real Fábrica de Tapices [Royal Tapestry Manufactory] and winners and runners-up received a diploma. The ceremony drew a large number of guests and the full range of pictures and videos of the event are available at the "Internet Somos Pacientes" online community (www.somospacientes.com).

The Award winners were the following:

CATEGORY: PATIENTS

Section: Awareness-raising and Health Education
The award went to Valencia's Association of Families of Alzheimer's Sufferers, for their documentary "Las Voces de la Memoria" [The Voices of Memory] and the use of music therapy with Alzheimer's patients. The two runners-up were the Spanish Association of Epileptics, for their campaign "Conocer la Epilepsia nosh ace iguales" [Getting to know about Epilepsy puts us on an equal footing], and the Spanish Federation of Diabetics for their awareness-raising and communication campaign on diabetes, aimed at the general public and diabetes patients in particular.

Section: Services for Members
This year's award went to the Leon Association of Laryngectomees for their activity in favor of people with people who have undergone laryngectomies and, in particular, for creating the Association's own choir. The two runners-up were the National Association of Apert's Syndrome, for the Association's progress since it was first set up twelve years ago and its activities for sufferers and their families, especially "Casa Apert"; and ASPANION, a Valencia-based child cancer association, for their services for young cancer sufferers and their families, helping them enjoy quality of life.

Section: Commitment to Research
The Spanish Federation of Cystic Fibrosis was declared this year's winner for its communication and fostering of research activity, and for its participation in scientific research projects. ELA España and the Diogenes Foundation for Research into Amyotrophic Lateral Sclerosis were the 2011 runners-up: ELA for its collaboration with other European associations in the development of clinical trials, and the Diogenes Foundation for its basic lines of research and clinical trials for amyotrophic lateral sclerosis.

Section: History of Helping Patient Groups
This is a new section in the Patients Category and aims at acknowledging the past and ongoing work of a patient organization to help sufferers. The jury gave the award to the Spanish Cancer Association for its longstanding work since it was first set up in 1953 and for the range of services that the Association offers cancer patients and their families.

CATEGORY: SOCIETY

Section: Scientific societies, Healthcare collectives and Professional organizations
Joint winners: The Spanish Endocrinology and Nutrition Society and the Spanish Society for Research into Obesity, for their joint efforts in the fight against obesity.

Section: Hospitals, Healthcare centers and Patient assistance centers
Zaragoza's San Juan de Dios Hospital took this year's award for its volunteering program and the hospital's activities for volunteers, from emotional support and social and cultural activities, to assistance and palliative care.

Section: The media
The award went to Unidad Editorial for its commitment to health information as shown in publications such as Diario Médico and Correo Farmacéutico and in the health section of the online edition of its daily El Mundo (elmundo.es)

Section: Business, Institutions and Organized Collectives
This year's winner is Albinos Spanish Program, and the award comes in recognition of ASP's program of prevention and treatment of skin tumors among albino patients in Tanzania.

CATEGORY: SOCIETY

Extraordinary Recognition goes to HM Queen Sofia for her constant support for illness in general and, in particular, her support for the Alzheimer project through the Queen Sofia Foundation.

Collaboration with Patients Organizations

In 2011, FARMAINDUSTRIA took part in a long and varied list of events, including meetings, working sessions, informal exchanges, seminars and so on, with Patients Organizations, all aimed at sharing experiences and giving support to the associations' work.

FARMAINDUSTRIA representatives visited literally dozens of Patients Associations up and down Spain in an effort to become better acquainted with this collective and its activities and needs, as well as providing patients with Information on the pharmaceutical industry's activities. For example, FARMAINDUSTRIA paid a visit to the offices of several regional associations in Galicia, such as the Federation of Associations of Alzheimer's and other forms of dementia sufferers, the Federation of Associations of Families of Mental Patients, the Association of Breast Cancer Patients, the Association of Kidney Sufferers, the Association of Neuromuscular Illness Sufferers, as well as local and regional Hemophilia Rheumatology, Multiple Sclerosis and Parkinson's disease Patients Associations. Similar meetings took place in Navarre with representatives of the region's

FARMAINDUSTRIA WAS IN BRUSSELS TO ATTEND THE CELEBRATIONS PRIOR TO THE EU'S 5TH DAY OF THE PATIENT, WHERE IT PRESENTED A REPORT ON COMPLIANCE WITH PATIENTS' RIGHTS

TDA, Hyperactivity and Impulsivity Association, Bone Marrow Donors, Retinal Association, Mental Health Association, Allergy and Asthma Patients, the "Saray" Breast Cancer Victims Association, the regional chapter of the Spanish Cancer Association, regional associations of Diabetes Sufferers' and Neuromuscular Patients, and the regional section of Spain's Coordinating Confederation of the Differently-Abled (comprising 11 organizations In Navarre alone). FARMAINDUSTRIA representatives also met with The Spanish Confederation of Associations of Alzheimer's Sufferers' Families, a Pamplona-based organization that brings together nearly 300 organizations from all over Spain.

More meetings were held nationwide—particularly in the Madrid region and on many occasions at the FARMAINDUSTRIA offices—with representatives of a wide range of Patients Associations.

2011 saw the public debut of the Aragon Patients Forum (Spanish acronym FAP), of which FARMAINDUSTRIA is a founder member. The FAP was set up at the initiative of Aragon's regional chapter of the Spanish Confederation of the Physically and Organically Differently-Abled whose overriding goal is to promote and defend the health and social conditions of patients and differently-abled people in Aragon.

On 5 July 2011, the FARMAINDUSTRIA FOUNDATION hosted the 2nd Pharmaceutical Industry and Patients Associations Seminar, in Madrid, a debate forum on issues of interest to Patients Associations. One of the day's main subjects of debate by representatives of the pharmaceutical Industry and a hundred or so Patients Associations was the shared concern over the risks posed to the sustainability of Spain's National Health System in the current economic downturn.

In addition, FARMAINDUSTRIA took part in a variety of talks, seminars, conferences and general meetings organized by Patients Associations. Examples included the event held at the Menendez Pelayo International University and organized by the Spanish Breast Cancer Federation, or the National Seminars on Kidney Illness organized by the National federation of Kidney Illness Sufferers, held in November 2011 at Spain's Ministry of Health, Social Policy and Equality.

FARMAINDUSTRIA representatives also travelled to the seat of the European Social and Economic Council in Brussels prior to the EU's 5th "Day of the Patient Rights", for the presentation of a Report on the enforcement of patient rights. The Report reveals that the hardest right for patients to exercise is access to treatment, where patients encounter a number of stumbling blocks.

The Association's Magazine for Patients: 'Pacientes'

In 2011, FARMAINDUSTRIA FOUNDATION brought out four more issues (numbers 19, 20, 21 and 22) of its quarterly journal 'Pacientes', which looked at the challenges facing Spain's public health system, the risks to its sustainability and the measures required to ensure the existing standards of healthcare provision. The magazine also featured the declaration of 2011 as International Alzheimer's Day,—an initiative aimed at supporting research on this illness—and highlighted the role of related volunteer work in the EU, which is essential to Alzheimer's Sufferers Associations, and which ultimately led to declaring 2011 European Volunteer Day.

2011 also saw the start-up of an online version of the magazine, available at the Farmaindustria website, and offering interactive content.

New Internet Platform: "Somos Pacientes"

In 2011 work got under way to update Spain's Map of National Patients Organizations, a nationwide directory of more than 1,400 organizations representing patients, and for which FARMAINDUSTRIA drew up a list of more than 5,500 associations related to healthcare and patients. Each association was invited to figure on the Map by returning the online application forms available at www.mapadepacientes.es.

The Map of National Patients Organizations formed the basis for a new and ambitious e-platform called "Somos Pacientes" [We are Patients], which can be accessed at www.somospacientes.com. Targeted at associations of patients and the differently-abled and their families, carers and healthcare specialists across Spain, "Somos Pacientes" provides information, participation and training schemes, services and collaborative work opportunities.

somos pacientes

The overall idea is to make the platform an online meeting and engagement point for anyone directly or indirectly involved or interested in healthcare, particularly patient organizations. "Somos Pacientes" is an open and participative network, featuring a range of sections and content of interest for associations, patients and their families, the general public and all kinds of healthcare professionals.

This new online platform features current affairs, interviews, a calendar of events, video content, feedback and opinion channels, training opportunities and debate forums for associations; the latter are encouraged to post their own content to explain their activities and needs and to convey their opinions, and engage in debate and other forms of exchange. The team behind "Somos Pacientes" provides patient associations with a regular supply of fresh information as well as support and follow-up services. The platform sets out respond to the needs of a patients' association movement and its goal is to serve as a meeting point and as a space for help and cooperation for the hundreds of associations of patients and the differently-abled to be found all over Spain.

3.2.4. "COMMUNICATION 2.0"

In 2011, as part of its Strategic Communication Program, FARMAINDUSTRIA began to delve deeper Into the benefits of Communication 2.0 to exploit its potential to enhance and consolidate traditional communication methods and tools.

This incursion into the domain of cutting-edge ICT-based social communication followed two basic lines of approach:

1. the Association's active presence in this sphere, and
2. the regular monitoring of FARMAINDUSTRIA's online and social network presence and measuring the buzz generated by the Association and the pharmaceutical sector as a whole.

Presence in social networks

FToday, FARMAINDUSTRIA can be followed on Twitter and Facebook, where it has Its own profiles, and on YouTube where it has its own channel ("FUNDACIÓN FARMAINDUSTRIA") for disseminating the Association's audiovisual materials.

The Association has two Facebook profiles. "FUNDACIÓN FARMAINDUSTRIA" spreads the word on its activities and engages with patient associations and third-sector collectives. At the end of 2011, the page chalked up more than 500 friends and followers, mainly from patient associations. The second profile aims at engaging with the media and its professionals, a professional grouping that accounts for the more than 200 friends tallied at the end of 2011. The association uses this channel to send out press releases and provide the media with links to issues of interest to FARMAINDUSTRIA.

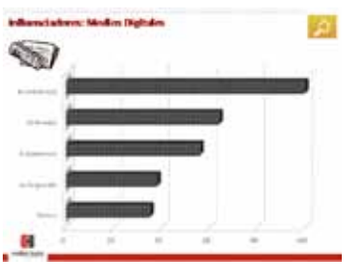
FARMAINDUSTRIA set up its Twitter profile in 2011 and uses it as a regular communication and engagement channel delivering press releases, pictures, information on activities, links to information of interest to the industry, and messages to other users varying according to the Associations strategic needs and goals.

FARMAINDUSTRIA ended 2011 with 1,800 followers making it the European innovative pharmaceutical sector's number one organization in terms repercussion and activity on Twitter, and one of the most influential Spanish healthcare stakeholders on this particular social networking site.

Monitoring

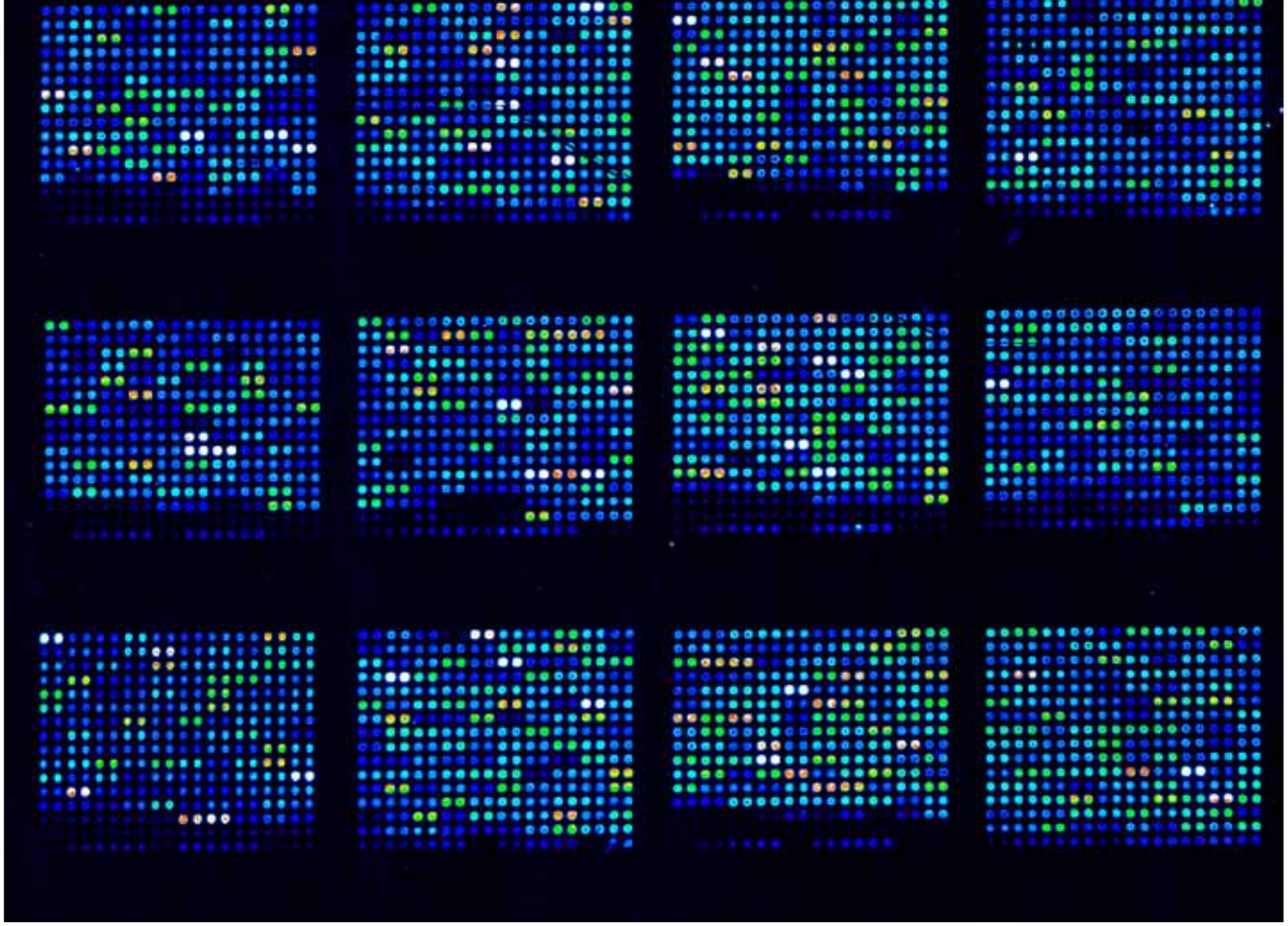
The 2011 Annual Monitoring Report of FARMAINDUSTRIA's and the Spanish pharmaceutical sector's presence on the 'net and on online social networking sites registered more than 7,000 posts and comments on the Association, with an upward trend over time, in line with the increasing activity carried out by FARMAINDUSTRIA using this type of media.

The same Report reveals that FARMAINDUSTRIA generated more than two million impacts last year on Twitter alone. Most of them were registered as of July 2011, coinciding with increased activity.



Spain's pharmaceutical sector generated almost 75,000 posts and comments In 2011: 22,000 were online media articles and the remainder was blog posts or on social media sites.

The Report also analyzes which of the online media, bloggers and Twitter users were most active in touching on issues of interest to the pharmaceutical industry.



3.3.

MEMBER SERVICES

3.3.1.
‘ONLINE’ SERVICES

FARMAINDUSTRIA is a pioneer in the reduction of paper in the information flow between associations and their members. Back in 2004, it decided to make its circulars (more than 1,000 documents a year sent out to over 200 member companies) 100% paper-free, thus obtaining an 85% reduction in the flow of paper between the Association and its members.

Today, a similar policy applies to the generation and distribution of documents drawn up exclusively in digital format, bringing FARMAINDUSTRIA that bit closer to its goal of 100% digital document management.

Implementing these policies would be impossible if it weren’t for sound planning and the use of first-rate web-based tools that enable controlled, agile and secure access to each and every document.

For this reason, FARMAINDUSTRIA is practically re-writing not only each of its corporate portals (Public and Private) but also its monographic portals designed to address specific issues.

Corporate Portals: Public and Private

In 2011, FARMAINDUSTRIA overhauled and upgraded its Public and Private portals, adding new sections and aligning them to new needs by reviewing the tools and processes for searching and accessing information, restructuring links-banners and conducting a thorough check of the English-language versions.

Themed Portals

Improvement and adaptation work is ongoing on the Associations themed portals which are as follows:

- Media portal (social networks).
- Patients portal (social networks).
- Innovative Medicines (the new website has entered production).
- National Intranet Group.

Two new portals have been added:

- The new "e4ethics" portal (the new events management app has entered production).
- The Board of Governors Intranet.

Portals for managing RDL 8/2010

Production of the first phase of the web portal that made it possible to manage the implementation of RDL 8/2010 got under way in 2010, and 2011 saw the start of production on the second phase which connects the different Official Pharmaceutical Professional Associations, allowing them to manage their own settlements and adjustments, as well as handling queries on the record of deductions.

In 2011, the design of the third phase of the project began: it involves connecting the web environment to the bank branch responsible for managing economic resources.

This group of portals handles nearly 100,000 operations a year by more than 500 users authorized by member companies and the Pharmaceutical Professional Associations.

Online services: The statistics

Online services usage, storage and operation rates either remained flat or increased in 2011.

The number of users who access FARMAINDUSTRIA portals each day now stands at more than 6,000 individuals, peaking occasionally at 10,000.

The Association's general portals registered more than 1.2 million individual hits in 2011, 70% of them on the Public portal.

FARMAINDUSTRIA'S GENERAL ONLINE PORTALS REGISTERED 1.2 MILLION INDIVIDUAL VISITS IN 2011, OF WHICH 70% TOOK PLACE IN THE PUBLIC PORTAL

FARMAINDUSTRIA'S WORKING GROUPS SET OUT TO ENCOURAGE ACTIVE PARTICPATION AND KNOWLEDGE EXCHANGE BETWEEN MEMBER COMPANIES AND THE ASSOCIATION ITSELF

By country of origin, and without taking into account unidentifiable IP addresses, the USA, for the first time ever and at a considerable distance leads Spain in the number of accesses, followed by Germany, the UK and Switzerland among the five most active countries.

546,199	Unidentifiable
325,659	USA
248,057	Spain
71,417	Germany
18,728	UK
10,506	Switzerland
8,698	Peru
6,261	Portugal
5,691	Belgium
5,020	France
4,186	Italy

3.3.2. WORKING GROUPS

The FARMAINDUSTRIA Working Groups (WGs) set out to foster knowledge exchange between member companies and their active participation in the Association in an effort to define the pharmaceutical industry's position on a range of industry issues and to forward subsequent proposals to the Board of Governors and the Board of Directors so as to develop them strategically.

In 2010, when the Association's governing bodies were last renewed, the WGs were updated for a new nine-year period. Similarly, their working rules were redefined and a new annex was introduced referring to competition regulations.

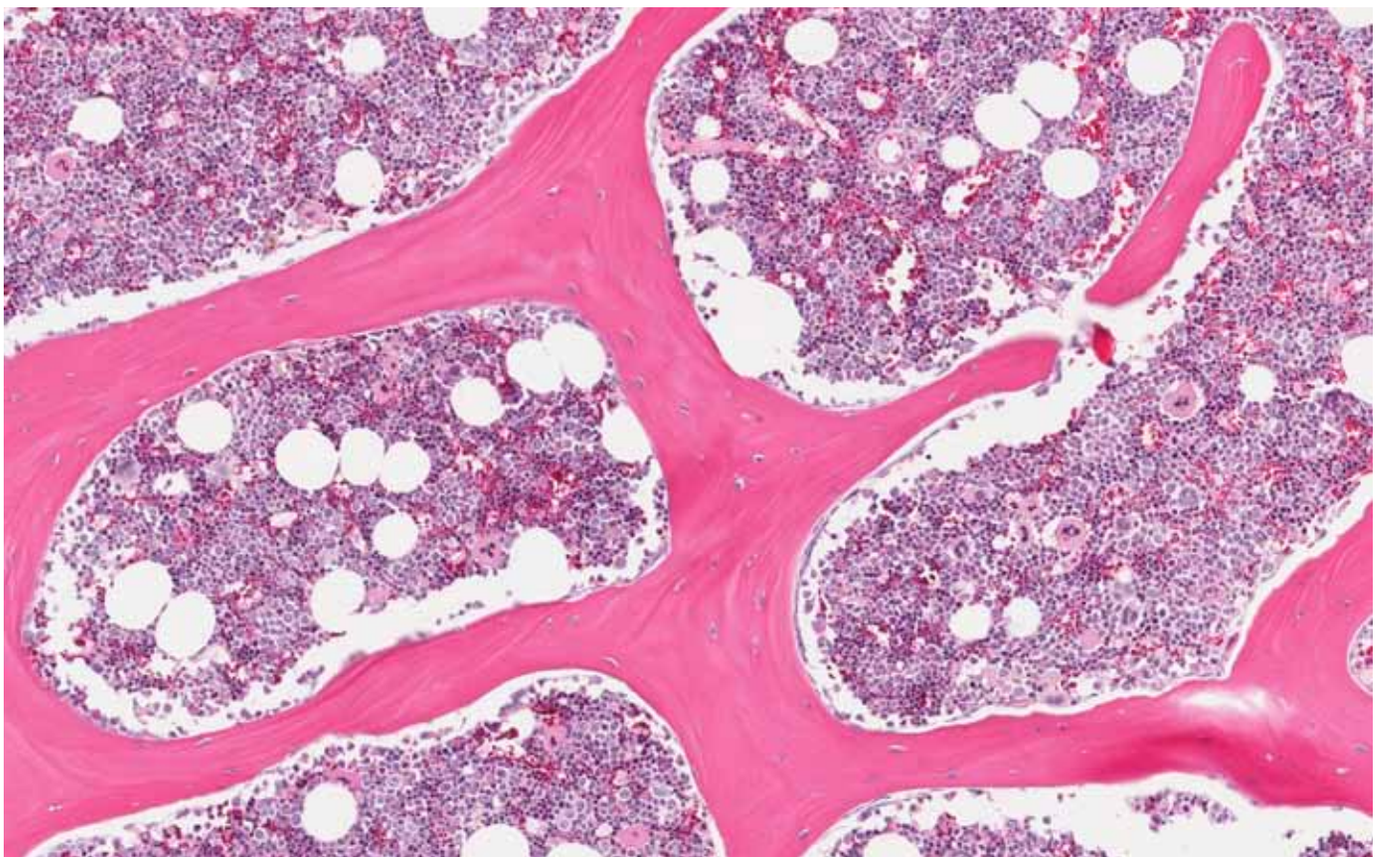
Today there are 19 WGs in all in FARMAINDUSTRIA, and their names and main activities are as follows:

1. Sustainability and Economic Regulatory Activity.
2. Health Technologies Assessment.
3. Hospitals Debt.
4. Technical Regulation of Medicines.
5. Manufacture and Traceability.
6. The Environment.
7. Pharmacovigilance.
8. Vaccines.

9. R&D/Biotechnology.
10. Clinical Research.
11. Medical and Research Directors (BEST).
12. Orphan Medicines.
13. Legal Services.
14. Tax.
15. Human Resources.
16. Code of Good Practice.
17. Competitiveness and Internationalization.
18. Relations with the Autonomous Regions.
19. Communication.

The Sustainability and Economic Regulatory Activity WG

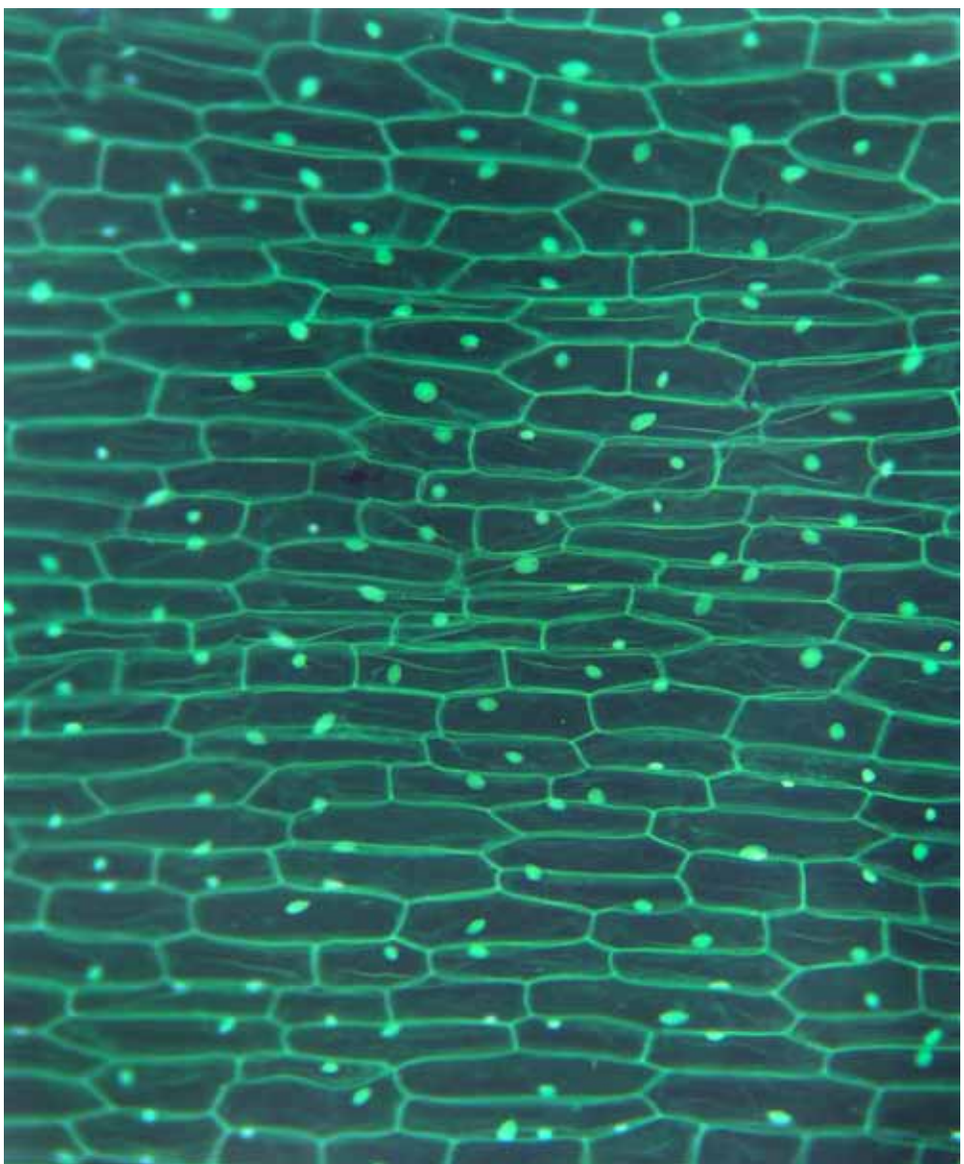
Throughout 2011, this WG continued to carry out active monitoring of regulatory activity and institutional initiatives related to the economic regulation and the sustainability of Spain's Public Health System. It is worth highlighting this WG's monitoring of the public consultation called by the European Commission on 28 March 2011 on plans to update the regulations on transparency in pricing decisions and medicine refunding in Europe, calling on interested parties to convey their respective positions on the review of Directive 89/105/EEC (more often referred to as the Transparency Directive). This public consultation encouraged a harder look at the best way to update this legal measure and ensure transparency in national processes on pricing and refunding, and giving EU patients faster and broader access to medicines.



IT IS WORTH HIGHLIGHTING FARMAINDUSTRIA'S POSITION ON ACTIVE INGREDIENT PRESCRIPTIONS, WHCH EMPAHSIZES RESPECT FOR THE DOCTOR'S FREEDOM OF PRESCRIPTION

Reference should also be made to the WG's detailed assessment of the content, economic impact and implementation of RDL 9/2011 and its supplementary regulations, in particular as concerns the following aspects:

- the modification of Article 85 of Law 29/2006 which establishes the prescription of active ingredients as the default option, and eliminates the preference for generics in the event of equal prices and equal maximum discounts;
- the increase in deductions, up from 7.5% (as laid down by RDL 8/2010) to 15%, affecting medicines that have been on the market for more than ten years, except in those cases specified by the aforesaid legal text;
- the changes in reference prices (elimination of the option of a gradual approach, elimination of points 6 and 7 of Article 93, and the integration of Galenic innovations in reference groupings when a generic is included in the same form in the financing), and
- the introduction of mandatory cost-effectiveness reports for new medicinal products.



Regarding these points, it is worth highlighting the WG's and FARMAINDUSTRIA's positioning on the Prescription of Active Ingredients: they have both stated repeatedly that this principle must respect a doctor's freedom to prescribe as laid down in the RDL itself, that this freedom must not be in any way obstructed or curtailed by the Spanish regions' e-prescription systems, and that there be no restrictions on a doctor's right to recourse to the exceptions envisaged by the RDL, taking into account that the prescription of branded medicines ~~-a~~lways provided that this is available at a lower price— has no negative economic impact and aids the therapeutic process.

Similarly, the WG monitored the processing of Resolution 28 December 2011, proposed by the Directorate-General of Pharmacy and Healthcare Products, which determined the new medicine groupings to be dispensed in pharmacies with an official prescription or dispensing order and their reference prices, and called for a review of the reference prices set by Order SPI/3052/2010, 26 November, and, in the second place, Resolution 28 December 2011, proposed by the Directorate-General of Pharmacy and Healthcare Products, and which determined the new medicines groupings for hospitals and their reference prices.

In this respect, the Association has helped the industry to formulate its allegations against the two projects of the resolution on reference prices, with particular emphasis on the following aspects:

- the inconvenience of setting reference prices for hospital medicines (the procurement of which takes place using mandatory competition procedures stipulated by the Law on Public Sector Contracts);
- the need to ensure that the generic that gives rise to the creation of a given grouping is genuinely traded (as well as the presentation on which its reference price is based), and
- the need to exclude complex medicines (e.g. biosimilars) from reference prices due to the negative effects that their inclusion might have on patients and on innovation.

A supplement to this work, the WG carried out a highly detailed analysis of the implications of the list of homogeneous groupings of the lowest prices in an effort to pass on its comments and observations to the health authorities.

At the same time, the WG continued to monitor the caseload arising from both the review processes of certain innovative products and the requests for the updating of prices lower than 2 euros of medicines not subject to reference prices, and facilitating, through FARMAINDUSTRIA, communication between the companies affected and the Ministry of Health, Social Policy and Equality.

The WG also took part in the observations formulated by FARMAINDUSTRIA regarding the information update released by Spain's Medicines and Healthcare Products Agency on the procedure for a medicine to qualify as a "Galenic Innovation of Therapeutic Interest", as laid down in Order SPI/30 52/2010, 26 November, which determines the

medicine groupings and their reference prices and regulates certain aspects of the Reference Price System. In this sense, the Medicines and Healthcare Products Agency criteria take into account some of the requests made by FARMAINDUSTRIA, e.g. the possibility that a Galenic Innovation facilitates the therapeutic process by reducing the dosage (e.g. from several doss to a single one each day) may be considered a "Galenic Innovation of Therapeutic Interest", always provided that the reduced dosage is coherent with the therapy or the duration of the treatment.

Changing tack slightly, with regard to the development of a web tool for the Association's portal for processing and validating the data required for complying with RDL 8/2010, several members of the WG volunteered to take part in a pilot with a number of Professional Associations to start-up the tool, assess its operational efficiency and, where necessary, propose Improvements. Similarly, the WG was instrumental in following up the contacts made by FARMAINDUSTRIA to outsource part of the process of implementation of the deduction laid down by RDL 8/2010 (in particular the part concerning payments management) effective as of early 2012.

Finally, the Autonomous Regions WG worked alongside the Sustainability and Economic Regulatory Activity WG o monitor the measures and proposals on pharmaceutical provision proposed by Spain's regions.

The Health Technologies Assessment WG

Set up in 2006, this WG sets out to draw up technical documents on the major issues that affect economic and financial assessment procedures for medicines.

Over the past twelve months, this WG has convened on two occasions and drew up a number of analysis and study documents on the procedures in place in the most relevant international institutes and bodies (in France, Germany, Sweden, England, Scotland and others) for assessing medicines; they also looked at agencies and organisms in Spain (both national and regional) that assess healthcare technologies.

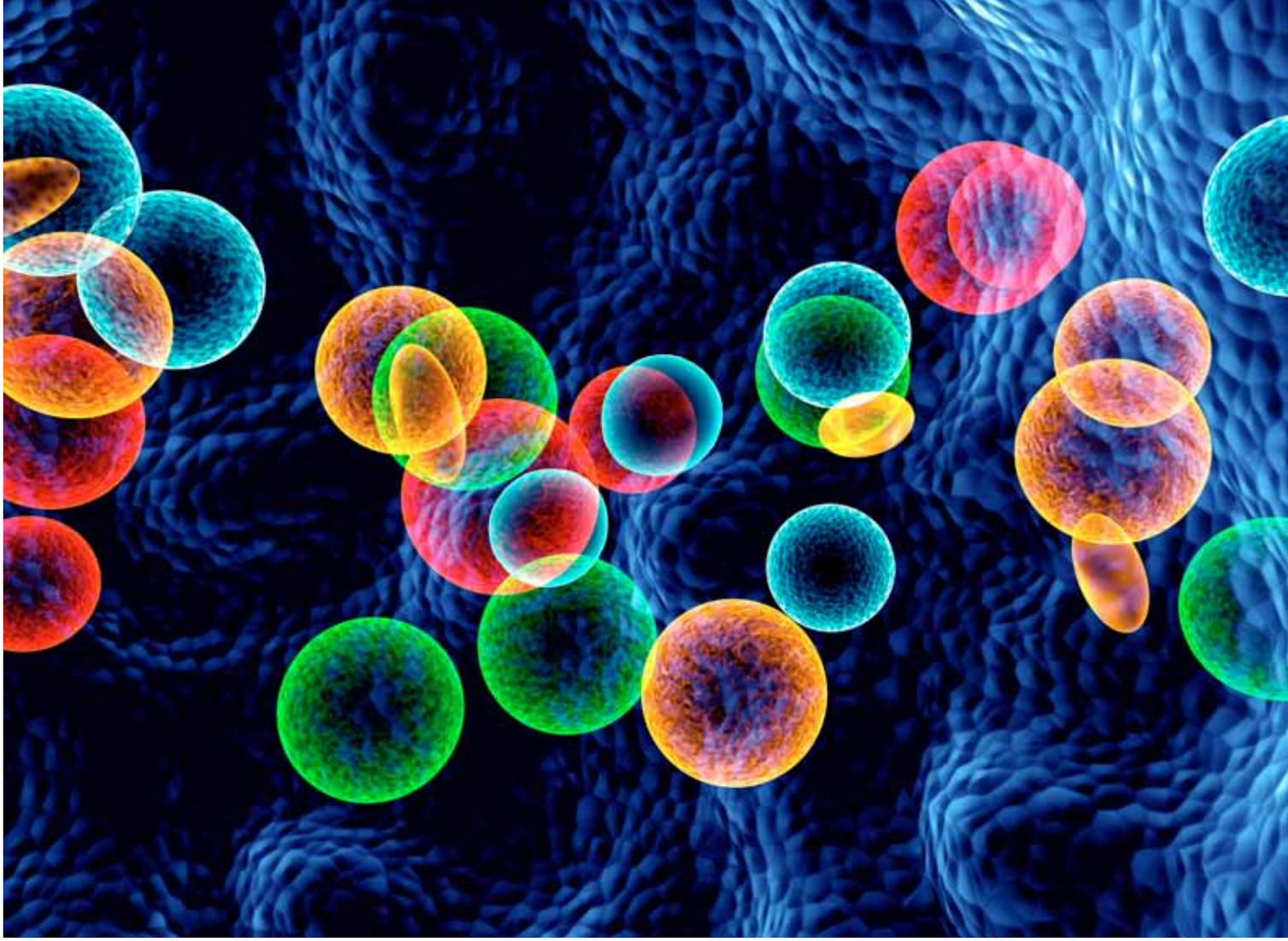
THE HTA WORKING GROUP WAS SET UP TO DRAW UP TECHNICAL DOCUMENTS ON ISSUES THAT AFFECT THE ECONOIMIC EVALUATION OF MEDICINES

At the same time, the WG drew up a technical document on the critical aspects of procedural issues and methodologies that need to be addressed and resolved in the sphere of the economic and financial assessment of medicines.

Over the coming months, the WG will be working on this and other technical documents detailing the pharmaceutical industry's approach to Issues related to the assessment of medicines.

The Hospital Debt WG

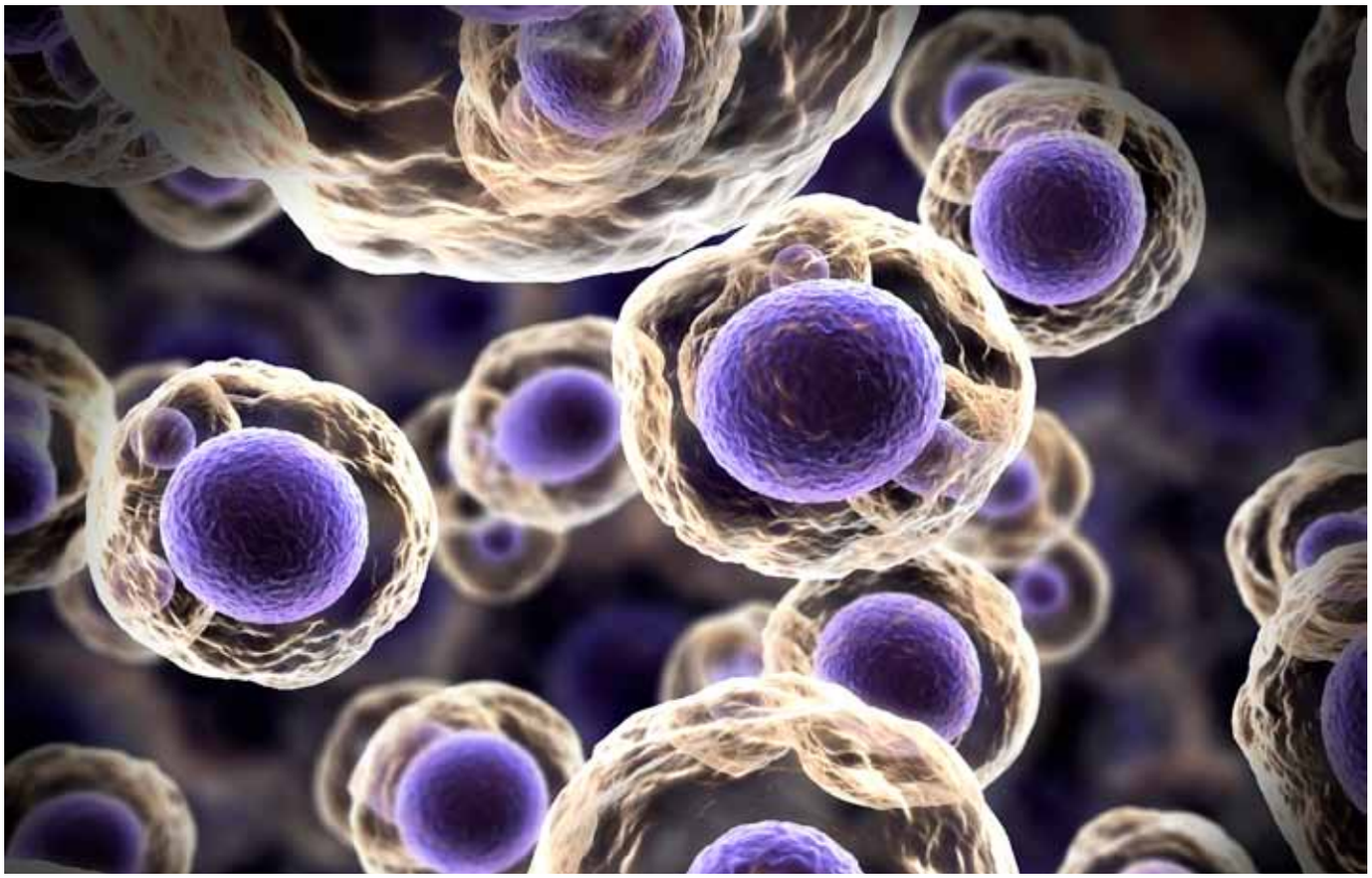
Throughout 2011, this WG continued to conduct an in-depth analysis of the debt problem arising from state hospital pharmaceutical supplies in Spain's regions.



FARMAINDUSTRIA conducted regular quarterly surveys to monitor debt volume and arrears, as well as sales data, which it used to track movements and trends in the hospitals market in each region.

The problem was found to be worsening at a considerable rate, ~~ho~~spital debt In Spain stood at nearly 6.4 billion euros at end-2011, with an average payment period of 525 days overall for the Public Health System. FARMAINDUSTRIA responded by stepping up its media and institutional campaigns, drawing the authorities' attention to the sheer scale of the problem, putting forward a list of possible remedies and calling for sufficient funding for the health system as an absolute priority over other less efficient areas of public spending, in an effort to safeguard existing public healthcare provision standards. The extensive media coverage resulting from the Association's efforts helped to place the troubled state of Spain's healthcare system squarely in the public eye and make it a major political concern.

At the same time the Hospital Debt WG, mandated by the Association's governing bodies, set up an ad hoc group focused on coming up with financial solutions to the hospital debt problem.



Mention should also be made of Farmaindustria's active participation in a Working Group set up by CEOE, the Spanish employers' confederation, to analyze and draw attention to the problem of central, regional and local government's arrears which the Association's Hospital Debt WG had been monitoring closely.

The institutional efforts carried out by Farmaindustria and other Spanish business organizations aimed at this serious problem to show positive results in the first quarter of 2012, when the Spanish Government came up with several approaches to help public administrations to settle their outstanding payments with their suppliers.

On the one hand, the resulting budget provision, in the shape of an ICO credit line for the regions, was certainly an important step in the right direction, but it gave rise to technical problems that have yet to be ironed out. Regarding this provision, Resolution 23 February 2012 was ruled by the General Secretariat of the Treasury and Financial Policy, and defined the principle of financial prudence applicable to all debt operations carried out by the regions included in the Common Regime and cities with a Statute of Autonomy which resort to the ICO-Regions 2012 directing financing.

On the other hand, a supplementary financing mechanism was put In place to facilitate payment to suppliers of local and regional authorities. The following three provisions applied:

- RDL 4/2012, 24 February, which lays down the information and procedural requirements for setting up a financing mechanism for facilitating payments to suppliers of local authorities;
- Agreement 6/2012 of the Fiscal and Financial Policy Council, 6 March 2012, laying down the overall lines for an extraordinary financing mechanism to meet payments to suppliers, and
- RDL 7/2012, 9 March, establishing a fund to facilitate all kinds of debt and payments operations on the capital markets, and allowing local and regional authorities to settle outstanding payments with suppliers.

The Hospital Debt WG analyzed these provisions and their corresponding regulations meticulously, and forwarded to FARMAINDUSTRIA and the Ministries involved the points that needed to be clarified or required improvement, to ensure the success of the procedure for settling the debt.

At the time of going to print, work continues on the new payments procedure for local and regional authorities, and the Government expects the first payments to be settled in June 2012.

In addition, in 2011 the WG continued to keep a watchful eye to ensure that hospital tender applications comply strictly with current law on public procurement. The Group continued to send letters to hospital management heads calling on them to make the necessary changes to adapt to the Consolidated of the Law on Public Sector Procurement and the doctrine of the Consultative Council on Public Procurement, and received positive responses on a number of counts. In other cases, several appeals were lodged (and are currently pending) against a number of regional dossiers containing conditions that were in clear violation of current law.

Similarly, the WG has kept close tracks on national and European public procurement laws, which are detailed in other sections of this Annual Report.

Finally, in close coordination with the Autonomous Regions WG, the Hospital Debt WG continued to hold meetings with the Andalusia Public Health Authority to address the Framework Agreement processed in late 2011 and to track progress on "SIGLO" project that the Andalusian health authorities are developing through the Public Procurement Provincial Platforms.

Moreover, both WGs are participating actively in the processing of the new Framework Agreement on medicines procurement for all of the healthcare provision centers that fall within the sphere of responsibility of the Catalonian Healthcare Institute, and which had just come into effect when this Annual Report went to print.

IN 2011, THE HOSPITAL DEBT WORKING GROUP CONTINUED TO ANALYZE REGIONAL AUTHORITIES' DEBT WITH SUPPLIERS OF MEDICINES TO PUBLIC HOSPITALS

THE ENVIRONMENT WORKING GROUP MONITORED THE MOST IMPORTANT LEGAL REGULATIONS, SUCH AS THE ONE ON THE PARTIAL DEVELOPMENT OF THE LAW OF ENVIRONMENTAL RESPONSIBILTY

The Technical Regulatory Activity on Medicines WG

Due to EU law's considerable influence on technical regulatory activity on medicines, many of this WG's activities are centered on the provisions arising directly from EU regulations or issued initiatives adopted by Spain's Medical Products Agency (Spanish abbreviation AEMPS) and subsequently adapted to national requirements.

One of the most relevant steps taken by the Agency in 2011 came when it applied the so-called "Sunset Clause" introduced into Spanish law by virtue of the transposition of EU regulations and which involves cancelling all of the authorizations that did not go to market in a period of more than three years following their application.

The WG analyzed the possible exceptions to the application of this provision to avoid jeopardizing the interest of pharmaceutical companies, and informed the AEMPS.

The WG also debated (and provided information on) other provisions such as the simplification of translations of EU procedures, processing authorization via the centralized procedure, the regulation of temporary suspension or termination of trading.

Apart from keeping tabs on regulatory activity, this WG provided highly detailed information on the AEMPS's day to day activity as regards processing records and variations The WG's proposals were forwarded to the Agency in an attempt to shorten processing times and improve the Agency's array of IT applications.

The Manufacture and Traceability WG

Owing to the relatively restricted scope of Spain's current traceability regulations (RDL/2011), this particular WG's activities have been limited mainly to monitoring the streamlining of antibiotics packaging called for by RDL 8/2010, at the initiative of the AEMPS, and which is currently still being studied given the difficulties involved in putting it into practice.

Also, the European Commission must have ready for 2014 a Delegated Act laying down the requirements for pharmaceutical companies as regards traceability, and which involves close tracking of these provisions in this WG's future meetings.

The Environment WG

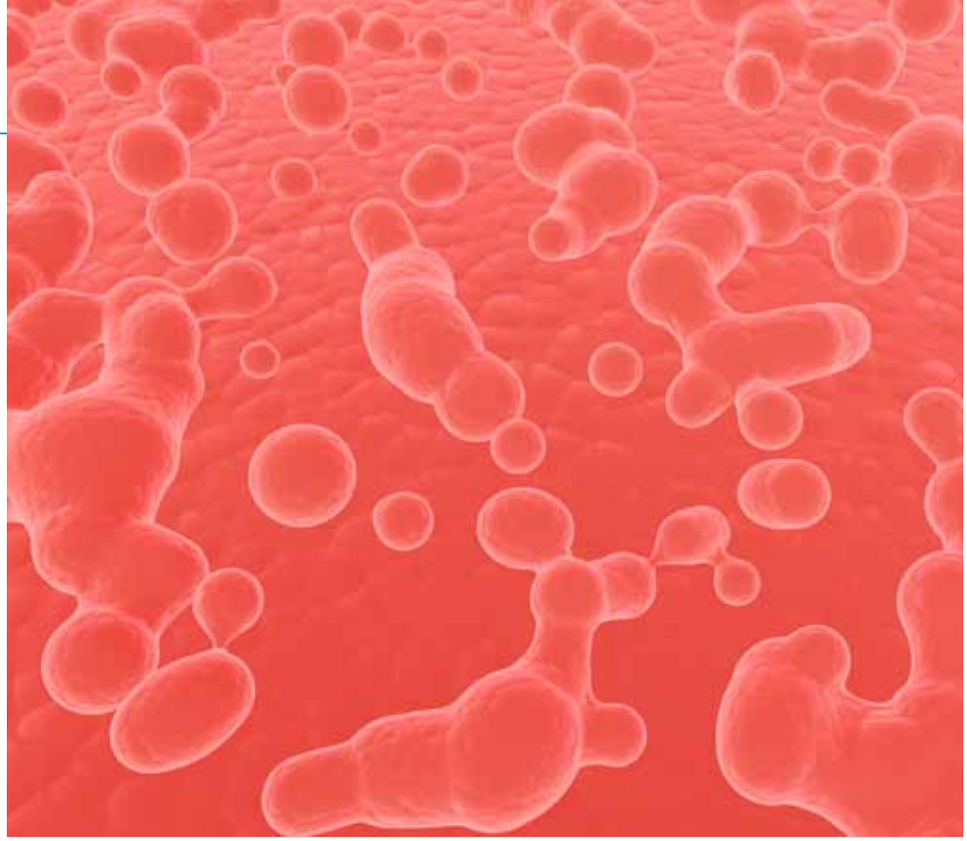
In 2011, this WG worked alongside the "SIGRE" packaging waste management system to monitor major regulatory initiatives with important repercussions for the entire sector, such as the Partial Regulations on the Development of the Law of Environmental Responsibility, the Framework Agreement on Waste and the European List of Waste (LoW), the Proposal for Directive to modify the Directive on Environmental Quality Norms in water policies, and the Framework Directive on Water, which will review the

list of priority substances; and monitored other environmental initiatives which affect the pharmaceutical industry (e.g. waste, effluent and emissions).

Given the complexity of the administrative provisions on environmental matters, this WG makes regular efforts to ensure that all interested parties are kept well-informed. Also, Farmaindustria has continued to sit on the Environment Committees of Spain's main employers' organizations (CEOE, FEIQUE) and has collaborated closely with the Ministry of Agriculture, Food and the Environment on a range of issues that affect the pharmaceutical industry.

The Pharmacovigilance WG

Throughout 2011, this WG has kept very close tabs on EU law on pharmacovigilance to acquaint itself with possible consequences of its transposition at the national level. This law requires traders to increase their transparency when it comes to providing safety information to healthcare professionals and their patients alike. It also calls for greater transparency in the compilation of safety information directed at the general public, risk management plans, post-authorization safety and efficiency studies and early-warning signals, among others. The Group also helped to review a range of EMA or European Commission documents aimed at informing traders on the implementation periods for the new requirements, the new timetable/deadlines for mandatory safety



reports and, fundamentally, those laid down in Article 57.2 which requires traders to provide the EMA with highly detailed information (in digital format) on their complete list of EU-authorized medicinal products.

It is worth highlighting the WG's considerable efforts in reviewing and drafting observations of the drat versions of the first seven modules of the EU's Pharmacovigilance Good Practices, the pleadings on which are being coordinated by the EFPIA.

SPECIAL MENTION SHOULD BE MADE OF THE PHARMACOVIGILANCE WORKING GROUP'S REVIEW OF AND COMMENTS ON THE DRAFT FOR THE SEVEN FIRST MODULES THAT WILL MAKE UP THE EU'S GOOD PRACTICES ON PHARMACOVIGILANCE

The transposition of this law to the national level has been a priority in the Association's relations with the AEMPS, and the Group, at the Agency's request, helped to draw up a proposal of activities to be carried out by the professionals responsible for pharmacovigilance in Spain.

The Group has drawn up pleadings against a Q&A document on how post-authorization studies are carried out and which has circulated information that points to possible adverse effects of medicines in Compassionate Use situations.

The Catalonian Regional Pharmaceutical and Healthcare Products Authority, along with other institutions, also helped the AEMPS to draft a document on Good Pharmacovigilance Practices which will be used in checks and controls in Spain. The document is available on the AEMPS website, along with an English language version translated by the WG.
http://www.aemps.gob.es/industria/Inspeccion-BPFV/docs/CTI.BPFV.127.00.11.pdf

FARMAINDUSTRIA was part of a multidisciplinary team, led by the AEMPS and set up by a number of experts on medicinal products, which revised the list of medicines that are required to include a warning, in the form of a pictogram, on their packaging when their active ingredients make driving hazardous. The revised list and the corresponding

recommendations included in the technical file and the instructions leaflet of these active ingredients are available on the AEMPS website.
http://www.aemps.gob.es/industria/etiquetado/conduccion/listadosPrincipios/home.htm

This WG is currently engaged in a pilot for filing regular safety reports in digital format using the electronic Common Technical Document (eCTD) interface. It has set up a specific group to assess the viability of e-mailing safety documents or so-called "Dear Doctor Letters" (messages addressed to healthcare professionals via science societies). This initiative, which has been very well received by the Agency, delivers a number of benefits: messaging is faster, cheaper and more efficient and allows senders to interact with receivers and forward messages. The WG and the science societies are studying the viability of this kind of messaging and work is under way with the Agency to fine-tune the procedure.

The Vaccines WG

This WG stems from the sheer importance and singularity of vaccines, and it works in perfect synch with the European Vaccine Manufacturers (EVM), dependent on the EFPIA.

The past twelve months have seen two highly relevant events in this field:
1. The publication of Law 33/2011, on Public Health, 4 October, which includes, among others, a provision stating that the National Health System Inter-Territorial Council must agree upon a Single Vaccination Calendar for the whole of Spain, which regional authorities may only modify for epidemiological motives.
2. The publication of the Framework Agreement for the joint procurement of seasonal flu vaccines for season 2011/2012 as a first step towards activating a nationwide central procurement body.

The WG worked to translate these procurement procedures to regional authorities, demanding strict compliance to these procedures and asking them to take into account the conditions the technical peculiarities involved In the manufacture and use of vaccines.

The WG has also driven a number of actions aimed at fostering the value of vaccines and compliance with international vaccination recommendations.

OCTUBRE 2011 SAW THE PUBLICATION OF LAW 33/2011; ITS PROVISIONS INCLUDES THE AGREEMENT ON A SINGLE NATIONWIDE VACCINATION CALENDAR IN SPAIN

The R&D and Biotechnology WG

Among other objectives, this WG, made up of 34 member companies, sets out to draw up positions and put forward proposals to institutions of relevance to the sector, with particular attention to cooperation between the industry, small biotech companies and state research centers, as well as rolling-out the instruments need for this cooperation activity and conveying FARMAINDUSTRIA's differentiated and complementary contribution.

In early 2011, FARMAINDUSTRIA launched the "Farma-Biotech" cooperation program in which a hand-picked group of Spanish biotech companies and specialist research centers took part in a series of interactive seminars with pharmaceutical companies, in which they presented products currently under development and which represent potential cooperation opportunities among both parties.

Between February and July 2011, FARMAINDUSTRIA organized four seminars (two in Madrid and two in Barcelona) on five fields: Central Nervous System, Cancer, Respiratory System, Inflammation and Autoimmune Illness. Each seminar took the shape of an individual forum aimed at identifying the value-added obtained from the exchange of information on demand and supply of differentiated and innovative biotech products in the sphere of new therapies and Innovative medicinal products.

Three more seminars were scheduled for 2012. The first, dealing with Contagious Illnesses and Inflammatory Processes, was held on 14 March in Barcelona, and the next two will be held in Zaragoza and Madrid. All of the presentations are available at www.medicamentos-innovadores.org.

THE R&D AND BIOTECH WORKING GROUP SETS OUT TO ENCOURAGE INDUSTRY PARTICIPATION IN NATIONAL AND INTERNATIONAL PHARMACEUTICAL R&D PROJECTS AND PROGRAMS

This WG is also aimed at encouraging industry players to take part in national and international pharmaceutical R&D programs, especially the Innovative Medicines Initiative (IMI) and in the activities of the Spanish Technological Platform for Innovative Medicines. It also continued to engage with the Ministry of Economy and Competitiveness and the Ministry of Industry, Energy and Tourism for the monitoring and roll-out of support programs for R&D (INNPACTO, INNPRONTA, INNCORPORA, PROFARMA).

The Clinical Research WG

In 2011, this WG has carried out close monitoring of Spanish and EU legislative initiatives on clinical research.

The Group also monitored the functioning of the Clinical Research Ethics Committee's (Spanish abbreviation CEIC) "SIC CEIC" telematics application and has proposed improvements

to Spain's Medicines and Healthcare Products Agency, in an effort to expedite and simplify electronic transmission of application forms for the CEIC's authorization of clinical trials. Similarly, and to avoid the need for developers to send In formation of the trials to the regional authorities, the WG has presented a proposal to the Agency suggesting giving the regional authorities access to the information compiled by this IT application.

An ad hoc group, specializing in contract models for clinical trials, has reviewed and made comments on the proposals of new contract models for clinical trials used in Andalusia and the Basque Country and has proposed a model for use In hospitals in Tenerife (in the Canary Islands) and which Is currently pending approval.

The WG has also worked with the Ministry of Health's Sub-Directorate General of Public Health to speed up import/export permits for biological samples to/from outside of the EU customs area.

Regarding deviations of clinical trials that should be notified to the Medicines and Healthcare Products Agency, the WG proposed to the Agency a draft explanatory document on what to notify, the information to be included in the deviations and the procedure for communication issued by developers.

The WG also took part in a major project alongside the Pharmacology and Therapeutics Department of the Madrid Autonomous University's Medical Faculty, which makes up the content of an online course on Good Clinical Practice. The course responds to an initiative launched by the WG's member companies' interest in the regular training of researchers and collaborators in this field. It is available on the Madrid Autonomous University's online training website (https: //moodle.uam.es) and can be accessed at the Technological Platform for Innovative Medicines website (http.//www-medicamentos-innovadores-org).

Regarding Personal Health Data Protection in clinical research, FARMAINDUSTRIA has drafted a document on Good Practices on Data Protection ~~-en~~dorsed by Spanish Data Protection Agency ~~-di~~rected at researchers and aimed at helping them to comply with these regulations.

Finally, and as In previous years, FARMAINDUSTRIA kept up its regular contacts with the Medicines and Healthcare Products Agency, proposing improvements in the authorization of clinical trials, especially authorizations of studies at an early stage and linked to products still at the research stage.

THE MEDICAL AND RESEARCH DIRECTORS WORKING GROUP HAS ITS SIGHTS SET ON DESIGNING A CLINICAL RESEARCH STRATEGY FOR SPAIN

WG on Medical Research Directors (The "BEST" Project)

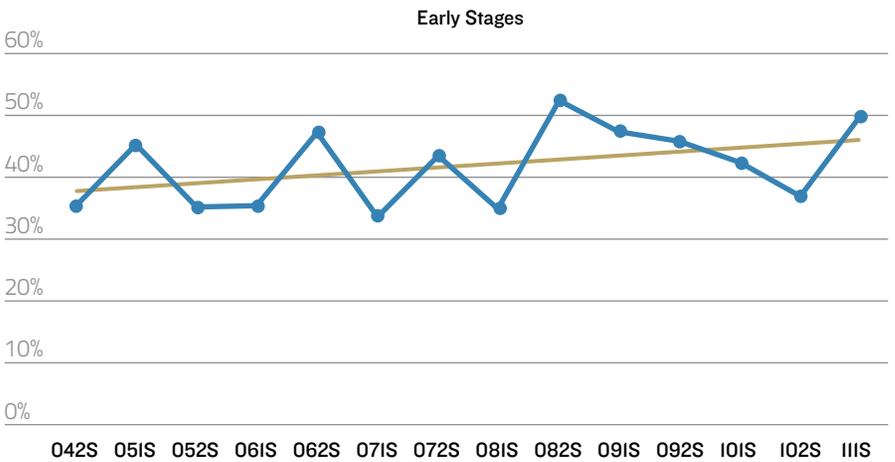
Set up six years ago as a platform for excellence in clinical research, this WG is part of the Spanish Technological Platform for Innovative Medicines. It focuses on designing the strategy and promotion of the competiveness of Spanish clinical research, and facilitates processes and improves performance indicators (time, recruitment, international comparison) in order to achieve the best possible environment for conducting clinical trials, with particular emphasis on the early stages.

CLINICAL TRIALS FOCUS ON FOUR MAIN THERAPEUTIC AREAS : CANCER, CARDIOVASCULAR DISEASE, NEUROSCIENCES AND ANTI-INFECTIOUS DISEASE

The "Metrics" database, updated in June 2011 (11th edition), contains Information on key Indicators of 1,511 clinical trials (of which 635 are completed trials) and 90% are multi-centre and international trials. The main therapeutic areas of these trials are Cancer, Cardiovascular, Neuroscience and Anti-Infectious Illnesses.

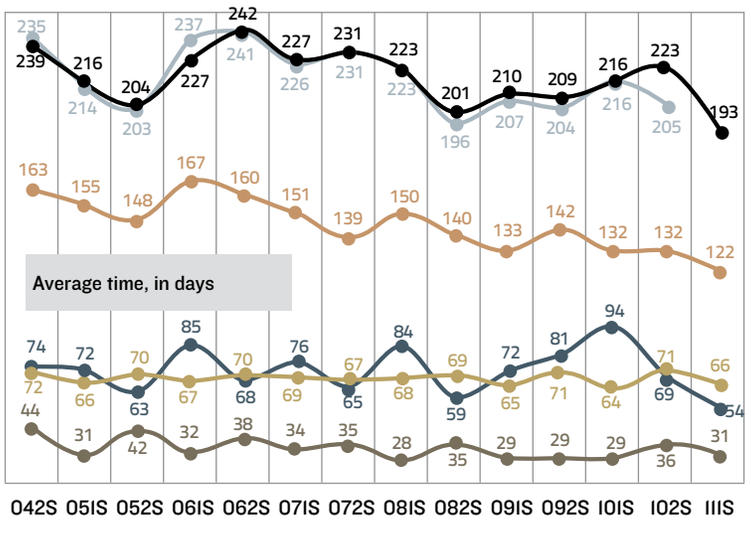
At the same time, the WG has detected a rise in the number of early stages of clinical research, especially at the beginning of Phase II.

CLINICAL TRIALS AT STAGES IA, IB Y II AS A PERCENTAGE OF TRIALS PER HALF-YEAR
The proportion of clinical trials at an early stage is growing steadily



The database includes indicators of roll-out times for trials and recruitment rates per center, as well as a section on international benchmarking. Overall, all the time indicators have dipped over successive half-years, mainly the contract phase (120 days, on average) and, therefore, the overall roll-out time for clinical trials (an average 190 days). This trend has been constant since the project was first rolled-out in 2005. However, the simultaneous rather than sequential management of contracts and the authorization by the Center would go a long way towards cutting roll-out times of a clinical trial.

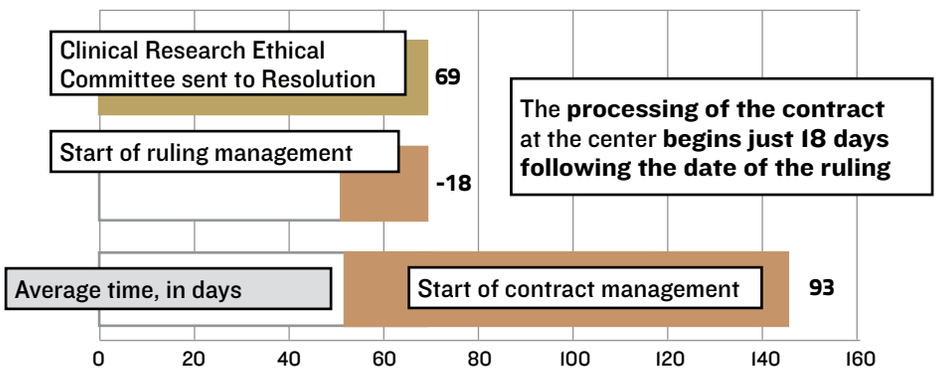
TRENDS IN TIME INDICATORS



Ethical Committees and Participating Centers in Technical Committees with the date forwarded to the Clinical Research Ethical Committee of reference in each half-year

CONTRACT STAGE

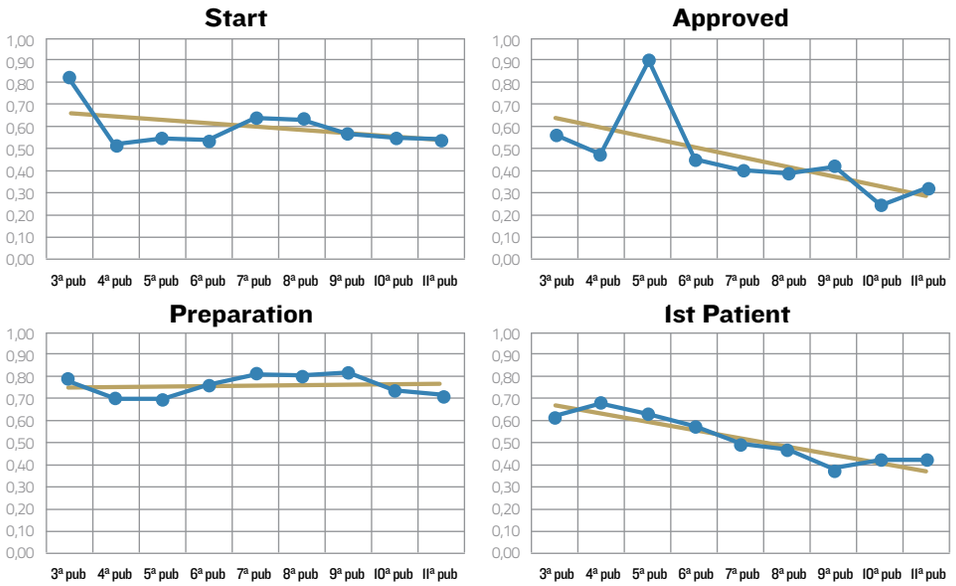
The simultaneous rather than sequential management of contracts and the authorization by the Center would go a long way towards cutting roll-out times of a clinical trial.



In 2011, the international benchmarking module compared Spain to other countries and found that Spain had improved mainly in the approval phase and the inclusion of the first patient in a clinical trial.

BI: INTERNATIONAL BENCHMARKING: TRENDS IN SUCCESSIVE ACTIONS

Spain compared to other countries (Spain's position/ total number of countries). The lower the figure, the better the results.



The diagram below shows that the patients recruitment rate, measured in completed clinical trials, has risen steadily over recent half-years.

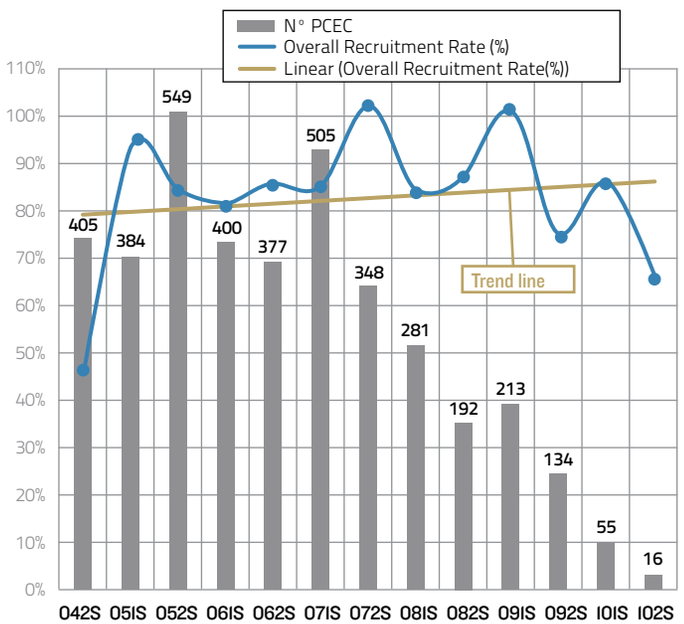
THE ORPHAN MEDICINES WORKING GROUP, WHICH IS HIGHLY RELEVANT BOTH SOCIALLY AND FROM A HEALTHCARE POINT OF VIEW, AIMS AT DEVELOPING AND MARKETING THESE PRODUCTS WHILE ATTEMPTING TO ENSURE EQUAL ACCESS TO THEM

TRENDS IN RECRUITMENT RATES

Progress of the **recruitment rate** in finished clinical trials

The situation appears to be improving

Participating Centers in Technical Committees with the date forwarded to the Clinical Research Ethical Committee of reference in each half-year



"BDMetrics" is a reliable database on which to base discussions and increased efficiency and to come up with shared solutions by developers, researchers, managers and administrations. Improving approval and roll-out times for clinical trials is a key tool for positioning Spain correctly in competitive recruitment processes. The expanded data (broken down in different areas) are available at www.medicamentos-innovadores.org.

The Orphan Medicines WG

Orphan Medicines are extremely important in social and healthcare terms because they are aimed at the treatment of rare illnesses, at times with very few potential patients, which means that they require specific incentives to aid their research, development and commercialization.

This WG deals with all aspects that favor the development and commercialization of Orphan Medicines, In conditions of equality of access, especially in the face of growing obstacles at the regional level as a result of the budgetary impact of this kind of products.

This WG has also addressed other areas, such the functioning of EU procedures or institutional support for the consolidation of a national register of rare illnesses depending on Spain's "Carlos III" Medical Institute. A number of guest speakers have taken part in meetings on this subject.

The various institutional actions were carried out in coordination with the Spanish biotech employers association ASEBIO, with the aim of providing the broadest possible industry support for this field.

The Legal Services WG

As in previous years, the Legal Services WG focused its efforts on analyzing the main legislative measures adopted by the public administrations, such as the passing and coming into effect of RDL 9/2011, 19 August, which introduced measures aimed at improving the quality and cohesion of the National Health System, contributing to fiscal consolidation and raising the amount of State guarantees for 2011, as mentioned in other sections of this Annual Report.

This WG monitored especially the new text of Article 85 of Law 29/2006, included in RDL 9/2011, and which has led to different interpretations at the regional level, and which called for close monitoring of its application in each region.

Special mention should be made of the Resolutions on the determination of new medicine groupings and their reference prices in pharmacies and hospital dispensaries, published in December 2011, and which are analyzed in detail in this Annual Report.

Public hearing procedures granted to FARMAINDUSTRIA have been scheduled for a number of national-level regulations (including Draft RDs on Nurse Prescription, Health Specialties, and Authorization of Non-Industrial Medicines for Advanced Therapy) and regional-level

THE LEGAL SERVICES WORKING GROUP'S ACTIVITIES CENTER ON THE MAIN LEGAL MEASURES ADOPTED BY CENTRAL, REGIONAL AND LOCAL AUTHORITIES

regulations, such as the Madrid Advisory Committee on Pharmaceutical Provision, among others.

In 2011, this WG addressed a number of issues that are also the subject of debate in other WGs and which have been mentioned in other sections of this Annual Report but which, due to their legal repercussions, need to be addressed by this Group (e.g. the negotiations on the Pharmaceutical Industry Collective Bargaining Agreement, the changes to the Code of Healthcare Professionals and Patients, and the Association's processing of and actions on the settlement of arrears on hospital supplies.

The Tax Affairs WG

In 2011, this WG held its annual seminar on changes in tax law and looked at a range of topics including the following:

- the main tax law changes in 2011,
- the main inspections and legal rulings
- the treatment by and the effects on VAT of the sales volume forecast in the Additional Disposition of Law 29/2006 on Guarantees,
- the accountancy procedures for the deduction of RDL 8/2010 at the end of the fiscal year
- changes in notifications and the mandatory notification via electronic transmission, and
- the infraction procedure begun by the Commission regarding the VAT rate applicable to the delivery of medical equipment.

Similarly, the Group monitored FARMAINDUSTRIA's participation in the CEOE's Tax Committee—distributing each document generated by the Group—, and representing the Association on the Public Aid Committee of the CEOE's R&D Commission, joining in the debate on a range of issues, such as the employers' organization's proposals for improving and stepping-up the effectiveness of R&D tax breaks.

In addition, throughout 2011, the Group channeled tax queries through FARMAINDUSTRIA and received regular updates on tax law changes and official rulings of interest to the industry as a whole.

THE TAX WORKING GROUP IS MONITORING RDL 12/2012 WHICH INTRODUCED A RAFT OF MEASURES AIMED AT CUTTING PUBLIC SPENDING AND HAD DIRE EFFECTS ON PHARMACUETICAL COMPANIES IN SPAIN

The WG also monitored RDL 9/2011, which introduces a number of temporary tax measures affecting corporate tax on large companies and VAT.

Along similar lines, the WG analyzed RDL 13/2011, 16 September, which temporarily reinstates capital gains tax, and RDL 20/2011, 30 December, which introduced urgent budgetary and financial measures aimed at correcting the public deficit, and which modified Corporate Tax, with special reference also to increases in Income Tax and Real Estate Tax and the extension to 2012 of a number of tax benefits.

The Group also monitored, through the CEOE, the Draft Order which approved Corporate Tax and Non-Resident Income Tax return forms for permanent establishments and organizations that come under the regime of income obtained from abroad while based in Spain, for the tax periods starting between 1 January and 31 December 2011; laying down instructions

on the declaring and payment procedures, and establishing the general conditions and the procedure for tax returns via electronic data transmission.

Finally, at the time of going to print, the WG is monitoring RDL 12/2012, 30 March, which introduces a raft of tax and administrative measures aimed at bringing down the public deficit, contains measures affecting, among other matters, deferred tax benefits, reducing the use of tax benefits derived from the freedom of amortization, restricting the amount of deductible financial expenses and, regarding deductions aimed at incentivizing certain activities (R&D), temporarily reducing the maximum amount deductible. Similarly, mention should be made of the changes affecting the payment of Corporate Tax by installments, which should be taken Into account by large companies when it comes to preparing the settling payment installments for tax year 2012.

The Human Resources WG

In 2011, this WG, made up of the heads of the HR departments of Farmaindustria member companies, focused on the negotiations on the 16th Chemical Industry Collective Bargaining Agreement, which was approved on 18 October 2011.

FARMAINDUSTRIA also continued to take part in the monthly meetings of the Joint Committee on the Interpretation of the Collective Bargaining Agreement, the Spanish Federation of Chemical Industries' (In Spanish, FEIQUE for short) Socio-Labor Committee, and the joint

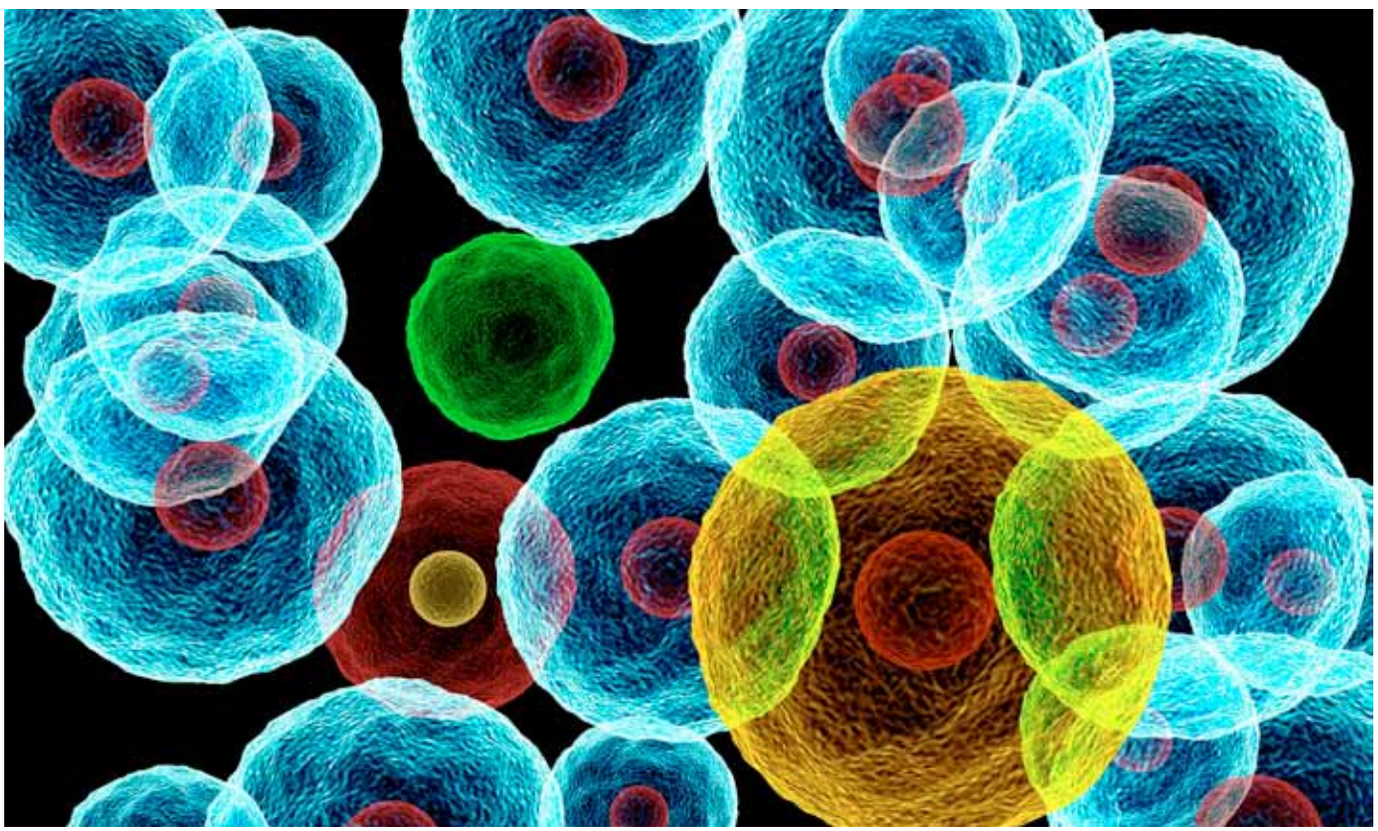
committees set-up under the auspices of this Collective Bargaining Agreement. It also sits on the CEOE's Committees on Labor Relations and Social Dialog, among others.

The Code of Good Practices WG

In 2011, this WG continued to monitor the self-regulation system and worked on the implementation of the text of the Codes approved by the Association's Extraordinary General Meeting, held In October 2010.

The WG's work focused mainly on analyzing the impact of extra-territorial legislation on self-regulation systems, the concept of Fair Market Value in services provision, information on international events, and austerity and efficiency measures in scientific congresses, among other matters.

On 4 April 2011, the EFPIA and FARMAINDUSTRIA signed a Collaboration Agreement whereby the Association's Ethical Oversight Unit took on the responsibility for the coordination and management of the European Congresses via a website open to the general public. As of 9 June 2011, to meet this goal, an electronic communication system is in place to facilitate communication at these events, for assessment under the criteria established by the EFPIA Code. This Agreement comes as part of the development and implementation of the Leadership Statement approved by EFPIA Council members in June 2010.



Similarly, the WG looked closely at the modifications in the EFPIA Code on Promotion (regarding samples) and Patients. On this particular code, in June 2011, the EFPIA's General Assembly gave the green light to a new version of its International Code on Relationships between the Pharmaceutical Industry and Patient Organizations which must be implemented by national associations by 1 January 2012 and which is dealt with extensively in other sections of this Annual Report.

THE CODES OF GOOD PRACTICES WORKING GROUP HAS ANALYZED THE CHANGES MADE TO THE EFPIA CODES ON PROMOTIONS AND PATIENTS

The Farmaindustria Board gave the go-ahead to a new version of the Spanish Code including the aforesaid provisions on 20 December 2011 and was ratified by the General Assembly in June 2012.

Also, the Farmaindustria General Assembly, held on 26 October 2010, approved the new texts of the Code of Good Practice on Medicines and the Relationships between the Pharmaceutical Industry and Healthcare Professionals, the Development Guide and the Regulations of the Control Bodies.

Similarly, the Group has monitored the queries attended by the Ethics Committee, and put forward to the Association's Board a proposal to publish all the queries that are of general interest, in order to enhance the principle of transparency that underpins the self-regulation system.

At the moment, the Code WG is working through two groups set up to address specific issues: on the one hand, the proposals of the Communication WG on good practices in the pharmaceutical industry's media relations and, on the other, analyzing the implementation of the Code's Articles 16 and 17 (services provided by healthcare professionals and/or by their professional associations).

The Competitiveness and Internationalization WG

This WG sets out to foster the industrial competitiveness and internationalization of member companies. In 2011 it stepped up its activity by consolidating internationalization as Spanish companies' principal means of overcoming the downturn, even though the downturn has also done much to erode their export capacity.

In this respect, the Group's member companies decided to continue to reorganize its strategy and to make proven tailored actions for companies and/or territories a priority. In 2011 tailored actions were carried out in Colombia, Chile, Turkey, Taiwan and Tunisia.

Similarly, the Group extended its range of activities to the fight on trade barriers, with particular emphasis on actions Turkey; this country rejected the mutual recognition of the EU's Code of Good Practice in Manufacturing and then went on to demand personal inspections of its authorizations to importers. This turned out to represent a de facto trade barrier which has blocked numerous products currently awaiting trading permits for the Turkish market.

A new international section was set up in the website of the Farmaindustria Statutory National Group providing members formation on a range of events, documents and reports

THE AUTONOMOUS REGIONS WORKING GROUP HAS CLOSELY MONITORED THE REGIONS' LEGAL INTITIATIVES AND THEIR REGULATORY DEVELOPMENT

aimed at helping internationalization processes. The website is made up of four sections: Foreign Trade, Calendar of Events, Presentations and Documentation, all of which are updated weekly.

The Relations with the Autonomous Regions WG

As laid down by Farmaindustria's Governance Bodies, this WG reviews, analyzes and monitors regional pharmaceutical policy and fosters spaces of collaboration for autonomous regions, scientific societies, professional and political organizations, institutions and social organizations, helping to create an environment that favors pharmaceutical innovation and preserves the unity of Spain's pharmaceutical market.

In 2011, this WG was made up of 51 member companies, representatives of the Associations statutory groupings, and convened every two months.

Importantly, it monitored closely regional regulatory activity (and its development) related to healthcare policy and access to the pharmaceutical provision. It also worked on fostering communication and internal information mechanisms.

In particular, over the past twelve months it worked on a range of topics, including the following:

- implementing RDL 9/2011 in each region;
- the Active Ingredient Prescription;
- the automatic substitution of prescriptions (in the Basque Country, Cantabria and Aragon);
- Galicia's regional catalog of medicines financed by the public health system;
- the auction of medicines In Andalusia;
- the regional committees on the assessment of medicines;
- the moving of hospital diagnostics medicines to hospital dispensing;
- the central purchasing bodies for medicines, and
- e-prescriptions and e-medical records.

The Barcelona Delegation

The FARMAINDUSTRIA delegation in Barcelona has continued to carry out outstanding work on issues of interest to the Association's member companies, working shoulder-to-shoulder with a number of the Association's departments.

Similarly, the Delegation has worked closely with the FARMAINDUSTRIA National Statutory Group, in the role of both Technical and Organization Secretary for the Association's meetings and for its constant supply of online information for member companies at the FARMAINDUSTRIA portal.

It also continued to provide advisory services and helped member companies on a range of queries, e.g. tax, public contracts, hospital debt and e-billing, among others.

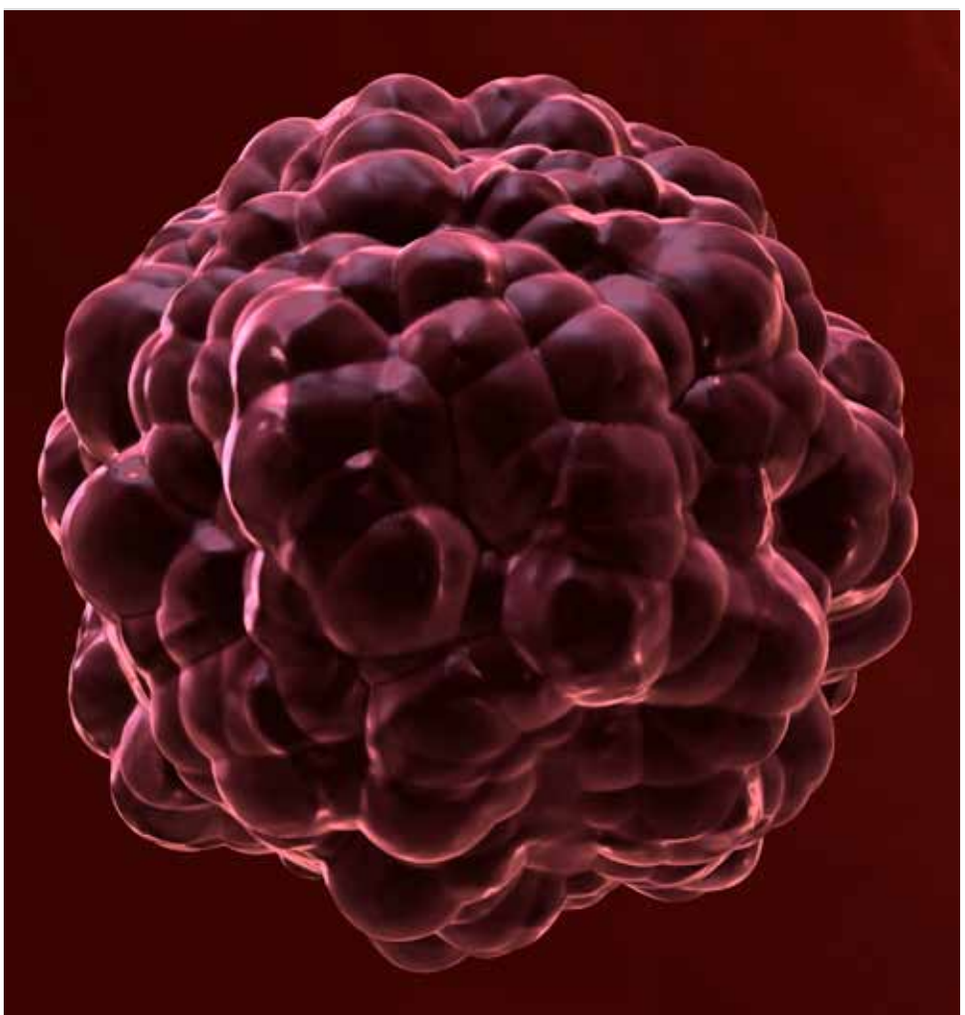
In 2011 the Delegation played an active role in the processing of the Framework Agreement on Medicine Supplies for all of the centers dependent on Catalonia´s Public Health Institute,

and with the meetings held with the heads of Andalusia's Public Health Service in relation with the inclusion of the pharmacy area in the SIGLO project.

The Delegation has been the venue for regular meetings (face-to-face and teleconference) of the different FARMAINDUSTRIA WGs. These meetings strengthened active participation and the exchange of knowledge between member companies. Furthermore, the Delegation staged the meetings of the Association's Governance Bodies, Statutory Groups and with other organizations (e.g.COASHIQ, ANEFP, SIGRE, etc.).

Moreover, the Delegation has taken part in a broad range of regional activities, and collaborated actively with academic institutions and organizations related to the pharmaceutical industry.

In 2011, the Barcelona Delegation continued to sit on the FedeQuim (a "non-profit organisation whose objective is to defend the rights and interests of the chemical companies, especially in Catalonia") Delegate Joint Committee in an effort to interpret the text of the Chemical Industry's Collective Bargaining Agreement and sat on the meetings of the Federation's Socio-Labor Committee.



THE SPANISH TECHNOLOGICAL PLATFORM FOR INNOVATIVE MEDICINES (PTEMI) IS THE SPANISH BENCHMARK FOR THE INNOVATIVE MEDICINES INITIATIVE (IMI)

The activities carried out by the Delegation have involved an exhaustive monitoring of all of the changes related to and affecting the pharmaceutical industry, with the ultimate goal of offering uninterrupted advisory services to Catalonia-based Spanish member companies.

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

Six months after it was created, the Spanish Technology Platform for Innovative Medicines (In Spanish, PTEMI for short) is now consolidated as an initiative backed by the pharmaceutical industry and academic institutions, clinical researchers and public administrations, with the aim of encouraging R&D on innovative medicines in Spain.

The PTEMI is Spain's referent on the Innovative Medicines Initiative (IMI), a joint initiative of the EFPIA and the European Commission designed to promote research into new medicines, in an effort to strengthen Europe's position in the field of pharmaceutical research, make Europe a more attractive investment proposition where research is concerned, and, in the long run, give EU citizens faster access to top-quality medicines. In 2011, the PTEMI worked towards encouraging international collaboration and at helping and providing support for interested parties. It worked hard to help organize the "Information Days" event and others, and sat on all the meetings organized by both IMI and the EFPIA.

The Innovative Medicines Initiative has 30 projects currently underway, 15 from the first call for entries (2008), 8 from the second and seven form the third, with an overall budget of 570 million euros. Similarly, it is thought that the fourth call, in July 2011, will start up a further seven projects.

THE INNOVATIVE MEDICINES INICIATIVE (IMI) - PROJECTS

	Call I	Call 2	Call 3	Call 4 (forecast)	TOTAL (forecast)
Number of projects	15	8	7	7	37
Number of EFPIA teams	160	66	54	61	341
Number of academic teams	194	105	101	108	508
Number of SME* teams	26	22	14	30	92
Number of Patient Organizations	10	1	6	0	17
Number of regulatory agencies	7	0	2	1	10
Number of other partners	3	0	3	4	10
Contribution IMI JU (Đmillion)	109.6	80.7	111.8	93.6	395.7
EFPIA contribution in kind (Đm)	132.6	65.9	70.8	93.6	362.9

* Small and Medium Enterprises

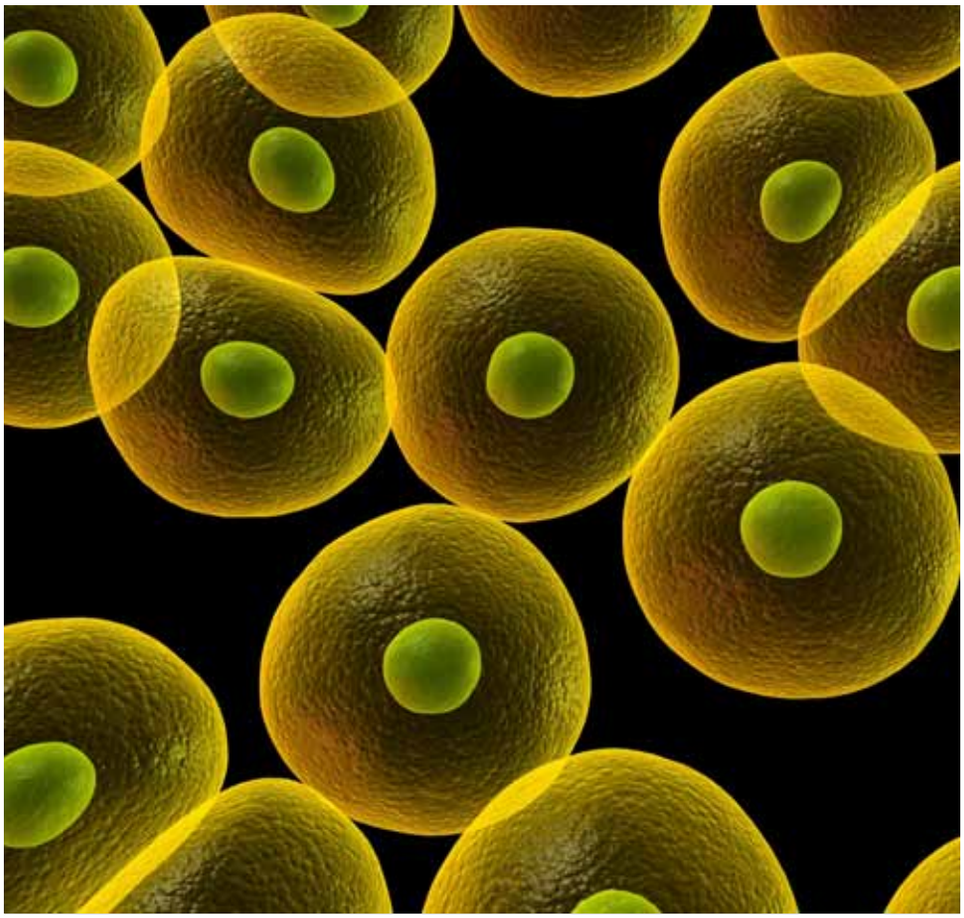
FARMAINDUSTRIA is a member of the European Academy of Patients for Technological Innovation (EUPATI for short), an IMI consortium for the Third Call, which provides patients with

comprehensive and objective scientific information on pharmaceutical R&D. The 29-member organization, led by the European Patients' Forum, is a unique combination of pan-European patient organizations, academic organizations and not-for-profit organizations specializing in patient participation, as well as businesses and EFPIA member companies. The IMI consortium sets out to increase well-informed patients' capacity to provide advice and counseling, e.g. in clinical trials, alongside regulatory bodies, and to sit on ethical committees. EUPATI give the patients objective, high-level and cutting-edge training on innovation In therapeutics. For more information, visit www.patientsacademy.eu.

In 2011 PTEMI also began a review of IMI's Strategic Agenda on Research, owing to the changes produced in the European biomed R&D situation since IMI was first set up in 2007. This way, the new and successive calls for project entries respond to the new milestones contained in the revised document. The revision was carried out jointly by all of the stakeholders of pharmaceutical R&D.

THE UPDATED STRUCTURE OF THE REVISED STRATEGIC AGENDA ON RESEARCH

On 27 February 2012, PTEMI issued the fifth call for entries of projects, and on 26 March, the Spanish Platform, in conjunction with the Centre for Industrial Technological Development (CDTI) and Madrid's "Carlos III" Health Institute, organized the "IMI Information Day" in Madrid, where a team of IMI experts explained the new rules of participation, which are now more flexible in some aspects.



IN FEBRUARY 2011, FARMAINDUSTRIA LAUNCHED A PILOT AIMED AT FACILITATING COOPERATION BETWEEN SPAIN'S PHARMACEUTICAL AND BIOTECH SECTORS

PTEMI's activities in 2011 included the following:

The Farma-Biotech Cooperation Program. As part of PTEMI's activities, in February 2011 FARMAINDUSTRIA launched a pilot aimed at facilitating collaboration between the pharmaceutical industry and Spain's biotech sector.

This initiative aims to aid the development of biotech companies In the Spanish pharmaceutical industry, making the most of synergies with the sector and highlighting FARMAINDUSTRIA's differentiated and complementary contribution to the process. Between February and July 2011, Farmaindustria organized four Professional Meetings (two in Madrid and two in Barcelona) on the Central Nervous System, Cancer, Respiratory System, Inflammation and Autoimmune Disease. Each Meeting was conceived as an individual forum with an environment of interaction capable of conveying the value-added derived from the exchange of information between the supply and demand sides of biotechnology, with the right amount of differentiated and innovative content, in the sphere of new therapies. There are plans to hold three more Meetings In 2012: the first was held on 14 March in Barcelona, focusing on Infectious

Disease and Inflammatory Processes, and there are two more Meetings scheduled for Zaragoza and Madrid.

The PTEMI also published the Guide to Centers Generating Molecules of Pharmaceutical Interest, a catalog that brings together the centers that generate new chemical structures of use to R&D on medicines, to create an instrument capable of distributing Information on Spain's research capacity in the pre-clinical phases of research on new medicines. The two-fold objective is to promote cooperation in the development of new medicinal products and attract Investment to the pre-clinical phases of research.

Most of the PTEMI's activities are aimed at disseminating and fostering actions directed at all of the agents involved in the Science-Technology-Enterprise system, in order to showcase the results of research activities or the sector's public and private interests, with the aim of promoting cooperation between the different players. On 14 and 15 February 2012, the PTEMI organized and coordinated its 5th Annual Conference, held In Barcelona, along with the Spanish Technological Platform on Nanomedicine, and similar platforms on healthcare Technologies and Biotechnology Markets, under the theme "Fostering Open Innovation". More than 230 attendees looked at the need to continue to promote public-private cooperation models based on the concept of Open Innovation in the field of biomedical R&D and Innovation. The event's presentations and videos are available at www.medicamentos-innovadores.org

The PTEMI's communication vehicle is its web portal (www.medicamentos-innovadores.org) which stands as a referent in Spanish pharmaceutical biomedical research, and acts as a meeting point and coordination center for activities, information and communication among its users. It publishes a monthly newsletter on PTEMI's activities which goes out to more than 1,800 subscribers. The web portal's content is published in Spanish and English and is updated weekly.

THE PTEMI WEB PORTAL (WWW.MEDICAMENTOS-INNOVADORES.ORG) STANDS AS A YARDSTICK IN SPANISH PHARMACEUTICAL BIOMEDICAL RESEARCH

3.3.4. SELF-RREGULATION SYSTEMS

The Spanish Pharmaceutical Industry Self-Regulation System is made up of three Codes:

- The Spanish Code of Good Practices in the Promotion of Medicines and Relations between the Pharmaceutical Industry and Healthcare Professionals (from hereon, the "Relations with Healthcare Professionals Code"

- The Spanish Code of Good Practices in the Promotion of Medicines and Relations with Patient Organizations (from hereon, the "Relations with Patient Organizations Code"

- The Farmaindustria Code Type on Personal data Protection In the Field of Clinical research and Pharmacovigilance (form hereon, the "Type Code")

At the end October 2010 the Association approved a new version of the Relations with Healthcare Professionals Code, introducing important changes affecting hospitality and meetings (Article 11), Studies (Article 14) and services provided by healthcare professionals or by their professional organizations and bodies (Articles 16 and 17).

On the matter of hospitality and meetings (Article 11), the new Code prohibits member companies from collaborating or otherwise participating in events with a marked entertainment, leisure or cultural content, as well as prohibiting the colaboration with those that promote the assistance of accompanying persons them from promoting people to attend them. This change sets out to standardize the main guiding principles with which member companies may organize or sponsor events or take part in an event organized by third parties.

Prior to this new version of the Code, this requirement applied mainly to events organized and/or sponsored by pharmaceutical companies. The main difference now is that it also applies to events organized by third parties.

To make this rule effective, the Code made a clear distinction between:

- Events organized or sponsored mainly by a pharmaceutical company. This requirement came into effect the day after the new Code was approved (27 October 2010).

- Events in Spain organized by third parties. An adaption period was agreed upon (until 30 June 2011) to allow pharmaceutical companies to comply and to enable organizers of such events (scientific societies, professional organizations, and others) to adapt their respective official calendars of events.

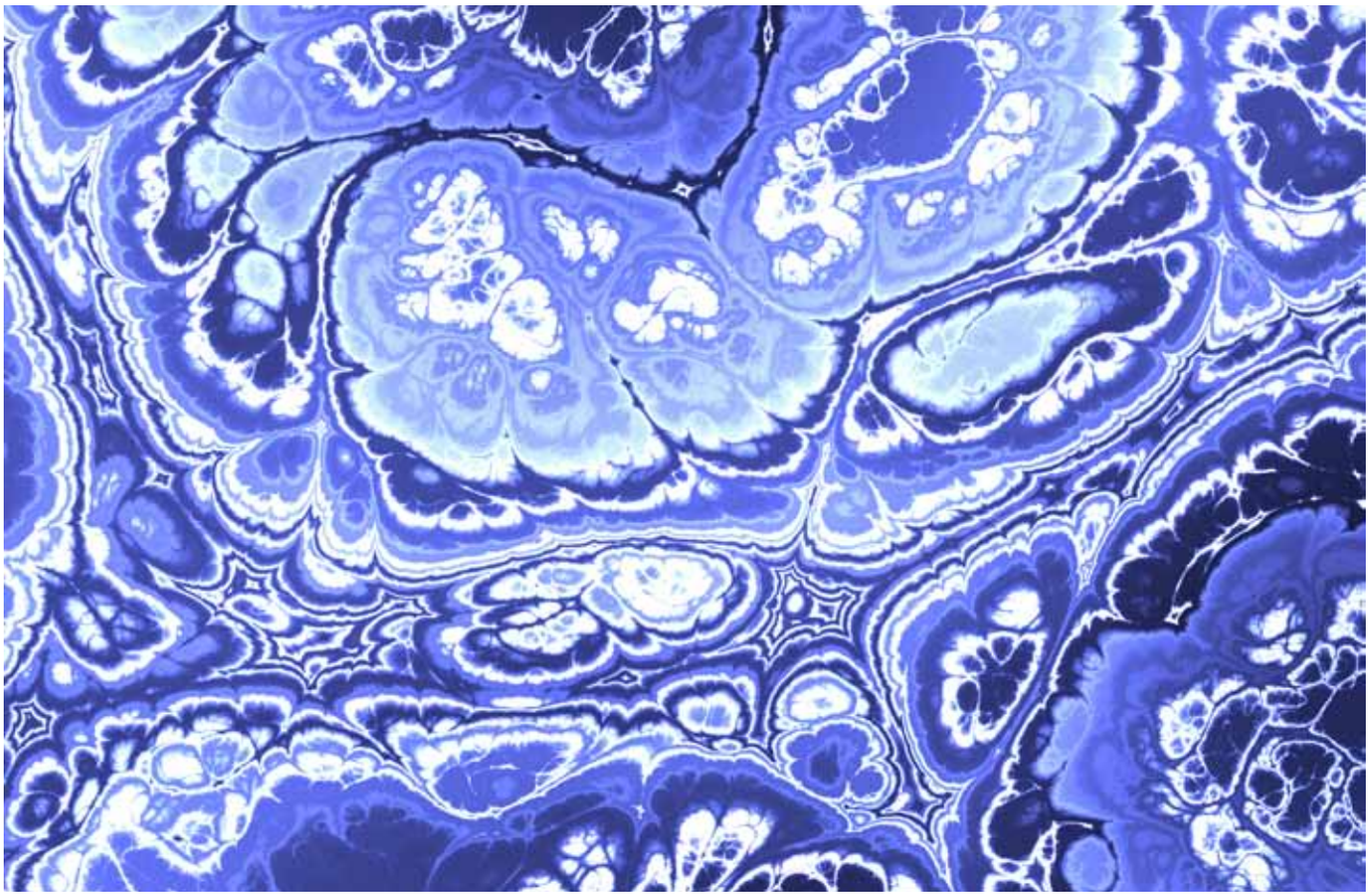
CORPORATE HOSPITALITY AND SOCIAL GATHERINGS: PHARMACEUTICAL COMPANIES ARE NOT ALLOWED TO COLLABORATE OR TAKE PART IN EVENTS COMPRISING ENTERTAINMENT, LEISURE OR CULTURAL ACTIVITIES

- International events organized by third parties. It is necessary to synchronize these new, more restrictive criteria with the pharmaceutical industry associations' work at the European level (EFPIA) and at the global level (IFPMA), in an effort to unify international standards on the organization of congresses and scientific meetings.

There is a need to synchronize the requirement of these new and more restrictive criteria with the progress made by pharmaceutical companies at the European and global level (EFPIA and IFPMA) in an effort to unify international standards on the organization of scientific congresses and gatherings.

In the first half of 2011, the FARMAINDUSTRIA Ethics Oversight Unit focused on communicating and explaining to scientific societies, Secretariats-General and other interested parties the pharmaceutical industry's position on the organization and management of congresses.

Regarding rules on Studies (Article 14), the new Relations with Healthcare Professionals Code introduces two new sections:
Article 14.3, which defines and regulates—in line with the existing national and international criteria—so-called "Market Research Studies" Article 14.4, which defines as



"promotional action" any information-compiling practice or initiative not envisaged in sections 14.1, 14.2, 14.3 or in Articles 16 and 17 of the Code.

These changes not only clearly define the types of initiatives subject to the procedures for the notification of studies as envisaged In Article 10 of the Regulations on the Organs of Control of the Self-Regulation System; they also allow us to distinguish between each type of project according to their nature, methodology, characteristics and intentionality. The drop in notifications received came solely as a result of this change.

As far as services are concerned (Art. 16 and 17), a result of the abovementioned modification and with the aim of guaranteeing the best possible relations between the industry and healthcare professionals, member companies gave the go-ahead to a new notification procedure that covers services provided by organizations made up of healthcare professionals (Art. 16) and those provided by individual healthcare professionals (Art. 17). The implementation of this new procedure strengthens the self-regulation system because, on the one hand, it makes it easier to differentiate and classify each activity carried out by the pharmaceutical company and, on the other hand, it helps to identify the requirements applicable to each company.

FOR THE SECOND YEAR IN A ROW, IN 2011 THERE WERE FEWER INCIDENTS REPORTED TO THE ASSOCIATION'S ETHICS COMITTEE

Similarly, in December 2011, FARMAINDUSTRIA's Organs of Governance approved a new version of the Code of Relations with Patient Organizations.

This came about when the EFPIA's General Assembly (June 2011) approved a new version of the European Code which Included a number of changes and adaptations that needed to be Implemented at the national level before 1 January 2012.

The main changes are as follows:

- the obligation to provide detailed information (including fees due) on the collaboration provided by pharmaceutical companies to Patient Organizations (Article 5);

- the regulation of agreements of collaboration/service provision between pharmaceutical companies and Patient Organizations (Article 6), and

- the alignment of the obligations on hospitality and meetings (Article 7)to the conditions required by the Code.

Concerning the Type Code, 2011's most important activities included the drafting of the following documents:

- Guidelines for companies wishing to join the Type Code under the category of Data unlinked to an identifiable person and Personal data.

- A declaration of intent regarding personal data protection. A document drafted jointly by the Spanish Agency for the Protection of Data and the regional agencies of Catalonia, Madrid and the Basque Country have been sent to the General Managers of the main hospitals accounting for most of the research conducted in Spain.

- Registration of the mixed brand (word and logo) "The FARMAINDUSTRIA Code of Data Protection" at the Spanish Patent and Trademark Office.

- A document on the Good Practices on Data Protection directed at researchers involved in clinical studies.

The last two of these initiatives (mixed brand and good practices for researchers) are applicable only to member companies.

The activity of the Type Code Monitoring Committee has focused on analyzing the applications of companies wishing to adhere to these initiatives and the changes in data protection law with a potential impact on the sector, as well as preparing and drafting the aforementioned documents.

As in previous years, and in compliance with Article 78 of RD 1720/2007, 21 December, approving the implementing regulation of the Organic Law 15/1999, 13 December, on

Personal Data Protection in July 2011, the Second Memorandum of this Type Code was presented, summing up the dissemination activities carried out and aimed at encouraging companies to adhere to the Code and to become acquainted with it.

Actions by the Ethics Commission

In 2011, and for the second year running, there was a slight fall in the number of complaints presented to the Ethics Commission.

As the figures below show, 37.5% of the complaints were settled between the parts thanks to the mediation of the Ethics Committee, and only 37.5% were referred to the Self-Regulation Jury, because in the remaining 25% an agreement was reached prior to the Committee's meeting.

Eight of the complaints brought before the Ethics Committee concerned the alleged violation of the Code, mainly affecting the scientific content of promotional material and other promotional activities (distribution of promotional material, incentives, samples, etc.). The table below shows the number of complaints registered in 2011, grouped according to different criteria:

Complaints	**8**
Admitted	**8**
Plaintiffs	
Member companies	**5**
USD	**3**
Respondents	
Member Companies	**8**
Mediation by the Ethics Committee	**3**
Settlements	**3**
Referred to the Self-Regulation Jury	**3**
Not Admitted by the Self-Regulation Jury	**1**
Sanctions	**2**
Settlement prior to de Mediation	**2**

Actions by the Ethics Oversight Unit

The following are some of the main activities as regards the dissemination of the self-regulation system:

- participation in national and international conferences and seminars;
- meetings with the regional heads of promotions activity;

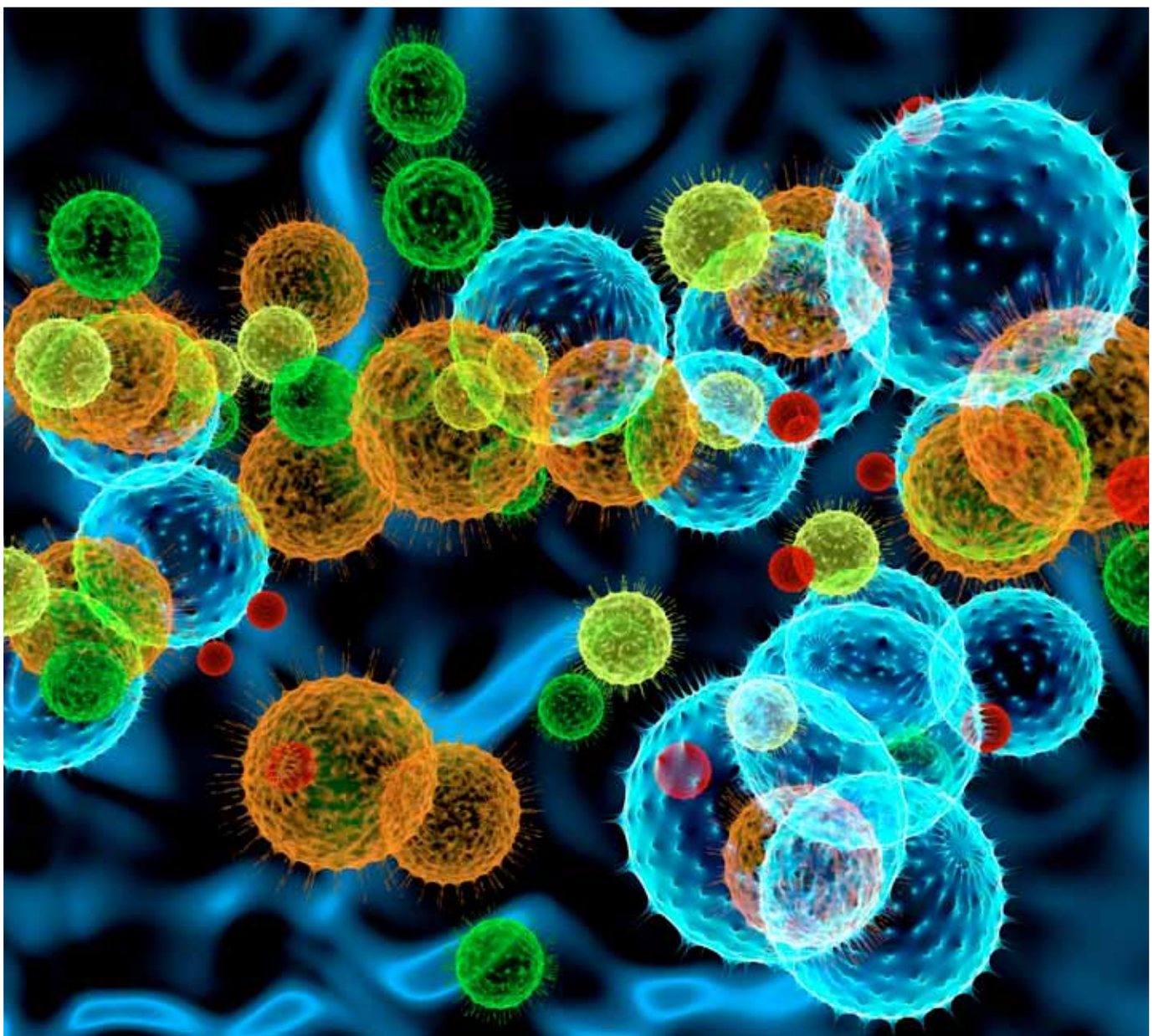
▪ collaboration in training on codes, in courses, postgraduate studies and specialist masters degrees;

▪ participation in national congresses organized by scientific societies, and

▪ meetings with pharmaceutical companies to identify room for improvement in the self-regulatory system.

The main specific activities on the Code on Relations with Healthcare Professionals were as follows:

▪ participation in Madrid and Barcelona in the winter seminars organized by the Pharmaceutical Research and Marketing Group;



- advisory work and collaboration with scientific societies that organize events, conveying to them the changes approved in this sphere; and

- improvements to the communication procedure of studies and the roll-out a new procedure for communicating services.

Advisory work and collaboration

Throughout 2011, the Unit centered its efforts on disseminating and spreading the word on the Code on Relations with Healthcare Professionals, approved in October 2010, particularly so bearing in mind the important changes affecting collaboration and sponsorship of events and gatherings of a professional and scientific nature.

Similarly, the changes to the notification procedure for studies and the roll-out of the new procedure for the notification of services led to the need for more advisory work and collaboration with pharmaceutical companies to revise, modify and improve procedures and even set up internal ones.

Notwithstanding the above, and in compliance with the function assigned to the Unit by the Regulations of the Organs of Control of the Self-Regulation System (namely "to provide advice, guidance and training on the Codes"), the Unit has stepped up its collaboration and assistance work in the following ways:

- by reviewing, adapting and improving the internal procedures in place in pharmaceutical companies and intended to ensuring compliance with the Code and the regulations on the promotion of medicines;
- through permanent and continued support to pharmaceutical companies and third parties involved;
- by participating actively in gatherings and forums organized by FARMAINDUSTRIA alongside regional authorities and the media, and
- by attending international gatherings organized by the EFPIA or IFPMA. (Mention should be made of the fact that the Director of the Ethics Oversight Unit continues to sit on the Code Steering Group, and is the current Vice-Chair of the Compliance Committee, the Chair of the EFPIA's Code Committee, and Chair of IPFMA's Adjudication Group (the IFPMA's court of first instance).

In 2011 four binding queries were processed and four circulars were sent out in connection with the Code of Relations with Healthcare Professionals and the Code of Relations with Patient Organizations.

Control and prevention

Compared with the previous year's figures, preventive actions fell in 2011 (a total 3,131 as opposed to 3,482) as did the number of complaints presented on the initiative of the Unit (3 in 2011; 4 in 2010).

IN 2011, FOR THE FIRST TIME EVER, THERE WERE FEWER PREVENTIVE ACTIONS AND FEWER CASES REPORTED AT THE INTIIATIVE OF THE ETHICS OVERSIGHT UNIT

FARMAINDUSTRIA'S INITIATIVE TO CREATE A LIST OF EVENTS ORGANIZED BY THIRD PARTIES WAS SEEN BY THE EFPIA AS A STEP TO IMITATE

Regarding the analysis and verification of events and scientific meetings, in 2011 the total number of events processed once again exceeded the 5,000 mark (specifically, 5,335 events, up 255 on 2010).

In 2011, the number of activities notified as "studies"—in compliance with Article 14 of the Code of Relations with Healthcare professionals—came to 626 (98 less than in 2010). The dip stemmed from the roll-out of the new procedure for the notification of "services", which has helped to distinguish between "studies" and other types of projects involving the paid collaboration of healthcare professionals or their professional associations. The Unit verified and cleared more than 90% of the studies notified.

Finally, of the 357 projects notified under the heading "Services"—as per Articles 16 and 17—a total 282 (roughly 80%) were analyzed and cleared. However, the Unit feels that there is considerable room for improvement in this area and it plans to promote the drawing up of development manuals laying down principles and guideline's for pharmaceutical companies.

ETHICS OVERSIGHT UNIT

The Spanish Code of Good Practices in the Promotion of Medicines and Relations between the Pharmaceutical Industry and Healthcare Professionals and Patient Organizations

Activity in the period 2004-2011

		2004	2005 jan-dec	2006 jan-dec	2007 jan-dec	2008 jan-dec	2009 (a) jan-dec	2010 jan-dec	2011 (b) jan-dec	Accumulated apr 04-dec 11
EVENTS	ANALYZED	Apr-Dec	2005	2,199	2,926	3,388	3,878	5,080	5,335	25,498
	No irregularities found	Jan-Dec	2006	1,909	2,616	3,087	3,345	4,383	4,862	22,310
	% suitability	Jan-Dec	2007	86.81%	89.41%	91.12%	86.26%	86.28%	91.13%	
STUDIES	ANALYZED	Jan-Dec	2008				687	724	626	2,037
	No irregularities found	Jan-Dec	2009 (a)				379	546	565	1,508
	% suitability	Jan-Dec	2010				57.79%	75.41%	98.26%	
SERVICES	ANALYZED	Jan-Dec	2011 (b)						357	357
	No irregularities found	Jan-Dec	Accumulated						282	282
	% suitability	Apr 04-Dec 11							78.99%	
Preventive actions		814	1,801	1,376	2,092	2,440	2,670	3,482	3,131	17,806
Reports USD		18	11	9	18	8	12	4	3	83*

* 12 final rulings by the Self-Regulation Jury in favor of the EOU.
* 62 resolved through mediation by the Ethics Committee, acknowledging infringements and accepting corrective measures.
* 3 settlements between the parties before reaching the Ethics Committee.
* 5 filed at the request of the EOU.
* 1 dismissed by the Self-Regulation Jury.

(a) Studies Notification System approved by the 2008 Code.
(b) Services Notification System approved by the 2010 Code.

NB. This table provides a summary of the Unit's data (annual and accumulated) from the start of its activities until 31 December 2011.

Collaboration Agreement with the EFPIA: The "e4ethics" Platform.

This initiative, approved by FARMAINDUSTRIA in 2005, involved the drawing up of the so-called "List of events organized by third parties". It has been adopted by the EFPIA as a benchmark and the Federation has requested FARMAINDUSTRIA's advice and assistance to help set up a similar platform that goes under the name "e4ethics".

The EFPIA-FARMAINDUSTRIA agreement envisages the technical support for the platform's design, functioning and maintenance, as well as the necessary advice, analysis and consultation services for assessing the events notified via this platform in accordance with Article 9 of the EFPIA Code.

The platform was launched and came into service on 9 June 2011, with a trial period until 15 November; from that date onwards it will become fully operational. Further Information on the Platform is available at http://www.efpia-e4ethics.eu o en http://www.FARMAINDUSTRIA.es.

3.3.5. LABOR RELATIONS

The 16th Chemical Industry General Collective Bargaining Agreement

Talks on the 16th Chemical Industry General Collective Bargaining Agreement got under way on 24 February 2011 with the first round of talks at the negotiating table (comprising FEIQUE and the labor unions FIA-UGT and FITEQA-CCOO). These talks came at the same time as an overall analysis of the reform of collective bargaining; as a result, many of the aspects and modifications to be introduced in the were linked to progress made in in these talks and could not be specified until the end of the negotiations.

The circumstances surrounding the signing of the Chemical Industry General Collective Bargaining Agreement represented a milestone in the history of the Agreement, which was signed on 18 October by the Spanish Federation of Chemical Industries (Spanish abbreviation FEIQUE) and the Chemical Industry Federation of the Comisiones Obreras labor union (FITEQA-CCOO), though not by the FITAG-UGT union. This means that the new Agreement is limited in terms of efficiency and contractual scope, which, in turn, means that its field of application covers only those directly represented by the members present at the Negotiation Table, i.e. CC.OO union members and those who voluntarily subscribe to the Agreement.

THE CHEMICAL INDUSTRY'S GENERAL COLLECTIVE BARGAINING AGREEMENT RUNS UNTIL 31 DECEMBER 2012 WITH RETROACTIVE EFFECT AS OF 1 JANUARY 2011

The 16th Agreement was not published in Spain's Official Gazette as normally required by the National Department of Labor because its efficiency is limited. As a result, in accordance with Article 4, the Agreement came into effect on 2 November 2011, two weeks after it was signed.

The Agreement runs until 31 December 2012, with retroactive effect as of 1 January 2011, coinciding with the period covered by the State Agreement on Collective Bargaining.

Similarly, the signatories of the 16th Agreement expressed their will to adjust the Agreement to the terms of the 2nd State Agreement and they will analyze the formulas needed to meet the wage restraint targets set by the State Agreement for the period 2012-2014. To meet these targets, a Study Committee was set up, as envisaged in the Agreement's 2nd Transitional Provision, and the parties have committed to setting up the Negotiations Committee of the next Collective Bargaining Agreement in October 2012.

3.4.

INTERNATIONAL RELATIONS

3.4.1.
THE EUROPEAN CONTEXT

FARMAINDUSTRIA's activities on the European stage have come mainly in the shape of its participation in the European Federation of Pharmaceutical Industries (EFPIA), consolidating the Association's presence in 29 committees and working groups within the Federation, as well as in the many meetings of its governing bodies, namely the Board, the Executive Committee and the Heads of Association Committee.

The EFPIA Annual General Meeting

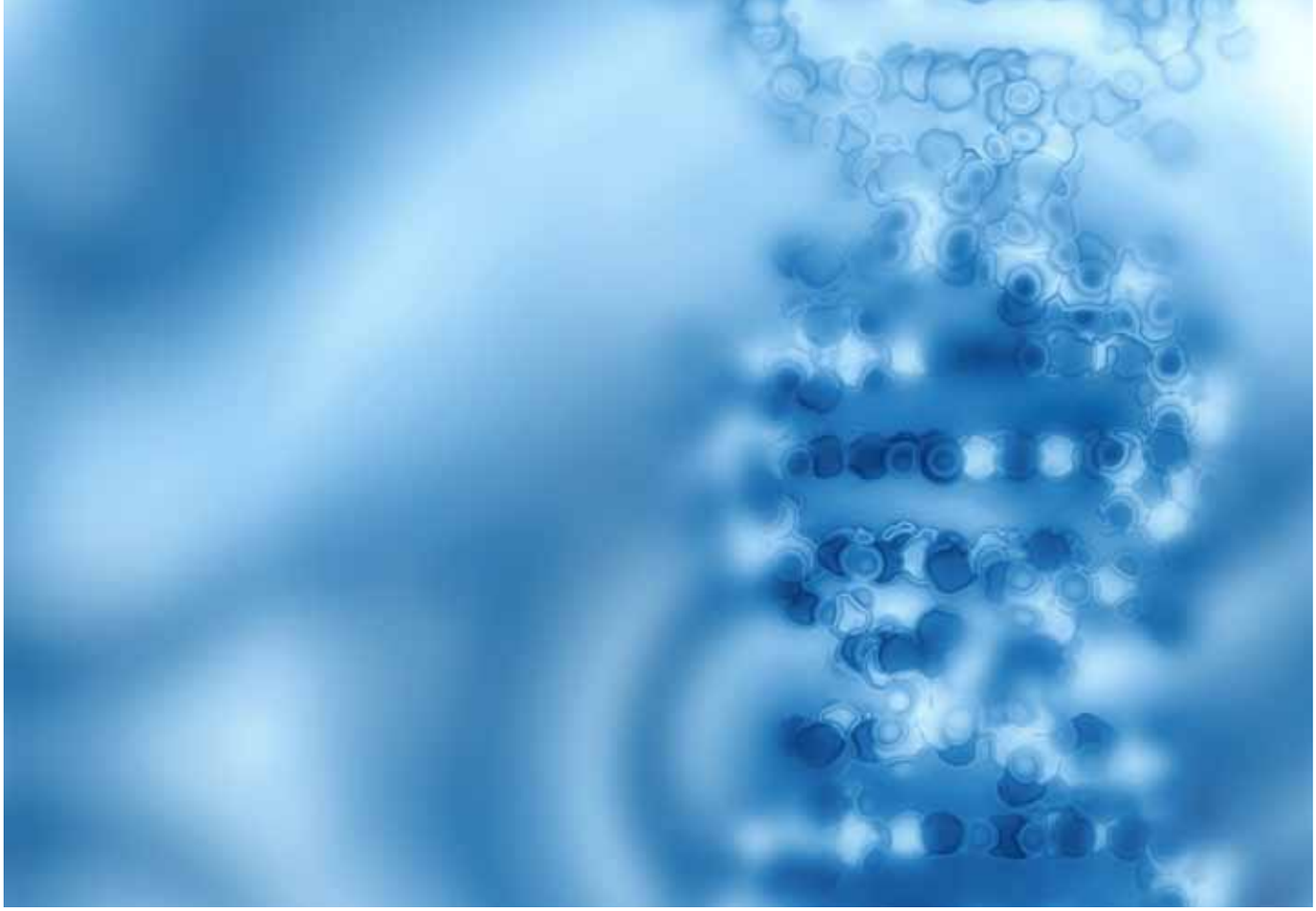
The EFPIA Annual General Meeting was held in June 2011 in Brussels, under the theme "The healthy road towards old age: A lifelong and worthwhile effort". At the same time as the General Assembly, a number of meetings were held with EFPIA's governing bodies and with the exceptional participation of the President of the European Commission, José Manuel Durão Barroso and EU Health Commissioner John Dalli. EFPIA Chairman Andrew Witty and the Federation's recently appointed Director-General Richard Bergström both stressed the need to strike alliances to help take on new and important public healthcare challenges. They underscored the pharmaceutical industry's staunch commitment to engage permanently with the authorities in an effort to guarantee care for patients and come up with more efficient healthcare systems.

The governance bodies also gave their approval to the fundamental points of the EFPIA's strategy for 2011/2012, the most important of which are the following:

- the national development of pharmaceutical policies in the context of the current economic downturn;
- the Pan-European project to serialize medicines;
- the evaluation of healthcare technologies;
- the fight on microbacterial resistance, and
- actions in emerging markets.

EFPIA Executive Committee Meetings

In 2011 this body called five meetings made up of European company directors (Heads of Europe) and the Directors-General of the main national associations (Heads of Association), whose role is to implement the strategic activities in accordance with the priorities laid down by the Board of the EFPIA. In 2011, the Committee paid particular attention to developments at the national level as regards pharmaceutical public spending cuts in the context of a grave economic downturn.



The main decisions adopted by the Federation's Executive Committee included the following:

- To report regularly on the main spending control measures adopted In different member states
- To develop a single EU-wide system of serialization and coding for medicines
- To implement at the national level the "EFPIA Declaration on leadership in ethical practices in the pharmaceutical industry".

Country Team Spain

The function of these Working Groups (referred to as Country Teams) involves the organization of regular information and best-practice exchange sessions between companies and associations in order to obtain a common evaluation of the main issues in each country, including local strategies, scenarios and operational planning, thus ensuring greater efficiency when it comes to defining short- and long-term strategies with a close eye on the possible domino effect that pharmaceutical policies tend to have at the European level.

National associations have sovereignty over the development and implementation of national-level strategies. The role of the Country Teams is merely to provide support and to set up an exchange of information on best practices.

Following the founding session of the Spanish Country Team in 2010, two more meetings were held, both in Barcelona (Spain). The first looked at the impact of the pharmaceutical spending cuts carried out on a national scale and In the different Spanish regions, and FARMAINDUSTRIA outlined the Association's short- and long-term future strategies, including the strategy on the regions, the new communications plan and healthcare as a priority in public investment.

THE COUNTRY TEAMS' FUNCTION IS TO ORGANIZE REGULAR INFORMATION AND GOOD PRACTICES EXCHANGE SESSIONS FOR COMPANIES AND ASSOCIATIONS

After Spain's general elections, held in November 2011, and following the setting-up of the new government, a new Country Team meeting was called in which Farmaindustria addressed the main issues of interest for the pharmaceutical industry -possible solutions to the debt outstanding to hospitals, brand positioning, the compatibility between Innovation and sustainability in Spain's National Health service, etc. -and the meeting ended with an open debate on possible strategies for tackling these issues.

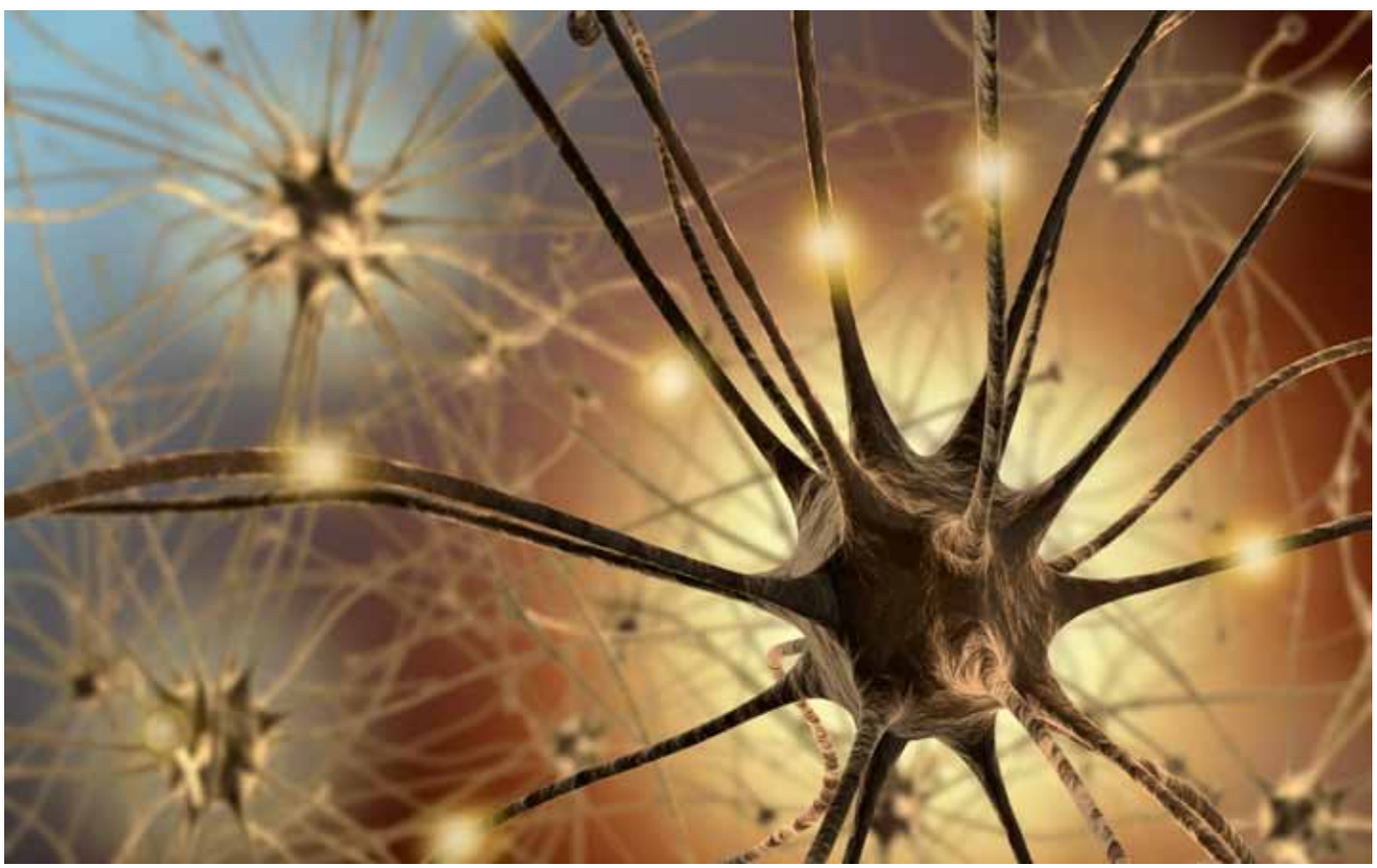
Health Technologies Assessment

In 2011, the EFPIA's Health Technologies Assessment (HTA) Working Group, in which FARMAINDUSTRIA takes part, gave the go-ahead to a strategy based on three basic principles:

1. The distribution of resources and the overall efficiency of healthcare systems. The HTA's application to all of the system's components and not just to medicines.

2. A greater commitment in the HTA's joint actions directed by the European Commission and the Member States.

3. Closer monitoring and the comparison of initiatives at the national level.



During the conference of the European network of HTAs (EUnetHTA for short), held in Poland, a position paper was presented titled "The value of the pharmaceutical industry's participation in HTA processes". The paper outlined the pharmaceutical industry's contribution to HTA processes, in terms of policy design and the definition of specific assessment methodologies.

Europe's pharmaceutical industry has expressed its interest in strengthening its cooperation with EUnetHTA, in an effort to create a new robust regulatory framework for HTA. Thus, the EFPIA and Farmaindustria advocated for a system based transparency and the participation of the full range of stakeholders in order to turn HTA into a tool that helps to improve resource allocation, guaranteeing the continuity of Innovation, making new treatments more accessible for patients, and increasing the overall efficiency of health systems.
The joint position paper is available at this link:
http://www.efpia.eu/content/default.asp?PageID=559&DocID=12353.

DURING HUNGARY'S PRESIDENCY OF THE EU IN THE FIRST HALF OF 2011, IT DEFINED A STRATEGY, BASED ON SUSTAINABLE HEALTHCARE SYSTEMS

EU Legislative Proposals

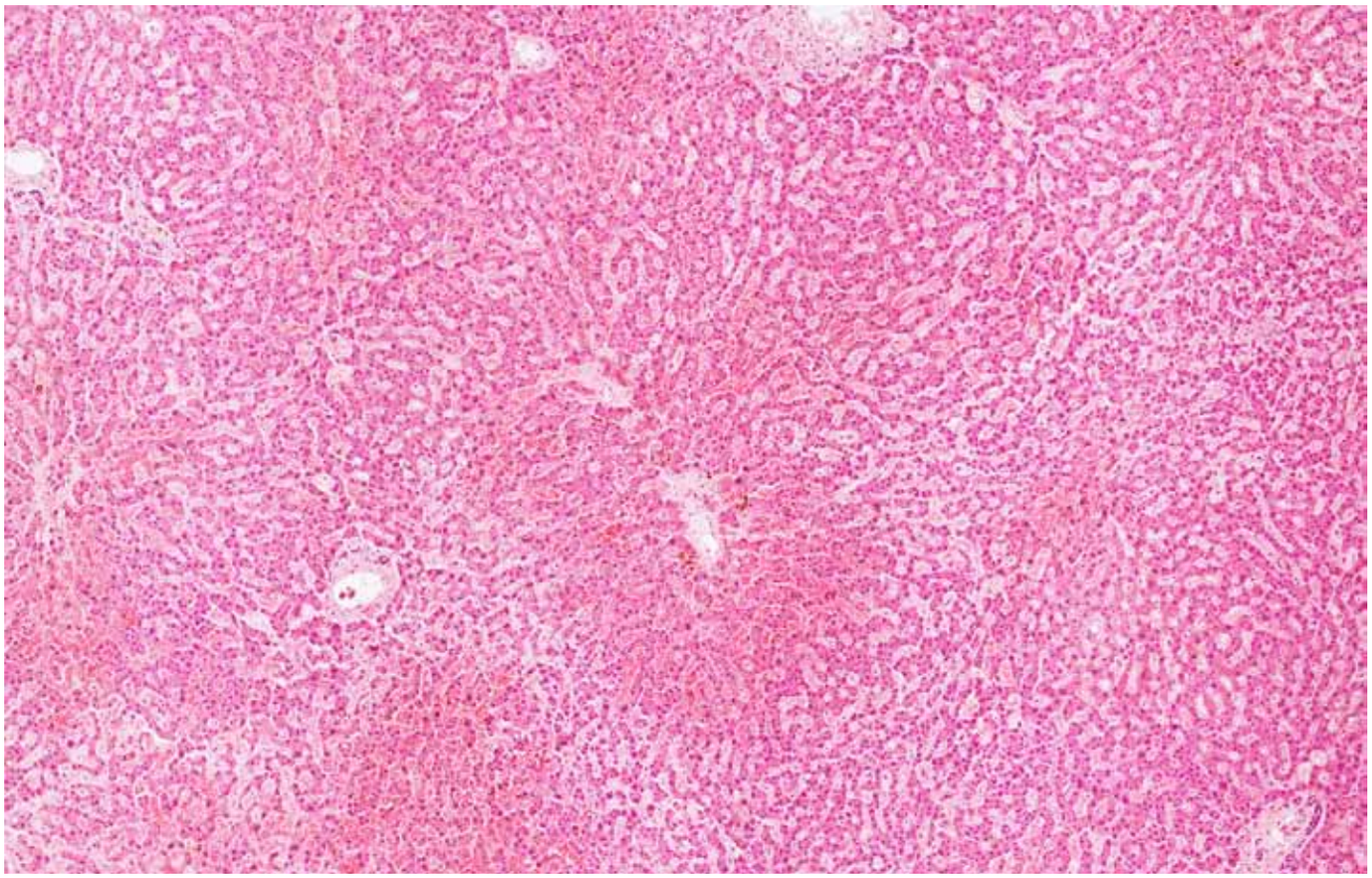
In the first half of 2011, the Hungarian presidency of the EU defined a strategy based on sustainable health systems, underscoring the challenges posed by the economic crisis, population ageing, a shortage of healthcare professionals and the need to use new technologies efficiently, particularly for modernizing health systems. Later, in the second half of 2011, the Polish presidency of the EU placed among its healthcare priorities non-contagious illnesses in relation to healthy ageing and the importance of innovation. Regarding pharmaceutical policy, the Presidency pledged to put forward a proposal to review the Transparency Directive and stepped up efforts to review the Directive on Clinical Trials.

1. The Pharmaceutical Package

Following the publication, at the end of 2008, of the three legislative proposals on Pharmacovigilance, Counterfeit Medicines and Information to Patients, the main new measures that appeared in 2011 were as follows:

- The Pharmacovigilance Directive. After its adoption in 2010, its implementation must be completed by July 2012. In this respect, last year the European Commission launched a public consultation to ensure that the measures to be adopted were "adequate for the objectives defined and balanced in relation to the overall objective of the rules governing medicines, namely to safeguard public health and the correct functioning of the internal market". In 2011 there was progress on a range of issues such as the choice of a standard for delivering online/electronic-based information on medicines, the identification of the technological requirements for its final implementation or the drafting of explanatory documents on major issues.

- In June 2011 the EU Transport, Telecommunications and Energy Council adopted the text of the European Parliament's and the Council's Directive 2011/62/UE on Counterfeit Medicines (it obtained a consensus on the first reading in the European Parliament) which establishes a Community-wide code on Medicines for Human Consumption, with regard to the prevention



of the introduction of fake medicines in the legal supply chain. Among other provisions, the Directive requires that Member States include a range of safety measures on the packaging of prescription medicines (and on non-prescription ones considered high-risk) designed to facilitate their individual identification and their verification, along with anti-tampering measures. Similarly, the active ingredients must comply with Correct Manufacturing Regulations, regardless of whether they are produced within the EU or in third countries. This fact must be checked by the medicine's manufacturers. The Directive also establishes an EU-wide vigilance system aimed at avoiding the circulation of fake medicines.

FARMAINDUSTRIA organized in Madrid several working sessions on the implications of this Directive for the pharmaceutical sector, concentrating on authorized medicine traders' obligation to introduce safety measures on medicine packaging as of 2017. At these working sessions, the EFPIA's Coding and Serialization Supervision Working Group explained to the companies that comprise the FARMAINDUSTRIA Board of the Pan-European model proposed by the EFPIA based on 2D datamatrix barcodes for adoption by the European Commission and Member States. In addition, FARMAINDUSTRIA hosted a working luncheon with representatives of EFPIA, FEDIFAR, AESEG and CGCOF, to exchange points of view on this model.

At the end of 2011, the European Commission published a Concept Paper laying out a number of technical alternatives for identification and verification of medicines within the EU and which, according to Directive 62/2011, would be selected using the procedure known as a "Delegated Act". The document, open to public consultation, provides a range of options on safety measures, means of verification, repository systems (databases), as well as formulas for creating positive and negative lists of medicines that will ultimately be required to include the abovementioned safety measures. The Commission also published an additional Concept Paper on the rules governing the relationships between European pharmaceutical companies and third-country producers of active ingredients. FARMAINDUSTRIA assisted in the wording of the final documents drawn up by the EFPIA.

▪ Regarding the Directive on Information to Patients, which recognizes the pharmaceutical industry's right to stand as a source of information on the products that it researches, produces and trades in, the European Parliament gave the go-ahead to a compromise text at the end of 2010 which led the European Commission to publish a new proposal incorporating a number of the Commission's own amendments and comments. However, and despite the efforts of the two EU Council presidencies in 2011, the lack of agreement between Member States, and the reservations concerning the viability of the measures included in the abovementioned proposal (they pose a possible threat to existing systems in some EU Member States) have left the Proposal on the brink of rejection by both the Council and the European Commission.

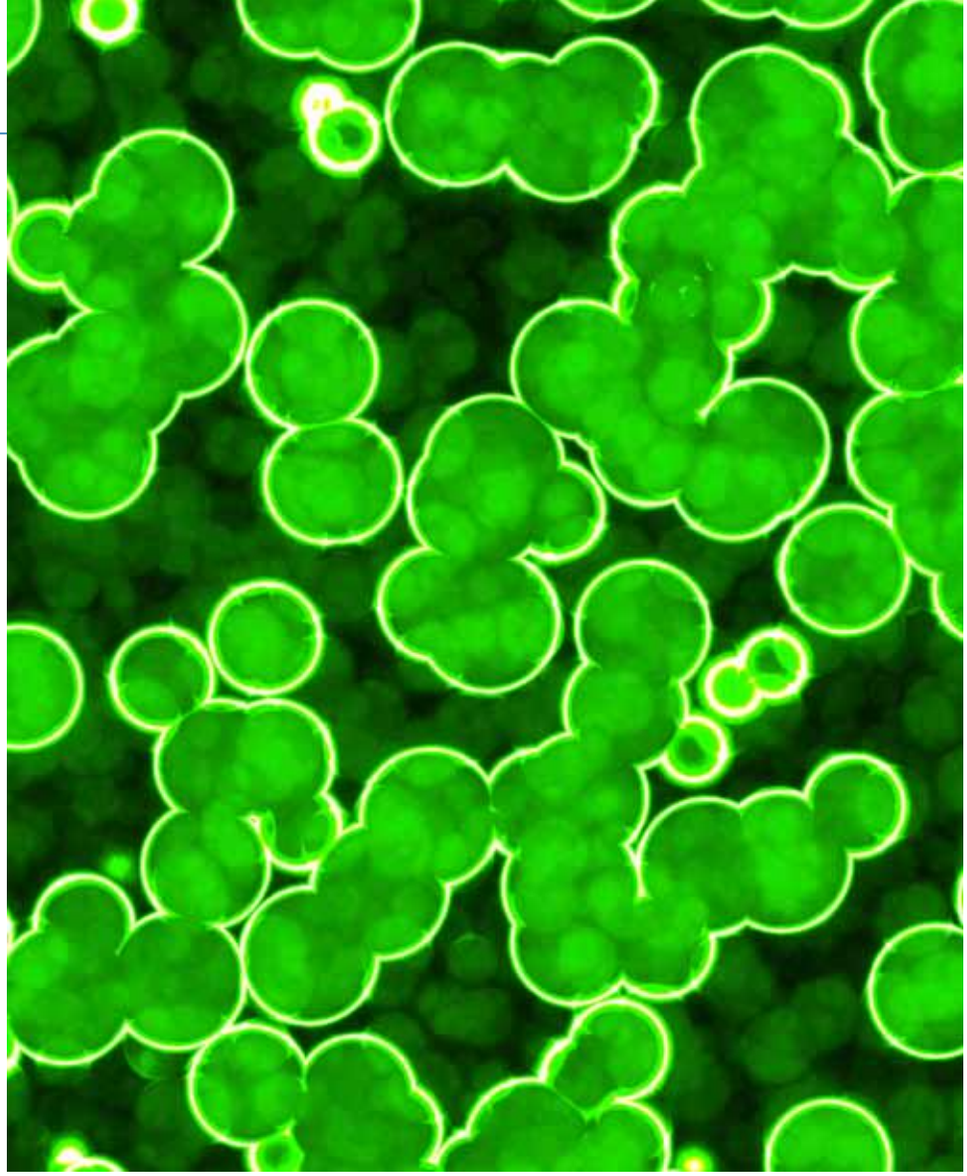
IN 2012 THE EUROPEAN COMMISSION MADE PUBLIC ITS PROPOSAL OF THE REVIEW OF DIRECTIVE 89/105/CEE ON TRANSPARENCY IN THE MEASURES THAT REGULATE THE PROCESSES OF PRICING AND REFUNDING OF MEDICINES IN THE EU

2. Review of the Transparency Directive

Following the period of public consultation, in early 2012 the European Commission published its proposal of the review of Directive 89/105/CEE, concerning the transparency of the measures regulating pricing processes within the EU with the ultimate aim of ensuring that "patients have faster access to medicines". The proposal sets out to cut down the time required in each country for making pricing decisions and reduce the refund period to 120 days in the case of innovative medicines and 30 days in the case of generics, compared with the current period of 180 days, and to impose penalties when these periods are not met. FARMAINDUSTRIA agreed with this proposal; however, it emphasized the need to continue to work towards improving European patients' access to pharmaceutical innovations and warned of the negative consequences of practices such as international price referencing. The proposal for the Directive will be debated in the European Parliament and the Council and, following the statutory co-decision process, final adoption is scheduled for late 2013. FARMAINDUSTRIA has begun intense institutional contacts with the Spanish government and EU representatives, and is getting directly involved at every stage of the legislative process.

3. Directive on Cross-Border Healthcare. Recognition of prescriptions within the EU

Following the adoption in March 2011 of Directive 2011/24/EU, concerning the application of patients' rights to cross-border healthcare assistance, the Commission launched a public consultation in order to meet several of the objectives laid down by the Directive. Specifically, in Article 11, the Directive states that Commission must adopt "measures enabling healthcare professionals to verify the authenticity of the prescription [...] by drawing up a non-exhaustive list of elements that must appear in the prescription and which must be



THE EFPIA SENT A DOCUMENT TO THE EUROPEAN COMMISSION DEFINING AN ACTION PLAN ON LAB EXPERIMENTS ON ANIMLAS, AND AIMED AT AVOIDING THE DUPLICATION OF PROVISIONS IN NATIONAL LAWS

clearly identifiable in every format", as well as "measures that facilitate the correct recognition of the medicines and healthcare products prescribed in one Member State and dispensed in another". In addition, the Directive envisages the adoption of systems that provide information to patients on prescriptions, the package leaflet and the instructions for use of the medicine (including information on the active ingredients and the correct dosage). The Commission has launched a public consultation to compile the contributions from the main sectors involved on the processes and systems that contribute to optimizing the recognition of cross-border prescriptions within the UE.

4. Lab experiments on animals

After Directive 2010/63 on the use of animals in clinical trials was passed in 2010, the EFPIA presented a position paper to the European Commission that sets out to define an action plan on this issue to 2013, the deadline for the transposition of the Directive by Member States. The EFPIA calls for the adoption of national laws that duplicate provisions already contained in the Directive, promotion of their transposition and implementation through training and communication programs, the exchange of good practices and the trimming of red tape, as well as the setting up of an EU-wide network of reference centers on animal-based research. In addition, the EFPIA recommends including specific expenditure items for this field In the EU Budget, as well as encouraging public-private partnerships aimed at

obtaining raising additional funds and/or resources that enable existing research facilities and instruments to be adapted to the parameters required by the new regulations.

5. Review of the Clinical Trials Directive

In 2011, the European Commission launched a public consultation on a Concept Paper on the review of the Clinical Trials Directive, scheduled for 2012. The Paper analyzes the response to the first public consultation carried out by the Commission on this subject in 2009/2010. The key points analyzed are as follows:

- cooperation in the assessment and follow-up of applications for clinical trials;
- optimized adaptation to the practical requirements and a more harmonized approach to the procedural aspects of clinical trials:
- compliance to good practices in trials carried out in third countries, and
- the figures and data used in trials.

The Commission continued the review work during 2012 taking into account the EFPIA's positioning with, among other aspects, the need to ensure that the EU is capable of attracting investment in pharmaceutical R&D over the coming decades.

6. The Community Patent

In December 2011 (during the Polish presidency of the EU) the European Parliament and Council reached an agreement on the raft of measures regarding this matter. Under the terms of the agreement, in 2012 Member States will continue to negotiate the development of a range of measures aimed at establishing a Community Patent (by means of regulations), and at setting up, through an international agreement, an EU-wide Single European Patent Court and a linguistic regime for the system. This way, the EU intends to bring down patent costs by 80% and to reduce the legal confusion produced by the multiple languages currently in use. The proposals approved include the possibility of third countries applying for an EU patent, as well as special provisions for SMEs (e.g. lower application and renewal fees). Regarding the linguistic regime, the officially recognized working languages are English, French and Germany, although applications are allowed in all other official EU languages, with compensation for companies that incur translation costs. This regime has been appealed by Spain and Italy and the negotiations on the final location of the seat of the Single European Patent Court are currently at a standstill.

7. Public consultation on e-healthcare

The Directorate-General of the European Commission has commissioned the so-called "Digital Agenda" ~~it~~ has launched a public consultation on e-healthcare ~~in~~ an effort to optimize the benefits that can be obtained from applying ICTs to healthcare provision. The Commission invites all interested parties, including healthcare and industry professionals, and patients, to voice their opinion on the fundamental benefits of e-healthcare, the stumbling blocks to its large-scale implementation and the measures that the European Commission should take to overcome those obstacles.

8. The European Commission Communication on Competition and Industrial policy

In April 2012, the European Commission presented a Communication titled "Industrial

IN 2011, THE EBE WORKED ALONGSIDE THE COMMISSION AND THE EUROPEAN INVESTMENT BANK ON AN ACTION PLAN AIMED AT IMPROVING THE FINANCING OF SMALL- AND MEDIUM-SIZED BIOPHARMACEUTICAL ENTERPRISES

Policy: Strengthening Competitiveness" which is the final part of a comparative report on competition in the EU and highlights the sizeable differences between Member States when it comes to competitiveness. It also calls on and encourages Member States to apply as soon as possible policies that "contribute to attaining levels of competitiveness coherent with participation in the Euro and in the internal market". Thus, the Directorate-General of Industry defines six fundamental areas of action:

1. to shift towards more innovative, knowledge-based sectors;
2. foster industrial innovation:
3. promote sustainability and efficient use of resources;
4. enhance the business environment (reduce administrative charges);
5. make the most of the advantages offered by the single market, and
6. support SMEs (financing, Internationalization, and access to markets).

All of these documents are available at the following link:
http://ec.europa.eu/enterprise/policies/industrial-competitiveness/industrial-policy/index_en.htm

Biotechnology

In 2011, the European Biopharmaceutical Enterprises group (EBE) worked closely with the Commission and the European Investment Bank on an Action Plan (presented officially in 2011) to improve the financing of biopharmaceutical SMEs. At the same time, the EBE worked shoulder-to-shoulder with the European Medicines Agency on a variety of fields, including tailored medicine, the simplification of regulations on orphan medicinal products, or the substitution by biosimilar medicines (on which the European biopharmaceutical sector has published a Position Paper). Similarly, the EBE continued to collaborate with the Innovative Medicines Initiative (IMI), encouraging its member companies to participate actively in this initiative.

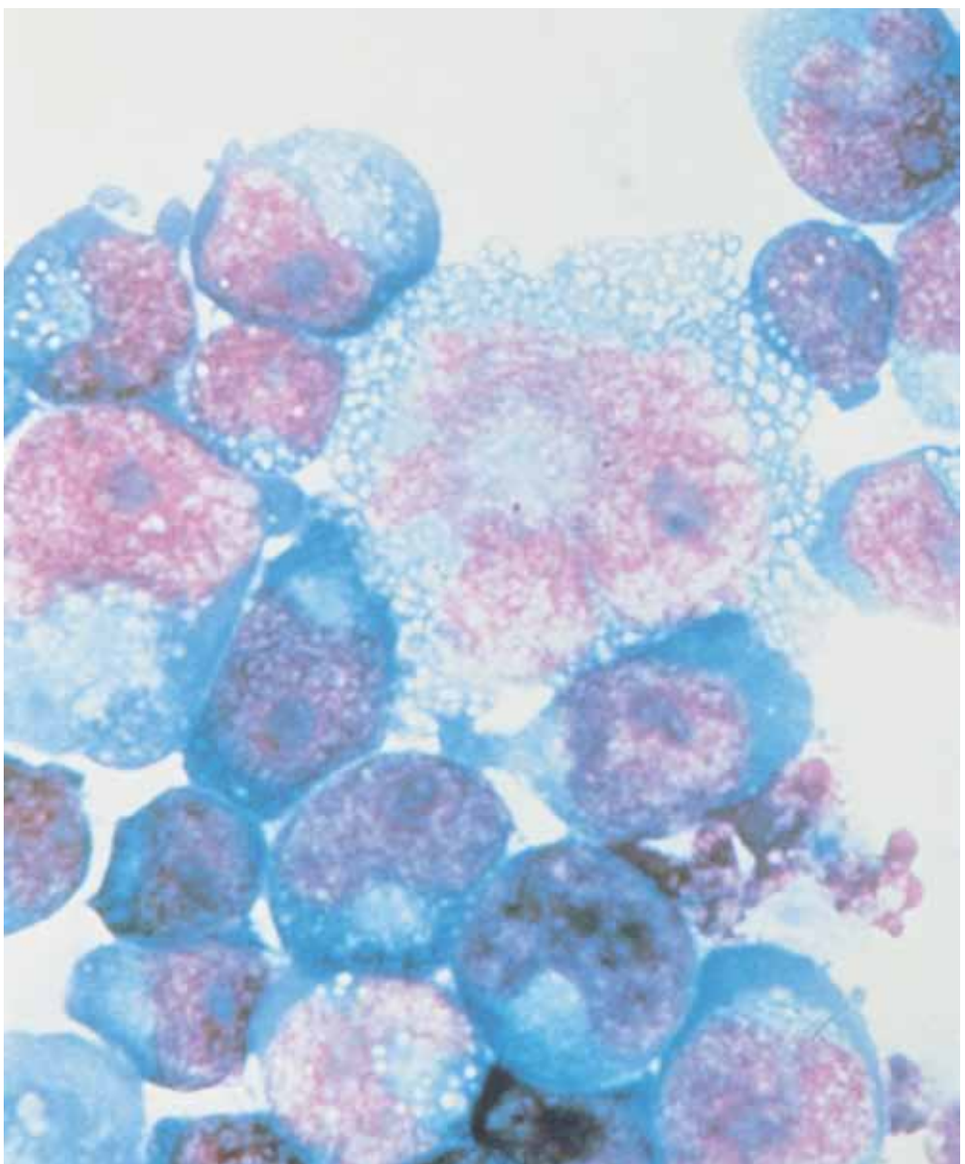
Foreign Trade. Actions in third countries

The EFPIA's work on the international scene is carried out by its Foreign Trade Committee in which FARMAINDUSTRIA participates actively. The Committee promotes the interests of Spain's pharmaceutical sector in its relations with emerging countries.

The Canada-European Comprehensive Economic and Trade Agreement (CETA). This international agreement, scheduled for adoption in 2012, went through a critical phase in 2011 owing to a lack of equalization in terms of the Industrial Property rights of pharmaceutical companies. FARMAINDUSTRIA has carried out an intense activity, both at national and EU levels, holding contacts with senior management at the Directorate-General of Commerce and Investment, and the EU's General Secretariat of Trade Policy, conveying the pharmaceutical sector's position on the following issues, among others:

- The standardized protection of the Supplementary Protection Certificate:
- The standardization of periods and scope of the rights of data protection, bringing them into line with EU standards, and
- The effective incorporation of the right of appeal in cases of patent law violations by local companies.

The India-European Free Trade Agreement. In successive rounds of negotiations in 2011, the EFPIA voiced its concerns to EU Trade Commissioner Karel de Gutch over the fact that the innovative pharmaceutical industry's priorities were not on the agenda during the final stages of the EU-India trade negotiations. In particular, the Federation reminded the Commissioner that the provisions included in this Free Trade Agreement ought to benefit both economies and adapt themselves to India's rapid economic growth rate. Even so, despite acknowledging the Indian authorities' capacity to meet the healthcare challenges facing its country, there were a number of key Issues for the European pharmaceutical industry such as the period of protection of data or the elimination of major regulatory barriers which were not addressed at any point in the negotiations. Subsequently, the EFPIA, aligned with Business Europe, has called on the Commission to assess the potential economic impacts of the coming into effect of this Agreement which, in the opinion of a number of industrial sectors, is considerably unbalanced, and as a first step towards resuming negotiations with the Indian authorities.



Other areas. Preferential Trade Agreements were upheld in 2011 and 2012 in a number of strategic areas and trade associations such as Mercosur, Japan, Malaysia and Singapore.

It should be mentioned that FARMAINDUSTRIA engaged in a process of coordination of its member companies with the aim of drawing up a Sector File on the pharmaceutical industry, as requested by the Sub-directorate General of Foreign Trade and which was later included in the corresponding EU-level File. The Sector File details the main trade barriers encountered by European pharmaceutical companies in the course of their thrust for internationalization. The Sector File will be used by European Commission as the basis for the design of the EU's Foreign Trade policy.

3.4.2. THE INTERNATIONAL STAGE

FARMAINDUSTRIA's international activities come mainly in the shape of the Association's active participation in the various committees of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). The Federation has defined the following basic priorities:

- The adoption of the global strategy and action plan on the fight on counterfeit medicines;
- strategies on biosimilar products, and
- the recent review of the IFPMA's Code of Good Practices in Medicine Promotions (mentioned in other sections of this Annual Report).

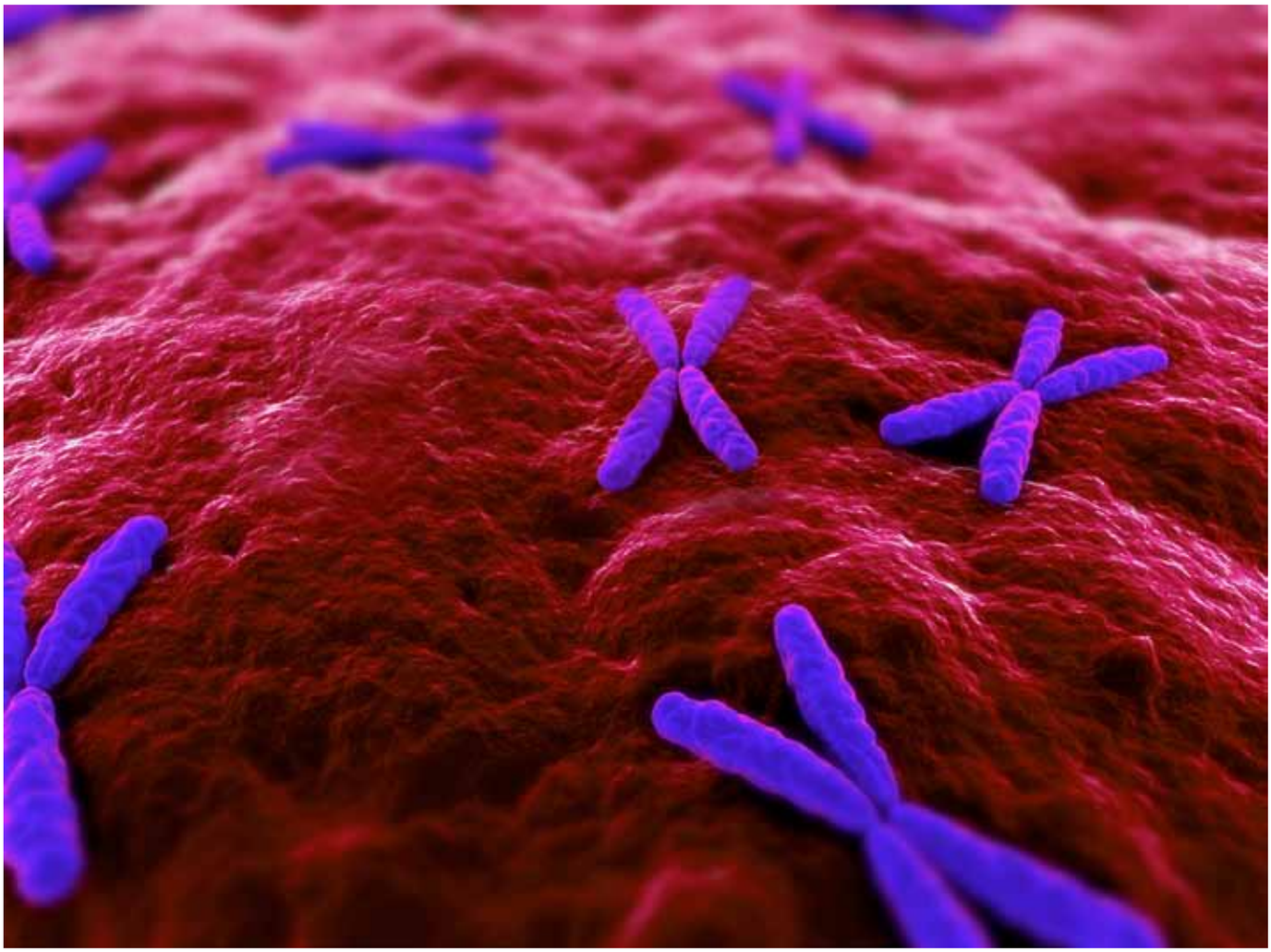
Additional priorities for 2012 include non-communicable illnesses, steping up the fight on counterfeit medicines, the standardization of industrial property regulations, R&D partnerships with emerging countries and the continued review of the Code of Good Practices.

FOLLOWING THE INTRODUCTION OF THE FIRST W.H.O. MANUALS ON THE APPPROVAL AND DEVELOPMENT OF BIOSIMILAR PRODUCTOS, SEVERAL COMPANIES HAVE TAKEN STEPS TOWARDS PROMOTING SPECIFIC LAWS

Illnesses affecting the Third World. CEWG, a new "advisory" group of experts

The greatest progress made on the Global Strategy and Action Plan on Research on illnesses affecting the Third World was the setting-up in 2010 of a new "advisory" team of experts, known as the Consultative Expert Working Group (CEWG), which analyzed sustainable alternatives capable of financing R&D on this type of illness, with particular attention to "the disconnection of industrial property rights in R&D in Third World countries". This group convened in April 2011 and was joined by the IFPMA which emphasized the pharmaceutical sector's role in the research on illnesses and the development of skills. The IFPMA worked with the World Health Organization (WHO) and the CEWG in particular through intense institutional activity and communication to ensure the participation of the innovative industry in this process.

In this context, the IFPMA published a Report titled "Technology Transfer: a Collaborative Approach to Improve Global Health" which looked at 50 success cases, from which the Report drew a number of conclusions based on the pharmaceutical industry's more than 20-year track record in this field.



The document is available at the following link:
http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Technology_Transfer_Booklet_2011.pdf

Biosimilar products

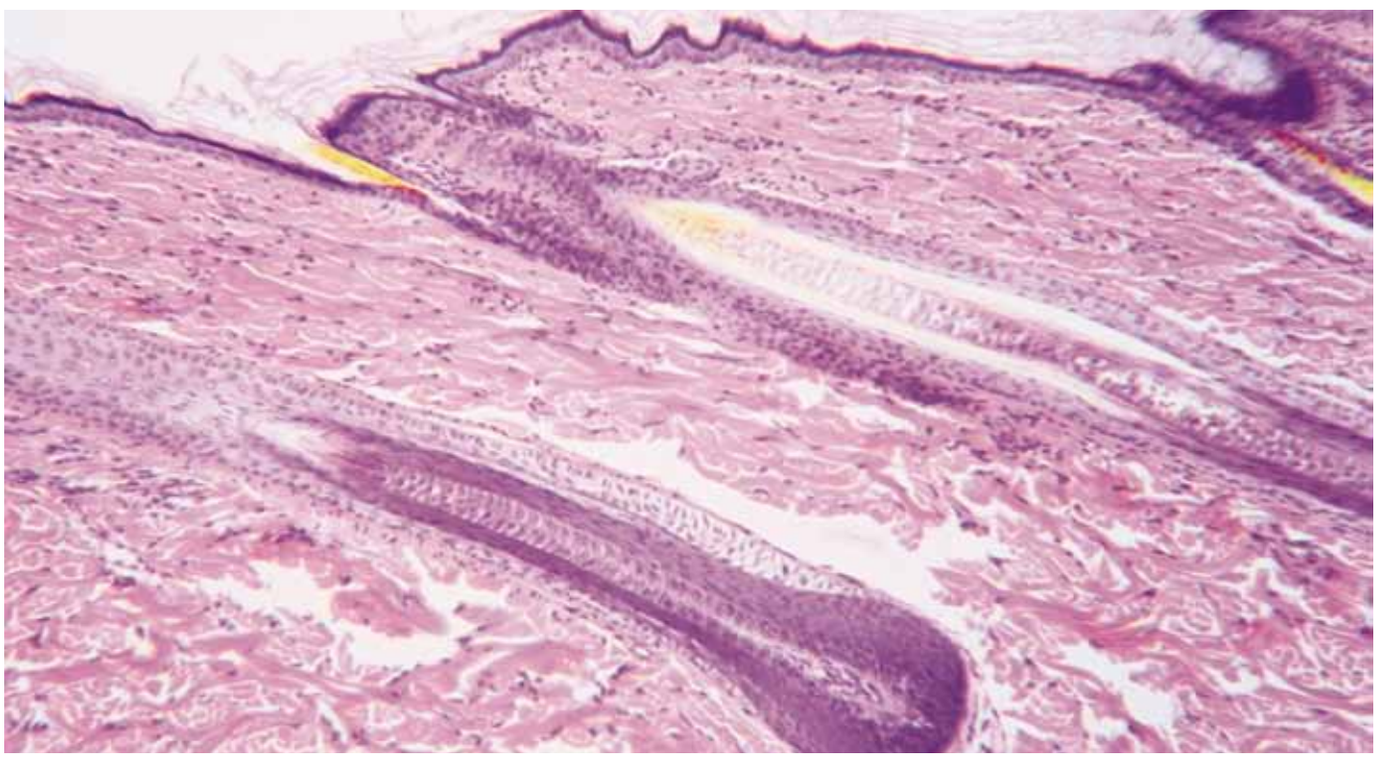
From the introduction in 2006 of the first WHO manuals on the approval and development of biosimilar products, several countries worldwide have promoted a specific legislation on the licensing and authorization of these products. However, the parameters laid down by the WHO manuals have not always been followed very closely which has left public health at serious risk as well as distorting the playing field. Subsequently, the IFPMA's governance bodies have agreed to set up a Working Group on Biotherapeutics charged with implementing a plan that includes political and communication campaigns aimed at promoting access to an effective and top-quality biotherapeutic medicines market, thus protecting patients' health by bringing national regulatory standards into line with those set down by the WHO. The strategy has a three-fold aim, namely:

1. To create opportunities for engagement and the exchange of good practices through training workshops;
2. to draw up Position Papers and analyze real cases with the aim of informing external stakeholders on the value of biotherapeutic medicines, the need to uphold strict quality standards in order to ensure patient's' safety, and the importance of innovation capable of giving rise to R&D on new medicines; and
3. the design and publication of background material.

The worldwide fight on counterfeit medicines

The contribution to the worldwide fight on counterfeit medicines was centered on new Member States' Working Group on Sub-standard, Fake, Non-legitimate, Imitation or Deceptively-Labeled Medicine Products The Group's inaugural meeting was held in March 2011; however, no concrete results emerged because the Group failed to come to an agreement on the border-line between the counterfeiting of medicines and intellectual property violations.

However, the Executive Committee of the WHO called for the setting-up of a new international mechanism aimed at fighting counterfeit medicines worldwide under the leadership of a number of Member States and with the WHO acting, finally, as an advisory body. The future ratification of this mechanism by the WHO General Assembly will mean, de facto, the dismantling of the former IMPACT multi-sector platform, whose work and independence were questioned in the past by a number of Member States.



The IFPMA continued to implement its strategy on counterfeit medicines by publishing a document titled "Ten Principles on Counterfeit Medicines" and several items of external communication literature, and by organizing a range of awareness-raising events in close collaboration with institutions such as Spain's Institute for Pharmaceutical Safety.

In 2012, the IFPMA upheld its strategy on Counterfeit Medicines with a number of actions aimed at creating a broad international accord on the war on fake medicines under the auspices of the United Nations or another of the international agencies involved. At the regional level, the Federation will be encouraging the compilation and analysis of official data on counterfeit medicines and there are plans to organize several awareness-raising campaigns adapted to local peculiarities.

Non-Communicable Diseases (NCDs)

The WHO's Strategic Plan lists NCDs among its major priorities, and they are monitored by a new IFPMA committee which, in 2011, presented its strategy aimed at stemming the increase of NCDs in the Third World and in emerging nations. This strategy reveals that despite the immediate and abundant availability of highly effective medicines (including generics) patients in emerging nations find it very hard to access them. The Study highlights four priority areas:

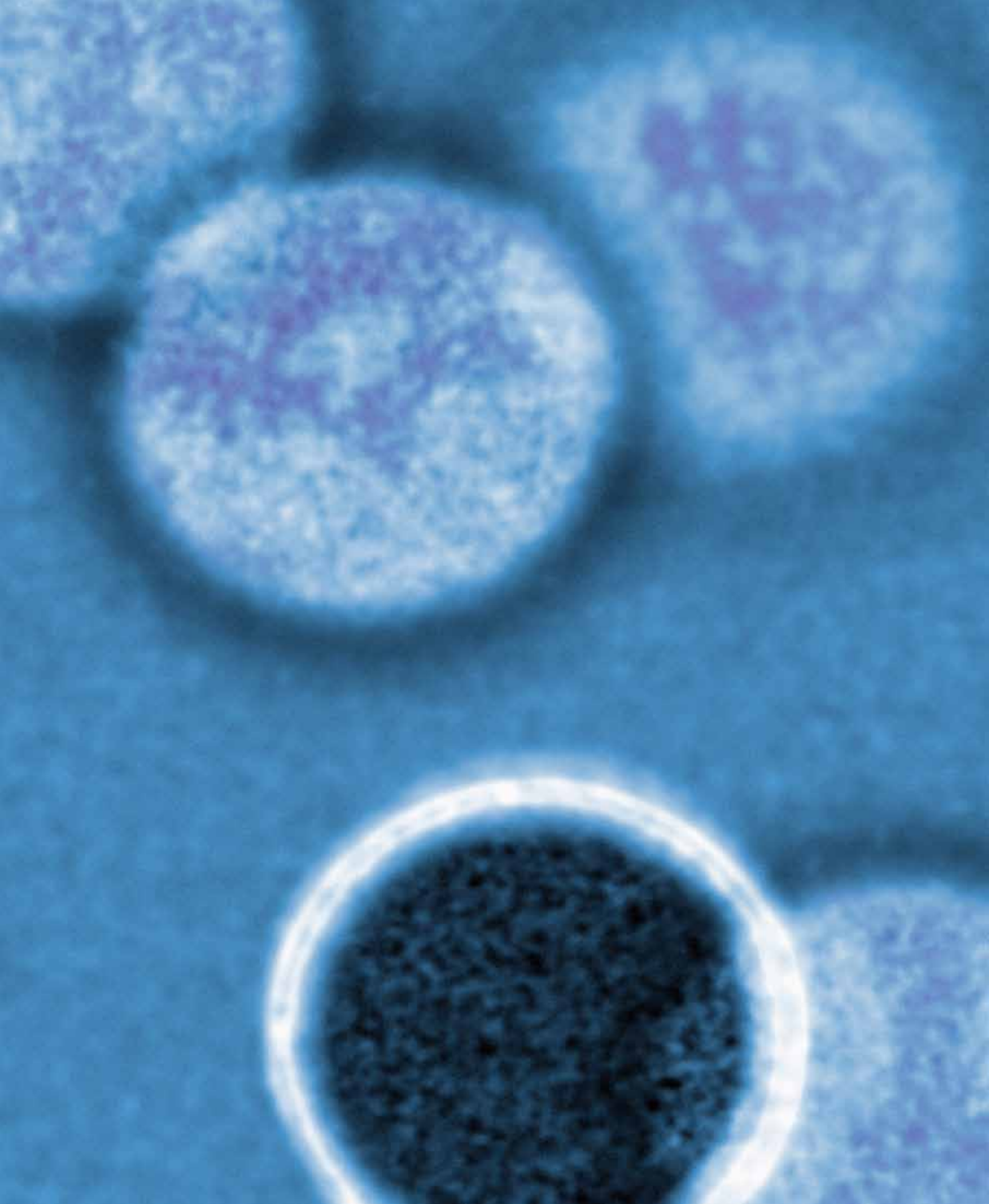
- coming up with innovative methods aimed at helping patients to stick to the treatment;
- overcoming barriers that hamper the availability of medicines in remote and underprivileged areas, e.g. surcharges and taxes, or the sale of counterfeit medicines;
- improving access to primary attention, and
- eliminating regulatory restrictions that obstruct the availability of this kind of medicines.

Antimicrobial Resistance

The theme of World Health Day 2011 was the resistance to treatment with antibiotics on a global scale. The IFPMA presented a Position Paper on this issue which placed the weight of responsibility on prescriptions and the correct use of antibiotics, while calling for measures aimed at stimulating R&D on new and more efficient antibiotics (e.g. tax breaks, greater protection of IP rights or even market commitments in advance and awards for meeting targets).

Bilateral Meetings

Two meetings were held in 2011 between the National Associations of the five main European markets (Germany, France, Italy, Spain and the United Kingdom), one in Rome and the other In Basel. On both occasions, the representatives of each Association took the opportunity to exchange up-to-date information on recent national government spending cuts, as well as best practices in strategic engagement with governments, favoring—against the backdrop of a global economic downturn—a stable and predictable environment for the innovative pharmaceutical industry. Similarly, working sessions were organized to identify and implement best practices in the internal and external workings of the National Associations, optimizing the impact of their strategies and actions in the face of an environment of economic austerity.



04. SIGRE MEDICINAL PRODUCTS AND THE ENVIRONMENT

Sigre Medicamento y Medio Ambiente [SIGRE Medicinal Products and the Environment] is an environmental initiative designed by FARMAINDUSTRIA aimed at helping people get rid of unwanted medicines (or those that have past their sell-by date) and medicine packaging in a safe and convenient way, without harming the environment.

2011 was the 10th anniversary of the SIGRE System, and this special date came as the ideal opportunity to weigh up the results and review the major efforts carried out over this time by the pharmaceutical industry, distribution companies and pharmacies.

The anniversary was marked by a number of events culminating in a special one-day event held at the end of 2011 at the seat of Spain's Ministry of the Environment and Rural and Marine Affairs. It was chaired jointly by the Secretary of State for Climate Change, the Secretary-General of Health and the chairman of SIGRE, and brought together relevant professionals from the fields of healthcare and the environment.

During the same event, a panel of judges, headed by the lawyer Antonio Garrigues, presented the "SIGRE Awards" which acknowledge activities aimed at raising awareness of the correct use of medicines and environmental initiatives carried out by the pharmaceutical industry, distribution companies and Institutions in the pharmaceutical Industry, as well as recognizing media interest in the recycling of medicines.

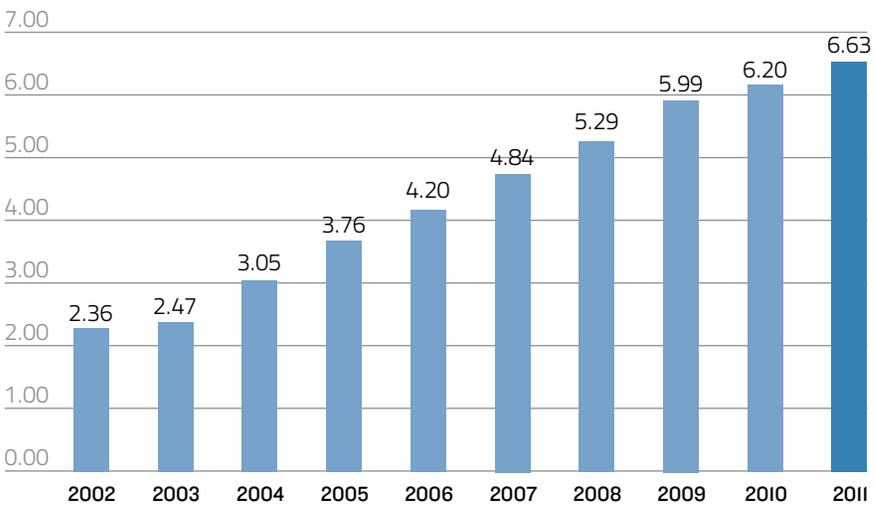
2011 MARKED THE TENTH ANNIVERSARY OF "SIGRE", A WASTE MANAGEMENT SYSTEM WITH MORE THAN 20,900 COLLECTION POINTS FOR MEDICNE PACKAGING AND UNWANTED/LEFTOVER MEDICINES

Environment Declaration 2011

Each year, SIGRE presents its Environmental Declaration to Spain's central and regional Departments of the Environment. It contains information on the total number and weight of medicines on the market, the amount of packaging elements and leftover/unwanted medicines registered at the more than 29,000 SIGRE collection points, and explains the environment-friendly treatment applied in each case.

According to the latest Declaration, 2011 saw a slight increase (+1.3%) In the number of units traded by pharmaceutical companies and greater collaboration on the part of consumers (up more than 7%) which confirms that this environment and healthcare initiative has been very well received by people up and down Spain.

KG/1,000 ROOM-MONTH 2002-2011 IN SPAIN



In addition, in 2011 the pharmaceutical Industry stepped up its efforts to reduce the environmental Impact of its packaging, as can be seen in the conclusions of the "3rd Report on the Follow-Up of the Company Prevention Plan 2009-2011".

During this 3-year period, the overall Kr/Kp Indicator (packaging weight / product weight), established in the packaging regulations to gauge the success of the prevention measures applied by packaging companies, could not have been better, with an overall total reduction of -9.1%. Thanks to this figure, the Plan has overshot the targets laid down by the environment authorities.

SIGRE revamps its membership contract

The former SIGRE membership contract, through which pharmaceutical companies take part in this environment initiative, expired on 30 June 2011. This was seen to be a good moment to adapt some of the contract's clauses to legal changes that had taken place over recent years, and to make a number of improvements to this Integrated Ma-

nagement System. Even so, the new version of the SIGRE contract has maintained the essence of the structure and content of the former one.

As of 1 July 2011, the new membership contract will regulate member companies' participation In Sigre until 30 June 2016 and will enable them to comply with Law 11/1997, on Packaging and Royal Decree 1345/2007, which regulates the procedures affecting the authorization, registering and dispensing conditions of industrially-produced Medicines for Human Consumption.

Biotran, the new waste management contractor

When the contract between SIGRE and its former waste-management contractor was close to expiring, SIGRE called a tender for the collection, sorting and environmental treatment of medicine packaging and leftover/unwanted medicines left by consumers at the various SIGRE Collection Points.

Ten different projects from highly reputable waste management companies answered the tender.

Advised by IDOM, an engineering company, which studied and analyzed the different projects, SIGRE's board of directors chose Biotran as the best offer, and was particularly impressed by the level of innovation that the company had proposed for the new waste sorting plant.

Other factors also weighed in favor of Biotran, such as the forecast of greater amounts of recycled waste and the application of new technologies that would lead to greater levels of control, traceability and safety in the management of this type of waste.

Biotran started to manage waste for SIGRE on 1 January 2012 and will continue to do so for the next five years.

Spain's AEMPS provides information on SIGRE on its package inserts

In 2011, the Spanish Agency for Medicines and Health Products (Spanish abbreviation AEMPS) sent out a circular announcing the mandatory text for package inserts to guide consumers on the correct use of leftover/unwanted medicines.

"Medicines must not be flushed away or thrown out with household waste. Take leftover/unwanted medicine and its packaging to your local pharmacy's SIGRE Collection Point. Please direct all your queries on how to get rid of leftover/unwanted medicines and their packaging to your pharmacist. This way, you'll be helping to protect the environment".

The AEMPS considers that these instructions on the package insert are necessary to dispose of medicine waste correctly from households and to protect the environment.

ENVIRONMENT-FRIENDLY MEDICINAL WASTE DISPOSAL CAN ONLY BE GUARANTEED THROUGH THE COOPERATION OF THE MAN AND WOMAN ON THE STREET

Communication campaigns

Communications is a fundamental lynchpin for SIGRE to encourage the correct management of medicine waste. Campaigns aimed at heightening public awareness and obtaining people's help are the only way to ensure that medicine waste is handled correctly and in an environment-friendly way. Accordingly, in 2011, SIGRE continued to carry out public awareness campaigns in an effort to make people aware of the need to use medicines correctly, not only from a healthcare point of view, but also from an environmental perspective. As a result, SIGRE continued its public awareness campaign, "Recycling medicines is a very healthy habit", first rolled-out in 2010.

Along similar lines, the "Prescription for Health + Prescription for the Environment" campaign, an information campaign on how SIGRE works and what its goals are, aimed at doctors and medical staff, was extended to Spain's Murcia region.

Sigre has also adopted and made the most of so-called "communication 2.0" practices by increasing the amount and type of information channels at its disposal and by improving its position in a range of internet search engines.

Finally, to mark its 10th anniversary, SIGRE has brought out a range of materials aimed at making known its major milestones over this period.

11th Pharmaceutical Company Seminars

On 8 June 2011 Sigre's 11th Annual Information Seminar gathered a large pharmaceutical-company audience in Barcelona. The event sets out to inform on a range of current SIGRE issues and to highlight salient aspects of medicine waste management and other interesting topics.

As well as the usual technical explanations of SIGRE activities and results, the Seminars presented the final conclusions of the study on the UE's different models for medicine waste management and analyzed the opportunities offered by cement factories to use different types of waste, including medicines waste, as a source of energy.

SIGRE and medicine recycling in Europe

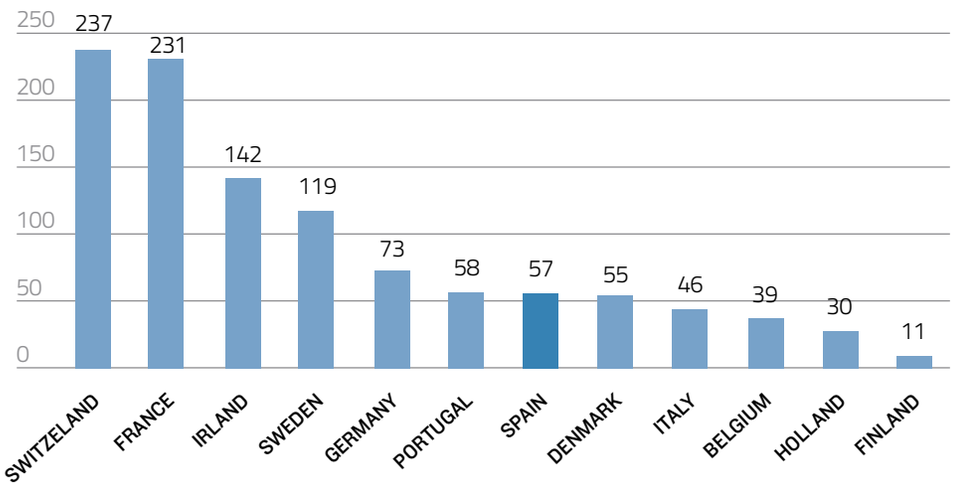
In conjunction with the firm of consultants Ernst & Young, SIGRE has compiled a study that analyzes the different existing models of medicines and packaging waste in 18 European member states. The study underscores the sheer diversity of these systems; these, however, share some important common denominators, namely that collection points are located at pharmacies and, in most cases, public awareness campaigns are carried out.

However, there are also many differences as regards the agents involved in the logistics process of collection and management, and in terms of models of ownership and financing.

Compared with the rest of the systems looked at by the study, SIGRE stands out for the active participation of pharmaceutical industry players, its inverse logistics model and the use of a sorting plant for waste produced by packaging, all of which leads to higher percentages of recycling and the possibility of sorting waste by treatment types In order to ensure their correct elimination.

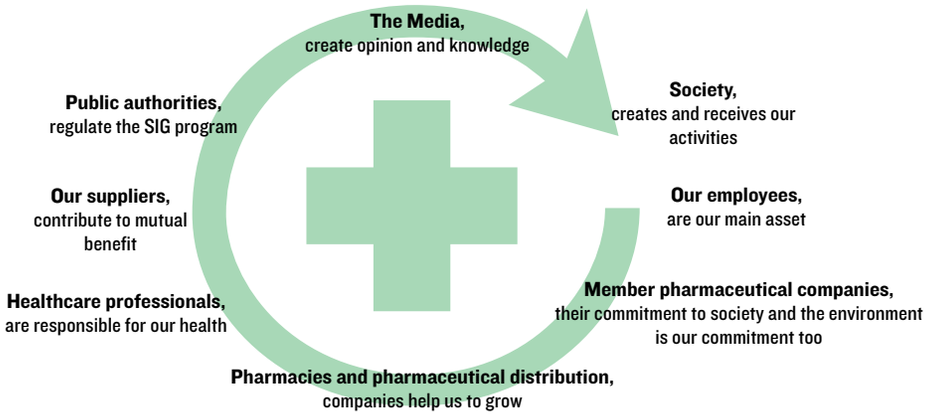
According to European Environment Agency data, Spain is halfway up the table of European countries in terms of the volume of medicines/packaging waste generated in the home.

LEFTOVER MEDICAL PRODUCTS AND PACKAGING COLLECTED PER CAPITA IN 2007 (Grammes/year)



Corporate Social Responsibility

The fact that Spain's pharmaceutical industry undertakes Corporate Social Responsibility (CSR) initiatives is proof of its commitment to bring value to society.



That's why, as a collective pharmaceutical industry initiative, from the day it was first set up SIGRE has always upheld a commitment to make every effort to meet the expectations of its many and varied stakeholders. True to this pledge, in 2011 SIGRE carried out a long list of CSR actions, including the following.

SIGRE HAS TAKEN ON A COMMITMENT TO DETECT AND ATTEMPT TO MEET THE EXPECTATIONS OF THE RANGE OF STAKEHOLDERS THAT HAVE AN INTEREST IN THIS ENVIRONMENTAL AND HEALTHCARE INITIATIVE

- Drew up the First Report of the Follow-Up of SIGRE's Strategic Plan for Corporate Social Responsibility 2010-2012.

- Gave the green light to SIGRE's Human Resources Policy.

- Published its second Social Responsibility Report (2010), rated "A Checked" according to Global Reporting Initiative principals, the leading international standard in sustainability reports.

- Drew up its second Progress Report for the UN Global Compact, rated "Advanced", by the UN (the highest score for the implementation of the principles and the transparency of the progress reports prepared by Global Compact member companies. So far there are only 183 organizations in the world that have achieved this distinction.

- Held on to its four-fold AENOR certification for its Quality, Environment, Energy and Workplace Risk Prevention systems.

- Upheld its support for the organization of "Emissions offset events" in the shape of a range of pharmaceutical industry events.

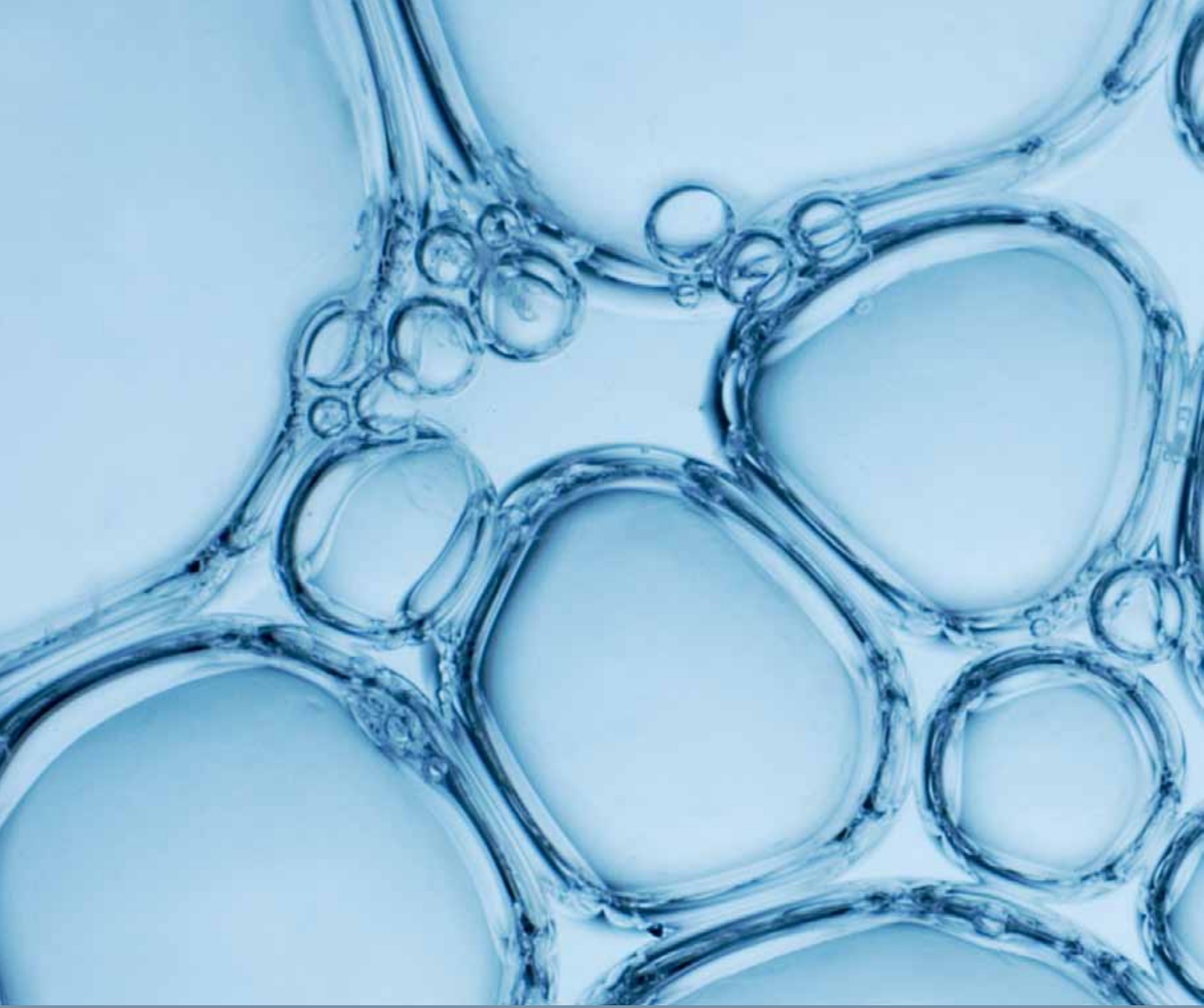
Similarly, FARMAINDUSTRIA, as a member of Spain's Association for Advertising Self-regulation (AUTOCONTROL for short) a member of the European Advertising Standards Alliance, received the Annual Corporate Social Responsibility Certificate with which SIGRE takes on a moral commitment to exercise responsibility in its freedom to use commercial communication, helping to enhance advertising self-regulation. FARMAINDUSTRIA continues to sit on the Board of Directors of AUTOCONTROL.

Forums and Congresses

SIGRE continued to take part in a variety of forums and congresses to make known the pharmaceutical industry's efforts to protect the environment. In particular, in 2011, Sigre, along with Spain's leading integrated systems, took part in the "Foro ABC Natural" forum, with a lecture titled "Recycling: a social demand".

Also, the Packnet Steering Committee (Packnet is short for the Spanish Technological Platform for Packaging and Wrapping), appointed SIGRE's Director-General as the Platform's First Vice-Chairman. This comes as acknowledgement of the pharmaceutical industry's pioneering role in environment-friendly packaging and wrapping design.

SIGRE also took part in other environment and healthcare forums, including Spain's Club del Medio Ambiente (Environment Club); the efficient packaging waste management summit organized by the Institute of Sustainability in Resources; "Recapacicla", a seminar organized by the Andalusia regional government; a number of debates and conferences hosted by universities, and many other similar events.



02.

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1. THE PHARMACEUTICAL INDUSTRY IN EUROPE

In recent years, the EU's economic activity has been seriously affected by the downturn that started in the USA in the second half of 2007 and which, because of the global nature of markets, spread across the planet and caused the EU's activity to fall flat in 2008, followed by severe recession in 2009. In 2010 there were signs of a possible recovery when the EU registered +2.0% growth (1.9% in the Eurozone), but the economy lost its footing once again in 2011 and promised to get worse in 2012.

A look at quarter-on-quarter growth rates shows the gradual slowing of economic growth in Europe in 2011, which worsened in the second half and led to negative growth in the last half of the year. This trend also appeared, to a greater or lesser extent, all over Europe, although some countries, like Italy, Belgium, Holland and Portugal, entered into technical recession by chalking up two successive quarters of negative growth, while other countries, such as Spain and the UK followed suit in the 1Q2012.

This sluggishness has led to a rise in unemployment in the EU-27 countries, where the unemployment rate went from 9.5% in 2010 to 9.9% in 2011.

In turn, the downturn and increased joblessness led to a fall in tax income and higher public expenditure in the shape of state subsidies, jeopardizing the deficit targets for EU member states. This served to erode market confidence and things were made worse by the fear that the ensuing spending would have a negative impact on economic growth and lead to higher financing costs for the sovereign debt of member states. The effects of this vicious circle are particularly evident in the EU's so-called peripheral countries, namely Spain, Greece, Portugal and Italy.

The outlook for the EU in 2012 is bleak. In fact, the European Commission's February 2012 Interim Report forecast for GDP growth in the Eurozone in 2012 is -0.3%.

This situation, plus the fact that EU policies focus mainly on public spending cuts, is hitting pharmaceutical markets hard because they rely strongly on public spending and are particularly sensitive to regulatory change.

In addition, in recent years patents are running out on certain major active ingredients which are difficult to replace in companies' product portfolios.

These difficulties are mirrored by pharmaceutical sales in Europe. The World Pharmaceutical Market Summary (compiled by the firm of consultants IMS Health), shows that in EU pharmaceutical markets sales dipped by 1%, compared with 3% growth in the USA, +18% in LatAm, +6% in Australia and Japan, +13% in China and +15% in India.

Per country, growth ranged from +2% in Germany to -6% in Spain; for the second year running, out of the EU's top five, Spain's pharmaceutical market performed worst.

SALES IN THE EU'S MAIN PHARMACEUTICAL MARKETS

	Δ 2011/2010 (%)	% of total sales in the five countries 2011
Germany	2%	34.4
France	0%	26.1
UK	1%	12.7
Italy	-2%	14.3
Spain	-6%	12.5
Total 5 countries	-0.6%	100.0

Source: FARMAINDUSTRIA, IMS World Pharmaceutical Market Summary.

Finally, on a more aggregated level, it should be said that despite this long list of problems, Spain's pharmaceutical industry continues to enjoy a good standing in the EU and the world. The table below shows that Spain is Europe's number 4 market in terms of sales[1], ranks fifth in terms of job creation and sixth in terms of pharmaceutical production.

1. Turnover in this case refers to total sales at Pharmaceutical Company Prices (sale of pharmaceutical products in pharmacies + sales in hospitals + sales through other sales channels).

EU PHARMACEUTICAL INDUSTRY GENERAL DATA (2009)

Country	No. of Companies (1)	Production (Đm) (2)	Jobs	Sales Int. (PVL) (Đm)	Foreign Trade (PVL) (Đm) (3)	
					Imports	Exports
Germany	304	26,381	104,605	27,047	34,303	47,550
Austria	119	2,175	10,697	2,996	4,931	5,552
Belgium	122	5,419	31,966	4,320	31,294	37,407
Denmark	**36**	**5,769**	**20,223**	**2,073**	**2,377**	**5,714**
Spain	198	14,152	39,155	14,744	12,208	7,902
Finland	58	1,058	5,623	1,979	1,667	843
France	264	24,953	100,355	27,146	19,647	24,761
Greece	64	1,008	14,000	5,850	3,940	938
Holland	40	5,664	16,900	4,654	10,124	9,908
Ireland	54	21,700	24,500	1,888	2,848	20,663
Italy	199	23,395	67,500	18,540	15,357	11,523
Portugal	130	1,973	9,761	3,716	2,244	501
UK	55	18,319	72,000	12,512	15,099	22,912
Sweden	66	6,226	14,766	2,771	2,925	6,380
TOTAL EU-15	**1,709**	**158,192**	**532,051**	**130,236**	**158,965**	**202,555**

NB: Does not include Luxembourg owing to its scant significance.
(1) EFPIA member companies.
(2) All data refer to the production of pharmaceutical specialties and raw materials for human and veterinary consumption, except Germany, Spain and Ireland, where they refer solely to human consumption.
(3) Foreign pharmaceutical trade (SITC 54). Includes veterinary products.

Source: FARMAINDUSTRIA, EFPIA members companies In each country, Eurostat.

2. THE PHARMACEUTICAL INDUSTRY IN SPAIN

2.1.

R&D AND INNOVATION

Investment in R&D and Innovation is a key driver of competitiveness and economic growth. In the current economic scenario, there is an urgent need to work towards a growth model based on high-productivity and R&D intensive sectors. This is acknowledged by Law 14/2011 on Science, Technology and Innovation, whose Preamble states: "[...] Spain's productive model relies mainly on construction and tourism, so there is a need to drive change by making a commitment to research and innovation as means of achieving an economy based on knowledge which will ensure more balanced, diverse and sustainable growth".

So it comes as no surprise to learn that the most developed countries give the greatest importance to policies that contribute to encouraging investment in R&D and Innovation activities. In this respect, the EU, through the Lisbon Strategy, sets its sights on two basic targets for R&D in 2010, namely increase spending on R&D to 3% of GDP, in the EU, and ensure that at least two thirds of this spending come from the private sector.

Both targets are closely linked because bringing R&D investment up to 3% of GDP calls for the private sector to act as the main driver and financing source for research, especially given the current scenario of fiscal consolidation in which fiscal expansion policies are being ditched in an effort to reduce the major imbalances in public finances.

Sadly, those targets have not been met. In 2010, total EU Investment in R&D came to 2% of GDP, and just over half of financing (54.1%) came from the private sector[2].

Looking to the future, the European Commission's "Europe 2020 Strategy", picks out innovation as a priority area, pointing out that "[...]the EU's R&D spending accounts for less than 2% of GDP, compared with 2.6% in the USA and 3.4% in Japan, due mainly to lower levels of private investment. But it's not just about the amount of money spent on R&D: the EU needs to focus on the impact and composition of its R&D spending and improve the conditions for conducting R&D in the private sector In Europe. Half of the difference with the USA stems from our smaller percentage of hi-tech companies".[3]

Accordingly the Commission urges EU states to "[...] make spending on knowledge a priority, e.g. by using tax breaks and other financial instruments to channel greater private investment towards R&D" and lists among its five top priorities "an R&D investment target of 3% of GDP, especially by improving the conditions required for private investment in R&D and by creating a new indicator monitoring Innovation".

Turning to Spain, in 2010 this country invested the equivalent of 1.39% of GDP, a figure well below the EU average and which leaves Spain lagging behind countries such as Portugal, Ireland, Slovenia, Estonia or the Czech Republic, all of whose economies are less developed than Spain's. The Business Participation Indicator puts Spain a long way from the EU average and the targets, because the percentage of business financing of R&D in Spain comes to just 43.4%, the lowest level on record since 1994 and ten points below the EU average.

So in order for Spain get closer to EU standards in R&D, it needs urgently to follow policies that effectively encourage private R&D, particularly in the most tech-intensive sectors. This is especially so in the current fiscal consolidation scenario, in which public money for R&D has been seriously lacking in the past three years (2010, 2011 and 2012). This is giving rise to an investment imbalance that only private enterprise is capable of restoring.

This makes the pharmaceutical industry's contribution invaluable. It is, after all, the most important, by turnover and in terms of value-added, of the three manufacturing sectors that INE, Spain's National Institute of Statistics, refers to as "high-tech"[4], accounting

2. Data for 2009 (latest available at time of going to press).
3. Complete text available at: http://ec.europa.eu/commission_2010-2014/president/news/documents/pdf/20100303_1_es.pdf

for 59% of the revenues generated by this select industrial band of technology front-runners.[5]

The Spanish pharmaceutical Industry's latest results (published in INE's "R&D Activity Statistics") confirmed yet again its role as an R&D front-runner. The 2010 figures speak for themselves:

▪ It's the industrial sector that invests most in R&D in Spain: in 2010 it invested more than 966 million euros in R&D, accounting for 19.8% of Spanish industry's total R&D investment for that year.

Even so, this figure is lower than the 21.6% registered in 2009, and comes as a result of the lower relative growth in pharmaceutical R&D compared to other industrial sectors as a consequence of hefty cuts in public pharmaceutical spending in Spain. These measures are hitting pharmaceutical R&D investment which, as the table below shows, registered negative growth (-0.1%) in 2010, the lowest figure on record in the sector since the year 2000 and considerably lower than the growth rate for total R&D investment for Spanish industry as a whole (+9,2%).

R&D ACTIVITY IN SPANISH COMPANIES (2010)

Sector	R&D dedicated staff*	R&D Spending (€m)			
		Internal	External	Totals	% increase on 2009
Total industry	38,721	3,534.74	1,346.93	4,881.67	9.2%
Pharmaceutical Industry	**4,665**	**628.92**	**337.43**	**966.35**	**-0.1%**
Automotive	3,335	382.20	445.69	827.88	99.6%
Other transport equipment	4,439	572.63	193.52	766.15	13.1%
Aerospace	2,940	397.81	117.39	515.20	22.2%
ICT, electronic and optical products	3,749	232.19	24.90	257.09	-3.2%

(*) Full-time staff.
Source: FARMAINDUSTRIA, Spanish National Institute of Statistics (Statistics on R&D activity 2009 and 2010).

▪ The pharmaceutical industry is the industrial sector that creates most R&D-related jobs[6], with 4,665 full-time dedicated professionals, accounting for 12% of the total jobs in R&D generated by this sector. Moreover, they are highly-skilled jobs because nearly half professionals are researchers.

▪ The pharmaceutical sector also ranks top of the industrial table in terms of internal costs (research conducted internally in companies), basic research (26% of the industry total) and applied research (28% of the total).

IF WE WANT TO REACH EUROPEAN RESEARCH STANDARDS, WE NEED TO PROVIDE EFFECTIVE INCENTIVES FOR PRIVATE R&D

4. Source: INE (Hi-Tech Sector Indicators 2010).

5. Other Hi-Tech manufacturing sectors are ICT, electronic and optical products (CNAE 26) and Aeronautical and Space Construction and associated machinery (CNAE 30.3); Source: INE (Hi-Tech Sector Indicators 2010).

▪ Another important feature of pharmaceutical research is its high levels of self-financing (84.1%), a remarkable figure when you consider the volume of investment carried out by the industry despite Spain's ongoing credit squeeze.[7]

▪ Finally, and despite these significant figures, the most important thing for any sector is to commit firmly to research and then translate it into positive results, thus aiding its country's economic development.

In this respect, a prime indicator of efficiency in any sector is the number of companies that file for a patent over a given period as a percentage of the number of companies that conduct research In that sector. Measured by this indicator, the pharmaceutical industry tops (by far) the Spanish industrial sector and business league in terms of research productivity: in Spain, more than a third (35.9%) of pharmaceutical companies involved in R&D projects in 2010 filed for at least one patent in the period 200-2010.

These figures highlight the pharmaceutical industry's role as front-runner in terms of both R&D activity and strategic importance when it comes to coming up with a growth model for Spain that puts its money on high-productivity and tech-intensive sectors.

Even so, it would be wrong to omit that the rate of investment in R&D in Spain's pharmaceutical Industry slowed in 2010, which has taken some of the shine off the sector compared with others. This slowdown is likely to continue in 2011 given that initial forecasts suggest that pharmaceutical R&D is set for another fall, for the second year in a row.

6. Employment data in terms of Full-Time Employees (FTE).

7. The self-funding data refer exclusively to the percentage of internal R&D financed with own funds, given that the INE does not publish data on self-funding data for external R&D.

In this sense, we should recall that a high-risk business model such as the pharmaceutical one, marked by long R&D cycles, ever-increasing costs and beset by growing regulatory demands, needs a stable regulatory framework allowing companies to plan ahead efficiently for investments.

At the moment, regulatory stability is still a long way off in Spain in view of the central and regional government's severe pharmaceutical spending cuts carried out In 2011 (looked at in other sections of this Annual Report) which are ravaging pharmaceutical companies' bottom lines as they follow in the wake of the measures adopted in 2010. The slowdown in the Spanish pharmaceutical market comes hand-in-hand with diminishing company resources, which could place investment at risk and which is leading many companies to reconsider the viability of their R&D centers in Spain.

At the same time, the temporary measures for 2012 and 2013, brought about by RDL 12/2012, 30 March, which introduced a raft of tax and administrative measures aimed at reducing the public deficit and corporate tax deductions (in which deductions for R&D were of considerable importance to the pharmaceutical sector) have led to greater instability.

Also, despite the introduction of very positive measures, e.g. the regional and local authorities' Settlements Plan for Suppliers, which will come as a shot in the arm in terms of cash flow (especially for SMEs and the self-employed), R&D is currently in a delicate situation in Spain. So it would be a good idea to introduce short term measures—without placing public savings targets and the necessary fiscal consolidation at risk— to allow strategic industrial sectors, such as the pharmaceutical Industry, to develop its full potential and make a solid contribution to economic growth.

A HIGH-RISK BUSINESS MODEL SUCH AS THE PHARMACEUTICAL ONE CALLS FOR A STABLE REGULATORY FRAMEWORK THAT ALLOWS COMPANIES TO PLAN THEIR INVESTMENTS ADEQUATELY

THE PRESCRIPTION MARKET WAS AFFECTED BY THE COMING INTO FORCE OF RDL 9/2011 WHICH, AMONG OTHER THINGS, MADE ACTIVE INGREDIENT PRESCRIPTION MANDATORY COUNTRYWIDE IN SPAIN

2.2.

THE INTERNAL MARKET

In 2011, sales of medicines in Spain fell by -5.1%, coming to 13,941 million euros at Pharmacy Retail Prices (PRP); 69,5% of those sales came from pharmacy sales and the remainder from hospital dispensaries.

THE INTERNAL MEDICINAL PRODUCTS MARKET

	Pharmacies (1)	Change (%)	Hospitals (e)	Change (%)	Total	Change. (%)
2009	10.852,46	3,8	4.011,51	14,3	14.863,97	6,4
2010	10.478,20	-3,4	4.211,68	5,0	14.689,88	-1,2
2011	9.685,26	-7,6	4.255,93	1,1	13.941,19	-5,1

(1) Medicines sales in pharmacies, net of deductions (4%, 7.5% and 15%).

(e) Estimated figure. The historical data series has been reconstructed on the basis of FARMAINDUSTRIA'S "Annual Survey on Hospital Pharmaceutical Debt", breaking the continuity published in the Association's earlier Annual Reports. Figures refer to medicines sales in National Health System hospitals, net of discounts and deductions (figures for Catalonia include the Catalonian Institute of Health)..

Source: FARMAINDUSTRIA, IMS and own estimates.

The combined effect of government measures to reduce public spending and regulatory changes at the regional level has led to slower sales in pharmacies (-7.6%) and a rise of just 1.1% In the hospital market, leading to an overall fall of -5.1% in total medicines sales.

Early 2011 saw the introduction of Ministerial Order SPI/3052/2010, which brought with it 15 new groupings to the Reference Price System and revised the reference prices of the groupings created by Ministerial Orders issued in 2006, 2007, 2008 and 2009, on the basis of modifications introduced by RDL 4/2010 (the reference price of each grouping is set by the product with the least cost per treatment per day and the gradual fall in the price goes from -30% to -50%). Similarly, in 2011 the Galenic Innovation Declaration expired on 85 medicinal products, forcing them to lower their prices to the reference price in their respective grouping.

Moreover, the prescription market was affected by the coming into force of RDL 9/2011 (mentioned previously in this Annual Report), which, among other changes, extended the Active Ingredient Prescription to the whole of Spain, making it compulsory to dispense active ingredients and at the lowest price in each grouping of medicines that are identical in composition and pharmaceutical form and dosage.

Through this RDL, in October 2011 the Ministry issued a list of Homogenous Groupings, indicating the lowest price of each one, so that the pharmaceutical companies that so wished it aligned their prices with the lowest price. This list included practically the entire market, except those medicines declared non-substitutable and those for which there are no equivalent products.

Generics and branded medicines performed differently in 2011: the former rose by +36.5% in unit terms and +40.3% in value terms, while the latter fell by -6.4% in units and -12.3% in value terms.

THE MARKET FOR PHARMACEUTICAL SPECIALTIES SOLD THROUGH PHARMACIES (PHARMACY RETAIL PRICES)

	Units (thou.)	Change (%)	Sales PRP - Deductions	Change (%)
Prescription	1,230,229	2.6	9,330,114	-7.9
Branded	888,960	-6.4	8,152,259	-12.3
Generics	341,269	36.5	1,177,855	40.3
EFPs	90,379	-2.1	355,148	1.8
Total	1,320,608	2.2	9,685,262	-7.6

Source: FARMAINDUSTRIA, IMS and own estimates.

Barring a few specific exceptions, all medicinal products have aligned their prices with the lowest price in their grouping, which means that branded medicines are available at the same price as their generic equivalent. Today, 61% of units available on the Spanish market are sold at generics prices.

For its part, RDL 9/2011 brought important changes to the Reference Price System (RPS), such as the creation of hospital groupings or the elimination of the principle of graduality. Through the same RDL, those medicines not included in the Reference Price System, which have been on the market for more than ten years and which have no generic equivalent or biosimilar are now subject to a 15% deduction on Public Health System, up from the previous deduction of 7.5%.

Finally, Resolution 28 December 2011, issued by the Directorate General of Pharmacy and Healthcare Products, announced 31 new medicine groupings to be dispensed in pharmacies using the official prescription of the Reference Price System; five of the medicines are topical administration products and six are of the non-substitutable kind. The Resolution also does away with five groupings; in one of them the generics medicines that formed part of the grouping had its trading permit withdrawn, while the others were eliminated because the groupings' reference prices were below 3.12 euros. With this Resolution, the number of groupings included in the Reference Price System came to a total of 221 (204 molecules or associations). Three of them are currently inactive.

Including the groupings of this last Resolution, 50% of the prescription market units are included In the RPS, with a market share of 31.3%

APART FROM THE ODD EXCEPTION, THE PRICES OF ALL MEDICINAL PRODUCTS ARE NOW AT THE SAME LEVEL AS THE LOWEST-PRICED PRODUCT IN THEIR RESPECTIVE GROUPING; THIS MEANS THAT BRANDED PRODUCTS ARE AT THE SAME PRICE AS THEIR GENERIC EQUIVALENTS

Therapeutic Groupings

In 2011, virtually the entire range of therapeutic groupings was hit by the cost-cutting measure referred to earlier. Average prices dropped for all but four.

SALES OF PHARMACEUTICAL SPECIALTIES IN PHARMACIES, BY THERAPEUTIC GROUPS (2011)

Group	Units (thou.)	Share (%)	Change (%)	Values PRP (thou.) (*)	Share (%)	Change (%)	Average PRP (Đ)	Change (%)
A. DIGESTIVE & METABOLIC SYSTEM	211,238.7	16.0	3.4	1,437,846.2	14.2	0.4	6.81	-2.9
B. BLOOD & BLOOD PRODUCING ORGANS	63,929.1	4.8	1.1	398,432.2	3.9	-14.0	6.23	-14.9
C. CARDIOVASCULAR SYSTEM	246,185.7	18.6	3.0	1.875,643.3	18.5	-13.9	7.62	-16.4
D. DERMATOLOGY	58,897.0	4.5	-3.4	320,508.8	3.2	-3.0	5.44	0.4
G. GENITAL & URINARY	55,602.3	4.2	-0.6	718,772.2	7.1	-1.6	12.93	-1.0
H. HORMONES	20,282.6	1.5	5.6	219,461.1	2.2	-0.7	10.82	-6.0
J. ANTI-INFECTIOUS	54,073.6	4.1	4.8	331,891.1	3.3	-8.3	6.14	-12.5
K. HOSPITAL SOLUTIONS	2,863.0	0.2	1.3	3,184.3	0.0	-0.4	1.11	-1.6
L. CANCER & IMMUNE AGENTS	6,465.3	0.5	-1.2	485,365.9	4.8	-16.5	75.07	-15.5
M. LOCOMOTOR SYSTEM	112,069.5	8.5	1.7	610,355.1	6.0	-8.8	5.45	-10.3
N. CENTRAL NERVOUS SYSTEM	293,912.8	22.3	2.7	2,319,983.5	22.8	-2.4	7.89	-5.0
P. ANTI-PARASITE	1.209,0	0.1	3.6	8,793.1	0.1	1.4	7.27	-2.1
R. RESPIRATORY SYSTEM	135,721.7	10.3	1.4	1,109,932.4	10.9	1.4	8.18	0.0
S. SENSORY ORGANS	56,479.6	4.3	2.2	274,176.8	2.7	0.6	4.85	-1.6
T. DIAGNOSTICS AGENTS	51.6	0.0	-18.8	1,032.0	0.0	-17.1	20.00	2.2
V. VARIOUS	1,626.5	0.1	0.2	45,734.6	0.5	4.7	28.12	4.5
TOTAL	1,320,607.8	100.0	2.2	10,161,112.6	100.0	-5.6	7.69	-7.7

(*) Gross deduction value. Owing to the lack of disaggregated data, it has not been possible to eliminate the deductions (4%, 7.5% and15%) of the values of the different therapeutic groupings.

IN 2011, MOST THERAPEUTIC GROUPS WERE HIT BY SPENDING CUTS

Between them, the four most important therapeutic groups account for 67.2% of the total market (units) and 66.4% in value terms.

In 2011, the group that registered the biggest rise in sales was Group G: Central Nervous System, chalking up above-average increases in both in unit and value terms. This grouping contains some of the biggest selling medicines which, despite their low prices, have been hit by RDL 9/2011, e.g. pain relievers which make up 41% of the grouping and which although

their unit sales saw a 3.2% rise, suffered a -6% fall in their average price; or sedatives (19% of the grouping), whose average price fell by -9%.

Group C: Cardiovascular System, accounting for 18.5% of the total market, in unit and value terms, registered the biggest fall in average price in 2011 (-16.4%). Just over two thirds (67%) of the grouping's units are included in homogeneous groupings or those affected by the RPS, and 85% are in the biggest-selling subgroups such as cholesterol-lowing medicines or ACE inhibitors.

The products in Group A: Digestive System continued to buck the average both in unit and value terms: however, it is interesting to highlight the different trends followed by 2 subgroups that, between them, account for 70% of the total, in value terms:

Antacids, antiflatulents and anti-ulcer agents, which account for 42% of the grouping's total units, registered an 8% increase (units) in 2011, yet it's average price fell by -18%. More than 80% of this sub-grouping is included in the Homogeneous Groupings or is affected by the RPS.

Antidiabetics, which represent 20% of the Groupings' units, registered an average price Increase of 5% in 2011, well above the average, owing to not only the therapeutic innovations that have emerged to fight this illness but also the fact that most of these medicines are non-substitutable, and, as such, are not included in homogeneous groupings.

In the case of Group R: Respiratory System, both units and values rose by 1.4% in 2011, leaving their average price unchanged. There are two reasons for this: on the one hand, the price increase registered by EFPs and non-financed medicines (which account for 25% of units in this grouping) and the fact that this grouping's average price has risen by 7.6%; and on the other hand because this grouping has a large percentage of non-substitutable medicines and, because they are not included in a homogeneous grouping, their prices have not fallen at any moment.

It is also worth highlight the fall in average prices of Groups L: Anti-Cancer Medicines (-15.5%), B: Blood and Blood-Forming Organs (-14,9%), J: Anti-infective Agents (-12,5%) and M: Locomotor Systems (-10,3%), all of which contain a considerable proportion of medicines that have seen their prices fall to the level of the lowest price in their corresponding homogeneous groupings. Group L: Anti-Cancer Medicines saw the biggest price fall, due partly to the fact that In 2011 some hospital diagnostic products began to be dispensed in hospitals.

New launches

Last year, 414 new medicines came onto the market, with total sales amounting to 173 million euros. Of these, 299 are generics and 23 are based on newly traded molecules or associations. In all, the new products covered two main therapeutic areas: Cardiovascular System (102 products, two of which are generics) and Central Nervous System (92 products, 75 of which are generics)

IN 2011, 414 NEW MEDICINAL PRODUCTS CAME ONTO THE MARKET, REACHING TOTAL SALES WORTH 173 MILLION EUROS

2.3.

FOREIGN TRADE

Traditionally, the Spanish economy's productive structure has led to trade deficits, particularly through periods of economic bonanza in which the dynamism of internal demand drives exports, only to fall away during downturns such as the present one in which imports slow and companies look to overseas markets as a way of selling the products that are unwanted at home owing to weakened domestic demand, leading to a rise in exports. This way, Spain's trade deficit has gone from 9.5% of GDP in 2007 to (the year prior to the downturn) to 4,3% In 2011. Similarly, Spain's import-export coverage rate has also improved in this period, going from 64.9% in 2007 to 82.2% in 2011.

As regards the pharmaceutical industry, in 2011 foreign trade was more moderate that in 2010. In fact in 2011, and for the first time in the past eight years, the value of Spanish medicines exports was lower than the previous year's (-0.8%) ending the year at 8.808 billion euros. Several causes explain this reduced value of pharmaceutical exports, for example, the strong dip in pharmaceutical products prices, and the end of operations of a number of production plants brought upon by severe public spending cuts in Spain.

In any case, we should not forget that pharmaceutical products now account for 4.1% of Spain's total exports, when in 2000 they accounted for just 1.8%. In fact, the Spanish Customs and Special Taxes Department's Statistical Report on Foreign Trade—in its classification by customs duty chapters—ranks pharmaceutical products Spain's 5th export in volume terms in 2011, behind cars, fuels, reactors and machinery. This position is particularly relevant when you consider that in the year 2000, pharmaceutical products held only 18th place in the exports ranking.

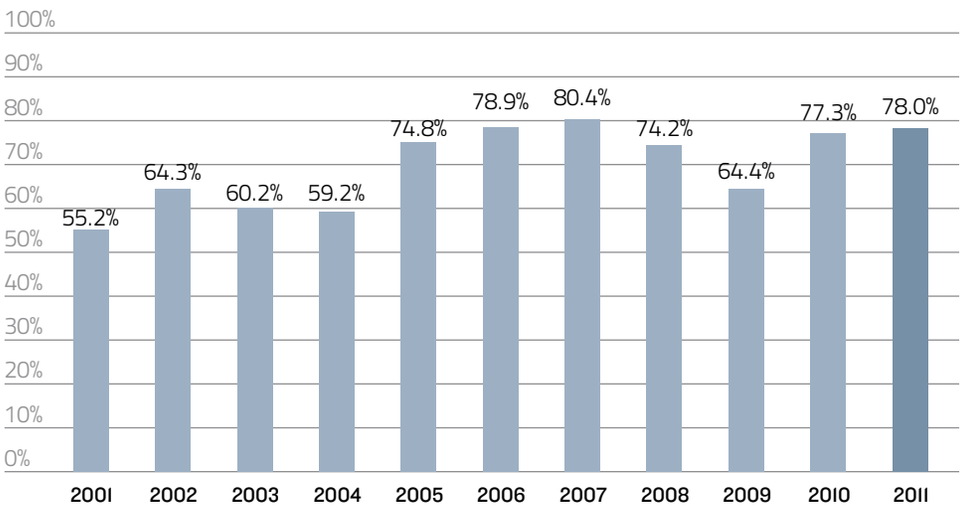
On the other hand, the value of medicine imports dropped for the second year running in 201 (-1.8%), to 11.289 billion euros.

Exports' lower fall than imports led to a slight improvement in Spain's pharmaceutical balance of trade in 2011: the deficit was trimmed by almost 130 million euros, and by more than 1.86 billion euros compared with the 2009 figures.

As the table below shows, this took the foreign trade coverage rate for medicines to 78.0% in 2011, the third highest coverage rate since historical data history on foreign trade in medicinal products became available in Spain.

PHARMACEUTICAL EXPORTS ACCOUNT FOR 4.1% OF SPAIN'S TOTAL EXPORTS

EXPORT COVERAGE RATES FOR MEDICINAL PRODUCTS



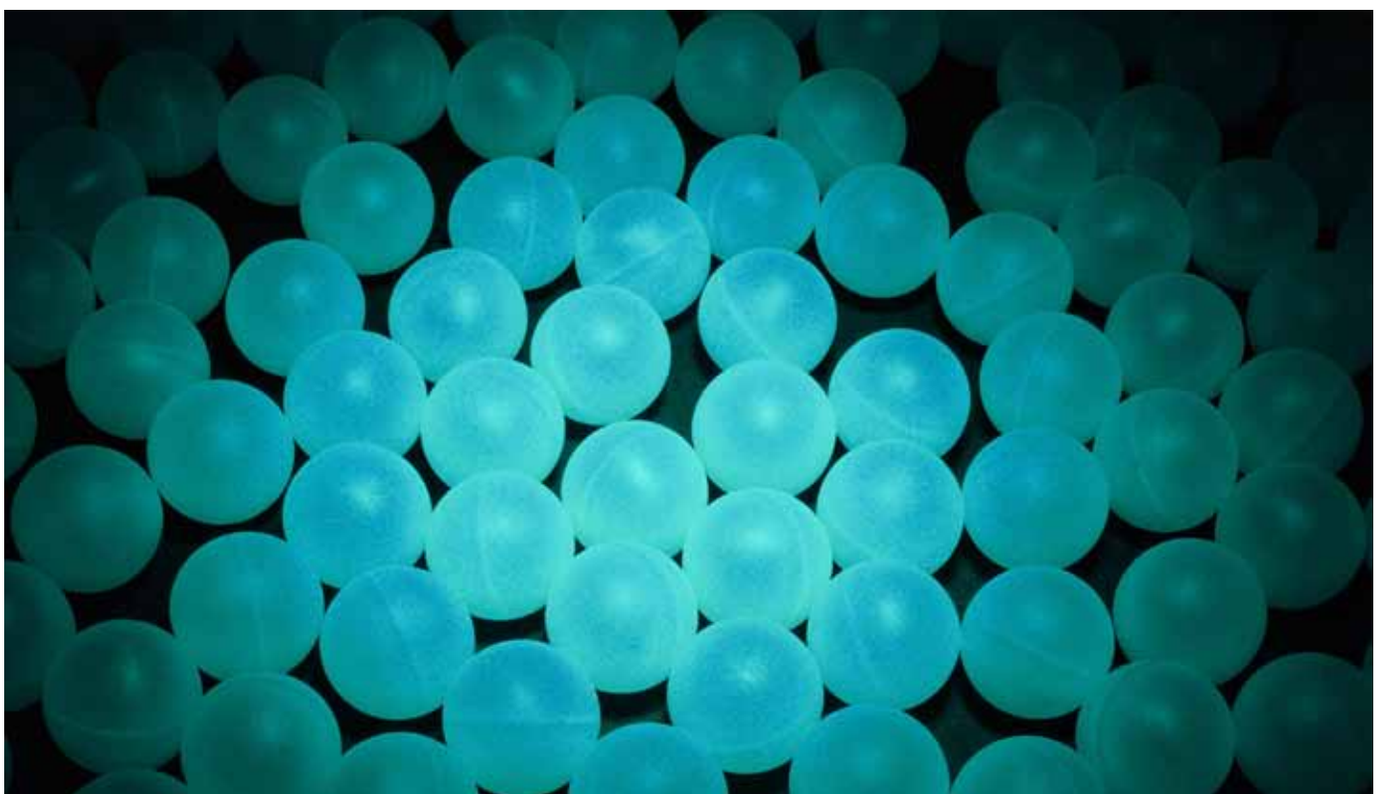
Source: Ministry of Economy and Competitiveness (State Secretariat for Commerce's Statistical Report on Spanish Foreign Trade).

Following the sharp fall in the Spanish pharmaceutical market registered in 2010 and 2011, stemming from Spanish central and regional governments' public spending cuts, many companies have found in overseas markets an alternative to their traditional reliance on the home market. However, given that roughly 70% of Spanish pharmaceutical exports go to Europe, member countries' markets are slow and this eroded the value of our pharmaceutical exports in 2011, and forecasts point to little improvement in 2012. Faced with this situation, Spain's pharmaceutical companies will have no choice but to seek out alternative/complementary markets abroad.

THE STRONG FALL IN SPAIN'S PHARMACEUTICAL MARKET IN 2010 AND 2011 LED MANY COMPANIES TO LOOK FOR ALTERNATIVES IN FOREIGN MARKETS

	2010		2011	
Economic Area	Exports (%)	Imports (%)	Exports (%)	Imports (%)
World Total	100.0	100.0	100.0	100.0
EU-27	59.4	69.7	54.5	67.5
France	11.8	9.0	9.4	11.2
The Netherlands	5.4	6.2	4.9	5.4
Germany	11.0	13.7	7.8	13.8
Italy	8.9	5.0	7.9	5.0
UK	8,0%	11,3%	6,5%	9,1%
Ireland	1.5	7.5	0.8	6.1
Belgium	1.2	5.0	1.2	5.2
Rest of Europe	13.5	6.7	14.0	7.2
Switzerland	11.1	6.1	11.5	6.6
Rest of the world	27.2	23.6	31.5	25.4
China	1.2	1.4	1.8	1.5
Japan	3.3	0.9	5.2	1.1
USA	7.2%	18.5%	7.0%	19.7%

Source: Ministry of Economy and Competitiveness (State Secretariat for Commerce's Statistical Report on Spanish Foreign Trade).



2.4.

SOCIAL SECURITY PHARMACEUTICAL SPENDING

According to Health Ministry figures, the number of prescriptions financed by Spain's National health System in 2011 rose by 1.6% in 2010, reaching to 973.2 million euros. However, as a result of the application of a number of cost-cutting measures introduced by RDLs 4/2010 and 8/2010, and which continued into 2011, the average cost per prescription fell by -10.2% in 2011, settling at 11.44 euros, asit was, ten years earlier. The result has been an unprecedented fall in pharmaceutical public spending in pharmacies of -8.8% in 2011.

The year also saw the number of prescriptions rise by 1.6%, the lowest increase registered in the past twelve years.

SOCIAL SECURITY SPENDING ON PRESCRIPTIONS DISPENSED THROUGH PHARAMACIES

Year	Spending (Đm RRP VAT)	Change (%)	Prescriptions (millions)	Change (%)	Cost/Presc. (euro)	Change (%)
2006	10,636.2	5.8	796.0	4.1	13.36	1.7
2007	11,191.3	5.2	843.4	6.0	13.27	-0.7
2008	11,960.5	6.9	889.5	5.5	13.45	1.3
2009	12,506.2	4.5	934.0	4.9	13.39	-0.5
2010	12,207.7	-2.4	957.7	2.5	12.75	-4.8
2011	11,136.4	-8.8	973,2	1,6	11.44	-10.23

Regional average pharmaceutical per capita spending

In Spain overall, pharmaceutical per capita spending came to 236 euros in 2011, down -9.1% on the previous year's figure. Regional figures vary considerably: Extremadura (297.4 €) and Galicia (296.6 €) are on the top rungs of the ladder, while the Balearic Isles (183.7 €) and Madrid (182.7 €) are at the lower end.

THE NUMBER OF PRESCRITPIONS DISPENSED IN 2011. PAID FOR BY SPAIN'S NATIONAL HELATH SYSTEM, WAS UP 1.6% IN 2010

PER CAPITA PHARMACEUTICAL SPENDING PER REGION (2011)

REGION	Spending share (%)	Per capita spending	
		Euros	Incr. s/2010 (%)
EXTREMADURA	3.0	297.4	-7.7
GALICIA	7.4	296.6	-10.9
ASTURIAS	2.8	293.2	-7.5
VALENCIA	12.6	274.9	-9.0
MURCIA	3.5	262.4	-8.7
ARAGON	3.1	260.4	-10.4
CASTILE- LEON	6.0	259.6	-8.4
CASTILE-LA MANCHA	4.8	254.9	-10.3
LA RIOJA	0.7	245.5	-9.8
THE BASQUE COUNTRY	4.8	244.5	-7.8
CANTABRIA	1.3	238.4	-7.4
NATIONAL AVERAGE	100.0	236.0	-9.1
NAVARRE	1.3	230.9	-8.7
CANARY ISLES	4.4	229.2	-9.5
CATALONIA	15.1	223.2	-9.0
ANDALUSIA	16.4	216.5	-9.6
BALEARIC ISLES	1.8	183.7	-7.5
MADRID	10.6	182.7	-8.4
CEUTA	0.1	174.8	-5.8
MELILLA	0.1	154.1	-5.0