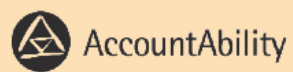


Sustainability  
Report

**2015**

***Committed  
to the future***

In accordance:



Members of:



Sustainability  
Report

**2015**

***Committed  
to the future***

**EVALUATION SURVEY**

We'd like to continue improving our report in the coming years and would therefore be grateful if you could complete the brief survey you'll find at:

**[www.esteve.es/sustainabilitysurvey](http://www.esteve.es/sustainabilitysurvey)**

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**JOAN ESTEVE**  
Chairman

**ALBERT ESTEVE**  
Chief Executive  
Officer



# Introduction

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For ESTEVE, 2015 was a year in which we consolidated the positive trend in all our business activities, achieving good results not only in economic terms but also at a social and environmental level. This Report covers the results achieved in those three areas which reinforce the sustainability of the Company and its environment.

Regarding good governance, an important decision was taken in 2015 and carried out fully in 2016, namely independent external advisors joining the Board of Directors as members. These changes help the Group to continue improving the professionalism of its governing bodies and encourage good practices in its corporate governance. Another advance in this area has been the implementation of ESTEVE's Code of Ethics and its corresponding communications channel in Spain. It is planned to implement this Code internationally in 2016.

In the area of research, it is worth mentioning that two in-house research programmes into new molecular entities for treating pain have now completed clinical phase II. The project to treat Sanfilippo A syndrome, in collaboration with Autonomous University of Barcelona, is also making good progress and we are currently developing a process to produce samples for its clinical trials. We have also extended our gene therapy platform with two new projects to treat Sanfilippo B and Hunter's syndrome. All these are rare and devastating diseases which are particularly prevalent among children.

At the beginning of 2016, and as part of the collaborative HIVACAT project which aims to develop a vaccine to treat HIV, a spin-off company was also created, Aelix Therapeutics. This will initially focus on developing the HIVACAT T-cell Immunogen (HTI) as a therapeutic vaccine to treat HIV infection.

ESTEVE's commitment to society is expressed through many different channels which are covered in the Society section of this Report, but from 2015 we'd particularly like to highlight the alignment of our areas of social contribution with the United Nations' Sustainable Development Goals (SDG) published in September 2015, contributing to those areas which, due to the nature of our business, we particularly want to focus on: namely access to health and promoting healthy habits, employment integration and caring for the environment.

In our commitment to the environment we should also note that, in 2015, we started up a photovoltaic plant to provide the electricity consumed by the pharmaceutical factory, which will help to reduce costs and also our CO<sub>2</sub> emissions, a reflection of our commitment to renewable energy sources.

Being accountable to our main stakeholders is also a commitment we renew year after year through this Report, which has been drawn up following the *Global Reporting Initiative* (GRI) standards in their latest G4 version, also verified externally by an independent third party.

We hope you will find this latest edition of the Sustainability Report of interest.

Key data from 2015

# Figures



Economic

**872 M€**  
net sales

**516 M€**  
international  
sales

**25.9 M€**  
invested in  
industrial assets

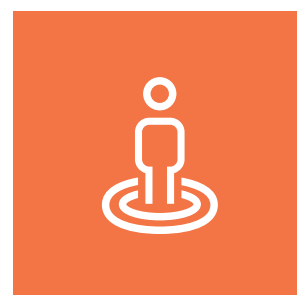


Patients

Total allocated  
to R&D&i  
**66.3 M€**

**2** in-house  
research  
programmes on  
pain complete  
Phase II

**8** projects aimed  
at improving care  
for chronic patients



Clients

**40** product  
launches

Training for over  
**48,000** health  
professionals

**+7%** increase in  
website clients





Strategic partners,  
suppliers &  
institutions

More than **40**  
licence agreements

More than **30**  
collaborations with  
various institutions

**7** agreements  
with special  
employment  
centres

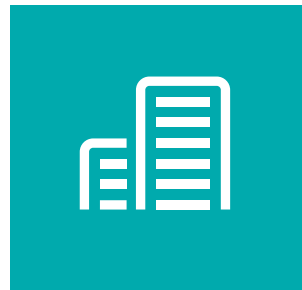


Internal  
collaborators

**2,278**  
people employed  
worldwide

**89.9%**  
of the workforce  
trained, with an  
average of 17 hrs/  
collaborator

**40%** of the  
workforce under  
the performance  
management  
system



Society

**263** participants  
in the Corporate  
Volunteer  
Programme

**10.2 tonnes**  
of food and  
**1.4 tonnes** of  
clothes donated

**9,412**  
beneficiaries via  
collaboration  
with 23 social  
organisations



Environment

**5,000 m<sup>2</sup>**  
of photovoltaic  
panels to reduce  
140 tonnes of CO<sub>2</sub>

Offsetting  
**374  
tonnes** of CO<sub>2</sub>  
emissions

**9.4 M€**  
invested in the  
environment

Key data from 2015

# Facts

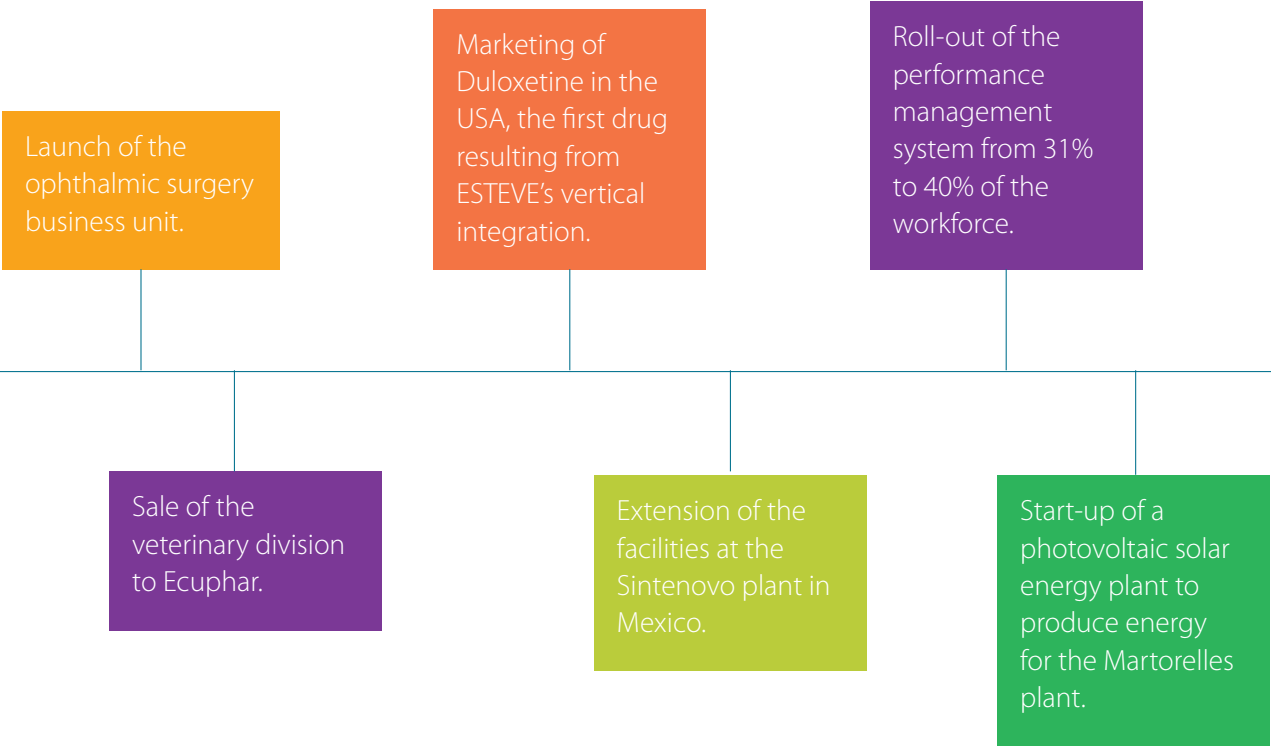
Implementation of the ESTEVE Code of Ethics and the communications channel for all employees in Spain.

Two in-house research programmes into new molecular entities to treat pain complete Phase II.

Creation of the spin-off of the HIVACAT project "Aelix Therapeutics" to develop a therapeutic AIDS vaccine.

Global alliance signed in the area of R&D between ESTEVE and Mundipharma-Purdue for innovative products to treat pain.

Development of manufacturing process to continue with clinical trials for Type A Sanfilippo syndrome.





# 01.

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Company

---

Profile and

---

Good

---

Governance

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*ESTEVE, with its head office in Barcelona, has eight subsidiaries on three continents (Europe, America and Asia) and sells its products in more than 60 countries.*



**872M€**

net sales



**516M€**

international sales



**25.9M€**

invested in industrial assets

# 01.

## Company Profile and Good Governance

### 1.1 A BRIEF OVERVIEW OF ESTEVE



More information  
about ESTEVE's history  
and values at  
[www.esteve.com](http://www.esteve.com)

ESTEVE is a chemical and pharmaceutical Group that has focused its business on the area of health since, in 1929, Dr. Antoni Esteve i Subirana founded the first company. Today ESTEVE is renowned for its devotion to research, its international expansion and ability to generate strategic alliances.

ESTEVE is divided into three business areas:

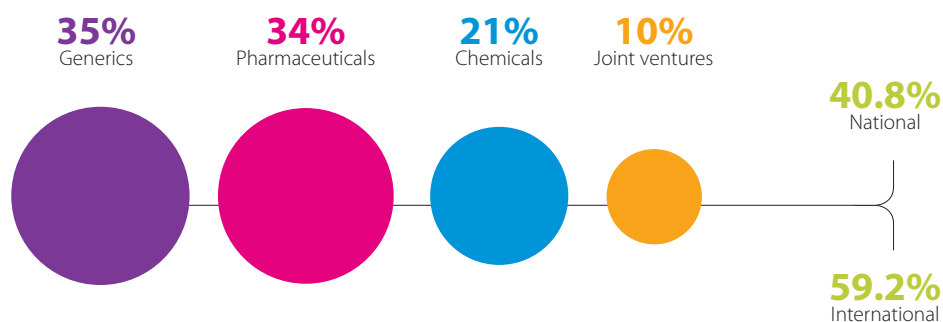
**Pharmaceuticals:** Research and Development (R&D) and marketing of ethical and OTC<sup>1</sup> drugs in Spain.

**Generics:** Development, manufacture and marketing of generic products.

**Chemicals:** R&D, manufacture and marketing of active pharmaceutical ingredients (API).

ESTEVE is also expanding its supply of products and services in the area of health and well-being via various joint ventures. For more information see the strategic alliance section.

> ESTEVE's net sales total 872 million euros.



<sup>1</sup>  
OTC (over the counter).

[G4-3, G4-7, G4-9]



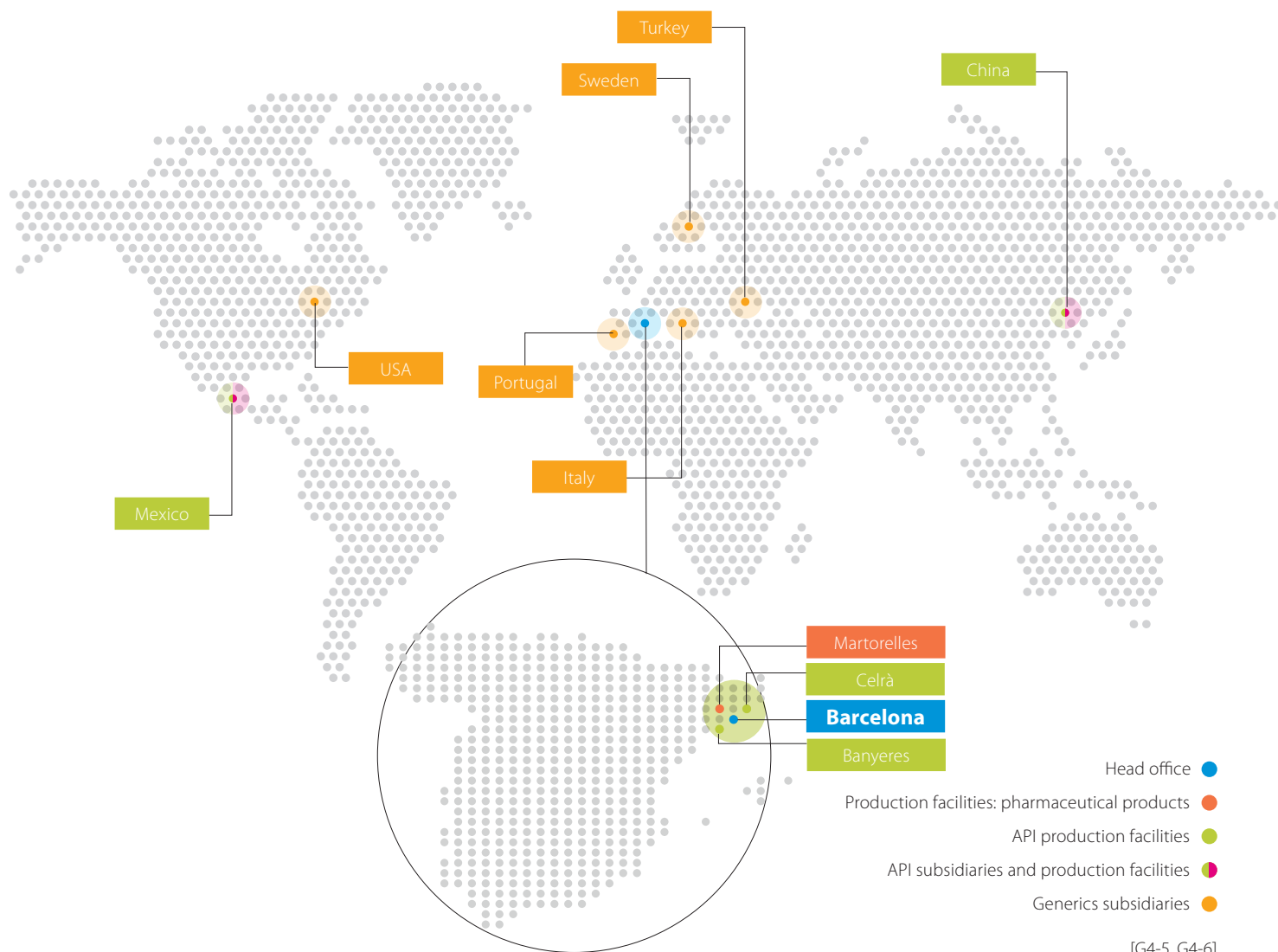
ESTEVE, with its head office in Barcelona, has eight subsidiaries on three continents (Europe, America and Asia) and sells its products in more than 60 countries.

ESTEVE employs  
**2,278**  
collaborators  
worldwide



**74%**  
in Spain

### > Map of ESTEVE's offices and production facilities around the world





## 1.2 BUSINESS MODEL

The ESTEVE business model covers the whole life cycle of innovative and generic pharmaceutical drugs and products: from research into new molecular entities, active ingredients, galenic forms, the manufacture and distribution of these products and their associated services.

This cycle is covered via the following supply chain for the Group's three business areas: pharmaceuticals, generics and chemicals.

### SUPPLY CHAIN

INCORPORATION OF NEW PRODUCTS	PURCHASING	MANUFACTURE	DISTRIBUTION	MARKETING & SALES
<b>PHARMACEUTICALS</b>				
Development of new chemical entities via: <ul style="list-style-type: none"> <li>• In-house research programmes</li> <li>• Collaboration programmes</li> <li>• Combined research units</li> </ul>	Purchase of raw materials and conditioning material	<ul style="list-style-type: none"> <li>• Manufacture of products at the ESTEVE's pharmaceutical plant (Martorelles)</li> <li>• Manufacture of products at third party pharmaceutical plants</li> </ul>	Distribution of finished products to: <ul style="list-style-type: none"> <li>• Hospitals</li> <li>• Pharmaceutical distributors</li> <li>• Pharmacies</li> </ul>	<ul style="list-style-type: none"> <li>• Own sales network visiting GPs and specialists in Spain</li> <li>• Via "out" licence agreements to distribute to other countries where ESTEVE has no sales network</li> </ul>
"In" licence agreements: <ul style="list-style-type: none"> <li>• Ethical drugs</li> <li>• OTC products</li> <li>• Healthcare products</li> </ul>	Purchase of finished products (vast majority)  Purchase of raw materials and conditioning material	<ul style="list-style-type: none"> <li>• Manufacture of products by third parties</li> <li>• Manufacture of products at own plant (Martorelles)</li> </ul>	Distribution of finished products to: <ul style="list-style-type: none"> <li>• Pharmaceutical distributors</li> <li>• Pharmacies</li> <li>• Hospitals</li> </ul>	<ul style="list-style-type: none"> <li>• Own sales network visiting GPs and specialists</li> </ul>
<b>GENERICS</b>				
Development of own generic drugs (own pharmaceutical innovation laboratory or external laboratories)	Purchase of raw materials, conditioning material and/or finished products	<ul style="list-style-type: none"> <li>• Manufacture of products at own plant (Martorelles)</li> <li>• Manufacture of products by third parties</li> </ul>	Distribution of finished products to pharmaceutical distributors and pharmacies (Pensa)  To other pharmaceutical firms (Pensa Dose)	<ul style="list-style-type: none"> <li>• Own sales network visiting pharmacies, doctors and/or distributors (Pensa)</li> <li>• Via "out" licence agreements for their distribution by other pharmaceutical firms (Pensa Dose)</li> </ul>
"In" licence agreements: <ul style="list-style-type: none"> <li>• Of generic drugs developed by third parties</li> </ul>	Purchase of raw materials, conditioning material and/or finished products	<ul style="list-style-type: none"> <li>• Manufacture of products by third parties</li> <li>• Manufacture of products at own plant (Martorelles)</li> </ul>	<ul style="list-style-type: none"> <li>• Distribution of finished products to pharmaceutical distributors and pharmacies</li> </ul>	<ul style="list-style-type: none"> <li>• Own sales network visiting pharmacies, doctors and/or distributors (Pensa)</li> </ul>
<b>CHEMICALS</b>				
R&D of manufacturing processes for active pharmaceutical ingredients (APIs) <ul style="list-style-type: none"> <li>• For innovative drugs</li> <li>• For generic drugs</li> </ul>	Purchase of raw materials and conditioning material	<ul style="list-style-type: none"> <li>• Manufacture at own plants (Spain, China and Mexico)</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmaceutical firms</li> </ul>	<ul style="list-style-type: none"> <li>• Selling to other pharmaceutical firms worldwide</li> <li>• Selling to ESTEVE's pharmaceuticals business</li> </ul>



## BUSINESS ACTIVITIES

ESTEVE bases its business model on a solid diversification strategy supported by two areas: activities and markets.

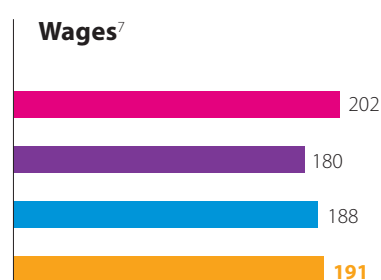
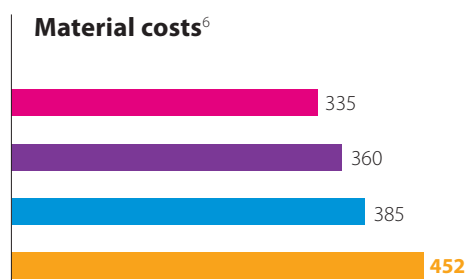
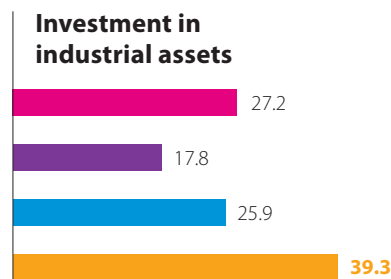
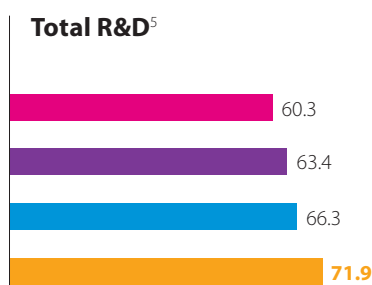
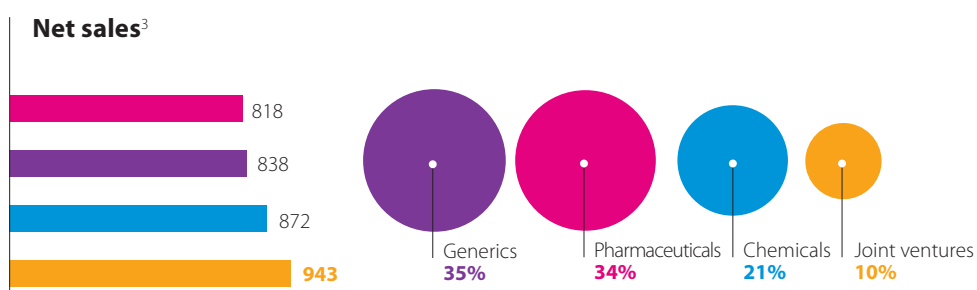
ACTIVITIES			THERAPEUTIC AREAS	KEY CLIENTS / MARKETS	MAIN PRODUCTS
PHARMACEU-TICALS	Ethical	R&D and marketing of ethical drugs and healthcare products	Diabetes, cardiovascular, respiratory, analgesics/ pain, central nervous system, ophthalmology	GPs and specialists in Spain	Alipza Dafiro Prometax Rilast Jalra / Zomarist Xeristar Yantil Zonegran Masdil Vals Liplat Aremis Artilog Loxifan Aquoral Oftanmácula Oftaclean Bilina
	OTC	Development and marketing of pharmacy and OTC products	Sleep, dermatological and gastrointestinal disorders	Pharmacists, nursing staff and patients in Spain	Dormidina Triptomax Fortasec Laxadina Calmiox Daktarin Topionic After Bite Repel Bite
GENERICS	Pensa Dose	Development, manufacture and marketing of drugs for third parties	Gastrointestinal, central nervous system, diabetes, cardiovascular and other products	Leading generic and OTC companies worldwide, as well as innovative companies looking for a third party to develop and manufacture their products	Omeprazol optimizado, Pantoprazol, Lansoprazol, Esomeprazol, Duloxetina and other products
	Pensa Pharma	Marketing of generic drugs	Practically all therapeutic categories	Pharmacists, doctors, distributors and insurance companies in various countries	Omeprazol, Esomeprazol, Pantoprazol, Lansoprazol Duloxetina and other products
CHEMICALS	EQ, Sintenovo, EHP	R&D, manufacture and marketing of active pharmaceutical ingredients	Presence in a range of therapeutic areas	ESTEVE and other pharmaceutical companies worldwide	Active pharmaceutical ingredients and advanced intermediate products

[G4-4, G4-8]

## 1.3 KEY ECONOMIC FIGURES

In 2015 there was considerable growth in the Group's international activity and a positive trend in margins. Moreover, at the beginning of 2015 a worldwide collaboration agreement was signed with Mundipharma-Purdue for the global development of a new generation of drugs to treat pain, reinforcing and enhancing the efforts made in Research and Development over the last few years. During the first half of 2015 the Group's veterinary business was also taken over by the Belgian company Ecuphar, as well as its whole workforce. With this transaction the Group now focuses on developing its current businesses and veterinary has been added to a project for future development.

### > Economic indicators<sup>2</sup> (Million euros)



<sup>2</sup> Includes 50% of the consolidation of ETH and Isdin, except in R&D and investment. Does not include the Company's capitalisation broken down in terms of debt and equity as this is confidential information.

<sup>3</sup> Net sales are considered to be the Group's turnover.

<sup>4</sup> Forecast.

<sup>5</sup> Includes R&D expenditure and investment.

<sup>6</sup> Material costs include the Group's raw materials and goods.

<sup>7</sup> The Group's total expenditure on personnel.

<sup>8</sup> The Group's total taxes (Company Tax and other taxes). Does not include VAT as this is not expenditure.

[G4-DMA, G4-9, G4-EC1]



## 1.4 CORPORATE GOVERNANCE

ESTEVE's governance structure follows the criteria of good practices for corporate governance, combining all the positive aspects of a family firm with the best of a listed company in order to ensure the successful, sustainable development of the Group and its business operations.

As of 30 March 2016 the Shareholders' General Meeting approved the proposal passed by the Board of Directors establishing changes in the Group's governing bodies, specifically incorporating three independent board members with a renowned professional track record, as well as renewing the members from the different committees reporting to the Board of Directors.

### GOVERNING BODIES

- **Shareholders' General Meeting.** Presided over by Joan Esteve, this is made up of all those with shares in ESTEVE and holds the power among the owners.
- **Board of Directors of the ESTEVE Chemical-Pharmaceutical Corporation.**
  - Chairman: Joan Esteve.
  - Board members: Albert Esteve (Chief Executive Officer), Antoni Esteve, Sílvia Gil-Vernet, Jordi Esteve, Santiago Descarrega, Maria Pagés, Jesús Caínzos, Alessandro Banchi and Julio Rodríguez. The last three members had, prior to this date, been external advisors to the Board.
  - Secretary: Jordi Faus.
  - Vice-Secretary: Joaquín Monleón.

With these changes, the following former members are no longer a part of the Board: Josep Esteve (who will continue to preside over the Dr. Antonio Esteve Foundation) and Joaquim Targa; Rossend Tost, hitherto an external advisor; Josep M<sup>a</sup> Ràfols, General Secretary of the Corporation; and Agustí Jausàs, hitherto Secretary to the Board.

- **Chief Executive Officer.** Position held by Albert Esteve. Appointed by the Board of Directors. Implements the strategy agreed by the Board, managing the executive structure and the day-to-day business.

Following the best practices of good governance, there are several committees made up of Board members and external advisors that support the Board of Directors.

The current committees are as follows: the Audit Committee, the Appointment and Redress Committee, the NEXT Committee which will be in charge of issues related to corporate strategy and the New Molecular Entities Committee which will be responsible for R&D strategy.

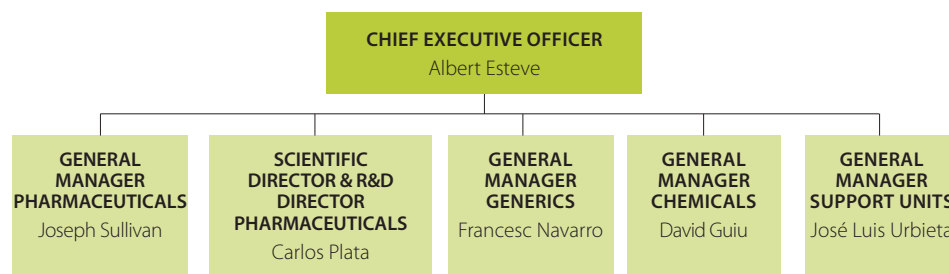
Of note in 2015 was the start-up of the Ethics Committee, which reports to the Board of Directors through the Audit Committee.

The Corporate Governance Bodies are governed by the Internal Regulations of the Board of Directors which define, in addition to the mission and aims, the operational procedures, procedure for new members and all aspects related to its management. The different committees also have their own regulations.

[G4-34]

## EXECUTIVE STRUCTURE

ESTEVE's executive structure is made up of three business areas (Pharmaceuticals, Generics and Chemicals) and a fourth area that includes the Support Units (Sustainability, Human Resources, Finance, Information Technology, Legal & Compliance and Communication).



## 1.5 STAKEHOLDER RELATIONS AND MATERIALITY

ESTEVE aims to create shared value with its stakeholders through responsible management that contributes to the sustainability of the Company and of the environment in which it operates.

The priority issues to be dealt with by the Company are identified through dialogue with its stakeholders and through the materiality analysis.

The Company's stakeholder relations are managed by the people in charge of each area or department, who establish a dialogue with stakeholders to know their needs and opinions and to respond via different channels (interviews, surveys, regular meetings, etc.).

The Sustainability area carries out interviews with each person in charge to update the stakeholder map and determine how frequently dialogue is required with each group. The results of this process are systematically documented and taken into account when drawing up ESTEVE's Sustainability Report and Corporate Social Responsibility Master Plan, thereby responding to their needs and concerns.

Through this procedure, we make sure the Company considers the three management principles of the AA1000APS (2008) standard which make up a model of a company characterised by:

### **INCLUSIVITY:**

maintaining permanent, open dialogue with stakeholders.

### **RELEVANCE:**

identifying key issues (demands, expectations).

### **RESPONSIVENESS:**

responding to each of these issues.



The main stakeholder groups dealt with by the Company are:

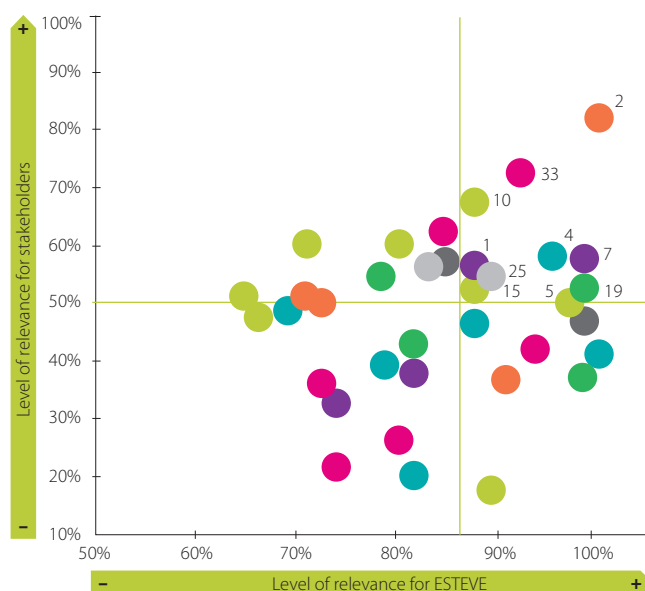


Prior to drawing up this Report a materiality study was also carried out to discover and highlight the most relevant issues for stakeholders and for the Company.

The materiality study is made up of the following phases:

- **Identifying issues.** The issues to be examined, grouped into categories, were determined by means of an overall analysis of companies in the sector, as well as opinion leaders for the sector, opinion leaders for CSR (Corporate Social Responsibility) and findings from previous dialogues with stakeholders. This resulted in 36 aspects grouped into 6 categories: good governance and ethical behaviour, people's health and well-being, CSR in the supply chain, an optimum work environment, commitment to local communities and preserving the environment.
- **Prioritising material aspects.** Internal and external consultations were carried out to rank the previously identified aspects. ESTEVE management took part internally while externally consultations were held with opinion leaders for the sector, CSR opinion leaders and companies in the sector, as well as analysing the press.
- **Validation.** Finally, the materiality analysis was presented and validated by heads of the different stakeholder groups and the General Management of the Support Functions.

As a result of this process, the following material aspects have been identified, covered in the next sections of the Report, as well as the impact of each aspect by Stakeholder:



MATERIAL ASPECTS	SECTION
2. Ensuring regulatory compliance	1.6
33. Optimising the use of resources and managing waste to minimise environmental impact	7.1, 7.2, 7.3
10. Ensuring transparent information	1.6
4. Having a Code of Ethics, promoting an ethical culture, having channels and providing a response	1.6
7. Talking with and responding to our Stakeholders	1.5
1. Having good practices to guide the Governing Bodies	1.4
25. Providing employees with professional training and development	5.3
19. Guaranteeing patient safety	2.2, 2.3
15. Guaranteeing compliance of the code of good practices in relations with healthcare professionals and organisations	1.6
5. Respecting and protecting human rights	1.6

MATERIAL ASPECTS IDENTIFIED	IMPACT OF THE ASPECT BY STAKEHOLDER					
	SHAREHOLDERS	COLLABORATORS	CLIENTS	SUPPLIERS	GOVERNMENT	SOCIETY
2. Ensure compliance with laws and regulations	●	●	●	●	●	●
33. Optimise the use of resources and the management of waste to minimise environmental impact	●		●	●	●	●
10. Ensure the transparency of information	●	●	●	●	●	●
4. Have a Code of Ethics, promote an ethical culture, have channels and give a response	●	●	●	●	●	●
7. Promote dialogue and respond to our Stakeholders	●	●	●	●	●	●
1. Have good practices for the functioning of the Governing Bodies	●		●	●	●	
25. Offer training and professional development to employees	●	●	●			
19. Guarantee patient safety	●		●	●	●	●
15. Guarantee compliance of the code of good practices regarding healthcare professionals and organisations	●	●	●		●	●
5. Respect and protect human rights	●	●	●	●	●	●





## 1.6 COMPLIANCE AND ETHICAL MANAGEMENT

### COMPLIANCE FRAMEWORK

ESTEVE's compliance framework focuses on three broad areas through which the Company's policies and procedures are established to ensure compliance by the Company's collaborators and potentially also third parties.

These areas are:

#### ESTEVE'S CODE OF ETHICS

It establishes the essential principles, commitments and behaviour in relations with stakeholders.

#### SELF-REGULATION CODES FOR THE INDUSTRY

They involve the commitment by ESTEVE to carry out its business in accordance with ethical criteria of professionalism and responsibility.

#### THE MODEL TO DETECT AND PREVENT OFFENCES

Establishing systems of organisation and management that include vigilance measures and controls to stop offences from being committed.

### CODE OF ETHICS

ESTEVE's Code of Ethics forms an essential part of the Company's ethical management. It establishes the essential principles, commitments and behaviour in relations with stakeholders. ESTEVE employees must comply with the Code and all firms that deal with the Company must also apply these principles and adopt similar behaviours.

The Code of Ethics was implemented in 2015 in all the companies of the ESTEVE Group in Spain by means of a dissemination plan and online acceptance of the Code by all employees. It has been planned to implement the Code internationally in 2016.

ESTEVE has an Ethics Committee, responsible for promoting the dissemination, understanding, updating and compliance of the Code of Ethics. The Ethics Committee is a permanent advisory and executive body that acts totally independently within its area, being responsible for supervising the effectiveness of the channel for queries and reports related to non-compliance.

It reports to the Board of Directors through the Audit Committee and is made up of the Areas of Internal Audits, Legal & Compliance, Human Resources and Sustainability. Its work is governed by the "Ethics Committee Regulations" and the "Protocol for receiving and dealing with queries and reports of non-compliance".



More information about the Code of Ethics at [www.esteve.com](http://www.esteve.com)

### CHANNEL FOR QUERIES AND REPORTS OF POSSIBLE NON-COMPLIANCE

ESTEVE provides its employees with a range of channels to express any doubts they may have regarding the interpretation of the Code of Ethics, as well as to report possible instances of non-compliance they may become aware of, through:

[G4-DMA, G4-14, G4-56, G4-57, G4-58, G4-SO4]



Their direct  
boss



Human Resources  
Department



Email



Post

In 2015 there were the following queries and reports of non-compliance:

#### Number of queries: 7

- Conflict of interest: 2
- Formal acceptance and others: 5

#### Number of reports of possible non-compliance: 8

- Conflicts of interest: 3
- Product: 3
- Asset protection: 1
- Professional development: 1

All reports were analysed and treated confidentially. Approximately 60% were well-founded.

The Company has taken the appropriate disciplinary and/or corrective measures in the case of well-founded reports in order to put an end to behaviour that goes against the Code of Ethics and prevent such conduct in the future.

## COMMERCIAL CODES OF GOOD PRACTICE

In 2015 the Pharmaceutical area continued to strictly comply with the self-regulation codes for the pharmaceutical industry, as well as with the corporate codes of the licensing companies.

ESTEVE continues to strengthen its commitment to the “Code of Good Practice of the Pharmaceutical Industry”, especially in training internal personnel and in raising awareness among healthcare professionals and organisations of the decision taken by the Pharmaceutical Industry to publicly disclose the capital transfers carried out in 2015 to both groups. The data corresponding to 2015 will be published in June 2016 on the Company’s website.

ESTEVE has also maintained its commitment to comply with the codes of good practice in those sectors where it operates, such as the Anefp and Fenin Codes.

### 9

The following are reported as significant non-compliance, fines, sanctions or claims: those notifications with a definitive ruling or agreement and totally 10,000 euros or more settled in the reporting year.

[G4-DMA, G4-14, G4-56, G4-57, G4-58, G4-EN29, G4-EN34, G4-SO5, G4-SO7, G4-SO8, G4-SO11, G4-PR2, G4-PR4, G4-PR7, G4-PR8, G4-PR9, G4-LA16, G4-HR3, G4-HR12]

## REGULATORY COMPLIANCE

Respect for the law and regulations in all those countries where the Company operates, as well as compliance of commercial codes of good practice, are commitments and expected behaviours of ESTEVE's Code of Ethics. The compliance system and risk audits help to ensure this is the case.

In terms of incidents regarding any non-compliance of laws, regulations or voluntary codes in 2015, there was no significant complaint, fine or penalty<sup>9</sup>.



## VOLUNTARY COMMITMENTS

As a company committed to ethics and transparency as part of its corporate responsibility, ESTEVE has joined the following voluntary commitments:

VOLUNTARY COMMITMENTS	DESCRIPTION
10 PRINCIPLES OF THE UNITED NATIONS GLOBAL COMPACT	<ul style="list-style-type: none"> <li>Member since 2002. As a member of the Spanish Global Compact Network, ESTEVE highlights its commitment to Human Rights, the dignity of working conditions, protection of the environment and the fight against corruption. The progress report is drawn up every year.</li> <li>Member of the UN's Caring for Climate initiative to combat climate change.</li> </ul>
RESEARCH	<ul style="list-style-type: none"> <li>Phase II and II clinical trials are published on the IFPMA website<sup>10</sup>.</li> <li>Via the Ethics Committee of the Parc Científic de Barcelona, ESTEVE guarantees compliance of current regulations related to the health and welfare of animals used in pre-clinical research.</li> </ul>
GOOD PRACTICES IN PROMOTING DRUGS	<ul style="list-style-type: none"> <li>Member of the Code of Good Practice of the Pharmaceutical Industry, ANEFP and FENIN.</li> </ul>
RESPONSIBLE COMMUNICATION	<ul style="list-style-type: none"> <li>ESTEVE belongs to the Association for the Self-Regulation of Commercial Communication and complies with its Advertising Code of Conduct.</li> </ul>
COMPANY AND BIODIVERSITY PROGRAMME	<ul style="list-style-type: none"> <li>ESTEVE joined this programme in 2011, promoted by the foundations Global Nature and AccióNatura, whose aim is to raise awareness of the importance of biodiversity and the role played by companies in conserving and protecting it. Various projects were carried out in 2015 that are described in the biodiversity section.</li> </ul>
AGENDA 21 – CITIZEN COMMITMENT TO SUSTAINABILITY. BARCELONA 2012-2022	<ul style="list-style-type: none"> <li>A member since 2002 and membership renewed in 2012. Three business sectors take part in this initiative (business, public and non-profit), consisting of a road map for the sustainability of Barcelona over the next 10 years.</li> </ul>
GLOBAL REPORTING INITIATIVE (GRI)	<ul style="list-style-type: none"> <li>Annual production of the Sustainability Report following the GRI standards since 2008, verified externally.</li> </ul>

**10**  
International Federation of  
Pharmaceutical Manufacturers  
& Associations.

[G4-14, G4-15]

## CERTIFICATION

ESTEVE works in accordance with the following good practices and its sites have the following certificates, obtained in:

GOOD PRACTICES	GMP	GLP	FDA	PMDA	KFDA	SFDA
	Good Manufacturing Practice	Good Laboratory Practice	Food & Drug Administration	Pharmaceuticals & Medical Devices Agency	Korea Food & Drug Administration	Saudi Food and Drug Authority
Regulatory bodies	Catalan government and Spanish Agency for drugs and healthcare products		US health regulatory agency	Japanese health regulatory agency	South Korean health regulatory agency	Saudi Arabian health regulatory agency
Martorelles, Spain	2015		2015			2013
Celrà, Spain	2015		2013	2007	2015	
Banyeres del Penedès, Spain	2015		2013		2011	
Shaoxing, China	2011		2015			
Jiutepec, Mexico	2010		2015	2013		
Parc Científic Barcelona, Spain		2012				
Chemical R&D Centre, Barcelona, Spain			2015			

CERTIFICATION	ISO 14001: 2004	OHSAS 18001: 2007	OHSMS 18000-(GB/T28001: 2001)
	Environment	Health & Safety	
Martorelles, Spain	2014	2014	
Celrà, Spain	2014	2014	
Banyeres del Penedès, Spain	2014	2014	
Shaoxing, China	2015		2015
Jiutepec, Mexico	2013	2013	
Parc Científic Barcelona, Spain		2014	
Chemical R&D Centre, Barcelona, Spain	2015	2014	



## 1.7 RISK MANAGEMENT AND OPPORTUNITIES

Proactive risk management helps to identify, measure and manage risk to ensure our business goals are achieved and people, assets and the environment are protected, thereby increasing the Group's long-term sustainability.

In line with an approved annual plan, the Internal Audit Department assesses the efficacy and efficiency of the controls set up to mitigate risk, as well as the implementation of the action plans agreed. The findings from the audits are reported to the management of the areas in question, the CEO and the Audit Committee.

The following actions **were particularly of note in 2015:**

- Start-up of the Ethics Committee. Drawing up and approving its regulations, as well as the operating procedure for the channel for queries and reports.
- Half-yearly short-term risk and opportunity assessment related to fulfilling the budgets of 2015 and 2016.
- Review and update of risks related to pharmaceutical products, taking into account the type of product and market, as well as to what extent risk is managed.
- Definition of the project to implement a business continuity plan at the Martorelles plant with the aim of restoring activity as quickly as possible in a possible crisis situation. Implementation will begin in 2016
- Follow-up of the implementation of the Policy and Set of Rules for Information Security. After the phase to review compliance, the correction phase has now begun, in accordance with the aspects identified to be improved. Follow-up of awareness regarding Information Security by means of informative "pills" and training for specific areas.
- Carrying out the following internal audits:
  - Procedure used to file and manage legal documents digitally.
  - Procedure used to allocate costs of the support and corporate areas for business activities.
  - Evaluation of internal control for purchasing and sales processes at Breckenridge Pharmaceutical Inc.
  - Procedure used to manage payment collection at the European Generics subsidiaries.
  - Evaluation of the guarantee of quality at subsidiaries and head offices of the Generics and Pharmaceutical business.

The process used to analyse the risks entailed in significant new investment projects, requiring approval by the Board of Directors (for example, buying or setting up new firms), includes aspects related to Human Rights. However, in 2015 there were no projects of this type.

ESTEVE regularly updates its risks, including the economic, social and environmental dimensions. In 2015 no significant risks were detected regarding Human Rights nor threats related to child exploitation or forced labour.

No risk or incident was detected in any subsidiary related to corruption that required specific measures to be taken.

[G4-DMA, G4-14, G4-HR5,  
G4-HR6, G4-HR9, G4-SO3]

# 02.

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## Patients

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*By way of recognition  
of its commitment to  
innovation, ESTEVE has  
once again been rated as  
Excellent by the Plan  
Profarma.*



Total allocated to R&D&I

**66.3 M€**



**2**

in-house research programmes on  
pain complete Phase II



**8**

projects aimed at improving care  
for chronic patients



# 02.

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# Patients

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## 2.1 RESEARCH, DEVELOPMENT AND INNOVATION (R&D&I)

Each of ESTEVE's business areas has its own R&D&I structure. Integrated collaboration between all groups, as well as with third parties with complementary capacities, allows ESTEVE to take on the global development of drugs covering all phases of research.

ESTEVE applies an active policy of strategic collaboration and alliances with universities, public research centres, technology firms and other pharmaceutical companies in order to establish a network of excellence to help it become a crucial player in the ecosystem of biomedical innovation.

By way of recognition of its commitment to innovation, ESTEVE has once again been rated as *Excellent* by the *Plan Profarma*.

### R&D INTO NEW MOLECULAR ENTITIES

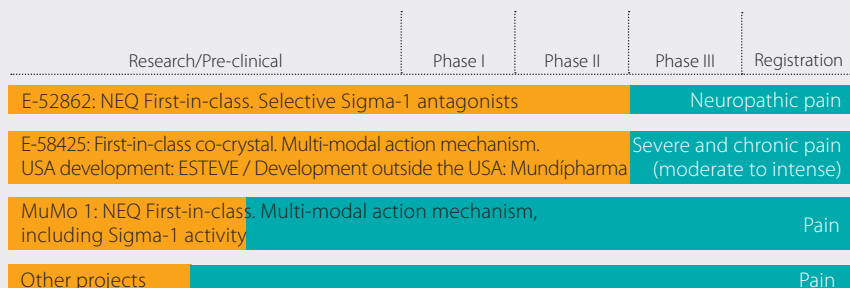
Pharmaceutical R&D aims to discover and develop new drugs that provide significant therapeutic value and improve patients' quality of life. Its R&D projects focus on providing patients and healthcare professionals with solutions to their therapeutic requirements not sufficiently covered by available treatments with a strong impact on society.



ESTEVE's in-house R&D projects in the field of New Molecular Entities (NEM) focus on pain treatment complemented with other biotechnological projects aimed at other therapeutic areas, developed together with external groups under different types of collaboration models.

## Proprietary research programmes

### > Pain programmes (Proprietary R&D programmes)



NEQ: new chemical entities.

The projects **E-52862** and **E-58425** particularly stand out due to their **degree of innovation**.

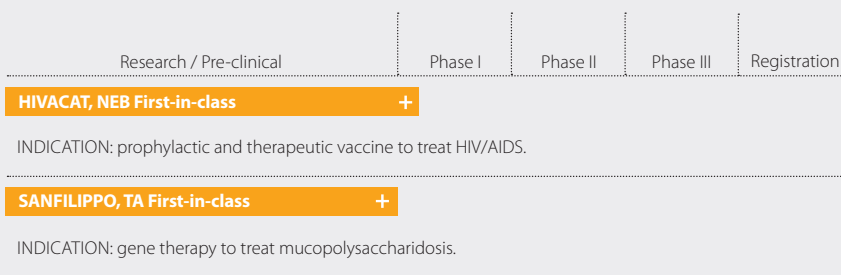
- **E-52862** is the first development of selective Sigma-1 antagonist to treat severe chronic pain and neuropathic pain. This project has great potential to resolve significant therapeutic needs that are currently not being met. In 2015 positive results were obtained from the Phase II clinical trials in a range of patient populations so that work has now begun to go on to the next phase.
- **E-58425** consists of a co-crystal that provides products with significant advantages as an analgesic compared with combination techniques and also using different components separately. E-58425 is the first co-crystal of two active ingredients in Clinical Phase II. The results obtained in the first trial in patients have provided an excellent profile in terms of efficacy and security that support the carrying out of clinical trials to confirm these results, which are now in preparation, both in Europe and in America.

A multi-modal technology platform (**MuMo**) is also being developed with the aim of combining, within the same molecule, action on several therapeutic targets involved in pain relief. This platform includes projects covering a wide degree of innovation, currently in the discovery and pre-clinical phases.

An agreement has been set up between ESTEVE and Mundipharma-Purdue, a global benchmark in pain relief. This unprecedented alliance includes three of the projects mentioned, designed by ESTEVE for critical medical needs not currently met and regarding several types of pain, corresponding to the highest level of innovation as each one is first in class.

## Collaborative programmes

### > Collaborative R&D programmes



**NEB:** new biological entities.

**TA:** alternative therapy.

- **HIVACAT.** Aims to discover and develop a prophylactic and therapeutic vaccine for acquired immunodeficiency syndrome (AIDS). Resulting from collaboration between the IrsiCaixa Institute for AIDS Research, the Unit for Infectious Diseases and AIDS at Hospital Clínic in Barcelona and ESTEVE, with support from the “la Caixa” Foundation, the departments of Health & Innovation and also Universities & Business of the Catalan government, ICREA and the Fundació Clínic, at the beginning of 2016 a spin-off company was created, namely Aelix Therapeutics.

Aelix Therapeutics will initially focus on developing the HIVACAT T-cell Immunogen (HTI) as a therapeutic vaccine to treat HIV infection.

- **Sanfilippo project.** Focuses on developing a gene therapy to treat Type A Sanfilippo syndrome, a disease that causes mental deterioration and premature death and for which there is currently no specific treatment available. Work is also being carried out on therapies for related diseases such as Type B Sanfilippo syndrome and Hunter’s syndrome. The project is carried out in strategic collaboration with the Animal Biotechnology and Gene Therapy Centre at the Autonomous University of Barcelona.

Gene therapy for the treatment of Type A Sanfilippo syndrome is currently in the advanced pre-clinical phase and a study of the natural history of the disease has been started that will serve as a control for the efficacy of the clinical trial. The protocol from the first clinical trial of Phase I/II has been evaluated and approved by the Clinical Research Ethics Committee of Hospital Sant Joan de Déu.

Therapies for the treatment of Type B Sanfilippo syndrome and for Hunter’s syndrome are currently in the initial pre-clinical phase.

ESTEVE has obtained *Orphan Drug* status by the European Commission and the FDA for Type A and B Sanfilippo syndrome and for Hunter’s syndrome. The Company invests considerable effort in researching into gene therapy for these rare diseases which are pathologies for which there is no treatment.

The projects for new molecular entities have received aid from the Ministry of the Economy and Competitiveness (Spanish government), through the Centre for the Development of Industrial Technology, CDTI (E-52862, MuMo projects) and through the programmes INNPACTO (HIVACAT, Sanfilippo) and RETOS (Phenopain), all co-financed by the European Regional Development Fund, ERDF. We have also received aid from the European Commission through the 7th Framework Programme (Neuropain) and from the Corporate Competitiveness Agency, ACCIÓ, of the Catalan government (E-58425).



### Mixed research units: 'Open innovation'

Active collaboration with external groups of excellence (academic institutions) is gradually building up a new model of network research, started a few years ago. ESTEVE now has three mixed units at centres of excellence:

- Institut Català d'Investigació Química (Catalan Chemical Research Institute) located in Tarragona and dedicated to the design and production of new molecules with therapeutic potential.
- University of Santiago de Compostela, dedicated to high performance *in vitro* pharmacological evaluation.
- Pompeu Fabra University, dedicated to *in vitro* pharmacological evaluation.

### International collaborative research

ESTEVE plays an active role in the IMI Joint Technological Initiative, a public-private partnership between the European Commission and EFPIA, the European Federation of Pharmaceutical Industry Associations, of which ESTEVE is a member.

Within the IMI, in 2015 ESTEVE took part in the following projects:

- eTOX: Development of Expert Systems for *in Silico* Toxicity Prediction.
- EuroPain: Pain Research.
- EMTRAIN: European Medicines Research Training Network.
- Open PHACTS: An Open, Integrated and Sustainable Chemistry, Biology and Pharmacology Knowledge Resource for Drug Discovery.
- EUPATI: European Patients' Academy on Therapeutic Innovation.

ESTEVE also takes part in the NeuroPain consortium financed by the VII Framework Programme of the European Union.

### Bioethical research

ESTEVE's research is extremely thorough in bioethical aspects, both in terms of clinical research and also in pre-clinical research using laboratory animals.

The Company strictly follows current legislation in clinical trials, previously obtaining all mandatory permits from the Spanish Drug and Health Product Agency or from the corresponding regulatory authority in the country where the clinical research is taking place, always having authorisation from the management of the centres where clinical trials are carried out and approval from the corresponding Clinical Research Ethics Committees.

Active collaboration with external groups of excellence (academic institutions) is gradually building up a new model of network research, started a few years ago.



More information  
about ESTEVE's R&D  
at **[www.esteve.com/investigacion-desarrollo](http://www.esteve.com/investigacion-desarrollo)**

ESTEVE has a strong ethical commitment towards protecting the animals used for research. To this end, the Company duly notifies the corresponding body of any experimental procedures and submits them to the Animal Research Ethics Committee of the Parc Científic de Barcelona, which safeguards the wellbeing and health of animals used in all procedures carried out at its facilities, where ESTEVE's Drug Discovery and Pre-Clinical Development centre is located.

## R&D INTO INNOVATIVE PHARMACEUTICAL FORMS

Pharmaceutical innovation is carried out both at the modern facilities located at the Martorelles plant and also with international partners to be able to access technologies and know-how not available internally.

The Martorelles pilot plant complies fully with the Good Manufacturing Standards so that, in addition to the phases of development and analytical validation, batches for clinical trials, registration, industrial transfer, etc. are also being produced here, all implementing the most advanced recommendations to date such as Design of Experiments (DoE) in development and Quality By Design (QbD) and Process Analytical Technology (PAT) in the industrialisation phase.

The Pharmaceutical Innovation area has also collaborated with an external network of Development Centres and international partners to tackle projects using technologies not available internally and thereby complete a portfolio with great innovative potential.

### **In 2015 the following projects** were carried out:

- Generics: In total, 11 generics projects were carried out internally and five projects externally. Of these, three have formulations protected by patent.
- New chemical entities: A response has been made to the pharmaceutical drug and development requirements of the two products currently under research as part of the collaboration agreement signed with Mundipharma. Different pharmaceutical formulations and new doses of Saco and Sigma have been developed, completing the pharmaceutical requirements to present an application for clinical trials, as well as the necessary drugs to carry these out, both for Phase I and also for Phase II/III.

- Continual control in process has been introduced in two products via near infrared technology (NIR), improving the reliability of production processes and reducing analysis times.
- A new model has been implemented to extrapolate results from stability tests, helping to predict the performance of formulations in terms of their stability. This technique reduces the number of analyses required as well as predicting the shelf life of a specialty according to the type of packaging used.
- A laboratory information management system has been implemented to reduce and improve the time required for analyses.
- New pharmaceutical technologies have been introduced (Hotmelt extrusion, capacity to coat with organic solvents) and processes have been automated in the pilot plant and analysis laboratory (blister packer, automation of dissolve tests).
- The quality project "Més Qualitat" has been implemented, introducing a faster and more efficient view for the quality system.

A new model has been implemented to extrapolate results from stability tests, helping to predict the performance of formulations in terms of their stability.

Throughout the year, these actions have had the following results:



**20 bioequivalence studies** carried out successfully



Completion of **three registration dossiers** to be presented as "First to File" in the United States



Approval of two new registrations: **Dolomidina** and **Duloxetine** in the United States



Presentation for approval of **four new registrations** of generic drugs

## R&D INTO NEW PRODUCTION PROCESSES FOR ACTIVE PHARMACEUTICAL INGREDIENTS (API)

The R&D unit of ESTEVE's Chemicals business focuses on developing innovative production processes for active pharmaceutical ingredients, both new chemical entities and generics.

**In 2015** it collaborated with improvements in the production processes of two new chemical entities for ESTEVE's Pharmaceuticals business.

Dedication to third party projects has increased, taking part in the development and transfer to production plants, both in Spain and also in China and Mexico, of new chemical entities for several multinationals. Generics continued its usual activities, of note being the transfer of several products of different therapeutic activities to the plants in Celrà and China.

Collaboration with other companies has increased in the area of generic products. Work is also being carried out to introduce new technologies, which will be completed in 2016. Some of the generics projects have benefitted from state support via a Centre for Technological Industrial Development.

## 2.2 QUALITY MANAGEMENT

The chemical and pharmaceutical industry is a highly regulated sector in which each stage in the production cycle of a drug is subject to very strict rules to safeguard the health and safety of people and patients.

Of note at ESTEVE is the position of the Pharmaceutical Quality Head, whose role is to safeguard the correct implementation and execution of the Group's Pharmaceutical Quality System, ensuring and being responsible for all products meeting:

- The established quality standards throughout their life cycle.
- The needs of patients, health professionals, authorities and clients.
- The applicable legal and regulatory requirements, both local and international.

ESTEVE complies with the rules guaranteeing drug quality and safety in all processes, from research (GLPs and GCPs<sup>11</sup>) to production (GMPs<sup>12</sup> and Act 29/2006, of 26 July, on Guarantees and the Rational Use of Drugs) and the distribution of drugs for human use (GDPs<sup>13</sup> and 2013/C 343/01). This applies to all ESTEVE's production plants located in different countries (Spain, Mexico and China). The Quality Management system applied is the same for all API production centres.

ESTEVE has Quality Management Systems (QMS) based on GMP compliance as well as compliance with other equivalent standards and guidelines, such as those developed by the ICH (International Conference on Harmonisation). The key elements of the QMS are as follows:

- a) Control of production-related incidents: evaluated via a system to detect deviations, with corrective and preventative actions.
- b) Change management: to handle changes affecting production, analysis, teams, systems and relevant GMP procedures so that they can be evaluated in order to minimise risks.
- c) Batch release. In the case of drugs, each batch of finished product is certified by a qualified person before being released for sale, supply within the country or export in order to guarantee that the product has been made in accordance with the GMPs and the Sales Authorisation.
- d) Programme of inspections carried out by ESTEVE:
  - Internal: auditing both the Quality System and the different departments involved in producing and controlling drugs and APIs, whose aim is to verify the degree of GMP compliance for the processes carried out.
  - External: all suppliers of active ingredients and key raw materials as well as other suppliers related to GMP and GDP activities are evaluated in accordance with the pre-established policy.
- e) Inspections carried out by third parties. Both clients and authorities regularly inspect all production plants to confirm compliance with standards and to have the necessary guarantees.

In 2015 there were three product recalls, although none of these had any repercussions for people's health.

**11**  
Good Laboratory Practices and Good Clinical Practices.

**12**  
Good Manufacturing Practices.

**13**  
Good Practices for the correct distribution of drugs for human use.

[G4-DMA, G4-14, G4-PR1 , G4-PR2]



Up to the end of 2015 Esteve Química had presented 49 DMF (Drug Master Files<sup>14</sup>): 25 in the United States, 8 in Canada, 6 in Korea, 7 in Japan and 2 in China, as well as 21 CEPs (Certificate of Suitability European Pharmacopoeia<sup>15</sup>) in Europe.

## 2.3 PHARMACOVIGILANCE MANAGEMENT

In 2015 all pharmacovigilance duties were carried out at a corporate level, involving more than 980 product registrations which include over 180 active ingredients sold in more than 10 countries of the European Union.

The **most important activities** carried out in **2015** were as follows:

- Training sessions were carried out on pharmacovigilance for various internal and external groups.
- Very close monitoring and revision of safety in all adverse events occurring in Phase I and II clinical trials with drugs under research E-52862 and E-58425 and ongoing assessment of the risk/benefit ratio for these drugs.
- Collaboration with Mundipharma in establishing specific security agreements to exchange information on the E-52862 and E-58425 molecules under development.
- Activities to detect safety signals with all adverse reactions received. In 2015 no safety warning occurred with drugs sold in Europe.

ESTEVE's pharmacovigilance system has been audited by one of the licensors, as well as by the department to ensure R&D quality, with satisfactory results. Four subsidiaries were also audited (Germany, Italy, Portugal and Sweden), as well as external suppliers in Germany and Sweden. No significant observations were detected.

In 2015, the EMA (European Medicines Agency) implemented processes to improve coordination of European pharmacovigilance systems between all member States, involving changes and new procedures to communication safety information between the pharmaceutical industry and patients, healthcare professionals and regulatory authorities, as well as increasing transparency in areas of safety information for the population at large.

## 2.4 PROJECTS AIMED AT PATIENTS

As part of its commitment to add value as a relevant partner in the system, ESTEVE has made chronic illnesses its main focus of innovation in the area of health, carrying out different projects that aim to improve the quality of life of chronic patients.

Chronic illnesses are the main cause of death and disability in the world and account for around 80% of healthcare spending. The ageing population and gradual increase in the prevalence of these pathologies therefore threaten the sustainability of health systems and innovation in health is consequently an essential instrument in tackling chronic illnesses.

### 14

Document describing the quality of a product, including the technical specifications, analytical methods and processes required to make and sell the product.

### 15

Document describing the quality of a product, evaluated by the EU Pharmacopoeia and allowing it to be sent to any EU member state.

[G4-DMA, G4-PR1, G4-PR2]

## ESTEVE'S COMMITMENT TO CHRONIC PATIENTS

ESTEVE aims to collaborate in preventing chronic pathologies, stimulating and facilitating innovation among healthcare professionals, encouraging the participation of different agents between different levels of the system and promoting research, training and the management of knowledge in this field, via the following projects:

NAME	PROJECT DESCRIPTION	RESULTS IN 2015
<b>CRONEXA</b>	A multidisciplinary alliance promoted by ESTEVE, SEMI (Spanish Society of Internal Medicine) and semFYC (Spanish Society of Family and Community Medicine) with the aim of providing solutions to the key challenges posed by chronic illness for health professionals in their daily work.	A training course has been produced for medical personnel, covering four areas: adherence, therapeutic inertia, treatment suitability and self-care.  This course will be implemented in 2016.
<b>EXPERTSALUD</b>	A service offered by ESTEVE to help chronic patients manage their health better. By means of a free app, patients can arrange when they take their medicine, programme alerts and monitor key clinical variables. This has been endorsed by 10 Scientific Societies.	ESTEVE has presented the app to the public health departments of various autonomous communities in Spain as well as private health insurance firms. In the autonomous community of Catalonia two collaboration agreements have been signed with public bodies: TIC-Salut and the Catalan Health Institute.
<b>VACS PROJECT (HEALTH SKILLS ASSESSMENT)</b>	Study carried out in collaboration with ESTEVE and the Global Institute of Public Health and Health Policy of the International University of Catalonia (IUC), endorsed by the Spanish Patient Forum.  It will be used to detect those patients who will obtain the most benefit from group skills training (an "expert patient" scheme) and/or those who will need individual monitoring to improve the self-care of their illness.	The instrument has been designed to identify, intuitively and quickly, those people with poor health skills (knowledge, habits, etc.) to help medical centres carry out a more individualised monitoring of patients that helps them with their self-care.
<b>EXPERT PATIENT SCHEMES</b>	Programme by ESTEVE and the Catalan Health Institute, the first of its kind in Spain. It started in 2006 as an initiative in which the main agent is the expert patient him or herself, passing on knowledge and skills to other people suffering from the same chronic health disorder.	The collaboration in 2015 involved extending the scheme and also Designing the Future seminars: "Person-Centred Care, a shared goal".
<b>ACTIVE PATIENT</b>	Programme sponsored by ESTEVE, among others, that aims to help patients improve their knowledge of their illness and their self-control, achieving better results in health and optimising healthcare resources.	Programme implementing the expert patient model of Stanford University (USA) in the Community of Valencia in 2015, which will continue throughout 2016.
<b>UNIVERSITY OF PATIENTS</b>	This initiative came out of the collaboration between ESTEVE and the Josep Laporte Foundation (currently Fundació Salut i Entorn - FSIE) and the Autonomous University of Barcelona in order to carry out information and training activities aimed at patients.	The collaboration agreement between ESTEVE and the FSIE was renewed, comprising the new "Doctor visit kit" (Cantabria) and a study of qualitative usability for the ExpertSalud app (Catalonia).



NAME	PROJECT DESCRIPTION	RESULTS IN 2015
<b>MEDAFAR</b>	Programme carried out with the Pharmaceutical Care Foundation and SEMERGEN (Spanish Society of Primary Healthcare Doctors) to improve coordination between GPs and local pharmacists regarding patients with possible drug-related problems.	This was presented in the autonomous communities of Valencia and Extremadura in order to implement a pilot study.
<b>CONECTA72</b>	ESTEVE, together with the Galician Health Service - SERGAS, has co-developed the dissemination of a programme to improve continued assistance for patients once they have left hospital. Within 72 after they leave hospital, a health professional contacts patients to check they have understood the care and medication prescribed.	This programme will be implemented in all hospitals and health centres in Galicia in 2016.

## ONLINE SERVICES AIMED AT PATIENTS

The main therapeutic areas of ESTEVE's pharmaceutical activity have online initiatives to offer patients useful, top quality information and tools. Patients can access the websites directly or through their healthcare professional.



Available at  
**[www.esteve.com](http://www.esteve.com)**

# 03.

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## Clients

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*The Company relates  
to its clients through various  
communication channels,  
both face-to-face as well as  
virtual.*



**40**

product launches



Training for over

**48,000**

health professionals



**+7%**

increase in website clients

# 03.

## Clients

Through its three business areas (Pharmaceuticals, Generics, and Chemicals), ESTEVE has an extensive range of clients, although primarily health professionals, public administration and other pharmaceutical companies.

The Company relates to its clients through various communication channels, both face-to-face (representative visits, training courses, congresses and specialised seminars, etc.) as well as virtual (corporate website, presence on social networks, etc.).

### 3.1 NEW PRODUCT LAUNCHES

In 2015, ESTEVE carried out 40 product launches<sup>16</sup> through its different business units:

Innovative drugs:

**2**

Pharmacy products:

**3**

Generic drugs:

**32**

Active pharmaceutical ingredients:

**3**

### 3.2 HEALTH PROFESSIONALS

> Marketing innovative drugs



Via its network of representatives for medical and pharmaceutical visits, ESTEVE visits in Spain almost

**75,000**  
health professionals



**59,031**  
doctors  
(28,216 GPs and the rest specialists)



**981**  
nurses



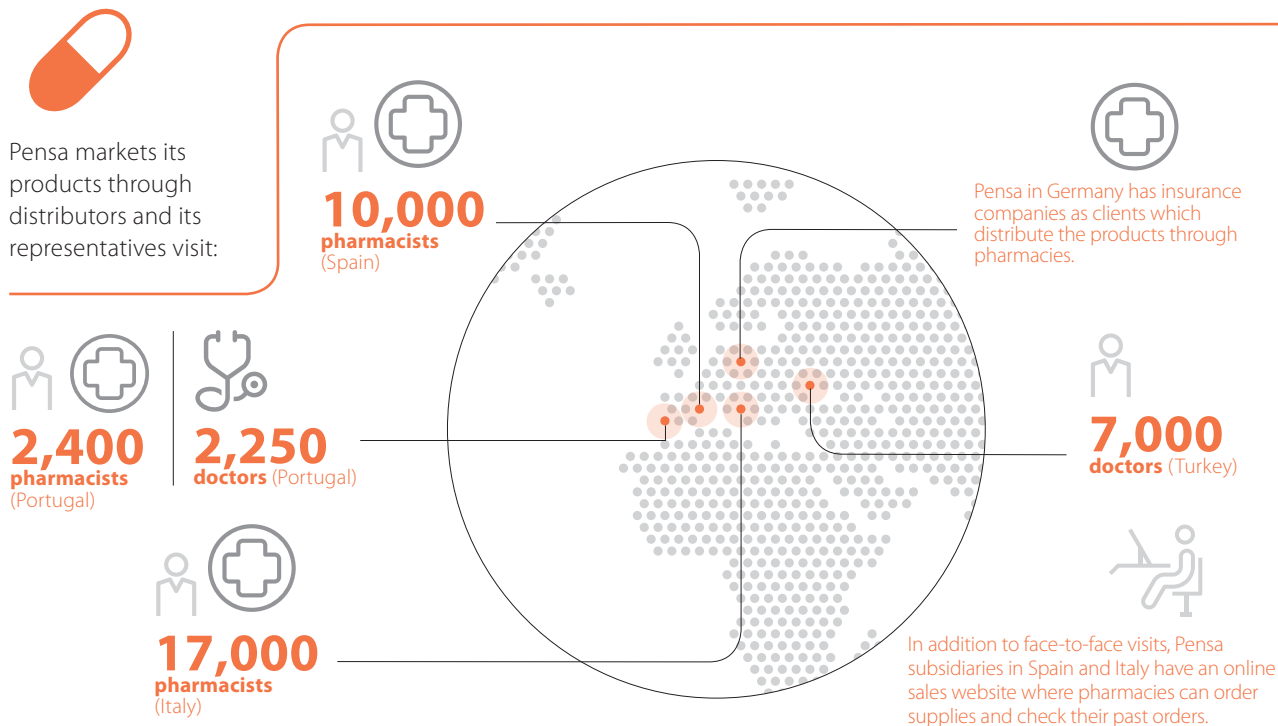
**14,000**  
pharmacists

<sup>16</sup>

Defined as: new presentation/product/market of all ESTEVE's business units and in all geographical areas where the Company operates.



## > Marketing generic drugs





### ONLINE CLIENT RELATIONS

Online client relations have grown progressively (+7% in 2015), reaching 98,800 website users in 2015. This constant virtual dialogue allows ESTEVE to offer a wide range of training and informative activities.

### TRAINING SERVICES AIMED AT HEALTH PROFESSIONALS

The high degree of collaboration enjoyed between ESTEVE and its clients can be seen in the extensive range of training offered by the Company, helping to improve the quality of its clients' services.

		NO. OF COURSES HELD	NO. OF HOURS TRAINING ON COURSES	NO. PROFESSIONALS REGISTERED
	DOCTORS AND PHARMACISTS (CLASS-BASED)	2,202	4,576	26,330
	DOCTORS AND PHARMACISTS (ONLINE)	34	637	22,073
<b>TOTAL</b>		<b>2,236</b>	<b>5,213</b>	<b>48,403</b>

## PHARMACEUTICAL PRODUCT INFORMATION

The main targets for product information are healthcare professionals and patients and this is provided via the following channels:

- **Labelling, leaflets and packs.** Regulated by law and approved by the Spanish Drug and Health Product Agency (AEMPS)<sup>17</sup>, by the corresponding regulatory authority in each EU country or by the EMA (European Medicines Agency), according to the registration procedure being followed in each case. All new registrations include Braille and the rest are gradually being adapted as changes or adaptations are made.
- **Advertising.** All advertising for OTC drugs are presented to the Self-Control bodies and ANEFP (Association for Health Self-Care) for their validation and to obtain the stamp of approval.
- **Medical sales representatives.** Regularly inform healthcare professionals (doctors, pharmacists and veterinary surgeons) of product characteristics, recent studies, new indications, etc.
- **Corporate website.** ESTEVE has a service on its website<sup>18</sup> with information on drugs, as well as an online client attention service.

## 3.3 PUBLIC ADMINISTRATIONS AND PHARMACEUTICAL-HEALTHCARE ORGANISATIONS

In 2015, through ESTEVE's Institutional Relations department, agreements were signed with the following organisations and bodies: Andalusian Council of Official Colleges of Pharmacists, Spanish Society of Health Information, Barcelona University, ASISA, IDIS Foundation, Association of Family and Community Nurses of Catalonia, Spanish Society of Primary Healthcare Pharmacists, Spanish Society of General Practitioners, Pharmaceutical Care Foundation, Official Colleges of Pharmacists in the different provinces and with the regional governments of Catalonia, Castile and Leon, Community of Valencia and Castile-La Mancha. Via these agreements, ESTEVE collaborates in developing programmes and services that improve health solutions and affect the sustainability of the system.

Regarding pharmaceutical business, the Company's opinions are channelled through Farmaindustria (employers' association) in which, since the end of 2014, Antoni Esteve serves as President and different collaborators take part in the 20 specific working groups.

The Company also takes part in ANEFP, the Association for Health Self-Care. Since 2012 ESTEVE's Chief Executive Officer, Albert Esteve, has been one of the Vice-Presidents and Eugeni Sedano has been President of the Institutional Relations committee.

In 2015 ESTEVE also formed part of FENIN, the Spanish Federation of Healthcare Technology Companies, due to the launch of the new ophthalmic surgery unit.

### 17

The sector is currently regulated by: Spanish Act 29/2006 on Guarantees and Rational Use of Medicines; Royal Decree Law 4/2010, on the Rationalisation of Pharmaceutical Expenditure; Royal Decree Law 8/2010, on Extraordinary Measures to Reduce the Public Deficit; Royal Decree Law 1345/2007 on the Authorisation and Registration of Medicines; Royal Decree 1416/1994 governing the Advertising of Medicines for Human Use.

### 18

Restricted area for health professionals to consult regarding ethical products.

[G4-DMA, G4-PR3]





### 3.4 PHARMACEUTICAL FIRMS

Other pharmaceutical companies are also ESTEVE clients, via different models of collaboration:

#### **“OUT” MARKETING LICENCES**

In 2015 ESTEVE signed a distribution agreement with WEIFA AS for its product Dormidina® in Norway and Sweden. The product is already on sale in Portugal and Finland.

#### **DEVELOPMENT, MANUFACTURE AND MARKETING OF DRUGS FOR THIRD PARTIES**

Pensa Dose is the business unit specialising in the development, manufacture and marketing of generic drugs and new chemical entities for other pharmaceutical firms.

Pensa Dose bases its competitive strategy on an approach involving Customer Intimacy and Reliability according to which clients are the main focus of attention in order to understand and respond immediately to their needs. The following was achieved in 2015 as a result of this strategy:

- Renewing its main contracts which expired in 2015.
- Introducing new products to existing clients.
- Consolidating its international expansion in emerging markets.

#### **DEVELOPMENT, MANUFACTURE AND MARKETING OF ACTIVE PHARMACEUTICAL INGREDIENTS FOR THIRD PARTIES**

As it has a relatively small client portfolio, Esteve Química holds regular personalised meetings and is also present at the major trade fairs in its sector. These meetings help to detect clients' concerns and points for improvement so that we can subsequently take joint action to remedy them.

Work focused in 2015 on obtaining and consolidating manufacturing projects for other pharmaceutical companies at ESTEVE's chemical plants in Spain, Mexico and China and on selecting future active ingredients for generic products, for their development and manufacture.



# 04.

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Strategic  
partners,  
suppliers and  
institutions

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*ESTEVE builds alliances and partnerships of value based on cooperation, transparency and open dialogue that help to consolidate stable, long-lasting relations.*



More than

**40**

licence agreements



More than

**30**

collaborations with various institutions



**7**

agreements with special employment centres

## 04.

# Strategic partners, suppliers and institutions

ESTEVE builds alliances and partnerships of value based on cooperation, transparency and open dialogue that help to consolidate stable, long-lasting relations.

## 4.1 STRATEGIC PARTNERS

To maintain a portfolio of innovative pharmaceutical products with high therapeutic value, both the pharmaceuticals and generics areas have established licensing and collaboration agreements with other pharmaceutical firms.

### • “In” licences to market innovative products

In 2015, resulting from new collaboration agreements with companies in the sector, the pharmaceutical area extended its portfolio in Spain with highly innovative drugs and healthcare products. The following are the most significant:

PRODUCT	INDICATION/CATEGORY	PARTNER
DAPAGLIFLOZINA DAPAGLIFLOZINA+METFORMINA	Anti-diabetic SGLT2	AstraZeneca
CORTAGRIP®/COLDZYME®	Cold and 'flu	Enzymatica
OPHTHALMIC SURGERY PORTFOLIO	Intraocular lenses, base solutions, viscoelastic solutions, etc.	VSY Biotechnology

The portfolio of “in” licences for pharmaceuticals in 2015 was as follows:

> 40 PRODUCTS / LICENCES  
> 25 PARTNERS  
PARTNERS FROM EUROPE, USA AND JAPAN








### • Licences to market generic drugs

Pensa ended 2015 with 32 new launches and more than 375 products sold in the subsidiaries where it operates: Spain, Portugal, Italy, Turkey, Nordic countries, Germany and the United States.

## 4.2 STRATEGIC ALLIANCES

### JOINT VENTURES

For years ESTEVE has established joint ventures with other companies to encourage innovation and the development of new products and services in the area of health.

JOINT VENTURES		
ISDIN (1975) 	ISDIN aims to provide skincare with reliable and scientifically proven products and to investigate, develop and sell innovative products for the skin.	50% ESTEVE 50% Puig
Zhejiang Huayi Pharmaceutical (ZHP) (2000) 	Both joint ventures were set up with the Huadong Pharmaceutical Group, one of the leaders in its sector in China.	25% ESTEVE 75% Huadong Pharmaceutical Group
Esteve Huayi Pharmaceutical (EHP) (2005) 		77% ESTEVE 23% Huadong Pharmaceutical Group
Esteve Teijin Healthcare (ETH) (2009) 	Alliance with Teijin Pharma (Japan), home respiratory therapy service.	50% ESTEVE 50% Teijin Pharma
BalanceLabs (2012) 	Alliance with Calidad Pascual to offer products and services for people with special metabolic requirements.	50% ESTEVE 50% Calidad Pascual



### GLOBAL ALLIANCE TO PROMOTE INNOVATION IN THE TREATMENT OF PAIN

In January 2015, Mundipharma-Purdue and ESTEVE signed a global alliance to develop worldwide a new generation of drugs for pain relief. This agreement reaffirms ESTEVE's commitment to constant and sustained investment in R&D&i and to meeting medical needs that are not currently covered, focusing particularly on the area of pain. For Mundipharma-Purdue this represents an opportunity to expand its franchise of innovative treatments for neuropathic pain, severe and moderate pain.

## 4.3 SUPPLIERS

At ESTEVE, the supplier selection process is systematised, focusing on compliance with product and quality technical specifications and also taking account the availability of certified management systems, such as ISO 9001 (Quality), ISO 140001 (Environment) and OHSAS 18001 (Occupational Health and Safety), among others.

As part of its responsible purchasing policy, whenever possible ESTEVE prioritises local supplies and the hiring of staff from special employment centres, with more than 70% of workers being at least 33% disabled. ESTEVE currently collaborates with seven special employment centres.

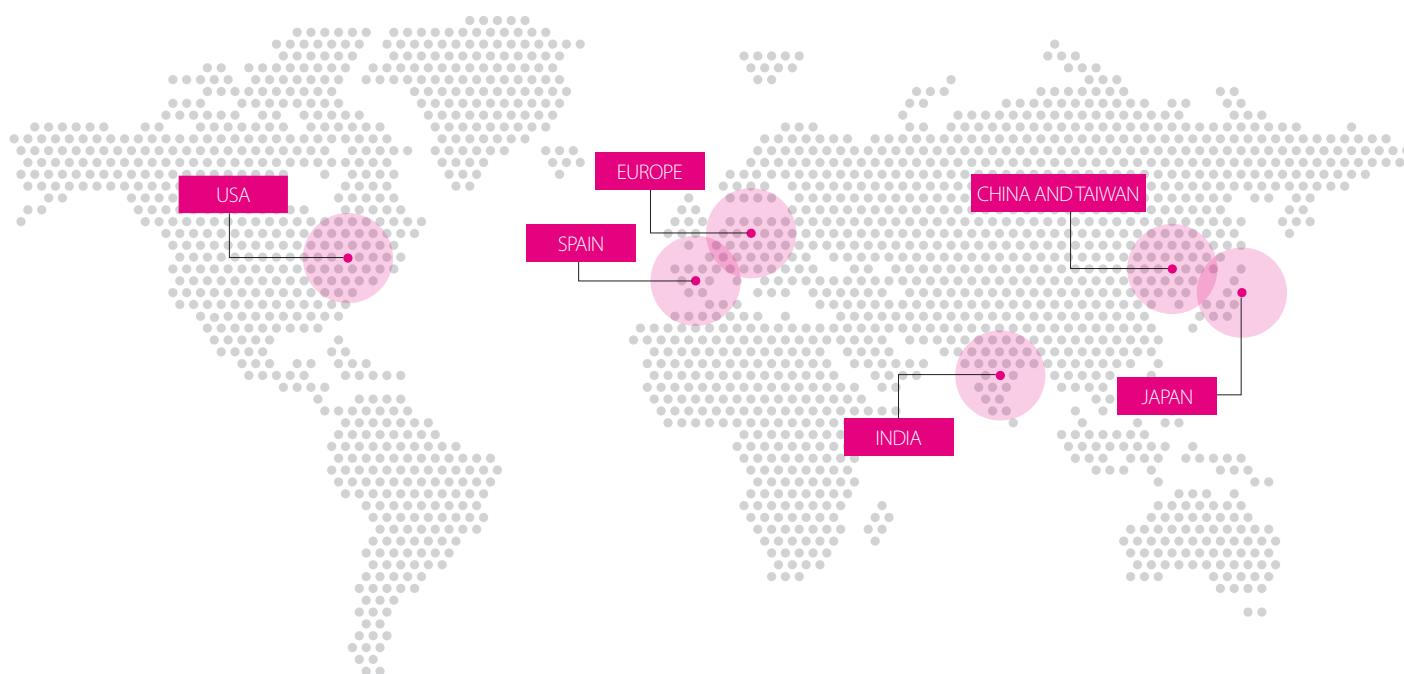


## PHARMACEUTICAL SUPPLIERS

In 2015 the Martorelles pharmaceutical plant (Spain) worked with 80 suppliers of raw materials, of which 67.7% are local<sup>19</sup> and 93.1% European, so that the risk associated with Human Rights is deemed to be almost zero.

### > Geographical distribution of suppliers

	RAW MATERIALS	PACKAGING MATERIAL
REGION OF ORIGIN	FINANCIAL VALUE OF PURCHASES (%)	FINANCIAL VALUE OF PURCHASES (%)
<b>SPAIN (LOCAL)</b>	<b>67.70</b>	<b>78.22</b>
EUROPE	25.43	21.47
CHINA AND TAIWAN	2.91	0
USA	1.34	0.31
JAPAN	0.5	0
INDIA	2.12	0



#### 19

Local suppliers are those whose tax code belongs to the same country where ESTEVE manages its purchases.



## CHEMICAL SUPPLIERS

In 2015 Esteve Química in Spain had 98 raw material suppliers. 37.7% of these purchases came from suppliers from the European Union, 9.3% being local.

Of the 98 raw material suppliers for Esteve Química in China, 98.7% of the purchases came from local suppliers.

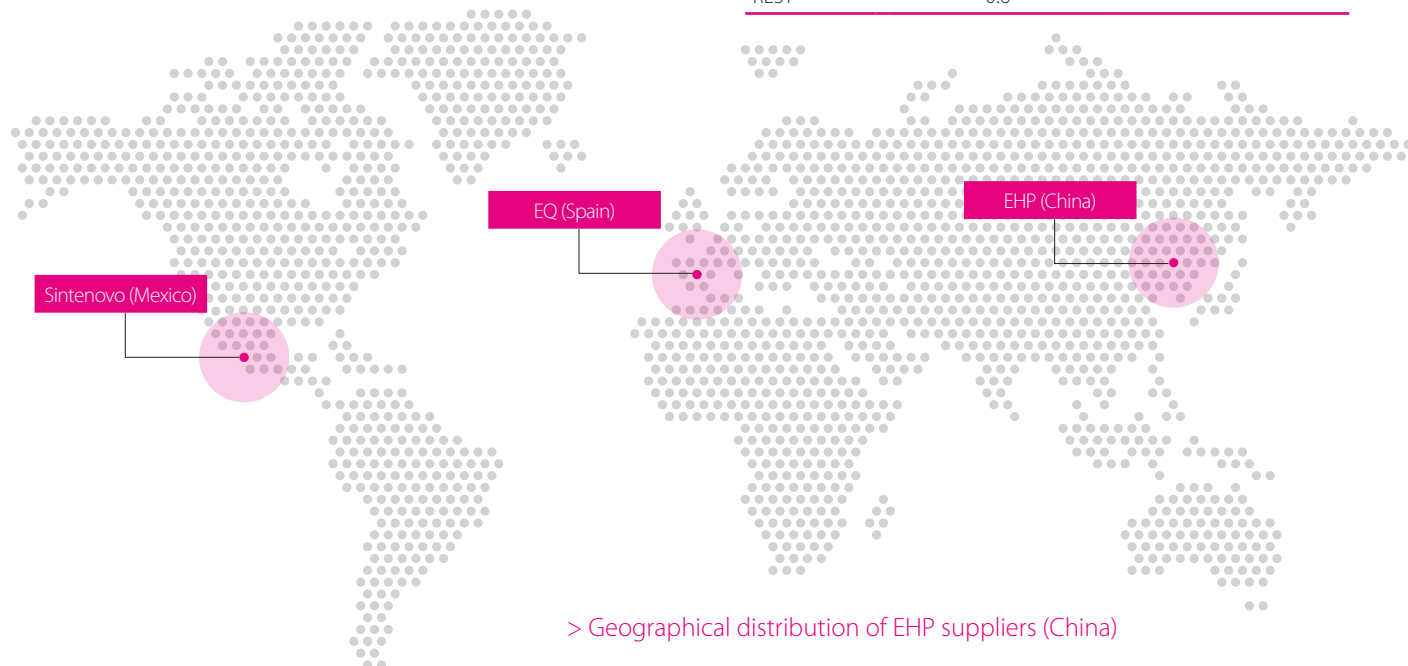
And in Mexico, raw materials were bought from 42 suppliers, 33.4% of these purchases being local.

### > Geographical distribution of SINTENOVO suppliers (Mexico)

	RAW MATERIALS	PACKAGING MATERIAL
REGION OF ORIGIN	FINANCIAL VALUE OF PURCHASES (%)	FINANCIAL VALUE OF PURCHASES (%)
<b>MEXICO</b>	<b>33.4</b>	<b>100</b>
CHINA	32.0	–
USA	20.2	–
SPAIN	6.5	–
EU (EXCEPT SPAIN)	0.2	–
REST	7.7	–

### > Geographical distribution of EQ suppliers (Spain)

	RAW MATERIALS	PACKAGING MATERIAL
REGION OF ORIGIN	FINANCIAL VALUE OF PURCHASES (%)	FINANCIAL VALUE OF PURCHASES (%)
<b>SPAIN</b>	<b>9.3</b>	<b>100</b>
EU (EXCEPT SPAIN)	28.4	–
CHINA	48.0	–
JAPAN	2.7	–
USA	6.6	–
MEXICO	4.4	–
REST	0.6	–



### > Geographical distribution of EHP suppliers (China)

	RAW MATERIALS	PACKAGING MATERIAL
REGION OF ORIGIN	FINANCIAL VALUE OF PURCHASES (%)	FINANCIAL VALUE OF PURCHASES (%)
<b>CHINA</b>	<b>98.7</b>	<b>100</b>
REST	1.3	–





Esteve Química regularly audits key raw material suppliers and no incident was detected in 2015.

The audit questionnaire includes, among other aspects, a specific section to verify compliance with the principles of the Global Compact (Human Rights and Labour Standards). The verification of compliance with these principles has been favourable in all audits carried out.

## 4.4 INSTITUTIONS

ESTEVE collaborates and participates actively in the following institutions:

### INSTITUTIONS IN THE CHEMICAL-PHARMACEUTICAL SECTOR

- Spanish Association for the Pharmaceutical Industry (Farmaindustria)
- Spanish Generic Medicines Association (AESEG)
- Spanish Association of Fine Chemical Manufacturers (AFAQUIM)
- Spanish Association for Biotechnology Firms (ASEBIO)
- Spanish Association for Self-Medication Healthcare (ANEPF)
- Association of the European Self-Medication Industry (AESGP)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Catalan Business Federation for the Chemical Industry (FEDEQUIM)
- Business Federation of the Spanish Chemicals Sector (FEIQUE)
- Spanish Federation of Healthcare Technology Companies (FENIN)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- General Council of Official Colleges of Pharmacists (CGCOF)

### SCIENTIFIC AND RESEARCH ORGANISATIONS

- Academy of Medical Sciences of Catalonia and the Balearic Islands
- Centre for Studies to Promote Research (CEFI)
- Bioregion Foundation of Catalonia
- Catalan Research and Innovation Foundation
- Knowledge and Development Foundation (CYD)
- Foundation for Technological Innovation (COTEC)
- Catalan Chemical Research Institute (ICIQ)
- IQS Foundation
- Royal Academy of Pharmacy of Catalonia
- Royal Academy of Medicine of Catalonia

### INSTITUTIONS FOR CORPORATE SUSTAINABILITY

- Agenda 21 Local Barcelona (Citizen Commitment to Sustainability)
- Council of Companies for Nature (CEN) of Acció Natura
- COASHIQ (Autonomous Commission for Occupational Health & Safety in Chemical and Similar Industries)
- UN Global Compact Network Spain (ASEPAM)
- Respon.cat (Business initiative to develop CSR in Catalonia)

### CULTURAL INSTITUTIONS

- Orfeó Català – Palau de la Música Catalana
- MACBA Foundation (Museum of Contemporary Art of Catalonia)

### ACADEMIC INSTITUTIONS

- University of Santiago de Compostela, Autonomous University of Barcelona, Barcelona University
- ESADE
- IESE

# 05.

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Internal

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collaborators

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*Equal opportunities and respect for diversity are intrinsic to ESTEVE.*

*The Company boosts equal opportunities and promotes non-discrimination due to reasons of gender in its human resources policies.*



**2,278**

people employed worldwide



**89.9%**

of the workforce trained, with an average of 17 hrs/collaborator



**40%**

of the workforce under the performance management system

# 05.

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# Internal

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# collaborators

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ESTEVE's commitment to its collaborators is aimed at their development and at care for the environment in which they carry out their activity. That's why dialogue and participation is encouraged, a good working climate is created, measures are implemented to achieve a work-life balance, company benefits are provided and action is taken to prevent occupational hazards.

## 5.1 EMPLOYMENT AND LABOUR RELATIONS

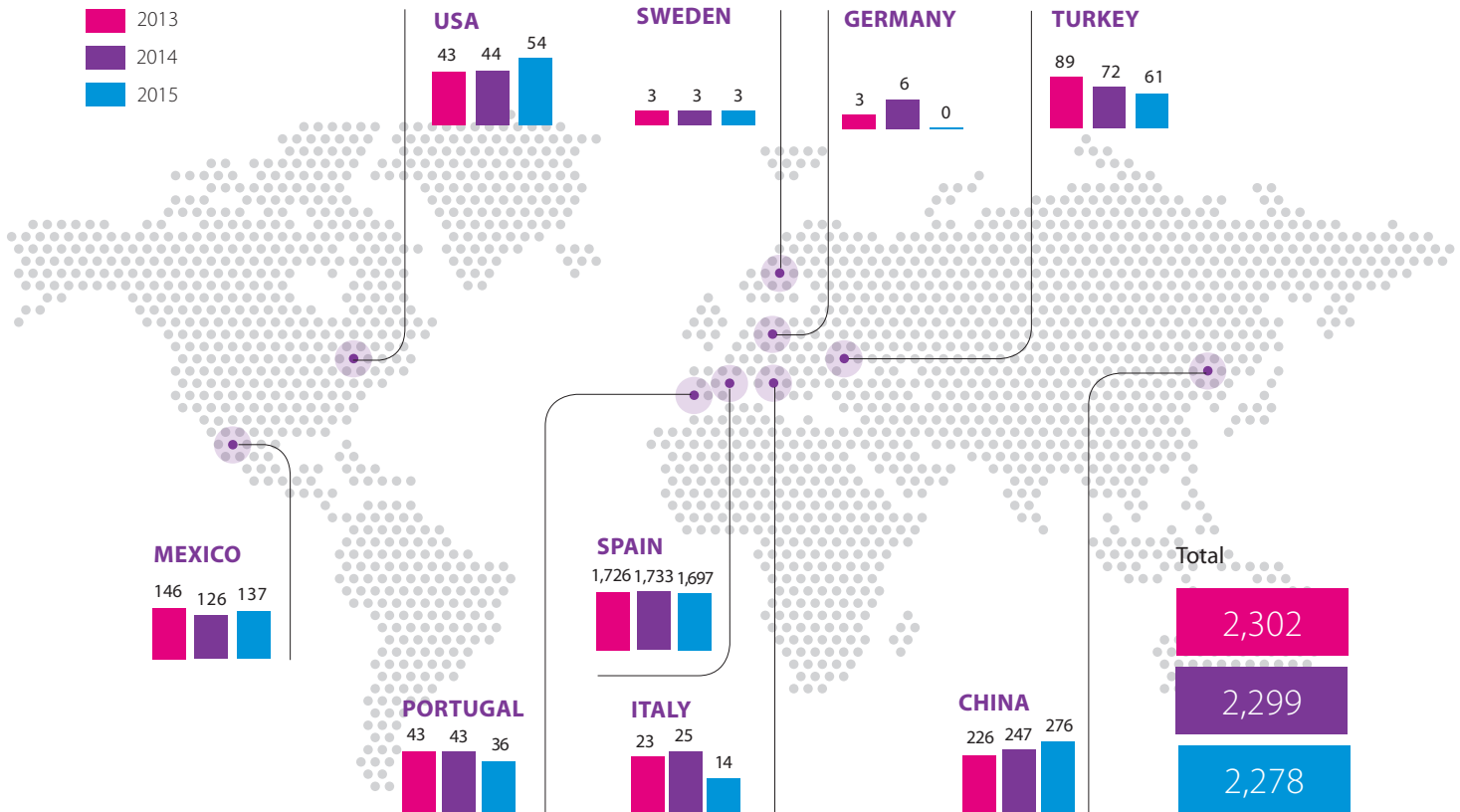
In 2015 the number of ESTEVE employees remained stable in general terms compared with the previous year (-0.9%) although there were variations by country due to the need to adapt the workforce to different business circumstances. The most significant variations were due to the following:

- The sale of the veterinary business with an impact in Spain, Italy, Portugal and Germany.
- The growth in the chemicals business with an impact on the plants in Mexico and China.
- The adaptation of the generics subsidiaries business, decreasing in Turkey and growing in the United States.





## > Number of employees by country

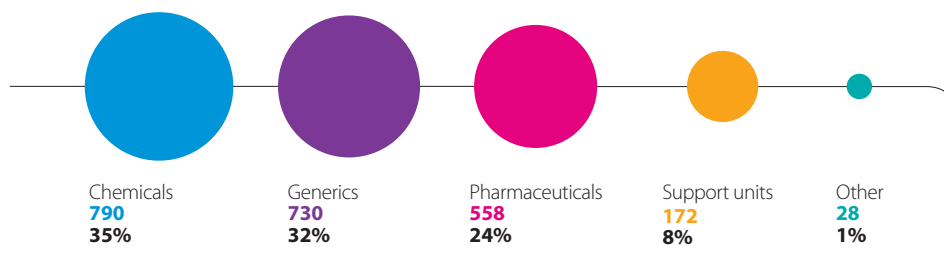


In addition to staff on the payroll, ESTEVE also has 6.6% external personnel<sup>20</sup>.

## NUMBER OF EMPLOYEES BY ACTIVITY

The number of employees by activity has remained similar to the previous year.

## > Employees by activity



**20**

Includes temporary employment agencies and all those people performing a service for ESTEVE on behalf of and responsible to another company.

[G4-9, G4-10]



## TURNOVER AND NEW RECRUITS

The average staff turnover<sup>21</sup> has increased slightly compared with the previous year (from 9.13% to 10.67%) due to the impact of selling the veterinary business and the turnover of the plants in Mexico and China.

New recruits<sup>22</sup> represented 9.88% of the workforce which has meant that the number of employees has remained almost the same as last year.

### > Breakdown of staff turnover<sup>23</sup>:

REGION	Europe: 192 // 10.6%	America: 18 // 9.4%	Asia: 33 // 12%
AGE	<30: 30 // 14.9%	30-50: 160 // 9.7%	> 50: 53 // 12.5%
GENDER	Women: 84 // 9.4%	Men: 159 // 11.5%	

### > Breakdown of new recruits<sup>24</sup>:

REGION	Europe: 121 // 6.4%	America: 40 // 23.5%	Asia: 64 // 26.1%
AGE	<30: 76 // 37.8%	30-50: 136 // 8.2%	> 50: 13 // 3.1%
GENDER	Women: 95 // 10.6%	Men: 130 // 9.4%	

## TYPES OF CONTRACT, WORKING DAY AND WORK-LIFE BALANCE MEASURES

ESTEVE's policy is to provide permanent employment contracts and 87% of its employees have these. This percentage rises to 98% if we exclude China, where temporary contracts are given following customary practices in line with the country's legislation.

Regarding the working day, 96% of the employees are full-time and 4% part-time, compared with 3% the previous year. The demand for part-time work has increased in Spain to improve employees' work-life balance.

#### 21

Average turnover: no. of people leaving per year/workforce at 31/12/2015 x 100.

#### 22

New recruits: no. of new employees joining per year/workforce at 31/12/2015 x 100.

#### 23

Number of employees leaving the Company in absolute terms and as a percentage of this group.



#### 24

Number of new employees joining the Company in absolute terms and as a percentage of this group.

[G4-10]





NO. OF EMPLOYEES	CONTRACT TYPE		WORKING DAY	
	PERMANENT	TEMPORARY	FULL-TIME	PART-TIME <sup>25</sup>
SPAIN	1,659	38	1,617	80
MEXICO	137	0	137	0
PORTUGAL	35	1	35	1
ITALY	14	0	14	0
CHINA	10	256	276	0
USA	53	1	53	1
SWEDEN	3	0	3	0
TURKEY	61	0	61	0
<b>TOTAL</b>	<b>1,972</b>	<b>306</b>	<b>2,196</b>	<b>82</b>
 Men	1,170	210	1,372	8
 Women	802	96	824	74

ESTEVE has implemented measures to balance work and home life, as well as paid leave so that collaborators can develop their careers under the same conditions, irrespective of their family situation.

## LABOUR RELATIONS

ESTEVE pays particular attention to labour relations in all countries where it operates, aimed at successfully handling negotiations with workers' representatives, involving them in the management's goals and challenges for the future and thereby reaching agreements that are satisfactory for both parties. The percentage of employees covered by collective agreements is 87.7%.

ESTEVE's approach to corporate responsibility towards its workers can be seen in the sale of the Veterinary division to Ecuphar in May 2015. Right from the start, one key aspect in the negotiations was that the jobs should be protected.

Ecuphar specialises in animal health and, to date, had not been present in the south of Europe, offering opportunities to grow to the division and to all the professionals of Esteve Veterinaria, taking on the employment conditions of the whole team. During the sale, several informative meetings were held with those affected to resolve any legal doubts involved in this change and to support them throughout the process.

ESTEVE has implemented measures to balance work and home life, as well as paid leave so that collaborators can develop their careers under the same conditions, irrespective of their family situation.

### 25

Part-time contracts and shorter working days are included under "Part-time".

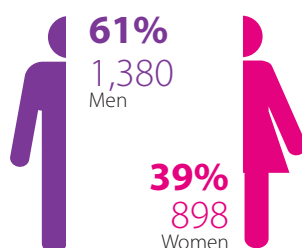
[G4-DMA, G4-10, G4-11, G4-HR4]

## 5.2 DIVERSITY AND EQUALITY

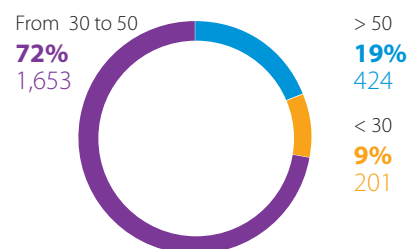
Equal opportunities and respect for diversity form an intrinsic part of ESTEVE's values. The Company boosts equal opportunities and promotes non-discrimination due to reasons of gender in its human resources policies related to recruitment, training, promotion and payment.

### > All employees

#### Employees by gender



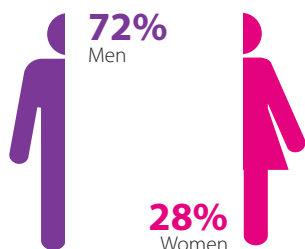
#### Employees by age



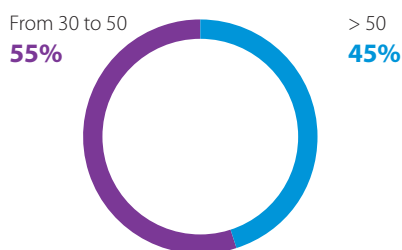
Regarding functional diversity, the percentage of employees with a disability is 0.8% of the whole workforce, of which 50% are women and 50% men.

### > Management Teams

#### Breakdown by gender



#### Breakdown by age



#### Breakdown by nationality







In the Generics subsidiaries 100% of the management posts are filled by locals as a knowledge of the country is fundamental for the business.

On the other hand, the production plants in China and Mexico have Spanish directors (2 and 3 respectively) in order to guarantee ESTEVE's management style is maintained.

## 5.3 TALENT MANAGEMENT

Identifying and developing talent is one of the priorities of the Human Resources Department together with the Company's directors and managers.

### KEY SKILLS FOR THE FUTURE AND CULTURAL CHANGE

To ensure the Company is sustainable, its organisational culture needs to be in line with the new demands of the environment. To this end, in 2015 several cultural change projects were started, defining the key attitudes, skills and behaviours for transformation (ACTs: Spanish acronym for Key Transformation Attitudes).

These projects have been carried out in the Support Units, in Pharmaceuticals and at the Martorelles pharmaceutical plant. The internal collaborators have been involved in defining the (ACTs: Spanish acronym for Key Transformation Attitudes).

The Esteve Digital project should also be noted, whose aim is to manage information more efficiently, boost collaborative work and encourage innovation via online communities.

### PERFORMANCE AND POTENTIAL

Managing performance is a process in which, via regular meetings, supervisors and collaborators exchange information on the goals and skills of the profile in order to improve the match between people and their jobs.

In 2015 significant progress was made in extending this process to more people in the organisation, going from 31% of the workforce in 2014 to 40% in 2015.

Spotting potential among collaborators and its subsequent development is the responsibility of the Directors and Managers together with the Human Resources department and this must help decision-making when the organisation is changing, prioritising internal talent.

In 2015 a project was also started to evaluate and develop leadership among the management staff (90 approximately), which will continue in 2016. In 2015 37% of the team took part.

Identifying and developing talent is one of the priorities of the Human Resources Department together with the Company's directors and managers.

## TRAINING AND DEVELOPMENT

In 2015, training continued to focus on needs resulting from regulatory requirements and job changes, as well as work on a new model which will be implemented in 2016.

	2013	2014	2015
TRAINING HOURS/EMPLOYEE	15.8	16.7	17
TRAINING COVER <sup>26</sup>	94.4%	83.5%	89.9%

## COOPERATION PROGRAMMES WITH EDUCATIONAL CENTRES

ESTEVE supports educational centres as a strategy to encourage training and employment among young people, taking out agreements along two lines:

- 1) Internship agreements: 21 university students, 12 more than the previous year, carried out internships at different ESTEVE work centres.

### > Students on internships



- 2) Master in Fine Chemical Experimentation: a joint initiative between the Autonomous University of Barcelona and Esteve Química. The Master lasts two years.

### > Participation in 2015:



**5**  
students completed  
the Master in  
December 2015  
(7th course)



**6**  
students started  
their first year of the  
Master (8th course)

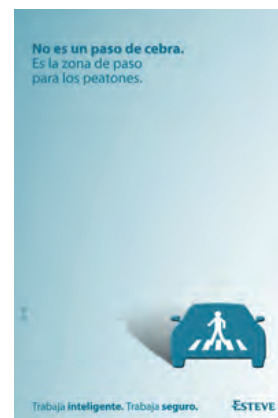


**6**  
students have been  
chosen to start studying  
in January 2016  
(9th course)

**26**

Percentage of people out of the total workforce who, during the year, attended at least one course or seminar.

[G4-DMA, G4-LA9]



## 5.4 HEALTH & SAFETY

ESTEVE strives to ensure that the people who form part of the Company maintain and improve their safety, health and well-being.

To this end, Management Systems have been implemented and are continuously improved, following the international standards OHSAS 18001 in all ESTEVE's production and R&D centres, including mechanisms to involve all workers, audits and key indicators as tools to measure results on a regular basis.

In 2015 the annual follow-up audits were passed satisfactorily in Mexico and Spain and certification renewed in China.

It should be noted that, in 2015, ESTEVE joined the Luxembourg Declaration, undertaking to integrate the basic principles of promoting health at work in managing the health of its workers, as well as complying in the area of preventing occupational hazards.

Procedures have also been carried out to obtain Certification as a Healthy, Safe and Sustainable company to form part of the European network of healthy companies.

ESTEVE promotes well-being and the improvement of health through actions and campaigns aimed at minimising accidents, incidents and illnesses:

- **Information and recommendations:** information is provided at sales team meetings, on noticeboards at work centres and on the intranet, regarding: diet, monitoring cholesterol, diabetes, stress, obesity, recommendations for doing sport, vaccination campaigns, etc.
- **“Work Smart: Work Safe” campaign:** the aim is to raise awareness among internal collaborators and third parties working at the Company's facilities of how to work more safely.
- **“Stop, Think, Act” campaign:** incorporated within the Safety Observations project, which aims to improve the preventative culture, avoiding unsafe behaviour that can cause accidents.

ESTEVE promotes well-being and the improvement of health through actions and campaigns aimed at minimising accidents, incidents and illnesses.



- **Safe, Efficient Driving:** specific campaigns and training videos to reduce traffic accidents during business and private journeys.
- **Healthy Work:** health lies at the core of our mission. Actions are carried out aimed at promoting healthy habits based on the four areas of “Move Europe”: toxic habits, physical activity, healthy diet and stress. The campaign “Move, for you and for them” combines the promotion of healthy exercise as a habit among collaborators and also helping society.



## ACCIDENT RATE

The percentage of accidents leading to sick leave among ESTEVE employees and external workers is as follows:

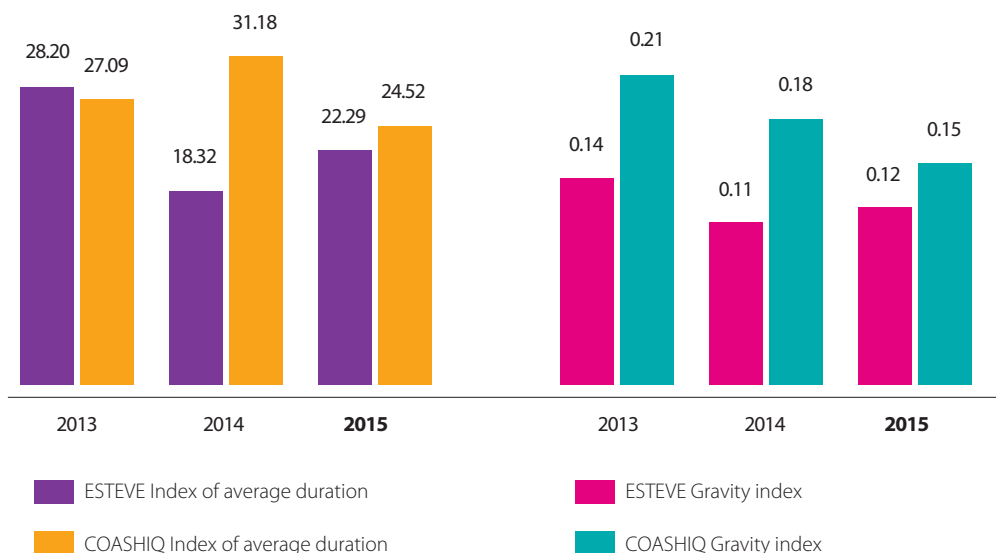
	2013 (%)	2014 (%)	2015 (%)
Accidents WITH sick leave (no. accidents/workers)	0.9	1.1	1.0
Accidents WITHOUT sick leave (no. accidents/workers)	1.5	2.0	1.4
Accidents to/from work W & WO leave (no. accidents to/from work/workers)	0.8	0.4	0.9
<b>Total accidents</b>	<b>3.2</b>	<b>3.5</b>	<b>3.3</b>
Occupational illnesses	0	0.05	0.2
Number of accidents external personnel with sick leave	4	0	3



Unlike accidents occurring to and from the place of work, the total number of accidents occurring to ESTEVE workers at work centres, with and without sick leave, has fallen compared with the previous year.

It should be noted that, although the total days of sick leave have risen by 2% for ESTEVE as a whole<sup>27</sup>, due mainly to a single accident in the area of Generics sales in Spain, the figures for Gravity rates<sup>28</sup> and average duration have remained below the average for the sector, especially in the case of the Gravity index:

### > Gravity and average duration of the accidents



It should also be noted that ESTEVE has received an incentive for its contribution to reducing accidents in the workplace, for its compliance with the requirements established by Spanish law.

During the reporting period, no accident occurred either with ESTEVE or external personnel with fatalities. All the accidents were slight and the incidence of occupational illnesses, specific or high risk, was zero.

### ABSENTEEISM AT WORK

The absenteeism rate<sup>29</sup> at ESTEVE in Spain for 2015 was 2.7%, only 0.3% higher than last year's rate. For the rest of the regions, the figure remained the same at 2.5% in the case of America and at 1.1% in Asia.

**27**  
Not including data for subsidiaries in Turkey, Sweden, Germany or the USA.

**28**  
Relates the number of days lost in accidents involving sick leave with the actual hours worked, multiplied by 1,000.

**29**  
This indicator reflects the total hours absent due to medical visits, indisposition, illness and official permits of ESTEVE's workers, within a work day, divided by the number of total theoretical hours that should be worked per year by employees on the payroll, calculated as the average of the absenteeism figures for each of the companies reported.

# 06.

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## Society

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*ESTEVE's commitment to society focuses on three areas of priority: access to health, employment integration and caring for the environment.*



**263**

participants in the Corporate Volunteer Programme



**10.2 tonnes**

of food and

**1.4 tonnes**

of clothes donated



**9,412**

beneficiaries via collaboration with 23 social organisations

## 06. Society

ESTEVE establishes relations of mutual collaboration with institutions from its sector and from civil society in the communities where it operates, has signed up to the 10 principles of the Global Compact since 2002 and is committed to the Sustainable Development Goals (SDG) of the United Nations published in September 2015, which are:



The Company's commitment to society focuses on three areas of priority:

- **Access to health**, especially in developing countries. SDG 2 and 3.
- **Employment integration** of the most vulnerable groups in Spain. SDG 8.
- **Caring for the environment**, supporting projects to restore and improve areas close to its business centres. SDG 13 and 15.

These three areas, in turn, help to reduce poverty (SDG 1) and inequality (SDG 10).





## 6.1 CONTRIBUTION TO SOCIETY

An important part of ESTEVE's social responsibility is developed through collaboration with a range of organisations, prioritising its commitment to health, with local communities and in line with the Company's values.

In 2015, ESTEVE's contribution to society through all its activities (pharmaceuticals, chemicals, generics and support units) was in line with the previous year, both in the number of organisations it has collaborated with and also its investment.

STAKEHOLDER	AMOUNT (€)	NO. OF ORGANISATIONS
HEALTHCARE ORGANISATIONS	547,959	96
PATIENT ORGANISATIONS	48,356	23
CIVIL SOCIETY ORGANISATIONS	405,451	61
<b>TOTAL</b>	<b>1,001,766</b>	<b>180</b>



Social actions form part of the Company's contribution to society and are aimed at people in a more vulnerable situation. These are carried out through non-profit civil society organisations with which the Company maintains a stable, long-term collaboration, a relationship it attempts to strengthen and expand as far as possible.

## 6.2 CORPORATE VOLUNTEERS

The key areas of the corporate volunteer programme are the same as for its social action, emphasising social and environmental problems. Volunteers help to reinforce ESTEVE's relationship with the organisations it also works with for its social actions.

VOLUNTEERS / ORGANISATION / DEGREE OF SATISFACTION	2015
Number of volunteers in field operations	263
Number of volunteers involved in "Move, for you and for them"	260
Number of employees making a financial donation for humanitarian emergencies <sup>30</sup>	284
Number of organisations involved in collaborations	25
Average degree of participant satisfaction	9.4 out of 10

### 30

In 2015 the collaboration with humanitarian emergencies focused on the earthquake in Nepal and the refugee crisis.

[G4-EC1]



## 6.3 OUTSTANDING ACTIONS AND ACHIEVEMENTS



### ACCESS TO HEALTH

#### BY THE COMPANY (SOCIAL ACTION)

##### Drugs donation.

Via **Farmamundi**, 22 shipments to 13 countries via 15 NGOs.

##### Humanitarian aid and Emergencies.

Through the **FAHE of Farmamundi**, 4,800 people attended in 13 countries.

##### Child vaccination.

Participation in the **GAVI Alliance**. 1,184 children vaccinated in Mozambique in 2015 (5,917 children since the start of the collaboration).

##### Operations for children in the Third World.

Via the **CUIDAM programme** of Hospital de Sant Joan de Déu. An 8-year-old child from India was operated for a congenital bladder extrophy, with highly satisfactory results. Since this initiative started ESTEVE has helped to operate on 26 children.

##### Food donation.

Collaboration with the **Barcelona Food Bank** since 2003. 555 beneficiaries in 2015.

#### BY EMPLOYEES (CORPORATE VOLUNTEERS)

##### “Saint George with a heart”

Accompanying, handing out roses and books to the elderly at the El Caliu Home and to mothers at risk of social exclusion at the Santa Isabel Home. April 23.

##### “SOS Nepal” and “SOS Refugees”.

Financial donations by ESTEVE employees for these two humanitarian emergencies through the Red Cross and the Humanitarian Aid Fund of Farmamundi, respectively.

##### “We can all give blood”.

Annual blood donation campaign at the ESTEVE facilities in Catalonia with the collaboration of the Blood and Tissue Bank. 49 people gave blood.

##### “Move, for you and for them”.

With two goals: to help improve the health of internal collaborators and to improve access to food for children at risk of exclusion. 102,292 kilometres covered by ESTEVE collaborators: running, walking and cycling, from April to September, and 1,737 children's menus donated via the Dining Room Grants programme of Aldeas Infantiles.

##### Food collection campaign.

6th campaign to collect food before Christmas by collaborators at an international level and the 2nd before summer in Catalonia. Result: 10.2 tonnes of food collected (the Company doubles the contribution made by the employees).

Participation in collecting food at supermarkets in six provinces and collaboration in sorting food at the Barcelona Food Bank for its subsequent distribution. 130 tonnes of food sorted.



## EMPLOYMENT INTEGRATION

### BY THE COMPANY (SOCIAL ACTION)

#### **Fostering Talent programme of the Princesa de Girona Foundation.**

The aim is to increase the employability of young people with higher qualifications from disadvantaged backgrounds.

#### **Class of Entrepreneurs: Learn and venture - by the Prevent Foundation.**

Focused on providing disabled people with the necessary knowledge to create or accelerate a company, combining training and mentoring.

#### **Paidós project by Cáritas.**

The aim is to eradicate the consequences of hereditary poverty and stop it from becoming chronic. ESTEVE's contribution was used for housing, education, employment and socialisation.

### BY EMPLOYEES (CORPORATE VOLUNTEERS)

#### **"Fostering Talent".**

Three ESTEVE mentors accompanied three young people while they were looking for work or changing their job.

#### **"Class of entrepreneurs".**

Three ESTEVE volunteers took part in the class as trainers, tutors and mentors. One of the young people mentored by an ESTEVE volunteer won a scholarship to start up his project.

#### **"Give your clothes new life".**

2nd campaign to collect clothing in May and October at the centres in Catalonia through the Training and Employment Foundation of Cáritas. 1.4 tonnes of clothes donated.

#### **"Different skills".**

Adaptation of the Fontajau Home (Fundació Ramón Noguera) for the disabled in Girona, with the collaboration of the residents, on October 18.







LOOKING  
AFTER THE  
ENVIRONMENT

BY THE COMPANY  
(SOCIAL ACTION)

**Protecting and restoring habitats.**  
ESTEVE forms part of CEN (Council of Companies for Nature) of the **Acciónnatura** Foundation, helping to protect and restore natural areas.

**Reforestation in Chiapas (Mexico).**  
Project promoted by ECODES which has environmental benefits (conserving biodiversity) and also social benefits (developing the more vulnerable rural population).

**“Reactiva” programme.**  
ESTEVE donates materials no longer in use such as computers, office material, etc. to the Resource Bank for their subsequent distribution to several NGOs in the Third and Fourth World. The contribution in 2015 was given to Pont Solidari.

BY EMPLOYEES  
(CORPORATE VOLUNTEERS)

**“Environment Seminars” in collaboration with Acciónnatura.**  
Removal of exotic species, planting indigenous species and ringing birds at the Riera de Sant Miquel in Banyeres del Penedès and the Torrent de Can Sunyer in Martorelles. April 19.





## 6.4 DR. ANTONIO ESTEVE FOUNDATION

This was created in 1983 by the children of Dr. Antonio Esteve i Subirana to honour the memory of their father. The Foundation operates with total independence from ESTEVE's companies and its main aim is to stimulate progress in pharmaceutical therapies by means of communication and scientific discussion.

In 2015, 56 events were organised and 33 publications generated (see the table). The following were particularly of note:

- International meeting on philanthropy and research
- Awarding the 14th Research Prize
- 26 training seminars (two of them in Mexico)
- Design and start-up of an online course on scientific writing
- Participation in a training workshop in Toulouse
- Inauguration of prizes for innovation in teaching
- Participation in 2 scientific congresses (SEE in Santiago de Compostela and SEF in Valencia).



The Foundation organises scientific activities and coordinates different formats of publications which are distributed free of charge on the website at **[www.esteve.org](http://www.esteve.org)**

### > Initiatives by the Dr. Antonio Esteve Foundation

ACTIVITIES AND PUBLICATIONS	2015	TOTAL <sup>A</sup> 1983-2015
EVENTS		
INTERNATIONAL MEETINGS	1	27
ROUND TABLES, SEMINARS AND DEBATES	31	193
OTHER ACTIVITIES <sup>B</sup>	24	203
<b>TOTAL ACTIVITIES</b>	<b>56</b>	<b>423</b>
PUBLICATIONS		
BOOKS AND NOTEBOOKS	3	92
ARTICLES	25	185
OTHER PUBLICATIONS <sup>C</sup>	5	16
<b>TOTAL PUBLICATIONS</b>	<b>33</b>	<b>293</b>



**A**  
Cumulative total of 716 initiatives (events and publications) since 1983.

**B**  
Includes conferences, research prizes and special collaborations, book presentations, various activities.

**C**  
Other publication formats for general release.

# 07.

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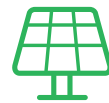
## Environment

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*ESTEVE's responsibility  
towards the environment  
can be seen in its  
certification for its ISO 14001  
management system at all  
its production plants.*



**5,000**m<sup>2</sup>

of photovoltaic panels to reduce  
140 tonnes of CO<sub>2</sub>



Offsetting

**374** tonnes

of CO<sub>2</sub> emissions



**9.4**M€

invested in the environment

# 07.

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# Environment

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ESTEVE's responsibility towards the Environment can be seen in its certification for its ISO 14001 management system at all its production plants (in Spain, Mexico and China). These systems are based on continued improvement and include audits and key indicators to regularly measure results. This certification covers all the work carried out by ESTEVE such as its R&D, production of active ingredients and the manufacture and marketing of pharmaceutical products.

The latest and most demanding criteria of environmental management are also taken into account, beyond the current legislative requirements.

In 2015 all the annual control audits were passed satisfactorily and the ISO 14001:2014 renewed in China.

Optimising resources and managing their consumption responsibly is one of ESTEVE's key areas of environmental action in those countries where the Company has a presence.

## 7.1 OPTIMISING RESOURCES

Optimising resources and managing their consumption responsibly is one of ESTEVE's key areas of environmental action in those countries where the Company has a presence.

These variations are essentially due to the variety of the portfolio of chemical products produced and to the activity of the Martorelles pharmaceutical plant during the weekend, which involves a reduction in performance due to various services being required (steam, compressed air, heating/air conditioning, etc.) even though not all the production lines were being used.

Regarding the consumption of raw materials, although the overall figure rose by 18%, 3.4% of the total is reinvested in the processes themselves, resulting in the re-use of 722 tonnes of solvents in the Chemicals area, for example.

In 2015 the mains electricity consumed by the centres in Spain mostly (91%) came from renewable sources and, in the centres outside Spain, an evaluation has begun of the viability of using such sources of energy.

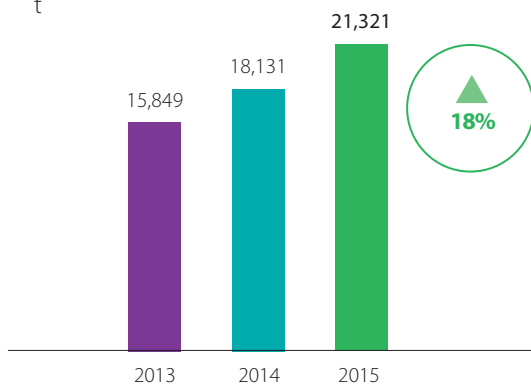
It should be noted that, of ESTEVE's total water consumption, 90% comes from the municipal supply and 10% from underground water, with 8% of the volume being reused.



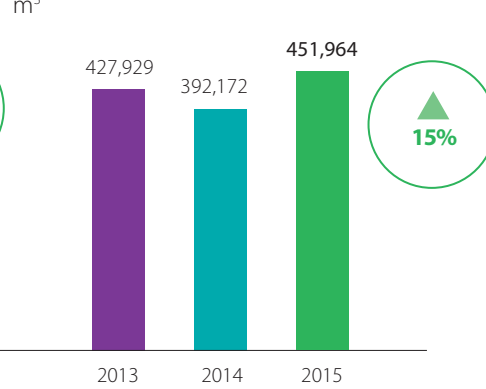


### > Consumption of raw materials

t

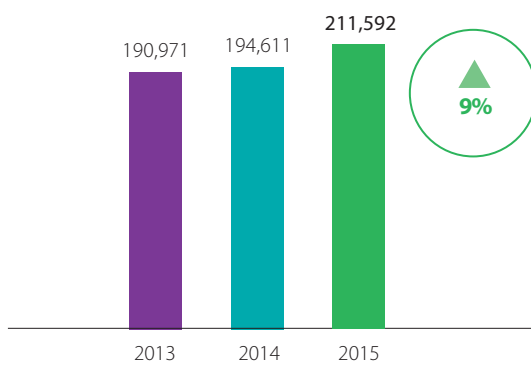


### > Consumption of water

m<sup>3</sup>

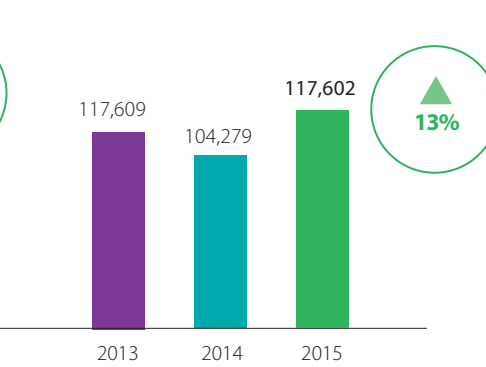
### > Consumption of electricity

GJoules



### > Consumption of gas

GJoules



[G4-EN1, G4-EN2, G4-EN3,  
G4-EN6, G4-EN8]

## 7.2 CLIMATE CHANGE AND EMISSIONS

ESTEVE is committed to combating climate change and, as a result, since 2009 has been part of the United Nations “Caring for Climate” programme.

Voluntarily actions are carried out to reduce the consumption of electricity and CO<sub>2</sub> emissions, incorporating renewable energy sources, implementing improvements in the facilities and promoting sustainable behaviour.

ESTEVE’s commitment to combat climate change can be seen in the campaign **“Add your gesture, take away CO<sub>2</sub>”**. The following key actions were carried out in 2015:

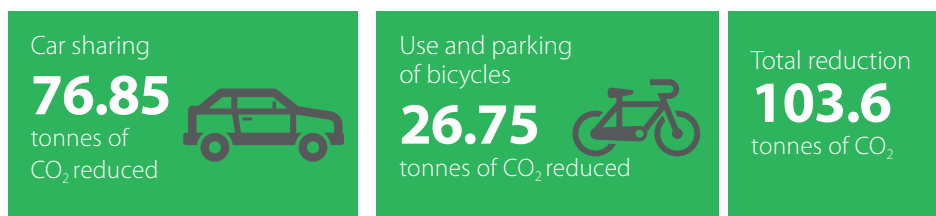
- Green energy: renewal, for the third consecutive year, of the purchase of energy from renewable sources by the centres in Spain.
- Carrying out projects resulting from the energy audits at centres with the highest consumption levels in Spain, aimed at reducing costs, consumption and CO<sub>2</sub> emissions. In Generics, the following actions at the Martorelles plant were particularly significant:
  - Installation of 5,000 square metres of photovoltaic panels to produce electricity for the plant’s consumption. Since it was connected and switched on in September 2015, this system has generated a total of 95,734 kW, a reduction of 65 tonnes of CO<sub>2</sub>.
  - Replacing 860 lights in the zones of Picking, Uhlmann 3 and 4 and Pellets 2 with ECO-TUBO fluorescent tubes (T-5 with electronic ballast), with an estimated reduction of 142,416 kWh and 38,156 kg of CO<sub>2</sub>.
  - Optimising consumption by using BlauEnergy energy management software.

[G4-DMA]





- Campaign to raise awareness of Mexico's collaborators regarding the importance of individual actions in reducing CO<sub>2</sub> emissions. The key points covered by the campaign are: heating and air conditioning, lighting, switching off electronic equipment when not in use, transport to meetings and the responsible use of transport.
- Reduction of 104 tonnes of CO<sub>2</sub> from implementing ESTEVE's Sustainable Mobility Plan: describing the daily mobility options available to collaborators in Spain and proposing more sustainable alternatives in line with the specific situation of each centre. In 2015 the following was achieved:

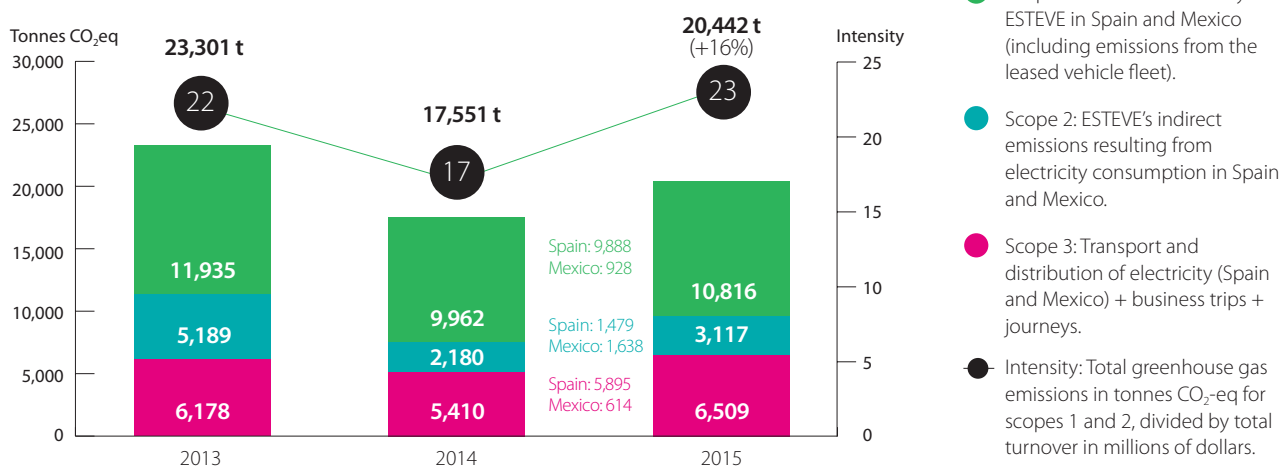


We encourage the use of public transport and bicycles, the use of new technologies to avoid having to travel, and safe, efficient driving by disseminating awareness-raising videos.

Offsetting 374 tonnes of CO<sub>2</sub> through a reforestation project in Chiapas (Mexico), promoted by ECODES as part of the Zero CO<sub>2</sub> initiative. Apart from helping to combat climate change, this project also has environmental benefits (conservation of biodiversity) and social benefits (development aid for the more vulnerable rural population).

Preparing and managing the annual greenhouse gas inventory in Spain and Mexico, according to the *Greenhouse Gas Protocol (GHG protocol)*. The results can be seen below:

## > Annual greenhouse gas inventory



[G4-DMA, G4-EN15, G4-EN16, G4-EN17, G4-EN18, G4-EN19]

In spite of the measures implemented to reduce consumption and emissions, ESTEVE's total emissions have increased by 16% compared with 2014. Essentially this rise is due to the increase in the energy consumed required by the particular mix of products made during the year. However, 2015's emissions are 12% lower than those in 2013 thanks to the efficiency of the control measures implemented, the purchase of Green Energy in Spain and also the monitoring and control of consumption.

## OTHER EMISSIONS

ESTEVE carefully manages and thoroughly monitors each of the environmental factors.

In terms of emissions into the atmosphere, the production plants have piping systems for the gases and vapours generated by the production processes which take them to 'scrubbers' and, in Celrà (Girona), there is also a cryogenic plant and Regenerative Thermal Oxidation (RTO) plant that treats the emissions piped from the scrubbers.

At the Chemicals centres:

- In Spain:
  - Information is provided that's required by the E-PRTR (European Pollutants Release and Transfer Register) on the mass emission of nitrogen oxides (NOx), sulphur oxides (SOx), non-methane volatile organic compounds (NMVOC), emissions of carbon monoxide (CO), dichloromethane (DCM), chlorine and inorganic compounds such as HCl and particulate matter emissions (PM10).
  - Balances of solvents are carried out and reported to verify they comply with the legislation on the emission of volatile organic compounds.
- In Mexico, the total emissions of NOx and particulates (PST) issued into the atmosphere are calculated. The figures for each of these emissions are NOx = 552.7 kg/year, particulates = 59.62 kg/year.

The Company also has gradual plans to replace refrigerant and/or heating gases and equipment affected by regulations on ozone-depleting substances. The equivalent emissions associated with the use of these gases has been quantified as within Scope 1 of the reported GHG emissions and are not very significant in terms of ESTEVE's total emissions.

## 7.3 EFFLUENT AND WASTE MANAGEMENT

### EFFLUENTS

The Company has waste water treatment plants at its chemical production plants in Spain and China and all production centres have control systems to ensure the quality of the waste water disposed is appropriate and remains below the contamination parameters established by the legislation applicable in each country.

All ESTEVE's production plants exhaustively and operationally monitor the waste water parameters established by the local legislation of the country in question. No significant leak was detected in 2015 that could have affected the quality of the waste water.



Information available on the website: <http://prtr.ec.europa.eu>.



ESTEVE does not dispose of any waste water directly into the sea or rivers. All waste water goes into the public sewerage system of the zone in question. In 2015, a total of 350,196 m<sup>3</sup> of waste water was disposed of into the sewerage system, 77% of the total volume.

The breakdown of treated waste water by region is as follows:

ASIA	AMERICA	EUROPE
32%	7%	61%

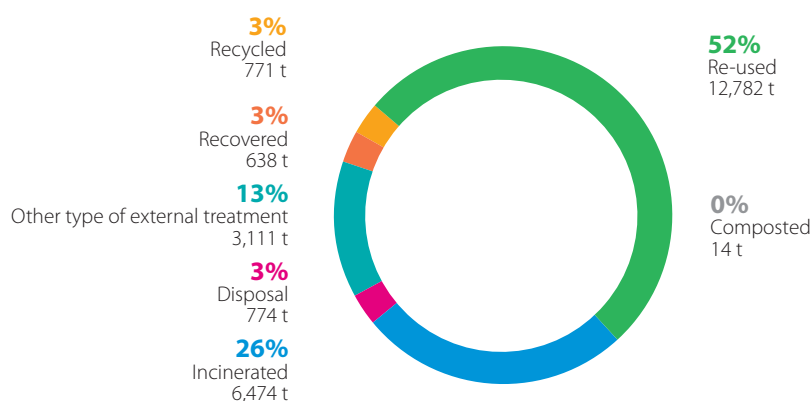
## WASTE

The amount and treatment of waste generated at ESTEVE in 2015 is as follows:

### > Waste 2015



### > Destination/ treatment of waste



The annual quantity of waste depends on the amount of finished product produced and, to a greater extent, on the type and variety of the finished products which generate differing amounts of waste.

Management in terms of the most appropriate treatment and the destination of this waste is carried out bearing in mind the characteristics of each type (composition, degree of hazard, origin, etc.), the environmental legislation of the country where the Group operates and good environmental practices.

ESTEVE continues to carry out actions to minimise the waste generated at source, constantly focusing on the following:

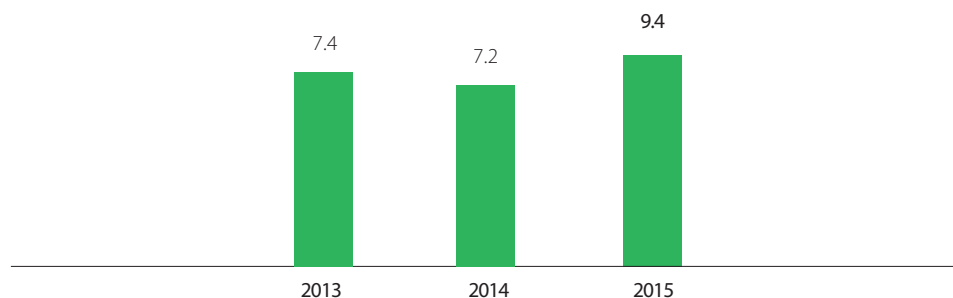
- Optimising production process stages in order to reuse solvents as a raw material at the chemical plants.
- Optimising the generation and management of solvent waste from Chemicals, identifying those with the greatest impact on the environment and costs.
- Improving the separation and recycling of waste from Pharmaceuticals.
- Reusing assets and materials in order to optimise costs, minimise their environmental impact and increase social action through the "Reactiva" programme, in collaboration with the Resources Bank. In 2015, 612 units were handled, mostly IT equipment.
- Reducing the environmental impact of packaging and containers for pharmaceutical products within ESTEVE's Business Prevention Plan, as a member of SIGRE<sup>31</sup> and ECOEMBES<sup>32</sup>.

## ENVIRONMENTAL INVESTMENT

In 2015, ESTEVE allocated investment and expenditure to minimising impact on the environment of various types (principally water and air), to preventing risks and improving working conditions and control installations associated with environmental protection, as shown in the graph:

### > Environmental expenditure and investment

Millions of euros



**31**

SIGRE: Integrated System of Drug Packaging Recovery promoted by the pharmaceutical industry to collect pharmaceutical products and ensure packaging is minimised. For more information see <http://www.sigre.es/>

**32**

ECOEMBES: Non-profit organisation that manages the recovery and recycling of plastic packaging, cans and cartons (yellow recycling bin) and cardboard and paper (blue recycling bin) throughout Spain. For more information see <http://www.ecoembes.com>

The most relevant investment in 2015 was related to reducing and monitoring emissions into the atmosphere and water via installations to conduct and treat emissions, improving condensation capacity, collecting effluent waste and managing water, energy efficiency and savings, etc., in order to improve the management of the most significant environmental areas according to the requirements of each work centre.



## 7.4 PRESERVING BIODIVERSITY

None of ESTEVE's production plants is located within protected natural areas although, due to these facilities being close to some areas of interest, actions are carried out to conserve and improve riverside woodland (willow, alder and poplars) for the Ter (Girona) and the streams from the Parc Serralada Litoral in Martorelles (Barcelona).

In addition to its relations with its immediate environment, ESTEVE has also extended its commitments in these area and forms part of the Council of Companies for Nature of Acciònatura, helping to protect and restore habitats. With recovery projects in the Mediterranean wetlands in Sils (Girona) and Ullals de Panxa (Delta del Ebro-Tarragona), the steppes and temporary lakes at Clot de la Unilla (Lleida), tropical broadleaf woodland in the Biosphere Reserve of Sierra Gorda (Querétaro-Mexico) and other zones of forest and wetlands in Peru and woodland in As Nogais (Lugo-Galicia), as well as work to conserve the Brown Bear in the Pyrenees, which is a threatened species.

It should be noted that ESTEVE printed publications use eco-responsible paper (FSC certified – Forest Stewardship Council).







# 08.

## Commitments

### 8.1 ACHIEVEMENT OF COMMITMENTS 2015

COMMITMENTS	GOALS	DEGREE OF ACHIEVEMENT
<b>Have good practices for corporate governance</b>	• Implement the Code of Ethics in Spain and prepare its international implementation in 2016.	
	• Continue to support public-private partnerships that contribute to the HIVACAT (AIDS vaccine) and Type A Sanfilippo Syndrome projects.	
<b>Improve the health and well-being of society</b>	• Advance in the development of the SIGMA and SACCO projects to improve the quality of life of those suffering from pain.	
	• Draw up ESTEVE's Strategic Plan on chronic illness to respond to the problems and needs of the National Health System and contribute to its sustainability.	
<b>Promote corporate responsibility among our suppliers</b>	• Continue to extend the application of responsible purchasing criteria in the selection and monitoring of the supply chain (general purchases and raw materials at the Martorelles plant).	<b>Postponed until 2016</b>
	• Continue to roll out the performance system to other areas in the Company.	
<b>Encourage an optimum work environment for our collaborators</b>	• Define the type of culture and behaviours required to adapt the Company to the new environment and the demands of society.	
	• Start to implement the Healthy Company model at ESTEVE.	
	• Reduce the accident rate in pharmaceutical, chemical and generics business so that the frequency rates are lower than those of COASHIQ in their respective sectors.	
<b>Collaborate with local communities</b>	• Draw up the CSR Master Plan to respond to the needs of stakeholders and contribute to the Company's sustainability.	
	• Provide employees with new socio-environmental initiatives so that they can participate and contribute voluntarily to alleviate current needs.	
<b>Preserve the environment</b>	• Carry out a technical and legal feasibility study to implement renewable energy projects at the Jiutepec plant in Mexico in order to reduce CO <sub>2</sub> emissions.	
	• Continue to incorporate environmental requirements in the packaging design of our products.	



## 8.2 COMMITMENTS 2016

COMMITMENTS	GOALS
<b>Have good practices for corporate governance</b>	<ul style="list-style-type: none"> <li>• Implement the Code of Ethics and communication channels internationally.</li> <li>• Continue to support research into minority diseases: Sanfilippo A, Sanfilippo B and Hunter's syndrome.</li> </ul>
<b>Improve the health and well-being of society</b>	<ul style="list-style-type: none"> <li>• Continue advancing in the development of the SIGMA and SACCO projects to improve the quality of life of those suffering from pain.</li> <li>• Implement the VACs project (Health Skills Assessment), which will allow healthcare professionals to identify those people at risk of having poor skills (knowledge, habits) in health and to train them to manage their illness better.</li> </ul>
<b>Promote corporate responsibility among our suppliers</b>	<ul style="list-style-type: none"> <li>• Encourage the development of CSR among our main suppliers by creating a model for selecting and evaluating suppliers.</li> <li>• Continue to roll out the performance system to other areas in the Company.</li> </ul>
<b>Encourage an optimum work environment for our collaborators</b>	<ul style="list-style-type: none"> <li>• Implement the second phase of the leadership assessment and development programme.</li> <li>• Implement the Health Company Model and actions to promote health 2016, according to the <i>Move Europe</i> areas.</li> </ul>
<b>Collaborate with local communities</b>	<ul style="list-style-type: none"> <li>• Launch "Smiles", the name and identity of ESTEVE's corporate volunteer programme, implementing the actions planned for all three areas.</li> <li>• Evaluate tools and criteria for analysing the return from social investment.</li> </ul>
<b>Preserve the environment</b>	<ul style="list-style-type: none"> <li>• Sintenovo to join the Clean Industry programme promoted by Mexico's environmental ministry (Phase 1).</li> </ul>

# Appendices

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## **APPENDIX 1. CHARACTERISTICS OF THE REPORT**

### **PARAMETERS OF THE REPORT: PROFILE, SCOPE AND COVERAGE**

This edition of the ESTEVE Sustainability Report for the year 2015 includes information from the period 2013-2015. The document has been prepared based on the main conclusions of the materiality study carried out at the end of 2015. This study helps to accurately define the Company's main stakeholders as well as the most relevant aspects this sustainability report should report on, based on the stakeholders' demands and expectations. The aim of this document is to convey a balanced and reasonable view of ESTEVE's performance regarding sustainability, taking into account the economic situation and the context within which the firm operated in 2015.

This Report has been prepared following the criteria established by the Global Reporting Initiative (standard GRI-G4, core option), which can be consulted at the following website: [www.globalreporting.org](http://www.globalreporting.org). This document has also been verified by an external, independent company, on the request of the Management of ESTEVE Chemical-Pharmaceutical Corporation.

This Sustainability Report reports on the degree of compliance of the principles of the AA1000APS 2008 AccountAbility Principles Standard.

The scope of the Report has been established according to the relevance of the Company's activities, taking into account the diversity of the chemical and pharmaceutical areas and also valuing the different impacts resulting from its production plants and its distribution and sales networks. In this respect, "significant locations of operation" are deemed to be those countries with production facilities (Spain, China and Mexico).

The Report's scope is as follows:

- The economic-financial information includes data from all companies that form part of the ESTEVE Group. The audited consolidated financial statements include 50% of the information from the joint ventures for all items except the figures for expenditure and investment on R&D and industrial assets.
- The information on human resources includes activities carried out at the headquarters, the production plants and the sales delegations in Spain, the chemical production plant at Jiutepec in Mexico, the EHP chemical production plant in China and the sales delegations or subsidiaries in Portugal, Italy, Turkey, Sweden and USA.
- The data for Esteve Veterinaria have been included up to the end of April 2015. After this date the business was sold to Ecuphar.

- The section on preventing occupational hazards includes all the workforce data for Spain, the chemical production plant at Jiutepec in Mexico, the EHP chemical production plant in China and the sales delegations in Italy and Portugal.
- Finally, the chapter on the environment includes data on all the activities in Spain, the chemical production plant at Jiutepec in Mexico, the EHP chemical production plant in China and the sales operations in Italy and Portugal.

## COMPANIES INCLUDED IN THIS REPORT

The ESTEVE group is made up of different companies that operate primarily in the fields of fine pharmaceutical fine chemicals and drugs. The following companies are included in this Report:

### Pharmaceuticals:

- Laboratorios del Dr. Esteve, S.A. (Spain). Dedicated to researching and developing new drugs. It produces and markets drugs for human use.

### Generics:

- Pensa Pharma, S. A. (Spain). Dedicated to marketing generic drugs.
- Pensa Pharma S.p.A. (Italy), Pensa İlaç (Turkey) and Pensa Pharma AB (Sweden). Generic drugs for the Italian, Turkish and Scandinavian market, respectively.
- ToLife-Pensa (Portugal). Portuguese generics subsidiary.
- Breckenridge (USA). Generics subsidiary of Pensa Pharma in the USA.

### Chemicals:

- Esteve Química, S.A. (Spain). Dedicated to researching and developing new processes, producing and marketing active pharmaceutical ingredients.
- Sintenovo, S.A. de C.V. (Mexico). Dedicated to researching, developing and marketing active pharmaceutical ingredients.
- Esteve Huayi Pharmaceutical, Ltd. (China). Dedicated to developing, producing and marketing main active ingredients The Company is also partly owned by the Hangzhou East China Pharmaceutical Group Co., Ltd.



The **2015 Sustainability Report** has been drawn up by a specific committee at ESTEVE, thanks to the collaboration of a large number of professionals from the different areas of the Company. For any issues regarding the 2015 Sustainability Report you can contact:  
CSR Area. Av. Mare de Déu de Montserrat, 221, 08041 Barcelona, Spain; telephone +34 93 446 60 00 or visit the following link: [www.esteve.es/sustainabilityreport](http://www.esteve.es/sustainabilityreport)

## APPENDIX 2. EXTERNAL ASSURANCE REPORT



*Free translation from the original in Spanish. In the event of a discrepancy, the Spanish language version prevails.*

### INDEPENDENT ASSURANCE REPORT ON SUSTAINABILITY REPORT

To the Management of Corporación Químico-Farmacéutica ESTEVE, S.A.:

We have carried out our work to provide limited assurance on the sustainability indicators contained in Appendix "Table of GRI G4 indicators" of the 2015 Sustainability Report (hereinafter "sustainability indicators") of Corporación Químico-Farmacéutica ESTEVE, S.A. and its corporate group (hereinafter "ESTEVE") for the year ended 31 December 2015, prepared in accordance with the general and specific standard disclosures proposed in the Sustainability Reporting Guidelines of the Global Reporting Initiative (GRI) version G4 (hereinafter "GRI G4 Guidelines").

#### Responsibility of the Management ESTEVE

The Management of ESTEVE is responsible for the preparation, content and presentation of the Sustainability Report in accordance with the GRI G4 Guidelines "Core" option. This responsibility includes designing, implementing and maintaining the internal control considered necessary to ensure that the sustainability indicators are free of material misstatement due to fraud or error.

The Management of ESTEVE is also responsible for defining, implementing, adapting and maintaining the management systems from which the necessary information is obtained to prepare the sustainability indicators.

#### Our responsibility

Our responsibility is to issue a limited assurance report based on the procedures that we have carried out and on the evidence that we have obtained. We have carried out our limited assurance engagement in accordance with International Standard on Assurance Engagements 3000 (ISAE 3000) (Revised), "Assurance Engagements other than Audits or Reviews of Historical Financial Information", issued by the International Auditing and Assurance Standards Board (IAASB) of the International Federation of Accountants (IFAC).

A limited assurance engagement is substantially less in scope than a reasonable assurance engagement. Therefore the assurance provided is also less.

The procedures carried out are based on our professional judgement and included enquiries, observation of processes, inspection of documentation, analytical procedures and tests of review, based on sampling, which have generally been as follows:

- Meetings with the personnel of several units of ESTEVE involved in the preparation of the Sustainability Report.
- Analysis of the procedures used to compile and validate the data and information presented in the sustainability indicators.

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- Analysis of the adaptation of the sustainability indicators of ESTEVE to the GRI G4 Sustainability Reporting Guidelines.
- Verification, by review tests applied to a selected sample, testing of internal controls and performance of analytical and substantive tests on the quantitative and qualitative information of the sustainability indicators of ESTEVE. We have also verified that the information has been adequately compiled from the data provided by ESTEVE's sources of information.

#### **Our Independence and Quality Control**

We have complied with the requirement of independence and other requirements of the Code of Ethics for Accountants issued by the International Ethics Standard Board for Accountants (IESBA), based on the main principles of integrity, professional competence and due care, confidentiality and professional conduct.

PwC applies International Standard on Quality Control (ISQC 1) and consequently, our firm has a global quality control system which includes policies and procedures on the compliance of ethical requirements, professional standards and applicable statutory requirements.

#### **Limited Assurance Conclusion**

As a result of the procedures carried out and evidence obtained, nothing has come to our attention that causes us to believe that the sustainability indicators of ESTEVE for the year ended 31 December 2015, contain significant errors or have not been prepared, in all material respects, in accordance with GRI G4 Guidelines.

#### **Use and Distribution**

Our report is issued solely for the Management of ESTEVE, in accordance with the terms and conditions of our engagement letter. We accept no responsibility to third parties other than the Management of ESTEVE.

PricewaterhouseCoopers Auditores S.L.

M<sup>a</sup> Luz Castilla  
13 June 2016

## APPENDIX 3. TABLE OF GRI G4 INDICATORS

GENERAL STANDARD DISCLOSURES	PAGE	DESCRIPTION OF THE INDICATOR
<b>STRATEGY AND ANALYSIS</b>		
<b>G4-1</b>	5	Provide a statement from the most senior decision-maker of the organisation (such as CEO, chair, or equivalent senior position) about the relevance of sustainability to the organisation and the organisation's strategy for addressing sustainability.
<b>ORGANISATIONAL PROFILE</b>		
<b>G4-3</b>	12	Name of the organisation.
<b>G4-4</b>	15	Primary brands, products and services.
<b>G4-5</b>	13	Location of the organisation's headquarters.
<b>G4-6</b>	13	Report the number of countries where the organisation operates, and names of countries where either the organisation has significant operations or that are specifically relevant to the sustainability topics covered in the Report.
<b>G4-7</b>	12	Report the nature of ownership and legal form.
<b>G4-8</b>	15	Report the markets served (including geographic breakdown, sectors served and types of customers and beneficiaries).
<b>G4-9</b>	6, 12, 16, 55	Report the scale of the organisation, including: total number of employees; total number of operations; net sales; total capitalisation broken down in terms of debt and equity and quantity of products or services provided.
<b>G4-10</b>	55, 56, 57, 58	a. Total number of employees by employment contract and gender. b. Total number of permanent employees by employment type and gender. c. Total workforce by employees and supervised workers and by gender. d. Total workforce by region and gender. e. Report whether a substantial portion of the organisation's work is performed by workers who are legally recognised as self-employed, or by individuals other than employees or supervised workers, including employees and supervised employees of contractors. f. Report any significant variations in employment numbers (such as seasonal variations in employment in the tourism or agricultural industries).
<b>G4-11</b>	57	Percentage of total employees covered by collective bargaining agreements.
<b>G4-12</b>	14	Describe the organisation's supply chain.
<b>G4-13</b>	8, 9	Report any significant changes during the reporting period regarding the organisation's size, structure, ownership, or its supply chain, including: <ul style="list-style-type: none"> <li>• Changes in the location of, or changes in, operations, including facility openings, closings and expansions;</li> <li>• Changes in the share capital structure and other capital formation, maintenance and alteration operations (for private sector organisations);</li> <li>• Changes in the location of suppliers, the structure of the supply chain, or in relationships with suppliers, including selection and termination.</li> </ul>
<b>G4-14</b>	21, 22, 23, 24, 25, 34	Report whether and how the precautionary approach or principle is addressed by the organisation.
<b>G4-15</b>	23	List externally developed economic, environmental and social charters, principles or other initiatives to which the organisation subscribes or which it endorses.
<b>G4-16</b>	51	List memberships of associations (such as industry associations) and national or international advocacy organisations the organisation belongs to.

[G4-32]

GENERAL STANDARD DISCLOSURES	PAGE	DESCRIPTION OF THE INDICATOR
<b>IDENTIFIED MATERIAL ASPECTS AND BOUNDARIES</b>		
<b>G4-17</b>	85	a. List all entities included in the organisation's consolidated financial statements or equivalent documents. b. Report whether any entity included in the organisation's consolidated financial statements or equivalent documents is not covered by the Report.
<b>G4-18</b>	18, 19, 20, 84, 85	a. Explain the process for defining the Report content and the aspect boundaries. b. explain how the organisation has implemented the reporting principles for defining report content.
<b>G4-19</b>	20	List all the material aspects identified in the process for defining Report content.
<b>G4-20</b>	18, 19, 20	For each material aspect, report the aspect boundary within the organisation.
<b>G4-21</b>	18, 19, 20	For each material aspect, report the aspect boundary outside the organisation.
<b>G4-22</b>	84	Report the effect of any restatements of information provided in previous reports, and the reasons for such restatements.
<b>G4-23</b>	84	Report significant changes from previous reporting periods in the scope and aspect boundaries.
<b>STAKEHOLDER ENGAGEMENT</b>		
<b>G4-24</b>	19	Provide a list of stakeholder groups engaged by the organisation.
<b>G4-25</b>	18, 19, 20	Report the basis for identification and selection of stakeholders with whom to engage.
<b>G4-26</b>	18, 19, 20	Report the organisation's approach to stakeholder engagement, including frequency of engagement by type and by stakeholder group, and an indication of whether any of the engagement was undertaken specifically as part of the Report preparation process.
<b>G4-27</b>	18, 19, 20	Report key topics and concerns that have been raised through stakeholder engagement, and how the organisation has responded to those key topics and concerns, including through its reporting. Report the stakeholder groups that raised each of the key topics and concerns.
<b>REPORT PROFILE</b>		
<b>G4-28</b>	84	Reporting period.
<b>G4-29</b>	84	Date of most recent previous Report.
<b>G4-30</b>	84	Reporting cycle.
<b>G4-31</b>	85	Provide the contact point for questions regarding the Report or its contents.
<b>G4-32</b>	84, 86, 87, 88	a. Report the 'in accordance' option the organisation has chosen. b. Report the GRI Content Index for the chosen option (see tables below). c. Report the reference to the external assurance report, if the report has been externally assured.
<b>G4-33</b>	84, 85, 86, 87	a. Report the organisation's policy and current practice with regard to seeking external assurance for the Report. b. If not included in the assurance report accompanying the Sustainability Report, report the scope and basis of any external assurance provided. c. Report the relationship between the organisation and the assurance providers. d. Report whether the highest governance body or senior executives are involved in seeking assurance for the organisation's Sustainability Report.



GENERAL STANDARD DISCLOSURES	PAGE	DESCRIPTION OF THE INDICATOR
<b>GOVERNANCE</b>		
<b>G4-34</b>	17	Report the governance structure of the organisation, including committees of the highest governance body. Identify any committees responsible for decision-making on economic, environmental and social impacts.
<b>ETHICS AND INTEGRITY</b>		
<b>G4-56</b>	21, 22	Describe the organisation's values, principles, standards and norms of behaviour such as codes of conduct and codes of ethics.
<b>G4-57</b>	21, 22	Report the internal and external mechanisms for seeking advice on ethical and lawful behaviour, and matters related to organisational integrity, such as helplines or advice lines.
<b>G4-58</b>	21, 22	Report the internal and external mechanisms for reporting concerns about unethical or unlawful behaviour, and matters related to organisational integrity, such as escalation through line management, whistleblowing mechanisms or hotlines.

INFORMATION ON THE MANAGEMENT APPROACH AND INDICATORS	PAGE	OMISSIONS		DESCRIPTION OF THE INDICATOR
		Omissions identified	Action plan	
CATEGORY: ECONOMIC				
Aspect: Economic performance				
G4-DMA	16			
G4-EC1	16, 67	Not currently available: the economic value retained.	In the medium term ESTEVE will establish the procedures required for its measurement. Available in 2018.	Direct economic value generated and distributed.
CATEGORY: ENVIRONMENT				
Aspect: Materials				
G4-DMA	74			
G4-EN1	74, 75			Materials used by weight or volume.
G4-EN2	74, 75			Percentage of materials used that are recycled input materials.
Aspect: Energy				
G4-DMA	74			
G4-EN3	74, 75			Energy consumption within the organisation.
G4-EN6	74, 75	Not currently available: the rationale for energy savings and the reduction in the use of indirect energy.	In the medium term ESTEVE will establish the procedures required for their measurement. Available in 2019.	Reduction of energy consumption.
Aspect: Water				
G4-DMA	74			
G4-EN8	74, 75			Total water withdrawal by source.
G4-EN10	74			Percentage and total volume of water recycled and reused.
Aspect: Emissions				
G4-DMA	76, 77, 78			
G4-EN15	77			Direct greenhouse gas emissions (scope 1).
G4-EN16	77			Indirect greenhouse gas emissions on generating energy (scope 2).
G4-EN17	77			Other indirect greenhouse gas emissions (scope 3).
G4-EN18	77			Intensity of greenhouse gas emissions.

INFORMATION ON THE MANAGEMENT APPROACH AND INDICATORS	PAGE	OMISSIONS		DESCRIPTION OF THE INDICATOR
		Omissions identified	Action plan	
<b>G4-EN19</b>	77			Reduction of greenhouse gas emissions.
<b>G4-EN20</b>	78			Emissions of ozone-depleting substances.
<b>G4-EN21</b>	78 The total emissions from the chemical activity centres in Spain are: 461 kg CO <sub>2</sub> ; 79,611 kg NMVOC; 3,014 kg NOx ; 370 kg SOx			NOx, SOx and other significant air emissions.
<b>Aspect: Effluents and waste</b>				
<b>G4-DMA</b>	78, 79			
<b>G4-EN22</b>	79			Total water discharge by quality and destination.
<b>G4-EN23</b>	79			Total weight of waste by type and disposal method.
<b>G4-EN24</b>	78			Total number and volume of significant spills.
<b>Aspect: Compliance</b>				
<b>G4-DMA</b>	21			
<b>G4-EN29</b>	22			Monetary value of significant fines and total number of non-monetary sanctions for non-compliance with environmental laws and regulations.
<b>Aspect: Overall</b>				
<b>G4-DMA</b>	80			
<b>G4-EN31</b>	80	Not currently available: breakdown of expenditures and investments.	In the medium term ESTEVE will establish the procedures required for their measurement. Available in 2019.	Total environmental protection expenditures and investments by type.
<b>Aspect: Environmental grievance mechanisms</b>				
<b>G4-DMA</b>	21, 22			
<b>G4-EN34</b>	22			Number of grievances about environmental impacts filed, addressed, and resolved through formal grievance mechanisms.
<b>CATEGORY: SOCIAL PERFORMANCE</b>				
<b>SUB-CATEGORY: LABOUR PRACTICES AND DECENT WORK</b>				
<b>Aspect: Training and education</b>				
<b>G4-DMA</b>	59, 60			
<b>G4-LA9</b>	60	Not currently available: breakdown by employee category.	In the medium term ESTEVE will establish the procedures required for its measurement. Available in 2019.	Average hours of training per year per employee by gender, and by employee category.

INFORMATION ON THE MANAGEMENT APPROACH AND INDICATORS	PAGE	OMISSIONS		DESCRIPTION OF THE INDICATOR
		Omissions identified	Action plan	
<b>G4-LA11</b>	59	Not currently available: breakdown by employee category.	In the medium term ESTEVE will establish the procedures required for its measurement. Available in 2019.	Percentage of employees receiving regular performance and career development reviews, by gender and by employee category.
<b>Aspect: Labour practices grievance mechanisms</b>				
<b>G4-DMA</b>	21			
<b>G4-LA16</b>	22			Number of grievances about labour practices filed, addressed, and resolved through formal grievance mechanisms.
<b>SUB-CATEGORY: HUMAN RIGHTS</b>				
<b>Aspect: Investment</b>				
<b>G4-DMA</b>	93			
<b>G4-HR2</b>		Regarding training in human rights (preventing occupational hazards, equality and labour relations), a total of 13,114 hours were given to 63.2% of the entire workforce in countries with production activity (Spain, China and Mexico).		Total hours of employee training on human rights policies or procedures concerning aspects of human rights that are relevant to operations, including the percentage of employees trained.
<b>Aspect: Non-discrimination</b>				
<b>G4-DMA</b>	21			
<b>G4-HR3</b>	22			Total number of incidents of discrimination and corrective actions taken.
<b>Aspect: Freedom of association and collective bargaining</b>				
<b>G4-DMA</b>	57			
<b>G4-HR4</b>	57	Not currently available: the procedures used to assess suppliers with significant risk in the area of human rights.	In the medium term ESTEVE will establish the additional procedures required for their assessment. Available in 2017.	Operations and suppliers identified in which the right to exercise freedom of association and collective bargaining may be violated or at significant risk, and measures taken to support these rights.
<b>Aspect: Child labour</b>				
<b>G4-DMA</b>	25			
<b>G4-HR5</b>	25	Not currently available: the procedures used to assess suppliers with significant risk in the area of child labour.	In the medium term ESTEVE will establish the additional procedures required for their assessment. Available in 2017.	Operations and suppliers identified as having significant risk for incidents of child labour, and measures taken to contribute to the effective abolition of child labour.

INFORMATION ON THE MANAGEMENT APPROACH AND INDICATORS	PAGE	OMISSIONS		DESCRIPTION OF THE INDICATOR
		Omissions identified	Action plan	
Aspect: Forced or compulsory labour				
G4-DMA	25			
G4-HR6	25	Not currently available: the procedures used to assess suppliers with significant risk in the area of forced or compulsory labour.	In the medium term ESTEVE will establish the additional procedures required for their assessment. Available in 2017.	Operations and suppliers identified as having significant risk for incidents of forced or compulsory labour, and measures to contribute to the elimination of all forms of forced or compulsory labour.
Aspect: Security practices				
G4-DMA				
G4-HR7		Not currently available: information on the percentage of security personnel trained in the area of human rights.	In the medium term ESTEVE will establish the procedures required for its measurement. Available in 2019.	Percentage of security personnel trained in the organisation's human rights policies or procedures that are relevant to operations.
Aspect: Indigenous rights				
G4-DMA				
G4-HR8		Not applicable.	Does not apply at there are no production centres in indigenous towns.	Total number of incidents of violations involving rights of indigenous peoples and actions taken.
Aspect: Assessment				
G4-DMA	24, 25			
G4-HR9	25			Total number and percentage of operations that have been subject to human rights reviews or impact assessments.
Aspect: Supplier human rights assessment				
G4-DMA				
G4-HR10		Not currently available: the percentage of new suppliers that were screened using human rights criteria.	In the medium term ESTEVE will establish the procedures required for its measurement. Available in 2017.	Percentage of new suppliers that were screened using human rights criteria.
Aspect: Human rights grievance mechanisms				
G4-DMA	21			
G4-HR12	22			Number of grievances about human rights impacts filed, addressed, and resolved through formal grievance mechanisms.

INFORMATION ON THE MANAGEMENT APPROACH AND INDICATORS	PAGE	OMISSIONS		DESCRIPTION OF THE INDICATOR
		Omissions identified	Action plan	

#### SUB-CATEGORY: SOCIETY

##### Aspect: Anti-corruption

<b>G4-DMA</b>	21, 25			
<b>G4-SO3</b>	25			Total number and percentage of operations assessed for risks related to corruption and the significant risks identified.
<b>G4-SO4</b>	21			Communication and training on anti-corruption policies and procedures.
<b>G4-SO5</b>	22			Confirmed incidents of corruption and actions taken.

##### Aspect: Anti-competitive behaviour

<b>G4-DMA</b>	21			
<b>G4-SO7</b>	22			Total number of legal actions for anti-competitive behaviour, anti-trust and monopoly practices and their outcomes.

##### Aspect: Regulatory compliance

<b>G4-DMA</b>	21			
<b>G4-SO8</b>	22			Monetary value of significant fines and total number of non-monetary sanctions for non-compliance with laws and regulations.

##### Aspect: Grievance mechanisms for impacts on society

<b>G4-DMA</b>	21			
<b>G4-SO11</b>	22			Number of grievances about impacts on society filed, addressed and resolved through formal grievance mechanisms.

#### SUB-CATEGORY: PRODUCT RESPONSIBILITY

##### Aspect: Customer health and safety

<b>G4-DMA</b>	21, 34, 35			
<b>G4-PR1</b>	34, 35			Percentage of significant product and service categories for which health and safety impacts are assessed for improvement.
<b>G4-PR2</b>	22, 34, 35			Total number of incidents of non-compliance with regulations and voluntary codes concerning the health and safety impacts of products and services during their life cycle, by type of outcomes.

##### Aspect: Product and service labelling

<b>G4-DMA</b>	21, 42			
<b>G4-PR3</b>	42			Type of product and service information required by the organisation's procedures for product and service information and labelling, and percentage of significant product and service categories subject to such information requirements.

INFORMATION ON THE MANAGEMENT APPROACH AND INDICATORS	PAGE	OMISSIONS		DESCRIPTION OF THE INDICATOR
		Omissions identified	Action plan	
<b>G4-PR4</b>	22			Total number of incidents of non-compliance with regulations and voluntary codes concerning product and service information and labelling, by type of outcomes.
<b>Aspect: Marketing communications</b>				
<b>G4-DMA</b>	21			
<b>G4-PR7</b>	22			Total number of incidents of non-compliance with regulations and voluntary codes concerning marketing communications, including advertising, promotion, and sponsorship, by type of outcomes.
<b>Aspect: Customer Privacy</b>				
<b>G4-DMA</b>	21			
<b>G4-PR8</b>	22			Total number of substantiated complaints regarding breaches of customer privacy and losses of customer data.
<b>Aspect: Regulatory compliance</b>				
<b>G4-DMA</b>	21			
<b>G4-PR9</b>	22			Monetary value of significant fines for non-compliance with laws and regulations concerning the provision and use of products and services.





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