

CSR Report

2018



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1. About Rovi



1.1. Group profile



ROVI is a specialised, fully-integrated pharmaceutical company engaged in the research, development, toll manufacturing and marketing of small molecules and biological specialties, with three major pillars of growth:

- Pharmaceutical specialties: with a diversified portfolio of its own and licensed innovative products, protected by patents. The LMWH Division, which represented 40% of Group sales in 2018, should be highlighted.
- Toll manufacturing of pre-filled syringes and oral forms.
- A solid, low-risk R&D policy.

All the companies that form the ROVI Group are aware that their activity is conducive to the health improvements provided by their products and wish to provide a response to certain social demands in relation to the impacts of their activities on society and the environment. For this reason, ROVI's economic development must be compatible with its conduct in respect of ethics, society, employment, the environment and respect for human rights.

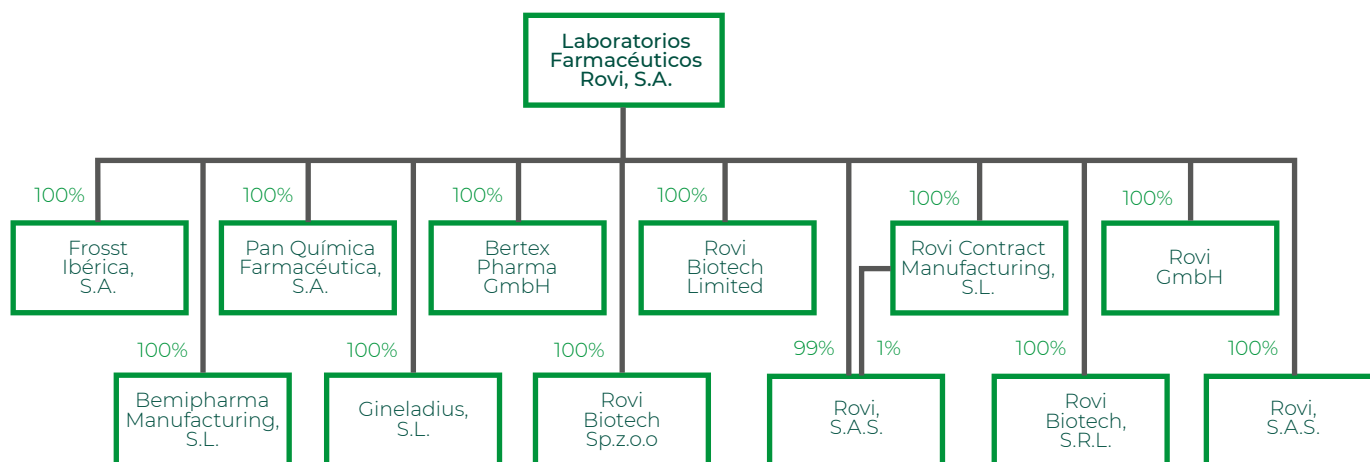
[102-1, 102-3, 102-5]

COMPANY INFORMATION

Name:	Laboratorios Farmacéuticos Rovi, S.A.
Address:	Julián Camarillo, 35. 28037 Madrid. Spain
Telephone:	0034 91 375 62 30
Website:	www.rovi.es
Share capital:	3,364,137.90 euros
Number of shares:	56,068,965
Par value:	€0.06 share
Activity:	Manufacturing and marketing of pharmaceutical products and toll manufacturing services.
Markets:	Markets: The ROVI group has direct presence in Spain, Portugal, Germany, France, United Kingdom, Italy and Poland and is listed on the Barcelona, Bilbao, Valencia and Madrid Stock Exchanges.



CORPORATE STRUCTURE



[102-4, 102-45]

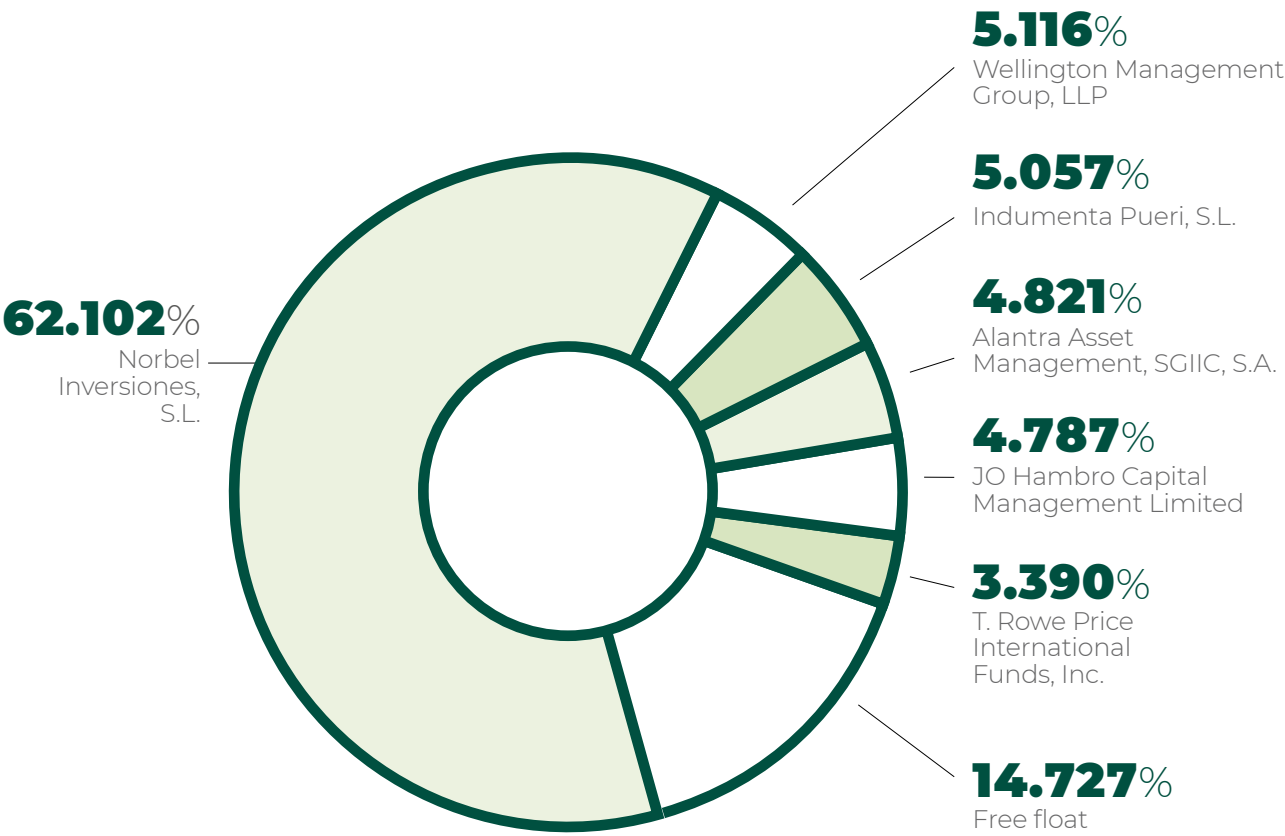
Corporate name	Address	Actividad
Laboratorios Farmacéuticos ROVI, S.A.	Madrid, C/Julián Camarillo, 35	A
Pan Química Farmacéutica, S.A.	Madrid, C/Rufino González, 50	A
Gineladius, S.L.	Madrid, C/Rufino González, 50	B
Rovi Contract Manufacturing, S.L.	Madrid, C/Julián Camarillo, 35	A
Bemipharma Manufacturing, S.L.	Madrid, C/Julián Camarillo, 35	A
Bertex Pharma GmbH	Inselstr.17. 14129 Berlin (Germany)	C
Frosst Ibérica, S.A.	Alcalá de Henares, Avenida Complutense, 140 Madrid (Spain)	A
Rovi Niotech, Ltda	La Paz (Bolivia)	A
Rovi Biotech Limited	Davis House, 4th floor, Suite 425, Robert Street. CRO 1QQQ Croydon (United Kingdom)	A
Rovi Biotech, S.R.L.	Viale Achille Papa, 30. 20149 Milan (Italy)	A
Rovi GmbH	Rudolf-Diesel-Ring, 6. 83607 Holzkirchen (Germany)	A
Rovi S.A.S.	Rue du Drac, 24. 38180 Seyssins (France)	A
Rovi Biotech sp. z o.o. or Rovi Biotech spółka z o.o	Warsaw, Mokotów, ul. Rzymowskiego 53, 02-697 Warsaw, Poland	A

- A** Manufacturing, marketing and sale of pharmaceutical, healthcare and medicinal products.
- B** Import, export, purchase, sale, distribution and marketing of articles related to comprehensive women's healthcare.
- C** Development, distribution and trading of pharmaceutical products related to microparticle technology.

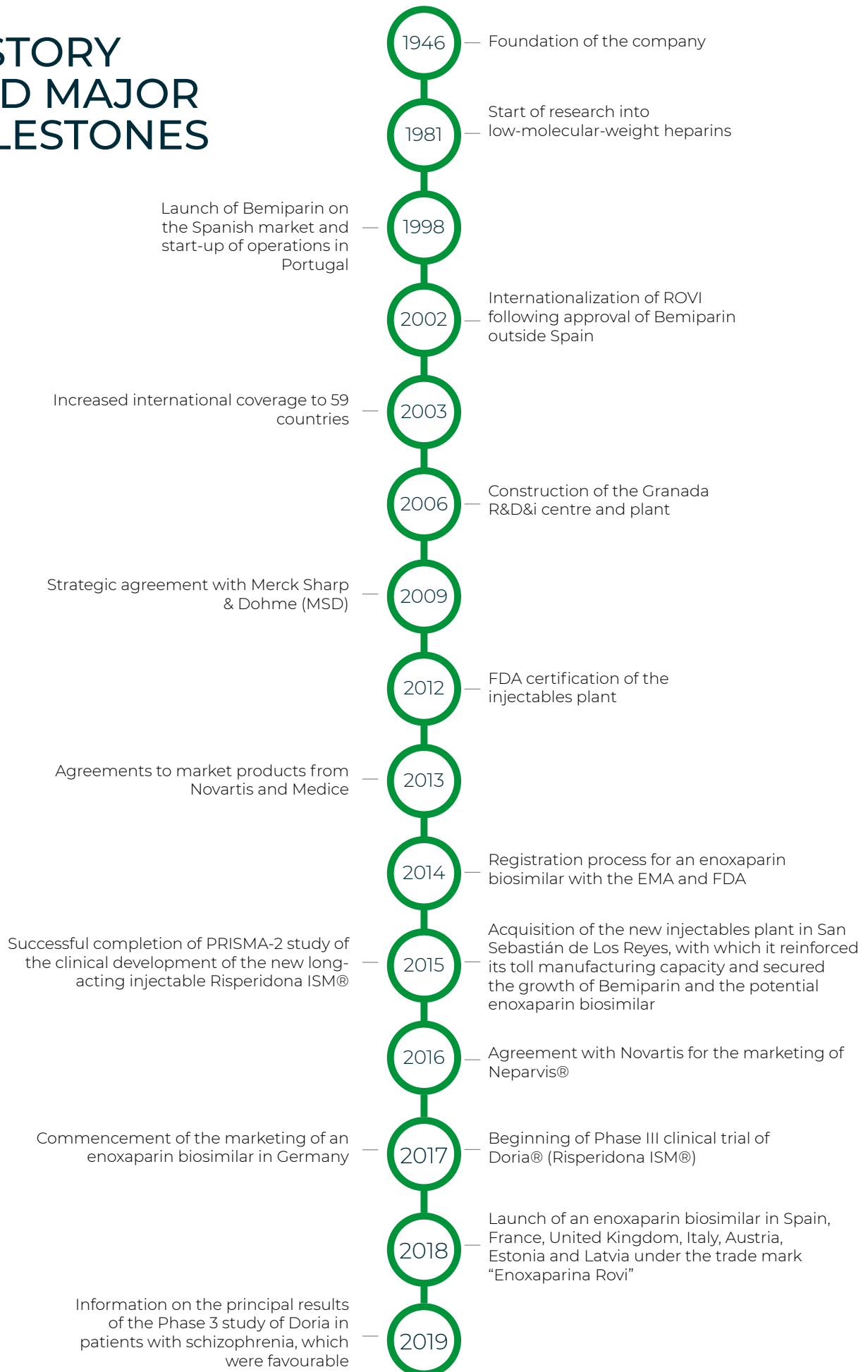


(*) As of December 31, 2018, this company wasn't included in the consolidation scope.

SHAREHOLDERS



HISTORY AND MAJOR MILESTONES



TRADEMARKS, SERVICES AND PRODUCTS

[102-2]

ROVI concentrates its activity on nine main therapeutic areas:

- Cardiovascular
- Osteoarticular/Women's health
- Anaesthesia/ Pain
- Diagnostic imaging contrasting agents
- Central nervous system
- Urology
- Endocrinology
- Respiratory system
- Primary healthcare

ROVI's growth engines are Bemiparin, the distribution licence agreements (Neparvis®, Volutsa®, Orvatez® and Ulunar®), the enoxaparin biosimilar, the existing pharmaceutical specialty product portfolio, new product distribution licences and new customers in the toll manufacturing area



PHARMACEUTICAL SPECIALTIES

ROVI has a diversified portfolio comprising more than forty of its own and licensed products. This portfolio has a defensive profile, since it has been practically unaffected by reference pricing in Spain.

ROVI aspires to become a world leader in low-molecular-weight heparins (LMWHs). To achieve this, it has two products from its own research: Hibor® and Enoxaparina. The low-molecular-weight heparin division accounts for 40% of total group sales.

Hibor®

Hibor (Bemiparin) is a low-molecular-weight heparin (fast-acting anticoagulant) used to prevent and treat venous thromboembolic disease (VTD) in both surgical and medical patients, and for the acute long-term treatment of patients who have suffered VTD. VTD is a serious and potentially fatal process, the main characteristic of which is



the formation of a fibrin clot, thrombosis, inside the veins of the deep vein system, with the consequences that may result from the evolution of the venous thrombus, which may grow, progress and fragment. In the event of fragmentation, some of the fragments may reach the lung and cause pulmonary embolism. In Spain alone, it is estimated that close to 65,000 cases of deep vein thrombosis occur every year, as well as a further 25,000 cases of pulmonary embolism (data extrapolated from Thromb Haemost 2000, 2001 and 2005).

Over recent years, Bemiparin has become one of the main treatments for this disease worldwide, having expanded its presence to 56 countries as the result of a strategic alliance network. Currently, Bemiparin is ROVI's principal product and accounts for 32% of the group's operating revenue.

Enoxaparina ROVI

ROVI began marketing its enoxaparin biosimilar (low-molecular-weight heparin) in Spain under the trademark "Enoxaparin ROVI". With this launch, ROVI expanded its presence in Europe, which had commenced in 2017 with the marketing of the product in Germany and been extended to the United Kingdom and Italy in the first half of 2018 and to Austria, Estonia, France and Latvia in the second half, in addition to Spain. Furthermore, also in 2018, ROVI signed an agreement with Biogaran SAS, the leading French pharmaceutical company in generics and biosimilars and a subsidiary of Laboratorios Servier, to market its enoxaparin biosimilar in France on a semi-exclusive basis.

ROVI's enoxaparin sodium biosimilar is an anticoagulant that belongs to the low-molecular-weight heparin group. It is used to treat and prevent deep vein thrombosis and pulmonary embolism.

As of 31 December, 2018, ROVI had obtained authorisation to market its enoxaparin biosimilar in all the European countries except Greece and Luxembourg. The enoxaparin market is more than 900 million in Europe (according to estimates based on the 2018 sales reported by Sanofi-Aventis), with a market share of 75% concentrated in Germany, France, Spain, United Kingdom, Portugal and Poland (QuintilesIMS-2015 figures), countries in which ROVI hopes to market its product directly through its subsidiaries. Outside Europe, in 2018, ROVI signed an agreement with Hikma Pharmaceuticals PLC, a listed multinational pharmaceutical group, for the exclusive distribution and marketing of its enoxaparin biosimilar in 17 MENA (Middle East and North Africa) countries: Saudi Arabia, Jordan, Algeria, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Libya, Palestine and Lebanon. Furthermore, ROVI signed an agreement with Sandoz, a division of Novartis AG and one of the world leaders in generic and biosimilar medicines, for the distribution and marketing of its enoxaparin biosimilar in 14 countries/regions (Australia, New Zealand, Philippines, Hong Kong, Singapore, Vietnam, Malaysia, Canada, South Africa, Brazil, Colombia, Argentina, Mexico and Central America). Under this agreement, ROVI grants Sandoz an exclusive licence to market the product in three of these countries, Hong Kong, Singapore and Vietnam.

ROVI manufactures and packages its enoxaparin biosimilar in Spain thanks to its four production plants, in which it invested 17,2 million euros between 2014 and 2016 in order to increase capacity and prepare for this new production milestone. Enoxaparin sales totalled 30.2 million euros in 2018.

With the enoxaparin biosimilar, ROVI aspires to become one of the main European -and, in the medium- and long-term, world players in a 900-million-euros market where there are only two other biosimilars, likewise increasing its presence in emerging markets with a potential of 500 million euros, due to the competitive edge provided by the vertical integration of processes in the group.

The following are the products marketed under licensing agreements that make the greatest contribution to the Group's EBITDA:





Neparvis®

ROVI began to market Neparvis® (sacubitril/valsartan) of Novartis in December 2016. This product is indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection (the proportion of blood leaving the heart) fraction.

Hirobriz® Breezhaler® and Ulunar® Breezhaler®

In the last quarter of 2014, ROVI commenced the marketing of Breezhaler (indacaterol maleate), and Ulumar Breezhaler (indacaterol maleate and glycopyrronium bromide) in Spain. Both these active substances are long-acting bronchodilators indicated for the maintenance treatment of Chronic Obstructive Pulmonary Diseases (COPD) in adult patients and administered by inhalations through the Breezhaler device. ROVI markets the two products under licence from Novartis

Volutsa®

ROVI began to market Volutsa (solifenacin succinate and tamsulosin hydrochloride), an Astellas Pharma product, in 2015. It is indicated for the treatment of moderate to severe storage systems symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia (BPH) in men who are not responding adequately to monotherapy treatment.

Vytorin®, Orvatez® and Absorcol®

Vytorin® (ezetimibe and simvastatin), Orvatez® (ezetimibe y atorvastatin) and Absorcol® (ezetimibe) are products used as adjunctive therapy to diet in patients with hypercholesterolemia and are the first of the five MSD marketing licences granted to ROVI. In the second quarter of 2018, the patent for the active substance ezetimibe expired and, therefore, the price of Absorcol® dropped. Likewise, generic medicines formulated with ezetimibe and simvastatin have recently started to be marketed and, therefore, the price of Vytorin® has been lowered in order to maintain its competitiveness.

Medikinet® and Medicebran®

Medikinet (methylphenidate hydrochloride with modified release) and Medicebran (methylphenidate hydrochloride with immediate release) are prescription products indicated for treatment of ADHD (Attention Deficit Hyperactivity Disorder) in children and adolescents. Both products are from the company Medice and ROVI has been distributing them on an exclusive basis in Spain since December 2013.



In the first quarter of 2019, ROVI announced the acquisition of two products, Falithrom® and Polaramine®. These purchases are within the framework of its operating leverage strategy for its international subsidiaries.

Falithrom®

In January 2019, ROVI announced the purchase of Falithrom®, which had belonged to Hexal AG, a company belonging to the Sandoz Division of Novartis, in order to distribute it directly in Germany. Under this agreement, Falithrom® will be marketed directly in Germany by ROVI, once the administrative procedures to authorise the transfer of the marketing authorisation have been completed with the German Federal Institute of Medicines and Medical Devices (BfArM).



This product is used for the prevention and treatment of thromboembolic disease, including venous thrombosis and pulmonary embolism, as well as the prevention of ischemic strokes in patients with atrial fibrillation.

Polaramine® and Polaracrem TM

ROVI has reached an agreement with a subsidiary of Merck Sharp and Dohme (“MSD”) whereby it acquires certain rights for MSD’s dexchlorpheniramine maleate product line, allowing it to distribute this product directly in Spain in its different pharmaceutical forms (tablets, syrup and ampoules, marketed under the trademark POLARAMINE®, and cream, marketed under the trademark POLARACREM™) and in France in its injectable form (ampoules).

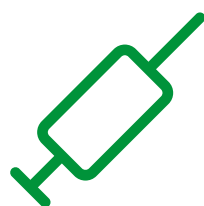
This product line belongs a group of medicines known as antihistamines. They are indicated for the symptomatic treatment of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, allergic cutaneous manifestations of urticaria or angioedema; and reactions to blood or plasma. It is also indicated, together with adrenalin or other appropriate measures, for treatment of anaphylactic reactions after the acute manifestations have been controlled. These products often relieve cutaneous manifestations such as allergic eczema, atopic and contact dermatitis, insect bites, dermographisms and drug reactions.



Diagnostic imaging contrast agents and other hospital products

ROVI is one of the market leaders in the marketing of contrast agents, hospital products for imaging diagnosis (computed tomography, magnetic resonance imaging, ultrasound scan, etc.). This area, which accounts for approximately 10% of the company’s revenue, comprises a broad product portfolio, including those marketed under licence from Bracco: Iomeron® and Iopamiro® (for computed tomography and intervention), Multihance® y Prohance® (for magnetic resonance imaging), Sonovue® (for ultrasounds), and Bracco Injeenering: EmpowerCTA+®, EmpowerMR® and CT Exprès (contrast injection systems and compatible disposable material).

The hospital product portfolio is completed by healthcare products for care and maintenance of intravenous catheters (Fibrilin® and Fibrilin Salino®).



**TOLL
MANUFACTURING**

ROVI has been successful in strategically positioning itself to take advantage of the trend among pharmaceutical companies to outsource their manufacturing processes. This allows the company to make use of the high manufacturing capacity available at its facilities by providing the whole range of manufacturing services for injectables, suppositories and oral solid forms.

The company, through its three production plants, two of which are used for injectables (ROVI Contract Manufacturing in Madrid and the San Sebastián de Los Reyes plant), while the other specializes in oral forms (Frosst Ibérica), provides manufacturing services to other companies for a wide range of pharmaceutical forms, including pre-filled syringes, vials, suppositories, tablets, hard capsules and sachets.



ROVI's profile is unique in this market, due to the unification of all the services within the same company, from the development of a project until the final product release, including preliminary clinical trials, stability studies and physical, chemical and microbiological analyses, with the resulting saving of time and money for the customers. Thus, it provides a personalised service depending on the needs of each customer.

The contracts signed with the customers for whom ROVI manufactures usually have an average term of between 3 and 5 years, which helps to generate a considerable, stable flow of revenue. Furthermore, the long regulatory process that a pharmaceutical company has to undergo to change its manufacturer makes the toll manufacturing business model generate "lifelong customers", as long as the service provided is optimal in meeting the customers' needs.

Contract manufacturing is divided into:

Injectables

ROVI is currently one of the leading pre-filled syringe manufacturers in Europe in terms of the number of units manufactured (filled) per year. With a total annual production capacity of 270 million units, there are very few competitors in this market, since entry barriers are high, given the biological nature of the medicines manufactured and the aseptic conditions (handling of the product in sterile, microbiologically-controlled rooms) in which the pre-filled syringes are filled.

ROVI has a plant specialised in the filling and packaging of parenteral solutions in pre-filled SCF syringes of from 0.5ml to 20ml (filled from 0.2ml to 20ml) and in vials of from 2ml to 10ml. These syringes and vials are filled in aseptic conditions in sterile rue and there is also terminal sterilisation if the product so requires. Additionally, there is the possibility of placing safety devices in the syringes. The annual capacity for vials is 60 million, while it is 150 million for suppositories. The plant has been approved by the European and United States regulators. It has also been approved by the authorities of Korea, Brazil and the Gulf States and holds the certifications ISO9001, ISO14001 and OSHAS.

Over recent years, ROVI has increased its production capacity subsequent to agreements such as the one signed with Crucell Spain in 2015, which led to the acquisition of the assets of the injectables manufacturing plant located in San Sebastián de los Reyes, with the basic purpose of allowing the ROVI Group's production lines for injectables (other than those that Crucell had been manufacturing) to be expanded in the future. In 2016, it was approved by the European health authorities and began to operate at full capacity in 2017 and 2018.

Oral solid forms

ROVI has a plant for solid forms that has a long tradition in the manufacture of pharmaceutical products and uses the most advanced technology for the manufacture of oral forms (tablets, coated tablets, hard capsules and sachets). The plant, with 83,000 square metres, has a global annual capacity of 3,000 million tablets, 300 million hard capsules and 30 million sachets, using different production lines. Furthermore it has storage capacity for 9,000 pallets.

In order to supply all markets, this plant is approved by the European and United States authorities. It has also been approved by the Japanese, Mexican, Brazilian, Kenyan and Belarusian authorities and those of the Gulf States.



KEY FIGURES

[102-7]

(millions of euros)	2018	2017	2016	2015
Total revenue	304.8	277.4	266.7	247.0
EBITDA	29.5	29.9	39.4	31.8
Net financial debt	-62.8	1.1	-9.0	12.1
Employees	1,224	1,191	1,150	1,098

1.2. Business model

ROVI is a leading pharmaceutical company engaged in the research, development, manufacturing and marketing of small molecules and biological specialties. It has three principal pillars of growth:

- Pharmaceutical specialties: diversified portfolio of its own products with long-term patents. ROVI aspires to become one of the world leaders in low-molecular-weight heparins (LMWHs) as a result of the extensive experience of the LMWH Division.
- Toll manufacturing: specialist in pre-filled syringe solutions and oral forms
- Sound, low-risk R&D policy

ROVI's nature, principles and commitment to the activity it is engaged in has allowed it obtain a series of competitive edges, positioning it as one of the main leaders in its market niche in a sector which, moreover, has high entry barriers.

Since it was founded in 1946, ROVI has been engaged mainly in the study and development of drugs based on heparin, a fast-acting anticoagulant, and, since 1981, of its fractioned derivatives, low-molecular-weight heparins (LMWHs). As a result of ROVI's 70 years' experience, its main product, Bemiparin, has positioned itself as one of the



principal treatments for venous thromboembolic disease worldwide. The launch of the enoxaparin biosimilar in 2017 represented the logical evolution of ROVI's experience in the low-molecular-weight heparin field.

Diversified portfolio protected by patents

The company has over 40 products on its portfolio (including both its own and licensed products) for which there is growing demand and which are virtually unaffected by the reference pricing system in Spain. They are grouped into nine therapeutic areas, with around thirty products either for treating different complaints or for various diagnostics systems:

- Cardiovascular
- Osteoarticular (women's healthcare)
- Respiratory
- Anaesthesia – pain relief
- Diagnostic imaging contrast agents
- Central nervous system
- Urology
- Endocrinology
- Primary healthcare

ROVI has launched 14 new products since October 2005.

Infrastructure with operating advantages

ROVI is one of the main companies in the toll manufacturing business in the sector and among the world leaders in pre-filled syringe production. It has one of the largest European plants for manufacturing oral solid forms, exporting to more than 40 countries.

Its production plants in Madrid and Alcalá de Henares, together with the San Sebastián de los Reyes plant, have allowed a constant increase in injectables production lines and are approved by the European and United States regulators –the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), respectively–.

Low-risk innovation

ROVI operates with a low-risk strategy, concentrating on diseases with extensive medical requirements. Furthermore, the company allocates a large part of its revenue to research, in order to remain in the vanguard in terms of both products and manufacturing and development systems.



1.3. World presence

[102-6]

Laboratorios Farmacéuticos Rovi, S.A. currently has its registered office in Madrid (Calle Julián Camarillo, 35). In addition to these offices, in 2017, ROVI opened new offices in Pozuelo de Alarcón, Madrid (Calle José Isbert, 2), where the management team, the marketing and sales areas, and other central group services are located.

ROVI operates directly in the following countries:

- Spain, where a large part of its marketing operations take place, as well as all its manufacturing services and Research & Development activities.
- France
- Portugal
- Italy
- Germany
- United Kingdom
- Poland*

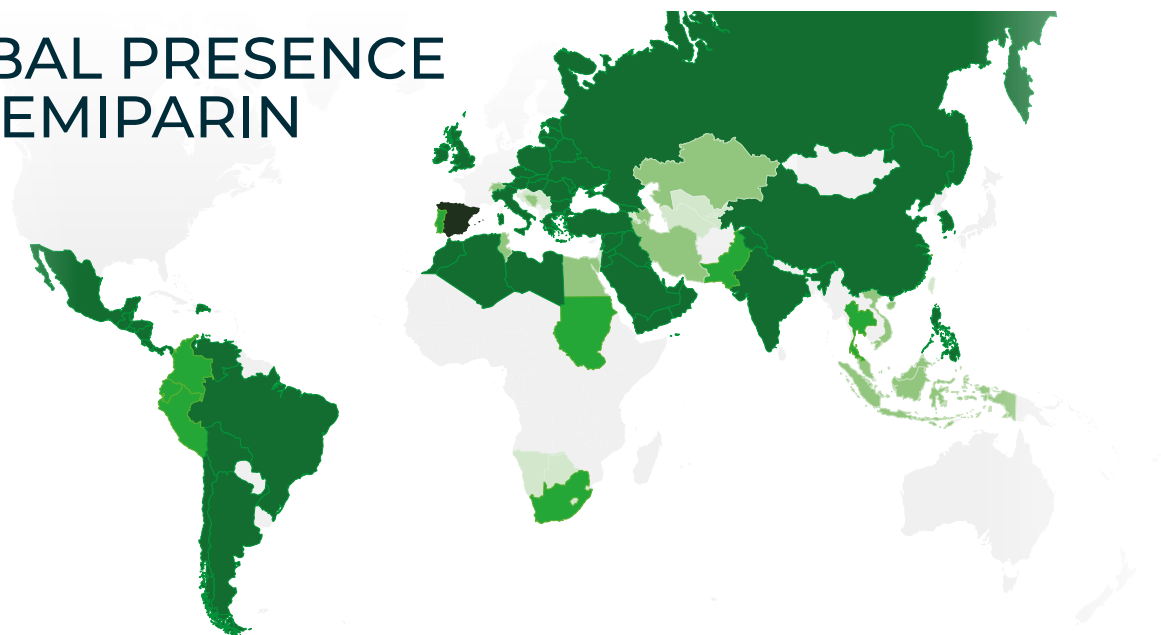
In the last six of these countries, ROVI has corporate structures through which it carries on pharmaceutical product marketing activities directly. In the cases of the French and Polish subsidiaries, the marketing of the products had not commenced as of 31 December, 2018.

Additionally, through strategic alliances with international partners, at the end of 2018, ROVI was distributing its main product, Bemiparin, in more than 50 countries all over the world and the enoxaparin biosimilar in Germany, Austria, Spain, Estonia, France, Italy, Latvia and the United Kingdom. Likewise, ROVI has three toll manufacturing plants and exports to over 40 countries.

(*) As of December 31, 2018, this company wasn't included in the consolidation scope.



GLOBAL PRESENCE OF BEMIPARIN



● **ROVI Group**
● **55 countries** in which the product has been launched through strategic alliances
● **+60 countries** in which registration has been approved
● **10 countries** in which registration is pending approval
● **14 countries** in which registration process is in progress

<p>Latin America <i>Currently marketed in</i></p> <ul style="list-style-type: none"> - Argentina - Belize - Costa Rica - Dominican Republic - El Salvador - Guatemala - Honduras - Nicaragua - Panama - Venezuela - Chile - Bolivia - Mexico - Brazil <p><i>Registration approved</i></p> <ul style="list-style-type: none"> - Ecuador - Peru - Colombia 	<p>Europe <i>Currently marketed in</i></p> <ul style="list-style-type: none"> - Albania - Austria - Belarus - Bulgaria - Czech Republic - Georgia - Greece - Estonia - Hungary - Ireland - Italy - Latvia - Lithuania - Moldavia - Poland - Romania - Russia - Slovakia - Slovenia - Turkey - United Kingdom - Ukraine <p><i>Registration approved</i></p> <ul style="list-style-type: none"> - Portugal <p><i>Pending approval</i></p> <ul style="list-style-type: none"> - Bosnia & Herzegovina - Kazakhstan - Switzerland - Azerbaijan <p><i>Registration process</i></p> <ul style="list-style-type: none"> - Armenia - Kyrgyzstan - Croatia - Serbia & Montenegro - Tajikistan - Turkmenistan - Uzbekistan 	<p>Africa <i>Currently marketed in</i></p> <ul style="list-style-type: none"> - Libya - Algeria - Morocco <p><i>Registration approved</i></p> <ul style="list-style-type: none"> - Sudan - South Africa <p><i>Pending approval</i></p> <ul style="list-style-type: none"> - Tunisia - Egypt <p><i>Registration process</i></p> <ul style="list-style-type: none"> - Botswana - Lesotho - Namibia - Swaziland <p>Middle East <i>Currently marketed in</i></p> <ul style="list-style-type: none"> - Jordan - Kuwait - Yemen - Bahrain - Syria - Oman - Iraq - Saudi Arabia - Lebanon - Qatar - UAE <p><i>Pending approval</i></p> <ul style="list-style-type: none"> - Iran <p><i>Registration process</i></p> <ul style="list-style-type: none"> - Israel 	<p>Asia <i>Currently marketed in</i></p> <ul style="list-style-type: none"> - Hong Kong - South Korea - India - China - Philippines <p><i>Registration approved</i></p> <ul style="list-style-type: none"> - Pakistan - Thailand <p><i>Pending approval</i></p> <ul style="list-style-type: none"> - Indonesia - Malaysia - Vietnam <p><i>Registration process</i></p> <ul style="list-style-type: none"> - Taiwan - Singapore
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2. Responsible and sustainable management



2.1. Statement by the Chief Executive Officer



[102-14]

Responsibility is one of the distinguishing features of ROVI's day-to-day activity. Our company has accumulated decades of experience working in an area that is as essential to society as healthcare and, as a company, we are clear that our goal is to help to improve patient health with top-quality products, manufactured to the highest standards of excellence and with the greatest respect for the environment.

Corporate social responsibility (CSR) is a crucial part of ROVI's identity. It is incorporated into the company's business strategy to ensure its long-term sustainability and reinforce the confidence of its stakeholders. CSR forms part of its governance, management and day-to-day activity.

CSR strategy decisions are made by the Management Committee and, finally, the Board of Directors. To channel them, ROVI has put in place action policies that express its commitment to business ethics and provide guidance for the Board of Directors and other group bodies in their relations with stakeholders.

In this area, in 2018, many of ROVI's efforts were aimed at reinforcing its commitment to ethical management and transparency. An example of this is the updating of the Code of Ethics, the Antibribery and Anticorruption Policy and the Code of Ethics for Suppliers, in order to furnish the organisation with a framework for action that ensures that our day-to-day activity is carried on ethically, honestly, morally and legally, in accordance with the principles and values that define ROVI and its subsidiaries.

In the course of its activity as a pharmaceutical company, ROVI does not only provide top-quality pharmaceutical products, but also supports the research and sharing of scientific knowledge that allows the knowledge of certain pathologies to progress. All this is carried out from a company of Spanish origin that has decided to maintain and reinforce its activity in Spain while, at the same time, expanding its international presence with subsidiaries in the main markets of the European environment.

We are convinced that only companies committed to sustainable development have a future. Those that bet on constant creation of high-quality, stable employment; that take action to reduce the environmental impact of their activity to a minimum; that make investment in research and knowledge-sharing a priority; and that ensure that their day-to-day is subject to ethical business criteria. That, at least, is ROVI's vision for forthcoming years, so as to keep growing as a responsible company, in line with the objectives of the United Nations Global Compact.

Juan López-Belmonte Encina

CEO of Laboratorios Farmacéuticos ROVI



2.2. CSR Strategy and objectives

[102-11, 102-16, 103-1, 103-2, 103-3]

ROVI's mission, vision and values are the guidelines that govern all the decisions made in relation to both business development and the professional performance of its workers, guiding the group's business strategy:

Mission

“We work for the well-being of society and to improve the quality of life of patients and the attention they receive, promoting human health through researching, manufacturing, marketing and distributing medicines and other healthcare products”.

Vision

“We aspire to be recognized as a benchmark for our work in the research and development of new products and to be perceived as a trusted supplier due to our commitment to the manufacture, marketing and distribution of medicines and healthcare products”.

Values

Honesty, integrity and ethics	Team, co-operation, involvement	Efficiency
Consistency Self-criticism Equity Justice Honesty Legality	Commitment Co-operation Empathy Co-responsibility Solidarity	Justice Objectivity Balance Determination Profitability
Patient benefits (Customer satisfaction)	Respect	Innovation
Commitment Involvement Empathy Proximity Proactiveness	Consideration Truthfulness Honesty	Proactiveness Involvement Creativity



All these factors form the backbone of ROVI's day-to-day management through the following principles for action:

[102-12]

Legality	Compliance with current legal regulations in the places where ROVI companies are located.
Human rights	Support the principles of the United Nations Global Compact by adopting and transmitting them, as well as those of other international instruments, especially in the areas of human rights, workplace practices, the environment and anti-corruption.
Ethics	Follow the guidelines of the Code of Ethics , which includes the company's commitment to the principles of business ethics and transparency in all its spheres of action and regulates responsible conduct on the part of all group professionals in the course of their work.
Honesty	Promote free market practices, rejecting any kind of illegal or fraudulent practice and implementing effective mechanisms to prevent, monitor and penalise irregularities.
Communication	Foment communication and dialogue channels , as well as promoting the group's relations with shareholders, investors, employees, customers, suppliers and, in general, all its stakeholders. Thus, the group contributes to harmonising business values and social expectations by adapting, as far as possible, the group's policies and strategies to the interests, concerns and needs of stakeholders, using all the communication tools available, including direct contact and the group's corporate website.
Environment	Conservation and promotion of the environment. ROVI carries on its activity with the firm commitment of contributing to sustainability from an environmental standpoint. This commitment materializes by integrating the environment into the different business areas, conserving biodiversity, preventing pollution, managing resources efficiently and adapting to and mitigating climate change, in accordance with the group's Environmental Policy.
Contribution to society	The taxes ROVI pays in the places where it operates are the main contribution that group companies make to sustaining public funds and, therefore, are one of its contributions to society.
Transparency	<p>Commitment to transparency as a way to transmit confidence and credibility among stakeholders. This will entail:</p> <ul style="list-style-type: none"> a. Providing stakeholders with relevant and accurate information, complying with any legal public information requirements that may exist. b. Preparing and publishing financial and non-financial information, using, in the latter case, an internationally-accepted methodology, and submitting the information to the appropriate internal and external review processes that guarantee the reliability of the information and encourage continuing improvement.



On the basis of these principles, the fact that ROVI's economic development must be compatible with ethical conduct -socially, in the labour area, environmentally and in terms of respect for human rights- is accepted. The work carried out to transmit, know and implement these values, which are likewise used to guide the actions and decisions of the Board of Directors and other ROVI bodies in their relations with stakeholders, expresses the group's commitment to business ethics and sustainability.

In this respect, the following support tools have been developed:

- 1. Corporate Social Responsibility Policy**
- 2. Integrated Management Policy (Environment and Occupational Health and Safety)**
- 3. Code of Ethics**
- 4. Annual Social Corporate Responsibility Report**

Applying these tools and principles in ROVI's day-to-day allows a constant direction and strategy to be maintained in order to attain the following sustainability goals:

GOALS	Favour attainment of the group's strategic objectives.
	Improve the group's competitiveness by implementing management practices based on innovation, equal opportunities, productivity, profitability and sustainability.
	Manage risks and opportunities derived from the changing environment responsibly, maximizing the positive impacts of the group's activities in the different territories where it operates and minimizing any adverse impacts as far as possible.
	Promote a culture of ethical conduct and increase business transparency, in order to generate credibility and confidence among stakeholders, including society as a whole.
	Promote trust relationships and value creation for all stakeholders, providing all of them with a balanced and integrating response.

The incorporation of Corporate Social Responsibility into the management of the ROVI group takes place through the General CSR Policy, which explains that the Management Committee is responsible for designing, evaluating and making general reviews of the Corporate Social Responsibility Policy. Overseeing and ensuring that Management meet the goals that have been fixed and respect the company's social interest objective is the task of the Board of Directors.

In 2017, a permanent internal body, called the Social Responsibility Committee/Social Performance Team, was created, with the capacity to inform, provide advice and make proposals. Within its sphere of action, as one



of the duties assigned to it, this Committee reports to the Management Committee and the Nomination and Remuneration Commission on the degree of progress in implementing the CSR Policy and strategy.

At the same time, the duties of the Audit Committee include reviewing the corporate social responsibility policy, ensuring that it is orientated towards value creation, and monitoring CSR strategies and policies, assessing the degree of implementation thereof. This Committee also oversees and evaluates the processes concerning relations with the different stakeholder groups.

Additionally, the ROVI group has reinforced the CSR area by including a specialised professional, whose functions include solely communication and CSR, reporting to the Human Resources Manager and the Communication, CSR and Institutional Relations Manager.

2.3. Our stakeholders

[102-40, 102-42, 102-43]

In ROVI's business strategy, corporate social responsibility (CSR) is crucial to ensure the company's long-term sustainability and reinforce the confidence of the different groups of stakeholders to which ROVI is related. ROVI considers CSR to be a commitment acquired with society, given the importance of its work and products in improving people's health and quality of life. Therefore, over recent years, it has carried on intensive activity to support research and foment the prevention and knowledge of certain diseases.

The company has identified six groups that contribute directly or indirectly to good business results. The goals it hopes to reach in its relationship with each one of them are:

Employees

To generate enthusiasm and provide training and motivation.

Suppliers

To allow them to find in ROVI a partner for mutual benefit.

Shareholders

To create more value in a way that can be sustained in the long term.

Customers/Patients/Professionals

To offer products based on quality and experience..

Society and environment

To make an active contribution to social progress and environmental protection.

Public authorities

To create channels for cooperation with the public authorities.



Means of communication with stakeholders and obtaining feedback from them

The company strives to maintain constant and fluid dialogue to detect and respond to stakeholder interests, thus contributing to the business's long-term viability. To do this, it has a number of communication and consultation channels in place to find out the needs of its stakeholders and respond to their expectations and needs:

Workers

- Suggestion boxes: these may be found throughout the facilities and are intended enable employees to submit anonymous communications concerning improvements.
- Confidential communication mechanisms for irregularities considered illegal, criminal or a breach of the principles of ROVI's Code of Ethics or internal rules and policies.

Suppliers

- A voluntary document called "CSR Commitment" is sent to all the group's suppliers and subcontractors. This document requests certifications or urges them to adopt good practices.
- On-site audits which check that
 - Suppliers operate in accordance with national and local regulations.
 - There are no significant breaches of workplace safety rules.
 - No practices infringing workers' rights exist.
- Confidential communication mechanisms for irregularities considered illegal or a breach of ROVI's Code of Ethics for Suppliers.

Shareholders

Since the company was first listed on the stock markets, it has reported regularly on all its activities and applies its 'Policy for Communication with Shareholders, Institutional Investors and Proxy Advisors'.

DIRECT INVESTOR COMMUNICATION CHANNELS:

- ir@rovi.es
- Web form at www.rovi.es/contacto

Shareholders have the possibility of receiving ROVI's financial information automatically through an e-mail alert system and the group provides regular, prompt and relevant information on the company, such as presentations and legal documents on economic and financial aspects and corporate governance, which may be consulted on the corporate website www.rovi.es.



Customers

It is essential for the group to establish lasting business relationships based on closeness, an attitude of permanent service and trust. All this begins with total transparency and openness to these through the different channels of established consultations, to manage requests for information both from international partners and from direct clients, patients and professionals.

In this way, since 2008, the international distribution partners of Bemiparina have the web www.bemimed.com and since 2009, ROVI has an exclusive portal for health professionals on its website (www.rovi.es) to channel their requests for information. In each of the companies of the group, there are trained professionals for the attention of the main queries that may arise both to direct clients (partners or wholesalers) and to patients and professionals.

This is the way in which claims can also be received, at which point the company starts an investigation process in order to identify the cause and prevent it from repeating itself. This investigation may involve several departments or even suppliers and / or subcontractors. The effectiveness of these actions is analyzed, annually, in the revision of the system by ROVI's Management.

In the same way ROVI, as a manufacturer and distributor of medicines, is committed to the safety of the patients to whom our medicines are administered. To do this, it has established the appropriate controls so that the drugs maintain the best benefit / risk balance and, in addition, has implemented a pharmacovigilance system that allows detecting possible adverse reactions that occur with our medicines and health products. An adverse reaction is any response to a medication that is harmful and unintentional.

ROVI has various email addresses enabled, depending on the country, for reporting adverse reactions:

Country	Telephone	Email
Spain	+34 91 761 75 61 / +34 661 888 642	farmacovigilancia@rovi.es
Portugal	+351 213 105 617 / +351 918 466 100	farmacovigilancia@rovisa.com.pt
United Kingdom	+44 (0) 203 642 06 77	uk-pharmacovigilance@rovi.com
Germany	+49 8024 478255	pharmakovigilanz@rovi.com
Italy	+39 3457081782	farmacovigilanza@rovi.com
France	+33 476 969 621	fr-pharmacovigilance@rovi.com
Poland	+48 608 096 772	phv@pharmconsult.com.pl

Society and environment

ROVI's commitment to society and environmental protection is firm and constant and forms part of its day-to-day activity.

The company's environmental policy is based on commitments to continuous improvement, legal compliance and additional voluntary requirements. In relation to environmental queries, ROVI has a corporate procedure (SOPc813 "Communication, Participation and Consultation") through which it manages communications (queries, complaints, etc.) related to the environment and occupational health and safety. On the corporate website (www.rovi.es), the quality, environmental and occupational health and safety certifications held by group companies are available to the public.

Furthermore, ROVI uses part of its resources to promote medical research. Over recent years, the company has carried on intensive activity to support research and foment the prevention and knowledge of certain diseases.



2.2. Materiality analysis

[102-44, 102-47]

In order to determine which issues are most important to ROVI and its different stakeholders and include these items in the company's Annual Report, a materiality analysis was carried out in 2018 with the assistance of the consultancy firm PwC. The work consisted of an external diagnosis –in which analyses were made of four companies in the same sector, 15 reference studies and information appearing in the general, financial and industry-related media– and an internal diagnosis –with a self-evaluation of the group's performance and six interviews with members of the management team–. Thus, 20 material issues were identified and are discussed in this report, grouped into eight categories:



GOOD GOVERNANCE AND ETHICAL CONDUCT

1. Responsible governance
2. Ethics and compliance
3. Risks and crisis management



TRANSPARENCY AND DIALOGUE

4. Information transparency
5. Dialogue and relations with stakeholders



PRODUCT QUALITY AND SAFETY

6. Product quality
7. Pharmacovigilance and product safety



ENVIRONMENT

8. Circular economy
9. Atmospheric emissions
10. Climate change
11. Drug pollution



RELATIONS WITH CUSTOMERS, PATIENTS AND HEALTH PROFESSIONALS

12. Attention to and relations with customers, patients and health professionals



WORK ENVIRONMENT

13. Safety and well-being
14. Training and development
15. Attracting and retaining talent
16. Internal dialogue and communication



SUPPLY CHAIN

17. Responsibility in the supply chain



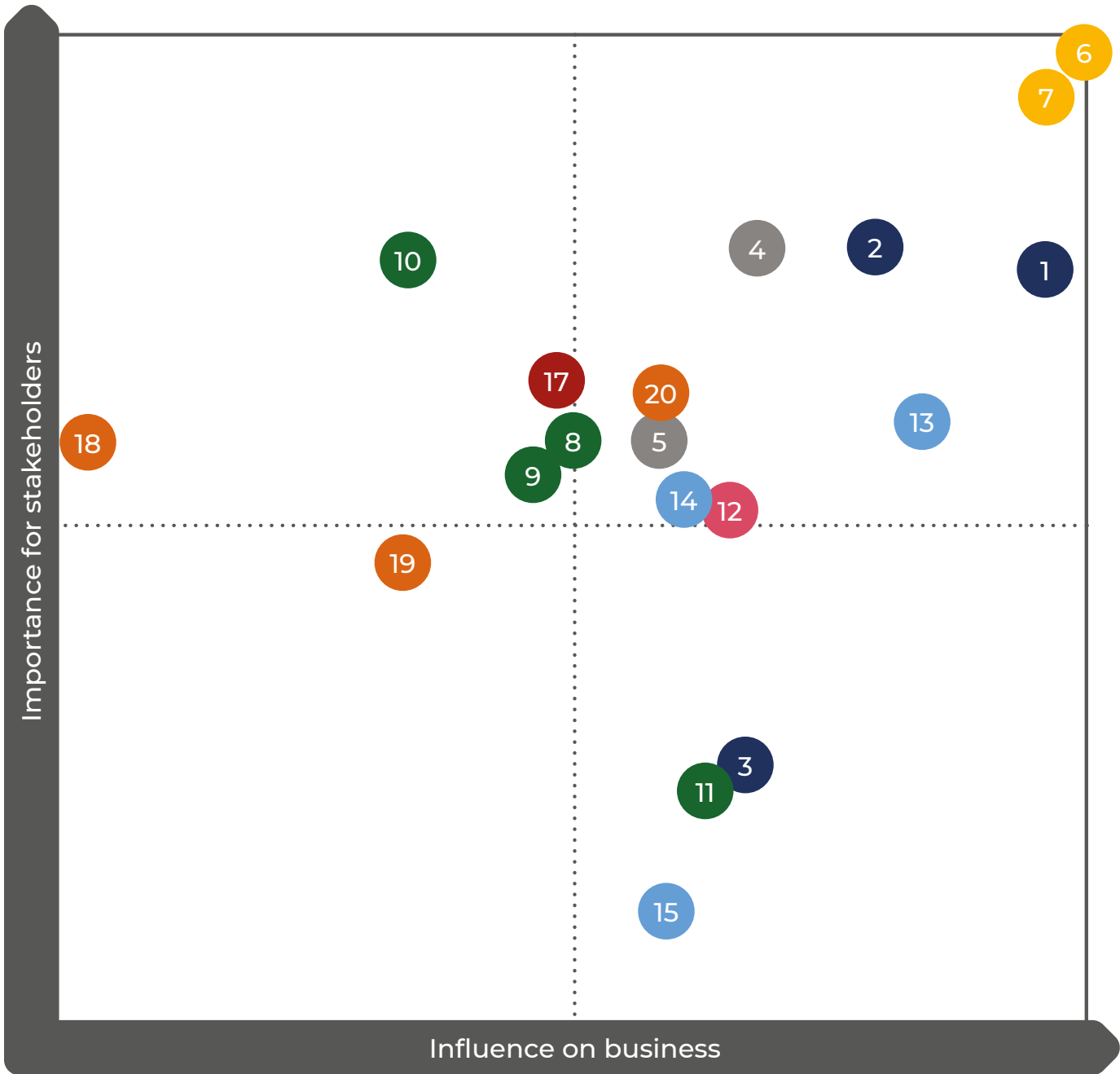
HEALTH AND WELL-BEING OF SOCIETY

18. Access to medicines
19. Research and development
20. Contribution to the social and economic progress of the communities in which ROVI operates



The following materiality graph shows the degree of influence of these matters on ROVI's long-term objectives. This influence has a dual axis: the influence on business success and the importance for stakeholders.

MATERIALITY GRAPH



2.5. Ethics and integrity

In order to reaffirm the values and principles crucial to ROVI's activities, the group has a Code of Ethics, approved by the Board of Directors, the objective of which is for all interactions with shareholders and society in general to be governed by ethics and good practices. This Code of Ethics is binding on all employees and provides guidance in the course of their duties and in the event of conflicts of interest.

According to the Code, the company undertakes to apply the highest standards of ethics and transparency in its communications, information records and reports, in relation to both financial matters and its products and activities. This implies the obligation that, when preparing the group or individual accounting, financial statements, books, records and accounts, legal requirements must be met and current accounting principles must be correctly applied, in order to give an accurate picture of the company's business activities and financial situation.

Likewise, ROVI has a "Code of Ethics for Suppliers", the main objective of which is to ensure that its suppliers and other components of the chain respect current legislation and the values and principles of ROVI while providing services to the group.

The body responsible for ensuring compliance with the Code of Ethics is the Compliance Function (formed by the Compliance Department and the Compliance Committee), to which this duty is assigned in its "Compliance Charter", approved by the Audit Committee on 25 July, 2017. The Compliance Committee is a permanent internal collegial body that reports directly to the Audit Committee and is considered an advisory body to said Committee in compliance matters. The Compliance Department is the area responsible for performing the day-to-day compliance coordination activities, providing support to the Compliance Committee and reporting on relevant matters.

Likewise, ROVI has an Ethics Channel, which can and should be used by any company employee to inform the Ethics Committee –the body responsible for managing the Channel– of any breach of current legislation, the Code of Ethics, internal policies and/or the voluntary codes and standards to which ROVI has adhered, such as the Code of Good Practices of the Pharmaceutical Industry, as well as any financial or accounting irregularities. ROVI employees may communicate with the Ethics Channel at the e-mail address canaletico@rovi.es or by physical mail.

Likewise, ROVI has a specific Ethics Channel for suppliers partners, external collaborators, etc. that allows them to report any irregularity or breach of the ROVI group's Code of Ethics for Suppliers they may detect to the organisation. Various mechanisms have been put in place to enable suppliers to communicate with ROVI's Ethics Channel for Suppliers, among which the e-mail address canaleticoprovedores@rovi.es is included.

The two channels are regulated by the "Regulations of the Ethics Channel for Employees and Suppliers", the latest update of which was approved by the Audit Committee on 7 November, 2017. These Regulations state that the body responsible for managing these channels is the Ethics Committee, which is likewise responsible for ensuring that all reports received are handled and managed appropriately, in full and confidentially. This body is responsible for analysing cases of non-compliance and proposing corrective measures. The possible penalties derived from non-compliance are the responsibility of the Human Resources Department.



The company has an Anti-Bribery and Anti-Corruption Policy that applies to all ROVI's employees and agents and sets out the guidelines that they must all observe in order to avoid any conduct that could be classified as corruption. [205-2]

ROVI undertakes to actively support the Universal Declaration of Human Rights and requires its employees to comply with said principles in their day-to-day activity in the group. The company combats practices contrary to human dignity and workplace discrimination.

During 2018, ROVI personnel received training in the Code of Ethics. This training had two main goals: first, to reinforce the idea that all employees and members of governing bodies of ROVI are subject to the Code and that it is binding on all of them and, second, to provide training on all the principles for action contained in the Code of Ethics, with their possible applications and interpretations.

ROVI also strives to monitor and verify the recommendations of the Unified Code of Good Governance for Listed Companies and, therefore, (i) on 25 July, 2017, the Board of Directors approved a new update of the Internal Code of Conduct in the Securities Markets, which adapts the actions of the Company, its governing bodies, employees and other persons subject to the rules on conduct to securities market-related legislation; and (ii) on 7 November, 2017, the Audit Committee approved the Regulations of the Audit Committee in line with the CNMV's Technical Guide 3/2017 on Audit Committees. Thus, the company has mechanisms to prevent conduct that is damaging to its shareholders and stakeholders, such as a concentration of power, lack of transparency or lack of auditor independence.



2.6. Risk management

ROVI has a Risk Management and Control System that allows any possible contingency that could prevent the attainment of corporate objectives to be identified, classified, assessed and provided with a response.

The objectives of this system, which is supervised by the Audit Commission, are to promote attainment of the proposed objectives, avoid adverse impacts derived from the materialisation of risks, preserve the company's image and reputation, ensure continuity in the analysis and detection of possible threats, obtain reliable accounting information and reinforce confidence in the company's compliance with the applicable rules.

ROVI follows a risk management and control model based on three lines of defence:

- The first line of defence is formed by the group's different operating areas, which, in the course of their day-to-day operations, must identify, classify, assess and monitor the risks, in accordance with the risk level accepted by ROVI.
- The second line of defence comprises the risk control and management service. This service is responsible for the implementation of the risk control and management system, cooperating in initially establishing it and, once it is in place, contributing to its enhancement, monitoring its performance and coordinating its development.
- The third line of defence is Internal Audit, which supervises the internal control and risk management systems by auditing both the first and second lines of defence.

Responsibility for risk control, monitoring and management

According to the company's Regulations of the Board of Directors, the Board of Directors, at a full Board meeting, is responsible for approving the Risk Management and Control Policy, including tax risks, as well as the regular monitoring of the internal reporting and control systems. Exercising this responsibility, in May 2016, the Risk Management and Control Policy, which includes ROVI's general risk management principles, was approved. According to this Policy, the bodies involved in said management are:

- **Audit Committee:** body responsible for reviewing and supervising the company's internal control and risk management mechanisms, as well as their efficacy, so that the main risks can be appropriately identified, managed and made known.
- **Management Committee:** identifies, classifies, assesses and monitors the risks, taking the categories of risk and acceptable risk levels fixed by the Audit Committee into account, and applies the measures in place to mitigate the impact in the event that any risks materialise.
- **Head of Risk Management and Control System:** has the task of implementing the System, cooperating in initially establishing it and, once it is in place, contributing to its enhancement, monitoring its performance and coordinating its development. Likewise, he/she reports periodically to the Audit Committee on the correct operation of the System and/or, if applicable, any risks that may have materialised.



RISK CONTROL AND MANAGEMENT PROCESS

[102-15]

The steps that ROVI follows in risk management are as follows:

- **Fixing the risk level.** Annually, the Audit Committee establishes a risk classification in accordance with the possible impact (financial, strategic, reputational, etc.), considering the probability of occurrence
- **Identification.** The different areas of ROVI proceed to identify the risks that could affect attainment of the company's objectives. Once they have been identified, risks are classified as follows:
 - **Strategic risks:** those that affect high-level objectives, directly related to ROVI's strategic plan.
 - **Operational risks:** those that affect objectives related to the efficiency and efficacy of the operations, including objectives concerning performance and profitability.
 - **Reporting risks:** they affect objectives concerning the reliability of the information provided both internally and externally.
 - **Compliance risks:** those that affect compliance with the applicable rules and legislation.
- **Assessment.** Each one of the risks identified is assessed in accordance with the probability of occurrence and impact. The assessment obtained will determine the position of each risk on the corporate risk map.
- **Determination of the response to a risk.** Measures are adopted to tackle any possible contingencies as efficiently and economically as possible, minimizing exposure. At the same time, mechanisms and procedures must be put in place to allow management to supervise the implementation of actions to neutralize any risk detected and control their effectiveness.
- **Risk management monitoring.** All the departments have both periodic and continuous information systems capable of duly capturing any changes that have either already taken place or will be taking place in the future that might prevent attainment of objectives under the forecast conditions, as well as the viability, efficiency, efficacy and sufficiency of the responses established for the different risks.
- **Reporting to the Audit Committee.** The Audit Committee is informed on at least the following aspects of risk management at least every six months:
 - Whether the Risk Control and Management System is operating efficiently or not, taking possible changing conditions, both internal and external, into account.
 - Whether Risk Management incidents are detected and solved swiftly.
 - Whether the Map has been duly updated with the applicable changes (changes in the risks considered, any applicable new risks, etc.).
 - Whether any of the risks included in the Catalogue or any other risk materialized in the preceding period.



Control and risk management systems in relation to the process of issuing financial reporting (ICFR)

The system for Internal Control over Financial Reporting (ICFR) aims to obtain reasonable certainty as to the reliability of the financial reporting. The bodies responsible are:

- The **Board of Directors**, responsible for the existence and continuity of an appropriate and effective ICFR in accordance with the version of the Regulations of the Board of Directors approved on 26 April, 2016.
- **Senior Management** performs the functions of implementing and designing the ICFR, as is likewise set out in the aforementioned Regulations.
- The **Audit Committee** is the body responsible for overseeing ICFR, as stated in the company's Bylaws, the Regulations of the Board of Directors and the Regulations of Audit Committee, which assign the following responsibilities, among others, to it:
 - To oversee the process of preparing and presenting the financial reporting on the company and, where applicable, the group, ensuring it is complete; reviewing compliance with legal requirements, delimiting the consolidated group and the proper application of accounting policies; and putting forward proposals aimed to safeguard the integrity of the financial reporting to the Board of Directors.
 - To regularly review and oversee the internal control and risk management systems and the efficacy thereof, in order for the main risks to be identified, managed and made known appropriately.
 - To review the clarity and integrity of all the financial reporting and related non-financial reporting that ROVI makes public, such as the financial statements, management reports, risk management and control reports and corporate governance reports, evaluating in which cases the statutory auditors should be involved in reviewing any of the additional reports to the financial statements.



3. Customers, patients and professionals



3.1. Management principles

ROVI has a triple commitment with customers, patients and professionals. They are the centre of its day-to-day activity and it wants to achieve a high degree of satisfaction with them, creating solid and long-lasting relations of trust.

The principal goal is, therefore, to permanently seek to meet the needs and expectations of its customers, whether it be by providing “a la carte” services in the toll manufacturing area or by offering the best treatment options to health professionals, not forgetting the patients, who may benefit from the latest advances and best medicines for treatment of their complaints.

Aware that quality and experience are the basis of the company's business, the group's General CSR Policy establishes a service based on these factors as the principle for action in relation to these stakeholders, thus assuming the following list of implicit commitments:

- To bet on innovative pharmaceuticals as a growth engine for ROVI.
- To pay special attention to protecting the health and safety of our customers and patients throughout the life cycle of our products.
- To observe due confidentiality in data processing.
- To manage and solve their queries and complaints in the shortest time possible.
- To monitor customer experience via surveys that measure their satisfaction and other means and systems that allow permanent active listening to the customer in all those processes and operations in which the latter relates to the company.
- To operate appropriate and efficient communication channels, using the best-adopted means to do so.
- To observe and comply with the rules that regulate communication and marketing activities and assume the voluntary codes that endow such actions with transparency and veracity.

The group divides its activity into toll manufacturing and the distribution of products that are either manufactured at its plants or marketed under a license. ROVI offers other laboratories the possibility of outsourcing their manufacturing processes for a broad range of pharmaceutical forms, including pre-filled syringes, vials, suppositories, tablets, hard capsules and sachets.

Likewise, ROVI's products are distributed to international subsidiaries and partners, pharmaceutical wholesalers, pharmacies and hospitals all over Spain, which form a new group of differentiated customers for the company. Finally, ROVI has been working as a marketing partner for medicines and medical devices of other companies for years.



The group considers it essential to establish long-lasting commercial relationships based on proximity, with a permanent approach of providing service and trust. To do this, it has set up a query channel for information requests by both international partners, through an exclusive portal created in 2008 (www.bemimed.com), and direct customers, patients and professionals.

3.2. Balance of the year and future challenges

Guaranteeing the safety and efficacy of the products that the company places in the market is the main goal of ROVI and all the people who form part of it. To do this, all group companies have procedures that describe the controls carried out in all process phases, including product research and development, the receipt of raw materials, packaging materials, production, storage and distribution, until the products are consumed by our customers.

The standards in place meet the company's internal requirements and also the external requirements imposed by the regulatory bodies of the different products that make up ROVI's portfolio.

In order to assess compliance with these procedures, internal audits of all the group's facilities are performed regularly. Annually, there are management reviews, in which the main points that require improvement in our organisations are analysed.

Furthermore, the quality audits performed by external entities show the commitment to continuing improvement and the upholding of high-quality standards.

Moreover, depending on the frequency established in the legislation applicable to the products, all the group companies are inspected by either the Spanish health authorities or those of the countries to which their products are exported.



3.3. Innovation

Research and development are strategic factors in order to compete in today's market and differentiate the company from others in the sector. ROVI is a company committed to innovation, with a patent portfolio comprising more than 500 patents, 408 of which have been granted, while 98 are in the examination and evaluation phase.

ROVI's activity of research, development and manufacture of pharmaceutical products is coordinated entirely in Spain, distributed over the Madrid and Granada centres. The company is, therefore, fully committed to innovation and this involvement has materialised in figures showing the growing R&D investment in 2018, when it increased to 32.4 million euros, in comparison with the 28.3 million euros of 2017 and the 17.5 million euros of 2016, as a result of projects such as the development of the Phase III trial of Risperidona ISM® and the Phase I of Letrozol ISM®.

Current developments in research are directed primarily at three areas: drug-release technologies, glycomics and multilayer technologies applicable to urethral catheters. ROVI's research and development product portfolio concentrates mainly on heparin derivatives and other glycosaminoglycans and the development of new controlled-release systems based on the patented ISM® technology, in order to obtain new pharmaceutical products that allow the daily administration of drugs in chronic or prolonged treatments to be replaced by controlled-administration systems.

ROVI has made significant progress in the development of the first candidate of its leading-edge drug-release technology, registered under the trademark DORIA®. This first candidate guarantees prolonged release of risperidone, a second-generation antipsychotic medicine the use of which is consolidated for the treatment of schizophrenia. After successfully completing the program for Phases I and II of Doria®, ROVI commenced the pivotal Phase III trial, PRISMA-3, with the recruitment of the first patient in May 2017 and an update of the project was published with details of the design and the cost of Phase III, together with a presentation given to analysts in October, 2017. In March 2019, ROVI published the principal favourable results of the DORIA® Phase III study, which show that primary and secondary efficacy variables have been achieved for patients with acute exacerbation of schizophrenia. Consequently, ROVI plans to file an NDA (New Drug Application) –an application that is filed with the FDA (Food and Drug Administration) in the United States– in the second half of 2019.

The PRISMA-3 study is a randomised, multicentric, double-masked, placebo-controlled clinical trial to evaluate the efficacy and safety of monthly intramuscular injections of the product registered under the trademark DORIA® in patients with acute exacerbation of schizophrenia. In the United States and Europe, there are around 3 million patients (source: IQVIA) diagnosed with schizophrenia disorders. This complaint cannot be cured but there are treatments that control the symptoms efficiently. These treatments used second-generation antipsychotics (SGA), which have a predictable efficacy and safety profile. From among them, risperidone is one of the most widely-used active substances.

Long-acting injectables (LAIs) are becoming the benchmark for the care of schizophrenia, rather than the oral treatment, and, with Doria®, ROVI hopes to occupy a prominent position in schizophrenia treatment with LAIs in the United States and Europe, with an estimated total value of 4,200 million dollars in 2021 –3,300 million dollars in the United States and 930 million dollars in the five main markets in Europe– (source: IQVIA).



In addition, in November 2017, the clinical development with Letrozol commenced. This is the first long-acting aromatase inhibitor for the treatment of hormone-dependent breast cancer and ROVI's second ISM® technology-based candidate. During 2018, the first Phase I clinical trial was carried out, the LISA-1 study. This is an open, single-dose, dose-increasing study to evaluate the pharmacokinetic profile, safety and tolerability of intramuscular injections of Letrozol ISM®, with different concentrations, in healthy post-menopausal women.

The two projects represent a significant economic effort for the company, backed by the granting of public funds from the Technological Industrial Development Centre (CDTI).

At the same time, ROVI keenly drives and supports research, both at academic level and within the Spanish business fabric through small- and medium-sized companies. To do this, it holds agreements with different universities in order to combine efforts and reinforce scientific, technological and educational activities, as well as spreading knowledge, in Spain, continuously cooperating with the University of Granada in research activities and the training of scientific personnel through projects within the framework of the incentives awarded by the Technological Corporation of Andalusia. Likewise, during the 2018 annual period, ROVI led two research consortia with small- and medium-sized companies, BIOMAP, within the framework of the Feder Interconnecta Program, and BLUESPE, which likewise obtained financing from the Industrial Technological Development Centre.



3.4. Quality

Guaranteeing the quality, safety and efficacy of the products it places in the market is the principal objective of ROVI and all the people who form part of it. To do this, all the group companies have put in place procedures that describe the controls performed at all stages of the processes, including product research and development, the receipt of raw materials, packaging materials, production, storage and distribution to our customers.

The standards in place meet the company's internal requirements and the external requirements imposed by the regulatory bodies of the different products that make up our portfolio. In order to assess compliance with these procedures, internal audits of all the group's facilities are performed regularly. Annually, there are reviews by group management, in which the main points that require improvement in all the organisations that form part of the group are analysed.

Furthermore, the quality audits performed by external entities show ROVI's commitment to continuing improvement and the upholding of high-quality standards. Depending on the frequency established in the legislation applicable to the products, all the group companies are inspected by either the Spanish health authorities or those of the countries to which their products are exported.

		Lab. Fcos Rovi	Pan Química	Lab. Fcos. Rovi perm. Establish. Portugal	Rovi GmbH (Germany)	Rovi Biotech Limited (United Kingdom)	Rovi Biotech S.R.L. (Italy)	Rovi S.A.S (France)	SUB. DISTR.
General	Units manufactured / Uds. Distribuidas	19,571,222	25,353	296,268	312,691	135,192	1,168,506	0	21,509,232
Customer complaints	No. customer complaints	155	9	10	13	3	4	0	174
	Complaints / million units.	7.92	354.99	33.75	0	22	3	0	8.09
Customer queries - quality + therapeutic	No. customer queries	237	0	9	171	19	0	0	246
	Queries / million units	12.11	0.00	30.38	547	141	0	0	11.44



3.5. Pharmacovigilance and product safety

Laboratorios Farmacéuticos ROVI, as a medicine researcher, manufacturer and distributor, is very much committed to the safety of the patients to whom its medicines are administered in relation to the detection of any adverse reaction, i.e. any unintended, harmful response to a medicine.

In this respect, it has established the appropriate controls to ensure that the medicines maintain the best benefit/risk balance and, furthermore, has implemented a pharmacovigilance system that allows any adverse reactions to medicines and health products it markets to be detected.

Moreover, ROVI has various means of communication in place, such as the e-mail address farmacovigilancia@rovi.es and a telephone number (**+34 91 761 75 61**) for notification of adverse reactions, in addition to ROVI's website, which explains how to proceed if one wishes to notify an adverse reaction. The company immediately activates its pharmacovigilance system to collect the greatest amount of information possible to enable it to establish the appropriate cause-and-effect relationship between taking the medicine and the adverse reaction.

In compliance with the guidelines established, a total of 870 adverse reactions were recorded in 2018 in relation to all the medicines marketed by ROVI.



4. Human resources



4.1. Management principles

ROVI's commitment with its employees is the key to the company's success. The company strives for and promotes good relations, proper treatment and tolerance among its employees and the people with whom it works, by means of activities and training programmes and providing opportunities for dialogue and mediation.

The design and implementation of Human Talent Development Policies form the process whereby the ROVI group, depending on its objectives, establishes its personnel needs and defines its human talent management plans and programs, in order to integrate personnel management and practices into the organization's priorities.

For ROVI, the training and preparation of its employees is of crucial importance and, therefore, the company applies significant resources to investment in human capital. Through preparation and training, it foments professional evolution and growth, involving both professionals and their direct supervisors. Young professionals have the support of more experienced colleagues who guide them and help to develop their technical skills. Thus, ROVI favours and ensures the transfer of the knowledge and experience acquired by senior professionals, another of the great assets of the group's workforce, to the new generations.

Organisation of working hours

ROVI carries on its economic activities in three different environments: the industrial production area, the sales area and the industrial structure/offices area. The activity of each one of them has different dynamics, requiring different working hours and ways of organising working time. In all of them, the Company foments criteria for organising working time and time off to facilitate the best work-life balance possible, as well as enabling ROVI employees to exercise responsible parenting.

The industrial environment, which includes the employees working at the pharmaceutical product production plants, makes it necessary for employees who are engaged in manufacturing tasks or work directly related thereto to have working hours that coincide with the times of activity of the production processes. This means that this group of people works, in general, under a shift system. Since we are aware that shift work is more arduous, it is used when there is no other possible alternative that is compatible with the viability of the activity and the demand for the product manufactured and we strive to reduce the inconvenience of the shift dynamics as much as possible. The holiday period in the industrial area is also subject to the volume of activity and must, in general, be arranged on fixed dates for the whole workforce. At any event, we endeavour to ensure that it is always in summer and ROVI undertakes that at least half the holidays will be enjoyed in the summer period. Additionally, the time off scheduled to adjust the work calendar of this group of employees is fixed to coincide with school holidays, so that the employees can enjoy it with the rest of their families.

Employees in the sales area carry on their activity in daytime working hours, coinciding with those of the customers to whom they market ROVI's products. Given the nature of their activity, they have a high degree of independence in planning their work, which allows them to reconcile their work with any needs that may arise in their family life.



In the industrial structure and office area, time is organised through flexible working hours. This allows employees to start and end their working day with a margin of choice, depending on their needs or preferences.

In these last two groups, holidays are preferably taken in summer and, additionally, time off is arranged during school holidays.

4.2. Balance of the year and future challenges

The key figures concerning ROVI's personnel structure show that, in 2018, workforce management continued to follow the sustained upward path of previous years, consistently with the company's continuing growth strategy and intended to adapt the workforce to current business needs.

The recruitment management strategy foments stable employment through permanent and temporary contracts, both of which are used to cover, in a balanced manner, both structural needs and the specific need for workers at any given moment. This is shown in the distribution of the workforce, where permanent contracts and stable employment prevail.

In the recruitments carried out in 2018, the bet on job creation with young professionals continued, at the same time as they were supplemented by experienced professionals. Thus, a balanced workforce that allows the company's strategy to be implemented is achieved.

Likewise, the results of the Company's efforts to maintain and consolidate its workforce with a balance between men and women and promote the inclusion and access of candidates with disabilities under equitable conditions, consistent with the strategy of mainstreaming diversity and equal opportunities as part of its culture, may be observed.



[102-8]

DISTRIBUTION EMPLOYEES BY GENDER

	2018
Men	558
Women	666
TOTAL	1,224

DISTRIBUTION EMPLOYEES BY AGE/GENDER

	Men	Women	TOTAL
18-30 years	78	106	184
31-40 years	156	216	372
41-50 years	195	213	408
51-60 years	109	114	223
>60 years	20	17	37
TOTAL	558	666	1,224

DISTRIBUTION EMPLOYEES BY COUNTRY/GENDER

	Men	Women	TOTAL
Spain	550	654	1,204
United Kingdom	-	1	1
Germany	3	3	6
Italy	3	3	6
France	1	1	2
Portugal	1	4	5
TOTAL	558	666	1,224

DISTRIBUTION EMPLOYEES BY CONTRACT TYPE/GENDER

	Men	Women	TOTAL	DISTRIBUTION
Permanent Full-time	462	532	994	81%
Permanent Part-time	-	4	4	0%
Total permanent	462	536	998	82%
Temporary specific project or service	2	3	5	0%
Temporary due to work backlog	47	55	102	8%
Temporary substitution contract	4	6	10	1%
Training/Apprenticeship	27	49	76	6%
Temporary part-time	15	17	32	3%
Temporary full-time – people with disabilities	1	-	1	0%
Total temporary	96	130	226	18%
TOTAL	558	666	1,224	



DISTRIBUTION EMPLOYEES BY CONTRACT TYPE/AGE

	18-30	31-40	41-50	51-60	>60	TOTAL
Permanent	79	328	370	213	8	998
Temporary specific project or service	2	2	1	-	-	5
Temporary due to work backlog	31	31	33	7	1	103
Temporary substitution contract	1	5	3	1	-	10
Training/apprenticeship	69	6	1	-	-	76
Temporary part-time	2	-	-	2	28	32
TOTAL	184	372	408	223	37	1,224

Turnover

DISTRIBUTION DISMISSALS BY GENDER

	2018
Men	17
Women	16
TOTAL	33

DISTRIBUTION DISMISSALS BY AGE/GENDER

	Men	Women	TOTAL
18-30 years	2	0	2
31-40 years	3	4	7
41-50 years	5	8	13
51-60 years	3	2	5
>60 years	4	2	6
TOTAL	17	16	33



4.3. Equal opportunities and work-life balance

ROVI is committed to establishing and developing policies that include equal treatment and opportunities for women and men, with no discrimination based on gender or other personal characteristics in selection processes, promotions, personal development or the workers' remuneration policy.

To this end, it has an Equal Opportunities Plan to guarantee equal opportunities and non-discrimination and to promote the inclusion of new actions in this area that establish mechanisms in areas such as selection and hiring, internal promotion and professional development, training, remuneration, work-life balance, gender violence and harassment prevention, and communication. ROVI's commitment to equality and non-discrimination is also reflected in the company's Code of Ethics and the principles that govern training programmes and actions.

Applying the Equality Plan, an Equal Opportunities Commission has been created. Its key mission is to properly monitor the measures implemented and ensure that ROVI's commitment is met.

This equality policy is likewise reflected in ROVI's Board of Directors, where the selection criteria for the appointment of directors is based on the candidates' merit (people of recognized knowledge, skills and experience) and the potential candidates may include both men and women who meet these requirements. For this reason, one of ROVI's Equality Policy targets for director selection is that the number of women directors should represent at least 30 percent of total Board members in 2020.

In each and every one of the areas in which it carries on its activity, with regard to selection, promotion, wage policy, training, work and employment conditions, workplace health, the organisation of working hours, and work-life balance, ROVI assumes the principle of equal opportunities for women and men, paying special attention to indirect discrimination, defined as the situation where an apparently neutral rule, criterion or practice places a person of one gender at a particular disadvantage in comparison with a person of the other gender. As a result of these policies, the ROVI workforce has a higher percentage of women than men.

ROVI does not tolerate harassment and rejects any kind of violence, physical, sexual, psychological or moral harassment, the abuse of authority at work or any other form of harassment or conduct that generates an atmosphere that is intimidating or offensive in respect of the employees' rights. Therefore, ROVI has a Protocol for the Prevention and Handling of Cases of Moral and Sexual Harassment in the workplace, which all employees are obliged to know and respect.

To guarantee that any reports that may be received informing of a violation of the aforementioned Protocol, the Code of Ethics or, in general, any approved policy or procedure are handled properly and receive an appropriate response, ROVI has made an Ethics Channel available to its employees, suppliers, trading partners, agents and external collaborators. The Regulations of the Ethics Channel govern the procedure to follow to handle and process any reports or notifications received and ensure that, when faced with an action that potentially contravenes the Company's principles and values, the Company is able to react strictly, efficiently and diligently.



Work-life balance and support of co-responsibility therein

[401-2]

At ROVI, a set of measures to reconcile family life and work are applied, with options adapted to different personal and family situations aimed to create a work environment that allows a higher quality of life and harmony between the employees' family lives and their promotion and professional careers.

The Company applies the work-life balance measures contained in current legislation, as well the enhancements introduced by the Collective Agreement of the Chemical Industry.

Regarding working hours and time off, as stated above, ROVI has flexible starting and finishing times for office and industrial structure personnel, allows changes in shift or day between workers in the industrial area, and shorter working days adapted to the needs of each person. Likewise, it offers flexibility in the holiday calendars, provided it is compatible with the activity of the area in which the employee works.

In respect of remuneration, ROVI guarantees that maternity does not represent any decrease in the usual income of the pregnant woman. Thus, the Company pays a wage supplement that completes the benefit received from the Social Security to 100% of her salary. It also offers salary options, with the availability of nursery school vouchers, restaurant vouchers and health insurance. Furthermore, ROVI offers all its permanent employees cover by the life insurance policy paid by the Company.

In order to prevent avoidable travel and trips, ROVI provides all the personnel who so require with a laptop computer with connectivity to the ROVI network and encourages the use of videoconferences and on-line meetings. Likewise, if the work performed so permits, teleworking is organised during the last weeks of pregnancy. Additionally, at work centres where street parking is difficult, the company makes a series of parking spaces available to pregnant women to make it easier for them to get to work.

Disconnection from work

So that its employees can enjoy their time off effectively and conserve their personal and family privacy, ROVI foments policies aligned with disconnection from work, avoiding communication with employees through any channel (telephone, e-mail or any other) outside working hours unless there is an urgent, unforeseen need that cannot be met otherwise.

Likewise, meetings in the later part of the working day are avoided, in order to prevent overstepping working hours at the end of the day and thus affecting the work-life balance.

Remuneration policies

The average employee remuneration in 2018 was 38,735 euros, representing an increase of 1% in comparison with 2017.

The average remuneration of the members of the company's Management Committee in 2018, including fixed and variable remuneration and remuneration in kind, was 234,142 euros for men and 135,462 euros for women. The difference is because, in the case of the men, three of them are also Executive Directors and their salaries reflect the additional responsibilities they hold.



AVERAGE REMUNERATION OF MANAGEMENT COMMITTEE

	Men	Women	AVERAGE
Fixed remuneration	163,430 €	93,419 €	128,425 €
Variable remuneration	61,960 €	36,763 €	49,362 €
Remuneration in kind	8,752 €	5,280 €	7,016 €
TOTAL	234,142 €	135,462 €	184,802 €

Wage gap

ROVI is convinced of the need to apply the principle of equal pay for equal work effectively and takes said principle as the basis of its wage policy, applying it in its salary-fixing practice upon recruitment of the employee and in the salary reviews throughout the employee's working life.

AVERAGE REMUNERATION BY GENDER

	2018	2017	TOTAL VARIATION
Men	40,733 €	40,953 €	-1%
Women	36,738 €	35,534 €	3%
AVERAGE	38,735 €	38,244 €	1%

In order to ensure application of the principle of wage equality, ROVI monitors the gender wage gap by periodically assessing indicators that show wage gaps by job and gender, in order to follow up on any gender differences and reduce them.



AVERAGE RENERATION* BY PROFESSIONAL GROUP**/GENDER

	2018		2017		TOTAL VARIATION
	Men	Women	Men	Women	
1	15,311 €	14,892 €	0 €	17,472 €	73%
2	16,677 €	17,012 €	16,170 €	16,194 €	4%
3	19,000 €	19,266 €	18,209 €	19,065 €	3%
4	25,082 €	23,432 €	25,641 €	23,736 €	-2%
5	42,078 €	40,546 €	41,099 €	38,237 €	4%
6	50,426 €	36,687 €	52,153 €	37,993 €	-3%
7	51,208 €	47,265 €	54,958 €	44,413 €	-1%
8	105,465 €	105,050 €	153,205 €	146,637 €	-30%
0	202,978 €	130,182 €	197,584 €	112,505 €	7%
Subsidiaries	87,949 €	72,367 €	106,499 €	103,300 €	-24%

(*) Does not include scholarship remuneration, since scholarship-holders do not have a Professional Group

(**) Professional Group in accordance with the XIX Chemical Industry Collective Agreement

In 2018, ROVI engaged the audit firm PricewaterhouseCoopers Auditores S.L. to carry out a limited assurance review of wage group indicators by professional classification in Group companies. The indicators related to the annual period running from 1 April, 2017 to 31 March, 2018 and the reports were prepared on the basis of the methodology published in January 2015 by the Ministry of the Presidency, Parliamentary Relations and Equality in relation to calculating the gender pay gap.

AVERAGE REMUNERATION BY AGE/GENDER

	2018		2017		TOTAL VARIATION
	Men	Women	Men	Women	
18-30 years	21,966 €	21,983 €	21,099 €	19,787 €	7%
31-40 years	30,535 €	34,460 €	29,625 €	32,108 €	5%
41-50 years	47,312 €	45,095 €	46,989 €	45,167 €	0%
51-60 years	58,097 €	41,546 €	55,003 €	28,357 €	20%
>60 years	33,459 €	11,908 €	53,148 €	14,612 €	-33%

The aforementioned indicators make a diagnostic analysis of the group's workforce to find out the differences in the remuneration of men and women with the same jobs. The analysis of the indicators shows that there is no gender-based pay discrimination or differences in remuneration that is not based on personal factors (qualifications, work experience, length of service, etc.) or position (duties, degree of responsibility, working hours, etc.).



4.4. Attracting talent and training

The group's success indispensably requires selecting and retaining talent transparently and effectively. The Human Resources Department is responsible for designing and managing training policies and attracting and retaining talent, and is in charge of applying the Selection Policy in recruitments. This Policy is based on principles such as:

- Equal opportunities.
- Objectivity and impartiality. Selection processes are based on merits and capabilities.
- Confidentiality of the process.
- Favouring the recruitment of young people, people from disadvantaged groups and differently-abled people.
- Promotion and reinforcement of internal candidatures.

Making training a priority is a long-term investment so that the company's talent is well prepared and develops its highest potential. For ROVI, the training and preparation of its employees is crucial and, therefore, the company invests significant resources in human capital. Through preparation and training, it foments professional evolution and growth, involving both the professional and his/her direct supervisors.

For this reason, ROVI strives for the employees to have the necessary training to cover, not only the requirements of their present job, but also to tackle future needs derived from the use of new technologies, equipment, instruments, etc. or the need to take on greater responsibilities and more important projects.

To draw up the annual training plans, the training needs in each area are identified, a process in which the Human Resources Department, Group Management and Middle Management are involved. The annual plan is aligned with the strategic and business objectives. Through training, it is sought to efficiently help people to contribute and add value to the attainment and achievement of ROVI's strategic objectives.

Likewise, all employees have an Individual Development Plan. Depending on the specific needs identified, different alternatives and training plans are put into place in order to promote their career plans. ROVI works with a training model that foments self-responsibility and commitment. Thus, 10% of development and learning takes place through training actions in the classroom or in virtual or e-learning format and 20% takes place through feed-back, observation or with the support of mentors, coaches, professional associations, spaces for reflection, conversations with other people, leaders, etc. Lastly 70% of development and learning takes the form of job experience, applying new learning in real situations, problem-solving, participating in projects and new challenges, rotating through different departments, etc., always taking the professional profile and the needs of each area into account.



<p>Basic principles of ROVI Group's training programmes/actins</p>
<p>Training programmes will contain aspects related to respect for human rights and will foster an ethical culture.</p>
<p>No discrimination on the grounds of gender, age or origin. Professionals with equal positions and professional development have the same training opportunities.</p>
<p>Training actions will respect the current regulatory framework and demands of the work and business environment. ROVI will provide training in new legislation, so that workers know and comply with current laws.</p>
<p>The use of different training tools is favoured (classroom, on-line, platforms, etc.).</p>
<p>Sharing the knowledge that exists in the company, continuing learning and cultural exchange is encouraged.</p>

Scholarships, training programmes and cooperation with educational institutions

For the ROVI Group, cooperation with universities and professional training centres is of key importance in incorporating new, young talent into the company. This is why the we hold more than 20 agreements with Spanish universities at national level, so that undergraduates in their last year and students studying for a Master's degree or doctorate can carry out their practical training in different areas of the company, while professional training students can obtain their practical training credits with one of the group companies.

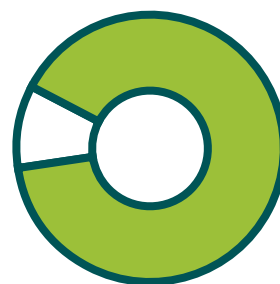
85% of the people who hold a scholarship with ROVI finally join the company with a contract. The possibility for young talents to train and the group's investment in this training is indispensable in order to have a good reserve of talent for the future.



90%
of the ROVI group's
scholarships are
remunerated



90%
of the
scholarships are
full time



90%
of the scholarships
last for
6+6 months



[404-1]

**HOURS OF TRAINING
BY PROFESSIONAL
CATEGORY**

	PROFESSIONAL CATEGORY									
	1	2	3	4	5	6	7	8	0	TOTAL
Hours of training	-	973.4	3,014.1	3,860.6	8,735.4	2,996.0	4,180.8	170.1	127.5	24,057.9

**HOURS PER
EMPLOYEE**

20.3

hours per employee
(average)

**TRAINING
INVESTMENT**

247.2€

euros per employee

4.5. Trade union information

ROVI has an appropriate understanding with the workers' representatives. Labour relations at ROVI are based on respect for the workers' legal representatives, strict compliance with the different applicable regulations and permanent dialogue that allows a constructive relationship of trust to be built between the two parties.

Dialogue with the workers takes place with smooth communication using all the resources available, especially meetings -both regularly, in accordance with a scheduled calendar, and specific, at the request of either the company or the workers' representatives. This allows the status of agreements to be monitored and any incidents arising from the company's day-to-day activity to be solved swiftly.

An important aspect of our works councils is that they are highly representative and participate in the Safety and Occupational Health Committees. On these committees, on a regular basis, the Company's actions in these areas are consulted, debated and proposed, as well as any incidents that have arisen and proposals for corrective measures.

[403-1]



The main matters discussed on these committees, where the company and the workers have equal representation, are the assessment and valuation of occupational hazards, the provision of individual protection equipment, the protection facilities, information and training on occupational hazards, among other issues. Through these joint bodies, ROVI's employees are represented in these matters at the highest level.

In 2018, labour relations ran as normal without any conflictive incidents. During the year, two significant negotiations were commenced and concluded in relation to items of remuneration, with a substantial change to working conditions and a move from one work centre to another, which concluded successfully.

ROVI informs its employees of matters of general interest, company milestones, agreements or organisational changes through the different channels available. The resources used try to make the best use of the latest technological advances available to reach the entire workforce, both the people who have access to office IT in the course of the work and those who do not. Thus, communication takes place through the internal television channel, notice boards, e-mail or the mobile phone application that is currently being implemented.

We should highlight the fact that all ROVI's employees in Spain work under the employment conditions regulated in the XVIII Collective Agreement of the Chemical Industry, last updated and signed in 2015. 100% of the employees are covered by this Agreement or by the agreements applicable in each specific work area (offices, sales, etc.). Not only does the company abide by the law, but it also implements certain enhancements, such as paying a supplement to Social Security benefits in the event of sick leave.

[102-41]

Employees of the subsidiaries in the rest of Europe are also governed by the pertinent collective labour agreement, except in cases where local legislation states they are subject to general labour legislation, given the low number of employees at the subsidiary.

4.6. Health and safety

The workers' well-being and health has a direct effect on the company's value creation. The management of personnel-related risks is the duty of the Health and Environment Department, which holds exclusive responsibility for aspects related to environmental management, as well as workplace safety and health throughout the group.

Said Department is responsible for managing workplace hazards. ROVI has an Integrated Environmental and Occupational Hazard Prevention Management Policy, applicable to the whole group, the objective of which to protect the life, physical integrity and health of all the workers, including both the group's own workers and those of the companies who work with it. This Policy is based on a series of corporate procedures, as well as local procedures or work instructions specific to each centre.



The principal occupational hazards identified by ROVI, following the corporate procedure for identifying hazards, assessing risks and determining controls, are mainly those inherent to a production plant: contact with and exposure to chemical products, noise exposure, overexertion, etc.

These risks are managed through planning the preventive activity (existence of specific procedures compliance with which minimizes the probability that these risks will materialize) and training (there are occupational hazard training plans and refresher plans). Furthermore, the risks identified are managed in accordance with the specific procedures created to control and regularly monitor the actions taken, such as those concerning work permits, safety inspections and the identification and evaluation of legal requirements.

The application of all these measures helped meet the accident rate target for 2018 in all the Group companies. Specifically, the ROVI Group set a goal of an accident rate (No. of accidents / No. of workers * 100) lower than 1.5% with sick leave and lower than 3.5% without sick leave. In addition, each plant, individually, defines specific prevention objectives. Examples of these are:

- Acquisition of a system for neutralising chemical products that allows injuries caused by contact with chemicals to be minimised in laboratory and production jobs in comparison with 2017. This goal was set at the Madrid and San Sebastián de los Reyes plants.
- Increase of 20% in comparison with 2017 of Production Area workers with broader prevention training. This goal was set at the Granada plant.
- Reduction in the moderate risk category associated to falling to a different level in the task of installing/removing the rotary valve of the roller compactor. This goal was set at the Alcalá de Henares plant.

In addition, in the aspect of promoting healthy lifestyle habits among employees, ROVI continued with the initiatives implemented in previous years, such as healthy breakfasts and vending at the plants, practising sports at nearby sports centres and participating in charity races, organised by ROVI's Corporate Social Responsibility area.

In order to prevent avoidable travel and trips, ROVI provides all the personnel who so require with a laptop computer with connectivity to the ROVI network and encourages the use of videoconferences and on-line meetings. Likewise, if the work performed so permits, teleworking is organised during the last weeks of pregnancy. Additionally, at work centres where street parking is difficult, the company makes parking spaces available to pregnant women.

FREQUENCY RATE FOR WORK-RELATED ACCIDENTS* BY GENDER

	2018
Men	3.176
Women	4.662
TOTAL	3.919

(*) Rate calculated as No. accidents / No. of hours worked * 1000000

WORK-RELATED ACCIDENTS SEVERITY RATE* BY GENDER

	2018
Hombres	0.229
Mujeres	0.125
TOTAL	0.177

(*) Rate calculated as No. of working days lost / No. of hours worked * 1000

WORK-RELATED ACCIDENT INCIDENCE RATE* BY GENDER

	2018
Hombres	0.375
Mujeres	0.674
TOTAL	0.524

(*) Rate calculated as No. accidents / No. workers * 100



Note: accidents on the way to work and data of ROVI group employees are included. Information on personnel hired through temporary employment companies are excluded.

The application of all these measures helped to meet the accident rate target for 2018 in all the Group companies, which was lower than 1.5% of accidents to number of workers at all the centres.

Accidents with sick leave	Days lost	Deaths
14	602.5	0
Frequency rate - accidents with sick leave	Severity rate	Incidence rate
3.919	0.177	0.524

Absence rate

For ROVI, good management in this respect has a direct effect on the workforce's health and well-being and, consequently, on productivity, the company's economic performance and attaining strategic goals.

ROVI's absence levels are below those in the sector where it carries on its activity, in spite of the fact that the number of days' absence in 2018 was 9,972, equivalent to 79,776 working hours lost, representing an absence rate of 2.09%.

	2018		2017	
	Economic group	Comp. Sector	Economic group	Comp. Sector
Total absolute	2.25%	3.44%	2.03%	3.20%
Absence rate	2.25%	3.44%	2.03%	3.20%
Absolute absence	2.09%	3.23%	1.84%	2.98%

	2018				2017			
	Days of sick leave	Days worked	Absence rate	Sector absence rate	Days of sick leave	Days worked	Absence rate	Sector absence rate
TOTAL	9,972	443,803	2.25%	3.44%	8,943	440,817	2.03%	3.20%

Source: Mutua de Accidentes de Trabajo FREMAP. Global Annual Absence Report ROVI GROUP



5. Suppliers



5.1. Management principles

[102-9, 102-10]

ROVI has put in place a series of specific action principles aligned with the company's principles and values, aware that suppliers are a group of strategic interest in its activities. The ROVI group makes its best efforts to comply with its commitments, where selection criteria and information transparency prevail, and is aware of the important role that suppliers play in its business in this respect.

ROVI has a supplier selection policy that includes a list of the criteria used to select each type of supplier. This policy envisages both initial and regular evaluations. Thus, a list of approved suppliers, kept by the Quality Department, is drawn up. There is also a Supplier Contracting and Payment Policy, aimed to establish a framework for relations with suppliers and creditors that is common to all the group. It states that suppliers with an annual volume of over 100,000 euros must always have a duly signed contract in force, regulates how invoices should be sent and recorded, and sets out the means of payment accepted.

As stated in the ROVI's Code of Ethics, any practice involving bribery or corruption as a way to obtain a decision favourable to the company's interests is rejected and practices intended to do business using undue means are not tolerated.

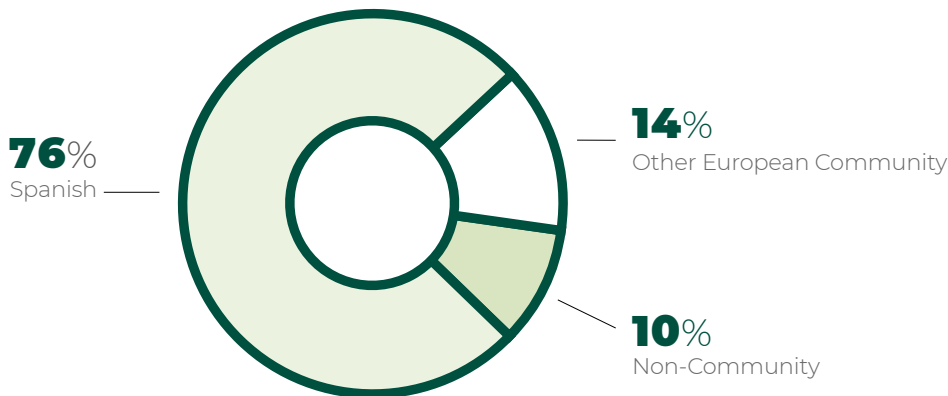
No ROVI employee may offer a third party any type of benefit that aims to influence illicitly or is offered with the intention of illicitly influencing the third party's capacity to adopt objective and legitimate business decisions. Likewise, ROVI employees are expressly prohibited from accepting any kind of corruption or bribery offered by a third party.

All interaction with health professionals, health organization, health systems, pharmacies, stores, purchasers, distributors, suppliers, commercial partners, public employees or any other third parties must be governed by legality and ethics and in line with ROVI's values, company policies, the applicable laws and industry standards.

ROVI has an anti-corruption policy that regulates both giving and accepting gifts. This policy must be known and observed by all the professionals. In no case may the acceptance or giving of gifts be used as a subterfuge for bribery or the concealment of an illicit action.



SUPPLIERS BY PURCHASE VOLUME



In 2018, ROVI worked with 7,819 suppliers from 35 countries. When analysing the types of supplier, attention should be drawn to the weight of the company’s Spanish suppliers, which represent 76% of the total, while more than 90% operate in European Union countries. In this respect, the effect of opening new subsidiaries in the main European markets, which also stimulates the contracting of local suppliers to provide services, should be highlighted. In addition to Spanish suppliers, if we consider the number of different suppliers (not the amount of their invoices), ROVI has a large number of German, Portuguese, French, British and Italian service providers.

5.2. Balance of the year and future challenges

Since 2013, the group has had a supplier payment policy in order to establish a common framework for relations with suppliers and creditors throughout the group. This guarantees total efficiency in accounting for invoices, an appropriate payment policy and greater consistency in negotiations. ROVI’s average supplier payment period in 2018 was 51 days, in line with the maximum payment periods provided for in Law 17/2010, which was amended by Law 11/2013.



5.3. CSR in the supply chain

ROVI requires all its suppliers to guarantee factors such as equal opportunities, occupational safety or care of the environment and to declare their commitment to basic principles of ethics and professional conduct. At the same time, it tries to involve suppliers and subcontractors in the adoption of the best corporate social responsibility practices in order to regulate their activities in accordance with the standards included in the certifications SA-8000, SGE-21 or similar.

The company has two mechanisms to try to guarantee and encourage the adoption of good social responsibility practices in its supply chain:

- It periodically sends a **voluntary document** entitled “**Commitment to CSR**” to all group suppliers and subcontractors, where it requests certifications such as SA-8000 or urges them to adopt good business practices. At present, more than 55% of the companies have signed this social responsibility commitment. ROVI's target is for all its suppliers to adhere to this initiative.
- **On-site** audits, in which it checks that suppliers operate in accordance with national and local regulations, that there are no significant non-compliances in respect of occupational safety and that there are no practices that infringe the workers' rights. Among other aspects, the auditors ensure that a safe work environment is provided, environmental legislation is observed, and employees do not suffer abuse or discrimination.

Additionally, the ROVI Group has a Code of Ethics for Suppliers, which establishes that all suppliers must respect the protection of fundamental human and labour rights recognised internationally. Specifically, the Code of Ethics for Suppliers requires all suppliers to comply with the following principles:

- Elimination of forced labour.
- Elimination of child labour.
- Respect for the right of association and collective bargaining.
- Equal opportunities and non-discrimination.
- The supplier must provide a fair work environment, free of any kind of violence.
- Respect for current legislation on working hours and remuneration.

Attention should be drawn to the fact that, as stated above, more than 90% of the ROVI Group's suppliers operate in countries belonging to the European Union and those that carry on their activity outside the European Union enjoy recognised prestige in the international community. This means that supplier non-compliance with Human Rights requirements is considered unlikely, limited and under control.



6. Society



6.1. Management principles

ROVI's activity has a direct impact on society at different levels and the group is very much aware of this. Since its beginnings, it has been permanently involved in supporting medical research and committed to higher education in Spain, and has acted responsibly in respect of both its tax obligations and its role as an employer and economic agent of proximity.

The group's General CSR Policy establishes contributing actively to social progress as a principle for action in relation to society and, in this respect, ROVI is committed to economic and social development in the areas where it carries on its activity.

Commitment to society

ROVI assumes the impact of its activity on society, assessing and managing the non-financial, ethical, reputational, social and environmental risks, and it commits itself to those social initiatives or activities that benefit society. ROVI considers that its priority areas of social action are improvements for those with disabilities and their incorporation into the workplace, the promotion of health, fostering research, commitment to training and corporate volunteering.

6.2. Balance of the year

ROVI holds agreements with public and private entities in order to combine efforts that reinforce scientific, technological and educational activities, as well as spreading knowledge.

In order for qualified students to access a work environment and improve their skills, knowledge and experience, the company has a training programme. In this respect, there are co-operation agreements with 73 educational centres (universities, institutions, official training centres and business schools) throughout Spain. This training helps students to commence their working life in a professional work environment and 49 people took part in 2018.



Commitment to research

[102-13]

At the same time, ROVI uses part of its resources to promote medical research. Over recent years, the company has carried on intensive activity to support research and foment the prevention and knowledge of certain diseases in collaboration with health professionals.

ROVI is very much involved in supporting co-operative research, holding important co-operation agreements with different public bodies and universities, such as the co-operation agreement with the University of Granada, with which it aims to combine efforts that increase scientific, technological and educational activities and the sharing of knowledge.

The Company likewise co-operates with scientific associations and societies of different types in supporting the health professionals' quest for innovation. An example is the SEFH/ROVI Hospital Pharmacy Development awards, which have been awarded jointly with the Spanish Hospital Pharmacy Society (SEFH) for the last two years and recognise projects that represent the contribution of innovative solutions that are beneficial to patient well-being and quality of life.

Since June 2016, ROVI, like the rest of the pharmaceutical industry, has been publishing the data of payments made to health professionals in order to endow this relationship with greater transparency. The amount used for these donations in 2018 will be disclosed in the group's 2018 Annual Report, as occurred in 2017.

[201-1]

ECONOMIC VALUE GENERATED AND DISTRIBUTED

MILLIONS OF EUROS	2018	2017	2016
ECONOMIC VALUE GENERATED	304.8	277.4	270.8
ECONOMIC VALUE DISTRIBUTED			
Shareholders	4.5	6.0	9.1
Suppliers	172.7	154.7	153.5
Society	-1.2	0.3	1.8
R&D	32.4	28.3	17.5
Employees	70.2	64.0	60.5
Providers of capital	0.8	0.9	0.5
Amortisation and depreciation	12.0	11.5	11.0
Reserves	13.4	11.8	17.0



Support to groups with disabilities

ROVI is aware that the group of people with disabilities is one of the groups at risk of social exclusion with the greatest difficulties in finding work. Additionally, it is convinced that the company is enriched by the contribution made by these differently-abled people, who provide it with added value.

In line with the foregoing, ROVI is committed to mainstreaming people with disabilities at work and encourages hiring them. Thus, at 31 December, 2018, 25 employees with disabilities were working for the company, 20 of them formed part of ROVI's direct workforce, while 5 were working through temporary employment companies.

- **ISS Facility Services (Gelim).** ROVI has contracted out the cleaning of its offices to people with disabilities.
- **Ilunion**, with which ROVI has contracted the laundry service.
- **Fundación Manantial**, which has the purpose of integrating people with severe mental disorders. ROVI cooperates with this foundation in several ways, since it is also certified for the secondary packaging of the company's products, in addition to catering services at group offices.

The Company holds an agreement with the Fundación Prodis whereby it conducts a supported employment programme aimed at the workplace inclusion of persons with intellectual disabilities who are able to perform high-quality work when they receive the necessary training and support. ROVI firmly believes in the personal, social and employment capacities of people with intellectual disabilities, who are able to perform high-quality work when they receive proper training and support.

In addition to the foregoing, ROVI carries out actions to foment the inclusion of this group in the workplace in two spheres. First, within its activities related to Corporate Social Responsibility, it provides economic cooperation to various non-profit entities that carry on their activities in the area of the workplace and social inclusion of persons with intellectual disabilities. Likewise, Special Employment Centres are its service providers in several different areas of the Company's activity.

The problems of physical accessibility in work environments and difficulty in using objects and products, irrespective of their technical, cognitive or physical skills, are barriers that hinder the full mainstreaming of people with disabilities in work and social environments.

Regarding the first of the barriers, ROVI strives for the work centres where it carries on its activity to be accessible to everyone safely, comfortably and autonomously.

In this area, ROVI is carrying out a remodelling plan at its work centres, intended to make them accessible for people with disabilities. Applying this plan, five of the organisation's seven work centres are now accessible and it is planned to adapt the two remaining centres to allow accessibility.

In addition, the products marketed by ROVI are also labelled in Braille, so that the visually impaired can use them autonomously, thus fully attaining the objectives for which they were designed.

And, finally, ROVI fosters sensitisation as the primary tool to combat barriers to persons with disabilities. In this respect, it conducts corporate volunteering activities in cooperation with non-profit organisations engaged in the social integration of persons with mental and intellectual disabilities. Thus, employees obtain first-hand knowledge of the main barriers that persons with disabilities have to surmount in their daily lives. These activities are made known through the company's internal television channel and periodic internal publications. Thus, the company's commitment to accessibility and inclusion is shared with the employees and ROVI strives to raise awareness of disabilities and combat the discrimination suffered by this group of people.



Social action, sponsorship and patronage

ROVI has a constant commitment to social action close to its environment and co-operates permanently with non-profit organisation. Thus, in 2018, it continued to co-operate with the Granada Red Cross in its child assistance and protection projects; with Proyecto Hombre Granada, in the continuity of its social reintegration activities; and with Fundación Recover, co-operating in its programmes to improve healthcare in Africa.

The company has continued to bet on co-operation with entities that work on the integration and mainstreaming of persons with disabilities through sport, such as Fundación También and Fundación Deporte & Desafío.

Working with many of these foundations, ROVI has been able to expand the corporate volunteering activities available, so that ROVI employees can get to know the world of disability first-hand, thanks to our inclusive sports events, such as the Adaptive Skiing Campus in Sierra Nevada (Granada), the Adaptive Descent of the River Sella (Asturias), the VII Sponsored Race of Madrid, and the Eco-Trekking and Multisports Days (both in Madrid). In 2018, 135 ROVI employees took part in some of the activities scheduled by the CSR Area.

Furthermore, continuing with its policy of promoting healthy living habits and co-operating with non-profit entities that work to include groups at risk or to improve healthcare in different countries, ROVI co-operated, for the first time, as a sponsor for several charity races, such as the VII Charity Race for Mental Health, organised by Fundación Manantial in Madrid, or the I Medicusmundi South Charity Race South, organised by Medicusmundi South (Granada).

Fundación Prodis also joined the list of foundations that co-operate with ROVI in 2018. In this case, through a dual channel: Prodis helped the company in the process of recruiting a person with Down's syndrome for ROVI's Human Resources Department, while its Special Employment Centre worked with the Corporate Social Responsibility Department as a supplier of sports material for corporate volunteering (T-shirts, caps, etc.). Thus, Prodis joined other suppliers, such as ISS Facility Services (Gelim), Ilunion or Fundación Manantial, which are engaged to provide certain services performed by persons with disabilities.

Additionally, throughout 2018, ROVI continued the work of the Donations Committee, which channels the requests for co-operation that ROVI receives from healthcare organisations and social or humanitarian entities. Its mission is to review each application and check that it complies with current legislation, the Code of Good Practices of the Pharmaceutical Industry and ROVI's Code of Ethics.

Volunteering and co-participation

Since 2016, ROVI has been running a corporate volunteering project, which has become one of the pillars of the company's social action, in order to continue to increase its commitment and solidarity. This programme's goal is to give all employees the chance to play a leading role in change, co-operating as volunteers with social actions organised with the foundations and NGOs with which ROVI has been co-operating for years. In 2018, this programme continued through the following activities:

- Charity Race for Mental Health, of Fundación Manantial (17 February).
- Adaptive ski-ing campus with Fundación También, also in Sierra Nevada, Granada (17 March).
- Mother's Day volunteering with Fundación Recover in Fuenlabrada (6 May).
- Eco-trekking with Fundación Deporte & Desafío, in Madrid (2 June).
- I MedicusmundiSur Charity Race in Granada, of MedicusmundiSur (1 July).
- Adaptive descent of the River Sella, with Fundación También, in Asturias (27 July).



- Multi-sports Day with Fundación Deporte & Desafío at the Somontes Sports Complex in Madrid (15 September).
- Charity Race to help children, of the Granada Red Cross, in Granada (28 October).
- También Madrid Charity Race, of Fundación También, in Madrid (28 October).

Relations with the public authorities and tax responsibility

As a provider of active substances, medicines and healthcare products, ROVI has an ongoing relationship with the health authorities. The group actively strives to be vigilant and for strict observation of the health authorities' requirements in all its activities – industrial development, manufacturing and supply of products, as well as supplying units for clinical trials-, always carried out in an environment of strict compliance with all legal and regulatory requirements that apply to them, as well as the authorisations granted by the authorities.

In addition, ROVI has a Corporate Tax Policy that establishes its commitment to strict compliance with tax requirements by applying good tax practices and acting transparently, paying taxes responsibly and efficiently and promoting relationships of co-operation with governments, endeavouring to avoid material risks and unnecessary conflicts. To support its tax practices, ROVI hires the services of an external tax advisor, who keeps the group updated on new tax developments and advises on any doubts that arise. Additionally, the tax advisor reviews the preparation and filing of the different taxes, as well as group decision-making on tax matters.

THOUSANDS OF EUROS	Profit before tax	Income tax paid	Government grants received
Laboratorios Farmacéuticos Rovi, S.A.	11,444	(3,108)	1,587
Laboratorios Farmacéuticos Rovi, S.A. permanent establishment Portugal	(343)	(33)	-
Laboratorios Farmacéuticos Rovi, S.A. permanent establishment Poland	(2)	-	-
Laboratorios Farmacéuticos Rovi, S.A. permanent establishment Germany	-	-	-
Rovi Contract Manufacturing, S.L. (*)	16,348	-	-
Bemipharma Manufacturing, S.L. (*)	(36)	-	-
Pan Química Farmacéutica, S.A. (*)	531	-	-
Gineladius, S.L. (*)	(9)	-	-
Frosst Ibérica, S.A. (*)	5,351	-	-
Bertex Pharma GmbH	-	-	-
Rovi Biotech, Limited	(30)	-	-
Rovi Biotech, S.R.L.	9	-	-
Rovi Biotech, GmbH	(82)	-	-
Rovi S.A.S.	(729)	-	-
Rovi Biotech, Ltda.	-	-	-
TOTAL		(3,141)	1,587

(*) These companies form part of tax group 362/07, of which Laboratorios Farmacéuticos Rovi, S.A. is the parent.



7. Shareholders



ROVI's two commitments to its shareholders are clear: value creation and transparency. The company, since it was first listed on the stock markets, has carried out intensive activity in investor relations and regularly reports on all its activities, updating and applying its "Policy for Communication with Shareholders, Institutional Investors and Proxy Advisors".

Likewise, it has different channels for direct communication with investors. Shareholders may, if they so wish automatically receive financial information on ROVI through an e-mail alert system and the group provides regular, one-off and/or significant information on the company in the form of presentations and legal, economic/financial and corporate governance documents, which may be consulted on the corporate website.

Investor relations activity

At the same time, ROVI carries on continuous activity throughout the year through meetings, forums and events with investors. During 2018, ROVI held 12 road shows, participated in 9 events with investors and made 23 visits to investors and teleconferencing calls. In total, this represented attention to more than 215 investors.

Analyst cover

At 31 December, 2018, ROVI was covered by 14 analysts. In 2018, two new analysts began to cover ROVI, Jefferies and Renta4, while another two, Banco Santander and Kepler Cheuvreux, resumed cover. The consensus of the analysts was a buy recommendation for ROVI with an average target price of 18.53 euros, 6% higher than the closing price of the share at 31 December, 2018, which was 17.45 euros.

Capital increase

[102-10]

In 2018, ROVI increased its equity by 88 million euros. Net transaction-related expenses were 3.9 million euros, meaning that the net capital increase was 84.1 million euros.

The purpose of the funds obtained from the capital increase was to partially fund the Phase III clinical trials of Risperidona ISM® and other expenses related to Risperidona ISM® until it was, if approved, marketed; to fund, fully or partially, the Phase I clinical trials of Letrozol ISM®; to support the current marketing of the enoxaparin biosimilar Becat®; and any other general corporate needs, possibly including acquisitions.

At the publication date of this report, ROVI has used 22.5 million euros of these funds to acquire Falithrom® and Polaramine®, among other uses.



Capital structure

At 31 December, 2018, significant shareholders with an interest of more than 3% are those shown below:

SIGNIFICANT SHAREHOLDERS

PERCENTAGE OF VOTING RIGHTS	DIRECT	INDIRECT	TOTAL
Norbel Inversiones, S.L.	62.102%	-	62.102%
Indumentaria Pueri, S.L.	-	5.057%	5.057%
Alantra Asset Management, SGIC, S.A.	-	4.821%	4.821%
T. Rowe Price Associates, Inc	-	3.390%	3.390%
JO Hambro Capital Management Limited	-	4.787%	4.787%
Wellington Management Group, LLP	-	5.116%	5.116%
TOTAL	62.102%	23.171%	85.273%

Significant shareholders hold 85.273% of ROVI's capital.

In October 2018, the increase in equity led to the dilution of the majority shareholders, Norbel Inversiones, S.L., whose interest dropped from 69.640% to 62.102%.

All the significant shareholders, except JO Hambro Capital Management, subscribed to the capital increase.

Attention should be drawn to the inclusion of Wellington Management Group as a significant shareholder. It subscribed to the capital increase with an interest of 3,013% and, between then and 31 December, 2018, increased its position by 2.103 percentage points, to 5.116%.



8. Environment



8.1. Environmental management principles

ROVI's commitment to environmental protection is firm and constant and forms part of its day-to-day activity. ROVI is aware that, in the course of its day-to-day work, it has an inevitable impact on the environment and on workplace safety and health in a number of ways, since each one of its companies is in a different context, depending on whether it is engaged in manufacturing or marketing and where it is located. Therefore, ROVI undertakes to reduce the effects of its activity to a minimum when and where this is possible, likewise allocating all the resources necessary to guarantee people's safety and health.

The Group's General CSR Policy highlight environmental care as an indispensable basis for its actions. Together with the principles of quality and workplace safety to protect ROVI's employees, it is one of the pillars that support the sustainable management principles of its activity from an environmental standpoint. It materialises in actions aimed to prevent pollution, manage resources efficiently and foster environmental responsibility, as set out in the Integrated Environmental Management and Risk Prevention Policy, which governs ROVI's activities in environmental matters.

The group has a Department that is exclusively responsible for environmental management-related aspects and those concerning workplace safety and health, which, in 2018, managed a budget of 1,042,972 euros, used for a number of actions based on continuing improvement in compliance with both legal requirements and additional voluntary requirements through implementation of efficient energy solutions, the rational management of natural resources and recycling of the waste produced, aspects that are the basis of the company's environmental strategy.

The key tool to ensure correct management of environmental aspects is the introduction of an environmental management system based on the criteria established by the international standard ISO 14001:2004 and the Eco Management and Audit Scheme Regulation (EMAS). These certifications recognise the quality of ROVI's environmental management system and assure its commitment to the environment in terms that go beyond current national legislation.

At present, the group companies Laboratorios Farmacéuticos Rovi, S.A., Rovi Contract Manufacturing S.L. and Frosst Ibérica S.A. hold environmental management systems certified under ISO 14001:2007. In 2018, these systems were likewise certified under the new version of the international standards, ISO 14001:2015.

ROVI has a corporate communication, participation and query procedure, through which queries, complaints, suggestions, etc. related to the environment and workplace health and safety are managed. On the corporate website (www.rovi.es), the environmental certificates held by group companies are available to the public.



Among the main risks related to the environmental activity, apart from those inherent thereto, are the risks concerning access to and verification of the environmental regulations in the different areas in which ROVI operates, as well as possible restrictions imposed by the authorities in particular locations, specifically the following:

- Non-compliance with legal requirements due to deficient identification of either legal requirements concerning the environment or environmental aspects or of emergencies, when this may lead to possible sanctions or stakeholder dissatisfaction.
- Failure to adapt to a change in the trend in legislation or any applicable new legislation on a timely basis.
- Possible administrative restrictions in force in particular locations.
- Impact on material and human assets due to an environmental incident of neighbours or employees.
- Bad environmental practices on the part of external companies providing services on a permanent basis or the Group personnel supervising them.
- Non-compliance with noise regulations that leads to contingencies or disciplinary sanctions.
- Pollution due to exceeding the pollutant emission limits on boilers or discharges to groundwater that may lead to an administrative sanction.
- Incidents in transporting hazardous waste that may lead to a sanction.
- Deficiencies in personnel training on environmental matters.
- Releasing emissions into the atmosphere due to the absence of mechanisms to prevent the product leaking from the equipment.
- Failure to check invoices that show consumption of an inappropriate amount of water or energy.
- Mixture of different kinds of waste and generation of hazardous waste.
- Absence of energy efficiency certification.
- Failure to file the annual waste report and minimisation plan on a timely basis.

In addition, ROVI manages indirect environmental aspects resulting from trading relations, products or services that may have adverse effects in the environmental area. For each production plant, an analysis is made of the life cycle of the process or product, where all direct and indirect environmental aspects involved (coming from suppliers) are identified bidirectionally. Once they have been identified, in accordance with the Corporate Procedure for Identification and Assessment of Environmental Aspects, the indirect aspects on which ROVI is able to take action are verified.

The possible materialisation of environmental risks is managed, likewise, through the Corporate Procedure for Identification and Assessment of Environmental Aspects, which sets out how environmental risks should be identified, reported and quantified.



8.2. Consumption and waste

ROVI's own activity generates a number of types of waste and a commitment on the part of the company itself, establishing waste treatment and reduction as one of its priorities in order to reduce the impact to a minimum and prevent its pollutive effects. Processes concerning waste treatment are aimed mainly to minimise it in the production processes and proper management once it has been produced, and to favour its use and recycling whenever possible.

Regarding energy, at all ROVI's product plants, water, electricity and gas indicators are verified and reported on a monthly basis, analysing any possible deviations. Likewise, in the Distribution business, the energy has been contracted with a provider of 100% renewable energy.

The key environmental indicators are shown below. The data have been divided among the different companies or businesses to allow them to be compared with each other, since the units produced are measured in different units for each one of the companies/businesses. Specifically:

- Manufacturing plant belonging to ROVI, S.A. in Granada: this is the plant where Bemiparin and Enoxaparin, the active substances of ROVI's principal own research products are produced. In this case, the units produced are measured in MUI, the activity of the active substance produced.
- Distribution business of Laboratorios Farmacéuticos ROVI, S.A. and subsidiaries: in this case, distributed units are used.
- Injectables production plants of Rovi Contract Manufacturing, S.L. (San Sebastián de los Reyes and Madrid plants): in this case, the units produced are expressed in individual units packed. Solid forms production plant of Frosst Ibérica, S.A. in Alcalá de Henares: here, the pack of solid forms is used as the unit produced (tablets, coated tablets, hard capsules and sachets).



[301-1, 302-1, 303-1]

WASTE*

	ROVI Granada	ROCM	Frosst	Distribution
Tonnes of hazardous waste generated	1.037	186	176	25
Tonnes of non-hazardous waste generated	1.336	464	283	1
TOTAL waste	2.373	651	459	25
Tonnes hazardous waste/million units	0.003	1.70	5.17	1.15
Tonnes non-hazardous waste/million units	0.004	4.24	8.31	0.03
TONNES WASTE/MILLION UNITS	0.008	5.95	13.49	1.18

ENERGY CONSUMPTION*

	ROVI Granada	ROCM	Frosst	Distribution
kWh electricity consumed	3,002,572	7,206,775	8,100,711	630,352
kWh energy / million units produced	10	65,863	238,256	29,306
kWh natural gas consumed	1,941,716	6,371,676	14,426,850	0
kWh natural gas / million units produced	6	58,231	424,319	0
Litres vehicle fuel	500	409	1,279	518,653

NATURAL RESOURCE CONSUMPTION*

	ROVI Granada	ROCM	Frosst	Distribution
m3 water consumed	27,399	51,842	62,516	985
m3 water / million units produced	0.1	473.8	1.838.7	45.8

(*) Figures for the last month of 2018 are an estimated based on the information for preceding periods.



Climate change

As a contribution to the fight against climate change, ROVI not only takes electricity consumption into account, but also measures other factors at its facilities, such as CO2 emissions from natural gas and diesel consumption derived from electricity and vehicles, as well as other substances that might act to destroy the ozone layer.

[305-1]

ATMOSPHERIC EMISSIONS*

	ROVI Granada	ROCM	Frosst	Distribution
Tonnes CO2 emitted	1.135	3.073	4.936	290
Tonnes CO2 / million units	0.004	28.08	145.18	13.47

(*) Figures for the last month of 2018 are an estimated based on the information for preceding periods.

ROVI's greenhouse gas emissions have always been insignificant, very much lower than the legally-established levels. Likewise, in the Distribution business, a Mobility Plan has been approved in Spain in order to try to reduce fuel and electricity consumption, which are the only emissions made.



9. Supplementary information



9.1. About this report

[102-46, 102-48, 102-49, 102-50, 102-51, 102-52, 102-53]

This report describes the main activities carried out by ROVI in Corporate Social Responsibility (CSR). On the annual basis decided by the company, ROVI wishes to report on the progress made and challenges associated to its CSR, as well as the actions that allow it to contribute to our society's sustainability in this respect for 2018.

This report has been prepared following the recommendations of the 2016 Global Reporting Initiative (GRI) standards. Point 9.2 of this document includes a table that links the indicator number with the section of this document where the relevant information is included. ROVI's commitment to ethical management and transparency is shown in the development of its internal codes. Furthermore, ROVI has applied standard SA-8000 "Social Responsibility" to the nature, size and impact of its activities, products and services, which helps to reinforce its principles for action.

The information included in this report covers the 2018 calendar year. The last annual report was drawn up in 2018 with the information for 2017. Thus, we present the report following the annual cycle.

The information provided in this document refers to the entire ROVI group, except in those cases where otherwise indicated.

If further information is required on any of the data included herein, the company has made a direct communication channel available at e-mail address ir@rov.es.



9.2. GRI Content Index

[102-55]

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CSR Report 2018



C/ José Isbert, 2
28223 Pozuelo de Alarcón (Madrid)
Tel: (+34) 91 021 30 00
www.rovi.es