



Laboratorios
farmacéuticos
ROVI

Integrated Report

—
2022





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ROVI

Integrated Report

2022



Index

1

Letter from the Chairman **5**

2

Our ESG performance and
contribution **7**

2.1
Summary of ESG Performance and
Contribution **8**

2.2
Key milestones in 2022 **11**

2.3
Our response to the Key Challenges
of 2022 **12**

3

Group profile **13**

3.1
Group Profile **14**

3.2
National and International Presence **16**

3.3
Ownership and Structure **20**

3.4
Business Units **21**

4

Our strategy and sustainable
growth model **29**

4.1
Market Context **30**

4.2
Identity and Commitment: mission,
vision and values **38**

4.3
Corporate Strategy **40**

4.4
Materiality **48**

4.5
ESG Master Plan **53**

5

Our financial performance in
2022 **57**

5.1
Results for the year **59**

5.2
Value for the Shareholder **64**

5.3
Tax Transparency **68**



6

Our responsible and sustainable management **71**

6.1

Our Commitment to Good Governance **72**

6.1.1. Our corporate governance model and structure **73**

6.1.2. Ethics and integrity in the business model **83**

6.1.3. Regulatory compliance **86**

6.1.4. Remuneration policy **89**

6.1.5. Global management and risk control **90**

6.1.6. Commitment and contribution to the SDGs regarding good governance **97**

6.2

Our Commitment to People **98**

6.2.1. Commitment to our customers, patients and healthcare professionals **99**

6.2.2. Commitment to our employees **104**

6.2.3. Commitment to our value chain **119**

6.2.4. Commitment and contribution to the environment in which ROVI operates **125**

6.2.5. Commitment and contribution to the SDGs regarding People **136**

6.3.

Our Commitment to the Environment **139**

6.3.1. Environmental policy, goals and commitments **140**

6.3.2. Environmental management system **142**

6.3.3. Sustainable use of resources **145**

6.3.4. Waste management and circular economy **151**

6.3.5. Mitigation of Climate Change **152**

6.3.6. Commitment and contribution to the SDGs regarding the environment **157**

7

European Union Taxonomy

159

8

About this Report

169

9

172

Appendix

Appendix I
Financial Performance **173**

Appendix II
Our Commitment to People **178**

Appendix III
GRI Content Index **186**

Appendix IV
Content Index: Law 11/2018 - GRI **190**

Appendix V
SDGs **196**

Letter from the Chairman

Dear Shareholders,

Since I became the chairman of the Company, this annual letter has furnished me with the opportunity to address all our stakeholders, particularly our shareholders, whose backing is essential to the our company's performance.

I would like to begin by highlighting the result of the evaluation of ROVI's ESG aspects by Sustainalytics, one of the leading independent firms in the research, evaluation and analysis of ESG and corporate governance topics. In 2022, ROVI was in the leading position among the 458 companies evaluated in the pharmaceutical industry category and in 22nd place out of a total of 970 companies in the sector, which includes biotechnology laboratory equipment and pharmaceutical companies.

There is no doubt that this reflects the strong commitment of each and every one of the professionals who form the ROVI Group. Not only do they conduct the Company's business, but they do so in a responsible and sustainable manner. In 2022, ROVI continued to boost its sustainable growth strategy through the approval of a three-year ESG Master Plan (2023-2026) by the Company's Board of Directors, aligned with the Group's Purpose and Values. It sets out the key environmental, social and corporate governance commitments and the goals, action plans and key indicators that allow the Group's performance in this area to advance and enable it to be evaluated.

2022 was a crucial year for ROVI from the strategic, operating and financial points of view. In a difficult economic environment, still affected by the pandemic, with geopolitical tensions combined with the energy cost increase and inflation, ROVI was capable of taking advantage of new opportunities, starting new projects such as the launch of Okedi® in Europe, strengthening the collaboration agreement with Moderna and achieving record results.

At present, we are undergoing a transformation process that will not only allow us to internationalise the Company and reposition it towards products with a higher value-added, but also to increase the production capacity in order to meet future demand.

In 2022, we reinforced our market position with operating revenue of 817.7 million euros, surpassing the previous year's figure by 26%, EBITDA that rose 37% to 278.9 million euros,



and net profit of 199.7 million euros, 30% up on 2021. All the foregoing was thanks to the strength of the CMO business, which grew 52%, and the specialty pharmaceutical business, where sales rose by 8%.

Regarding our growth outlook, in the first place, our main growth driver, the heparin division, accounted for 32% of sales in 2022 and is currently undergoing strong growth. It is precisely in this area where we aspire to become a world leader with our two low-molecular-weight heparins: Bemiparin and the enoxaparin biosimilar.

Bemiparin is a mature product that has been on the market for over 20 years and is the only second-generation low-molecular-weight heparin that guarantees effective 24-hour cover for all patient profiles with a single daily dose, both for the prevention of thromboembolic disease and to treat established venous thrombosis, with or without pulmonary embolism. As a result of this differentiation advantage and our sales capacity, we have been able to achieve a strong competitive position, with sales of 103.8 million euros in 2022, 36% of which were international sales.

Our enoxaparin biosimilar has become the main value generator in the low-molecular-weight heparin area. We began to market it in the fourth quarter of 2017 and sales have risen gradually since then, reaching 152.9 million euros in 2022, 23% higher than in the previous year. At present, our enoxaparin biosimilar is marketed in 38 countries and we hope to be present in over 90 countries in the coming years.

We are very excited by the growth potential of the heparin division. This is why we are so eager to work for greater vertical integration in our value chain and become self-



sufficient in heparins. In October 2022, we reached a joint venture agreement with Càrniques Celrà, S.L. and Grupo Empresarial Costa, S.L. for the creation, through Glicopepton Biotech, S.L., of one of the first national structures to self-supply an essential medicine, as is the case of low-molecular-weight heparins.

Second, regarding another of our growth drivers, the specialty pharmaceutical division in Spain, which accounted for 19% of sales in 2022, I would like to highlight our track record in launching new products, 15 in the last twelve years. Currently, we have a portfolio of over 40 products, including both our own and those of third parties, and we hope that this division will provide us with an opportunity for sustainable and profitable growth in the future.

Third, I draw special attention to our CMO division, which has an exciting outlook for the future. According to GlobeNewswire¹, the world market is expected to increase by 7% between 2022 and 2027 due to the growing trend among pharmaceutical companies to outsource their production activities.

In this respect, ROVI has been in the business for over 25 years, which makes us a leading company in the sector. In 2022, the CMO business accounted for 49% of sales and grew 52%, surpassing the high end of our guidance for 2022, which was between 30% and 40%.

Due to the results obtained and our effort in this division, we extended our collaboration with Moderna through signature of a ten-year agreement that will allow a significant increase in our production capacity, which we expect to be fully operational at the end of 2024. Under the terms of this agreement, we hope to manufacture not only the COVID-19 vaccine, but also future Moderna mRNA vaccine candidates.

Regarding the marketing of new products, we are very excited at the launch of Okedi® in Europe. This is a long-acting monthly risperidone injection to treat schizophrenia, based on our ISM® technology. Likewise, it is in the registration phase in the United States under the name of Risvan® and target is for it to be approved in the second half of 2023.

This launch has consolidated our internationalisation strategy as one of our pillars for future growth. At the end of 2022, Okedi® sales reached 2.0 million euros and we expect them to increase in 2023 as a result of higher penetration of the product in the countries where it is already present (Germany, United Kingdom and Spain) and its launch in other European countries.

Likewise, in the second quarter of 2023, the phase I clinical trial of three-monthly risperidone is expected to continue. This will complement the present formulation of Risperidone ISM® for the maintenance treatment of clinically-stable schizophrenia patients.

Furthermore, we are proud of the phase I results achieved with Letrozole ISM®, our second candidate based on the ISM® technology, for the treatment of hormone receptor-positive breast cancer. They confirm that this ISM® formulation provides a prolonged release of letrozole that produces sustained suppression of the oestrogenic hormones. After these results, the United States regulatory authority, the Food and Drug Administration (FDA), has required us to conduct a phase II clinical trial in patients with locally advanced or metastatic breast cancer, which we hope to begin in the near future.

These two new trials reflect our clear bet on the ISM® technology, which we hope will be a future growth driver for the Company.

This solid operating and financial outlook provides us with guarantees to tackle the challenges of investment and growth in the pharmaceutical sector. In 2022, we invested 51.4 million euros, 77% of which corresponded to investments in our facilities.

ROVI has a strong balance sheet, as seen from its net cash position of 54.2 million euros at 31 December, 2022. We trust that the strength of our balance sheet will allow us to take other opportunities to increase our sales and the return on our assets.

None of our achievements would be possible without the people who form ROVI, who give the best of themselves every day. I would like to thank them for their involvement and commitment. Without them, we would not have achieved the best results in ROVI's history. I would also like to thank our investors, shareholders, partners and customers for their support and their contribution to our exciting project. They are indispensable if we are to continue creating value for society overall.

We undertake to continue striving to contribute to ROVI's growth. This combination of effort and ambition will allow us to overcome the challenges and continue with our contribution to the progress of our society.

Juan López-Belmonte Encina

Chairman and Chief Executive Officer of ROVI

(1) GlobeNewswire, 27 April 2022.



2

Our ESG performance and contribution

2.1

Summary of ESG Performance
and Contribution

2.2

Key milestones in 2022

2.3

Our response to the Key
Challenges of 2022





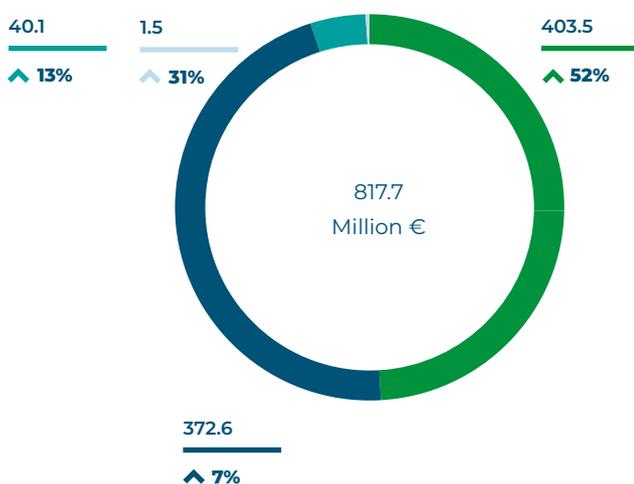
2.1. Summary of ESG Performance and Contribution

Financial figures

€ million	2022	2021	2020	2019	2018	2017	2016
Revenue	819.8	650.0	421.1	382.5	304.8	277,4	266,7
EBITDA (1)	278.9	202.9	94.2	60.9	29.5	29,9	39,3
EBIT	256.0	181.6	74.7	42.6	17.5	18,4	28,3
Net profit	199.7	153.1	61.1	39.3	17.9	17,2	26,1
Investment	51.4	40.9	39.7	40.5	26.4	19,9	18,1
Financial debt	72.2	73.2	74.4	84.8	34.2	43,2	33,8
Net financial debt	-54.2	-27.4	19.8	15.9	-62.8	1,1	-9,0

(1) Operating profit before interest, taxes, impairment, depreciation and amortisation.

Operating revenue 2022



- Contract manufacturing
- Prescription pharmaceuticals
- Contrast agents for diagnostic imaging and other
- Non-prescription pharmaceuticals (OTC) and other hospital products

26% Variation on 2021

Stock market information

	2022	2021
Number of shares	54,016,157	56,068,965
Closing price	€36.06	€73.80
Capitalisation at 31 December	€1,948 M	€4,138 M
Total dividend	53,580 thousand €	21,373 thousand €
Dividend per share paid in the year and charged to the previous year's profit	0.9556 euros	0.3812 euros
Pay out (as % of consolidated net profit)	35%	35%
Profit per share	3.70 euros	2.73 euros
PER (*)	9.75	27.0

(*) Price-earnings ratio or the ratio between the price of a share and its annual earnings.

Non-financial figures for 2022

1. Governance area



Percentage of
independent directors

42.85%

✓ 7.15 pp vs. 2021



Percentage of female
board members

42.85%

^ 26.15 pp vs. 2021



Percentage of local
senior management

100%

= vs. 2021

2. Social area



> Our consumers



- We guarantee the quality and safety of our products
- Pharmacovigilance system implemented

- Ratio claims / million units distributed:

8.35

^ 49.6% vs. 2021

> Our employees



Number of
employees at year
end

1,993

^ 13.8% vs. 2021

Percentage of
employees with
permanent contracts

89%

^ 12 pp vs. 2021

Diversity of
workforce

53%

Women

47%

Men

Hours of
training

56,885

^ 15.2% vs 2021

Percentage
of employees
covered by
collective
agreement

57%

> Our value chain

- European Medicines Verification Organisation (EMVO) System
- Code of Ethics for Suppliers – mandatory compliance

Over

3,000

suppliers

suppliers from

41

countries

95%

of suppliers
members of the
European Union

Local Spanish suppliers
bear the main weight

Spanish suppliers account
for **74%** of the global total
and **78%** of the European
total

> Our environment



Beneficiaries
of social
projects

225,587€

Donations to foundations,
collaboration agreements
and sponsorships

Economic value
distributed

820

million euros

43,000€

Donations of healthcare
equipment



3. Environmental area



Electricity consumption (kWh)

2022
28,935,843
2021
22,992,472
% Variation
26%



Fuel consumption (litres)

2022
378,520
2021
366,778
% Variation
3%



Hazardous waste generated (tonnes)

2022
5,223
2021
3,017
% Variation
73%



Scope 1 & 2 CO₂ emissions (tonnes CO₂ eq)

2022
7,309
2021
6,231
% Variation
17%



Natural gas consumption (kWh)

2022
30,618,062
2021
28,449,480
% Variation
8%



Water consumption (m³)

2022
206,487
2021
182,230
% Variation
13%



Non-hazardous waste generated (tonnes)

2022
3,703
2021
3,425
% Variation
8%

Compensation of 100% of the Group's Scope 1 and 2 emissions (7,310 tonnes).

Compensation of 659 tonnes of Scope 3 emissions.

2.2. Key Milestones in 2022

[GRI 2-6]

Extension of agreement with Moderna

In February 2022, ROVI extended its collaboration with Moderna to 10 years with the objective of increasing the compounding, aseptic filling, inspection, labelling and packaging capacities at the Group's facilities in San Sebastián de los Reyes and Alcalá de Henares.

This new agreement includes a series of investments that are expected to allow the manufacturing capacity of the Moderna COVID-19 vaccine to increase at ROVI's Madrid facilities in Spain.

Additionally, the company's facilities may also be used to provide service for future mRNA vaccine candidates of Moderna.

Approval and launch of Okedi® in Europe

The European Commission authorised the marketing of Okedi® (Risperidone ISM®) in February 2022. The product is now being marketed in Germany, the United Kingdom and Spain and is expected to be launched in further European countries within the next few months. Likewise, approval by the U.S. Food and Drug Administration (FDA) for marketing in the USA is expected.

Okedi® (Risperidone ISM®) is a prolonged-release injectable antipsychotic, developed and patented by ROVI, for the treatment of schizophrenia in adults for whom the tolerability and effectiveness has been established with oral risperidone. From the first injection, it immediately provides sustained therapeutic plasma levels, without the need for loading doses or oral risperidone supplements.



Juan López-Belmonte Encina, ROVI's
Chairman and Chief Executive Officer, said:

We are very excited at the launch of Okedi®, a long-acting monthly injection of risperidone to treat schizophrenia, based on our ISM® technology. This launch consolidates our internationalisation strategy as one of the pillars of our future growth."

Pharmaceutical industry leader in Sustainalytics

In August 2022, ROVI obtained the best ESG score of the 458 companies evaluated by Sustainalytics in the pharmaceutical industry category. With an ESG risk rating of 17.3 points, ROVI continues to have a low risk position and shows a 1.1 point improvement on the previous year's position (18.4 points).

Among the actions that allowed it to improve its score in 2022, ROVI's environmental commitment stands out, due to the commencement of greenhouse gas reduction programmes and the use of renewable energy. Additionally, ROVI was considered the sector leader in aspects such as the oversight of material ESG topics by senior management and its policy to combat corruption and bribery in the corporate governance area, as well as the implementation of a solid equality and non-discrimination policy in the social area.

Creation of the joint venture Glicopepton Biotech

In October 2022, Laboratorios Farmacéuticos ROVI, the Aragonese agri-food group Costa Food Group (of Grupo Costa) and the meat group Càrniques Celrà announced the creation of Glicopepton Biotech, S. L., a joint venture for the self-supply of heparins and products of high nutritional value for animal feed and fertiliser using pig by-products.

The project entails the creation of a plant of 25,000 m² in Fraga (Aragon), with a joint investment of 40 million euros from the three partners, 51% of which corresponds to ROVI. It will create around 30 direct jobs and 20 indirect jobs, forming a highly-skilled team. Furthermore, Glicopepton Biotech is a key initiative for both developing the concept of circular economy in the pig and pharmaceutical sectors and reinforcing the Spanish industry's capacity to be self-sufficient in the supply of a raw material that is indispensable for the production of low-molecular-weight heparins. Low-molecular-weight heparins (LMWHs) are anticoagulant drugs used to prevent and treat venous thromboembolic disease. They are biological products whose raw material is obtained from the intestinal mucosa of pigs.

2.3.

Our Response to the Key Challenges of 2022

[GRI 2-6]

In April 2022, Moderna and ROVI announced the recall of one lot (No 000190A) of the Moderna COVID-19 vaccines (Spikevax®) because a foreign body was found in one of the vials from this lot, which had been manufactured at ROVI's facilities. The affected vial was perforated and not administered.

The two companies were alerted to this issue through a complaint about the product from a vaccination centre in Malaga. The vial was returned for evaluation and investigation purposes.

The lot, comprising 764,000 doses, had been distributed in Norway, Poland, Portugal, Spain and Sweden between 13 and 14 January, 2022. Moderna made a cumulative search in its global safety data base and no safety problems had been reported in relation to the persons who received a Moderna COVID-19 vaccine from this lot.

Moderna and ROVI have continued with their commitment to work transparently and swiftly with the regulatory bodies to tackle possible consequences. In this respect, in 2021, ROVI developed a series of measures intended to correct and prevent future incidents, which it improved in 2022. Among them, the most significant are:

- > An improvement in the standard operating procedures to replace the production line.
- > Performing a complete inspection of the production line.
- > Establishing alert limits in the results of the automatic visual inspection.

As a result of the African swine fever in 2018, the pig population in China, which has the largest pig population in the world, decreased dramatically. This led to a very significant increase in the price of the raw material used in heparin production over the last few years.

Prices of the raw material for heparins remain high, even though China has now replaced the pig population it lost due to swine fever. In order to reduce dependence on third parties for heparin supplies, ROVI, through the creation of Glicopepton Biotech, aims to attain greater vertical integration and, in 2026, once the plant has come into operation, achieve self-supply of a high percentage of the sodium heparin needed. It is thus hoped to reduce the impact of the fluctuations in the raw material price, furnish the product with greater traceability and increase the division's margins.





3

Group Profile

3.1

Group Profile

3.2

National and International
Presence

3.3

Ownership and Structure

3.4

Business Units





3.1. Group Profile

[GRI 2-1, 2-6]

Laboratorios Farmacéuticos Rovi (hereinafter, “ROVI”, “the Group”, “ROVI Group”, or the “Company”) is a specialised, fully-integrated pharmaceutical group originating in Spain, engaged in the research, development, licensed manufacturing and marketing of small molecules and biological specialties.

In all its business lines, ROVI as a group is aware that its activity does not consist only of the health improvements provided by its products but that, additionally, it wishes to respond to the social and environmental demands related to the impact of its activity. To achieve this, ROVI's economic development must be compatible with its conduct in respect of ethical, social, labour and environmental issues, and respect for human rights.



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	> 3,240,969.42 euros
Number of shares	> 54,016,157
Par value	> €0.06 share
Activity	> Manufacture and marketing of pharmaceutical products and contract manufacturing services.
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.

History

Since it was founded in 1946, ROVI has contributed to creating value in society through the following significant milestones:





3.2. National and International Presence

[GRI 2-1, 2-6]

Since its foundation, ROVI has had a clearly international outlook. Its current presence in over 100 countries is the result of implementing a strategy oriented towards growth and internationalisation that began in 1998. This strategy continues to be one of the Group's goals in both organisational and commercial terms. Seeking cross-border opportunities allows it to diversity risks and expand its business.

The Group is present in both Spain, where it carries on a large part of its marketing operations and all its manufacturing services and research and development activities, and abroad, with subsidiaries in France, Portugal, Germany, Italy, United Kingdom and Poland, through which it is either currently marketing its products or plans to do so in the near future.

ROVI markets different drugs all over the world. Bemiparin is one of its main drivers and has the most extensive international track record (present in more than 60 countries).

Since 2017, the Group has boosted its international presence as a result of the marketing of its enoxaparin biosimilar, which is now present in 38 countries (Germany, Austria, Spain, Estonia, France, Italy, Latvia, United Kingdom, Portugal, Poland, Costa Rica, Sweden, Finland, South Africa, Israel, Peru, Netherlands, Panama, Dominican Republic, Canada, Malaysia, Albania, North Macedonia, Guatemala, El Salvador, Honduras, Georgia, Bahamas, Jamaica, Gabon, Democratic Republic of Congo, Trinidad and Tobago, Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo).

Bemiparin



Marketed in 62 countries

Likewise, ROVI seeks the international expansion of this product over the next few years as a result of, first, the competitive edge provided by entering a market where there are only four biosimilars and, second, the expected increase in emerging markets, whose economic potential is estimated at 700¹ million euros.

(1) Source: IQVIA Midas IT 2020

At the end of 2022, ROVI's enoxaparin biosimilar had been approved in 26 countries in Europe, as well as 31 in the rest of the world, with presence in 38 nations through different distribution agreements.

The Group has signed licensing agreements in over 90 countries, among which the following may be highlighted:

- > First, the agreement with Hikma Pharmaceuticals PLC for the distribution of the enoxaparin biosimilar in 17 countries in the Middle East and North Africa (Saudi Arabia, Jordan, Algeria, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Libya, Palestine and Lebanon).
- > Second, the agreement with Sandoz (a division of Novartis AG) for distribution in 14 countries or regions (Australia, New Zealand, Philippines, Malaysia, Canada, South Africa, Brazil, Colombia, Argentina, Mexico and Central America, with exclusivity for Hong Kong, Singapore and Vietnam).

In 2022, the enoxaparin biosimilar reached Brazil, Colombia, Luxembourg, Bosnia and Herzegovina, and Kosovo for the first time.

Growth potential of the enoxaparin biosimilar

2023

2024

Jordan	Argentina
Sri Lanka	Vietnam
Montenegro	Ukraine
Ecuador	UAE (United Arab Emirates)
Lebanon	Kuwait
New Zealand	Turkey
Paraguay	Belarus
Mexico	Malta
	China

Map showing global presence of bemiparin



LATIN AMERICA

Marketed:

Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua and Panama.

Registered:

Brazil, Venezuela, Chile, Bolivia, Argentina, Mexico and Belize.

EUROPE

Marketed:

Austria, Belarus, Czech Republic, Greece, Estonia, Latvia, Lithuania, Moldova, Russia, Turkey, Albania, Italy and Spain.

Registered:

Georgia, Ireland, Romania, Hungary, Slovakia, Slovenia, Ukraine, Bosnia & Herzegovina and Bulgaria.

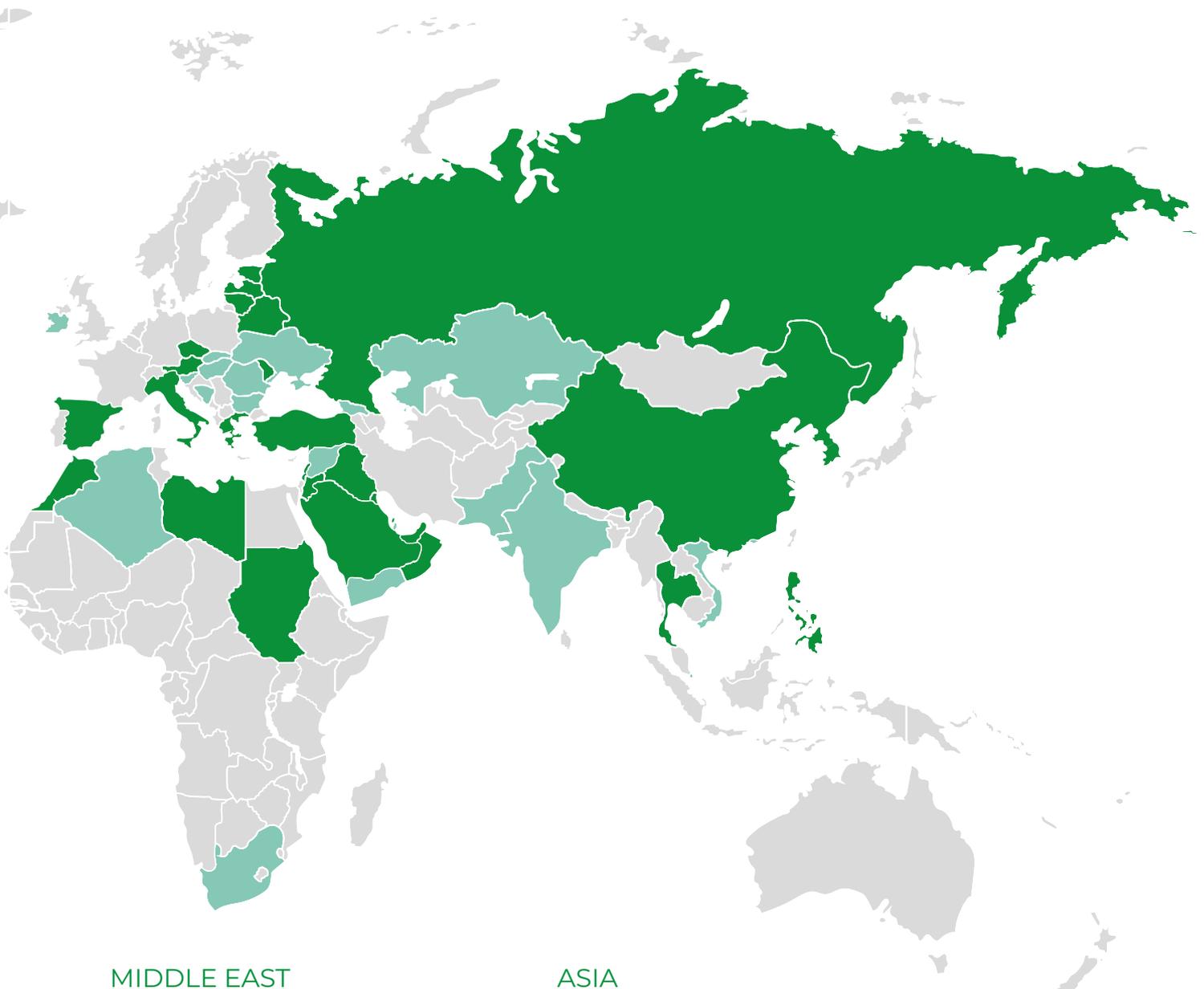
AFRICA

Marketed:

Libya, Morocco and Sudan.

Registered:

South Africa and Algeria.



MIDDLE EAST

Marketed:

Jordan, Kuwait, Bahrain, Oman, Iraq, Saudi Arabia, Lebanon and United Arab Emirates.

Registered:

Qatar, Yemen and Syria.

ASIA

Marketed:

South Korea, China, Philippines and Thailand.

Registered:

Kazakhstan, Pakistan, India, Hong Kong, Vietnam and Singapore.

Principal locations

Activity

- (1) Manufacture, marketing and sale of pharmaceutical, healthcare and medicinal products.
- (2) Import, export, purchase, sale, distribution and marketing of articles related to integral healthcare for women.
- (3) Development, distribution and sale of pharmaceutical products related to microimplant technology.



Spain

Corporate name: Laboratorios Farmacéuticos Rovi, S.A

Address:
C/Julián Camarillo, 35. Madrid.

Address:
C/José Isbert, 2. Pozuelo de Alarcón (Madrid).

Activity: (1)

Corporate name: Pan Química Farmacéutica, S.A

Address:
C/Rufino González, 50. Madrid.

Activity: (1)

Corporate name: Rovi Pharma Industrial Services, S.A.U.

Address:
Avenida Complutense, 140. Alcalá de Henares (Madrid).

Address:
C/Julián Camarillo, 35. Madrid.

Address:
C/Paseo de Europa, 50. Ctra. Madrid-Burgos, Km 20,9. San Sebastián de los Reyes, Madrid

Activity: (1)

Corporate name: Rovi Escúzar, S.L.

Address: C/Julián Camarillo, 35. Madrid.

Activity: (1)

Corporate name: Gineladius, S.L.

Address: C/Rufino González, 50. Madrid.

Activity: (2)

Germany

Corporate name: Rovi GmbH

Address: Ruhlandstr. 5. Bad Tölz.

Activity: (1)

Corporate name: Bertex Pharma GmbH

Address: Inselstr.17. 14129. Berlin.

Activity: (3)

United Kingdom

Corporate name: Rovi Biotech Limited

Address: 10-18 Union Street, Londres (Reino Unido).

Activity: (1)

France

Corporate name: Rovi S.A.S.

Address: Rue du Drac, 24. 38180. Seyssins.

Activity: (1)

Poland

Corporate name: Rovi Biotech sp. z o.o. o. Rovi Biotech spółka z o.o.

Address: Mokotów, ul. Rzymowskiego 53, 02-697. Varsovia.

Activity: (1)

Switzerland

Corporate name: ROVI Biotech GmbH.

Address: Bahnhofstrasse 10, 6300, Zug.

Activity: (1)

Italy

Corporate name: Rovi Biotech, S.R.L.

Address: Via Monte Rosa 91. Milán.

Activity: (1)

Portugal

Corporate name: Laboratorios Farmacéuticos Rovi S.A.

Address: Jardins da Parede, Rua do Phinhal, Lote 16. Parede.

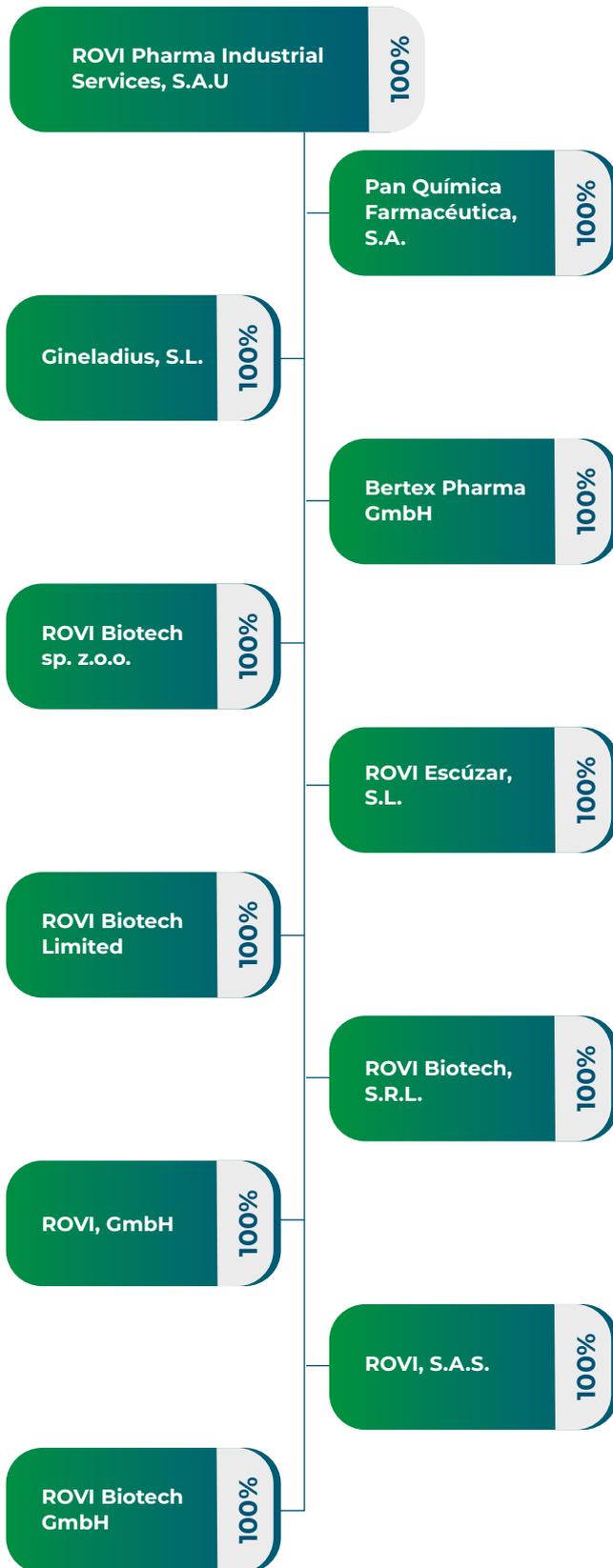
Activity: (1)



3.3. Ownership and Structure

[GRI 2-1, 2-2]

Corporate structure



Shareholder composition



Shareholder	Percentage voting rights		
	Direct	Indirect	Total
Norbel Inversores, S.L.	55.191%	-	55.191%
Indumenta Pueri, S.L.	-	5.057%	5.057%
Total	55.191%	5.057%	60.248%

Significant shareholders hold 60.248% of ROVI's capital. They include the company Norbel Inversiones, S.L., which holds 55.191% of the shares of Laboratorios Farmacéuticos Rovi, S.A. Norbel Inversiones, S.L. is owned by Messrs Javier López-Belmonte Encina, Juan López-Belmonte Encina and Iván López. Belmonte Encina (each of whom hold an interest of 33.333%).

The other shareholder with a significant interest has the following composition and characteristics:

- > Indumenta Pueri, S.L. is the asset management company of the Domínguez family, owners of the children's fashion company Mayoral in Malaga.

3.4. Business Units

[GRI 2-6]

ROVI is a pan-European company focusing on innovative products. It is stable, sound and experienced and follows a growth strategy based on three pillars: pharmaceutical specialties, contract manufacturing and R&D&I.



> Prescription products:

- Low-molecular-weight heparin division (LMWH).
- Own and licensed product division.

> Diagnostic imaging contrast agents and other hospital products



> Specialists in solutions for prefilled syringes, solid oral forms and vials.



> Innovative drug release technology, ISM@.

> Glycomics area.

> Multilayer technology for urethral catheters.

As a result of a combination of factors, among which the Group's stability, due to the growth of its recurring business and its strong financial position, sound strategy and clear pillars of growth may be highlighted, the Company's reactive profile has been reinforced. This has allowed operating revenue to rise year after year, materialising in growth of 26% in 2022.

Competitive edges

Benchmark company in LMWH

Since its foundation in 1946, ROVI has been mainly engaged in studying and developing drugs based on heparin, a fast-acting anticoagulant.

Since 1981, the Company has focused on the fractional derivatives of heparins, the low-molecular-weight heparins (LMWHs). As a result of ROVI's 70 years' experience, its main product, Bemiparin, has become one of the main treatments for venous thromboembolic disease worldwide.

In 2017, ROVI launched a biosimilar of enoxaparin, the leading molecule in the market, and currently aspires to become a leading company in the LMWH field.

Low-risk innovation

ROVI operates following a low-risk strategy, focusing on chronic diseases with broad medical needs.

The Company allocates a large part of its revenue to research, in order to remain in the vanguard of both the product area and manufacturing and development systems.

Infrastructure with operating advantages

ROVI is one of the main companies in the contract manufacturing sector and among the world leaders in the production of prefilled syringes, which it exports to over 50 countries.

Its production plants have been approved by the European and United States regulatory authorities, the European Medicines Agency (EMA) and Food and Drug Administration (FDA), respectively.

Diversified portfolio protected by patents

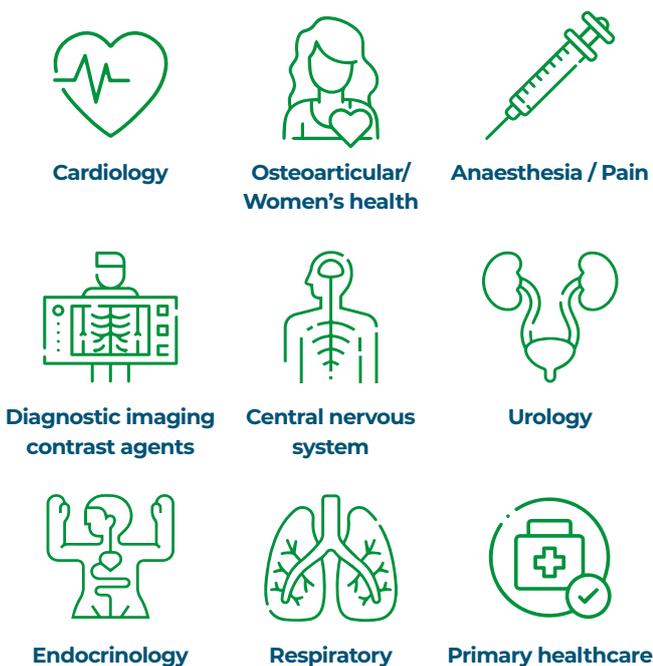
ROVI has launched 15 new products in the market in the last twelve years and currently has a portfolio of over 40 products, grouped into nine therapeutic areas. The portfolio includes both ROVI's own and licensed products and there is growing demand for most of them. They are virtually unaffected by the reference pricing system in Spain.



3.4.1. Specialty pharmaceutical area

ROVI has a portfolio of more than 40 of its own and licensed products. This makes the specialty pharmaceutical area one of ROVI's major pillars of growth.

The products are indicated for both the treatment and diagnosis of different complaints in nine therapeutic areas:



The specialty pharmaceutical area can be classified into two large blocs or divisions:

- 1. Prescription products
- 2. Contrast agents for diagnostic imaging and other hospital products

1. Prescription products

Low-molecular-weight heparins

ROVI aspires to become a world leader in low-molecular-weight heparins (LMWHs). To achieve this, it has two products from its own research, Bemiparin (Hibor®) and the enoxaparin biosimilar (Becat®). The low-molecular-weight heparin division accounted for 32% of total Group sales in 2022.

Hibor®

Hibor® (Bemiparin) is a low-molecular-weight heparin (fast-acting anticoagulant) indicated for the prevention and treatment of venous thromboembolic disease (VTE) in both surgical and medical patients.

Additionally, it is used for both the acute and long-term treatment of patients who have suffered VTE (venous thromboembolism), which has serious and potentially fatal symptoms. It is characterised by the formation of a fibrin clot, thrombosis, inside the veins of the deep vein system, with the consequences that may derive from the evolution of the venous thrombus, which may grow, progress or fragment. In the event of fragmentation, some of the fragments may reach the lung and cause pulmonary embolism.

In 2022, Hibor® (Bemiparin) represented 13% of ROVI's operating revenue. Its global positioning as one of the principal therapeutic alternatives for venous thrombosis is one of the main factors in its success and international expansion. It is now marketed in 35 countries as a result of ROVI's network of strategic partnerships.

Enoxaparin ROVI

ROVI's enoxaparin sodium biosimilar, launched in 2017, is an anticoagulant medicine belonging to the low-molecular-weight heparin group. It is used to prevent and treat deep venous thrombosis and pulmonary embolism. In 2022, enoxaparin sales totalled 152.9 million euros and accounted for 19% of ROVI's operating revenue.

The global enoxaparin market totals over 2,566 million euros (estimates IQVIA MIDAS IT 2020). The European market represents 52% of that total (around 1,323 million euros), with 86% of sales concentrated in 7 countries: Germany, France, Spain, United Kingdom, Italy, Austria and Poland (data IQVIA MIDAS IT 2020), where ROVI is already marketing its product through its subsidiaries. Likewise, it has received approval in all the EU countries where applications have been filed.

The Group manufactures and packages its enoxaparin biosimilar in Spain through its four production facilities and expects to increase its production capacity significantly over the next few years, due to the opening of the second plant in Escúzar (Granada).

Licensed products

The products marketed under licensing agreements that are most important in terms of their contribution to group EBITDA (more information in Chapter 5 of this report) are listed below.

Neparvis®

ROVI began to market Neparvis® (sacubitril/valsartan) of Novartis in December 2016.

It is a product indicated for the treatment of adult patients with symptomatic chronic heart failure with reduced ejection fraction (the proportion of blood leaving the heart).

Hirobriz® Breezhaler® and Ulunar® Breezhaler®

In the last quarter of 2014, ROVI began to market Hirobriz Breezhaler (indacaterol maleate), and Ulunar Breezhaler (indacaterol maleate and glycopyrronium bromide).

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®

In the first quarter of 2015, ROVI began to market Volutsa (solifenacin succinate and tamsulosin hydrochloride).

It is an Astellas Pharma product indicated for the treatment of moderate to severe storage 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® (ezetimiba and simvastatina), Orvatez® (ezetimiba and atorvastatina) y Absorcol® (ezetimiba). Vytorin® and Absorcol® were first marketed in 2011, while Orvatez joined them a few years later in 2015.

These products are indicated to treat patients with hypercholesterolemia and are always used as an adjunctive therapy to diet.

Medikinet® and Medicebran®

Medikinet (methylphenidate hydrochloride with modified release) and Medicebran (methylphenidate hydrochloride with immediate release) are products from the company Medice that ROVI has been

distributing on an exclusive basis in Spain since December 2013.

They are prescription products indicated for the treatment of ADHD (attention deficit hyperactivity disorder) in children and adolescents.

Okedi®

ISM® technology, which belongs exclusively to ROVI, represents an important alternative for treating chronic diseases with unmet medical needs. Using the ISM® technology platform, ROVI is developing new products to replace the daily administration of oral drugs by long-acting injectables.

In February 2022, ROVI obtained the approval of Okedi®, its first product based on the leading-edge drug administration technology ISM®, to treat schizophrenia in adults for whom the tolerability and effectiveness have been established with oral risperidone. The product was launched in Germany in April, the United Kingdom in July and Spain in September 2022.

2. Diagnostic imaging contrast agents and other hospital products

This area contributed 5% of the Company's operating revenue in 2022, reinforcing ROVI's position as one of the market leaders in the marketing of contrast agents and other hospital products for diagnostic imaging (computed tomography, magnetic resonance imaging, ultrasound scans, etc).

Some of the products that form the portfolio of this division are those marketed under licence from Bracco: Iomeron® and Iopamiro® (for computed tomography and other interventions), Multihance® and Prohance® (for magnetic resonance imaging), Sonovue® (for ultrasounds), and Bracco Injeenering: EmpowerCTA+®, EmpowerMR® and CT Expres (contrast injection systems and compatible disposable material).

The hospital product portfolio is completed by healthcare products for the care and maintenance of intravenous catheters, such as Fibrilin®.



3.4.2. Contract manufacturing

This is the ROVI Group's second pillar of growth, due to the high manufacturing capacity available at its facilities that allows it to operate this business line with an extensive range of contract manufacturing services (compounding, filling, inspection, labelling, packaging, blister packaging, installation of safety devices and serialisation) for a wide range of pharmaceutical forms (prefilled syringes, vials, tablets and sachets).

According to the GlobeNewswire report published on 27 April, 2022, the contract manufacturing market is expected to grow at a CAGR of over 7% until 2027. This growth places the company in a strategic position in the sector, given its experience (since 1994), growing capacity and flexibility.

In this respect, Moderna has selected ROVI as a preferred partner outside the USA for the manufacture of the active substance and the fill-finish of the COVID vaccine. This places the ROVI Group in a strategic position in the contract manufacturing sector since, in addition to producing the Moderna COVID-19 vaccine, the ROVI platform can also be used to provide service for any future mRNA vaccine candidates of Moderna.

ROVI's contracts with its customers have an average term of between 3 and 5 years, which allows a considerable flow of stable revenue to be generated. Furthermore, as a result of the long regulatory process that a pharmaceutical company has to undergo to change manufacturer, long-term relationships are built, based on mutual trust in the Group's contract manufacturing business model.

The Company has a unique profile in this market due to the unification of all the services within the same company, ROVI Pharma Industrial Services (ROVI PHIS), a subsidiary whose main characteristic is its high degree of technological specialisation in area of vaccine, biological product and biosimilar manufacturing. Through this company, the customer is offered a wide range of possibilities depending on their needs, thanks to the flexibility furnished by the wide range of filling manufacturing and packaging lines available at ROVI PHIS.

With exports to over 50 countries and international sales accounting for 98% of the business, ROVI PHIS is now one of the main companies in the high-value-added contract manufacturing business sector.

The Group currently has seven fully-consolidated production facilities, three of which are engaged in filling, finishing and packaging. (Madrid, San Sebastián de los Reyes and Alcalá de Henares). Two of these are engaged in the production of injectables (vials and syringes), while the third specialises in solid oral forms, secondary packaging and the manufacture and packaging of solid pharmaceutical forms. The three plants combine decades of experience working to the highest quality standards and allow integral solutions to be provided to customers. The maximum estimates of the technical capacities of these plants will depend on the equipment, the product mix and market needs.

Estimation of the technical capacities of the plants



245-280
million syringes.



80-100
million vials.



3,000
million tablets.



30
million sachets.

Injectables

There are very few competitors in this market due to the entry barriers, the biological nature of the medicines manufactured, and the aseptic conditions in which the prefilled syringes are filled (the product is handled in microbiologically-controlled cleanrooms).

At present, ROVI is one of the main prefilled syringe manufacturers in Europe in terms of the number of units manufactured (filled) per year. The Company has a facility in Madrid specialised in the filling and packaging of parenteral solutions in prefilled SCF syringes of between 0.5 ml and 20 ml (filled from 0.1 ml to 20 ml) and vials of between 2 ml and 20 ml. These syringes and vials are filled in aseptic conditions in cleanrooms (grade A), plus terminal sterilisation if the product so requires, also offering the possibility of placing safety devices in the syringes.

The facility is approved by the European and United States regulatory authorities. It has also been approved by the authorities of Korea, Brazil and the Persian Gulf States and holds the ISO9001, ISO14001 and OSHAS certifications.

This business line has become especially important to ROVI since 2020, due to the agreement with Moderna for the filling and packaging of the COVID-19 vaccine, the purpose of which is to meet demand outside the United States. Although the collaboration with Moderna was reinforced in 2021, it was in 2022 that it was definitively consolidated through a long-term (10 years) collaboration agreement to increase the compounding, aseptic filling, labelling and packaging capacities at the ROVI facilities in Madrid, San Sebastián de los Reyes and Alcalá de Henares. As a result, a series of investments are being undertaken to increase the manufacturing capacity at ROVI's facilities and will continue in the future. Likewise, under the new agreement, it will be possible to provide service for any future mRNA candidate vaccines of the Moderna Group.

The different actions taken to provide this service, which is so essential to both the Company itself and society, have included, since 2021, the recruitment of additional personnel (especially at the San Sebastián de los Reyes facility). At 31 December, 2022, the Company had an annual production capacity of approximately 245-280 million of syringes and 80-100 million of vials. This capacity had

reached 1,200 million doses of vials at 31 December, 2022, as a result of the installation of three new production lines in addition to the already-existing one, as well as compounding, filling, automatic visual inspection, labelling and packaging equipment, at the San Sebastián de los Reyes facility. Additionally, a new support line for mRNA production, with a production capacity of over 100 million doses per year, has been installed in Granada.

Solid oral forms

Thanks to the most advanced technology in the manufacture of oral forms, ROVI produces tablets and sachets at its Alcalá de Henares plant.

Approved by the European and United States authorities, as well as those of Japan, Mexico, Brazil, Kenya, Belarus and the Persian Gulf states, the Alcalá plant, with its 83,000 square metres, not only produces in solid format, but also has the facilities necessary for packaging both solids and injectables, partly due to its storage capacity of 9,000 pallets. This is why it has been designated as a centre of packaging excellence.



⁽¹⁾ Sterile preparations containing one or more active substances to be administered by injection, infusion or implantation in the body. Stored in single- or multi-dose containers.



3.4.3. Research, development and innovation

The third pillar of growth of Laboratorios Farmacéuticos Rovi is its research, development and innovation work. Its portfolio of products in the research stage focuses on three main areas: drug-release technologies, glycomics and medical devices.

A. Innovative drug-release technology, ISM®

Long-acting injectables (LAIs) are becoming the benchmark for the care of some complaints, such as schizophrenia, instead of the oral treatment. The ISM® technology is intended to obtain new pharmaceutical products whose release systems are controlled through long-acting injectables. The objective is to replace daily drug administration in patients who are undergoing long-term treatments for certain chronic pathologies, such as schizophrenia and some types of cancer.

The ISM® technology is currently exclusive to ROVI and is patent protected until 2033. Intended to overcome most of the disadvantages of prolonged-release oral or parenteral formulations, it has advantages such as simpler administration, higher encapsulation efficiency, greater stability of the active substance, greater control in the initial release of the drug, reduction in treatment frequency, etc.

It is based on the formation in situ of biodegradable matrices after administration of a carrier liquid, once it has been injected into the patient's organism. The product is presented in the form of a kit with two syringes. One of them contains the polymer and the active substance in solid form, while the second contains the liquid required for reconstitution. The product is prepared at the time it is used or administered to the patient. After the injection, the product precipitates in the muscle, giving rise to the formation of a solid/semi-solid implant by spreading the carrier through the patient's own corporal fluids.

This implantable system increases the stability of the composition considerably, with a series of competitive advantages such as:

- > Cool storage is not necessary.
- > Clinically-significant profiles are obtained as of the first day after the injection.
- > These profiles are maintained over time and reproduced after intramuscular administration, so no oral supplements or initial treatment guidelines are required.

At present, ROVI is developing this technology along two major lines:

Risperidone ISM®

Indicated for the treatment of schizophrenia in patients for whom the tolerability and effectiveness have been established with oral risperidone. At the beginning of 2022, years of development and research resulted in the approval of the first product by the European Commission: Okedi® (Risperidone ISM®). This meant that marketing began in Germany, United Kingdom and Spain in 2022 and marketing is expected to commence in other EU countries and the USA – after approval by the FDA – in 2023.

The effort to innovate in this line is continuing with the development of three-monthly Risperidone ISM® which would complement the current 4-weekly formulation of Risperidone ISM® for the maintenance treatment of patients with clinically stable schizophrenia. The regulatory toxicity studies needed to start the clinical development in humans have already been completed. The company is currently initiating all arrangements to conduct a phase I clinical trial to evaluate the safety, tolerability, and pharmacokinetics of various candidate formulations at different dose strengths and injection sites; this study is planned to begin in the first half of 2023.

Letrozol ISM®

Indicated for the treatment of breast cancer, it is a novel inhibitor of the enzyme aromatase, responsible for a fundamental step in the biosynthesis of oestrogens that breast cancer patients must take after the disease has been cured. The competitive advantage of this technology is that the inhibitor would no longer be taken orally but would be administered through a long-acting injection. i.e. the injections would be given less frequently than is the case at present.

The development of this product is progressing and Phase I of the clinical development has concluded. ROVI has obtained positive results in

phase I that confirm that this ISM® formulation provides a prolonged release of letrozole which produces a sustained suppression of oestrogenic hormones. These outstanding results allow ROVI to predict a superior oestrogen suppression compared to daily doses of oral Femara® (daily 2.5 mg doses) when Letrozole ISM® treatment starts with 100 mg doses at day 1 and week 8, followed by maintenance doses of 100 mg of Letrozole ISM® every 52 weeks. After several official interactions with the FDA, the company has been requested to perform a phase II clinical study in adult patients with HR+/HER-locally advanced or metastatic breast cancer, comparing Letrozole ISM® versus Femara®.

B. Glycomics area

Glycomics is the study and profiling of the sugars that compose a cell, including the glycosaminoglycans (GAG), which, in addition to their role in regulating blood coagulation, are involved in processes such as cellular growth, the immune response and inflammation.

Glycomics studies provide very valuable information in this respect, since they allow the receptors that participate in the interaction with each type of GAG to be determined, giving rise to new research and medical solutions.

The degree of specialisation and knowledge attained by ROVI in this area, derived from its own development of low-molecular-weight heparins – bemiparin and the enoxaparin biosimilar – allows the Group to continue working to expand the applications, indications and alternative action mechanism of heparin-derived products and other glycosaminoglycans, based on both anticoagulant and non-anticoagulant activity.

C. Multilayer technologies for urethral catheters

For a number of years, the Company has been working on various lines of development of new devices focused on preventing urethral tract infections, as well as the treatment of ulcers, since, when stents and urethral catheters are used, the high prevalence of bacteria may, in some cases, lead to the appearance of clinical symptoms and complications, including severe sepsis and death. The incidence of urine infections is still very high, since the formation of biofilms hinders the eradication of the microorganisms with antibiotics.

ROVI is continuing with the preclinical development of its multilayer technology, which uses polymeric materials to form a bioerodible system that depends on the bacterial metabolism. This provides significant advantages over the current state of the art, decreasing bacterial adhesion, facilitating biofilm elimination, reducing the appearance of encrustations and, to a large extent, preventing catheter blockage.







4 Our strategy and sustainable growth model

4.1

Market Context

4.2

Identity and Commitment:
mission, vision and values

4.3

Corporate Strategy

4.4

Materiality

4.5

ESG Master Plan



4.1. Market Context

[GRI 2 – 6]

Management of COVID-19 by the different healthcare systems and mitigation of the distribution problems are the key elements of the outlook for the pharmaceutical market until 2026, although there are some unknown factors, such as the ways in which the medical attention and the use of medicines that are not for the virus will be affected.

Leaving the pandemic aside, global spending on medicines continues to be driven by innovation and offset by losses of exclusivity and the lower costs of generics and biosimilars.

Global market environment: main trends affecting the pharmaceutical industry

Given the uncertainties arising from the pandemic in every sector, particularly the pharmaceutical sector, it is difficult to make market forecasts. In this respect, attention should be drawn to the report prepared by the consulting firm IQVIA *The Global Use of Medicines – Outlook to 2026*, published in January 2022. It states that the COVID-19 pandemic has been the global public healthcare crisis with the greatest impact in decades and that, at the same time, it has shown the resilience of the world healthcare systems, since they have easily adapted to the peaks in the demand.

Medicine use and spending trends have been affected by the immediate effects of the pandemic, with near-term spending expected to be 175 billion dollars lower over seven years to 2026 than it would have been without the pandemic, excluding the incremental spending on vaccines and therapeutics for COVID-19. Spending on COVID-19 vaccines and new therapeutics will generate over 300 billion dollars over the same period and the outlook is for a cumulative figure 133 billion dollars higher than projected before the pandemic.

In developed countries, the adoption of new treatments, offset by the life cycles of the patents and competition from generics and biosimilars, is still the main factor influencing medicine spending and growth.

The dramatic increases in access to medical attention in emerging countries were, historically, the principal drivers in the change in medicine use. However, this trend is decelerating and will lead to a decrease in volume in many markets. Increasingly, led by China, the emerging countries are often allowing access to newer medicines

developed by multinational companies earlier than in the past and providing access to a larger part of their population. These trends are accompanied by efforts to reduce spending, which is expected to reduce China's growth to a compound annual rate of between 2.5% and 5.5% through 2026, although they will continue to generate the highest absolute growth among emerging countries.

The world medicine market, using selling price levels, is expected to grow between 3% and 6% CAGR through 2026, reaching a total market size, including spending on COVID-19 vaccines, of around 1.8 trillion dollars in 2026.

Total cumulative spending on COVID-19 vaccines is estimated at 251 million dollars through 2026, largely concentrated in the first wave of vaccines, which was mostly completed in 2022 in developed countries, while completion is expected in 2023 in lower-income areas. However, boosters are expected to be required annually, or even more often, since the duration of immunity and the continual appearance of variants of the virus increase the importance not only of vaccination, but of recent vaccination. It is forecast that the adoption of initial vaccines and boosters will drop, due to the considerable level of hesitation in all geographical areas, even when low-income countries initially had difficulties in acquiring the vaccine.

Global medicine spending will slow down due to losses of exclusivity. It is forecast that, on a net price basis, the US market will grow between 0% and 3% CAGR over the next five years, which is lower than the 3.5% CAGR of the last five years. Japan, the third largest market in the world, will have



flat or decreasing medicine spending and will change from its former biennial policy to annual price cuts. Spending in Europe is expected to rise by a total of 51 billion dollars over the next five years, focusing on a greater adoption of generics and biosimilars to allow the financing of new products.

Spending on new products in developed markets through 2026 will, according to IQVIA, add 196 billion dollars, not including the impact of COVID-19 vaccines and new therapeutics, driven mainly by the greater availability of new medicines over recent years. Between 290 and 315 new active substances (NASs) will reach the market by 2026, with an average of 54 to 63 per year, which is similar to that of the last five years. The impact of losses of exclusivity will increase to 188 billion dollars over the next five years, mainly due to the availability of biosimilars, while the cumulative savings of the biosimilars in the same period are estimated at 215 billion dollars.

In five years' time, almost 60% of medicine spending will consist of specialty medicines in the developed markets and 45% in the global markets. The rest will consist primarily of older, more traditional therapies, which will become gradually cheaper as time passes.

The two leading global therapy areas (oncology and immunology) are forecast to grow by 9% to 12% and 6% to 9% CAGR, respectively, through 2026, lifted by significant increases in new treatments and medicine use. Oncology is projected to add 100 new treatments over the next five years, which will contribute almost 120 billion dollars and will raise the total market to over 300 billion dollars in 2026.

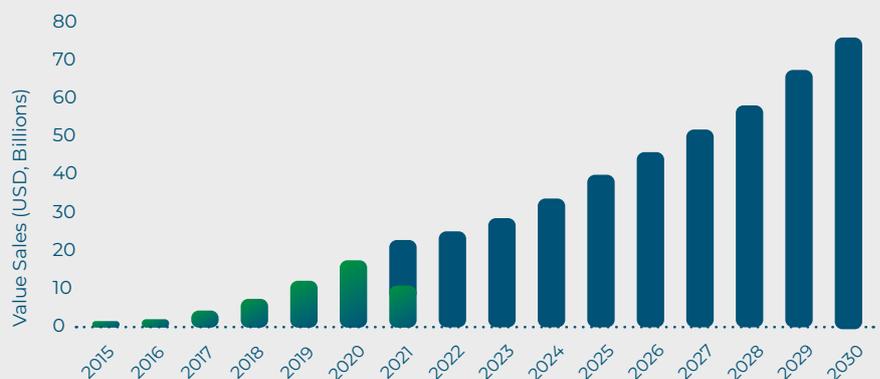
Impact of COVID-19 on medicine use

- > Medicine use in emerging countries has changed greatly since the outbreak of the pandemic but has remained more stable in developed countries.
- > Medicine use was interrupted in some therapies in 2020, at different times and with varying impacts depending on the country, but has returned to more stable patterns since then.
- > It is expected that thousands of millions of people will be vaccinated and receive booster doses for COVID-19 and it seems likely that significant variations between geographical areas will lessen with time.
- > Global COVID-19 vaccine spending will be 251 billion dollars through 2026, although cost and volume estimates vary.
- > Global spending, including COVID-19 vaccines and therapeutics, will exceed the pre-pandemic outlook by 133 billion dollars to 2026.
- > World market growth will return to pre-pandemic growth rates, in spite of the fluctuations from one year to another.
- > Millions of people will have long-term complications from the COVID-19 infection, although estimates vary considerably.

Outlook for biosimilars after the impact of COVID-19

In global terms, the adoption of parenteral biosimilars is increasing swiftly and it seems that this trend will increase over the next decade. According to IQVIA's¹⁾ Forecast Link, the value of biosimilars grew at a compound annual growth rate of 78% between 2015 and 2020, totalling approximately 17.9 billion dollars in 2020, and is expected to continue growing at a compound annual rate of 15% between 2020 and 2030, reaching 75 billion dollars in the next decade.

Evolution of Global Biosimilar Value Sales (USD)



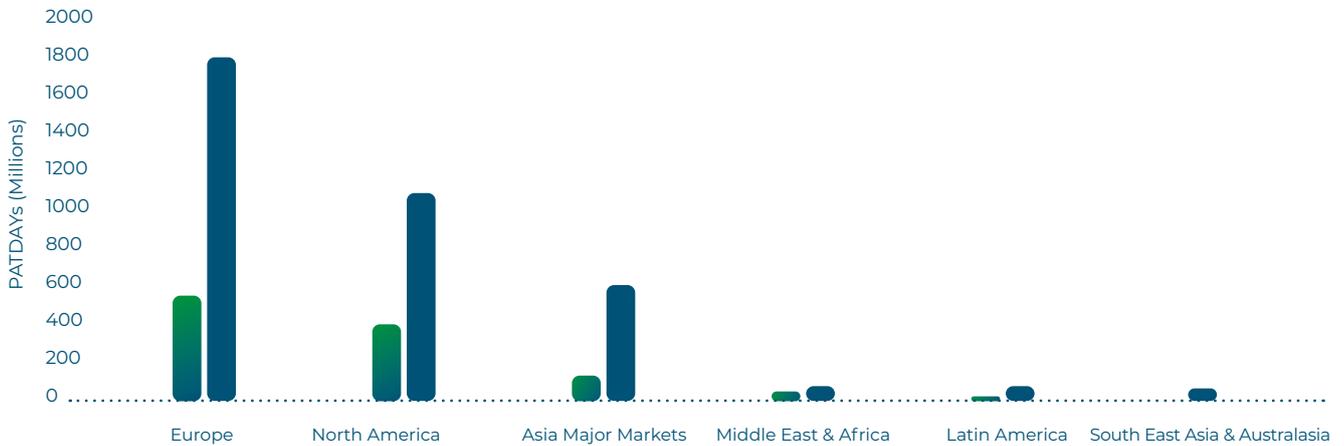
Source: IQVIA Forecast Link, Dec 2021; Historical data to Q2 2021 ● Historic ● Forecast

¹⁾ Biosimilars to continue rapid growth over the next decade (3 January 2022), IQVIA. Recovered from: <https://www.iqvia.com/blogs/2021/12/biosimilars-to-continue-rapid-growth-over-the-next-decade>



At country level, there are exceptions to these general observations, which may be partially explained by acceptance among prescribers and patients, the soundness of the policies that encourage their use, the price difference and whether the country employs a single or multiple winner bidding system.

Evolution of Biosimilar PAYDAYs 2020-2030 by Region



Source: IQVIA Forecast Link, Dec 2021; Bubble=PATDAY CAGR (2020-2030)

In Europe, for example, the European Medicines Agency (EMA) has left the decisions on interchangeability and substitution to each country. In addition, in response to the high cost of biologics for oncological indications, several countries have adopted policies that are increasing the use of biosimilars. For example, in Spain and Poland, biosimilars must have a price at least 25% and 40% lower than the original, respectively. In Norway, the oncological biosimilars have secured most of the hospital contracts, which has boosted the adoption of these products.

This scenario is vitally important to ROVI's development, since it has two key products on its portfolio. First, the enoxaparin biosimilar, a product essential to ROVI's future development, and, second, Letrozole ISM®, associated to the ISM® platform, which is intended to treat hormone-dependent breast cancer.

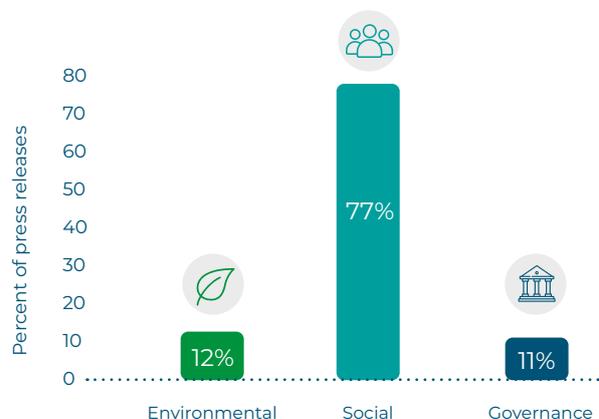
ESG in the pharmaceutical industry

The pharmaceutical industry has a series of goals among which improving people's health and quality of life stand out, fomenting an economic model based on skilled employment, research, development and innovation. This means that, globally, it is one of the key industries in making the achievement of the Sustainable Development Goals in 2030 a reality.

To attain this, over recent years, different opportunities to create value have been sought, not just in economic

terms, but also in the ESG (Environmental, Social, Governance) area, in order to transform a sector that needs to be coordinated, flexible and, as the pandemic has shown, able to adapt to the needs of a global and changing world.

In its study *ESG for pharmaceutical and life sciences companies*, PricewaterhouseCoopers set out a series of sustainability trends where social aspects are present in 77% of the communications of the pharmaceutical companies analysed, in comparison with 12% for environmental issues and 11% for questions concerning governance.



Source: Analysis by PwC's Health Research Institute of press releases and websites in 2021 of 32 pharmaceutical and life sciences companies.

According to the PwC study, the main ESG trends in the pharmaceutical industry in these three areas are summarised as follows:

Environmental



- > Sustainable vehicle fleet (hybrid and electric).
- > Carbon neutrality (5-10 years).
- > Waste management and reduction of manufacturing costs through investment in new technologies.

Social



- > Financial contributions for access to medicines and therapies, addressed to local communities.
- > Early adoption and inclusion of diversity in clinical trials for research and development.
- > Resilience of the supply chain through a diversity of suppliers and risk assessment.
- > Enhancement of product safety.

Governance



- > Full report on Corporate Social Responsibility to assess, measure and share ESG progress.
- > Establishment of an ESG department and/or ESG officer.
- > Gender and racial diversity on the Management Board.
- > Equal pay.
- > Good Governance policies (ethics, compliance, corruption, fraud, etc.).

Source: Analysis by PwC's Health Research Institute of the ESG reporting in 2021 of 32 pharmaceutical and life sciences companies.

In environmental issues, the sector's main measures are focused on achieving a reduction in CO₂ emissions and thus reaching the target of carbon neutrality. Likewise, since pharmaceutical production is water-intensive, the companies are working to develop innovative actions to reduce the use and wastage of water. At the same time, circularity measures are being developed for waste (such as recycling packaging or expired medicines).

In addition, regarding the production chain, there is a complementary dual trend: first, not to scatter processes over multiple locations, but to channel production within a single facility, to avoid fragmenting the production process. This achieves an increase in efficiency, a reduction in waste production, greater flexibility and a reduction in the likelihood of medicines being out of stock. At the same time, it makes it possible to work with local companies belonging to minorities, which allows greater access to the medicine and a lower environmental impact derived from a reduction in Greenhouse gases (GHG) emissions in transport.

In the social aspect, the main efforts are focused on three aspects: providing high-climático, safe products, performing clinical trials with patients who represent society overall, and fulfilling the mission of providing access to the medicine. Considering the product safety aspect in greater depth, the pharmaceutical industry plays an important role in obtaining a social benefit by taking proactive measures that help ensure that medicines and devices are used in the right way at the right time.



Regarding the last ESG aspect, governance, the pharmaceutical industry's efforts are focused on devoting resources to managing ESG practices and preparing reports that show how companies have identified, measured, quantified and assessed their ESG risks and, moreover, permit a comparison of the progress made by different companies in the sector.

National market context: main trends affecting the pharmaceutical industry

According to the first study on the industrial presence of the pharmaceutical sector in Spain, there are 103 plants manufacturing medicines for human use in the country, 11 of which manufacture biologics. If we add the active substance and veterinary medicine plants (46 and 24, respectively), the total is 173, belonging to 122 business groups. They generate over 183,000 direct, indirect and induced jobs and their production value is 16 billion euros, 75% of which is exported.

According to those responsible at Farmaindustria, the study data place Spain as one of the European countries with the highest potential for medicine manufacturing, precisely at a time when medicines have proven themselves to be a strategic and safety asset for a country. They add that there is a powerful industrial fabric, with a high presence of national and multinational countries for which Spain is a key part of their production chain.

The industry has invested an average of a billion euros a year over the last five years (4.8 billion), giving an investment/net asset ratio in excess of 20% – 27% in 2022 –, with environmental sustainability and energy efficiency as its great priorities, betting on guaranteeing the origin of the energy consumed.

According to this study, Spain has the right bases to become the great hub of medicine production in Europe, provided it defines a roadmap and medium- and long-term strategy that inspires confidence in the industry to make the necessary investments in this area.

Some of the sector's strengths are the high quality of the facilities, the competitive costs, the availability of advanced technology and skilled personnel and the attractive work environment. Farmaindustria also mentions a series of important urgent challenges in an environment of growing international competition, ranging from the high degree of dependence on other countries for raw material supplies to the need to boost investment in digitalisation and biotechnological plants. Likewise, the pharmaceutical industry employers' association draws attention to the fact that the administrations provide little support to industrial investments.

The future involves the Strategic Plan for the Pharmaceutical Industry announced by the Spanish Government², which may be the right instrument to

structure this boost to medicine manufacturing. Likewise, the Ministry of Health has promised that Spain will play a key role in driving the European Pharmaceutical Strategy during the Spanish presidency of the Council of the European Union, in the second quarter of 2023.



Strategic Plan for the Pharmaceutical Industry

In addition to the Pact for Science and Innovation, which was presented to the Government by Farmaindustria to drive the manufacturing of essential medicines in Spain, the Ministry of Health announced the new Strategic Plan for the Pharmaceutical Industry within its Recovery, Transformation and Resilience Plan. This will boost the supply chains and reinforce the sector's strategic needs. It will be supported by the future Law on Guarantees and Rational Use of Medicines and Medical Devices.

In this respect, it is sought to reinforce the strategic nature of the pharmaceutical industry and undertake initiatives that permit the development of the pharmaceutical sector, guaranteeing the supply, equitable access to new treatments and the sustainability of the healthcare system. Furthermore, Farmaindustria considers that this plan should be supported on three broad pillars: (i) reconciling the best access of patients to innovation with the sustainability of the healthcare system, (ii) reinforcing the production fabric, and (iii) making Spain into an international reference point for biomedical research, based on the leadership already won in the clinical trials of medicines.

⁽²⁾ Plan Estratégico de la Industria Farmacéutica (September 2022), Government of Spain. Recovered from : <https://www.lamoncloa.gob.es/serviciosdeprensa/notasprensa/sanidad14/Paginas/2022/080922-plan-estrategico-industria-farmaceutica.aspx>

Context of the markets where ROVI's principal products are present

Low-molecular-weight heparins

According to the latest studies, the size of the low-molecular-weight heparin (LMWH) market is expected to reach 5.7 billion dollars in 2028, representing a CAGR of 6.6% between 2021 and 2028, IQVIA states that the market is over 4 billion euros, with Europe and the emerging countries accounting for 83%.

Region	Enoxaparin sodium	Nadroparin calcium	Dalteparin sodium	Tinzaparin	Bemiparin sodium	Other	Total
Europa	1,323.3	173.3	145.8	297.5	107.9	62.6	2,110.4
Resto del mundo	687.3	176.3	73.7	16.3	23.7	297	1,274.2
USA - CAN	547.5	0.0	68.5	22.0	0.0	0.0	637.9
Japón	8.5	0.0	13.2	0.0	0.0	11.1	32.8
Total	2,566.5	349.7	301.2	335.8	131.6	370.6	4,055.3

Source: IQVIA MIDAS Q1 2020

ROVI's main products in this area are bemiparin (Hibor®) and the enoxaparin biosimilar (Becat®).

1. Bemiparin (Hibor®)

At national level, it represented a market share of approximately 33% as of December 2022, which meant it was in first place in the Spanish market.

At international level, the company has obtained the loyalty of consolidated network derived from long-term contracts with prominent local pharmaceutical distributors. Notwithstanding, in the medium-long term, it is forecast that international bemiparin sales will decline as a result of the international expansion of ROVI's enoxaparin biosimilar.

2. Enoxaparin biosimilar

Enoxaparin (such as Clexane/Lovenox) is the principal LMWH in the world and Europe is the main market (around 50%). ROVI is pursuing the goal of becoming one of the leading European players in a market that totals 1.3 billion euros, where it has unique competitive advantages.

In the long term, biosimilars tend to obtain 50%-70% of the market share of the reference product. Becat®, ROVI's enoxaparin biosimilar, was launched in September 2017 and already had total sales of 152.9 million euros in 2022. The product is present in 38 countries and approved in 57 countries, and ROVI continues signing agreements for it to be marketed in more than 90 countries within the next few years.

2.6 billion euros

Global Sales

1.3 billion euros

Sales in Europe

0.7 billion euros

Sales in Emerging Markets

721 million units

Global Sales

+5.7%

Global Q1 2018-Q1 2020 Rolling Annual Total

Source: IQVIA-MIDAS MAT 1Q-2020 Report



Potential market for ISM® technology

This innovative drug-release technology patented and developed by ROVI (ISM® Platform) currently has two main lines of development: Risperidone ISM® and Letrozole ISM®. The former is for the treatment of schizophrenia, while the latter is intended to treat hormone-dependent breast cancer.

1. Evolution and outlook for the schizophrenia market

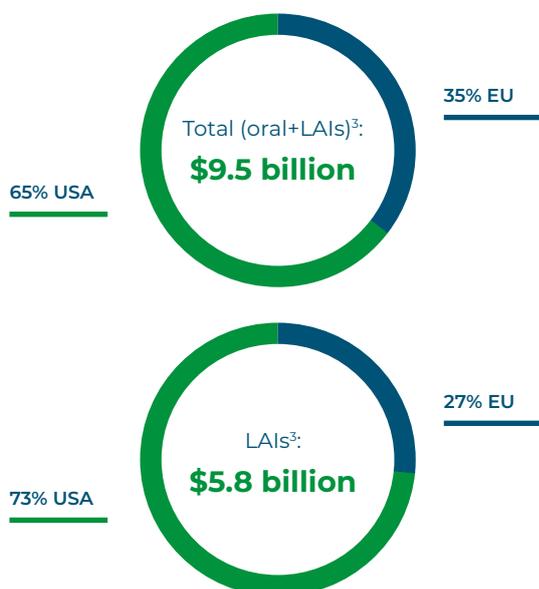
Schizophrenia is a chronic and progressive disorder that affects 21 million people worldwide and has an increasingly high lifetime prevalence.

In its treatment, long-acting injectable (LAI) technologies are becoming increasingly critical in the market and are becoming the option preferred by psychiatrists when tackling some of the essential unmet needs of the schizophrenia market.

The most important aspects of LAI technologies are:

- > They help improve treatment adherence, which, in turn, lowers the rate at which patients stop taking their medication, reducing relapses and hospitalisations in cases of schizophrenia. Treatment adherence is extremely important because each relapse leads to progressive and irreversible brain damage.
- > They reach therapeutic concentrations in plasma in a much faster and more sustained manner.

With regard to market share, Risperidone ISM® represents an opportunity for growth in a market that is attractive for new entrants with high growth forecasts. The figures for the scale of opportunities (in the schizophrenia market and LAIs) in the United States and Europe support this idea:



⁽³⁾ IQVIA-Midas TAM 3Q 2019 and ROVI's monthly treatments estimate.

⁽⁴⁾ Data Monitor 2017.

Spain is the largest market in Europe in LAI sales (23%)³.

> **United States** is the main market for the treatment of schizophrenia with LAIs, with LAI sales of 4.2 billion dollars. Although the penetration of LAIs in monthly treatments continues to be low, with 5.8% in terms of units, the injectables market for schizophrenia grew by 20% in the United States between the third quarter of 2015 and the third quarter of 2019.

> **Europe:** is the second largest market of LAIs for schizophrenia. In this case, the penetration in LAI units for monthly treatments is greater than in the United States market, totalling 8.4%, in a market of 1.6 billion euros, where growth between the third quarter of 2015 and the third quarter of 2019 was 8.5%.

Mention should be made of the fact that, in comparison with the United States market, competition in the European market is relatively low, due to the lower number of medicine options.

Given the current low penetration rate, sales of LAIs to treat schizophrenia are expected to drive the Company's future growth.

2. Evolution and outlook of the hormone-dependent breast cancer market

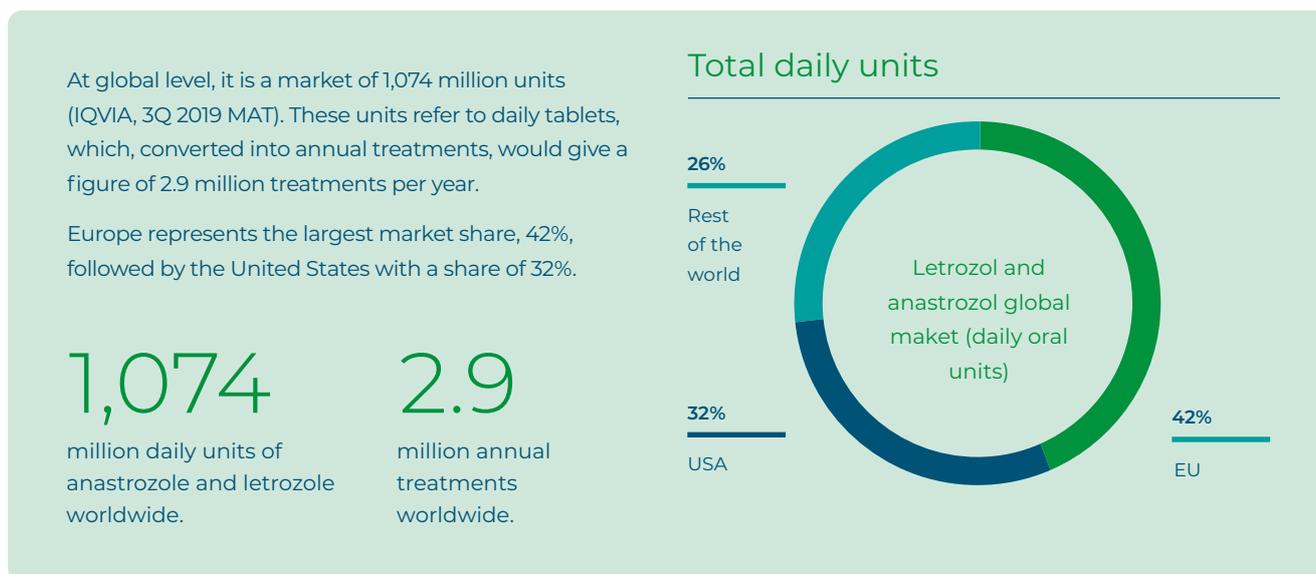
The diverse nature of breast cancers means that different treatments exist. After it has been cured, hormone receptor-positive (HR+) breast cancer requires the patient to continue with restrictive treatment for at least three years, in order to prevent relapses. This treatment consists of the inhibition of the enzyme aromatase, which is responsible for a fundamental step in oestrogen biosynthesis in post-menopausal women. Due to its ISM® technology, ROVI meets this need through Letrozole ISM® in a market which, unfortunately, is expected to grow over the next ten years.

In fact, revenue in the United States, Japan and the five most important EU markets is forecast to rise 16.7%⁴ between 2015 and 2024.

Absence of LAIs to treat this disease. As a result, there is a potential market derived from the high switch rate from oral treatment to LAIs.

However, LAIs are not currently present in this market although, given the improvement in treatment adherence and the efficacy of the drug, they are expected to become the treatment of choice. At present, the treatment is administered orally on a daily basis using either letrozole or anastrozole (both of which inhibit the aforementioned enzyme).

Taking the graph below as a reference (current oral inhibitor market), the wide margin that exists for the launch of Letrozole ISM®, once it has received the necessary authorisations from the health authorities, may be noted.



123 million daily units of exemestane worldwide

338.239 annual treatments

There is also a third oral molecule, exemestane, also an aromatase inhibitor, which could be a further candidate for replacement by the LAI. This molecule sells 123 million units worldwide (3Q 2019 MAT), representing 338,239 additional annual treatments, which could be added to the potential oral letrozole and anastrozole markets.

Attention should be drawn to the fact that, to date, no treatment that is under development has proved better than letrozole and many of those that are currently under clinical development are being studied in combination with aromatase inhibitors or as a second or third line of treatment for the disease in an advanced/metastatic stage. Therefore, it would seem reasonable to consider that the aromatase inhibitors will continue to be a key strategic therapy to treat hormone-dependent breast cancer for

Potentially the only LAI aromatase inhibitor in the hormone-dependent breast cancer market.

many years. Furthermore, to the best of our knowledge, to date, there is no public information on the existence of other developments of long-acting injectable aromatase inhibitors.

Since there are no competitors in the breast cancer market, a comparison with prostate cancer is used. Breast cancer can be compared to prostate cancer because its behaviour is similar in terms of prevalence. Gosrelin, histrelin, degarelix, leuprorelin and triptorelin are the molecules used to treat prostate cancer. These five molecules had a total market, in values, of 2.5 billion dollars in the United States and Europe at 3Q 2019 MAT (source: IQVIA). Unlike breast cancer, LAIs have a very significant presence in prostate cancer, accounting for 89% of the total market of LAIs and oral treatments in the United States and Europe.



4.2.

Identity and Commitment: mission, vision and values

[GRI 2-23]

ROVI's mission, vision and values are aligned with the Group's business strategy and are the foundation that guides and sustains all the Company's business decisions, both at corporate level and in the course of its operating functions.

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."

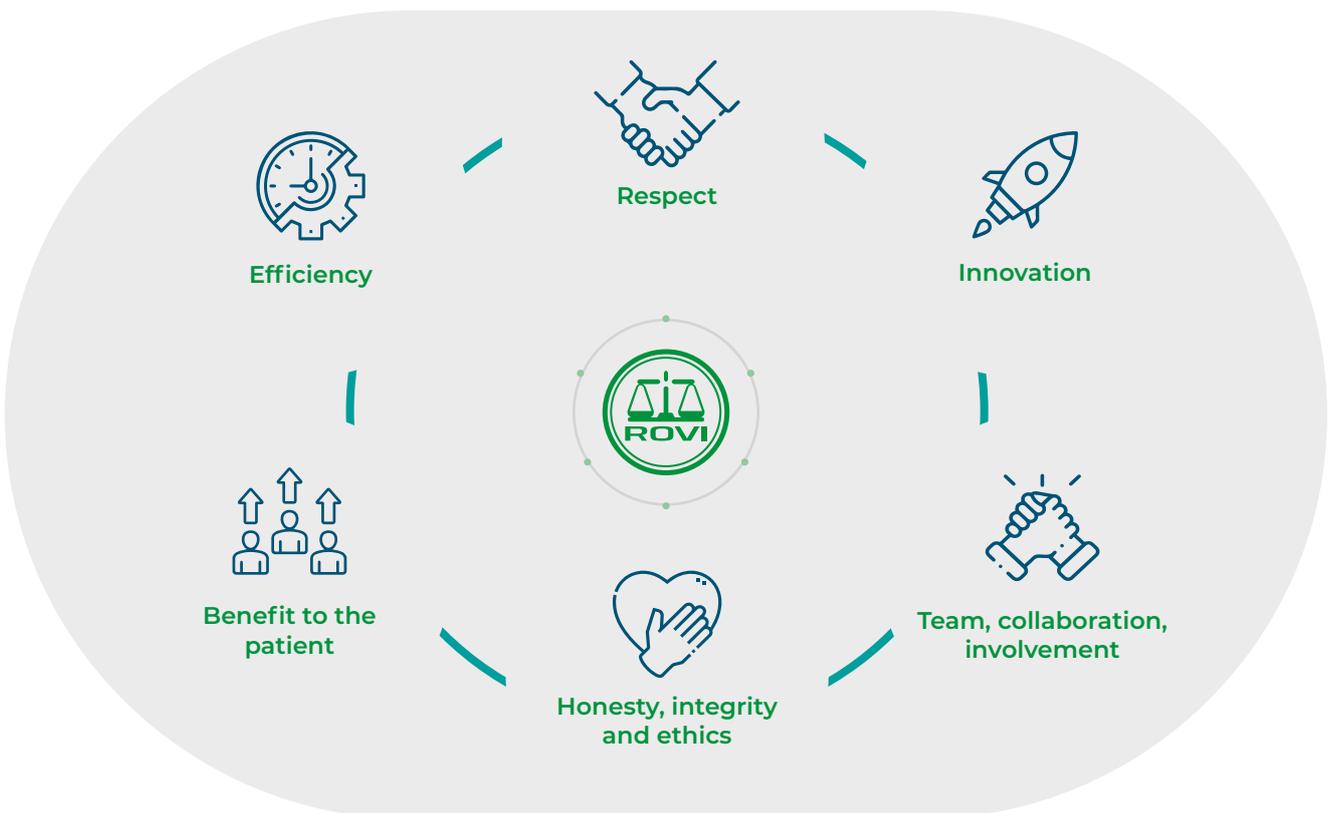
All the professionals at ROVI are aligned with the Group's mission, which allows them to integrate it into their activity, since they are aware that the ultimate goal is to create value and generate a positive impact on society.

VISION



"We aspire to be recognised 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



Principles for action

The Company has a series of principles for action that furnish ROVI's mission with consistency and method in its day-to-day corporate functions.



Ethics

To act in accordance with the guidelines set out in the Code of Ethics, which reflects the Company's commitment to the principles of business ethics and transparency in all its spheres of action.



Communication

To ensure that the commitment acquired by ROVI in its mission, vision and values extends to and is accepted by its stakeholders, seeking active dialogue and a strengthening of the relationships with them. Thus, it contributes to harmonising its business identity and social expectations by adapting, as far as possible, the Group's policies and strategies to the stakeholders' interests, concerns and needs.



Transparency

To transmit confidence and credibility among the stakeholder groups through a commitment to transparency. This will entail:

- A. Providing stakeholders with relevant and accurate information, complying with any legal requirements for public disclosure 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 to ensure its reliability.



Honesty

To favour free-market practices, rejecting any kind of illegal or fraudulent practice and taking effective measures to prevent, monitor and penalise any irregularities.



Environment

To contribute to sustainability from an environmental standpoint, making this materialise through the integration of environmental protection into the different business areas, the preservation of biodiversity, prevention of pollution, efficient resource management and the adaptation to and mitigation of climate change, as set out in the Group's Environmental Policy.



Human Rights

Respect for human rights is the maxim of any action taken by ROVI. As a member of the United Nations Global Compact, ROVI supports, adopts and transmits the integration of its principles among all its professionals.



Contribution to society

To meet customer needs by contributing to the production of high-quality, safe and reliable products in the places where it carries on its activity.



Legality

Compliance with the legal regulations in force in the places where the ROVI companies are located is one of the bases of their activity.



4.3. Corporate Strategy

[GRI 2-1, 2-22]

4.3.1. Major pillars of growth

In ROVI's business units, the Company has identified three main pillars of growth that will generate sustained value in the short, medium and long terms:

- > **Low-molecular-weight heparins (LMWHs)**
- > **Contract manufacturing**
- > **ISM® technology**

ROVI, aware of the need to achieve its economic development accompanied by ethical and sustainable conduct, integrates responsibility in ESG (Environment, Social, Governance) management into its business strategy. In this respect, ESG aspects are integrated as a transversal element that supports the development of the Company's

three major pillars of growth, in order to ensure sustainable growth in the short, medium and long terms.

In order for sound management of ESG aspects to materialise and form part of the Company's daily activity, ROVI has developed a three-year Master Plan (2023-2025) as a roadmap to follow. This Plan establishes strategic goals through which ROVI seeks to improve its performance and expand its commitment throughout its value chain and with its stakeholders. Further details of the ESG Master Plan may be found in chapter 4.5.

Considering each one of these three major pillars of growth individually, a series of advantages that make ROVI an excellent commercial partner have been identified:

PILLAR OF GROWTH



Low-molecular-weight heparins (LMWHs)

COMPETITIVE ADVANTAGES

- > Bemiparin HIBOR® is the LMWH with the highest anti-Xa/IIa rate, which may lead to greater antithrombotic activity without increasing the bleeding risk.
- > Bemiparin HIBOR® provides a more convenient treatment: only one daily injection is required, in comparison with other products from different pharmaceutical laboratories.
- > Aspires to be present in over 110 countries through an extensive and consolidated international network. Competitive price and high quality.
- > Vertical integration.
- > ROVI's knowledge of the LMWH market (over 70 years' experience).
- > Markets with high growth potential.



Contract manufacturing

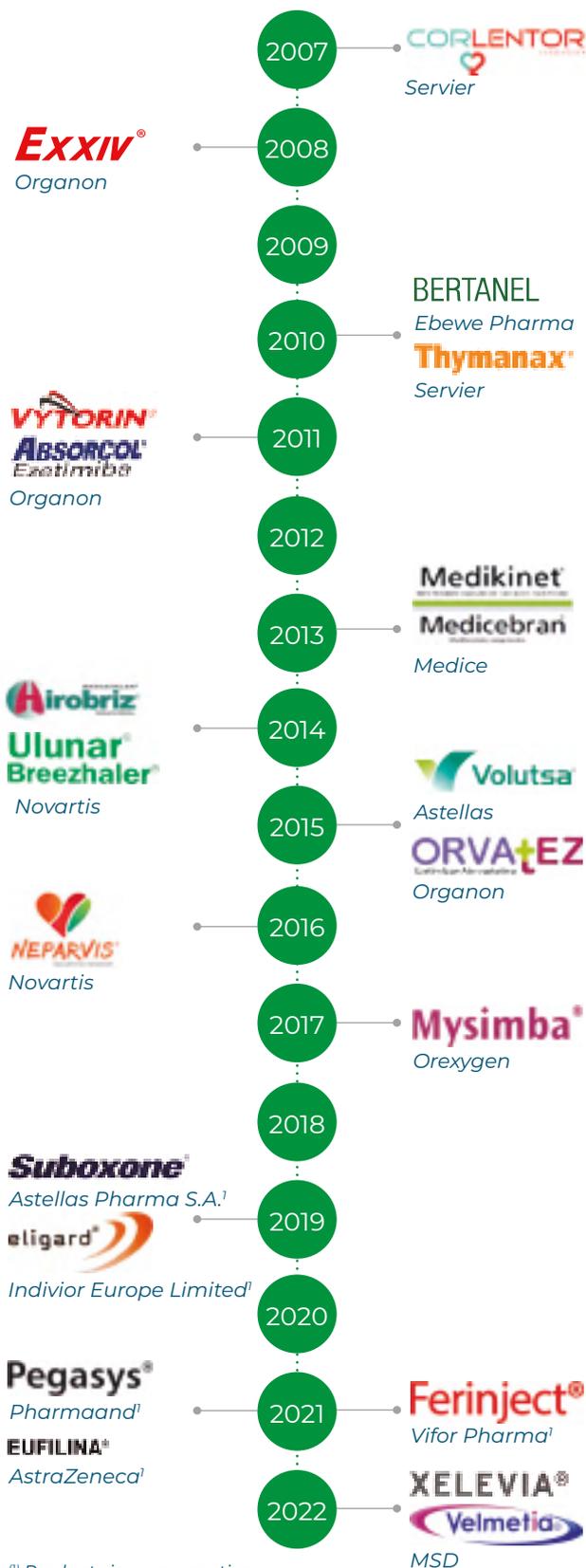
- > Among the world leaders in pre-filled syringe manufacturing. Fully-invested production facilities.
- > Helps absorb fixed costs and overheads, providing for a highly cost-competitive manufacturing position.
- > Particularly reinforces the LMWH division, which relies on ROVI's internal production capacities.
- > Agreement with Moderna, which is currently the main driver of this pillar.



ISM® technology

- > Lower frequency of doses. Long-acting injection.
- > Greater product stability.
- > Swift and sustained effect on the patient.
- > Choice of dose best adapted to the patient.
- > Launch of Okedi® in Europe to treat schizophrenia.

As a result of ROVI's capacity to create value, the Company is a preferred partner to distribute third-party products in Spain and has a solid portfolio of reference products from the main international pharmaceutical companies.



¹⁾ Products in co-promotion

4.3.2. Strategic priorities and goals

Since the outbreak of the COVID-19 pandemic, the Company has been tackling a changing and uncertain context. The development of this disease and its socioeconomic impact on future years has influenced ROVI's strategy, which has been adjusted precisely to the evolution of events to provide appropriate responses to the new challenges that have arisen.

In addition to the pandemic, the environment has presented other major challenges over recent years, but ROVI's performance during this period has been highly satisfactory. Within the framework of this successful performance, the Group established a series of long-term goals (2018-2023), which it reached two years earlier than forecast (2021).

	Operating revenue	EBITDA "without R&D"
Target established by ROVI for 2023	Double the 2018 operating revenue (303.2 x2= 606.4)	Multiply the EBITDA "without R&D" by 2.5 (63.0 x 2.5=157.5)
Starting point (2018)	303.2 million euros	63.0 million euros
Attainment of target (2021)	648.7 million euros	230.4 million euros
2022	817.7 million euros (growth 26%)	302.8 million euros (growth 31%)



After attaining this milestone in 2021, ROVI announced that it expected its operating revenue to increase by between 15% and 20% in 2022. These forecasts were met and operating revenue had risen 26% at the year end, surpassing the high end of the range forecast for 2022.

For 2023, ROVI expects its operating revenue growth to decrease by low-teen figures in relation to 2022, although growth of between 5% and 10% is expected in relation to 2021.

For 2023, ROVI is assuming a new post-pandemic scenario in which COVID-19 would foreseeably be a seasonal disease and, in principle, the vaccine would be administered once a year. For this reason, ROVI expects a stronger second half of the year compared to the first half regarding the CMO business. The first quarter of 2023 is expected to include revenues linked to the production of vaccines in the fourth quarter of 2022 but the second quarter of 2023 is expected to be the lowest quarter in terms of CMO sales.

Nevertheless, the uncertainty related to the evolution of the disease is very high, meaning that it is not possible to make a precise assessment of the effect that this new scenario might have on the contract manufacturing business. Likewise, under the terms of the agreement signed with Moderna, in February 2022 ROVI is continuing to invest in increasing the compounding, aseptic filling, inspection, labelling and packaging capacities at its facilities and expects said capacities to be fully installed at the end of 2024.

Growth drivers in 2023

ROVI will continue to work on and develop its main growth drivers, among which the following may be mentioned:

- > Enoxaparin biosimilar: granting of the marketing authorisation for an enoxaparin biosimilar outside Europe by the competent national authorities.
- > Licencing agreements with third parties, such as Neparvis®, Volutsa®, Xelenia® and Velmetia®.
- > New contracts in the contract manufacturing area.
- > Development of the long-term agreement (10 years) signed with Moderna in 2022, which will help strengthen ROVI's manufacturing division thanks to the investment to expand the capacity of the production plants.

- > ISM® technology, due to the launch of Okedi® in Europe and the potential marketing of Risperidone ISM® in the United States.

These growth levers are strongly supported by ROVI's track record, its experience, and the soundness of its business, based on its leadership in the specialty pharmaceutical division, as well as its high-value-added contract manufacturing services.

Considering the different business units of the ROVI Group and the existing business opportunities, in a context of potentially growing demand, ROVI expects 2023 to see the following important milestones:

1. Expansion of the agreement with Moderna

Through its company Pharma Industrial Services, S.A.U., which resulted from the union of the Company's contract manufacturing management units (ROVI Contract Manufacturing and Frosst Ibérica), ROVI has high potential in its contract manufacturing unit.

To a large extent, this potential derives from the important production and distribution agreement established with Moderna for the COVID-19 vaccine, which was expanded in 2021 and, subsequently, extended on 16 February, 2022. Through this new long-term (10 years) collaboration agreement signed in 2022, the compounding, aseptic filling, inspection, labelling and packaging capacities will increase at ROVI's facilities in Madrid, San Sebastián de los Reyes and Alcalá de Henares.

In addition to producing the Moderna COVID-19 vaccine, the ROVI platform will also be able to be used to provide service to future Moderna mRNA vaccine candidates.

This manufacturing unit's sales to third parties rose 52% in 2022, reaching 403.5 million euros, mainly due to the agreement with Moderna and the reorientation of the contract manufacturing activities towards products with a higher value-added.

2. ISM® technology

The solid R&D&I project portfolio is the basis upon which ROVI is building its future potential and growth, essentially through development of its ISM® technology.

Likewise, the potential of the ISM® technology stems not only from the frequency of medication, but also from the fact that it can be applied to new chronic therapeutic areas, including psychiatry and oncology.

Due to these characteristics, the **ISM® platform** has strong competitive advantages.

1	Predictability	PK* model & simulations already validated for Risperidone ISM® in clinical programme	High probabilities of success in Phase III in new developments
2	Usability	Improved stability	No cold chain needed
3	Flexibility	Selecting the most convenient posology depending on clinical needs	From 1 to 12-monthly administration
4	Improved clinical management	<ul style="list-style-type: none"> > Long-acting injection (1-12 months) > Plasma therapeutic levels from day 1 	Rapid onset and sustained clinical effect
5	Vertical integration	<ul style="list-style-type: none"> > Technological barriers (e.g. filling capacity) > Sound intellectual property protection > Manufacturing capacities 	<ul style="list-style-type: none"> > Protected technology > Integrated manufacturing plants

ROVI has spent approximately 23.9 million euros on developing R&D&I projects.

* PK stands for pharmacokinetic.



2.1. Risperidone ISM®

At present, the market track record shows that long-acting injectables (LAIs) are on the way to becoming a benchmark in the care of schizophrenia, replacing the oral treatment.

ROVI, with Risperidone ISM®, is endeavouring to occupy a prominent position in the United States and European markets for the treatment of schizophrenia. These markets represent a great opportunity for development for ROVI. The Company is betting on development of this medicine in a very encouraging market environment —5.8 billion dollars, divided into 4.2 billion dollars for the North American market and 1.6 billion dollars in the EU. (Source: IQVIA).

Likewise, given the characteristics of the schizophrenia market in qualitative terms, the following may be noted:

- > High treatment switch rates. Specialists swiftly switch the treatment of patients who show a deficient response

due to side effects or relapses, often related to poor treatment adherence, until they find the best drug for the patient.

- > There are not many specialists and, therefore, a new competitor can cover the psychiatrist community with a reduced sales force.
- > The effectiveness of LAIs is driving an increasingly early use of them in the treatment protocol, potentially for the early phase or first episode of the disease, rather than only after relapses (for example, they are now used after the second relapse while, only a few years ago, it was after the fourth relapse).

Moreover, the **advantages** obtained with **Risperidone ISM®** make a contribution to society by creating more value than other alternatives.

Fully supervised monthly injection (every 28 days)

- > Ongoing monitoring of non-adherence through regular interactions between patient and medical staff.
- > Reduce the risk of accidental or deliberate overdose.

Clinical utility of risperidone

- > Proven efficacy and safety of risperidone.
- > Very well-known drug among psychiatrists for the treatment of schizophrenia.

Therapeutic plasma levels reached 2 hours after the first dose, aimed at reducing the severity of the disease (Clinical Global Impression –Severity [CGI-S] and the symptoms. (Positive and Negative Syndrome Scale) [PANSS]) reduction from day 8

- > Fast onset of action after achieving therapeutic plasma levels from the first few hours after the first injection.
- > One of the Phase III efficacy endpoints is the time until PANSS score is reduced, aimed to occur at day 8.
- > No need to supplement with oral antipsychotic medication or loading doses.

In this business line, ROVI reached an important milestone at the beginning of 2022. The European Commission authorised the marketing of Okedi® (Risperidone ISM®) for the treatment of schizophrenia in adults for whom the tolerability and effectiveness had been established with oral risperidone.

This approval was based on the positive results of the pivotal PRISMA-3 study on the efficacy and safety of Risperidone ISM® in schizophrenia patients.

The results obtained in this study show that the two different doses (75 mg and 100 mg once a month) had achieved the prespecified primary and secondary efficacy endpoints, a key factor in treatment of patients with acute exacerbation of schizophrenia.

The primary efficacy endpoint, the PANSS total score (mean difference, CI: 95%), improved significantly with Risperidone ISM® 75 mg and 100 mg from the beginning until day 85, with adjusted differences of -13.0 (17.3 to -8.8; $p < 0.0001$) and -13.3 (-17.6 to -8.9; $p < 0.0001$), respectively.

Significantly improved mean changes for the secondary endpoint, the CGI-S score, from commencement until day 85, were also obtained for Risperidone ISM® in comparison with the placebo, -0.7 (-1.0 to -0.5; $p < 0.0001$), for both doses.

The statistically significant improvement in efficacy was already noted 8 days after the first injection in a reduction in the CGI-S score for both doses and, for the 100 mg dose, a reduction in the PANSS score.

In relation to the treatment-emergent adverse events reported during the PRISMA-3 study, the majority related to increased blood prolactin (7.8%), headaches (7.3%), hyperprolactinemia (5%) and weight increase (4.8%). No important new or unexpected safety information was reported.

Likewise, patients who successfully completed the double blind period were offered the opportunity to continue in a long-term, open-label extension phase (12 months) with injections of Risperidone ISM® (75 mg or 100 mg) every four weeks. New, clinically stable patients ("de novo" patients) were also able to enter this open-label phase of the study. This extension phase found that long-term treatment was efficient, safe and well tolerated in adult schizophrenia patients, irrespective of the initial severity of the disease or whether they had been treated previously with Risperidone ISM® during an acute exacerbation or switched from a stable dose of oral risperidone.

Regarding geographic scope, ROVI distributes or will distribute the product directly in the countries where has a direct presence through its subsidiaries (Germany, France, Italy, United Kingdom, Poland, Spain and Portugal), while, in the remaining European locations, it will be distributed through local or international distributors.

Additionally, Risperidone ISM® is expected to cross the borders of the EU during 2023.

ROVI, at its Capital Markets Day held on 24 November 2020, announced the filing of an NDA (New Drug Application), i.e. a registration dossier to obtain marketing authorisation in the USA, with the FDA (Food and Drug Administration). ROVI was informed of the delay in a decision on granting marketing authorisation for Risvan® (Risperidone ISM®) by the U.S. Food and Drug Administration ("FDA").

On 24 September 2021, ROVI received a Complete Response Letter from the FDA with outstanding questions on the Risvan® dossier, which were answered in January 2022. In the third quarter of 2022, the FDA issued a second Complete Response Letter, with some outstanding questions for ROVI and also with questions for one of its manufacturers. Both ROVI and the manufacturer provided answers to the FDA. The FDA has notified ROVI that the user fee goal date is 27 July 2023.

The grant of the marketing authorisation for Risvan® by the FDA is also subject to the closure of the observations issued by the FDA after the pre-approval inspection (PAI) of the plant where the product is manufactured (located in Madrid, Spain) that was conducted on the second half of June 2022. Responses to these observations were provided to the FDA and ROVI is awaiting the FDA's review of these responses and notification from the FDA as to whether or not a second inspection to ROVI's manufacturing plant is required to close the pending observations.

In addition, in January 2023 the FDA conducted the pending inspection of a supplier to close deficiencies found by the FDA in a process not related to Risperidone ISM®. As a result of this inspection, the FDA has issued new observations and the manufacturer is currently estimating a time frame to provide the responses.

*In the United States ROVI
aspires to obtain the same
indication as the other LAIs⁽¹⁾, i.e.
"treatment of schizophrenia in
adult patients".*

(1) Long-acting injectables.



2.2. Three-monthly Risperidone ISM®

ROVI is currently working on the development of ISM® technology with three-monthly risperidone, which will follow the same regulatory channel as Okedi® (a hybrid medicine for the EMA) and Risvan® (regulatory pathway 505b(2) for the FDA) and, again, the reference medicine will be oral Risperdal. The clinical trial (phase 1) is expected to begin in the first half of 2023 and will be an open-label single-dose study. Up to three prototypes will be tested on stable schizophrenia patients and, after the initial phase to select the final candidate, the pharmacokinetic modelling will be updated and the doses to establish the bridge with monthly doses of Okedi® 75 and 100 mg will be estimated. The high dose will also be tested in gluteus and deltoids.

As described for Okedi®, the linear pharmacokinetic behaviour of the technology and risperidone, together with the pharmacodynamic pharmacokinetic models already implemented for Okedi®, makes this clinical trial highly predictive of the future range of levels that will be achieved in steady state and, therefore, of the expected clinical response to this formulation.

The whole clinical programme will have very high visibility with regard to success after this study has been completed successfully.

2.3. Letrozole ISM®

In addition, the Company is continuing development of a long-acting letrozole injection that could provide a significant advance in the treatment of hormone receptor-positive breast cancer.



treatment of HR+ breast cancer, combined with the early interruption of treatment and the non-adherence that is common with these oral medicines, makes letrozole a perfect candidate for our ISM® technology.

Patient non-adherence to treatment is a real problem and the market is much in need of a long-acting injectable that guarantees adherence.

- > Bibliographical evidence suggests that, after 6 months, 51% of early breast cancer patients treated with aromatase inhibitors are not inhibited with Estradiol (E2).
- > This lack of inhibition is related to a significant risk of suffering breast cancer and death.

Letrozole ISM® is the second candidate to use ROVI's ISM® technological platform. This new medicine (in the research phase) is the first long-acting injectable aromatase inhibitor to treat hormone-dependent breast cancer.

Currently, ROVI has the results of the LISA-1 study, which confirm that the ISM® formulation provides a prolonged release of letrozole that produces sustained suppression of the oestrogenic hormones with a much lower annual amount of the drug for similar efficacy.

The LISA-1 study was an open-label single ascending dose

<https://clinicaltrials.gov/ct2/show/NCT03401320>



study. In each cohort, healthy post-menopausal women received daily doses of 2.5 mg of Femara until a steady state was reached (14 days), On day 15, an intensive PK profile was obtained for Femara over 24 hours and, after a washout period, the volunteers received a single dose of a 50mg or 100mg injection of Letrozole ISM®.

The result obtained showed that the total amount of the drug required for similar efficacy was approximately 9 times lower in comparison with Femara®.

Expected advantages of 100mg of Letrozole ISM® versus 2.5mg of oral Femara® (daily dose)

- > Greater oestrogen suppression. Bibliographical evidence shows 51% of patients are not inhibited with Estradiol (E2) after 6 months versus a forecast 2% after one year with Letrozole ISM®.
- > Reduction in the percentage of patients with a high risk of tumour progression or early breast cancer.
- > Convenient annual intramuscular injection versus daily oral dose.
- > Much lower annual amount of the drug for similar efficacy.
- > None of the non-adherence problems that arise from daily oral doses.

ROVI is continuing to review the whole clinical efficacy programme with the FDA, in particular the details of the phase II exploratory efficacy trial with post-menopausal women with advanced breast cancer. The phase II trial will provide support in preparing the phase III efficacy trial with letrozole as an adjunctive therapy for early breast cancer, which is the principal indication. Due to the size of the clinical programme, ROVI will evaluate the possibility of reaching an agreement with a partner.



Summary of ISM® technology

Product	Potential indication	Current status	Key milestones
Risperidone ISM® Risperidone, monthly	Schizophrenia	Approved	Marketing phase in Europe and in process of approval in USA
Letrozole ISM® Letrozole, annual	Breast cancer	Exploratory efficacy study in advanced HR+ breast cancer	Beginning of a clinical trial for efficacy
Risperidone, three-monthly	Schizophrenia	Preparation phase I	Start in first half of 2023

4.4. Materiality

[GRI 2-29, 3-1, 3-2, 3-3]

Identification of and relations with stakeholders

ROVI, aware of the repercussions of its activity in the social area, wishes to improve people's health and quality of life through technical excellence in its day-to-day, always taking the needs and expectations of its stakeholders into account. To do so, one of the key factors is the existence of proactive dialogue with the stakeholders that seeks to generate significant impacts on the environment in which the Group operates and make a positive contribution thereto.

Therefore, due to ROVI's commitment to society derived from its important research work and the manufacture of pharmaceutical products, the Company has identified six groups to which it has acquired a responsibility to create value by establishing a series of goals.

1. Employees



GOAL > To strengthen the feeling of belonging and corporate identity among its employees, seeking the best development and performance for its workforce.

RELATIONSHIP MECHANISMS

- > Suggestion boxes placed at the Company's facilities in order to make it easier for employees to submit anonymous communications concerning any improvements they have identified.
- > Confidential communication channels (canaletico@rovi.es, APP ROVI Rocks, mail service at the Pozuelo offices), through which any irregularities considered unlawful or criminal or that constitute a breach of the principles set out in ROVI's Code of Ethics may be reported.
- > Training, tutorials and meetings.
- > On-boarding process for new employees.
- > Annual and quarterly publications.
- > Skills and knowledge assessment.
- > Human Resources Department.
- > Corporate website.

2. Suppliers



GOAL > To seek services and products that provide the highest value-added to the Company under contracts that observe the Code of Ethics that ROVI has created for its suppliers.

RELATIONSHIP MECHANISMS

- > Meetings, phone calls and e-mails with suppliers and contractors.
- > Visits to the ROVI facilities by suppliers and vice versa.
- > Sending newsletters.
- > Sector conferences.
- > Quality assurance platforms, such as the EcoVadis Platform.
- > Corporate website.

3. Shareholders



GOAL > To create sustainable value in the short, medium and long terms.

RELATIONSHIP MECHANISMS

- > Policy for Communication with Shareholders, Institutional Investors and Proxy Advisors.
- > Direct investor communication channels (ir@rovi.es and the web form at www.rovi.es/contacto).
- > Automatic sending of relevant information on the Company by e-mail.
- > Annual and quarterly reports.
- > Investor Relations Department.
- > Corporate website: section for investors and shareholders.

4. Customers/Patients/Professionals



GOAL > To provide products and services based on quality, safety and the Group's experience.

RELATIONSHIP MECHANISMS

- > Yearly and half-yearly publications.
- > <https://www.rovi.es/en/medios-contacto>

5. Society and environment



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

RELATIONSHIP MECHANISMS

- > Environmental Policy
- > Corporate procedure (SOPc813 "Communication, participation and consultation") for queries, complaints, etc.
- > Participation in environmental and medical research forums to encourage or prevent certain activities.
- > Quarterly and annual publications.
- > Meetings with local representatives.
- > Corporate website (where the different quality, environmental and health and safety certifications appear).

6. Public authorities



GOAL > To create channels for cooperation with the authorities to favour people's health.

RELATIONSHIP MECHANISMS

- > Transparency and Continuous Communication Policy.
- > Annual and quarterly publications.
- > Cooperation through alliances with governmental bodies, especially the health authorities, at local, regional, autonomous community and national level.
- > Membership of sector associations at national and international level.
- > Corporate website.

To encourage active communication with stakeholders

The ROVI Group bets on permanent, constructive dialogue with its stakeholders as a key factor in developing its business strategy.

In this respect, it has the different communication channels described above, which not only allow the Company to maintain and strengthen the relationship with its stakeholder groups, but are also used as a way to identify the issues most important to them in relation to the Company's activity.

In the light of the foregoing, ROVI published 14 press releases in 2022 with relevant information regarding:

- > Financial statements.
- > New developments related to the Group's research programmes.
- > Collaboration agreements with Moderna for manufacture of the COVID-19 vaccine.
- > Agreement with the European Bank to drive innovation in the Spanish pharmaceutical sector.
- > ROVI's results in the Sustainalytics Sustainability Ranking.
- > Achieving carbon neutrality as a milestone in the Group's Environmental and Social Sustainability Policy.

Continuing the trend that began some years ago, ROVI remains active in its official social media profiles (Facebook, Twitter and YouTube), where it publishes new developments, as a supplementary channel for sharing relevant information on the Group.

Material aspects of the activity

In 2022, ROVI updated its materiality analysis, in line with the best sustainability practices and pharmaceutical sector trends in this area. This exercise showed the Group's sustainability context and the main ESG aspects on which strategy will focus over coming years.

The purpose of this update is to define significant priority ESG impacts for the Company and its main stakeholders, which will allow strategic priorities to be established in this respect and, at the same time, provide information transparency and appropriate accountability to the stakeholders.

For this task, ROVI received support from the external consultant PricewaterhouseCoopers S.L., involving its stakeholders and taking their interests into account through interviews and ad hoc questionnaires to find out the importance of each one of the principal material topics identified.



Methodological approach: double materiality

In the new global business environment, where there is an increase in sustainability demands and requirements, market positioning through integrated sustainability and business management in line with the expectations of the regulators and stakeholders is of fundamental importance to companies. Therefore, identification of a company's material issues in relation to sustainability is an essential element in meeting the demands of its stakeholders.

In this respect, since the Non-Financial Reporting Directive (NFRD) in the European Union, and now with its revision in the Corporate Sustainability Reporting Directive, as well as in the drafts of European standards prepared by the European Financial Reporting Advisory Group (EFRAG)

the concept of materiality is expanding and developing towards "double materiality", which some companies are already applying.

The concept of "double materiality" involves analysing both the organisation's impact on the environment and society (inside-out perspective or materiality of the impact) and the impact of certain matters on the organisation's value creation potential (outside-in perspective or financial materiality). In this context of change in which advances towards "double materiality" are being made, ROVI wishes to reinforce its analysis by integrating this new concept. The topic is considered material if it falls within any of the following three scenarios:

1.

Impact materiality perspective

A topic is material from the impact perspective if it generates significant impact(s) on people and/or the environment. These impacts may be:

- > Real or potential impacts;
- > Short-, medium- and/or long-term impacts;
- > Direct or indirect impacts derived from the company's activity.

Likewise, two factors must be taken into account:

- > The severity of the impact: scale, scope and irremediable nature.
- > Probability of the impact.

ROVI → Society and Environment

2.

Financial impact perspective

A topic is material from the financial perspective if it provokes or can provoke significant financial effects for the company that, as a final result, may affect the company's development, performance and/or positioning.

A topic is considered material from this perspective if it:

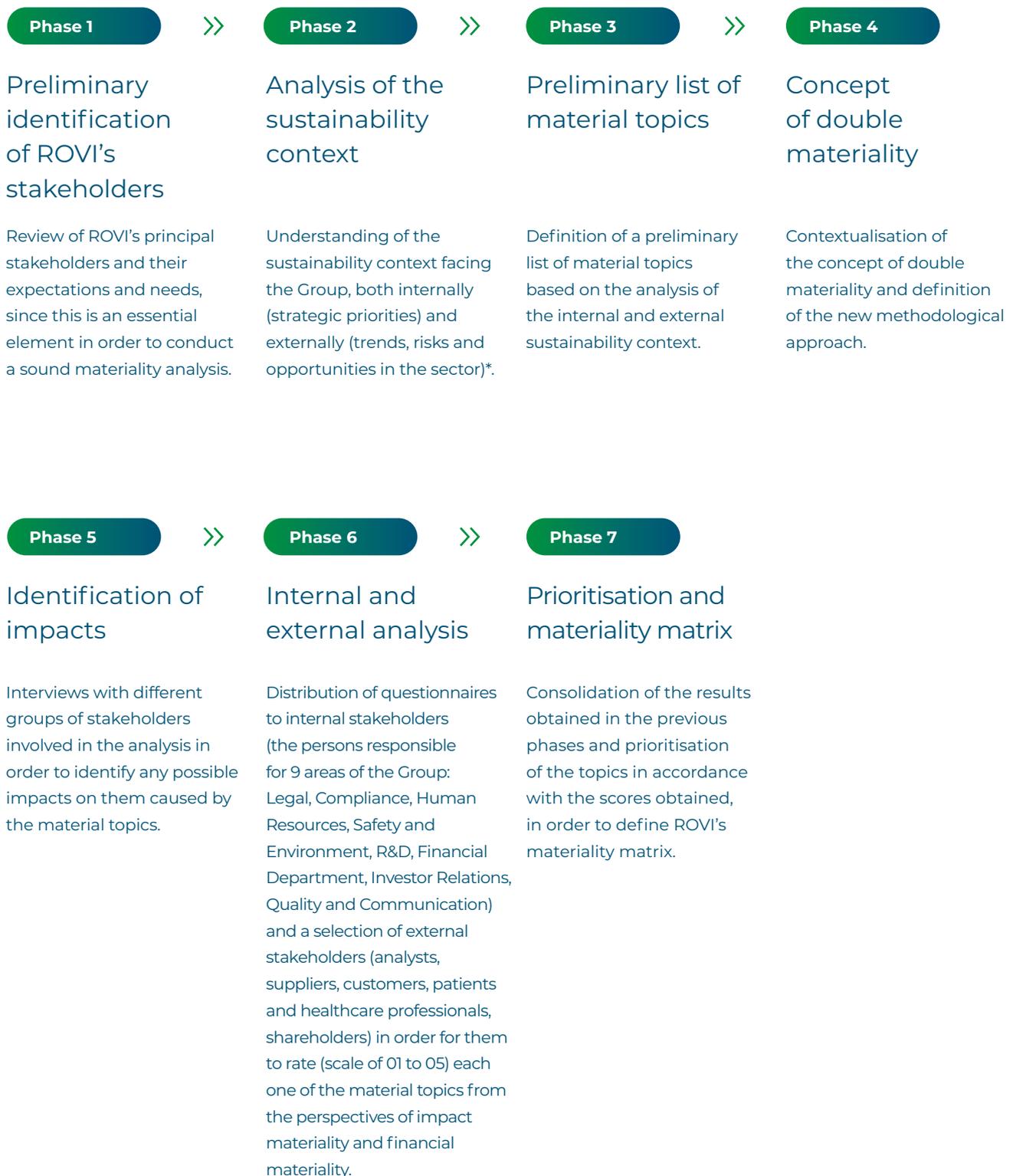
- > Can affect the company's capacity to continue using or obtaining the necessary resources in its business processes, as well as the quality and price of said resources.
- > Can affect the company's capacity to rely on its necessary relationships in business processes in acceptable terms.

ROVI ← External conditions

3.

Materiality from both perspectives

Phases of the update of the materiality analysis



() To correctly identify trends, risks and opportunity, ROVI's peers were benchmarked, sustainability standard setters such as SASB, GRI, WBCSD and WEB were consulted and applicable national regulations were taken into account (Law 11/2018 on Non-Financial Information and Diversity), as well as future legislation that will apply to the Group (European Sustainability Reporting Standards proposed by the EFRAG).*

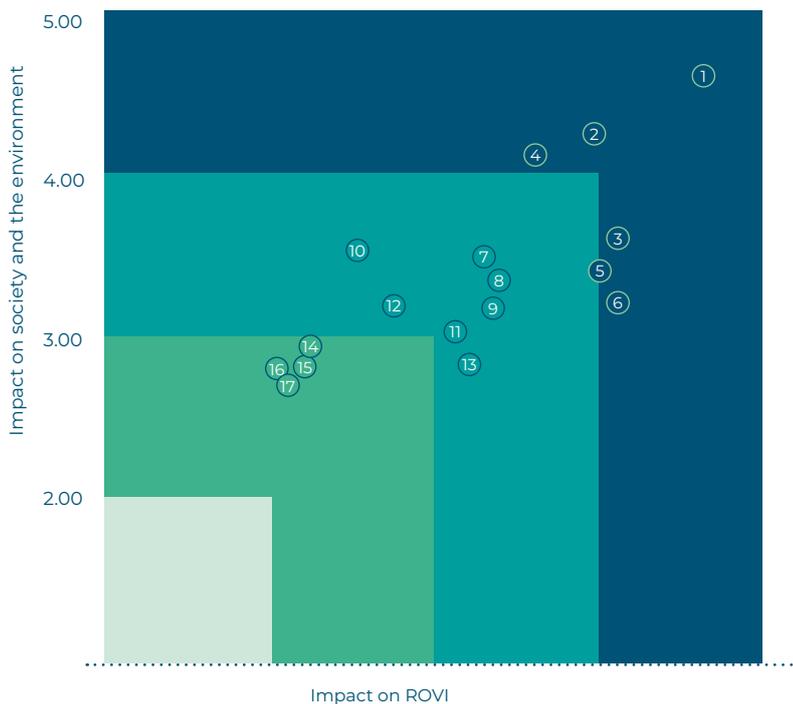


Identification of material topics

After this exhaustive analysis, the materiality matrix was prepared, representing the 17 topics selected in accordance with their economic, social and environmental importance for both ROVI and the other interested parties. The topics considered material are discussed in different chapters of this Report in accordance with the disclosure requirements established in Law 11/2018 on Non-Financial Information and Diversity and the Global Reporting Initiative (GRI) Standards.

The results of the materiality analysis were discussed with the persons responsible for the nine areas of ROVI involved in the analysis and were shared with the Nomination and Remuneration Commission and the Audit Committee of the ROVI Group.

Materiality matrix



Topic prioritisation

Critical

- 1 Ethics and compliance
- 2 Product quality and safety
- 3 Continuity and accountability in the value chain
- 4 Risks and crisis management
- 5 Research and development
- 6 Attracting, retaining and developing talent

Important

- 7 Responsible governance
- 8 Ethical marketing
- 9 Intellectual property
- 10 Employee safety, health and well-being
- 11 Privacy, data protection and cybersecurity
- 12 Circular economy and waste management
- 13 Atmospheric emissions and climate change

Relevant

- 14 Sustainable growth
- 15 Human rights
- 16 Drug pollution
- 17 Efficient water management

ESG dimension

- G
- S
- S
- G
- S
- S

- G
- S
- G
- S
- G
- E
- E

- Transversal
- S
- E
- E

E = Environment

S = Social

G = Governance

4.5. ESG Master Plan

In 2022, ROVI drew up its ESG Master Plan 2023-2025, which was approved by the Board of Directors in December and will allow the strategic ESG priorities to be established, transparently demonstrating the commitment to stakeholders in line with both the Group's Sustainability Policy and the Company's Mission, Vision and Values.

With a three-year horizon, from 2023 to 2024, the ESG Master Plan includes 19 ESG strategic goals that materialise in 43 follow-up indicators to be monitored. These goals and indicators were defined by the ESG Department in close collaboration with the heads of ROVI's different areas. Furthermore, by creating an ESG Committee, the Plan defines the processes for monitoring the follow-up indicators. The Board will receive annual reports on the progress made.

The starting point of the Master Plan is the double materiality analysis conducted in 2022 by

PricewaterhouseCoopers ("PwC") (see Chapter 4.4 Materiality), which identified the relevant priority ESG topics for the Group and its main stakeholders.

With the information resulting from (i) the double materiality analysis, through which the Company focuses on its material topics, (ii) the ESG aspects evaluated by the rating agencies, (iii) the disclosure requirements within the different non-financial reporting frameworks and (iv) present and future regulations, ROVI drew up its Master Plan 2023-2025 with the intention of boosting sustainability in the Company, highlighting its contribution to attainment of 11 of the 17 Sustainable Development Goals (SDGs) of the United Nations Agenda 2030, thus responding to society's demands.

ROVI's new Master Plan focuses on five priority areas:



1. Aspiring to become a **leader in governance committed to sustainability**



2. Betting on **sustainable management to combat the global environmental challenges**: fight against climate change, promotion of the circular economy and efficient water management



3. Positioning itself **as a key player in caring for persons and integrating specialised and diverse talent**



4. Promoting **responsible management of the supply chain**, ensuring ethical and environmental standards in each one of its links



5. Promoting **R&D&I activities** by establishing partnerships with key players





1. “Leader in governance committed to sustainability”

STRATEGIC GOALS:

- > Boost sustainability in the corporate governance model.
- > Implement efficient ESG risk management.
- > Ensure the quality and reliability of the non-financial information.
- > Adapt to the new sustainable financing models.
- > Promote good ethical conduct and compliance practices.

For ROVI, the relationship between the Board and the stakeholders takes on special importance in the present accountability context and, therefore, it is of fundamental importance to put measures in place to ensure the management and control of ESG aspects from the highest governance body, guaranteeing transparency and avoiding any risks that might affect the organisation’s sustainability. To this end, ROVI is striving to bring the whole Group into line in respect of regulatory compliance, with audits and inspections, as well as training and communication, on ethics- and compliance-related matters for all the employees and major suppliers. For the Company, regulatory compliance is of priority importance and any change that comes into force obliges the Group to update and adapt to accommodate it.

Likewise, ROVI updates its risk map annually and implements checks that allow the risks to be reduced and/or mitigated. In this respect, the continuous updating of the risk map, including ESG risks, and its resulting adaptation in terms of response, minimises future crisis situations and unfavourable environments.

Reducing the carbon footprint has been among ROVI’s priorities for several years and, for the third year running, it was neutral in Scope 1 and 2 carbon emissions. In this respect, over the next few years, the Company will focus its efforts on implementing measures to reduce Scope 1, 2 and 3 emissions and, ultimately, on compensating the tonnes of carbon it has been impossible to avoid.

For ROVI, waste generation is an inherent impact derived from its production process. Therefore, it is essential for it to have a strict and exhaustive waste management process. Likewise, it bets on promoting the maximisation of the life cycle of both the materials involved in the production process and the end products. Furthermore, water is an indispensable resource for ROVI due to the specific industrial activity of producing injectables. In relation to water resource management, the Group aims to improve the monitoring processes to ensure responsible water consumption.

2 “Sustainable management to combat the global environmental challenges”

STRATEGIC GOALS:

- > Achieve climate neutrality.
- > Integrate circularity into the activities and into waste management.
- > Promote sustainable water management.

3. “Key player in caring for people and integrating specialised and diverse talent”

STRATEGIC GOALS:

- > Ensure that specialised and diverse talent is attracted and retained.
- > Guarantee the health, safety and well-being of employees.
- > Encourage the development and continuous training of employees.
- > Ensure equality, diversity and inclusion.
- > Guarantee product quality and safety.
- > Promote programmes of access to medicines.

Identifying, attracting, developing and retaining talent is critical to ROVI’s performance. The matter involves comprehensive management of human capital, including issues such as equality, diversity and workplace inclusion, as well as training and development plans adapted to the Group’s different organisational levels.

ROVI has an absolute necessity to retain talent derived, first, from the strong competitiveness of the labour market in the pharmaceutical sector and, second, from the intensive, privileged and essential knowledge that the workforce enjoys once it has received the necessary training from the Group. In this respect, said knowledge is

necessary in order for the business to continuously advance and develop. Therefore, it is indispensable for training plans to exist, aligned with both Group strategy and the protocols and policies in force.

Likewise, ROVI strives to ensure the highest workplace health and safety standards in order for its employees to perform their jobs correctly. Therefore, the implementation of mechanisms and management systems that ensure employee protection emerge as an important topic for the Group, as well as looking after employee well-being in terms of work-life balance, disconnection and social benefits.

Furthermore, providing medicines with a stable quality is extremely important to ensure the efficacy and

safety of ROVI's products. To this end, internal measures that guarantee quality and safety throughout the entire life cycle are crucial to both the Group and the pharmaceutical industry.

Lastly, for ROVI, it is of fundamental importance to respond to one of the greatest demands made of the pharmaceutical sector: that it should help medicines to reach the greatest number of patients possible. In this respect, ROVI establishes and reinforces strategic partnerships with organisations responsible to distributing medicines to the most disadvantaged persons.

4 “Responsible management of the supply chain, ensuring ethical and environmental standards in each one of its links”

STRATEGIC GOALS:

- > Promote supplier alignment with the Company's Sustainability Policies.
- > Implement due diligence processes on sustainability in the value chain.

For ROVI, it is vitally important to have a responsible value chain that ensures that ESG criteria are integrated and respected. The Company continues to progress in consolidating the model for evaluation of the supply chain and management of its risks, where ESG criteria are monitored.

To this end, the Company is actively working to evaluate its suppliers, thanks to the implementation of mechanisms such as the EcoVadis platform and the prevention or, if necessary, mitigation of risks through the Code of Ethics for Suppliers, among other control systems.

ROVI aspires to be recognised as a leader due to its work in researching and developing new products. Developing lines of research that foment new collaborations with consortia and other entities is essential for the pharmaceutical industry and for ROVI. Likewise, it has been seen that products should be developed taking account of real therapeutic needs and executed complying with the highest ethical standards (clinical trials and animal testing).

5 “Promotion of R&D activities by establishing partnerships with key players”

STRATEGIC GOALS:

- > Establish and renew strategic partnerships.
- > Increase R&D investment.
- > Foster the transparency of clinical trial results.

Through compliance with this Master Plan, ROVI trusts it will continue to be a pharmaceutical sector leader considering five basic aspects that ensure integration of ESG aspects into the Company's strategy.





5

Our Financial performance in 2022

5.1

Results for the year

5.2

Value for the Shareholder

5.3

Tax Transparency

A large, semi-transparent, stylized 'ROVI' logo is overlaid on the background image. The letters are white with a slight shadow, and the 'O' is a square. The background is a blurred outdoor scene with trees and a path.



KEY FIGURES



Operating revenue

817.7

Million euros

+26% vs. 2021



EBITDA

278.9

Million euros

+37% vs. 2021



EBIT

256.0

Million euros

+41% vs. 2021



Net profit

199.7

Million euros

+30% vs. 2021



Net cash position

54.2

Million euros

+98% vs. 2021

ROVI increased its operating revenue by 26% and its net profit by 30%.

KEY MILESTONES 2022



Growth in heparin division

9%



Growth in the enoxaparin biosimilar

23%



Growth in contract manufacturing sales

52%



Launch of Okedi® in Europe.

5.1. Results for the year

2022 was a crucial year for ROVI from the strategic, operating and financial points of view, since it was able to achieve historic results. The year was marked by the growth of the enoxaparin biosimilar, the launch of Okedi® in Europe and the growth of the manufacturing area as a result of the agreement with Moderna.

ROVI is currently undergoing a transformation process that will not only allow its internationalisation to expand and reposition the Company towards products with higher value-added, but will also increase the production capacity to enable it to handle future demand.

Operating revenue

Operating revenue increased by 26% to 817.7 million euros, driven by the strength of the contract manufacturing organisation (“CMO”) business, sales of which grew by 52%, and the specialty pharmaceutical business, where sales rose 8%. Total revenue rose by 26% to 819.8 million euros in 2022.

Sales outside Spain increased by 41% versus 2021, reaching 553.4 million euros in 2022. 82.6 million euros (or 15%) of this figure related to international subsidiaries, mainly due to (i) the increase in international LMWH sales and (ii) the increase in the contract manufacturing organisation business. Sales outside Spain represented 68% of operating revenue in 2022 compared to 60% in 2021.

414.2M€

Specialty pharmaceuticals

403.5M€

CMO business

817.7M€

Operating revenue

Specialty pharmaceutical business

The specialty pharmaceutical business grew 8% compared to 2021, totalling 414.2 million euros in 2022.

Million euros	2022	2021	Growth %
Prescription-based pharmaceuticals	372.6	347.4	7%
Low-molecular-weight heparins	256.6	234.8	9%
Enoxaparin biosimilar	152.9	124.0	23%
Bemiparin (Hibor)	103.8	110.7	-6%
Sales in Spain	66.9	69.4	-4%
International sales	36.9	41.3	-11%
Neparvis	39.1	38.5	2%
Volutsa	17.8	16.3	9%
Vytorin & Absorcol & Orvatez	32.1	28.3	13%
Other products	36.0	41.4	-13%
Okedi	2.0	-	n.a.
Rebates to National Health System	-11.0	-11.9	-8%
Contrast imaging agents & other hospital products	40.1	35.5	13%
Other	1.5	1.1	31%
Total specialty pharmaceuticals	414.2	384.0	8%

Within the specialty pharmaceutical business, sales of prescription-based pharmaceuticals, which have a high strategic value for ROVI, grew 7% compared to the same period of the previous year, totalling 372.6 million euros in 2022.

Among the prescription-based pharmaceuticals, ROVI's heparin division is the principal growth driver. Heparin division sales (low-molecular-weight heparins and other heparins) rose 9% on the previous year, reaching 264.0 million euros in 2022. Heparin sales accounted for 32% of operating revenue at the end of 2022, compared with 37% in 2021.

ROVI aspires to join the worldwide leaders in the low-molecular-weight heparin field with its two products: Bemiparin and the enoxaparin biosimilar.

Sales of Bemiparin, ROVI's low-molecular-weight heparin (LMWH) dropped 6% to 103.8 million euros in 2022. International Bemiparin sales decreased 11% to 36.9 million euros, mainly due to lower sales in the Turkish and Russian markets. Sales of Bemiparin® in Spain (Hibor®) decreased 4% to 66.9 million euros in 2022 compared with the previous year, mainly due to lower penetration of the product in the prophylaxis segment.

Sales of the enoxaparin biosimilar increased 23% in 2022 compared with 2021, totalling 152.9 million euros, mainly as a result of (i) the launch of the product in five new countries in 2022; and (ii) the increase in demand for the product in the countries where it was already present.

Enoxaparin biosimilar commercialization

2017

Germany

2019

Portugal
Poland
Costa Rica
Finland
Sweden

2020

South Africa
Israel
Peru
Holland
Panama
Dominican Republic

2022

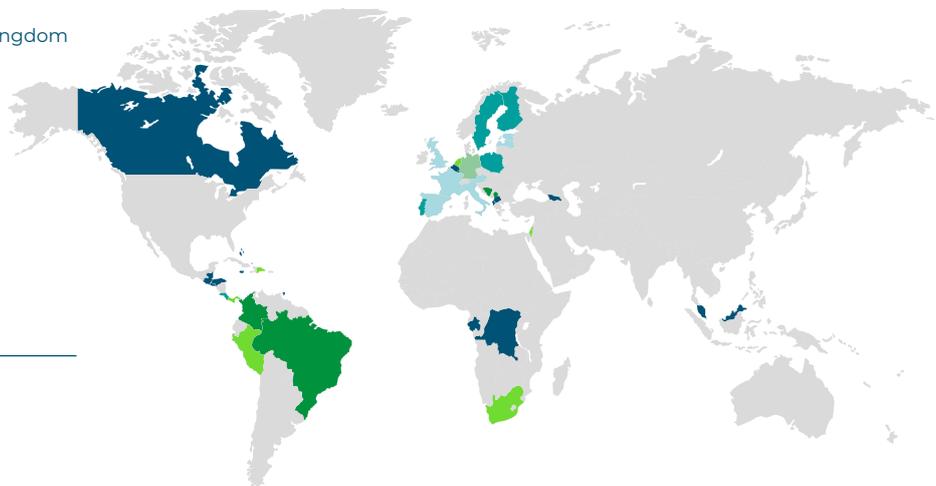
Brazil
Luxembourg
Colombia
Bosnia and Herzegovina
Kosovo

2018

United Kingdom
Italy
Spain
France
Austria
Latvia
Estonia

2021

Canada
Belgium
Malaysia
Albanian
North Macedonia
Guatemala
The Savior
Honduras
Georgia
Bahamas
Jamaica
Gabon
The Democratic Republic of the Congo
Trinidad and Tobago



On 4 October, 2022, ROVI presented Glicopepton Biotech, S. L., a joint venture with Càrniques Celrà, S.L. and Grupo Empresarial Costa, S.L. that involves the creation of one of the first national structures for the self-supply of heparins and products of high nutritional value to be used in the composition of animal feed and fertilisers.

Regarding other prescription-based pharmaceuticals, Neparvis®, Volutsa® and the hypercholesterolemia franchise (Vytorin®, Orvatez® and Absorcol®) lead the growth.

Sales of Neparvis®, a prescription product from Novartis that ROVI has been marketing since 2016 to treat adult patients with symptomatic chronic heart failure with reduced ejection fraction, increased 2% to 39.1 million euros in 2022, compared with the 38.5 million euros of 2021.

Sales of Volutsa®, a prescription-based product from Astellas Pharma indicated for moderate to severe storage systems and voiding systems associated with benign prostatic hyperplasia (BPH), which ROVI has been distributing in Spain since February 2015, rose 9% on the previous year, totalling 17.8 million euros in 2022.

Sales of Vytorin®, Orvatez® and Absorcol®, prescription-based products from Merck Sharp & Dohme (“MSD”), indicated as an adjunctive therapy to diet in hypercholesterolemia patients, increased 13% on the preceding year, totalling 32.1 million euros in 2022.

Likewise, in 2022 ROVI launched Okedi®, its first product based on the leading-edge drug delivery technology ISM®, to treat schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone. Sales totalled 2.0 million euros in 2022. The product was launched in Germany in April, the United Kingdom in July and Spain in September 2022.

According to the consultancy firm IQVIA, the Spanish innovative product market increased 4% in 2022 compared to the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales increased 7% in 2022, outperforming the market by 3 percentage points.

Likewise, in 2022, ROVI signed a new agreement with Merck Sharp and Dohme (MSD), to promote and distribute Xelevia® (sitagliptin) and Velmetia® (sitagliptin and metformin) in Spain. The marketing of both products began in January 2023 for a period of 3 years, renewable annually.

Sitagliptin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The metformin and sitagliptin combination is used to treat high blood sugar levels caused by type 2 diabetes. Metformin reduces the absorption of sugar from the stomach, reduces the release of stored sugar from the liver, and helps your body use sugar better.

In 2022, ROVI signed a new agreement with Teva Pharma S.L.U. to promote and distribute Baceq® (paliperidone) in Spain, a monthly injectable generic medicine corresponding to Xeplion® of Janssen Pharmaceuticals and indicated for maintenance treatment of adult schizophrenia patients

stabilised with paliperidone or risperidone. ROVI's hospital line is responsible for promoting this product in the hospital segment. Marketing of this product commenced in January 2023 for a period of ten years.

Thus, ROVI is seeking a prominent position in the psychiatry area by including a once-monthly injectable generic alternative on its portfolio, thus contributing to the sustainability of the public health system.

According to IQVIA data, in the twelve months up to December 2022 (MAT December 2022), the injectable antipsychotic market in Spain totalled 283.8 million euros. In the same period, the medicine Xeplion® held a 30% share of the injectable antipsychotic market in Spain.

Sales of contrast imaging agents and other hospital products increased by 13% to 40.1 million euros in 2022 compared to 2021. This increase shows the strong recovery of the Spanish and Portuguese hospital activity during this period after the effects of lockdowns during the pandemic.

Contract manufacturing organisation (“CMO”) business

The future outlook for the CMO business is extremely good. This market is expected to show an annual growth rate of over 7% until 2027, according to the GlobeNewswire report dated 17 April, 2022.

CMO sales increased by 52% to 403.5 million euros in 2022 because of (i) the booking of the income related to production of the COVID-19 vaccine, (ii) the booking of the income related to the activities to prepare the plant for production of the COVID-19 vaccine under the agreement with Moderna, and (iii) the reorientation of our CMO activities strategy towards products with a higher value-added.

The growth achieved in 2022 surpassed the higher end of the range of between 30% and 40%, published when the company released its 2021 results, by 12 percentage points.



In this respect, special mention should be made of ROVI's long-term collaboration agreement with Moderna, which was extended by signing a new 10-year agreement. This will allow (i) the compounding, aseptic filling, inspection, labelling and packaging capacities to be increased at ROVI's Madrid facilities and, in addition to producing the COVID-19 vaccine, (ii) the manufacture of other future Moderna mRNA vaccine candidates. Therefore, further industrial investments are being made in ROVI's facilities in Julián Camarillo, San Sebastián de los Reyes and Alcalá de Henares.

Profit

Gross profit increased 34% compared with 2021, totalling 518.9 million euros in 2022, reflecting an increase of 3.9 percentage points from 59.5% in 2021 to 63.5% in 2022. This increase is mainly because the CMO business performed well and contributed higher margins to group sales. The positive impact on the gross margin offset the increase in the LMWH cost of goods sold in 2022 compared to the previous year.

EBITDA rose 37% on the previous year, totalling 278.9 million euros in 2022, reflecting an increase of 2.8 percentage points in the EBITDA margin, which rose to 34.1% in 2022 from 31.3% in 2021.

EBIT increased 41% in comparison to 2021, rising to 256.0 million euros in 2022, reflecting an increase of 3.3 percentage points in the EBIT margin, which rose to 31.3% in 2022 from 28.0% in 2021.

Net profit rose to 199.7 million euros in 2022, a 30% increase on the 2021 figure, which was 153.1 million euros.

Gross profit:

518.9M€

+34% vs 2021

Net profit:

199.7M€

+30% vs 2021

R&D expenses

R&D expenses, mainly related to the ISM® technology platform, decreased 13% on the previous year, dropping to 23.9 million euros in 2022.

These R&D expenses are mainly related to the following:

- > preparing the development of the next phase of Letrozole ISM® and
- > developing the new formulation of Risperidone ISM® for a three-monthly injection.

Selling, general and administrative expenses

Selling, overhead and administrative expenses increased 39% on the previous year to 216.3 million euros in 2022, mainly as a result of:

- > the increase in the expenses related to production of the Moderna vaccine;
- > the increase of 5.4 million euros in energy-related expenses; and
- > the increase in the expenses related to launching Okedi® in Europe.

Income statement

€ Million	2022	2021	Growth %
Operating revenue	817.7	648.7	26%
Other income	2.1	1.3	58%
Total revenue	819.8	650.0	26%
Cost of goods sold	-300.9	-263.9	14%
Gross profit	518.9	386.2	34%
% margin	63.5%	59.5%	3.9pp
R&D expenses	-23.9	-27.4	-13%
Selling, general and administrative expenses	-216.3	-156.0	39%
Share of profit of a joint venture	0.2	0.2	9%
EBITDA	278.9	202.9	37%
% margin	34.1%	31.3%	2.8pp
EBIT	256.0	181.6	41%
% margin	31.3%	28.0%	3.3pp
Finance Income/(Costs)	1.9	1.1	82%
Profit before income tax	258.0	182.6	41%
Income tax	-58.3	-29.6	97%
Effective tax	22.6%	16.2%	6.4pp
Net profit	199.7	153.1	30%
Net profit attributed to parent company	199.7	153.1	30%
Profit attributable to minority interests	0.0	0.0	N/A

Sound financial position

One of ROVI's main goals is to have a low leverage capital structure. At 31 December, 2022, the Company had a **gross cash position** of 126.4 million euros, compared with 100.5 million euros at 31 December, 2021.

Net cash was 54.2 million euros, compared with 27.4 million euros at 31 December, 2021.

As of December 31, 2022, **bank borrowings** had decreased by 0.7 million euros. In December 2017, ROVI announced the European Investment Bank (EIB) had granted it a loan to support its investments in Research, Development and Innovation. The loan was for 45 million euros. As of December 31, 2022, ROVI had drawn 45 million euros against this credit line; 5 million euros at a variable interest rate of Euribor at 3 months

+ 0.844% (the latest interest rate paid was 2.092% in January 2023) and 40 million euros at a fixed interest of 0.681%. Repayment of the variable-interest loan started in October 2021 (quarterly repayments) and its current outstanding balance is 4.1 million euros. The credit at variable interest matures in 2028 and the credit at a fixed interest matures in 2029. Both include a grace period of 3 years.

In July 2022, ROVI announced that the European Investment Bank (EIB) had granted it a new loan to support its investments in Research, Development and Innovation. The loan is for 50 million euros with a repayment period of 10 years and a three-year grace period. It may be drawn down over a term of two years.

Capital expenditure (Capex)

In relation to Capex, the Group invested 51.4 million euros in 2022, compared with 40.9 million euros in 2021. Attention should be drawn to the fact that 39.6 million euros of this amount is investment Capex related to the ROVI facilities and 11.8 million euros is linked to maintenance Capex and other.



5.2. Value for the Shareholder

ROVI's goal is to align the Company's interests with those of the shareholders in order to construct and consolidate a relationship of mutual trust that allows a strong performance and the creation of value in the long term.

To this end, ROVI manages its relationship with shareholders and potential investors through the Investor Relations Department and its Shareholder, Institutional Investor and Proxy Advisor Communication Policy, which governs the actions taken by the Department and is applied actively, in order to maintain regular, smooth communication on all its activities.

Likewise, the Investor Relations Department is in constant communication with the rest of the areas of the Company, which allows any information requests from ROVI's investors and analysts to be satisfied.

Shareholder, Institutional Investor and Proxy Advisor Communication Policy



ROVI guarantees transparency, accuracy, immediacy, equality and symmetry in the information it provides to shareholders, institutional investors and the markets in general.

The main goal is to foment sharing information with shareholders on an ongoing and regular basis, not only when Ordinary General Shareholders' Meetings are called, but also by making effective channels available for them to receive constant information on any proposals that may be made in relation to the management of the Group in accordance with the law or following Corporate Governance recommendations.

Communication Channels



ROVI offers all its shareholders the possibility of automatically receiving all the Company's financial information through a system of e-mail alerts, while regular, one-off and important information on the Company, such as presentations and legal, economic, financial and corporate governance documents, may be consulted on the Group's portal.

Furthermore, it has three social media profiles (Twitter, LinkedIn and YouTube), through which it informs on new developments in the Group and shares its significant information, such as press releases and other activities related to corporate social responsibility.

Securities market information

At the end of 2022, the ROVI share price was 36.06 euros per share.

During 2022, ROVI acquired a total of 1,609,715 treasury shares (826,381 in 2021), paying 78.6 million euros for them (42.2 million euros in 2021). Likewise a total of 1,598,794 treasury shares were resold (831,586 in 2021) for an amount of 77.8 million euros (42.4 million euros in 2021). Said shares had been transferred at a weighted average cost of 80.6 million euros (31.4 million euros in 2021), giving rise to a loss of 2.7 million euros on the sale (profit of 10.9 million euros in 2021), which was taken to reserves. At 31 December, 2022, there were 644,114 treasury shares (633,193 at 31 December, 2021).

€ Million	2022
Ticker symbol	ROVI
Bloomberg ticker symbol	ROVI:SM
Reuters ticker symbol	ROVI.F
ISIN	ES0157261019
Number of shares in issue (31 dec. 2022)	54,016,157
Closing price (31 dec. 2022)	€36.06
Type of shares	Common shares (par value €0.06)
Capitalisation (31 dec. 2022)	€1,948 Mn
Market	Continuous market

Rovi's share buy-back programmes

On 23 February, 2022, ROVI announced the end of the buy-back programme that had begun on 3 November, 2021 and the beginning of a new buy-back programme effective 23 February, 2022.

End of the buy-back programme

ROVI announced that the meeting of the Board of Directors held on 22 February, 2022 had decided to end the buy-back programme that the Company had been conducting since 3 November, 2021. A total of 1,492,108 treasury shares had been acquired, i.e. 89% of the maximum number initially planned under the buy-back programme. ROVI paid 94.6 million euros to repurchase said shares at an average price of 64.63 euros per share.

Commencement of a new buy-back programme

Likewise, ROVI announced the beginning of a new buy-back programme for the Company's shares starting 23 February, 2022. On 29 March, 2022, ROVI announced the end of this second programme, having acquired 560,700 treasury shares, i.e. 100% of the maximum number initially planned under the buy-back programme. ROVI paid 38.6 million euros to repurchase said shares at an average price of 68.80 euros per share.

The purpose of the two buy-back programmes was to cancel ROVI shares (by reducing ROVI's share capital). The reduction of capital through the cancellation of 2,052,808 shares repurchased within the framework of the two aforementioned buy-back programmes was approved by the General Shareholders' Meeting on 14 June, 2022 and executed by entering the pertinent deed of capital reduction into public record.

The Company paid a total of 135.0 million euros for the purchase of 2,052,808 shares within the framework of the two buy-back programmes. The average price of the shares acquired was 65.77 euros.

After the aforementioned shares had been cancelled and removed from trading, the new share capital was 3,241 thousand euros (corresponding to 54,016,157 shares with a par value of 0.06 euros per share).



Evolution of the share

The price of the ROVI share decreased by 51.1% in 2022 compared with 2021.

2022 was Laboratorios Farmacéuticos Rovi's first full year on the benchmark index of the Spanish stock exchange, the IBEX-35, after it had been included in December 2021.

In this respect, in 2022, the ROVI share fell 51.1%, dropping from 73.80 euros at 30 December, 2021 to 36.06 euros at 30 December, 2022 while, in the same period, the Ibex-35 lost 5.6%, dropping to 8,229.1 points, and the Euro Stoxx fell by 11.7% to 3,793.6 points. ROVI's stock market capitalisation at 31 December, 2022 was 1,948 million euros (4,138 million euros in 2021).

The average daily trading volume from January to December 2022 was 165,713 shares (83,414 shares in 2021), including the volume traded on the block market and special transactions.

The average daily trading volume from January to December 2022 was 159,350 shares (82,597 shares in 2021), including the volume traded on the block market.

If only the volume (average) traded on the market is considered, it was 131,035 shares (vs 70,764 in 2021). The average daily volume (without blocks or special transactions) increased 185% in 2022 v. 2021.



Dividends

ROVI's General Shareholders' Meeting held on 14 June, 2022 resolved to distribute a gross dividend of 0.9556 euros per share entitled to receive it, charged to the 2021 profit. This was an increase of 151% on the dividend charged to the 2020 profit (0.3812 euros/share) and entailed the distribution of an amount equivalent to approximately 35% of the consolidated net profit for 2021. The dividend was paid out on 7 July, 2022.

ROVI will put a motion to the Annual General Shareholders' Meeting for a dividend of 1.2938 euros per share entitled to receive it, charged to the 2022 profit and retained earnings. This represents an increase of 35% on the dividend charged to the 2021 profit (0.9556 euros) and will entail the distribution of approximately 35% of the consolidated net profit for 2022 attributed to the parent company.

Investor relations activity

The Department's core strategy is to satisfy the demands and expectations of the Group's shareholders and investors. To this end, true to its principles of a close and transparent relationship, ROVI maintained constant activity throughout the year through meetings, forums and events with investors.

Furthermore, the Investor Relations Department, together with the Company's senior management, takes part in roadshows, multi-sectoral conferences and meetings at the Madrid offices, while also organising other actions, such as Investors' Day, visits to ROVI's production plants, webinars and presentations at different financial and healthcare sector forums.

In 2022, ROVI conducted 11 roadshows, took part in 95 calls with investors and attended 19 face-to-face and virtual conferences, which, overall, represented attention to 560 investors through 125 events at the end of 2022 (compared to 502 investors and 104 events in 2021).

	2022	2021
Roadshows	11	14
Calls with investors	95	68
Conferences	19	22

The most important events that ROVI attended in 2022 were the following:

- > Alantra, Equities Conference
- > BME, Foro MedCap 2022
- > BofA, Made in Iberia Conference 2022
- > Caixabank BPI, Iberian Conference
- > Credit Suisse, 2022 London Global Healthcare Conference
- > Exane BNP, 5th Mid Cap CEO Conference
- > Exane BNP, Spain Investor's Day
- > JB Capital, Spain & Portugal Equity Conference 2022
- > Jefferies, Pan-European Mid-Cap Virtual Conference
- > Jefferies, Healthcare Conference
- > Jefferies, London Healthcare Conference
- > Jefferies, "Back to School" Fireside Chat
- > JP Morgan, Pan-European Small/Mid Cap CEO Conference
- > Kepler, Digital Autumn Conference
- > ODDO, BHF Iberian Forum
- > ODDO, BHF Iberian Digital Forum 2022
- > Santander, Iberian Conference
- > Santander, Pharma Day



Likewise, at its meetings with investors, the main topics that aroused interest were the following:

Collaboration with Moderna

Information on ROVI's progress in formalising the agreement with Moderna for manufacture of the COVID-19 vaccine, as well as the investment in new lines to increase the Group's capacity.

R&D

Information on new developments in the ISM® technology developed by ROVI, as well as the candidate products based on this technology: Okedi®, Risvan®, Letrozole ISM® and three-monthly Risperidone ISM®.

LMWH

Information on ROVI's performance in the low-molecular-weight heparin market and its future lines of growth with the enoxaparin biosimilar, Becat®.

Sector trends

Information on the long- and medium-term trends in the pharmaceutical sector and how ROVI is adapting to them.

ESG

Information on how ROVI is integrating ESG criteria into its management and its relationships with its main stakeholders.

Information on ROVI's positioning in ESG risk according to the annual evaluation conducted by Sustainalytics.

Likewise, the Investor Relations Department establishes a direct relationship with the analysts who cover ROVI. At 31 December, 2022, ROVI was being covered by 12 analysts. In 2022, the consensus of the analysts was a buy recommendation with an average target price of 60.27 euros, 67% higher than the closing price of the share on 31 December, 2022, which was 36.06 euros.



Alejandro Conde



Patricia Cifuentes



Álvaro Lenze



Guillherme Macedo



Luis Arredondo



Pedro Echeguren



Joaquín García-Quirós



Álvaro Aristegui



James Van-Tempest



Pablo de Rentería



Francisco Ruiz



Juan Ros Padilla

5.3. Tax Transparency

[GRI 3-3, 201-4, 207-1]

Tax strategy

ROVI's Tax Strategy establishes the principles that govern the tax function in the Group and impregnate the tax processes that are applied in ROVI.

- > **Compliance.** The sustainability of the processes followed by the Group requires an unwavering commitment to contribute to the economic and social development of the different markets in which it operates. In the tax area, this commitment materialises primarily through compliance with all the Group's tax obligations and payment of all the taxes, levies and duties that accrue as a result of its trading activity, in accordance with the applicable local and international tax legislation.
- > **Ethics and responsibility.** Compliance with ROVI's tax obligations must be conducted using ethical and responsible practices, always meeting the highest standards of integrity, honesty, diligence and equity established in its Code of Ethics.
- > **Value creation.** The Group's corporate profile is a determining factor when defining its tax strategy, which is fully directed to attaining the Group's business goals and is integrated with the aforementioned corporate management model, seeking to create value for the shareholder.

The main implications of applying the principles mentioned in tax-related decision-making are the following:

- > Applying tax regulations in accordance with interpretation criteria established and published by the competent tax authorities.
- > Not using opaque structures for tax purposes.
- > Informing the Board of Directors, before it adopts the relevant decisions, on transactions that could impair tax transparency and tax compliance, as well as the tax consequences of transactions involving high sums of money or with special characteristics.
- > Valuation of transactions between group companies and any other type of related-party transaction at market prices.
- > Interaction with the tax authorities to resolve any issues that might arise in the area of tax compliance on the part of either the Company or a third party.
- > Existence of a whistle-blower channel, ROVI's Ethics Channel, which allows any financial or accounting irregularities to be reported to the Audit Committee and is decisive in detecting and preventing any possible tax irregularities.





Anti-tax fraud measures

Non-compliance with tax regulations is one of the risks that ROVI assesses regularly within the framework of the Risk Control and Management Policy, which is the Group's main mechanism to identify, assess and hierarchise the risk that could affect the organisation, including tax-related risks.

The structure and organisation of ROVI's tax function and the existence of controls in the tax processes make it easier to monitor the risk of failing to comply with tax regulations and ensure that it is always at an acceptable level that does not affect attainment of the Group's goals. In 2022 no event took place that involved the materialisation of the risk of non-compliance with tax regulations.

The tax function reports to the Financial Department, which is directly responsible for:

- > Controlling the effective implementation of the basic aspects of the tax strategy.
- > Establishing the procedures and control measures that guarantee that tax-related risks are assessed in the Group's decision-making process.
- > In the event that the level of risk is higher than acceptable, putting action plans in place to reduce the level of risk and monitoring the degree of compliance with said action plans.

Additionally, ROVI receives independent tax advice from an external source that guarantees the Group's compliance with its tax obligations, increases the Company's transparency in relation to said obligations, ensures that tax returns are filed meticulously, keeps company management updated on tax issues and helps solve any queries or differences in interpretation.

Tax information

ROVI pays special attention to compliance with the tax obligations that are applicable in each territory where it operates.

The following is the tax information of the entire Group for 2022 and Appendix I hereto sets out the tax contribution by company.

Profit before tax:

261,116

Thousand euros

Official grants received:

2,112

Thousand euros

Income taxes:

59,139

Thousand euros





6

Our responsible and sustainable management

6.1

Our Commitment to Good Governance

6.2

Our Commitment to People

6.3.

Our Commitment to the Environment





Introduction

ROVI, as a company that enjoys a sound position in the pharmaceutical industry at both national and international level, is striving to become a socially responsible company that makes an active contribution to sustainable development.

To this end, ROVI ensures it remains in the vanguard of industry trends by integrating all the aspects that may generate value for its main shareholders in the short, medium and long terms into its day-to-day. ROVI places a firm bet on its contribution to the environment by establishing a business model founded on differential

values, such as Sustainability, Quality, Research, Development and Innovation, and Environmental Protection.

The Group's bet on value materialises through its management in the three components of ESG, establishing its commitment and the principles that inspire it in this respect, which are set out in its policies, procedures and standards, as well as the goals and challenges in each one of the areas, which will be described in the chapters of this Integrated Report.

6.1. Our Commitment to Good Governance

KEY INDICATORS



- > Percentage of women on the Board: **42.85 % (3 of 7)**.
- > Percentage of independents on the Board: **42.85 % (3 of 7)**.
- > 100% of the workforce knows **ROVI's Code of Ethics**.
- > Average remuneration of Board members:
 - Women: **135 thousand euros**
 - Men: **496 thousand euros**

ASSOCIATED INTERNAL POLICIES



- > Director Remuneration Policy.
- > Risk Control and Management Policy.
- > Policy on the Composition of the Board of Directors.
- > Environmental and Social Sustainability Policy.
- > Policy on Related-Party and Intragroup Transactions.
- > Animal Testing Policy.
- > Senior Management Remuneration Policy.
- > Anti-Bribery and Anti-Corruption Policy.
- > Supplier Selection Policy.
- > Policy on Payment of Suppliers.
- > Succession Plan for the Chairman, Chief Executive Officer and Senior Management.

MILESTONES 2022



- > Hybrid Annual General Shareholders' Meeting (held face-to-face with the possibility of attending electronically).
- > Appointment of two new female directors in 2022, in order to increase board diversity and reach a percentage of female directors higher than 40% of the total number of members of ROVI's Board of Directors before the end of 2022, thus following the good corporate governance recommendations approved by the National Securities Market Commission (CNMV).

GOALS 2023



- > To provide recurrent training to marketing suppliers to ensure that, when providing their services, they fulfil the marketing ethics commitments acquired by ROVI.

CONTRIBUTION TO SDGs (SUSTAINABLE DEVELOPMENT GOALS)



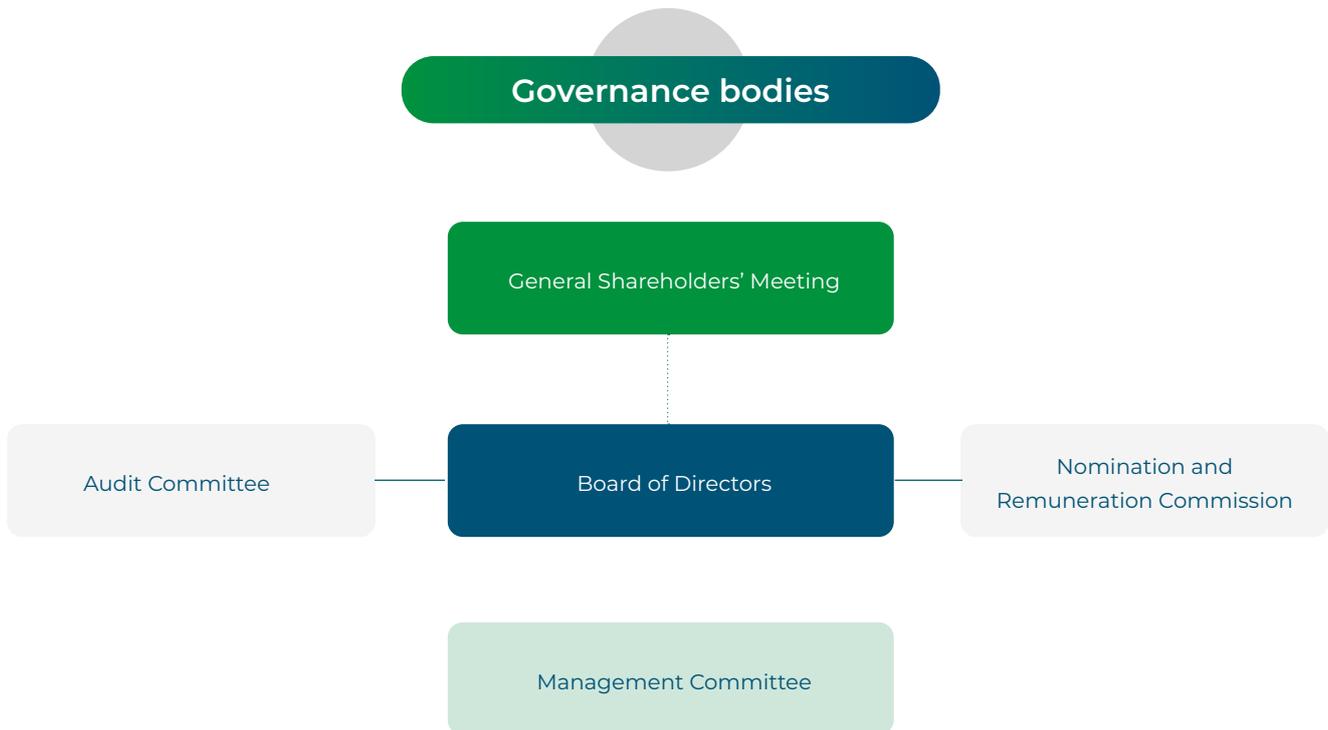
6.1.1. Our corporate governance model and structure

[GRI 2-28, 2-9, 2-13, 2-11, 2-10, 2-12, 2-18, 2-14, 405-1]

The corporate governance of ROVI takes the updated recommendations applicable to the Company into account. In particular, its internal regulations are adapted to the Good Governance Code of Listed Companies approved by the National Securities Market Commission (CNMV) in February 2015 and last revised in June 2020 (the "Good Governance Code"), as well as the CNMV's Technical Guide 3/2017 on audit committees at public-interest entities and Technical Guide 1/2019 on nomination and remuneration committees.

This model helps foster honest conduct on the part of ROVI in its relations with its stakeholders, building up a relationship of mutual trust that contributes to satisfying their interests, needs and expectations.

Efficiency in the operation of ROVI's Board of Directors, according to the latest self-evaluation performed for the financial year 2022 in accordance with article 5.7 of the Regulations of the Board of Directors.





General Shareholders' Meeting

Role	The Company's highest decision-making and control body for the matters within its competence.
Regulation	Its powers and operation are regulated by the Bylaws and the Regulations of the General Shareholders' Meeting.
Meetings	It meets at least once a year at the Ordinary General Meeting within the first six months of each year.
Competences	The competences attributed to this body by law include approving the governance body's corporate management and the annual financial statements for the preceding year and deciding on application of the profit, as well as appointing directors and auditors, although it may likewise deliberate and decide on any other item on the agenda that falls within its competence.
Right to attend	All holders of at least one share recorded in their name in the relevant account entry register five days before the General Shareholders' Meeting is held may attend the meeting.

The most recent Ordinary General Shareholders' Meeting of Laboratorios Farmacéuticos Rovi S.A. was held in Madrid on 14 June, 2022 on the first call. It reached the necessary quorum with the attendance of a total of 46,263,277 shares (30,937,031 present and 15,326,246 represented), representing 82.511% of the share capital (55.177% present and 27.335% represented). The following resolutions were passed at the meeting:

- > Approval of the individual annual accounts of the Company and the consolidated annual accounts of the Company and its subsidiaries for the year ended 31 December, 2021.
- > Approval of the statement of non-financial information included in the consolidated management report of the Company and its subsidiaries for the year ended 31 December, 2021.
- > Approval of the proposed application of the individual profit for the year ended 31 December, 2021, which was 65,143,321.71 euros. A resolution was passed to pay a dividend of 0.9556 euros gross per share to each one of the 56,068,965 ordinary shares in issue that was entitled to receive it on the pay-out date (53,579,502.95 euros) and allocate 11,563,818.76 euros to retained earnings.
- > Approval of the corporate management and activities of the Board of Directors in the year ended 31 December, 2021.
- > Approval of the ratification and re-election of Ms Marina Del Corral Téllez as an external proprietary director for the bylaw-stipulated term of four years.
- > Approval of the maximum annual remuneration of the members of the Board of Directors in their capacity as such for the year 2022, fixed at 1,000,000 euros.
- > Approval of the amendment of the Director Remuneration Policy for the period 2022-2024.
- > Approval of a reduction of the share capital by 123,168.48 euros through the cancellation of 2,052,808 treasury shares with a par value of 0.06 euros each, representing approximately 3.66% of the Company's share capital, with the resulting amendment of article 5 of the Bylaws.
- > Re-election of the account auditors of the Company and its consolidated group, KPMG Auditores S.L., for the year 2022.
- > Approval of the Company's Annual Director Remuneration Report on a consultative basis.

Board of Directors

Role	The Company's highest decision-making, oversight and control body, except in matters reserved to the General Shareholders' Meeting.
Regulation	Its powers and operation are regulated by the Bylaws and the Regulations of the Board of Directors.
Meetings	The Board of Directors met on 10 occasions in 2022. The percentage attendance (including proxies granted with precise voting instructions) was 100% of total votes.
Competences	<p>The competences that this body holds by law or in accordance with the Bylaws or the Regulations of the Board of Directors include:</p> <ul style="list-style-type: none">> Preparing the annual accounts and management report and proposing the application of the Company's profit.> Approving the Company's general policies and strategies, in particular the strategic plan, as well as the management objectives and annual budget.> Supervising and verifying that management meets the goals fixed, respects the corporate purpose and promotes the Group's corporate interests.> Supervising the preparation of the financial and non-financial information.> Calling the General Meeting and drawing up an agenda and the motions to be put to it, as well as publishing the announcements of the meeting.
Composition	In 2022, the Board of Directors was composed of seven members: three executive directors, three independent directors and one proprietary director, in accordance with the Good Governance Code recommendations on size, which state that the number of members should not be less than five or more than fifteen, and composition, with a majority of external directors.
Board committees	<p>Bodies for information and consultation:</p> <ul style="list-style-type: none">> Audit Committee.> Nomination and Remuneration Commission (NRC).



Nomination and Remuneration Commission (NRC)

Role Consultative commission of the Board of Directors.

Meetings This commission met on 8 occasions in 2022.

Competences

- > To report on and submit proposals for the appointment and dismissal of directors and senior management to the Board of Directors.
- > To assess the skills, knowledge and experience necessary on the Board, as well as the time and dedication required from Board members for the proper fulfilment of their duties.
- > To prepare and review the criteria that should be followed regarding the composition of the Company's management team and strive to ensure observance of the remuneration policy for directors and senior management and the transparency thereof.

Composition Formed by three independent directors, appointed on the basis of their knowledge, skills and experience in the tasks they are to undertake.

Audit Committee

Role Consultative committee of the Board of Directors.

Meetings It meets quarterly to review the financial information which, as a listed company, the Company must publish regularly, as well as the mandatory non-financial information. In 2022, this Committee met on eight occasions.

Competences

- > Oversight of the process of preparing the financial information, ensuring that it is comprehensive.
- > Regular review of the information and internal control systems and the Risk Control and Management Policy.
- > Oversight of corporate risks.
- > Oversight of the Crime Prevention Model.
- > To report on related-party transactions, ensure the independence of the statutory auditors and ensure the independence and efficacy of the internal audit service.

Composition Formed by three independent directors, appointed on the basis of their knowledge and experience in accounting, auditing or risk management, as well as their knowledge, skills and experience in the other tasks undertaken by the Commission.

Composition of the Board of Directors at 31 December, 2022.



Mr Juan López-Belmonte Encina

- Chairman and Chief Executive Officer
- *Executive Director*

- > Graduated in Economic and Business Sciences from CEU San Pablo, Madrid, in 1993.
- > Joined ROVI in 1994.
- > Appointed General Manager in 2001.
- > Chief Executive Officer since 2007.
- > Chairman of the Board of Directors since July 2021.
- > Chairman of the R&D&I Committee of the of the CEOE (Spanish Confederation of Business Organisations) from March 2015 until the end of 2018.
- > Appointed President of Farmaindustria in October 2020, position he held until October 2022.
- > Shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).



Mr Iván López-Belmonte Encina

- Second Deputy Chairman
- *Executive Director*

- > Graduated in Economic and Business Sciences, specialising in Auditing, from CEU San Pablo, Madrid in 1994.
- > Diploma in Advanced Studies, obtained in 2008, which recognised his research proficiency in the Financial Economics and Accounting area.
- > Joined ROVI in 1995.
- > General Manager, Commercial and Development since 2007.
- > Director of the Company since 2007.
- > Shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).



Mr Javier López-Belmonte Encina

- First Deputy Chairman
- *Executive Director*

- > Graduated in Economic and Business Sciences from Colegio Universitario de Estudios Financieros (CUNEF), Madrid, specialising in Financing, in 1998.
- > Joint Executive MBA from Brown University and the Instituto de Empresa in Madrid in 2017.
- > Joined ROVI in 2000.
- > General Manager of Industrial Operations and Chief Financial Officer since 2001.
- > Director of the Company since 2007.
- > He has been Vice President of the CEIM (Madrid Business Confederation-CEOE), a member of its Management Board and Chairman of its Health Commission.
- > He has been a member of the Social Council of the Universidad Autónoma de Madrid representing the CEIM and a member of the Board of Trustees of Fundación Universidad Autónoma de Madrid, representing the Social Council of the Universidad Autónoma de Madrid.
- > Shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).





Mr Marcos Peña Pinto

- Coordinating Director
- Independent Director
- Chair of the Audit Committee
- Member of the Nomination and Remuneration Commission

- > Law degree from Universidad Complutense de Madrid and passed the official examination to become a Technical Labour and Social Security Inspector.
- > Appointed as an independent director of the Company by co-option and accepted his appointment on 9 May, 2019.
- > From 1984 to 1989, he held the position of Labour Attaché at the Spanish Embassy in Italy.
- > From 1991 to 1996, he was the Secretary-General for Health at the Ministry of Health and Consumer Affairs and Secretary General for Employment and Labour Relations at the Ministry of Labour.
- > Between 2005 and 2006, he was appointed an expert member of the Economic and Social Council, which he presided until April 2020.
- > He has been a member of the Council of State due to his position as president of the Economic and Social Council.
- > He has held the position of chair of the Bargaining Committee for many collective labour agreements (e.g. Telefónica, RENFE, Repsol, Alcatel, Endesa, Astilleros, etc.).
- > In April 2020, Mr Peña was appointed to the Board of Trustees of the Fundación CEOE (Spanish Confederation of Business Organisations Foundation).



Ms Fátima Báñez García

- Director
- Independent Director
- Chair of the Nomination and Remuneration Commission
- Member of the Audit Committee

- > Degree in Law and Economic and Business Sciences from Universidad Pontificia de Comillas -ICADE E-3-.
- > Postgraduate degree in Company Administration from the University of Harvard, Boston, MA.
- > Public Management Leadership Programme at the IESE Business School.
- > Appointed as an independent director of the Company by co-option and accepted her appointment on 20 December, 2019.
- > From November 1997 to June 2000, she was a member of the Board of Directors of Radio Televisión de Andalucía.
- > Minister of Employment and Social Security in the Spanish government from December 2011 to June 2018, and provisional Minister of Health, Social Services and Equality from August to November 2016.
- > Member of the Spanish Congress of Deputies for Huelva (2000-2019) and chair of the Foreign Affairs Commission of the Lower House (2018-2019).
- > She has extensive international experience, having represented Spain on the EPSCO Council, at the G-20, at the Ibero-American Summits and at meetings of the OECD and ILO, as well as at international employment forums.
- > Ms Báñez is currently on the Board of Directors of Avangrind, INC. and chair of the Fundación CEOE (Spanish Confederation of Business Organisations Foundation).





Ms Marina del Corral Téllez

- Director
- *Proprietary Director*

- > Law degree from the University of Granada and Master in European Communities from the Universidad Politécnica de Madrid.
- > Graduated in Management and Administration of Foundations and Nonprofit Organisations from New York University, and completed the Senior Business Management Programme (PADE) of the University of Navarra (IESE) and the Good Corporate Governance Programme of the Instituto de Consejeros y Administradores (IC-A).
- > She began her professional career in 1988 with the law firm Cuatrecasas at its Brussels and Barcelona offices, where she was until 1993. She practised in the areas of European Union law, company law and commercial contracting.
- > Subsequently, until 2000, she joined the pharmaceutical multinational Sanofi-Aventis as head of the Legal Services Department in Spain.
- > She held the position of Secretary General for Immigration and Emigration of the Spanish Government from 2012 until 2018.
- > She has represented Spain in a number of European and international forums and, at present, is Director General of CEAPs (Business Circle for Attention to Persons) and is a member of the Madrid Bar Association and the Instituto de Consejeros y Administradores.

Mr Gabriel Núñez Fernández

Non-director secretary

Mr Ignacio Zarzalejos Toledano

Deputy non-director secretary



Ms María Teresa Corzo Santamaría

- Member
- *Independent Director*
- *Member of the Audit Committee*
- *Member of the Nomination and Remuneration Commission*

- > Degree in Economic and Business Sciences from the Universidad Pontificia de Comillas (ICADE).
- > Doctorate in Economic and Business Sciences from the University of Navarra.
- > Chartered Financial Analyst (CFA) credential and belongs to CFA Spain and the CFA Institute.
- > She was appointed as an independent director of the Company by co-option and accepted her position on 14 December, 2022.
- > Ms Corzo Santamaría worked at Renta 4, Sociedad de Valores y Bolsa, S.A. for six years, performing the functions of investment and financial analyst and other functions related to asset management, including the portfolios of derivatives and international investment funds.
- > Since 2005, she has been a lecturer at the School of Economics of the Universidad Pontificia de Comillas (ICADE-ICAI), where she lectures in the Financial Management Department.
- > From August 2018 until August 2022, Ms Corzo Santamaría was a member of the Board of Directors of Deutsche Bank SAE and of its Risk, Audit and Nomination and Remuneration Committees.
- > Currently, Ms Corzo is the Dean of the School of Economic and Business Sciences of the Universidad Pontificia de Comillas (ICADE). She continues to hold this position.



42.85%

Percentage of women on the Board
(as of 31 December, 2022)

+26.05pp vs 2021



42,85%

Percentage of independents on the Board
(as of 31 December, 2022)

-7.15pp vs 2021



Management Committee

Role To represent the main areas of the ROVI organisation and conduct the Company's day-to-day management.

Composition In 2022, it had 12 members, 25% of whom were women, while 75% were men.

Members of the Management Committee



Mr Juan López-Belmonte Encina

Chief Executive Officer



Mr Pedro Carretero Trillo

Hospital Network Manager



Mr Javier López- Belmonte Encina

General Manager of Industrial Operations and Chief Financial Officer



Mr Miguel Ángel Castillo San Román

International & Business Development Manager



Mr Iván López- Belmonte Encina

General Manager, Commercial and Development



Mr Ibón Gutierro Adúriz

Corporate R&D Manager



Mr Francisco Javier Angulo García

Human Resource Manager



Mr Fernando Martínez Garijo

Sales Effectiveness Manager



Ms Beatriz Ávila Alcalde

Sales Manager



Mr Miguel Ángel Ortega Sánchez

Industrial Manager



Ms Mercedes Benítez del Castillo Sánchez

Legal Department Manager



Ms Mª Rosario Perucha Pérez

Marketing Manager

The Management Committee reflects ROVI's commitment to promoting a policy of equal opportunities, avoiding any discrimination based on gender or other factors in wages, training, promotion opportunities or any other area within its sphere of action.

Special mention should be made of the fact that the presence of women on ROVI's Management Committee is 25%, 4.9 percentage points higher than the IBEX-35 average, which is 20.1%.



(Source: VI Study prepared by WomenCEO as of 31 December, 2022).

Integration of ESG criteria into management by the highest governance bodies

ROVI integrates ESG criteria into its day-to-day management and activity. Specifically, ESG strategy and policy are the responsibility of ROVI's highest decision-making body, the Board of Directors, which oversees and ensures that these aspects are transversal throughout the organisation.

To integrate ESG criteria into the different levels of the organisation, ROVI begins its task with the composition of the Board of Directors itself, which is committed to diversity defined in the broadest sense: age, gender, culture, knowledge and experience.

In this respect, ROVI has a Policy on the composition of the Board of Directors, the objective of which is to help ensure that proposals for the appointment and re-election of ROVI's directors are based on a prior analysis of the Board's needs and that the candidate selection process favours diversity, in such a way that decision-making is enriched and plural viewpoints are contributed to the debate on the matters that fall within the Board's competence.

Following the CNMV's recommendations on the percentage of total Board members that should be women, in 2022 ROVI's Board of Directors appointed Ms Marina del Corral Téllez as a new external proprietary director and Ms María Teresa Corzo Santamaría as a

new external independent director. Both of them were appointed by co-option. The Ordinary General Meeting held on 14 June, 2022 passed a resolution ratifying the appointment of Ms del Corral as a proprietary director and re-electing her for the bylaw-stipulated term of four years.

With these new directors, ROVI continues to progress in fostering gender diversity on the Board, which now has three women directors out of a total of seven members, meaning that women directors represent 42.85% of total Board members at the date of publication of this report.

Likewise, mention should be made of the fact that the remuneration of the Board members who perform executive functions takes ESG criteria into account. Specifically, their remuneration is linked to the attainment of individual objectives, based on non-financial social, environmental and climate change indicators and compliance with corporate governance rules, codes of conduct and internal procedures (such as risk control and management policies). Since 2021, in addition to these objectives, the variable long-term remuneration has included certain qualitative parameters associated to objectives related to the pharmaceutical industry (GMP – Good Manufacturing Practices), applied to guarantee the quality and safety of the products manufactured at the Company's industrial plants, and, likewise, objectives



related to certifications under the standards ISO 14001, on environmental management, and ISO 45001, on occupational health and safety management, at the Company's industrial plants.

For 2022, the short-term social, environmental and corporate governance qualitative targets materialised in:

- > Completion of the Equality Plan.
- > Compensation of the ROVI Group's CO₂ emissions.
- > Internal audits of compliance with the Code of Practice for the Pharmaceutical Industry (favourable result).

At corporate level, ROVI manages ESG aspects through its internal codes of conduct and corporate policies, which establish common principles and serve as a guide for the Company's performance in the social, environmental and governance areas.

Specifically, the Environmental and Social Sustainability Policy, approved by the Board of Directors, governs the Group's actions with the maxim that ROVI's economic development must be compatible with its conduct as regards ethics, society, employment, the environment and respect for Human Rights.

ROVI is a member of the United Nations Global Compact.



Likewise, all the areas are aligned with ROVI's mission, vision and values and are responsible for rolling out the ESG actions that respond to the commitments reflected in the Company's Sustainability Policy. In this respect, all the areas are aware that the ultimate purpose of their actions is to work for the well-being of society and improve the patients' quality of life and the assistance provided to them.

Additionally, the different areas of the Company, aware that ESG factors influence some of the challenges which could potentially face them, such as, for example, those associated to attracting and retaining talent, innovation,

the incorporation of new technologies, or supply problems, have identified a series of risks related to ESG criteria that have been included on the corporate risk map in order to define an action plan to manage the risks identified (for further details, see section 6.1.5 Global management and risk control).

Information transparency and accountability to stakeholders



ESG integration by the Board of Directors



ESG integration at other levels of the organisation



Identification of ESG risks via the Risk Control & Management Policy

Lastly, at all levels of the organisation, there is a strong commitment to information transparency and accountability to stakeholders, guaranteeing that all important issues related to ESG criteria are disclosed to the market in accordance with the applicable regulations, be it through corporate reporting, press releases, meetings with investors, etc., helping to create active dialogue with the stakeholders in this respect.

6.1.2. Ethics and integrity in the business model

[GRI 2-23, 2-26, 3-3]

Ethical principles

Compliance with ROVI's Code of Ethics must be present in all professional decisions and, therefore, all ROVI professionals must adapt their professional conduct to the following principles, established in the Code of Ethics:

- 1. Professionalism:** defined as acting diligently, responsibly and efficiently, seeking quality, excellence and innovation.
- 2. Integrity:** conduct shows integrity when it can be described as loyal, honest, in good faith and in line with the Group's values and interests.
- 3. Self-checking** tall decisions must be based on four premises:
 - a) The action must be ethically acceptable.
 - b) It must be legally valid.
 - c) It must be desirable for the Group.
 - d) The person making the decision must be willing to be accountable for it.

Ethics framework

The integration of ethics starts with the highest control body, the Board of Directors, which is responsible for approving the Code of Ethics, and transmitted to the other levels of the Company's organisation by providing information to all employees when they join the workforce.

In July 2022, the Code of Ethics was updated to improve the then current wording, highlight the Code's key messages and enhance it visually, with an improved layout. During the third quarter, actions were taken to communicate the new developments to the employees. Furthermore, in 2022, the Compliance area, responsible for ensuring compliance with the Code of Ethics, continued to impart on-line training on this topic to ROVI's employees. The training had two main goals:

- > To reiterate that all the employees and members of the governance bodies of ROVI are subject to this Code and that compliance is mandatory.
- > To reaffirm the key principles set out in the Code of Ethics and their possible applications or interpretations.

https://www.rovi.es/sites/default/files/Codigo_Etico.pdf

ROVI has a communication channel in place so that employees can report any irregularity they may note in respect of ethics: Ethics Channel for Employees.

ROVI employees may communicate with the Ethics Channel at the e-mail address canaletico@rovi.es, by physical mail, through the ROVI Rocks app, through their superiors or through the Human Resource Department.

Suppliers may communicate with the Ethics Channel at the email address canaleticoprovedores@rovi.es.

In order to guarantee confidentiality for whistleblowers, ROVI has Regulations of the Ethics Channel for Employees, approved by the Board of Directors. Channel users are protected by the rights to confidentiality and no retaliation and all the reports received are managed by a Managing Committee formed by the head of Internal Audit and the head of Compliance.

The content of the Ethics Channel is submitted to the Audit Committee every four months and an annual summary is provided to the Board of Directors.

100% of ROVI employees know the Code of Ethics from the moment they join the Company.

In 2022, ROVI received seven reports that were duly processed by the Managing Committee. The reports received were classified into the following types: two reports related to alleged sexual harassment, three reports related to alleged moral harassment, one report related to alleged fraud and one report related to alleged corruption. The Managing Committee has completed the investigation of five of these reports, while one report relating to moral harassment and another relating to corruption have not yet been resolved. Of the five investigations concluded, sexual harassment was found to exist in two of them and internal fraud was also found to exist in the report relating to said subject. However, no moral harassment was found to exist in the two investigations completed.

Likewise, ROVI has a Code of Ethics for Suppliers that regulates the principles its suppliers must respect when performing their contracts with the ROVI Group. Likewise, the Code informs them of the existence of the Ethics Channel for Suppliers.

For further details of this Code, see section 6.2.3. (Commitment to our value chain).

https://www.rovi.es/pdf/Codigo_Etico_para_Proveedores_de_ROVI.pdf

ROVI promotes knowledge and use of the Code of Ethics constantly through its app and continuous training.

ROVI, as a member of Farmaindustria in Spain and, therefore of the European Federation of Pharmaceutical Industries & Associations, EFPIA, must observe the standards of conduct that the industry has established in each territory.

Therefore, in Spain, all employees are obliged to comply with the Code of Practice for the Pharmaceutical Industry and, in the other territories where ROVI operates, ROVI employees must comply with one of the following codes:

- > The Code of Conduct drawn up by the EFPIA.
- > The Code of Conduct drawn up by the International Federation of Pharmaceutical Manufacturers & Associations, IFPMA.
- > The Code of Conduct drawn up by the Pharmaceutical Research and Manufacturers of America, PhRMA.
- > The Code of Conduct drawn up by the professional association to which ROVI belongs in each territory.

Likewise, ROVI does not make direct or indirect contributions to political campaigns, political parties or candidates.

Respect for human rights

ROVI, as a socially-responsible group, 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 Company.

Likewise, as a member of the United Nations Global Compact, ROVI supports, by adopting and transmitting them, the incorporation of the principles of said Compact, as well as other international instruments, such as the Core Conventions of the International Labour Organisation (ILO), related to respect for freedom of association and the right to collective bargaining.

In addition, the commitment acquired by ROVI extends throughout its value chain, ensuring that Human Rights are respected in the relationships established with suppliers. Specifically, through the Code of Ethics for Suppliers, with which compliance is mandatory, the following principles are established:

- > Elimination of forced labour.
- > Elimination of child labour.
- > Respect for the right of association and collective bargaining.



- > Equal opportunities and non-discrimination.
- > Fostering a just work environment, free of any kind of violence.
- > Respect for current legislation on working hours and remuneration.

ROVI has a platform, EcoVadis, to evaluate its suppliers. The aspects evaluated include respect for workers' rights and human rights.

During 2022, no reports were received through the Ethics Channel in relation to possible Human Rights violations.

ROVI holds a firm commitment to protect Human Rights. Therefore, it strives to ensure that the activities carried out within its sphere of influence, i.e. both those performed directly and those performed through third parties, do not violate Human Rights.

Animal Testing

Since studies using animals represent a small but vital part of research, ROVI firmly believes that it is essential to ensure animal welfare during the research phases of its products.

ROVI's Animal Testing Policy is approved by the Chairman and CEO and states that, although animal testing cannot be fully eliminated, the Company undertakes to replace, reduce and refine studies conducted with animals ("replacement, reduction and refinement").

In addition, all the studies that ROVI conducts with animals must be approved by an external Ethics Committee on Animal Experimentation that guarantees animal welfare, reducing their stress and suffering to a minimum.

ROVI adheres voluntarily to the Programme for Compliance with Good Laboratory Practices, promoted by the Spanish Agency for Medicines and Medical Devices.

In this respect, to draw up the Animal Testing Policy and ensure that it is applied correctly, ROVI has a Quality Manual that defines the procedures to follow so that animal testing is conducted in compliance with Good Laboratory Practices (GLP).

In 2021, ROVI has been certified as GLP compliant, having been inspected by the competent authorities to verify its compliance with the applicable requirements.





6.1.3. Regulatory compliance

[GRI 2-26, 3-3]

Role, functions and responsibilities of the Regulatory Compliance Department

The Regulatory Compliance Department holds the main responsibility for defining and applying ROVI's corporate strategy, in order to ensure that its activity is conducted in compliance with the highest standards of ethics, quality, professionalism and know-how of good practices in the pharmaceutical industry.

One of the essential activities carried out by this area, together with the Deontological Supervision Department, is to ensure compliance with the Code of Practice for the Pharmaceutical Industry, reviewing, both internally and externally (with the assistance of an independent third party), 100% of the marketing and health activities carried on by ROVI. In 2022, a specific compliance structure for each country was rolled out to all the subsidiaries to further guarantee these functions. This structure may be formed by internal or external resources, depending on the country.

Furthermore, the Regulatory Compliance Department works directly with the pharmacovigilance and medical areas on reviewing their processes for requesting studies and complying with data protection regulations.

ROVI's Regulatory Compliance System includes a Crime Prevention Model and a data protection risk and control framework. Furthermore, the ROVI Group's Compliance Policy ensures that compliance principles are applied to all areas of the organisation.

The Regulatory Compliance Department strives to ensure compliance with the Group's Code of Ethics and corporate policies.

Lastly, the head of the Department is the secretary of the Compliance Committee, whose purpose is to advise the Company and the Audit Committee on all aspects related to regulatory compliance.

ROVI's manufacturing area has its own head of regulatory compliance and quality, always ensuring direct communication between the group and plant compliance functions and fostering an interconnection between them when required.



100%
of the marketing and health activities are verified as compliant with the Code of Practice for the Pharmaceutical Industry.

Anti-bribery and anti-corruption mechanisms

ROVI has a “zero tolerance” policy towards bribery and corruption and rejects any activity that includes these practices as a way to pursue its own interests.

No ROVI employee may offer a third party any direct or indirect benefit that is able or intended to unlawfully influence the third party’s capacity to adopt objective and lawful business decisions. Likewise, ROVI employees are expressly prohibited from accepting any form of corruption or bribery offered by a third party.



Anti-bribery and anti-corruption mechanisms

Code of Ethics

Sets out ROVI’s commitment to combatting corruption and bribery, as well as how its employees should act if they observe any situation where this is a risk of corruption.

Anti-Bribery & Anti-Corruption Policy

Sets out the guidelines for action and the precautions that all ROVI Group employees should adopt to prevent or mitigate risks related to corruption and bribery.

Ethics Channel

Through which all employees must notify any situation that could involve an infringement of current legislation, the standards and codes to which ROVI has adhered voluntarily, internal policies, the Crime Prevention Model or accounting and financial regulations.

Per Diem and Expense Policy

ROVI has a Per Diem and Expense Policy in order to ensure that any expenses incurred by employees due to their work in the Company are authorised and traceable.

Code of Good Practice for the Pharmaceutical Industry

Guarantees consistency with good sector practices, ensuring that interactions with healthcare professionals are in line with the Code.

Deontological Supervision Department

Intended to monitor compliance with the Code of Practice for the Pharmaceutical Industry with quarterly audits by an independent external auditor.

Contract Approval Procedure

Before approving any contract signed by ROVI with a third party, it must be reviewed exhaustively by the Legal, Intellectual Property, Industrial and Regulatory Compliance Departments.

Audit Committee & Compliance Committee

Governance bodies to ensure crime risks are managed and supervised.

Crime Prevention Model

The Crime Prevention Model was drawn up taking account of the Group’s main business activities: the promotion and sale of medicines and the manufacture of both its own products and those of third parties.

Every two years, ROVI entrusts a review of the Model to an independent third party to assess whether it is operating correctly.

Anti-money laundering mechanisms

ROVI is considered a non-obligated entity in the terms of article 2 of Spanish Law 10/2010 on the Prevention of Money Laundering and Terrorist Financing. However, in order to strengthen its commitment to transparency and good governance, ROVI has various procedures in place to combat money laundering, adapted to each one of the stakeholder groups to which they are applicable.



Registration of new customers

Completion of the new customer registration template, which requires the corporate name, corporate address, contact particulars and banking details.

For medicine sales customers, their authorisation as a pharmaceutical product distributor.

Copy of the tax ID code or equivalent document.



Employees – Per Diem & Expense Policy

Reimbursement of expenses is preceded by the corresponding expense note, which must be accompanied by documentary support of the expenses. Employees must preferably settle the expenses they incur due to their work with the corporate credit card and cash payments must be kept to a minimum.



SUPPLIERS

Supplier Selection Policy

Sets out the criteria to follow for the selection of each type of group supplier, establishing an initial evaluation and subsequent regular evaluations in order for the suppliers to be approved.

Registration process for new suppliers

All new suppliers must complete a registration form and show their tax ID card or, in the case of foreign suppliers, their Spanish tax residency card, as well as their bank account holder certificate.

Supplier Payment Policy

Stipulates that suppliers with an annual volume of over 100,000 euros must always hold a duly-signed contract, as well as how invoices should be sent and recorded, and the accepted means of payment.

6.1.4. Remuneration policy

[GRI 2-19, 2-20]

Board of Directors

ROVI has a Director Remuneration Policy for the Company's Board members, in accordance with article 529 novodecies of the Capital Companies Law. The latest Policy was approved at the General Shareholders' Meeting of ROVI held on 14 June, 2022 and will be in force until 2024, unless the General Meeting adopts a resolution to change or replace it while it is in force.

The Director Remuneration Policy is based on the following principles:

> **Moderation and adaptation to best market practices:**

ROVI ensures that the remuneration of its directors is moderate and in line with the trends and practices regarding remuneration in its sector of activity or in companies that are comparable due to their size, activity or structure, in such a way that it is consistent with best market practices.

> **Proportionality:** the remuneration of the external directors will be as necessary to remunerate the dedication, qualifications and responsibilities required by the position, but not so high as to jeopardise the independence of the criteria of the non-executive directors.

> **Compatibility:** the remuneration received by the directors for performing their functions on the Board will be compatible with and independent of the remuneration or compensation established for those directors who carry out executive duties in the Company or its Group.

ROVI published The Annual Director Remuneration Report for 2022 after the Board of Directors meeting of 20 February, 2023 and states that:

- > The maximum total amount that the Company may pay its directors overall, in their capacity as such, may not exceed 1,000 thousand euros in each of the years to which the Policy is applicable.
- > Consequently, the Board of Directors distributed 631 thousand euros of said maximum total of 1,000 thousand euros among its directors.
- > Likewise, the Board decided to distribute a fixed global annual sum of 1,219 thousand euros among its executive directors.
- > Regarding the short and long-term variable incentive for the executive directors, the Board approved distribution of 433 thousand euros at the proposal of the NRC, taking

Revision of the Director Remuneration Policy

In 2022, the remuneration criteria for the members of the Board of Directors were updated to include the most usual and best considered criteria in the pharmaceutical industry. Thus, as part of the long-term incentive plan, in addition to taking account of the increase in the share value considering the evolution of comparable companies in the sector and the evolution of the consolidated EBITDA, some qualitative parameters were included (relating to social, environmental and corporate governance matters) that promote ROVI's sustainability. Likewise, criteria concerning the quality and safety of the products manufactured at the Company's industrial plants were included, complying with GMP (Good Manufacturing Practices) regulations.

account of the Company's 2022 results and the goals established for each director.

To allocate the variable amounts to the executive directors, the following criteria were applied:

- > Evolution of the operating revenue of the ROVI Group in accordance with the targets budgeted and set out in the Business Plan.
- > Achieving the strategic goals established in said Plan.
- > Investment transactions performed.
- > Attainment of strategic partnerships during the year that have helped the Company to reinforce its present and future bases for growth.
- > ESG metrics defined in the section "Integration of ESG criteria into the management of the highest governance bodies".
- > Financial criteria such as the evolution of the ROVI Group's consolidated EBITDA and the quoted price of the Company shares.
- > Criteria related to sustainability and the environment, such as meeting the standards ISO 14001, on



environmental management, and ISO 45001 on occupational health and safety management, at the Company's industrial plants.

- > Criteria related to compliance with applicable GMP (Good Manufacturing Practices) legislation to guarantee the quality and safety of the products manufactured at ROVI's industrial plants.

The average remuneration of the members of the Board of Directors () in 2022 for their work as directors was 496 thousand euros for men and 135 thousand euros for women.*

Except for the Chairman (who receives higher remuneration due to the functions associated to his role), all the directors receive the same remuneration in their capacity as such, with no discrimination on the grounds of gender, age, culture, religion or race. Each director accrued the proportional part of the fixed component allocated to him or her in accordance with the time for which he or she was a board member in 2022. In this respect, Ms Marina del Corral Téllez and Ms Teresa Corzo Santamaría joined ROVI's Board of Directors in May and December 2022, respectively.

Senior management

As stated in article 14 of the Company's Regulations of the Board of Directors, ROVI has a Senior Management Remuneration Policy, approved in 2018 and in force since then. This Policy was prepared by the Nomination and Remuneration Commission and approved by the Board of Directors.

Total remuneration paid to members of senior management in 2022 (including the Internal Audit Manager and excluding the remuneration received by the executive directors) was 1,877 thousand euros (1,706 thousand euros in 2021).

(*) The director remuneration is set out individually in detail in the Company's Annual Director Remuneration Report.

6.1.5. Global management and risk control

[2-12, 3-3]

Global management and risk control model

Risk management process

ROVI has a Risk Control and Management System, which allows any possible risks that could affect attainment of the corporate goals to be identified, classified and assessed and the response to each one of them to be determined and monitored. The Company considers that risk control and management contributes to achieving greater efficiency and efficacy in its operations and reaching its corporate goals.

An essential part of the Risk Control and Management System is the Risk Control and Management Policy, approved by the Company's highest governance body, the Board of Directors. It defines responsibilities and establishes the process to follow in risk assessment and management. Applying this policy, ROVI fixes the risk level it deems acceptable, identifies the different types of financial and non-financial risk, assesses them, determines the measures to tackle them, and oversees said measures.

ROVI's Risk Control and Management System operates comprehensively and continuously, consolidating the management by area, business unit or activity, subsidiary, geographical region or support area at corporate level. ROVI's risk management model is based on three lines of defence:

Fist line

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.

Second line

Comprises the risk control and management function. This function is responsible for implementation of the risk control and management system, cooperating in initially establishing it and, once it is in place, helping to enhance it, monitoring its performance and coordinating its development.

Third line

Internal Audit, which supervises the internal control and risk management systems.

The steps followed by ROVI in the risk management process are as follows:

- 1** > **Fixing the risk level**
The Audit Committee establishes the risk level considered acceptable, taking account of the risk appetite (level of risk ROVI is willing to accept to pursue its strategic goals) and tolerance (degree of variation on the risk appetite accepted in attaining the goals). Additionally, the scales to assess the risks are approved annually.
- 2** > **Risk identification and classification**
The different areas of ROVI identify the internal and external risks that could affect attainment of their objectives. The risks are classified into:
 - > **Strategic:** those that affect goals related to ROVI's Strategic Plan.
 - > **Operational:** they affect goals related to the efficiency and efficacy of the operations, including performance-and profitability-related objectives.
 - > **Reporting:** they affect the objectives related to the reliability of the information provided both internally and externally.
 - > **Compliance:** those that affect compliance with the different applicable regulations and laws.
- 3** > **Risk assessment**
Each risk is assessed in accordance with the variables of probability of occurrence and impact on the attainment of ROVI's goals, applying assessment scales approved by the Audit Committee. This assessment allows decisions to be made on the actions to be taken.
- 4** > **Determination of the response to the risk**
Once the risks have been assessed, the measures to tackle the risks identified as efficiently and economically as possible are determined and adopted, minimising exposure. At the same time, mechanisms and procedures are put in place to allow management to oversee the implementation of the measures to neutralise the risks and verify their efficacy.
- 5** > **Monitoring risk management**
All the departments have both periodic and continuous information systems, capable of duly capturing any changes that have already occurred or are going to take place that could prevent meeting the goals under the forecast conditions, as well as the viability, efficiency, efficacy and sufficiency of the responses established for the risks.
- 6** > **Information to the Audit Committee**
The Audit Committee is informed regularly on the following aspects of risk management:
 - > Effectiveness and efficacy of the Risk Control and Management System.
 - > Swift response to any incident that occurs.
 - > Updating (if applicable) of the risk map.
 - > Materialisation of risks.

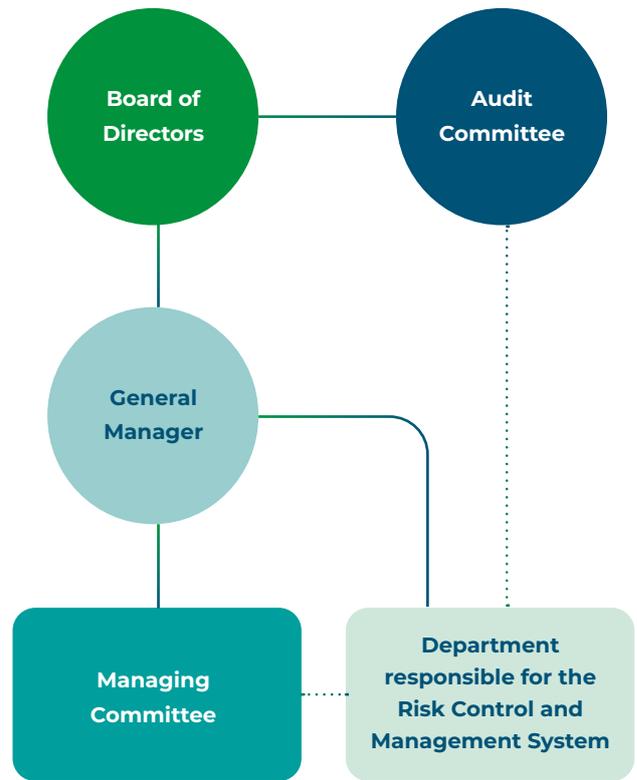
ROVI has a risk management tool that records the assessments of each one of ROVI's risks that are conducted regularly by the heads of the Group's different areas, as well as the strategies to respond to said risks. This tool provides greater internal control over the risks, since it continuously monitors the Group's business processes, allowing safer decision-making.



Risk management governance

According to ROVI's Risk Control and Management Policy, the bodies involved in risk management are those listed below, shown in the following organisation chart:

- Board of Directors:** governance body responsible for approving the Risk Control and Management Policy for both financial and non-financial risks, as well as regular monitoring of the internal information and control systems.
- Audit Committee:** body responsible for overseeing the Risk Control and Management System. To this end, it regularly reviews and oversees the internal risk control and management systems and the efficacy thereof, so that key risks are identified and managed correctly. Likewise, it is the body responsible for fixing the acceptable levels of risk.
- Management Committee:** a body reporting to the General Manager, responsible for identifying, classifying, assessing and monitoring the risks, taking account of the categories and acceptable risk levels fixed by the Audit Committee, in order to apply the measures necessary to mitigate the impact of the risks in the event that they materialise.
- Department responsible for the Risk Control and Management System:** responsible for implementing the Risk Control and Management System, helping to enhance it once it has been implemented, monitoring its operation and coordinating its development. Likewise, it must report to the Audit Committee at each of the latter's meetings on the correct operation of the System and, if applicable, any risks that have materialised.



..... Reporting line

Risk management is a continuous global process that involves all levels of the Company and all the Company's professionals.



Risk map

Risk summary

STRATEGIC RISK



Concentration of operations

Concentration of operations in specific customers and/or specific production plants.

Prices and rebates

Changes in the prescription criteria or market regulations intended to contain pharmaceutical spending.

Research and Development

Failure to conclude successfully – or as expected – the Research & Development projects that ROVI is conducting.

Supply chain

Changes in supply conditions of the necessary manufacturing materials or the products that ROVI markets.

Geopolitical and socioeconomic situation

Impact of the current geopolitical, socio-political and macroeconomic threats.

Competition

Actions by the competition that could have an adverse effect on ROVI.

Climate change

Risk derived from adapting to climate change-related requirements and regulations.

OPERATIONAL RISK



Quality

Incidents related to the quality of the products sold by ROVI and incidents in the clinical trials of medicines, side effects of the products sold by ROVI or incorrect management of the notifications in this respect.

Cybersecurity

Attacks causing breaches of cybersecurity.

Human capital management

Difficulty in attracting, motivating or retaining personnel.

COMPLIANCE RISK



Compliance

Failure to comply with the regulations applicable to the industry and/or ROVI's activities.

EMERGING RISK



Emerging

Regulatory changes. Entry into force of stricter regulations in financial, tax-related and/or operational terms.

The importance of cybersecurity and how ROVI responds

ROVI is aware of the special importance that cybersecurity has acquired after the emergence of COVID-19 and the resulting digitalisation of many operating processes, as well as the establishment of teleworking. However, ROVI has been considering this possible risk for years, monitoring and assessing it and putting prevention measures and action protocols in place in order to respond if any cyberattack were to materialise.

In this respect, the Company currently has internal rules and protocols in place that include the use of TIC resources or e-mail, as well as the use of confidential information. Additionally, to complement this, in 2021, ROVI implemented new adaptation and improvement measures and established a number of goals that will allow the Company to be ready in the event of any cybersecurity problem, ensuring a swift response in line with the highest standards.

One of the advances in 2022 was the implementation of the new Information Security Policy. This document formalises, guides and expands the information security activities that were already being implemented in the Company and that materialise in protecting both people and technological and information assets, as strategic elements of ROVI and its business, against harm, cyberattacks and malpractices of any origin, preserving and promoting a security culture that provides clear benefits by minimising the security risks.

ROVI management assumes and supports this Security Policy, which furnishes the organisation with an organisational structure dedicated to Information Security whose responsibilities include establishing and promoting the implementation of controls and protection measures for the pillars of security, from a standpoint of risk aversion and rationalisation, adapted to and appropriate for the business, governed by the Code of Ethics.

Measures



- > Remodelling and improvement of the OT networks.
- > Implementation of new technologies that warn of anomalous behaviour.
- > Installation of new virtual environments, or improvement of existing ones.
- > Cybersecurity training.
- > Creation of an IT Security Technical Office.
- > Development of the documentary framework necessary to comply with the standard ISO 27000:2015.

Goals



- > Keep updated and use the documentary framework established for standard ISO 27000:2015, in order to obtain certification in the future.
- > Include improvements in the process and business networks in the medium term, which will lead to improvements in performance and security in certain areas of ROVI.

Identification and management of climate change risks and opportunities

ROVI recognises the importance of informing its stakeholders on the impact of climate change on the company and the measures in place to manage the associated risks and opportunities.

In 2022, ROVI, in collaboration with external experts, carried out its first exercise to identify and quantify climate risks following the recommendations of the Task Force

on Climate-related Financial Disclosure (TCFD). In this year, ROVI focused on acute physical risks, which arise from the increasingly more severe and frequent extreme weather events, such as droughts, floods and hurricanes. These phenomena can cause direct harm to assets and infrastructure or alter the supply chains, thus reducing companies' asset values and profitability.

The study of exposure to acute physical risks derived from climate change was carried out on the basis of the specific locations of ROVI's five production plants in Spain.

Following the TCFD's recommendations, when selecting the scenarios, the criteria proposed by the Intergovernmental Panel on Climate Change (IPCC) were taken into account, taking a scenario with global warming of 2°C or less (RCP "Representative Concentration Platform" 2.6.). Likewise, a scenario of more than 2°C has also been included, specifically scenario RCP 8.5, which represents global warming of between 3.2°C and 5.5°C relative to pre-industrial temperatures. For both scenarios, the probability of occurrence and the potential impact for each one of the eight climate risks identified were evaluated. The years 2030, 2045 and 2070 were fixed as the horizons for materialisation of these risks.

The result of this analysis allowed ROVI to assess the financial impact of acute physical risks on each one of ROVI's production plants, concluding that, even in the most unfavourable scenario, RCP 8.5, only 0.1% of the total economic value of the five production plants would be affected by the impact of the set of risks analysed for any of the three horizons evaluated.

Only equipment failures derived from extreme global warming was considered to be a high risk for ROVI's plants in the short, medium and long terms. In this respect, the Company has drawn up a Mitigation Plan, which identifies all the equipment and facilities whose operation could be affected if temperatures were to rise above 42.3°C for the Madrid plants and 43.5°C for the Granada plants. For each piece of equipment and facility, a set of specific prevention and/or mitigation measures have been proposed, which will be implemented in upcoming years in order to increase the Company's resilience in the event of future impacts related to extreme heat.

In 2023, ROVI plans to make an in-depth analysis of the hydric stress risk, identified in 2022 as the principal chronic physical risk. In future years, it is also planned to tackle the analysis of both transition risks and climate change-derived opportunities.

Risks materialised in 2022

During 2022, several of the risks considered in ROVI's corporate risk map materialised. Specifically:

Recall of one lot of the Moderna COVID-19 vaccine

ROVI and Moderna recalled one lot (No. (n° 000190A) of the Moderna COVID-19 vaccine (Spikevax®) because a foreign body was found in a vial manufactured at the ROVI facilities. The foreign body was found before the vial was administered.

The lot recalled had been distributed in Norway, Poland, Portugal, Spain and Sweden between 13 and 14 January, 2022.

Moderna performed a cumulative search in its global safety database and, to date, no safety problem has been notified in relation to the persons who received the Moderna COVID-19 vaccine from this lot.

Delay in marketing authorisation

At its Capital Markets Day held on 24 November, 2020, ROVI announced that a NDA (New Drug Application) had been filed with the United States FDA (Food and Drug Administration), i.e. a registration dossier to obtain marketing authorisation in the United States.

On 24 September, 2021, ROVI received a Complete Response Letter from the FDA with outstanding questions on the Risvan® dossier, which were answered in January 2022. July 2022 was established as the estimate date for closure of the procedure (Goal Date).

In the second fortnight of June 2022, the FDA inspected the ROVI production plant where the product is manufactured, located in Madrid (Spain), prior to approval. ROVI has now filed the final report on correction of the deficiencies noted in the inspection and expects to receive the evaluation of the corrections, as well as notification as to whether the FDA will need to reinspect the ROVI facilities, within the period ending on the user fee goal date. The FDA's granting of marketing authorisation for Risvan® is subject to closure of the observations made by the FDA after the inspection.

Additionally, in the third quarter of 2022, the FDA issued a second Complete Response Letter with some outstanding questions for ROVI and also with questions for one of its manufacturers. ROVI has filed the final responses to the Complete Response Letter in 2023, including the outstanding issues that were awaiting a response from a ROVI supplier.

In January 2023, the FDA conducted the pending inspection of a ROVI supplier to close the deficiencies noted in a process unrelated to Risperidone ISM®. As a result of this inspection, the FDA issued a series of observations and the supplier is now estimating a time frame for providing the responses.

The FDA has notified ROVI that the user fee goal date is 27 July 2023.

Customer concentration

The collaboration with Moderna, which initially consisted of the fill-finish of the vaccines for outside the United States and, subsequently, also of participating in the manufacture of the active substance, has meant an opportunity that has provided ROVI with financial and operational benefits and furnished it with greater visibility while, at the same time, it has led to an increase in customer concentration risks, mainly in financial and operational terms.



Internal control systems: IFRS

ROVI has a system of Internal Control over Financial Information (ICFR) whose ultimate purpose is to ensure a reasonable degree of certainty that the financial reporting is reliable. The bodies responsible for ICFR are:

> **The Board of Directors:** responsible for the existence and continuity of an appropriate and effective ICFR.

> **Senior Management:** responsible for implementing and designing the ICFR.

> **Audit Committee:** responsible for overseeing the ICFR.

> **Internal Audit:** supports the Audit Committee in overseeing the ICFR.

> **Those responsible for processes involved in generating financial reporting.**

The five components on which the efficacy and efficiency of ROVI's ICFR system are based are:

Control environment

Appropriate organisational structure: the different responsibilities for preparing and overseeing the financial reporting are assigned.

ROVI's Code of Ethics: applicable to all the workers, it is the basis of the Company's ethical principles and includes a specific sector on financial integrity and protection of assets, whereby ROVI and its employees undertake to apply the highest standards of ethics and transparency in their communications, information records and reports on products and activities.

ROVI's Anti-Bribery and Anti-Corruption Policy: establishes that books, records and accounts that show the Group's assets and transactions accurately and in detail must be kept and preserved and an appropriate system of internal control over financial reporting must be maintained.

Control activities

Compliance: for each one of the significant processes involved in preparing and issuing the financial reporting, there are controls to ensure compliance with the goals of comprehensiveness, assessment, management, breakdown, comparability, existence, occurrence, and rights and obligations in financial reporting.

Review: ROVI reviews its ICFR system regularly and updates the controls and risks related to the financial reporting in the event that any changes that so require have taken place in the processes involved or the applicable regulations.

Information and communication

Manual on accounting policies: includes the key accounting principles to be taken into account when preparing the financial reporting.

Audit Committee: receives quarterly information, before it is submitted, on, among other aspects, compliance with regulatory requirements, the proper delimitation of the perimeter of consolidation and the correct application of accounting principles in the regular information.

Assessment of financial reporting risks

Risk control and management system: the risks managed include error or fraud in the financial reporting. The main details of the risk control and management system appear in the Risk Control and Management Policy.

Risk identification by area: for each area with a significant financial impact due to its quantitative or qualitative importance, the relevant processes and sub-processes are identified, as well as the risks that could cause errors in the financial reporting or fraud in the transactions, together with the control activities that mitigate these risks.

Oversight

Audit Committee: meets quarterly to review the regular financial information sent to the National Securities Market Commission. It oversees the process of preparing the quarterly, half-yearly and annual individual and consolidated financial information and ensures that it is comprehensive.

Internal Audit Department: provides support to the Audit Committee in overseeing the internal control of the financial reporting.

6.1.6. Commitment and contribution to the SDGs regarding good governance

SDG and Goal	Key messages on ROVI's contribution in 2022	Goals	Key contributions
 <p>GENDER EQUALITY</p> <p>Achieve gender equality and empower all women and girls</p>	<p>ROVI integrates its commitment to this SDG by establishing equality as a basic principle for good governance, offering the same opportunities of access to work and professional promotion.</p>	<p>GOAL 5.5</p>	<p>Promoting the inclusion of women on the Board of Directors and the Management Committee, where women account for 42.85% and 25% of the members, respectively.</p>
 <p>DECENT WORK AND ECONOMIC GROWTH</p> <p>Promote inclusive and sustainable economic growth, employment and decent work for all</p>	<p>From Group management, ROVI promotes and strives to ensure inclusive and sustainable long-term growth.</p>	<p>GOAL 8.3</p> <p>GOAL 8.7</p>	<p>Approval of internal policies and procedures such as the Code of Ethics, the Code of Ethics for Suppliers or the whistleblower channel.</p>
 <p>PEACE, JUSTICE AND STRONG INSTITUTIONS</p> <p>Promote just, peaceful and inclusive societies</p>	<p>ROVI operates in compliance with national and international ethical practices when conducting its activities.</p>	<p>GOAL 16.2</p> <p>GOAL 16.10. b</p>	<p>Zero tolerance of any kind of bribery or corruption, rejecting any action that includes these practices, thanks to a number of control mechanisms (Crime Prevention Model, Code of Practice for the Pharmaceutical Industry, Audit Committee, Compliance Committee, etc.).</p> <p>Regular review and adaptation of the Group's corporate policies to keep them in line with regulatory requirements, best market practices and the values promoted by the Group through democratic and inclusive processes.</p> <p>Support of the Universal Declaration of Human Rights.</p>



6.2. Our Commitment to People

KEY INDICATORS



- > Claims from customers/million units distributed: **8.35**.
- > Queries from customers/million units distributed: : **24.69**.
- > Total workforce: **1,993 employees**.
- > New hires maintained at year end: **242**.
- > Women on payroll: **53%**.
- > Permanent contracts: **88.7%**.
- > Employee turnover: **6.97%**.
- > Hours' training per employee: **28.54**.
- > Training investment per employee:
 - Women: 248 euros**
 - Men: 231 euros**
- > **3,000 suppliers** from **41 countries**.
- > Average payment period to suppliers: **54.42 days**.

MILESTONES 2022



- > New teleworking policy.
- > Update of Equality Plan.
- > 14% increase in workforce.
- > Development of the Campus ROVI platform.
- > Digitalisation of selection process for new candidates, commencing in the first quarter of 2023.
- > New agreements with universities and training colleges.
- > ROVI obtained an ESG risk rating of 17.3 (lower risk in sustainability), the best score in its sector.
- > Increase in the number of suppliers evaluated by the EcoVadis platform.
- > Implementation of a CRM to manage any customer incidents regarding product quality and orders.

ASSOCIATED INTERNAL POLICIES



- > Quality Policy.
- > Quality Management Policy of the Marketing and Distribution Division.
- > Quality Management Policy of the Development, Manufacturing and Control Division.
- > Integrated Policy for Environmental and Occupational Risk Prevention Management.
- > Code of Ethics.
- > Anti-Corruption and Anti-Bribery Policy.
- > Code of Ethics for third parties.
- > Medicine Access Policy.
- > Supplier Engagement and Payment Policy.
- > Environmental and Social Sustainability Policy.
- > Communication and Transparency Policy.

GOALS



- > Maintain the service level through the highest standards in responding to any claims from customers, patients and healthcare professionals (2022 and upcoming years).
- > Implementation of a system that digitalises the selection and management of human capital, making it more flexible (2022-2023).
- > Development and implementation of a new performance evaluation system (2024).
- > Continue developing active listening and engagement with local communities in the area where ROVI operates (2023).

CONTRIBUTION TO THE SDGs



6.2.1. Commitment to our customers, patients and healthcare professionals

Ensuring the Health and Safety of customers, patients and healthcare professionals is the key element that guides ROVI's development. The Group has internal and external control tools that guarantee aspects such as the quality, lawfulness and proper performance of its procedures.

ROVI has acquired a triple commitment to consumers, since these include customers, patients and healthcare professionals. The core of ROVI's day-to-day activity and its principal goal is to provide them with the highest degree of satisfaction, based on a long-term relationship of mutual trust.



Customers

Wholesalers who distribute the product manufactured by ROVI to the pharmacies.



Healthcare professionals

Doctors, nursing staff and pharmacists.



Patients

Final consumers who acquire ROVI's products.

ROVI's products include both the provision of à la carte services in its contract manufacturing area and the contact with the healthcare professionals to whom the best treatment options are offered, not forgetting the patients who can benefit from the latest advances and the best medicines to treat their complaints.

ROVI's commitment in this area is implemented through the Quality Policy, which sets the goal of continuous improvement in the service to customers, patients and healthcare professionals, always maintaining a high level of efficacy while, at the same time, striving to ensure Health and Safety in the workplace and promoting respect for and protection of the environment.

ROVI's senior management is responsible for implementing the Quality System (QS) and furnishing

the organisation with adequate resources to enable it to operate properly, always transmitting the importance of achieving, satisfying or surpassing the expectations placed on the development of new medicines while complying with legal and regulatory requirements.





6.2.1.1. Ensuring product quality and safety

The core of quality management at ROVI is to pay special attention to protection of the Health and Safety of its customers and patients throughout the entire life cycle of its products through strict compliance with both the Company's internal requirements and the applicable legislation established by the regulatory bodies.

To assess compliance with the product quality and safety procedures, internal audits are conducted regularly at all Group facilities and the Management Committee also conducts annual reviews in which the main points to be improved are analysed. Likewise, all ROVI professionals, as well as associated third parties, whose activities form part of the Quality System have the necessary product quality and safety training.

INTERNALLY



All group companies have procedures in place that describe the measures applied and the controls performed in all phases of the processes, including product research and development, the reception of raw materials, packaging materials, production, storage and distribution, until the product is received by the final consumer.

These internal procedures take account of Good Manufacturing Practice (GMP) for medicines, ensuring that the production and control of the products meet the quality level appropriate for their intended use and satisfy the requirements of the relevant authorities.

Likewise, Good Distribution Practice (GDP) is considered, ensuring that the Company has a robust quality system that includes risk management principles and appropriate tracing, as well as the organisational structure, procedures, processes, resources and activities necessary to guarantee that the product supplied maintains the necessary level of quality and good condition and remains within the legal supply chain during storage and transport.

EXTERNALLY



ROVI guarantees the safety of the product acquired by the consumers after passing a strict quality control through the following external audits:

- > Inspection by the Spanish Agency of Medicines and Medical Devices (AEMPS) every 3 years.
- > Inspection by the health authorities of the country to which ROVI exports its products under the applicable legislation.
- > ISO 13485:2016 on medical devices.
- > ISO 9001:2015 on quality management.
- > ISO 14001:2015 on environmental management.
- > SA8000 on social accountability – socially-acceptable practices in the workplace.
- > Audits of partners: with the frequency established in the audit programme, ROVI conducts regular audits of its partners to ensure compliance as established.

As soon as any falsified medicine is identified or there is any suspicion of falsification, ROVI is under the obligation to notify the competent authorities and the holder of the marketing authorisation for the medicine if the latter is not ROVI itself. To this end, ROVI has approved a procedure to identify falsified medicines and, if any are detected, investigate their possible origin, which it keeps updated. Any falsified medicines found in the supply chain will, furthermore, be physically separated immediately and stored in a specific area away from other medicines.

No ROVI products were recalled in the year 2022.

Furthermore, demonstrating its commitment to the safety of its products, ROVI conducts an annual simulacrum to ensure that, if any incident were to take place, the departments involved would know how to act in the least time possible.

6.2.1.2. Ensuring patient safety in clinical trials

Public information on ROVI's clinical trials:

> EU Clinical Trials Register:

<https://www.clinicaltrialsregister.eu/>



> US Clinical Trials Register:

<https://www.clinicaltrials.gov/>



ROVI is especially committed to ensuring the safety of the subjects who take part in its clinical trials. These studies are essential to ensure that new treatments have been properly tested and are sufficiently safe and effective for the general public.

The Quality Management Policy of ROVI's Development, Manufacturing and Control Division, which focuses on controlling medicines from the time they are manufactured until they enter the market, including the preclinical trial and clinical trial phases, ensures the existence of an efficient quality management system in the trials and their compliance with the relevant regulatory and safety requirements in the interests of the patients and the population, seeking effective and safe medicines.

As part of the Quality System, ROVI has the following documents:



> **Clinical trial protocol:** describes the goals, design, methodology, statistical considerations and organisation of the trial itself.



> **Clinical report on trial:** contains a detailed description of the study of any therapeutic, prophylactic or diagnostic agent performed on human subjects.

Likewise, ROVI complies with Good Clinical Practice (GCP), which encompasses a series of practices aimed to guarantee the rights of clinical trial subjects, ensures the quality of the data and avoids errors in clinical research. It includes ethical principles and rights obtained throughout history (Nuremberg Code, Belmont Report, Declaration of Helsinki). In this respect, GCP is defined as an international ethical and scientific quality standard for designing, recording and reporting clinical trials in which human subjects participate.





6.2.1.3. Promoting responsible marketing

[GRI 3-3, 417-2]

As a pharmaceutical company, ROVI guarantees ethical and responsible marketing, strictly observing the laws and standards of conduct established for promoting, marketing and selling its products. Specifically, the Company is subject to the Code of Practice for the Pharmaceutical Industry, which, among other aspects, regulates the promotion of prescription medicines in Spain.

The promotion of prescription medicines may only be addressed to healthcare professionals and, therefore, ROVI has internal procedures in place to ensure that all promotional materials and any scientific activities that take place are reviewed and approved. Likewise, 100% of the recruitments of healthcare professionals are reviewed and there are approval criteria for all kinds of hospitality to doctors. To consolidate its commitment to responsible marketing, ROVI holds annual training on the Code of Practice for the Pharmaceutical Industry and corporate policies, addressed to all marketing professionals, the sales network, the international department and the medical department.

Additionally, in 2022, an Ethics Officer responsible for the marketing activities in each country was appointed, a position that already existed at ROVI for the activities carried on in Spain. Alternatively, external consultants with expert knowledge of local regulations were engaged to perform this control and review function.

In relation to our product information and promotion, in 2022 no breaches of the regulations or voluntary codes to which ROVI has adhered were identified in relation to medicine advertising.

Codes that ROVI takes as a reference in its activity related to promoting medicines:

> Farmaindustria

Code of Practice for the Pharmaceutical Industry



> European Federation of Pharmaceutical Industries and Associations (EFPIA)

EFPIA Code of Practice



6.2.1.4. Maintaining active communication with our customers, patients and healthcare professionals

[GRI 2-29]

Having appropriate and efficient channels of contact with customers, patients and professionals and smooth active communication is essential to achieving ROVI's goal of providing the highest levels of transparency and integrity in all its interactions.

Pharmacovigilance system

As part of its commitment to active communication, ROVI has a Pharmacovigilance System, the aim of which is to identify, quantify, assess and prevent risks associated with the use of the medicines once they have been commercialised.

All employees whose functions are related to pharmacovigilance or product safety receive specific annual training on these aspects.

ROVI's Pharmacovigilance Department has a communication channel in place by e-mail (farmacovigilancia@rovi.es) or telephone [(+34) 91 021 30 00], both of which may be accessed through the Company's website (www.rovi.es).

When a notification, query, claim or complaint is received, this Department analyses whether it could be due to a quality and/or safety problem, in which case it will initiate the sign detection process that ROVI has implemented and will provide a response in the shortest time possible.

In this respect, the Company provides information on pharmacovigilance, notifications of adverse reactions and any other safety information related to ROVI products to all new employees in the welcome pack. Additionally, people belonging to the Quality Department, Marketing, Customer Service, Registrations, Medical Department, switchboard, Supply Chain, Business Development, Legal

Department, Compliance and Sales receive regular face-to-face training.

Continuing on-line training is also sent annually to all employees, irrespective of the department to which they belong.

In addition, as part of its active communication with its customers, patients and healthcare professionals, ROVI receives and manages the claims and queries they submit during the year.

The efficacy of the Pharmacovigilance System is reviewed annually by ROVI's senior management.

In all its interactions, ROVI ensures the protection, completeness, confidentiality, availability and privacy of personal information processed by the Company (on customers, patients and professionals). To this end, it is supported by its Data Protection Officer (DPO), responsible for advising on compliance with the applicable regulatory framework, the implementation of the specific procedures that regulate personal data processing, privacy policies and consent mechanisms for the use of personal data.





6.2.2. Commitment to our employees

Although the situation caused by COVID-19 has been the main focus of ROVI's human resources activity over the last couple of years in order to ensure employee safety, the Company's work activity gradually returned to normal in 2022, which allowed efforts to be addressed to the digitalisation of human capital management in order to boost efficiency and optimise the area.

ROVI, aware of the fundamental role played by the professionals in its workforce, strives constantly to consolidate its commitment to human capital and, therefore, looking after its employees and their development and performance forms an essential pillar of its business strategy. Since its activity began, ROVI has striven to create and maintain appropriate, safe and comfortable environments, with good treatment and tolerance. To this end, it promotes the personal and professional growth of its employees with a dual purpose: first, to achieve their well-being and, second, to meet individual and group expectations by seeking the greatest potential and the best skills and abilities.

Likewise, ROVI seeks a diverse, committed and ethical human team, where not only the know-how of its workforce is important, but also the existence of a team of professionals who project values to others.

To promote these values, which are intrinsic to the Company and the way it acts with its employees, it seeks inclusion and access to equitable conditions for candidates, as well as effective equality between men and women.

Additionally, at its centres, it promotes the best workplace practices by adopting measures that foment the work-

life balance and allow every employee to reconcile their responsibilities at work and at home.

Moreover, the Company benefits from its ongoing regular participation in different forums and meetings, such as Farmaindustria and PDFarma, which allows it to monitor the best sector practices for managing the people who form part of its business activity.

At the same time, aware of the importance of developing internal talent, as part of the training and development plans adapted to meet the needs noted in the talent management process, ROVI has a mentoring programme, which generates a flow of knowledge and mutual enrichment between professionals with a long track record at ROVI and new talent with drive, a renewed vision and training in the most modern technologies.

During 2022, with the decrease in pressure resulting from the collective effort to combat the pandemic, the exceptional measures put in place at the work centres were removed and, in September, ROVI returned to normality, except for some vulnerable people for whom the necessary protection measures were maintained. Regarding teleworking, this format already existed at ROVI before the pandemic and a specific policy has now been drawn up in response to current labour trends.

In order to continue developing the skills of the people who form the ROVI Group, different programmes, measures and actions, which will be discussed in this chapter, have been implemented, allowing talent management, based on six major areas, to become a cornerstone of ROVI's day-to-day business activity.

Ensuring workforce stability	Attracting and retaining talent	Ensuring Health and Safety	Fostering equal opportunities, diversity and inclusion	Fostering training and development	Achieving employee well-being
Fomenting quality and mostly permanent employment.	Selecting professionals aligned with Group values. Support and guidance in their time with the Group to promote their personal and professional development.	Active management of occupational risks to ensure the Health and Safety of its employees.	Creating workspaces where diversity and inclusion prevail and where all employees receive the same opportunities through equal treatment.	Training and development plans adapted to the needs observed in the talent management process.	Proactive listening with the employees in order to adopt the best measures in terms of work-life balance and employee well-being.

6.2.2.1. Ensuring the stability of our workforce

[GRI 2-7, 3-3, 401-1, 405-1]

Ensuring the Company's stability is a key factor for ROVI. At the end of 2022, the Company had over 1,993 employees with 14 different nationalities. This shows a 14% increase in the workforce in comparison with the preceding year, driven by the continuous development and growth of the business, explained, to a large extent, by the increase in the number of employees engaged in work relating to the marketing of Okedi® in Germany, Spain and the United Kingdom, as well as the expansion of the collaboration with Moderna and the start-up of the new plant in Escúzar (Granada).

Likewise, in 2022, the gender balance among professionals was maintained, with women accounting for 53% of the workforce and men accounting for 47%, as of 31 December, 2022. (For further details on the distribution of employees, see Appendix II.)

Along the same lines, ROVI is committed to good management of its human capital and promotes the stability of its employees, reflected, in the percentage of the workforce that holds permanent contracts (89%). The total number of dismissals in 2022 was 33.

Mainly permanent employment, low turnover rate and unaffected by seasonality are features of employment at ROVI.



931 women
with permanent contracts



836 men
with permanent contracts



89%
permanent contract



6.97%
Turnover rate



14%
Increase in workforce 2022



Diversity:
53% women
47% men
14 nationalities



6.2.2.2. Seeking to attract and retain talent

[GRI 3-3, 401-1]

Attracting the best professionals and helping them reach their greatest potential is the basis of talent management at ROVI. Therefore, the Human Resource Department designs and manages policies to attract and retain talent, applying the following principles:



Equal opportunities.



Objectivity and impartiality in selection processes, which are conducted on the basis of merits and skills.



Recruitment includes young people, people from excluded groups and differently-abled people.



Prioritisation of internal candidates.



Confidentiality of the process.

242

new hires in 2022

17

vacancies filled internally

As a result of this policy and likewise driven by the Company's growth in 2022, there were 242 new hires during the year. Additionally, whenever circumstances so permit, the Company favours internal promotion as a way to retain talent and reinforce professional development, leading to 17 internal promotions in 2022.

As a result of the high recruitment volume over recent years, ROVI has adapted its employee management from two standpoints:

New opportunities for growth, diversification and interaction

In 2022, work continued on the process to make attracting talent more flexible, based on a higher degree of digitalisation. This consisted of creating ROVI's own platform to record and monitor the process from the time the candidate is selected until he or she joins the company. The progress made in 2022 included the implementation of a video interview system, which makes selection processes faster and more flexible. This system is expected to become fully operative in 2023.

Likewise, ROVI has developed an extensive renewed training programme (welcome pack) for new employees, in order to onboard them in the best way possible.

The employees, one of the Company's essential assets

Regarding retaining talent, in order to ensure the greatest well-being of the workforce, the position of manager has become especially important and, therefore, it has been the subject of special development plans and the managers have been given the tools necessary for improved team management. This is to encourage a closer relationship and a more individualised treatment when measuring performance.

As an example of its commitment to attracting and retaining talent, ROVI has given talented young people the opportunity to train and develop in the Company. To furnish them with this opportunity, it collaborates with universities and professional training centres, which increased by 10% in 2022 to a total of 94 agreements, so that undergraduate students in their final year, students studying for a master's degree or doctorate and professional training students can carry out their practical training in different areas of the Group.



100%

of scholarships are remunerated

93%

of scholarships are full time

96%

of scholarships last 6+6 months

During 2022, 90 training contracts were signed and 59 scholarships were awarded.

6.2.2.3. Protecting Health and Safety

[GRI 3-3, 403-1, 403-4, 403-5, 403-9, 403-10]

The main commitments acquired by ROVI to protect the Health and Safety of its workers are to minimise the occupational hazards at the facilities and encourage healthy conduct in the workplace. To this end, through its Risk Control and Management Policy, ROVI has implemented a corporate procedure that has allowed it to identify a series of Health and Safety risks, mainly linked to the industrial activity, such as contact with and exposure to chemical products, noise exposure and overexertion, among others. As a result, through active management of its occupational hazards, which falls within the duties of the Safety, Health and Environment Department, ROVI has striven to safeguard the Health and Safety of its employees through the following mechanisms:

> **Integrated Policy for Environmental and Occupational Risk Management**, applicable to the whole Group, which sets out the principles for protection of the lives, physical integrity and health of the workers of both ROVI and its contractors.

Likewise, the Company establishes specific goals for the Group's plants:

- 50% increase in personnel trained in first aid under the Emergency Plan at San Sebastián de los Reyes and Alcalá de Henares.
- 5% increase in workers trained in first aid at the Granada plant in comparison with 2021.



- Implementation of an automatic system for solo jobs at San Sebastián de los Reyes and Julián Camarillo.
- Reduction in false fire alarms by installing a new switchboard/software at San Sebastián de los Reyes.
- Improvement in the following aspects of the evaluation of simulacrum at Julián Camarillo:
 - Training of personnel.
 - Suitability of the means and resources allocated .
- Identification of ergonomic improvements in manufacturing tasks at Alcalá de Henares.
- Reduction of exposure to chemical agents in Automatic Zone 2 and Plenum at Alcalá de Henares.
- Elimination of solid chemical products (benzethonium chloride and sodium chloride) from the manual loading operation in several production tanks at the Granada plant.

> **ISO 45001:2015 certification** of all ROVI's industrial plants in 2021, an international standard that guarantees the occupational hazard prevention systems.

> **Preventive activities and procedures** that minimise the likelihood of occupational hazards materialising.

> **Training plans**, which are reviewed and updated annually. In this respect, in 2022, a total of 56,885 hours of training were given and materialised principally in job-specific risk prevention courses and courses on how to act in an emergency.

> **Health and Safety Committees**, where 57% of ROVI's employees are represented.

> **Specific procedures to control and monitor actions**, such as regulation of work permits, safety inspections, identification and application of legal requirements, etc.

> **Encouraging a healthy lifestyle** by adapting the products in the vending machines to provide healthy and balanced nutrition, fostering sport through agreements with centres close to the facilities, etc.

As a result of these measures, the Company has low accident and absence rates.



In spite of the good results, ROVI strives to identify the main causes of accidents and absence among its workers, in order to foster specific measures to improve

these rates. In this respect, the Company monitors a series of indicators that allow it to monitor the accident and absence rates classified by type.



Accident rate

Work-related accident frequency rate:

7.025

N° of work-related accidents (including *in itinere*):

37

Work-related accident incidence rate (with sick leave: 1% and without sick leave: 2.5%):

1.856

of the accidents were *in itinere*:

13

Work-related accident severity rate:

0.176

N° fatal accidents

0



Absence rate

Working hours lost:

102,424

ROVI absence rate:

4.31%

Vs

Days worked:

677,998

Sector absence rate:

4.68%

Days' sick leave:

23,122

Measures and adaptation in relation to COVID-19 in 2022

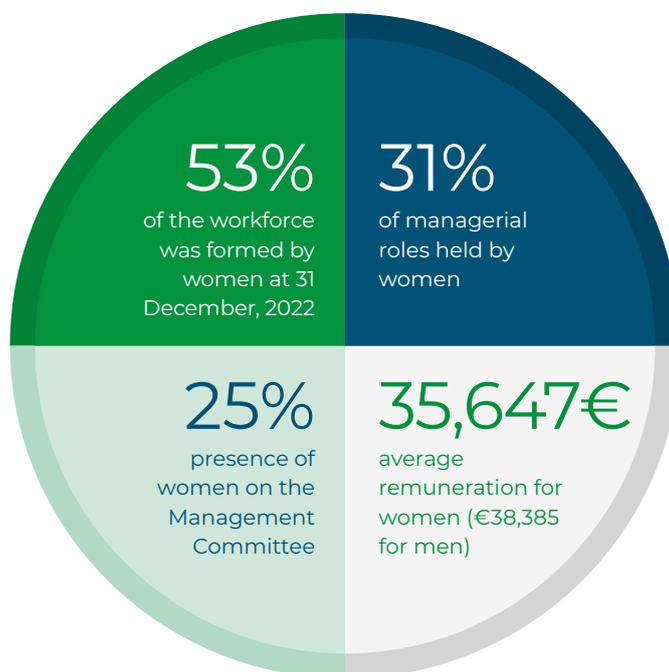
In 2020 and 2021, ROVI responded immediately with measures to ensure employee safety while maintaining continuity in the supply of medicines. In 2022, since the situation was returning to normal, these measures were gradually eliminated, although the recommendations issued by the Health Authorities continue to be followed and monitored, particularly at times when the incidence may increase or there may be new outbreaks.

In September 2022, normality returned to the work centres, where the possibility of teleworking – for which a new corporate policy was drawn up in the year – already existed before the pandemic. However, monitoring continued in order to ensure both early diagnosis and the evaluation of close contacts in the event of any positive cases.

6.2.2.4. Promoting equal opportunities, diversity and inclusion

[GRI 3-3, 405-1, 405-2]

ROVI bets on a business culture based on equal opportunities, diversity and inclusion in all the countries where it is present.



Equal opportunities

Given its firm commitment to genuine equal treatment and opportunities, ROVI fosters the absence of discrimination based on gender, race, social origin, age, civil status, sexual orientation, ideology, political ideas, religion or any other personal characteristic in all the Company's activities (selection process, promotion, remuneration plans, etc.).

This commitment to equal opportunities is implemented through four broad mechanisms:

<p>Equality Plan and Equal Opportunities Commission</p>	<p>Protocol for the Prevention and Handling of Cases of Moral and Sexual Harassment</p>	<p>Code of Ethics</p>	<p>Ethics Channel</p>
<ul style="list-style-type: none"> > Equality Plan (2022-2026) in accordance with Royal Decree 901/2020. > The Joint Monitoring Commission is responsible for ensuring that the Plan's goals are met and that the measures agreed are implemented on a timely basis with the necessary resources and, likewise, with the indicators, timelines and persons responsible for evaluating them. 	<ul style="list-style-type: none"> > It is compulsory for all members of ROVI and anyone related to the Company to know and respect this Protocol. > ROVI does not tolerate harassment and rejects any form of violence, physical, sexual, psychological or moral violence, the abuse of authority in the workplace and any other form of harassment or conduct that generates an atmosphere that is intimidatory or offensive with respect to the employees' rights. 	<ul style="list-style-type: none"> > Document in which respect for equality and non-discrimination materialises. 	<ul style="list-style-type: none"> > Mechanism implemented to manage and process the reports and notifications received. > Handles and responds to reports of breaches of policies, protocols or the Code of Ethics appropriately. > Guarantees a meticulous, efficient and diligent response in accordance with the values of ROVI.



New Equality Plan

The New Equality Plan (2022-2026) continues to enhance the application of the principal of equality between women and men at ROVI and has the following goals:

- > To collect information on the characteristics and management of ROVI's workforce in order to make a transversal analysis from a gender perspective.
- > To identify possible incidents in human resource management that imply the existence of possible inequalities or discrimination.
- > To identify possible changes in human resource management that can optimise the way it operates in general from the point of view of equal opportunities for women and men.
- > To construct an objective basis on which to implement measures aimed to improve equality within the Group.

To reach these goals, after making a diagnosis of the situation, the Plan sets out a series of measures to be implemented, classified into the following topics: recruitment and hiring; professional classification and promotion; training; remuneration; working conditions; work-life balance and co-responsibility; under-representation of women; awareness and communication; prevention of sexual harassment and gender violence; and occupational health.

** The Equality Plan has been signed by both ROVI and the employees' representatives in compliance with article 87 of the Workers' Statute concerning the negotiation of group collective agreements, to which article 2.6 of Royal Decree 901/2020 refers.*

Equal remuneration

ROVI contributes to equal remuneration opportunities by participating in the project promoted by Willis Towers Watson Services S.L that monitors the best sector practices in this respect, aligning with the best national and international practices.

Therefore, the commitment acquired to equal remuneration for work of the same value materialises in the indicators of average employee remuneration and the wage gap and is taken as a basis for defining ROVI's remuneration policy, which is applied to fix the salary both when the employee joins the Company and in subsequent salary reviews.

Average remuneration

In 2022, the average employee remuneration increased 4% due to the wage increase for all employees in accordance with the collective agreement, as well as a salary review for certain jobs in order to improve the Company's positioning versus its competitors through more competitive salaries.

Note: for detailed information on the average distribution per employee by age, gender and professional category, see Appendix II.

Wage gap

ROVI has been regularly analysing and monitoring its gender-based wage gap for many years in order to reduce it. For this reason, ROVI conducted a limited assurance review in 2018 and 2019 through PricewaterhouseCoopers Auditores, S.L., in which there was found to be no gender-based wage discrimination and no remuneration differences that were not based on personal factors.

In 2022, ROVI showed a gender-based wage gap of 8.1% (vs 7.6% in 2021).

As part of the adaptation of the new Equality Plan to Royal Decree 901/2020, PricewaterhouseCoopers S.L. carried out a remuneration audit in 2022, evaluating jobs in order to detect any wage gap and, if applicable, take corrective measures, monitor the evolution of wages and avoid any wage equality deviations.

The audit concluded that the ROVI workforce was balanced in line with the sector in which it operates. Furthermore, it determined that, at global remuneration level, no important differences unfavourable to women were observed in any of the groupings resulting from the evaluation of jobs. However, it detected room for improvement, which could be corrected by applying the following recommendations:

- > Focus efforts on reducing the differences noted related to the bonus under the collective agreement and the voluntary bonus.
- > Draw up a written protocol that allows the elimination of any kind of bias in awards, special bonuses, etc.

- > Promote the access of women to supplements for the work performed.
- > Review the wage gap annually in order to detect improvements or deterioration in the different items.
- > Regarding the distribution of the workforce, the Equality Plan will include measures aimed to correct the under-representation of women.



Average remuneration(*) by gender	2022	2021	% variation
Men	38,385	36,868€	4.1%
Women	35,647	34,082€	4.6%
Total	37,016	35,475€	4.3%
Wage gap	-8.1%	-7.6%	0.5pp

Average remuneration* by professional group** and gender	2022			2021		
	Men	Women	Wage gap***	Men	Women	Wage gap***
1	17,035 €	18,266 €	7%	16,657 €	18,277 €	10%
2	18,207 €	18,397 €	1%	17,777 €	17,995 €	1%
3	20,084 €	21,022 €	5%	19,493 €	21,004 €	8%
4	26,989 €	26,475 €	-2%	27,118 €	26,098 €	-4%
5	35,244 €	34,230 €	-3%	34,466 €	32,267 €	-6%
6	46,540 €	41,051 €	-12%	43,690 €	38,127 €	-13%
7	62,802 €	57,793 €	-8%	59,776 €	55,067 €	-8%
8	123,418 €	108,276 €	-12%	117,420 €	106,262 €	-10%
0	282,829 €	147,637 €	-48%	231,341 €	137,942 €	-40%
Subsidiaries	88,937 €	67,397 €	-24%	97,943 €	68,293 €	-30%

* Scholarship remuneration is not included because scholarship-holders do not have a professional group.

** Professional group according to the XX Collective Agreement of the Chemical Industry.

*** Wage gap calculated as the difference between the average salary of men versus that of women.





Diversity of nationalities and races

Although most of ROVI's activity takes place in Spain and, therefore, the majority of its employees are Spanish nationals, the Company has employees from different origins and races, betting on cultural diversity as a source of enrichment of the relations between its employees.

Likewise, in order to foster the sense of belonging to the Company, one of ROVI's priorities is to ensure that all its employees, irrespective of their location, have the same conditions and level of well-being at work.



Inclusion, protection and integration of people with disabilities

As a socially responsible company, ROVI maintains its commitment to the workplace integration of people with disabilities and has various measures in place that provide synergies between the parties involved.

Overall, ROVI endeavours to raise awareness among its employees as a tool to combat both the discrimination and the barriers experienced by people with disabilities. In this respect, it carries out corporate volunteering activities in collaboration with non-profit organisations, allowing the employees to see, in situ, the barriers that these people have to tackle in their everyday life.

Finally, as a way to make it easier to use the products it markets, ROVI labels them in Braille.

Recruitment

By enabling persons with disabilities to join the workforce, ROVI reduces their risk of social and financial exclusion.

For this reason, the Company holds agreements whereby it conducts support programmes intended to enable people with intellectual disabilities to find work.

ROVI firmly believes that, when people with intellectual disabilities receive the necessary training and support, they achieve an improvement in their personal, social and job skills.

37

employees with disabilities at 31 December, 2022 (30 internal employees and 7 external employees) (31 in 2021).



Financial collaboration

ROVI collaborates financially with a number of non-profit organisations that carry on their activity in the area of the social integration of people with intellectual or physical disabilities by conducting leisure and sports activities.

Likewise, it collaborates with several special employment centres for the personnel required for several services (see point 6.2.4.2. Boosting social action).



Accessibility

In order to achieve full workplace and social integration of people with disabilities, ROVI has undertaken measures to bring two kinds of barriers to an end:

- Physical obstacles to workplace access.
- The use of objects and products necessary for the job itself.

ROVI is constantly working to ensure that the work centres where its activity takes place are accessible to everyone safely, comfortably and autonomously. This is why all new plans for renovation works include this idea. Likewise, the workstation and tools are adapted to the needs of the employees who are going to use them.



6.2.2.5. Boosting training, development and performance evaluation

[GRI 3-3, 403-5, 404-1, 404-2]

ROVI is gradually implementing training and development plans and systems to conduct the performance evaluation process as part on its bet on a business culture based in its greatest asset: human capital.

Training and development

ROVI has an Annual Training Plan aligned with the Company's strategic goals and values, so that employees have the necessary training to perform their jobs correctly and are, likewise, prepared to meet new demands, particularly in the new technology area.

To draw up this Plan, the Human Resource Department works with group and middle management to create individual training projects through a process to detect needs based on two criteria: the specific needs of each area and the specific needs or personal interests of each employee.

The Annual Training Plan is established and updated based on the following essential principles:



Extensive training catalogue



Useful, diverse and updated training is available, respecting the current regulatory framework.

Wide range of training topics, including:

- > Human rights.
- > Equality and non-discrimination.
- > Health and safety.
- > Current regulations and legislation.
- > Quality.

Alignment with group values



- > Fostering the ethics culture of ROVI.
- > Fostering self-accountability and commitment.

Flexible training format



Adaptation to the existing context and employee needs (on-line, classroom, through feed-back, mentors, external associations, etc.).

40%

through classroom and/or virtual training.

20%

through feedback, observation or with the support of mentors, coaches, professional associations, spaces for reflection, conversations with others, leaders, etc.

40%

through on-the-job learning (applying real cases, problem-solving, participation in projects).

Knowledge sharing



- > Fostering the spreading and sharing of the knowledge existing in the Company.
- > Continuous learning and cultural exchange.

In 2022, development of the Campus ROVI training platform continued. In coming years, this will be the essential element for managing and recording employee training activity.

Likewise, as part of the technical training provided by Campus ROVI, special mention should be made of specific training in the products manufactured, pharmacovigilance procedures, quality agreements with external manufacturers and clinical trials.

Training at ROVI in 2022

(For further details on the training data, see Appendix II).



100%

of employees received some kind of training



56,885

hours of training imparted



28.54

hours of training per employee



100%

of employees with e-mail access received on-line training in the Code of Ethics



€240.30

average training expense per employee



€478,926

total investment in training

Performance evaluation

In some areas of ROVI, such as the sales and industrial areas, there are skill evaluation programmes that allow the professionals responsible for managing teams to monitor the skills established by the Company. During 2022, the implementation process continued in some areas and the pilot programme at the Alcalá de Henares plant was completed. The programme is expected to continue being rolled out the rest of the Group in the years 2023-2024.

These evaluations are conducted jointly by the managers and the team, analysing overall performance and the development of both generic and technical-functional skills. Additionally, commitment to the HSE (Health, Safety and Environment) culture and regulatory compliance will be evaluated.





6.2.2.6. Achieving the well-being of our employees

[GRI 2-29, 3-3, 403-6]

Ensuring an appropriate quality of life for its employees is a priority for ROVI. Therefore, it is developing a business model committed to a satisfactory work-life balance and strives to prevent professional development from hindering the balance with the personal and family lives of its workers.

In this respect, ROVI offers its professionals competitive remuneration and a series of services and social benefits adapted to the country and work centre, endeavouring to create a workplace atmosphere that foment the well-being and satisfaction of its professionals. Likewise, the Company includes criteria for flexibility and disconnection from work, as well as work-life balance measures, in the corporate policies.

ROVI's corporate policies include criteria for flexibility and disconnection from work, as well as work-life balance measures.

Disconnection from work

Measures in line with Royal Decree-Law 8/2019 on Urgent Measures on Social Protection and Combatting Labour Insecurity in the Working Day.

- > Actively avoid communication with employees outside working hours, unless there is an urgent, unforeseen need that cannot be met otherwise.
- > Avoid scheduling meetings in the later part of the working day to avoid overstepping working hours at the end of the day.
- > Protocol on disconnection from work, included in ROVI's working day register policies, whereby employees are not required to connect to the digital systems after working hours.

Flexible remuneration

- > Nursery school vouchers.
- > Restaurant vouchers.
- > Medical, life and accident insurance.

Working day register

Ensure compliance with the limits on working hours in a framework of legal certainty where workers are protected against abuse of their working time, as well as measures to avoid fraud in providing and paying social security contributions on overtime.

- > Rules on clocking in, which are a continuation of the policy already in place.
- > Generalised use of teleworking adapted to the activity of each job.
- > Elimination of overtime.

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.

- > Creating a quality work environment through a bet on the work-life balance.
- > Flexible starting and finishing times in certain areas.
- > Changing shifts with co-workers (especially in the industrial area).
- > Flexibility in scheduling time off.
- > Working hours adapted to the needs of each person.

- > Laptop that can connect to the ROVI network for all employees who so require.

Employee well-being

Social benefits

Maternity:

- > Improvement on government benefits (ROVI pays a wage supplement to complete the benefit received from the Social Security to 100% of the salary).
- > Teleworking in the last weeks of pregnancy if the job so permits.
- > At centres where parking is difficult, pregnant women have parking spaces.

Internal communication

ROVI strives to furnish close and transparent communication that is accessible to all employees, using different channels that allow it to provide information on matters of general interest, company milestones, agreements or organisational changes.

Additionally, ROVI has a corporate procedure on communication, participation and consultation through which communications (queries, complaints, etc.) related to the Environment and Occupational Health and Safety can be processed.

ROVI's internal communication channels

- > Internal television channel.
- > Notice boards.
- > E-mail.
- > Mobile app ROVI Rocks:
 - Keeps people up-to-date on new developments in the Group, in addition to including useful information on directories.
 - Provides access to the confidential consultation channel, ethics channel and the Ideas ROVI section, where employees can submit proposals for improvements in the Group.
 - Offers the possibility of entering an area of discounts and groups exclusively for ROVI employees.
 - Includes a virtual library section (called ROVIteca), with access to a catalogue of more than 2,000 titles of all kinds: novels, learning, magazines, children's literature, classics, etc.

Internal communication campaigns 2022

> Carbon neutrality

ROVI reported that, for the second year running, it achieved carbon neutrality for Scopes 1 and 2.



> Cybersecurity

Promoted by the IT Security Department, "The Cyberactive Principle" is a campaign to raise employee awareness of cybersecurity and includes specific training on detecting and identifying IT malpractices that could jeopardise the security of ROVI's information.

> Energy efficiency (Granada)

Awareness campaign on the efficient use of energy at the Granada plant within the framework of awareness training under ISO 50001.

> Special environmental campaign

Internal campaign for Environment Day to report ROVI's progress in this area: calculation of footprint, compensation projects in 2022.

> Special health and safety campaign

Campaign focused on giving visibility to good health and safety practices at the Company's facilities.

> Special SA8000 campaign

Raising awareness of standard SA8000 on Corporate Social Responsibility, with audio-visual content to explain the scope of the standard and the aspects it covers.



> ROVI's Wood.

Launch of ROVI's Wood initiative for a wood planted in the Madrid mountains in order to compensate for part of the emissions generated by ROVI's industrial activity.

> Code of Ethics.

Information campaign on the new Code of Ethics, approved in July.



6.2.2.7. Ensuring social dialogue

[GRI 2-30, 3-3, 402-1, 403-4]



Relations with the workers' representatives

Social dialogue followed its normal course at ROVI in 2022, with numerous meetings held with the main social partners for negotiation, information and consultation. The Company continues to base its labour relations on transparency, legal compliance and respect for and permanent dialogue with the social partners and workers' representatives, implementing these relations through smooth communication using all the means available, especially regular (in accordance with a planned schedule) and one-off (at the request of either the Company or the workers' representatives) meetings. This allows the status of the agreements signed to be monitored and any problems that arise in the Company's day-to-day to be solved efficiently.



The Group's Workers' Councils

The Group's Workers' Councils are the key mechanism to ensure dialogue on labour-related matters, since, through them, the Company's actions in a number of areas are consulted, debated and proposed.

In this respect, special mention should be made of the highly representative nature of the Health and Safety Committees and employee participation in them. These committees principally discuss the evaluation and assessment of occupational risks and any incidents that may take place, together with the pertinent measures to be adopted, the provision of personal protective equipment, protection facilities, and information and training on occupational risks

In addition, as in 2021, employee participation in the Workers' Council was encouraged regarding equality issues, particularly in the industrial area.



Employees covered by collective agreements

The whole of ROVI's workforce in Spain works under the conditions regulated by the Collective Agreement of the Chemical Industry, in force until 2023. At European level, the employees of the subsidiaries are also covered by the collective agreement of each geographic location, except in jurisdictions where local legislation establishes the application of general labour law. This occurs in subsidiaries with very few workers.

6.2.3. Commitment to our value chain

Ensuring that the ESG commitments that ROVI has acquired are respected throughout its value chain is the maxim that governs its relations with suppliers and subcontractors. To this end, ROVI makes every effort to promote ESG-related values among its suppliers and creditors before, during and after the production of its product portfolio.

Since suppliers are an essential group, ROVI bets on supplier relations based on solvency, commitment and alignment with the Company's principles and values. These contractual relationships are based on financial requirements, as well as ESG requirements set out the ROVI's corporate policies:

- > Supplier Engagement and Payment Policy, the geographic scope of which covers the entire Group. It includes issues that go beyond ESG, such as the methodology to follow for sending and recording invoices, the means of payment, etc., which guarantee that accounting with suppliers is homogeneous and efficient.
- > Code of Ethics for Suppliers.
- > Environmental and Social Sustainability Policy.





6.2.3.1. Ensuring sustainability in the supply chain

In order to ensure the Sustainability of the supply chain, ROVI monitors its value chain and, consequently, its suppliers and the other components of the chain. Before this monitoring, it is necessary to determine a framework that reflects the conduct that ROVI requires of its suppliers and, therefore, since 2017, it has had a Code of Ethics for Suppliers, which was revised in 2020.

This Code sets out the compulsory requirements for any service provider who works with the Group. Its content is similar to that of ROVI's internal Code of Ethics.

Monitoring supplier ESG performance has become essential to ROVI's activity as a key element in the value chain and its contribution to the Group's sustainability.

Code of Ethics for Suppliers

Human and Labour Rights

It urges suppliers to observe the protection of internationally-recognised Human and Labour Rights and the principles of elimination of forced and child labour.

- > Respect for the right of association and collective bargaining.
- > Equal opportunities and non-discrimination.
- > Providing a fair work environment, free of any type of violence, that strictly observes current legislation on working hours and remuneration.

Environment

It refers to respect for and care of the Environment. ROVI, in collaboration with the components of the supply chain, undertakes to combine efforts to reduce the impact of its activities on the environment to a minimum, placing emphasis on:

- > Observing environmental protection regulations.
- > Continuous updating of authorisations, permits and licences.
- > Implementation of system that ensure that emissions, liquid effluents and leaks are managed correctly and safely.

Health and Safety

Emphasis on health and safety, requiring compliance with labour and risk prevention laws.

Likewise, it promotes a healthy and safe work environment where the workers are trained in the prevention of workplace risks.

Management system

It expects its suppliers to implement a Management System that ensures compliance with the Code of Ethics for Suppliers as well as to adopt the best practices in accordance with current legislation and the most demanding standards, such as the SA8000 or SGE-21 certifications.

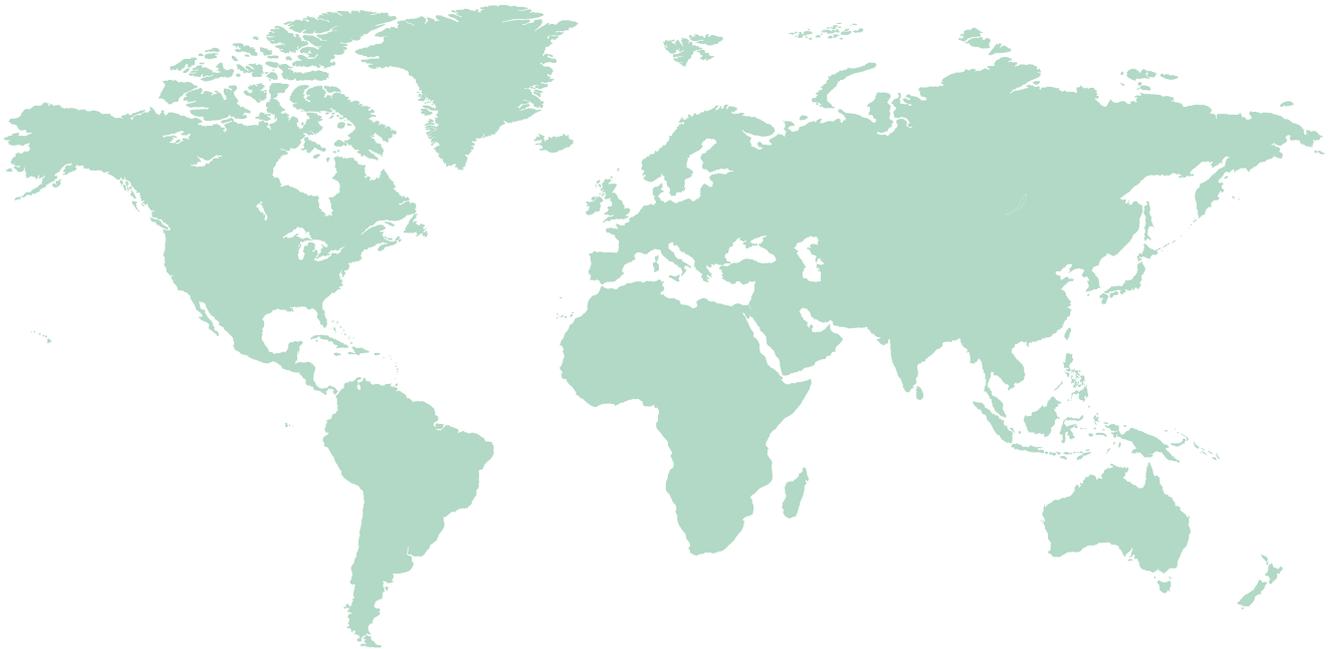
Business ethics

It strives to ensure that activities are carried out in compliance with the principles of business ethics. It requires transparent, responsible management that follows good marketing practices, with no type of corruption or conflicts of interest.

ROVI's supply chain in figures

Regarding the volume of ROVI's suppliers, in 2022, ROVI worked with over 3,000 suppliers from 41 countries. As a result of the Company's growth in its new subsidiaries in the main European markets, the international supplier network expanded in 2022 and currently has service providers from Germany, Portugal, France, United Kingdom, Italy and Poland. However, local suppliers of Spanish origin continue to bear the greatest weight.

The Group's average payment period to suppliers in 2022 was 54,42 days, while it had been 57 days in 2021, in accordance with the maximum periods provided for in Law 17/2010, amended by Law 11/2013. This figure has been calculated applying the criteria set out in the Sole Additional Provision of the Resolution of 29 January, 2016 issued by the Institute of Accounting and Account Auditing (ICAC).



Over
3,000
suppliers



From
41
countries



95%
of suppliers
members of the
European Union



Local Spanish
suppliers bear the
main weight



Spanish suppliers
account for **74%** of
the global total and
78% of the European
total



6.2.3.2.

Ensuring the safety and quality of the supply chain

[GRI 2-29, 3-3]

ROVI has taken a further step in its commitment to the supply chain. Not only has it established an internal regulatory framework with the requirements its suppliers must meet, but it also carries out 360-degree monitoring of the supply chain.

The Group has a supplier selection procedure. The type and scope of the control applied to the supplier will depend on the risk/impact of product or process purchased or subcontracted. Additionally, ROVI checks the relevant certificates of both suppliers and raw materials.

The initial evaluation of the supplier includes a risk assessment depending on the type of activity to be performed, since said activity may have a special impact on the product quality and/or the status of regulatory compliance of the product itself and/or ROVI's internal processes. In these cases, the risk assessment may include an audit at the supplier's facilities and the inclusion of specific clauses in the quality agreements signed between the two parties. Thus, a list of approved suppliers is drawn up and kept by the Quality Department.

Attention should be drawn to the fact that the Group not only evaluates its suppliers in respect of quality, but also promotes the best sustainability practices through two broad mechanisms:

Audits

The control mechanisms used by ROVI include on-site and remote audits, which ensure strict control over suppliers whose activities directly affect product quality and safety.

Through these audits, there is regular monitoring of compliance with both ROVI's requirements and regulatory standards.

ROVI has an Annual Plan managed through a risk analysis performed on all the suppliers with whom it works. The methodology followed is based on the analysis and assessment of its suppliers using different metrics. When the results are known, depending on the outcome, ROVI monitors each supplier more or less frequently.

Additionally, ROVI has an Annual Evaluation, a mechanism that provides information for the risk analysis, thus

facilitating the process of auditing third parties. In this case, the evaluation consists of finding out the extent to which a supplier may have caused problems, such as any potential unfit lots, impacts on the Company's reputation, etc.

ECOVADIS platform

Since 2020, ROVI has adhered to the EcoVadis Platform, a tool that assesses ESG aspects of its suppliers:

- > Environment.
- > Labour and human rights practices.
- > Ethics.
- > Sustainable purchasing.

This platform allows traceability of the performance of its suppliers and its methodology receives information from two sources:

- > The suppliers must complete a questionnaire of over 80 questions, providing evidence of their answers.
- > The platform itself makes an external study, considering issues such as data on complaints or public information in the press.

After the analysis, each supplier is rated with score of between 0 and 100, where the degree of ESG commitment is measured. This monitoring allows ROVI to detect possible non-compliances and thus request measures that provide solutions for the values and questions with low scores.

In this respect, the Company has fixed a goal in its ESG Master Plan in relation to the progressive increase in the number of suppliers evaluated in accordance with environmental criteria and good governance ethics, basing its prioritisation criteria on whether a supplier is located in a country where there is concern about respect for human rights and, likewise, on the invoicing volume.

6.2.3.3. Monitoring the life cycles of our products

ROVI, aware that the health and safety of its patients is a priority, has implemented a broad management and control framework that guarantees the safety and quality of its products during the production chain (see section 6.2.1. Commitment to our customers, patients and healthcare professionals).

Additionally, ROVI has put in place a series of mechanisms that reinforce this commitment in the rest of the stages of the product's life cycle. The COVID-19 pandemic has brought a significant increase in the distribution of falsified medicines in the market, which already showed alarming figures. In the period 2016-2020, the Pharmaceutical Safety Institute reported 38% growth in incidents related to falsifications. Although ROVI was aware of this problem previously, it has reinforced its control in recent years, in order to prevent this possible risk.

In 2022, due to the growing importance of the digitalisation of the process as a critical point in identifying falsified products quickly, ROVI implemented a CRM (Customer Relationship Management) mechanism to manage any incidents that might be detected in this or any other field.

Likewise, ROVI takes part in initiatives to for the destruction of medicines, including the engagement of managers responsible for treating "non-compliant" medicines, such as those returned by customers, those detected during production, or those that have expired before entering the sales channel. These initiatives include ROVI's adhesion to "Punto SIGRE", which strives to ensure proper environmental management of medicine packaging and medication waste generated at home through close collaboration between the pharmaceutical industry, pharmaceutical establishments and pharmaceutical distribution companies.

Internal procedures to combat product falsification

ROVI has a number of procedures in relation to the falsification of medicine, such as:

- > Procedure SOP-216 "Procedure for the Identification and Treatment of Falsified Medicines".
- > SOP-209: "Management of Deviations and Corrective and Preventive Actions at ROVI", which establishes an action plan if any possible infringement is detected.

Traceability: EMVO system

Since 2019, the European Medicines Verification System (EMVS), promoted by the European Medicines Verification Organisation (EMVO), has existed. This system arose as the result of a broad catalogue of measures adopted by the European Union through Directive 1011/62/UE, set out in detail in Delegated Regulation 2016/161. The system has been a pioneering mechanism to guarantee the reliability of the medicines received by the final patient in terms of both handling and falsification.

ROVI operates under this system, the basic mechanism of which is the serialisation of each pack by marking it with a unique safety code so that each product can be identified individually:

- > The inclusion of tamper evidence on each pack. This is an inviolability measure consisting of a security seal on each pack that guarantees that a product has not been opened previously.
- > Allocation of a safety code to each pack. This code is recorded in the EMVO system so that, when a pharmacy or hospital dispenses the medicine, it uses the code to verify that the laboratory has registered the pack in the system.

6.2.3.4. Promoting active communication with our suppliers

[GRI 2-29]

ROVI's relations with its suppliers are based on sound and exhaustive selection criteria and transparent information. None of this would be possible if, at the same time, regular communication were not generated through appropriate channels (see section 4.3.3. Dialogue with our stakeholders). Likewise, ROVI takes a series of measures to reinforce this communication:

- > ROVI's Ethics Channel, which is also open to suppliers. This is so much the case that the Code of Ethics for Suppliers establishes the obligation to notify any breach thereof to the Company, and it obliges suppliers to inform their employees and subcontractors of the existence of this channel. In this respect, various mechanisms are in place to enable suppliers to communicate with ROVI: the e-mail address canaleticoprovedores@rovi.es and a physical mailbox at ROVI's offices.
- > In 2022, as in previous years, ROVI imparted internal training to company personnel who interact with suppliers, mainly on accounting and tax topics.
- > Likewise, ROVI has a Communication and Transparency Policy with suppliers, through which it ensures regular information is provided to this stakeholder group. In this respect, in 2022, the Company sent communications to both new suppliers and some existing ones – where considered advisable –, informing them of the procedure for sending invoices and the incident management and payment processes.



6.2.4. Commitment and contribution to the environment in which ROVI operates

ROVI assumes the commitment to contribute to the sustainable development of the environment in which it operates by promoting its economic, environmental and social progress. Said environment is a reality that is taken into consideration for the Group's development and day-to-day decision-making.

The Group takes into consideration the social impact of its activity beyond its contribution to enhancing society's quality of life and health through its products. It has taken a wide range of actions that take account of the local community as an essential element.

ROVI is involved in a series of priority spheres of social action, such as mainstreaming disability in the workplace, fomenting health, commitment to training and corporate volunteering. Furthermore, it strives to assess and manage non-financial, ethical, reputational, social and environmental risks, making a commitment to those initiatives that benefit society.

This is shown by the recognition obtained by ROVI in the Sustainalytics evaluation, to which it submits itself voluntarily. Said company is a leader in providing studies, ratings and analytical data on environmental, social and governance aspects.

In 2022, **ROVI obtained the best ESG rating among the 458 companies in the pharmaceutical industry category whose ESG Risk Score** was evaluated. Through this, , as a result of an exhaustive analysis of ESG questions, Sustainalytics rates companies on a scale from 0 to 100, 100 being the maximum sustainability risk. Among the issues analysed, mention should be made of corporate governance, business ethics, bribery and corruption, product handling, access to services, human capital management and environmental management.



Furthermore, ROVI improved its ESG rating to 17.3 points versus the 18.4 points obtained in 2021. In addition to being first in its category, **the Company was 22nd out of a total of 970 companies in the entire sector, which includes**

biotechnology companies, pharmaceutical laboratories and laboratory equipment companies.

Among the actions that allowed the rating to improve in 2022, ROVI stood out for its environmental commitment, due to the implementation of greenhouse gas reduction programmes and the use of renewable energy. Additionally, ROVI was considered to be the sector leader in aspects such as oversight of material ESG issues by senior management and its anti-corruption/anti-bribery policy in the Corporate Governance chapter, as well as the implementation of a sound equality and non-discrimination policy in the Social area.

MSCI

Likewise, the Company's ESG aspects have been evaluated by MSCI, a rating agency that is highly respected among the investor community, having obtained an "A" rating since 2021(*). MSCI ESG Research provides ESG ratings of companies on a scale that runs from AAA ("leader") to CCC ("laggard") according to their exposure to ESG risks and how well they manage those risks relative to peers.



(* The use by ROVI of any MSCI ESG RESEARCH LLC or its affiliates ("MSCI") data, and the use of MSCI logos, trademarks, service marks or index names herein, do not constitute a sponsorship, endorsement, recommendation, or promotion of ROVI by MSCI. MSCI services and data are the property of msci or its information providers, and are provided 'as-is' and without warranty. MSCI names and logos are trademarks or service marks of MSCI.



Rating
ESG

2022	2021
17.3	18.4

(low risk between 10 and 20)

Sub-industry

(pharmaceutical companies)

2022	2021
1 st	2 nd

of 458

of 432

Industry group

(biotechnology + laboratory equipment + pharmaceutical companies)

2022	2021
22 nd	17 th

of 970

of 896

Global universe

2022	2021
2319	2309

of 14,913

of 13,573

Recognition during the year

15 January

The President of the Government, Pedro Sánchez, visited ROVI's facility in Granada to see the start-up of a new production line for the active substance of the mRNA vaccine at this facility. Also present were the Minister of Health, Consumer Affairs and Social Welfare, Carolina Darius, and the Mayor of Granada, Francisco Cuenca. The authorities toured the facility accompanied by Juan López-Belmonte, ROVI's Chairman and CEO; Miguel Ángel Ortega, ROVI's Industrial Manager, and Juan Carlos Gil, General Manager of Moderna.

14 June

Received the *Dirigentes* Award in the Quality category.



30 March

ROVI received the Salmon Award for the best stock market security of the year, awarded by the readers of *Expansión*, a daily newspaper specialising in economics and finance.



27 September

El Confidencial gave awards to ROVI and Moderna in the Science and Health and Science categories of the *Influyentes* Awards.

5 October

ROVI won the Pharmaceutical Laboratory Award of Farmaforum for the best sustainability and energy efficiency management.

6.2.4.1. Guaranteeing Access to medicines

In view of its commitment to managing the Group under ESG criteria, ROVI takes account of the need to promote access to medicines. Said access is considered essential to the Right to Health, inherent to all and recognised internationally since 1946. Therefore, the equitable access to safe and affordable medicines is vital to achieve the greatest level of health possible for everyone.

ROVI bases its raison d'être and business culture on this idea, promoting health to achieve the well-being and quality of life of its patients and the assistance provided to them as part of its mission. Therefore, during 2022, it undertook actions to meet this goal:

> Access to Medicines Policy.

ROVI, aware of the key role of the pharmaceutical industry in responding to society's healthcare needs, has a policy that establishes its commitment to reducing healthcare disparities. This policy, approved by the highest level of the Company's organisation (CEO), sets out the different principles for action, as well as the existing mechanisms to ensure access to healthcare and medicines.

In this respect, in 2022, ROVI updated this policy, undertaking to ensure production continuity, as well as the global distribution of its medicines at all times. Likewise, in the event of emergencies and/or exceptional situations, ROVI works with international and local entities to ensure a swift response to express demand for its medicines, supplying them through non-governmental organisations deployed in the area affected by the emergency.

> One-off exportations of medicines for humanitarian reasons.

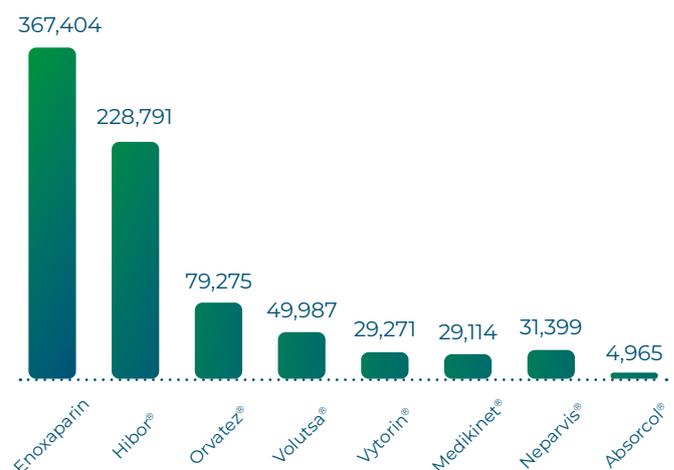
In exceptional situations, ROVI has a procedure in place to favour and expedite the swift dispatch of its products through third parties with strict and exhaustive regulatory compliance. Distribution may take place either through local distributors or international partners.

In 2022, the main area where this type of action took place was in sending healthcare material to Ukraine to alleviate the shortage caused by the armed conflict after the Russian invasion at the beginning of the year, which has led to the greatest humanitarian crisis in Europe in decades. The most prominent measures in this respect were the donations of first aid products through *Fundación Cofares*.

From its International Department, in constant communication with the Group's Quality and Compliance areas, ROVI ensures the lawfulness of the process, guaranteeing the health and safety of its patients. ROVI verifies and evaluates the distributors with whom it works through audits. Likewise, it supervises and checks the existence of an official document that permits distribution of the medicine in the destination country.

In addition, ROVI monitors the number of patients its reaches through its products in order to measure the real impact it generates on society through a new methodology that was implemented in 2021. This methodology uses the figure of sales to pharmacies for some of the Company's main own and licensed products as a source. It likewise uses the experience of the Medical Department to estimate the patient profiles most adapted to each medicine, taking account of the duration of the treatment, the dose, and an estimate of treatment adherence.

ROVI reached around 820,000 patients through its main products in 2022.



Data are shown for products representing 76% of ROVI's portfolio (in terms of billing in Spain).

6.2.4.2. Boosting social action

[GRI 3-3, 413-1]

In 2022, ROVI made active contributions to social progress, promoting health, encouraging research, commitment to training and environmental protection through its catalogue of activities and collaborations with non-profit organisations and foundations, making a positive impact on local communities.

In general ROVI contributes to sustainable development through a global institutional strategy that engages its stakeholders and promotes the design and implementation of awareness programmes. Likewise, it puts in place measures that allow a contribution to be made to development through volunteering, sponsorships, collaborations and other actions.

Corporate volunteering

One of the fundamental elements of ROVI's social action is its corporate volunteering programme, through which employees have the chance to play a leading role in change by co-operating with the different NGOs and foundations with which the Company works.

In 2022, these activities returned to being carried out in person, once the restrictions caused by the COVID-19 pandemic had disappeared. The common denominator of these activities is to foster interaction and mainstream disability using sport and play as connecting links.

To recognise the Group's work, Fundación Manantial, within the framework of the XI Edition of the *Miradas* Award, awarded ROVI its Solidarity Stamp, with which the Foundation acknowledges companies that promote workplace inclusion by employing people who have been diagnosed with mental health problems,

thus helping to reduce the stigma attached to mental health conditions and enhance the quality of life of those who suffer from them.



An example of this is the awareness activity carried out in collaboration with *Fundación Manantial* for ROVI's sales force, aimed to raise awareness and provide information on schizophrenia from the point of view of patients, their family members and the associative fabric.

Activities

6 February, 2022 > Race for Mental Health

Organised by *Fundación Manantial* and sponsored by ROVI, a group of 26 runners from the Company formed part of 2,500 athletes who participated in one of the three routes (2.5, 5 and 10 km) through the centre of Madrid.



13-19 June, 2022 > “Muévete por ellas” challenge

Fundación Recover organised the “Muévete por ellas” challenge, a virtual race to reach a total of 5,000 km among all the participants. There were different categories (running, walking or cycling) and 86 people from ROVI took part, including employees and their family members. The funds collected from this challenge was used for the “Mujeres tenían que ser” programme, aimed at improving healthcare for 4,000 women and girls in Africa and training over 150 healthcare professionals.





31 July, 2022 > XXI Adaptive Descent of the River Sella

As a result end of the restrictions caused by the pandemic, ROVI employees were able to return to their active participation in the XXI Adaptive Descent of the River Sella in collaboration with Fundación También. A group of 10 volunteers from ROVI shared canoes with people with some kind of disability to cover the 15 kilometres that separate the town of Arriondas from Llovió.

1 October, 2022 > Multi-Activity Day in Somontes

Under the auspices of Fundación Deporte & Desafío, a group of 16 ROVI employees, accompanied by their children, took part in a multi-activity day designed to raise awareness of functional diversity through handicrafts, dog-assisted activities and adaptive hockey.



8 October 2022 > Hiking on the Boabdil route (Granada)

Hiking along a stretch of the legendary Boabdil route, which runs through the Lecrín Valley (Granada). This activity was carried out in collaboration with Fundación Deporte & Desafío. 15 ROVI employees hiked six kilometres accompanying people with disabilities along the trails that connect Cozvíjar and Conchar.

6 November, 2022 > 11th Madrid También Solidario Race

41 ROVI employees, accompanied by their families and friends, took part in the 11th edition of the *Madrid También Solidario Race*, the competition that seeks to create an inclusive sports community.



Sponsorship, patronage and donations

In 2022, ROVI contributed a
total of 225,587 euros
 to foundations and non-profit entities in the form of:



As in previous years, ROVI continued to support different associations for the social integration and inclusion of differently-abled groups through contributions and maintained its support of social and environmental causes.

MAINSTREAMING DISABILITY



Fundación Manantial

ROVI has a programme with Fundación Manantial for the employment of people with mental illnesses to carry out activities related to the secondary packaging of medicines. It began in 2019 when the first recruits joined the Alcalá de Henares production plant. In 2020, it was extended to the Julián Camarillo plant (Madrid) and, in 2021, to the San Sebastián de Los Reyes plant.

Likewise, ROVI was the main sponsor of the 2022 Race for Mental Health promoted and organised by Fundación Manantial.



Down Granada

Down Granada works helping young people in Granada with Down's Syndrome to enter the labour market in local companies and co-operated with ROVI in training one of its young women to perform administrative tasks at the plant in the Health Technology Park (Granada).



Fundación Prodis

ROVI has an employment programme for young people with intellectual disabilities at the Pozuelo and Julián Camarillo offices (Madrid). Additionally, the Special Employment Centre has printed corporate material, such as training brochures or T-shirts for activities organised by ROVI's CSR area.



Fundación Deporte y Desafío

A non-profit organisation dedicated to mainstreaming disability sport. In 2022, ROVI continued to strengthen its co-operation agreement for adaptive skiing courses in Sierra Nevada (Granada) and held various volunteering activities in Madrid and Granada.



Fundación También

Non-profit organisation that works to include people with disabilities in sport. As it does each year, ROVI collaborated to acquire adaptive skiing material for the association. It also carried out a volunteering activity (Adaptive Descent of the River Sella) and sponsored the *Madrid También Solidaria Race* (November).



ISS Facility Services (Gelim)

Provides cleaning services at ROVI's offices.



Ilunion

A company whose purpose is to generate high-quality employment for people with disabilities. ROVI collaborates with this company for the laundry services for plant clothing.



Fundación A la par

A foundation engaged in the social and workplace integration of people with intellectual disabilities, which cleans the pallets used at the plants of ROVI Pharma Industrial Services S.A.U.

SOCIAL PROTECTION

ROVI has continued with its support of social and environmental causes.

 **Cruz Roja Granada**

Once again, ROVI collaborated with “Flag Day” in 2022, a day of activities focused on raising awareness regarding environmental sustainability.

 **Fundación Cofares**

In 2022, ROVI maintained its collaboration with Fundación Cofares through the Charity Golf Tournament and the Christmas Charity Concert. The funds collected in these activities were used in the *Sanemos Internacional* programme, which is intended to provide basic medicines and healthcare products to people with no financial resources or access to these items. In 2022, this programme focused its activity on Ukraine.

 **Solidarity Pantry of San Sebastián de los Reyes**

ROVI reached a collaboration agreement with the Solidarity Pantry of San Sebastián de los Reyes to periodically donate basic food and healthcare items to be distributed to low-income families in the town.



Donations Committee.

In addition to the activities mentioned above, in 2022, ROVI continued with 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 Practice for the Pharmaceutical Industry, ROVI's Code of Ethics, and the Social and Environmental Sustainability Policy.

From among the social and humanitarian proposals approved by the Donations Committee in 2022, the following may be highlighted:

International co-operation:



Fundación Recover

ROVI co-operates with its programmes to improve healthcare in Africa. The foundation supports the local community in healthcare matters both in situ and through a platform on which doctors in Spain train, and also diagnose, people located in Africa.



Fundación para el Desarrollo Integral de los Pueblos

ROVI collaborates in actions aimed to promote the integral development of the inhabitants of less industrialised countries with high poverty rates through participation, making the individual an agent in their own self-sustained development through cultural, productive and social training.

Social protection:



Fundación Empresa y Juventud (Aldeas infantiles)

Collaboration with the Serendipia Project to accompany and support people with intellectual disabilities through sheltered housing, where the beneficiaries learn basic skills to enable them to live an independent life.



Beyond Suncare

Donation to the NGO Beyond Suncare, whose activity focuses on improving the quality of life of people with albinism in Sub-Saharan Africa (Tanzania, Malawi, Senegal, South Africa, Rwanda and Uganda), mainly by working directly with this stigmatised group and education, and awareness in local communities. They have also created a sunscreen designed for persons with albinism that is fully produced in Africa by the group of persons with albinism who cooperate with the NGO.

Fines culturales:



Asociación Bailarines de Marín

Contribution to a group of dancers aged from 11 to 19 in order for them to participate in the Youth America Grand Prix, one of the most prestigious ballet competitions in the world.

6.2.4.3. Evolution of key R&D&I projects

Commitment to research

In order to remain always in the vanguard, ROVI is committed to Research, Development and Innovation, since they are strategic factors that enable the Company to act in a changing market environment and differentiate itself in the pharmaceutical sector.

The Group holds agreements with different universities to strengthen scientific, technological, training and knowledge-sharing activities in Spain, showing its support for research at an academic level. In this context, ROVI collaborates with the University of Granada, fostering research and training activities of scientific personnel through projects within the framework of the incentives awarded by the Technological Corporation of Andalusia.

During 2022, ROVI established its presence in the National Strategic Research Council in the project *"Biorreactores and Biotintas con heparin para la regeneración de Tejidos Elásticos"* ("Bioreactors and Bioinks with Heparin for Elastic Tissue Regeneration").

In addition, ROVI receives support from the Ministry of Science and Innovation through the State Research Agency with the *Torres Quevedo* Programme (PTQ), the objective of which is to promote the recruitment of doctors to carry out industrial research and experimental development projects or prior viability studies, in order to further the professional careers of the researchers and stimulate private-sector demand for personnel who are sufficiently qualified to undertake R&D programmes and projects, as well as helping to consolidate recently-created technological companies. The Group likewise receives support from leading entities such as the Industrial Technological Development Centre and the Technological Corporation of Andalusia.



In 2022, ROVI received funding for its lines of research and development of the following projects:

- > **IDI-20200346** – "Development of a new three-monthly formulation of Risperidone" (2019–2022).
- > **IDI-20210292** – "Definition of the profile of physicochemical characteristics of the Letrozole ISM® formulation" (2020–2023). Project led from the Granada R&D Centre and co-financed with ERDF funds.
- > **IDI- 20210941** – "Development of an innovative process to obtain a new low-molecular-weight heparin biosimilar" (2021–2023).
- > **IDI- 20220026** -"Evaluation of chronic toxicity in quarterly Risperidone ISM®" (2021-2023).

Likewise, in 2022, three Torres Quevedo grants remained active:

- > **PTQ2019-010712** - "Project to improve the purification process in low-molecular-weight heparins" (2020-2023).
- > **PTQ2021-011676** - "Novelties in the development of long-acting antipsychotics" (2022-2024).
- > **PTQ2021-011677** - "RESHAPE (Risperidone ISM Effectiveness in schizophrenia patients Hospitalised due to A relapse: a Prospective non-interventional Evaluation)" (2022 - 2024).

Due to the patent system and the protection of business secrets and R&D&I results, ROVI has a well-protected portfolio composed of 700 patent dossiers, 566 of which have already been granted, while 186 are in the examination and evaluation phase.

ROVI coordinates all its R&D&I activity in Spain, distributing it among the Madrid and Granada centres, with three R&D&I centres and two pilot plants for the manufacture of injectable medicines on which research is in progress.

Madrid Injectables Plant

R&D&I centre - Production

Annual production capacity:

165

million syringes



Certifications

ISO 9001 ISO 13485 ISO 14001 ISO 45001 SA 8000



Alcalá de Henares Plant

R&D&I centre - Production

Annual production capacity:

Tablets:

3,000

million units

Sachets:

30

million units

14 packaging lines

7 of which are for injectables



Certifications

ISO 9001 ISO 14001 ISO 45001 SA 8000



LMWH Production Plan (Granada)

R&D&I centre - Production

120,000

million international units (MIUs)



Certifications

ISO 9001 ISO 14001 ISO 45001 SA 8000





San Sebastián de los Reyes Injectables Plant

Production centre

Annual production capacity:

Syringes:

115

million units

Vials:

80-100

million units



Certifications

ISO 9001 ISO 13485 ISO 14001 ISO 45001 SA 8000



Okedi® - Risperidone ISM® (Madrid)

Pilot plant built for the clinical trials of Okedi®

Certifications

ISO 9001 ISO 14001 SA 8000



Letrozole ISM® (Madrid)

I+D+I centre

Certifications

ISO 9001 ISO 14001 SA 8000



Escúzar

Plant to manufacture the active substances of low-molecular-weight heparins. Validation lots have been manufactured for approval of the plant by the regulatory authorities. Commercial lots are expected to be manufactured in 2023.



6.2.4.4. Dialogue with local communities

[GRI 413-1]

ROVI, committed to the environment that surrounds it and the impact its activity generates on that environment, is aware of the importance of developing firm links with the communities in which the Group carries on its activity.

Maintaining flexible and smooth communication by participating in different forums and institutions is the best way to be able to take local communities into account. ROVI follows the best sector practices by monitoring and actively participating in information exchanges with Farmaindustria, the Asociación Española de Farmacéuticos de la Industria, the European Medicines Agency and other notified bodies or work groups.

Given that most of its activity is carried on at its facilities, attention should be drawn to the fact that, to construct and/or modify any of its plants, ROVI conducts a detailed study of the impact that this activity has on the surroundings in both environmental and social terms. Therefore, a basic aspect of the study is to meet the requirements of the community in which it operates and, to do so, it is indispensable to establish permanent and constructive dialogue with those who surround it.



In 2022, especially in the second half of the year, since the impact of the COVID-19 pandemic was diminishing, it was possible to resume institutional visits to our production plants. In this respect, ROVI's manufacturing plants in the Madrid Community and Andalusia receive visits of all kinds:

- > Nearby training centres and secondary schools, which are provided with information on the kind of professional openings that can be found in an industrial pharmaceutical company.
- > Meetings with healthcare professionals organised through the Marketing Department, which provide doctors with an overview of how medicines are produced.
- > Institutional visits, such as the visit of the President of the Spanish Government, Pedro Sánchez Castejón, to the plant in the Health Technology Park in Granada, or the visit of the President of the Andalusian Regional Government, Juan Manuel Moreno Bonilla, to the new Escúzar plant (Granada).



6.2.5. Commitment and contribution to the SDGs regarding People

The following is a brief description of ROVI's contribution to attaining the most significant Sustainable Development Goals (SDGs) concerning People:

SGS and goal	Key messages on ROVI's contribution in 2022	Goals	Key contributions
 <p>GOOD HEALTH AND WELL-BEING</p> <p>Ensure healthy lives and promote well-being for all at all ages</p>	<p>ROVI prioritised the Safety and Health of all the people it interacted with in its day-to-day operations (customers, patients, employees, suppliers, etc.), applying all the measures recommended by the experts and authorities to protect their health and improve their quality of life, thanks to the combined action of the pharmaceutical industry in producing medicines, which has accounted for 73% of the increase in life expectancy achieved over recent decades.</p>	<p>GOAL 3.4</p> <p>GOAL 3.8</p> <p>GOAL 3.9.b</p>	<p>Wide range of products, including Risperidone ISM® for the treatment of schizophrenia in acute patients.</p> <p>Active role in producing the COVID-19 vaccine.</p> <p>Collaboration with different organisations (among them, Fundación Recover) to promote access to healthcare, especially in territories with conditions that make medicines and quality healthcare difficult to access.</p> <p>Internal and external audits to guarantee quality, health and safety during the product's life cycle, especially from the design and research of the product until it is launched in the market (ISO 9001:2015; ISO14001:2015; ISO 13485:2016, AEMPS, EMA, etc.).</p> <p>Strong Occupational Health and Safety System, certified under standard ISO 45001:2015, which helps keep occupational accidents and diseases to a minimum.</p> <p>Mechanism for "one-off dispatches" in exceptional situations in order to favour access to medicines.</p>
 <p>QUALITY EDUCATION</p> <p>Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all</p>	<p>ROVI actively supports the implementation of a quality education system, both at corporate level and externally, through its collaboration with different educational centres and organisations, offering an extensive training portfolio that covers different areas, among which the following may be highlighted:</p> <p>Leadership abilities, time management, stress management and a wide range of technical training related to the pharmaceutical industry: Green Belt, Lean Six Sigma, GMPs, calibration, etc.</p>	<p>GOAL 4.3</p> <p>GOAL 4.4</p> <p>GOAL 4.5</p> <p>GOAL 4.7</p>	<p>Active collaboration with foundations and NGOs such as Down Granada, Fundación Prodis and Fundación para el Desarrollo Integral de los Pueblos, whose raison d'être is the inclusion of vulnerable people by promoting knowledge sharing.</p> <p>Knowledge shared with local communities through smooth communications, especially with the authorities of the location in which it is operating.</p> <p>Fostering quality education. 50% of ROVI's workforce holds a university degree.</p> <p>Collaboration agreements with organisations and academic centres to promote access to education and employability.</p> <p>Training plans adapted to the needs of each employee, maximising their skills and strengthening their professional development: 56,885 hours of training in 2022, corresponding to a total of 28.54 hours/employee (average).</p>

SGS and goal	Key messages on ROVI's contribution in 2022	Goals	Key contributions
 <p>GENDER EQUALITY</p> <p>Achieve gender equality and empower all women and girls</p>	<p>ROVI meets its commitment to this SDG by establishing equality as a basic principle for action and, consequently, striving to offer equal opportunities for access to work and professional promotion for all professionals, ensuring that there is no kind of gender discrimination in the course of its activity.</p>	<p>GOAL 5.5</p> <p>GOAL 5.2</p> <p>META 5.c</p>	<p>Regular monitoring of the gender gap.</p> <p>Approval of corporate policies and internal mechanisms such as the Equality Plan, the Equal Opportunities Commission or the Protocol for the Prevention and Handling of Cases of Moral and Sexual Harassment.</p> <p>Participation in the Project promoted by WILLIS TOWERS WATSON SERVICES S.L. regarding remuneration.</p>
 <p>DECENT WORK AND ECONOMIC GROWTH</p> <p>Promote inclusive and sustainable economic growth, employment and decent work for all</p>	<p>ROVI provides its employees with a work environment committed to respect, stability and workplace safety, in addition to developing work-life balance measures for its employees. This is in line with the best practices in the pharmaceutical industry, the leader in R&D investment and quality employment and one of the sectors that drives developed economies.</p>	<p>GOAL 8.2</p> <p>GOAL 8.3</p> <p>GOAL 8.5</p> <p>GOAL 8.6</p> <p>GOAL 8.7</p> <p>GOAL 8.8</p>	<p>Promotion of favourable work environments, which is established in the Internal Code of Conduct and the Code of Conduct for Suppliers.</p> <p>Training of employees to ensure the Health and Safety of the workforce.</p> <p>Stable workforce with 89% permanent contracts.</p> <p>Development of work-life balance measures, adjustments to workloads and measures for the disconnection from work of its workers.</p> <p>Bet on employment for young people: el 23% of the workforce is under 30</p> <p>100% of the employees are covered by Collective Agreements.</p>
 <p>INDUSTRIES, INNOVATION AND INFRASTRUCTURE</p> <p>Construir infraestructuras resilientes, promover la industrialización sostenible y fomentar la innovación</p>	<p>ROVI bets on innovation and technology to increase the productivity of its activities, discover new drugs and improve those that already exist in order to enhance the service it provides to its customers, patients and healthcare professionals. The implementation of these projects allows the Company to adapt to the needs of society and maximise value creation for all its stakeholder groups.</p>	<p>GOAL 9.1</p> <p>GOAL 9.2</p> <p>GOAL 9.5</p>	<p>Contribution to employment and the GDP in the countries where it operates, thanks to the technology and innovations in its products and the way it produces them.</p> <p>Investment in R&D&I activities.</p> <p>Increase in its workforce as a result of the manufacture of the COVID-19 vaccine.</p>



SGS and goal	Key messages on ROVI's contribution in 2022	Goals	Key contributions
 <p>REDUCED INEQUALITIES</p> <p>Reduce inequalities within and between countries</p>	<p>ROVI bets on reducing inequalities by fostering inclusive workplace environments, guaranteeing equal opportunities for all its workforce, always guided by the principle of no discrimination based on gender, race, social origin, age, civil status, sexual orientation, ideology, political opinions, religion or any other personal characteristic.</p>	<p>GOAL 10.2</p> <p>GOAL 10.3</p> <p>GOAL 10.4</p>	<p>Diversity in the nationalities of the members of the workforce.</p> <p>Contractual and economic collaboration agreements to provide employment and opportunities to differently-abled people (Fundación Manantial, Fundación Prodis, Ilunion, Fundación a la Par, etc).</p> <p>Promoting equal wages for work of the same value.</p> <p>Fomenting the accessibility of its workstations.</p>
 <p>RESPONSIBLE PRODUCTION AND CONSUMPTION</p> <p>Ensure sustainable consumption and production patterns</p>	<p>ROVI promotes the rational and respectful use of natural resources throughout its supply chain. It boosts the circular economy and bioeconomics through an exhaustive process to select and monitor its suppliers and creditors.</p>	<p>GOAL 12.6</p>	<p>Promotion of Sustainability throughout the supply chain, monitoring the suppliers by using, among other tools, EcoVadis.</p> <p>Adhesion to the System promoted by the European Medicines Verification Organisation (EMVO).</p>
 <p>CLIMATE ACTION</p> <p>Take urgent measures to combat climate change and its impacts</p>	<p>ROVI, aware of the needs of the environment to mitigate Climate Change, promotes active awareness among its stakeholders, particularly among its employees and suppliers, regarding the adoption of measures to foster care of the environment.</p>	<p>GOAL 13.3</p>	<p>Training portfolio on environmental issues.</p> <p>Adhesion to Punto SIGRE for the recycling of packaging with our without medicines.</p> <p>"ROVI's Wood" project.</p>
 <p>PEACE, JUSTICE AND SOLID INSTITUTIONS</p> <p>Promote just, peaceful and inclusive societies</p>	<p>ROVI operates observing national and international regulatory compliance and, committed to human rights, urges all its stakeholders to respect and foster them.</p>	<p>GOAL 16.2</p> <p>GOAL 16.10. b</p>	<p>Code of Ethics that reflects the Company's commitment to acting in accordance with the law, human rights and internationally-accepted ethical practices in all its operations.</p> <p>Availability of a Whistleblower Channel through which anyone may report activities that violate the Company's ethical and/or regulatory framework.</p>
 <p>PARTNERSHIPS FOR THE GOALS</p> <p>Revitalise the global partnership for sustainable development</p>	<p>ROVI collaborates actively with different organisations and institutions whose action focuses on achieving and promoting the United Nations Agenda 2030.</p>	<p>GOAL 17.17</p>	<p>Collaboration with and support of public and private institutions, including the Ministry of Science and Innovation.</p>

6.3. Our Commitment to the Environment

KEY INDICATORS



- > Environmental management certified under ISO14001:2015.
- > Recycling of 15% of non-hazardous waste.
- > Compensation of more than 7,970 tonnes of CO₂.
- > 100 % of the production plants completely avoid any Scope 2 carbon emissions.

ASSOCIATED INTERNAL POLICIES



- > Integrated Policy for Environmental and Occupational Risk Prevention Management.
- > Environmental and Social Sustainability Policy.
- > Climate Change Policy.

MILESTONES 2022



- > Contracts for 100% renewable energy for all the Group's manufacturing plants and main offices.
- > Production of renewable energy through the panels installed at the Alcalá de Henares and Granada plants in 2022.
- > Reduction of CO₂ emissions. Scopes 1 and 2 Carbon neutrality for the third year running.
- > Compensation of 100% of the Group's Scope 1 and 2 emissions (7,310 tonnes).
- > Measurement of Scope 3 carbon emissions.
- > Compensation of 659 tonnes of Scope 3 emissions.
- > The entire carbon footprint (Scopes 1, 2 and 3) for 2020 and 2021 was certified and recorded in 2022.
- > Commencement of ROVI's Wood, a reforestation project in the Madrid Sierra.



CONTRIBUTION TO THE SDGs



6.3.1. Environmental policy, goals and commitments

[GRI 3-3]

ROVI is committed to being an environmentally sustainable company. This is why, aware of the potential impacts that its activity could generate on the environment, it has rolled out a series of mechanisms to protect the environment, which materialise in the following policies:

Integrated Policy for Environmental and Occupational Risk Prevention Management, approved in 2020 and updated in January 2021, which guides the Company's sustainable management and action in environmental terms.

Environmental and Social Sustainability Policy, approved at the end of 2020, whereby ROVI materialises its commitment to Sustainability from an environmental and social standpoint, promoting the conservation of and respect for the environment in the different business areas.

Climate Change Policy, approved in 2020, whereby ROVI undertakes to assume a leading role in the fight against climate change, promote a corporate culture oriented towards raising its stakeholders' awareness of the magnitude of this challenge and the benefits associated to seeking a solution, and identify specific actions to mitigate and adapt to climate change.

Taking the policies mentioned above as a reference, ROVI carries on its day-to-day activity taking three broad perspectives into account:



Additionally, through said policies and perspectives, ROVI has defined a series of goals at corporate level that allow it to carry on its activity with a firm commitment to continuing and progressive improvement in terms of environmental impact:

- > Achieve efficient energy management by rationalising the use of its natural resources.
- > Promote the best waste management guidance, including waste minimisation and recycling in its activity whenever possible.

- > Implement a series of systems and measures that minimise the environmental impact, in order to extend the Environmental Management System certifications to the greatest number of Group companies possible.

In addition, since ROVI's main activity takes place in industrial facilities, the Company has established "plant-dependent goals". To this end, it has taken account of the situation at each plant and the room for improvement that exists, as well as the best sector practices in this area.

Plant: Julián Camarillo (Madrid)

**RESULTS 2021-2022:****Goals attained:**

- > Increase the actions aimed to enhance the stakeholders' image of the plant in environmental terms.
- > Reduce generation of the hazardous waste "laboratory wastewater" by 3% in comparison with 2020.
- > Reduce environmental noise emissions by 1dB by improving acoustic screening at the points closest to the limit stipulated in the applicable regulations.

**GOALS 2022-2023:**

- > Reduce environmental impact of the generation of the wastes medicines to be inertised and medicine mix to be inertised.
- > Compensate 100% of Scopes 1 and 2 CO₂ emissions generated in 2022.
- > Not to increase electricity consumption by more than 4% in 2022 in comparison with 2021.
- > Reduce Scope 1 CO₂ emissions 2% in comparison with 2021.

Plant: San Sebastián de los Reyes

**RESULTS 2021-2022:****Goals attained:**

- > Increase the actions aimed to enhance the stakeholders' image of the plant in terms of the environment and occupational health and safety.
- > Improve the result of the KPI deferred actions 40% on 2020.
- > Execute 10% of the actions detected in the report on the Energy Audit performed in 2020.
- > Reduce the environmental impact of the generation of medicine waste and expired raw materials, prioritising recovery treatments over destruction.

**GOALS 2022-2023:**

- > Offset 100% of the CO₂ emissions generated in 2022.
- > 5% reduction in the tonnes/million units of the wastes "laboratory waters" and "basic solutions" versus 2021.

Alcalá de Henares Plant

**RESULTS 2021-2022:****Goals attained:**

- > Mitigate 100% of the CO₂ emissions generated in 2021 due to electricity and fuel consumption (Scopes 1 and 2 of the carbon footprint).
- > Reduce the environmental impact of the treatment of the wastes "medicines" and "raw material" from 20 to 10.

**GOALS 2022-2023:**

- > Mitigate 100% of the CO₂ emissions generated in 2022 due to electricity and fuel consumption (Scopes 1 and 2 of the carbon footprint).
- > Reduce total CO₂ emissions by 44 Tn by decreasing gas consumption in comparison with the actual consumption in 2021 (885 Tn).
- > Reduce global energy consumption (gas and electricity) by 1% in comparison with the actual 2021 consumption.
- > Separation of the waste "contaminated filters" into "contaminated filters" and "non-contaminated filters".
- > Reutilisation of biosanitary containers by 70% in comparison with 2021.

Granada Plant

**RESULTS 2021-2022:****Goals attained:**

- > Generation of 200,000 kWh/year of energy for self-consumption (photovoltaic) in respect of forecast total electricity needs for 2021.

**GOALS 2022-2023:**

- > Reduce the frequency of transport (and, therefore, greenhouse gas emissions) to remove non-hazardous waste (non-contaminated cardboard and plastic) in 2022 versus 2021.
- > Reduce the consumption of the paper used for photocopies by 10% versus 2020.
- > Reduce the number of energy and fluid control-related incidents in comparison with the last two years.

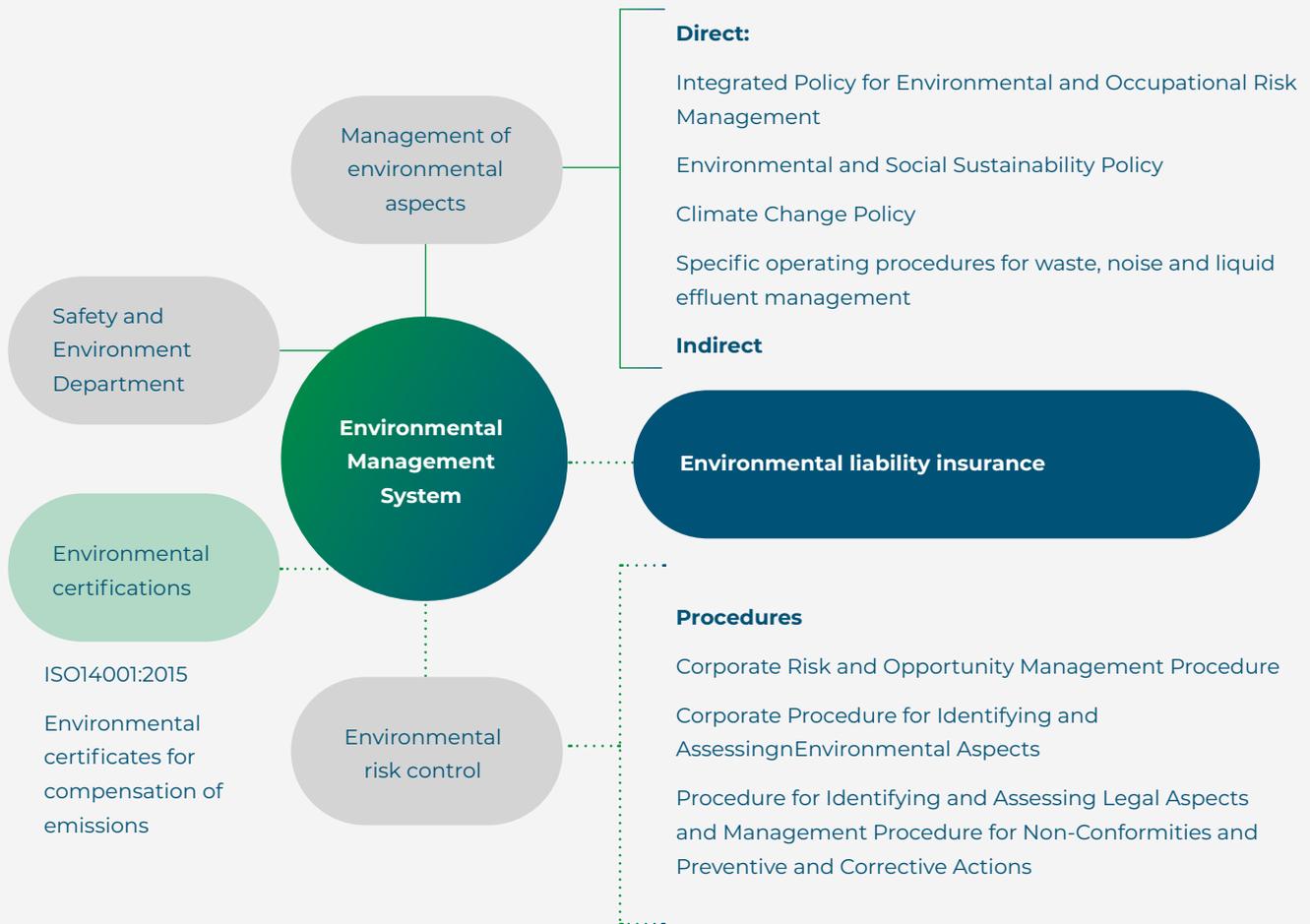


6.3.2. Environmental management system

[GRI 3-3]

Given its undertaking to conserve, preserve and protect the environment, ROVI has drawn up an Environmental Management System, implemented and certified under

ISO 14001:2015 and with a scope that encompasses the whole Group. The proper supervision of said system is the direct responsibility of ROVI's Safety and Environment Department.



The Safety and Environment Department, in collaboration with ROVI management, has developed said Environmental Management System on the basis of solid internal regulations, most of which cover direct environmental aspects through the following policies and procedures:

- > Integrated Policy for Environmental and Occupational Risk Prevention Management.
- > Environmental and Social Sustainability Policy.
- > Specific operating procedures to manage waste, noise and liquid effluents, intended to establish the methodology for controlling the waste, outdoor noise

levels and liquid effluents generated at ROVI's production plants.

In addition, ROVI considers and monitors possible indirect environmental aspects resulting from ROVI's trading relations with its suppliers. In this respect, ROVI carried out an analysis of the product life cycle and process at each production plant, in order to identify all possible environmental aspects and carry out exhaustive checks of the suppliers in relation to whom ROVI is able to take action.

ROVI's Safety and Environment Department has sufficient resources to ensure the correct operation and supervision of the system. In 2022, it managed a budget of 2.3 million euros allocated to safety and the environment

at each one of the plants and the associated prevention services, in compliance with the legal and voluntary requirements that ROVI has acquired.

This Department's team is formed by a total of 12 people, who are responsible for monitoring, analysing and assessing the Company's environmental matters, in order to adopt the best measures in relation thereto, always co-ordinating with the rest of the departments.

Likewise, ROVI has an Environmental Risk Control framework, integrated into the Environmental Management System, in order to identify any possible risks that could harm the Environment and act in accordance with the following approved procedures:

- Corporate Risk and Opportunity Procedure, which considers, among other aspects, environmental risk management (for further details, see section 6.1.5 "Global management and risk control").
- Corporate Procedure for Identifying and Assessing

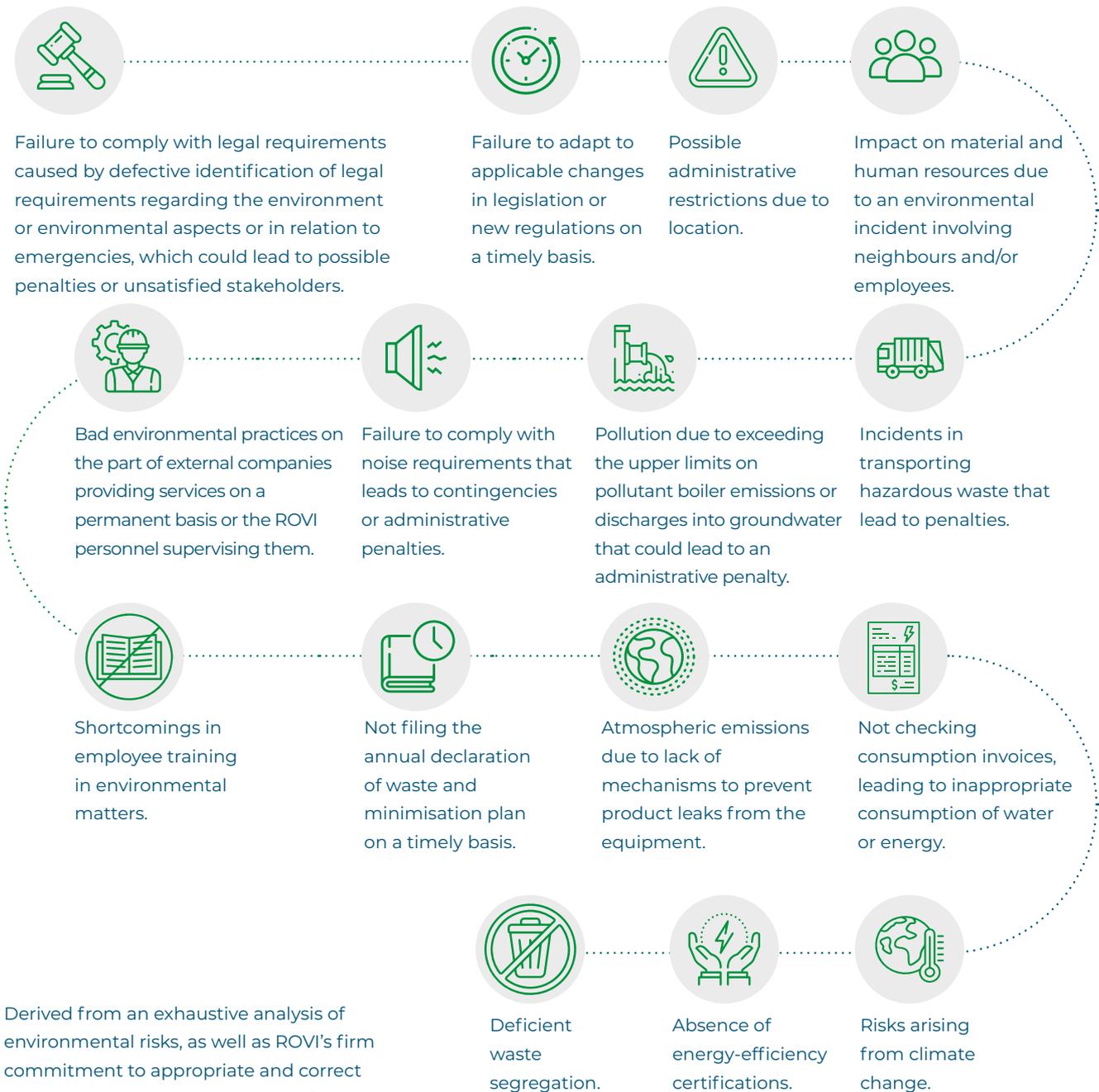
Environmental Aspects, the application of which allows the main environmental risks related to ROVI's own activity to be identified, notified and quantified, as well as those concerning regulatory issues and possible administrative restrictions when accessing new markets.

- Procedure for Identifying, Accessing and Assessing Legal and other Requirements, intended to identify the regulatory requirements regarding Safety and the Environment, as well as the requirements necessary to receive the relevant environmental authorisations.
- Management Procedure for Non-Conformities and Preventive and Corrective Actions, the application of which allows any possible deviations from the Environmental Management System to be identified, establishing procedures intended to prevent them and implement corrective actions.



Environmental risks

As a result of applying these procedures, ROVI has identified a series of risks that could have an impact on the environment:



Derived from an exhaustive analysis of environmental risks, as well as ROVI's firm commitment to appropriate and correct environmental management, the Company holds voluntary environmental liability insurance, which is renewed annually and acts as a financial guarantee for each one of the production plants.

Lastly, environmental protection is also included in the Corporate Communication, Participation and Consultation Procedure, whereby internal and external environment-related communications (queries, complaints, etc.) are managed. When ROVI receives these communications, it enters

them into the communications register and initiates the assessment and analysis process to provide a response and solution to the issue raised in the communication. In this respect, mention should be made of the fact that, in 2022, ROVI did not receive any complaints in this respect through any of the channels available and it did not paid any penalties related to damages to the environment.

6.3.3.

Sustainable use of resources

[GRI 3-3, 301-1, 302-1, 302-3, 303-2, 303-3]

In its commitment to respecting the environment, ROVI is very much aware of efficient management and the rational use of resources as key elements of its business vision. This principle materialises not only with the efficiency measures that the Company has adopted to reduce the impact of the industrial processes it performs, but also, before undertaking any new activity, it ensures that it will be conducted in a way that is respectful with the environment and surroundings where it operates.

In this respect, at all its production plants, water, electricity and gas indicators are checked and reported on a monthly basis (the last two through an energy monitoring platform), which allows consumption to be correctly monitored and, if any significant deviation is noted, reduced, in order to continue growing sustainably and observe current regulations.

In addition to ensuring a sustainable and responsible use of the products, this allows exhaustive monitoring of different environmental indicators (*), which may be consulted in the following sections of this report.

Energy consumption

In 2022, particularly the second half as regards the last quarter of the year, with the different measures announced by the Government and the situation of the international energy market, containment and saving measures became even more necessary in respect of energy.

In 2022, ROVI continued to use providers of 100% renewable energy for all its manufacturing plants, the head offices and Group subsidiaries.

Given ROVI's policy in this respect, as well as the measures already in place, such as obtaining 100% of the energy from renewable sources, it succeeded in keeping both the levels of energy saving and the costs stable.

During 2022, as in preceding years, different measures were adopted to save energy, in order to have a positive impact on the environment. To adopt these measures, each plant has a multidisciplinary team responsible for defining, implementing and monitoring the actions necessary to contribute to the definitive attainment of the plant-dependent goals fixed in previous years.

(*) The environmental indicators are calculated for the production plants and the distribution business, thus allowing a comparison between them.

Notwithstanding, it should be remembered that the measurement units are different for each one of them, taking the following points into account:

- > The production of the manufacturing plant for own products in Granada is production is measured in MIUs (millions of international units), since it produces bemiparin and enoxaparin, the active substances of ROVI's own main research products.
- > The Group's injectables production plants, located at the San Sebastián de los Reyes, Madrid and Alcalá de Henares plants. In the case of San Sebastián de los Reyes and, the units produced are expressed in individual units packed, while in Alcalá de Henares the packs of packaged oral solid forms (tablets and sachets) are used as the production unit.
- > The distribution business of Laboratorios Farmacéuticos Rovi, S.A. and its subsidiaries uses the units distributed.

Granada plant



MEASURES:

Energy efficiency measures

- > Energy management of the plant through an "Energy Management System" certified under standard ISO 50001 since 2021.
- > Installation of new monitoring points for the regenerative thermal oxidiser's energy consumption (electricity, gas and water).
- > Installation of a flow meter for sanitary hot water.
- > Replacement of steam traps.
- > Replacement of the hot water recirculating pumps by others that are more energy efficient.
- > Reducing the thermal comfort temperatures in common areas and offices in accordance with Royal Decree 14/2022.
- > Campaign to encourage plant employees to suggest ideas to improve the energy performance and awareness campaign on energy use.
- > Electricity contracts with guarantees of renewable origin.

Alcalá de Henares plant (Madrid)



MEASURES:

Energy efficiency measures

- > Regulation of steam pressure for introducing condensates at the plant. Change the pressure regulator in building 28.
- > Adjustments to the steam inlet to control the pressure of the flash tank.
- > Boiler control to automate start-ups in accordance with the demand for steam.
- > Replacement of luminaires in building 32.
- > Studies of photovoltaic installation for self-consumption, to be executed in 2023.
- > Adjustment of thermal comfort temperatures in accordance with Royal Decree 14/2022 and purchase of remote controls for autonomous heat sources subject to the Regulation on Thermal Installations in Buildings to limit the temperatures. Temperature adjustment in the rest of the rooms.
- > Electricity contracts with guarantees of renewable origin.



Julián Camarillo plant (Madrid)

**MEASURES:****Energy efficiency measures**

- > Monitoring and analysis of energy consumption figures through the monitoring platform and bills.
- > Predictive regression modelling of energy consumption based on production value, number of autoclave cycles, hours worked, degrees, days of air-conditioning and heating.
- > Installation of new monitoring points for greater control of the plants consumptions.
- > Replacement and optimisation with LED luminaires in the building B canteen and the building F technical water room.
- > Replacement of the pneumatic solenoid valves of the steam boilers.
- > Automatic programming of different air treatment units in building D at weekends.
- > Jacketing of valves and filters in the boiler room to prevent heat losses.
- > Installation of the inertia tank to reduce the number of start/stops of the coolers in building E.
- > Control and programming of shutdown of the steam generator in building F when there are no terminal sterilisation cycles.
- > Monitoring and support for temperature control in office areas in compliance with Royal Decree 14/2022.
- > Obtaining the energy certification label in the office buildings (buildings B and H), in accordance with Royal Decree 390/2021.
- > Energy efficiency measures contest to encourage ROVI employees to become involved in energy saving.
- > Electricity contracts with guarantees of renewable origin.

San Sebastián de los Reyes plant (Madrid)

**MEASURES:****Energy efficiency measures**

- > Monitoring and analysis of energy consumption figures through the monitoring platform and bills.
- > Change to capacitative compressed air purger to minimise the number of system purges.
- > Timer to shut down heating/air conditioning in the canteen and offices during employee rest periods.
- > Presence sensors in the canteen and other areas of the plant so that the lighting remains off when they are empty.
- > Study on installing a photovoltaic plant for self-consumption at the plant facilities.
- > Adjustment of thermal comfort temperatures in accordance with Royal Decree 14/2022 in common areas and offices.
- > Electricity contracts with guarantees of renewable origin.

In spite of adopting the aforementioned energy efficiency measures, energy consumption increased in 2022 for several reasons:

- > Start-up of the new plant in Escúzar (Granada).
- > Integration of the manufacturing process of the Moderna vaccines at the Julián Camarillo plant (Madrid).
- > Gradual return to the offices after the pandemic.



Electricity consumption

2022(*)	Escúzar	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/ AVERAGE
kWh electricity consumed	2,364,210	4,965,916	5,149,723	6,484,326	9,325,119	646,549	28,935,843
kWh electricity / million units	120	9	44,672	51,803	146,529	48,382	291,515
kWh natural gas consumed	1,925,593	4,462,606	3,821,715	6,944,536	13,463,612	0	30,618,062
kWh natural gas / million euros	98	8	33,152	55,480	211,559	0	300,296
Litres fuel Stationary sources (power generators, etc.)	500	135	676	288	2,000	0	3,599
Litres fuel Mobile sources (vehicles)	0	862	0	0	6,390	367,669	374,921

2021	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/ AVERAGE
kWh electricity consumed	3,707,332	4,593,953	5,188,822	8,867,576	634,789	22,992,472
kWh electricity / million units	8	37,548	69,737	136,424	36,540	56,051
kWh natural gas consumed	4,325,551	4,085,211	5,078,398	14,960,320	0	28,449,480
kWh natural gas / million euros	10	33,390	68,253	230,159	0	66,362
Litres fuel Stationary sources	1,000	0	0	5,164	360,614	366,778

Variation %	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/ AVERAGE
kWh electricity consumed	34%	12%	25%	5%	2%	26%
kWh electricity / million units	7%	19%	-26%	7%	32%	420%
kWh natural gas consumed	3%	-6%	37%	-10%	-	8%
kWh natural gas / million euros	-23%	-1%	-19%	-8%	-	353%
Litres fuel Mobile sources	-87%	-	-	-61%	-100%	-99%

(*)

Note I: Some of the data for the last month of 2022 are estimates based on the information from previous periods.

Note II: The TOTAL/AVERAGE column shows, in the case of consumption, the total sum of each plant or business unit and, in the case of the ratios of consumption per million units produced or distributed, the average of all the plants or business units.

Note III: There may be discrepancies in the totals or averages due to rounding up or down.

Special attention should also be drawn to the self-consumption of the Alcalá de Henares and Granada production plants in 2022. Respectively, they generated 3% and 3.22% of the total energy they consumed through the photovoltaic panels installed at their operational centres. For 2023, the photovoltaic installations of the Escúzar and San Sebastián de los Reyes plants are expected to come into operation.

2022	Electricity (photovoltaic) produced	Electricity (photovoltaic) consumed
Alcalá de Henares plant	286,516 kWh	9,325,119 kWh
Granada plant	159,971 kWh	4,965,916 kWh
Total	446,487 kWh	14,291,035 kWh

2021	Electricity (photovoltaic) produced	Electricity (photovoltaic) consumed
Alcalá de Henares plant	232,533 kWh	8,867,576 kWh
Granada plant	169,828 kWh	3,707,332 kWh
Total	402,361 kWh	12,574,908 kWh

Water consumed

ROVI integrates sustainable water management into its normal course of business, considering it a basic natural resource in pharmaceutical manufacturing. Therefore, the Company establishes measures regarding the use, treatment, reutilisation and discharge of water.

2022(*)	Escúzar	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/ AVERAGE
m ³ water consumed**	18,070	28,652	39,010	72,705	44,533	3,517	206,487
m ³ water / million units	0.9	0.0	338.4	580.8	699.8	263.2	1.620.0

2021	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/ AVERAGE
m ³ water consumed**	27,509	38,431	50,128	56,547	9,616	182,230
m ³ water / million units	0.1	314.1	673.7	870.0	553.5	482.3

Variation %	Granada	Madrid	SSRR	Alcalá de Henares	Distribución	TOTAL/ AVERAGE
m ³ water consumed**	4%	2%	45%	-21%	-63%	13%
m ³ water / million units	-51%	8%	-14%	-20%	-52%	-33%

(*) Note 1: There may be discrepancies in the totals or averages due to rounding up or down.

(**) Includes both the water consumption of the offices and the water consumption related to ROVI's production process.

Water consumption decreased considerably in 2022 due to the effectiveness of the awareness campaigns carried out at the plants. Notwithstanding, in 2023, work will be done to identify savings measures for water consumption to be implemented in future years.

Raw materials consumed

For ROVI, raw materials are an essential element of its value chain, from the moment the supplier is selected until they leave ROVI's facilities, including their reception and use at group facilities. Therefore, good raw material management is a priority for ROVI.

Tonnes of raw materials consumed

	2022	2021	Variation
Granada	1,468	996	47%
Madrid	318	114	179%
SSRR	2,370	53	n.a.
Alcalá de Henares	609	430	42%
Escúzar	163	-	n.a.

Respect for biodiversity

ROVI, aware of the importance of looking after the environment in which it operates from a number of standpoints, considers issues related to biodiversity and protected areas by drawing up Environmental Impact Assessment Studies, which are outsourced to third parties in accordance with legal requirements, before building any new facilities or in the event of a future renovation of existing facilities.

In this respect, ROVI carried out impact studies for all the Group's plants and production centres, finding that ROVI's activities do not represent a risk to the biodiversity in the areas where it operates. Additionally, ROVI actively collaborates on projects whose main aim is to reforest two areas located in Spain, thus responding to the need to safeguard biodiversity (for further information on these projects, see section 6.3.5. Mitigation of Climate Change).



6.3.4.

Waste management and circular economy

[GRI 306-2, 306-3]

Waste management, treatment and recycling

ROVI, aware that waste generation is inherent to its activity and committed to reducing the adverse environmental impact of the waste it generates, manages waste correctly as an essential mechanism to prevent pollution.

In this respect, ROVI has established a number of processes related to waste treatment, mostly oriented to minimising it in the production process and managing it properly when it has been produced, favouring its recovery through recycling or, in the cases where this is possible, reusing it.

This is so much the case that, as far as possible, the Group always seeks, through the authorised waste managers it works with, for the waste removed to be recovered, rather than destroyed. As a result of this action, ROVI has achieved a significant improvement in the process since, until 2020, hazardous waste was destroyed and transported to dumps to be managed correctly.

In 2022, 15% of non-hazardous waste was recycled. The types of waste that are recycled are paper, cardboard and the plastic trays and racks for syringes and vials (polypropylene and polystyrene).

2022(*)	Escúzar	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/ AVERAGE
Tonnes hazardous waste generated	148	4,413	144	344	161	14	5,223
Tonnes non-hazardous waste generated	241	1,508	366	523	1,061	4	3,703
Total waste	389	5,921	510	867	1,222	18	8,926
Tonnes hazardous waste / million units	0.007	0.007	1.2	2.7	2.5	1.0	7.6
Tonnes non-hazardous waste / million units	0.012	0.002	3.2	4.2	16.7	0.3	24.3
Total waste / million units	0.020	0.010	4.4	6.9	19.2	1.3	31.9
Tonnes non-hazardous waste recycled	0.2	14	133	84	311	4	546
Total non-hazardous waste recycled / million units	1.1	2.4	1.1	6.7	4.9	2.8	4.9

2021	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/ AVERAGE
Tonnes hazardous waste generated	2,355	111	426	117	8.6	3,017
Tonnes non-hazardous waste generated	1,341	207	1,019	853	4.5	3,425
Total waste	3,695	318	1,445	970	13.2	6,441
Tonnes hazardous waste / million units	0.005	0.9	5.7	1.8	0.5	1.8
Tonnes non-hazardous waste / million units	0.003	1.7	13.7	13.1	0.3	5.8
Total waste / million units	0.008	2.6	19.4	14.9	0.8	7.5

Variation %	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/ AVERAGE
Tonnes hazardous waste generated	87%	30%	-19%	38%	60%	73%
Tonnes non-hazardous waste generated	12%	77%	-49%	24%	-16%	8%
Total waste	60%	61%	-40%	26%	34%	39%
Tonnes hazardous waste / million units	44%	39%	-52%	40%	108%	325%
Tonnes non-hazardous waste / million units	-13%	87%	-70%	27%	9%	323%
Total waste / million units	23%	70%	-64%	29%	74%	323%

(*) Note 1: There may be discrepancies in the totals or averages due to rounding up or down.

Lastly, regarding waste management and circular economy, mention should be made of the fact that food waste has not been identified as a material issue for the Group.



6.3.5. Mitigation of Climate Change

[GRI: 3-3, 302-4, 305-1, 305-2, 305-4, 305-7]

Climate Change Policy and goals

Climate change will be one of the most important challenges that humanity will face in the 21st century. Since there are no borders that restrict or delimit its causes and consequences, the adoption of actions and measures aimed to mitigate it is an essential aspect, which will require the collaboration of all the global players and in which ROVI is participating.

In this situation, ROVI acknowledges the magnitude of the problem, identifying the need to tackle it from inside the Group on a combined and coordinated basis with governments, multilateral bodies, the private sector and society overall.

ROVI assumes its role as an organisation that strives to mitigate and adapt to climate change and, therefore, has an internal Climate Change Policy, updated in 2022 to include the commissioning of the Escúzar plant in 2023, whereby ROVI seeks to play a leading role in the fight against climate change. Likewise, through this Policy, ROVI undertakes to promote a corporate culture oriented towards raising the awareness of all its stakeholders of the magnitude of the challenge and the benefits associated to tackling its solution, identifying specific actions in the area of mitigating and adapting to climate change.

In this respect, ROVI has identified four key principles to guide it when putting its commitment to mitigating climate change into practice.



Reduction in greenhouse gas emissions

Gradually reduce CO₂ emissions originating from the production activities of the facilities and the Group's own vehicle fleet.



Reduction in non-greenhouse gas emissions

Reduce non-greenhouse gas emissions that affect air quality.

To do so, harmful gases will be identified and controlled, taking measures to reduce or eliminate these emissions.



Carbon neutrality

Achieve a carbon footprint of 0, meaning that the same amount of carbon dioxide as is released into the atmosphere is removed from it using different methods.



Renewable energies

Increase in the percentage of renewable energy consumed at the facilities until all the energy consumed comes from renewable sources.

Commitments to reducing emissions

ROVI, in its mission to meet one of its key commitments: mitigating climate change, fixed a series of plant-dependent targets to decrease direct and indirect CO₂ emissions in 2022, which achievement status is shown in the table below:

Plant	TARGET for 2022-2023	TARGET STATU as of December 2022
Alcalá de Henares plant	<p>Reduce total CO₂ emissions by 44 tonnes by decreasing gas consumption compared to actual consumption in 2021 (885 tonnes).</p> <p>Reduce by 1% the global energy consumption (gas and electricity) compared to actual 2021 consumption.</p>	A reduction of more than 1% in global energy consumption was achieved (10.4%).
Julián Camarillo (Madrid) plant	<p>Not to increase electricity consumption in 2022 by more than 4% versus 2021.</p> <p>Reduce Scope 1 CO₂ emissions by 2% versus 2021.</p>	This goal was not met, since electricity consumption was 13% higher than in 2021. The excess of electricity is principally due to the increase in line 3P3, which was not taken into account when calculating the target.
Granada plant	Reduce transport frequency (and, therefore, greenhouse-gas emissions) for the removal of non-hazardous waste (uncontaminated cardboard and plastic) in 2022 versus 2021.	Two compactors were installed at the plant, In 2022, three collections were made from the cardboard compactor and a further three from the plastic compactor, totalling 7,840 kg of cardboard and 5,500 kg of plastic. The ratio collections/kg of non-hazardous waste was lower in 2022 versus 2021.

Management of climate matters

ROVI is aware of the global problem arising from the growth over recent decades in the use of fossil fuels, whose combustion for electricity generation, transport, heating, industrial activities, etc. gives rise to greenhouse gas emissions, which have accelerated global warming and, consequently, increased the climate change problem. To tackle this problem, ROVI has a strategic framework called "AVOID, REDUCE, COMPENSATE", aimed to optimise energy consumption in the course of its activities and based on the following key principles:

> **AVOID** the generation of CO₂ emissions as far as possible. To this end, the Company carried out the following initiative in 2022:

- Signed contracts for renewable energy for the electricity required by the production plants. Thus, 100% of the production plants avoid the totality of emissions generated within Scope 2 of the Carbon Footprint relating to the acquisition of energy.

> **REDUCE** consumption of key resources, essentially in the industrial area, where most of the emissions are generated (and, therefore, where the greatest impact is produced). For this reason, ROVI has a monthly check procedure in place at its production plants, which analyses any possible deviations in water, electricity or gas consumption that allow the Company to establish specific

energy-saving or electricity or fuel consumption targets in collaboration with a multidisciplinary team that defines, implements and monitors the actions necessary to reach said targets.

> **COMPENSATE** voluntarily the CO₂ emissions that it has not been possible to either avoid or reduce during the year. For ROVI, this is a very important aspect of its environmental management and, therefore, the Company has initiatives to compensate the direct emissions produced during fuel consumption, such as the natural gas needed to start up the industrial boilers or the gas treatment and purification system. These emissions are included in Scope 1 of the carbon footprint. Thus, the Company helps combat the adverse effects of climate change, in addition to favouring the transition to a low-carbon economy.

As a result of this strategic framework, ROVI undertook the compensation of the totality of the Scopes 1 and 2 CO₂ emissions it was unable to avoid in 2022 through its collaboration in three large projects based on actions aligned with the United Nations Sustainable Development Goals, particularly contributing to those pivoting on respect and care for the environment.

With these projects, ROVI offset all the Group's Scope 1 and 2 CO₂ emissions and 659 tonnes of Scope 3 emissions that it was unable to avoid, with a total of 7,970 tonnes of CO₂.



ROVI's Wood

Planting a Wood with 2,000 trees in the Madrid Sierra (Spain).

Each employee was assigned a tree and was involved in planting it virtually. To this end, a digital platform has been created through which employees may activate the planting of a tree of the species they wish and watch the wood grow. This platform also shows updated figures of the compensation of emissions.

The compensation of emissions through ROVI's Wood is expected as from 2023 onwards.



San Nicolás Project

Reforestation project in the municipality of Cebreros (Ávila), registered with the Ministry for the Ecological Transition and the Demographic Challenge and certified with official credits.

The project is based on planting different species of trees on forest land that was burnt. The species planted are as follows: *Pinus pinea*, *Quercus faginea*, *Arbutus unedo*, *Quercus suber*, *Juniperus communis* and *Fraxinus spp.*

The initiative seeks to recover the degraded soil to create a new forest, with the ultimate goal of protecting the habitat, the soil, the landscape and biodiversity. Likewise, the project helps rural development by fomenting local employment and creating partnerships to attain environmental goals.

Las Pizarras Project

Hydroelectric project in the province of Santa Cruz in the Cajamarca region of Peru.

The project's goal is to generate electricity using the water of the Chancay River and provide it to the National Interconnected Electricity System (SEIN).



ROVI is aware of the important activity it carries on in the industrial area and the resulting environmental repercussions it may have on the surrounding area. Therefore, for a number of years, it has been working to reduce the harmful impacts it generates on the environment with the goal of becoming a carbon-neutral company.

As a result of this goal, ROVI has developed and implemented different lines of work that, for the third year running, allowed the Group to achieve Scope 1 and 2 carbon neutrality, thus also complying with the Group's Environmental and Social Sustainability Policy and the framework of its "Avoid, Reduce, Compensate" strategy.

In this respect, although ROVI is below the legal limits on greenhouse gas emissions, it is very much committed to the fight against climate change. Therefore, it monitors the CO₂ emissions from its consumption of natural gas and oil derived from its electricity production and the use of the Company's vehicles, as well as emissions of other particles and gases that have a harmful effect on the ozone layer.

This monitoring allows the Company to know and assess the advances that are taking place regarding emissions and establish the best measures to reduce its emissions into the atmosphere.

In 2022, ROVI, together with an independent external advisor, calculated its carbon footprint, including Scope 3. Thus, it was able to register it with the Ministry for the Ecological Transition (MITECO). During the year, ROVI worked to be able to certify its entire carbon footprint (Scopes 1, 2 and 3) in forthcoming years with the triple stamp of the MITECO (1) Calculate; 2) Reduce; 3) Compensate) and, in 2022, received the "Calculate" and "Compensate" stamps for the 2020 and 2021 data.



Atmospheric emissions of CO₂eq

2022(*)	Escúzar	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/AVERAGE
Tonnes of Scope 1 CO ₂ eq emitted	356	914	699	1,268	2,492	964	6,693
Tonnes of Scope 2 CO ₂ eq emitted(**)	612	-	-	-	-	4	616
Tonnes of Scope 2 CO ₂ eq avoided(***)	-	1,286	1,334	1,679	2,415	167	6,882
Tonnes of Scope 3 CO ₂ eq emitted	-	-	-	-	-	-	10,352
Tonnes of CO ₂ eq emitted / milion units	0.049	0.002	6	10	39	91	0.03

2021	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/AVERAGE
Tonnes of Scope 1 CO ₂ eq emitted	790	744	924	2,738	1,034	6,230
Tonnes of Scope 2 CO ₂ eq emitted	-	-	-	-	1.4	1.4
Tonnes of Scope 2 CO ₂ eq avoided(**)	927	1,148	1,297	2,217	157	5,746
Tonnes of CO ₂ eq emitted / milion units	0.002	6	12	42	60	24

Variation %	Granada	Madrid	SSRR	Alcalá de Henares	Distribution	TOTAL/AVERAGE
Tonnes of Scope 1 CO ₂ eq emitted	16%	-6%	37%	-9%	-7%	7%
Tonnes of Scope 2 CO ₂ eq emitted	-	-	-	-	n.a.	n.a.
Tonnes of Scope 2 CO ₂ eq avoided(**)	39%	16%	29%	9%	6%	20%
Tonnes of CO ₂ eq emitted / milion units	-11%	1%	-16%	-7%	53%	n.a.(****)

(*) Note I: To calculate the tonnes of CO₂ eq emitted into the atmosphere, the emission factors provided by the Ministry for the Ecological Transition and Demographic Challenge (MITECO) for electricity, natural gas and diesel fuel are used.

Note II: There may be discrepancies in the totals or averages due to rounding up or down.

(**) The increase in the Scope 2 CO₂ eq equivalents emitted was due to the inclusion of the new Escúzar plant (Granada) in the scope.

(***) Given that all ROVI's production plants (except the new Escúzar plant) and subsidiaries, as well as the main offices, have a 100% renewable energy supply certificate, the emission of the tonnes of CO₂ eq mentioned is avoided. Scope 2 emissions were reported for the first time in 2020, in order to reflect the Group's investment in clean energy.

(****) The variation of tonnes of CO₂ eq emitted/million units is not applicable because 2022 is the first year in which Scope 3 is reported.



Other emissions of gases harmful to the atmosphere*

2022	Granada	Madrid	SSRR
NOx (kg/year)	1,716	1,402	6,641
CO (kg/year)	2	27	1,522

2021	Granada	Madrid	SSRR
NOx (kg/year)	2,222	1,402	4,316
CO (kg/year)	65	27	213

Variation %	Granada	Madrid	SSRR
NOx (kg/year)	29%	0%	-35%
CO (kg/year)	n.a.	-1%	-86%

* This table shows the plants for which data are available.



6.3.6. Commitment and contribution to the SDGs regarding the environment

SDG and Goal	Key messages on ROVI's contribution in 2022	Goals	Key contributions
 <p>CLEAN WATER AND SANITATION</p> <p>Ensure availability and sustainable management of water and sanitation for all</p>	<p>ROVI implements its commitment to this SDG by establishing sustainable management of water resources. For ROVI, water is a basic natural resource in medicine manufacturing and, therefore, it establishes measures for the use, treatment, reutilisation and discharge of water.</p>	<p>GOAL 6.3</p> <p>GOAL 6.4</p>	<p>Reduction in the production of harmful effluents (basic solutions) derived from production of the COVID-19 vaccines.</p> <p>Reutilisation of water rejected by the vial washing machines for watering at the San Sebastián de los Reyes plant.</p>
 <p>AFFORDABLE AND CLEAN ENERGY</p> <p>Ensure access to affordable, safe, sustainable and modern energy</p>	<p>ROVI bets on clean energies and technologies by fixing energy-efficiency targets and measures at each one of its production plants, the ultimate aim of which is to reduce environmental impacts on the surroundings.</p>	<p>GOAL 7.2</p>	<p>Production of renewable energy through the panels installed at the Alcalá de Henares and Granada plants in 2021.</p>
 <p>DECENT WORK AND ECONOMIC GROWTH</p> <p>Promote inclusive and sustainable economic growth, employment and decent work for all</p>	<p>ROVI promotes efficient production, placing responsible resource management as the linchpin of its activities and striving to separate economic growth from the degradation of the environment.</p>	<p>GOAL 8.4</p>	<p>Signing contracts for 100% renewable energy for the totality of its manufacturing plants and the Group's main offices and subsidiaries.</p>
 <p>INDUSTRIES, INNOVATION AND INFRASTRUCTURE</p> <p>Build resilient infrastructures, promote sustainable industrialisation and foster innovation</p>	<p>ROVI operates by developing technologies and processes that optimise the sustainable performance of industrial plants, generating less environmental impact through the reduction of emissions, efficient use of resources and minimising and optimising the waste generated.</p>	<p>GOAL 9.4</p>	<p>Implementation of energy efficiency projects at the plants, including, among others:</p> <ul style="list-style-type: none"> > Optimisation of the climate control and boiler control systems at some of the plants. > Change in the lighting systems of some plants, adopting energy-efficient measures, such as the use of LED bulbs. > Installation of new-generation electricity and steam meters that allow better monitoring of consumption and emissions. > Installation of a thermal oxidiser at the Escúzar plant.



ODS y Objetivo	Mensajes clave de la contribución de ROVI en 2022	Goals	Principales contribuciones
 <p>RESPONSIBLE CONSUMPTION AND PRODUCTION</p> <p>Ensure sustainable consumption and production patterns</p>	<p>ROVI acts with the intention of becoming a company with a sustainable production model. It prioritises waste recovery before it is finally disposed of, applying the principles of the circular economy, as well as reducing its raw material consumption.</p>	<p>GOAL 12.2</p> <p>GOAL 12.4</p> <p>GOAL 12.5</p>	<p>Monthly checks and preparation of reports on water, electricity and gas indicators at all its production plants.</p> <p>Collaboration in the international “Las Pizarras” electricity project to generate renewable electricity.</p>
 <p>CLIMATE ACTION</p> <p>Take urgent measures to combat Climate Change and its impacts</p>	<p>In order to meet its commitment to combat Climate Change, ROVI establishes different lines of action to follow, placing priority on efficient environmental management based on fostering the best environmental practices in the sector.</p>	<p>GOAL 13.2</p>	<p>Collaboration in the international hydroelectric project “Las Pizarras” to generate renewable energy.</p> <p>Compensation of 100% of the Group's Scope 1 and 2 emissions.</p> <p>Measurement of Scope 3 of the Carbon Footprint.</p> <p>Certification and registration of the totality of the Carbon Footprint (Scopes 1, 2 and 3) for 2020 and 2021 in 2022.</p> <p>Integrated Policy for Environmental and Occupational Risk Prevention Management.</p> <p>Environmental and Social Sustainability Policy.</p> <p>Climate Change Policy.</p> <p>Certification of Environmental Management System.</p> <p>Energy audits.</p> <p>Preventive management of efficient machinery, lighting and computer equipment.</p> <p>Fostering the fight against climate change in all corporate areas.</p>
 <p>LIFE ON LAND</p> <p>Sustainably manage forests, combat desertification, halt and reverse land degradation, halt biodiversity loss</p>	<p>ROVI bets on and fosters care of land ecosystems, ensuring their viability for future generations.</p>	<p>GOAL 15.2</p>	<p>Commencement of the ROVI's Wood project to compensate emissions.</p> <p>Environmental Impact Study for all the production plants.</p> <p>Participation in the “San Nicolás” reforestation project, registered with the Ministry for the Ecological Transition and the Demographic Challenge (MITERD).</p>



7

European Union Taxonomy



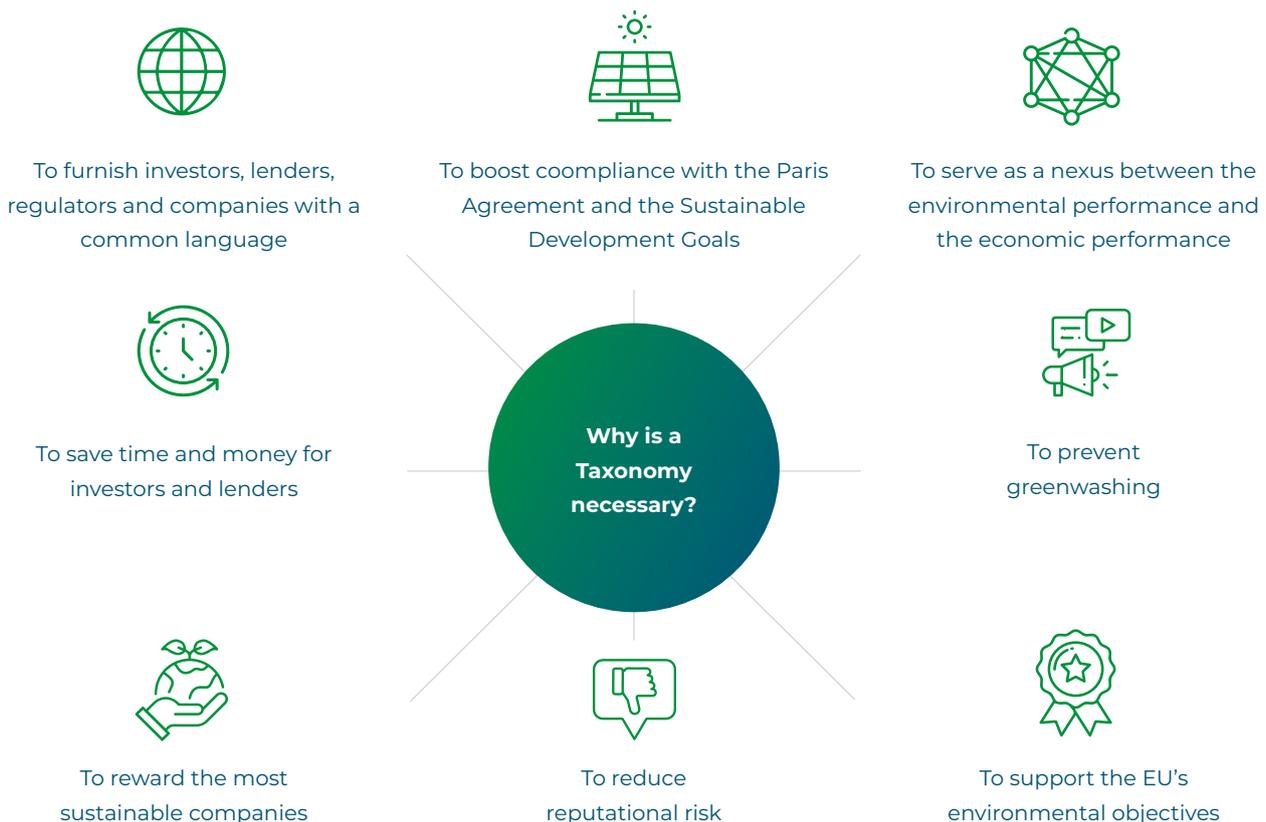


Background

The European Commission has adopted an ambitious package of general measures to help improve the flow of money towards sustainable activities throughout the European Union. Since they allow investments to be redirected towards more sustainable technologies and companies, these measures will help Europe achieve climate neutrality by 2050. One of these measures is the Taxonomy Regulation, Regulation (EU) 2020/852, which was followed by two delegated regulations to supplement it. First, Delegated Regulation 2021/2139 of 4 June, 2021, which established a list of economic activities that qualify as contributing substantially to climate change mitigation or climate change adaptation while causing no significant harm to any of the other environmental objectives. Second, the Delegated Regulation of 6 July, 2021 described the key indicators to be disclosed by companies subject to the obligation to publish Non-Financial Statements under articles 19a and 29a of Directive 2013/34/EU. As a result

of the foregoing, a classification system for sustainable economic activities was established, defining what is and what is not sustainable on the basis of objective criteria. Thus, a common language was constructed for investors and companies, firstly, to direct, first, investments towards more sustainable technologies and companies with a substantial positive impact on the climate and the environment and, secondly, to comply with the EU's climate objectives, the Paris Agreement and the Sustainable Development Goals of the United Nations.

In short, the EU taxonomy establishes a series of harmonised criteria to determine whether an activity is sustainable taking account of existing market practices and advice from a group of technical experts, thus laying the foundations for a series of standards and labels for sustainable financial products.



The EU taxonomy establishes two screening criteria:

> **Eligible activities:** an economic activity carried on by a company is eligible when it meets the description of one of the activities listed in the annexes of Delegated Regulation 2021/2139 of 4 June, 2021. Eligibility is potential in nature, i.e. an eligible activity is one that could be green in accordance with the EU taxonomy.

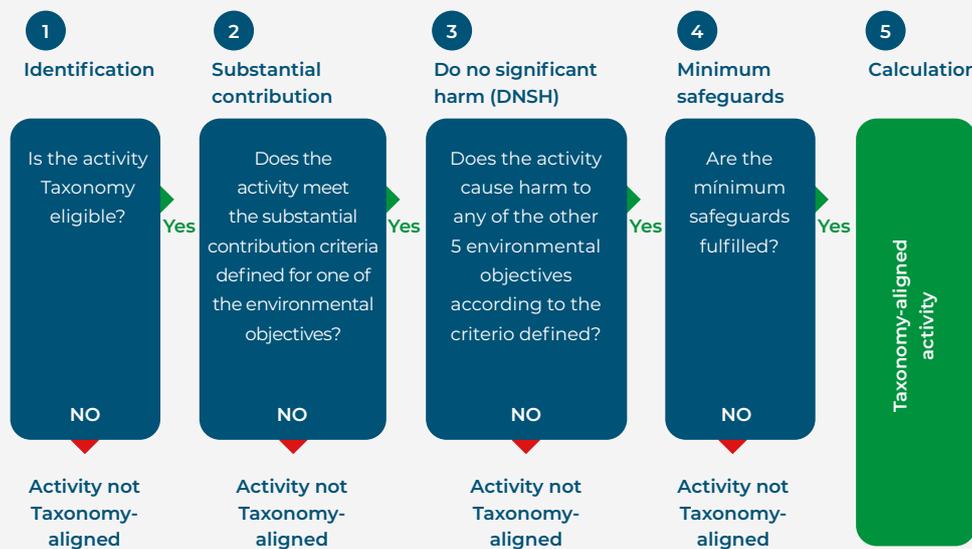
> **Aligned activities:** the alignment of an activity indicates its substantial contribution to one or more of the environmental activities defined by the European Commission. This concept is the result of meeting, not only the requirements contained in the definitions of the activities, but also the technical screening criteria of a substantial contribution (mitigation and adaptation),

the principle of doing no significant harm (DNSH) to any other objectives (water protection, circular economy, pollution prevention and biodiversity) and some minimum social safeguards.

Likewise, the Regulation establishes that three economic indicators must be disclosed: the percentages of the company's turnover, CapEx and OpEx represented by eligible or aligned activities.

For the reporting on the year 2021, the legal requirement regarding the information to disclose refers solely to eligibility. For the reporting on the year 2022, non-financial companies (which include the ROVI Group) must also disclose their KPIs with regard to alignment.

Implementation process



Timing and requirements

From 1 January, 2022

- > % of Taxonomy-eligible activities (turnover, CapEx and OpEx)
- > Qualitative information on accounting principles

From 1 January, 2023

For each Taxonomy-aligned activity

- > Turnover
- > CapEx
- > OpEx
- > CapEx plan
- > Qualitative information on accounting principles
- > Contextual information

Eligibility screening

The eligibility screening of the activities was conducted considering the information provided by different departments of ROVI in different business areas.

The activities carried out by ROVI in 2022 that are considered eligible in accordance with the Delegated Regulation of 4 June, 2022 are the following:

- > **Activity 5.4:** "Renewal of waste water collection and treatment".
- > **Activity 7.3:** "Installation, maintenance and repair of energy efficiency equipment".
- > **Activity 7.4:** "Installation, maintenance and repair of charging stations for electric vehicles in buildings.

> **Activity 7.5:** "Installation, maintenance and repair of instruments and devices for measuring, regulating and controlling energy performance of buildings".

> **Activity 7.6:** "Installation, maintenance and repair of renewable energy technologies".

The eligibility screening in 2022 was carried out in greater depth than in 2021, taking account of new updates, changes in legislation and FAQs (Frequently Asked Questions)¹. Therefore, the eligible activities in 2022 meet a more precise and homogenous criterion when compared with the information that other sector companies are disclosing to the market. In this respect:

¹ FAQs clarify the provisions that are already contained in the legislation. They do not add any extra requirements and are only intended to help financial and non-financial companies to implement the pertinent legal provisions.



- > In 2021, the CapEx relating to installing solar panels was linked to activity “4.1. Electricity generation using solar photovoltaic technology”. However, after the 2022 screening, it was determined that the OpEx for said activity in 2022 fell within the description “7.6. Installation, maintenance and repair of renewable energy technologies”, not activity 4.1. This was because ROVI’s main activity does not consist of generating electricity using photovoltaic technology but, however, it did incur maintenance expenses for renewable energy technologies, as per the description of activity 7.6.
- > Likewise, in 2021, the CapEx incurred in monitoring energy consumption was linked to activity “9.3. Professional services related to energy performance of buildings”. However, after the screening in 2022, it was determined that the OpEx for said activity in the year fell within the description of activity “7.5. Installation, maintenance and repair of instruments and devices for measuring, regulation and controlling energy performance of buildings”, not activity 9.3. This was because ROVI’s main activity does not consist of performing professional services related to energy performance of buildings but, however, it did incur maintenance expenses for the DEXMA platform, which monitors the energy consumption of the Group’s different plants, as per the description of activity 7.5.
- > Additionally, for the rest of the eligible activities reported in 2021, no CapEx or OpEx was incurred in 2022, so they are not eligible in said year.

In view of the foregoing, the approach and the assumptions adopted to determine the eligibility of the activities described above are set out below. In this respect, the starting point should be to consider ROVI’s main activity to be the production and commercialisation of pharmaceutical products and, therefore, a large part of its CapEx and OpEx are linked to the Group’s own production process.

> **Activity 5.4:** “Renewal of waste water collection and treatment.” As a result of the activity of its production plants, in 2022, ROVI incurred expenses for maintenance of the catch basin of some of its production plants (specifically, Alcalá de Henares and San Sebastián de los Reyes). The aforementioned activity is determined to exist derived from said maintenance expenses.

> **Activity 7.3:** “Installation, maintenance and repair of energy efficiency equipment”. In 2022, ROVI, committed to the energy efficiency of its facilities, obtained equipment

that allowed it to meet this commitment. In this respect, there were two principal lines of action: the installation of LED luminaires and the replacement of equipment by new, more efficient equipment (heat pumps and air-conditioning systems).

The criterion followed was for all the CapEx items related to replacements by more energy efficient equipment were eligible, apart from those items that had the sole purpose of cooling related to the production process, “process cooling”. In this connection, said cooling often affects the entire facility where the production process is taking place and, therefore, the Regulation on Thermal Installations in Buildings (RITE) is not met. In this situation, said items are not deemed eligible because they lose the potential measured through these indicators.

Therefore, the investment made to implement said measures, except those linked solely to the production process, contributed to determining the eligibility of this activity.

> **Activity 7.4:** “Installation, maintenance and repair of charging stations for electric vehicles in buildings (and parking spaces attached to buildings)”. In 2022, ROVI installed charging points for electric vehicles at several of its plants and offices.

> **Activity 7.5:** “Installation, maintenance and repair of instruments and devices for measuring, regulation and controlling energy performance of buildings”. In 2022, ROVI, committed to energy saving and efficiency, implemented controls such as presence detectors, room air-conditioning programmers and the use of a platform (DEXMA platform) that fosters energy saving at its plants and offices. Therefore, the investment made to implement these measures contributed to determining the eligibility of this activity.

> **Activity 7.6:** “Installation, maintenance and repair of renewable energy technologies”. In previous years, ROVI, committed to the use of renewable energy technologies, installed solar panels at some of its plants. In this respect, in order to boost their efficiency, ROVI incurred maintenance expenses at the plants where the panels are installed. Likewise, in 2022, ROVI installed new solar panels at its San Sebastián de los Reyes and Julián Camarillo plants. Therefore, both the maintenance expense and the installation of new panels contributed to determining the eligibility of this activity.

Alignment screening

The alignment screening of the activities was carried out considering the information provided by different departments of ROVI in different business areas.

After the process to identify the eligible activities, the following were analysed:

- > Technical criteria for substantial contribution to climate change mitigation/adaptation.
- > Causing no significant harm to any of the other environmental objectives (DNSH).
- > Minimum social safeguards.

Technical criteria for substantial contribution to climate change mitigation/adaptation:

In accordance with Annexes I and II and Delegated Regulation 2021/2139 of 4 June, 2021, for each CapEx and OpEx item linked to an eligible activity in 2023, compliance with the technical screening criteria set out in said Annex for each activity was analysed. In this respect:

- > For activity "7.3. *Installation, maintenance and repair of energy efficiency equipment*", eligible CapEx and OpEx items meet both the applicable minimum requirements set out in the national transposition of Directive 2010/31/EU and the classification in the two highest classes of energy efficiency in accordance with Regulation (EU) 2017/1369, when applicable. Likewise, it was determined that each one of the items mentioned complies with at least one of the individual measures set out in the regulations (see activity "7.3 in Annex I of the Delegated Regulation of 4 June, 2021, specifically the "Technical screening criteria" section).
- > For activity "7.4. *Installation, maintenance and repair of charging stations for electric vehicles in buildings*

(and parking spaces attached to buildings)", Annex I of Delegated Regulation 2021/2139 of 4 June, 2021 does not establish any additional requirements.

- > For activity "7.5. *Installation, maintenance and repair of instruments and devices for measuring, regulation and controlling energy performance of buildings*", it was determined that each one of the CapEx and OpEx items complies with at least one of the individual measures established in the legislation (see activity 7.5 of Annex I of Delegated Regulation 2021/2139 of 4 June, 2021, specifically the "Technical screening criteria" section).
- > For activity "7.6. *Installation, maintenance and repair of renewable energy technologies*", it was determined that each one of the OpEx items complies with at least one of the individual measures established in the legislation (see activity 7.6 of Annex I of Delegated Regulation 2021/2139 of 4 June, 2021, specifically the "Technical screening criteria" section).

DNSH:

Pursuant to Annexes I and II of Delegated Regulation 2021/2139 of 4 June, 2021, for each CapEx and OpEx item linked to an eligible activity in 2022, compliance with the requirements ("Do no significant harm") established for each activity was analysed. In this respect:

- > For activity "7.3. *Installation, maintenance and repair of energy efficiency equipment*", all the eligible CapEx and OpEx items comply with the requirements established in Appendix A² and Appendix C³.
- > For activity "7.4. *Installation, maintenance and repair of charging stations for electric vehicles in buildings (and*

parking spaces attached to buildings)", all eligible CapEx items meet the requirements established in Appendix A².

- > For activity "7.5. *Installation, maintenance and repair of instruments and devices for measuring, regulation and controlling energy performance of buildings*", all eligible CapEx and OpEx items meet the requirements established in Appendix A².
- > For activity "7.6. *Installation, maintenance and repair of renewable energy technologies*", all eligible CapEx and OpEx items meet the requirements established in Appendix A².

²ROVI has an analysis of physical climate risks and an adaptation plan for the risks identified as material. For further details, see chapter 6.1.5 of this report, "Identification and management of climate change risks and opportunities".

³None of the activities has given rise to the manufacture, commercialisation or use of any of the substances listed in Appendix C.

Minimum social safeguards:

The minimum social safeguards are set out in article 18 of Delegated Regulation 2020/852, which states:

“Minimum safeguards

1. *The minimum safeguards referred to in point (c) of Article 3 shall be procedures implemented by an undertaking that is carrying out an economic activity to ensure the alignment with the OECD Guidelines for Multinational Enterprises and the UN Guiding Principles on Business and Human Rights, including the principles and rights set out in the eight fundamental conventions identified in the Declaration of the International Labour Organisation on Fundamental Principles and Rights at Work and the International Bill of Human Rights.*

2. *When implementing the procedures referred to in paragraph 1 of this Article, undertakings shall adhere to the principle of ‘do no significant harm’ referred to in point (17) of Article 2 of Regulation (EU) 2019/2088.”*

In this respect, the requirements are divided into four core topics: Human Rights, Bribery/Corruption, Taxation and Fair Competition.

Human rights: ROVI holds a firm commitment to protect human rights and strives to ensure that the activities carried out within its sphere of influence do not violate human rights. To this end, it has different tools and mechanisms intended to ensure that this commitment is met (for further details, see chapters 6.1.2. “Ethics and integrity in the business model” and 6.2.3.1. “Ensuring sustainability in the supply chain” of this report).

Bribery/Corruption: ROVI is committed to “zero tolerance” of bribery and corruption, rejecting any action that includes these practices as a way to pursue its own interests (for further details, see chapters 6.1.2. “Ethics and integrity in the business model” and 6.1.3. “Regulatory compliance” of this report).

Taxation: ROVI holds a commitment to meet all tax requirements and apply the best tax practices, always reporting transparently on its activities and meeting its tax obligations responsibly and efficiently (for further details, see chapter 5.3. “Tax transparency” of this report).

Fair competition: ROVI is firmly committed to achieving long-term success through fair competition, not resorting to any practices that affect the free market, as stated in its own Code of Ethics. Therefore, it promotes ethical business management that respects competition law and avoids any unfair practice that means obtaining unfair advantages or that could affect free competition.

Calculation of key indicators

In line with the content of Annex I of the Delegated Regulation of 6 July, 2021, non-financial companies must disclose the percentage of the turnover, CapEx and OpEx represented by their eligible activities in 2021 and by their eligible and aligned activities in 2022. Taking the first article of said Annex as a basis, ROVI has calculated these indicators.

Likewise, it should be noted that the factors necessary to avoid double accounting were taken into account throughout the work process:

- The main information sources were the accounting and management information used in the consolidated income statement, based on the external reporting format for the National Securities Market Commission (CNMV).
- To analyse this accounting information, the subtotals were checked to ensure that the complete information was included at all times.

Calculation of the percentage of turnover

The proportion of turnover to which article 8(2), point (a), of Regulation (EU) 2020/852 refers, shall be calculated as the part of the net turnover derived from products or services, including intangibles, associated with Taxonomy-aligned economic activities (numerator), divided by the net turnover (denominator) as defined in article 2, point (5), of Directive 2013/34/EU. The turnover shall cover the revenue recognised pursuant to International Accounting Standard (IAS) 1, paragraph 82(a) as adopted by Commission Regulation (EC) No 1126/2008.

None of the activities led to revenue for ROVI.

Calculation of the percentage of CapEx

It is calculated as the numerator divided by the denominator as specified in points 1.1.2.1 and 1.1.2.2 of Annex 1 to the Delegated Regulation of 6 July, 2021, the denominator covering additions to tangible and intangible assets during the financial year considered before depreciation, amortisation and any re-measurements, including those resulting from revaluations and impairments, for the relevant financial year, excluding fair value changes. The denominator shall also cover additions to tangible and intangible assets resulting from business combinations.

For non-financial undertakings applying international financial reporting standards (IFRS) as adopted by Regulation (EC) No 1126/2008, CapEx shall cover costs that are accounted based on:

- > IAS 16 Property, Plant and Equipment, paragraphs 73, (3) point (i) and point (iii);
- > IAS 38 Intangible Assets, paragraph 118, (e), point (i);
- > IAS 40 Investment Property, paragraphs 76, points (a) and (b) (for the fair value model);
- > IAS 40 Investment Property, paragraph 79(d), points (i) and (ii) (for the cost model);
- > IAS 41 Agriculture, paragraph 50, points (b) and (e);
- > IFRS 16 Leases, paragraph 53, point (h).

For non-financial undertakings applying national generally accepted accounting principles (GAAP), CapEx shall cover the costs accounted under the applicable GAAP that correspond to the costs included in the capital expenditure by non-financial undertakings applying IFRS.

Leases that do not lead to the recognition of a right-of-use over the asset shall not be counted as CapEx.

The numerator equals to the part of the capital expenditure included in the denominator that is any of the following:

- a. Related to assets or processes that are associated with Taxonomy-aligned economic activities;
- b. Part of a plan to expand Taxonomy-aligned economic activities or to allow Taxonomy-eligible economic activities to become Taxonomy-aligned ('CapEx plan') under the conditions specified in the second subparagraph of point 1.1.2.2 of Annex I of the Delegated Regulation of 6 July, 2021 (relative to the 'CapEx plan');
- c. Related to the purchase of output from Taxonomy-aligned economic activities and individual measures enabling the target activities to become low-carbon or to lead to greenhouse gas reductions, notably activities listed in points 7.3. to 7.6 of Annex I to the Climate Delegated Act, as well as other economic activities listed in the delegated acts adopted pursuant to Article 10(3), Article 11(3), Article 12(2), Article 13(2), Article 14(2) and Article 15(2) of Regulation (EU) 2020/852 and provided that such measures are implemented and operational within 18 months.

ROVI includes the aggregated CapEx of the eligible activities as the numerator. In this respect, attention should be drawn to the fact that the amount that appears as the numerator is the result of an exhaustive analysis, which consists of checking that each one of the invoices associated to the CapEx included meets the description contained in the taxonomy regulations. Thus, the CapEx numerator is the value recorded on invoices⁴. The denominator is the Group's total CapEx, which includes investments in both tangible and intangible assets and investments in right-of-use assets.

Calculation of the percentage of OpEx

The proportion of OpEx to which article 8(2), point b), of Regulation (EU) 2020/852 refers shall be calculated as the numerator divided by the denominator as specified in points 1.1.3.1 and 1.1.3.2 of the Annex 1 to the Delegated Regulation of 6 July, 2021, the latter covering direct non-capitalised costs that relate to research and development, building renovation measures, short-term lease, maintenance and repair, and any other direct expenditures relating to the day-to-day servicing of assets of property, plant and equipment by the undertaking or third party to whom activities are outsourced that are necessary to ensure the continued and effective functioning of such assets.

Additionally, non-financial companies that apply national GAAP and are not capitalising right-of-use assets shall include lease costs in the OpEx.

The numerator equals to the part of the operating expenditure included in the denominator that is any of the following:

- a. Related to assets or processes associated with Taxonomy-aligned economic activities, including training and other human resources adaptation needs, and direct non-capitalised costs that represent research and development;
- b. Part of the CapEx plan to expand Taxonomy-aligned economic activities or allow Taxonomy-eligible economic activities to become Taxonomy-aligned within a predefined timeframe as set out in the second paragraph of point 1.1.3.2 of Annex I to the Delegated Regulation of 6 July, 2021 relative to 'CapEx plan'.

⁴In cases where the invoices that form the CapEx recorded are not, in their totality, linked to an activity described in the regulations.



c. Related to the purchase of output from Taxonomy-aligned economic activities and to individual measures enabling the target activities to become low-carbon or to lead to greenhouse gas reductions as well as individual building renovation measures as identified in the delegated acts adopted pursuant to Article 10(3), Article 11(3), Article 12(2), Article 13(2), Article 14(2) or Article 15(2) of Regulation (EU) 2020/852 and provided that such measures are implemented and operational within 18 months.

For ROVI, the OpEx indicator considers solely costs related to research and development, short term leases and maintenance and repairs. Individual building renovation measures any other direct expenditures relating to the day-

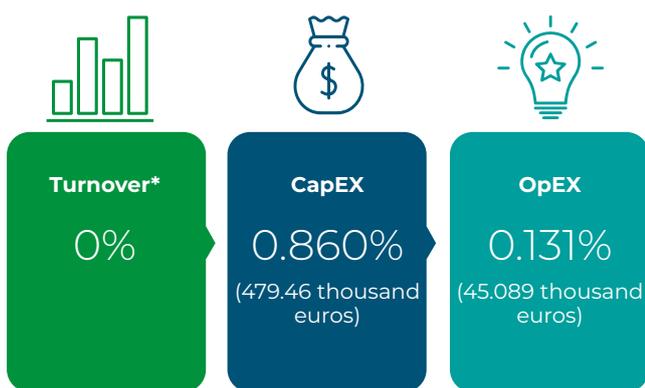
to-day servicing of assets of property, plant and equipment by the company or third party to whom activities are outsourced that are necessary to ensure the continued and effective functioning of such assets are not considered as OpEx.

Consequently, the denominator will cover the expenditures of these three OpEx items for the whole ROVI Group, while the numerator consists of the same items, but only for activities recognised as eligible.

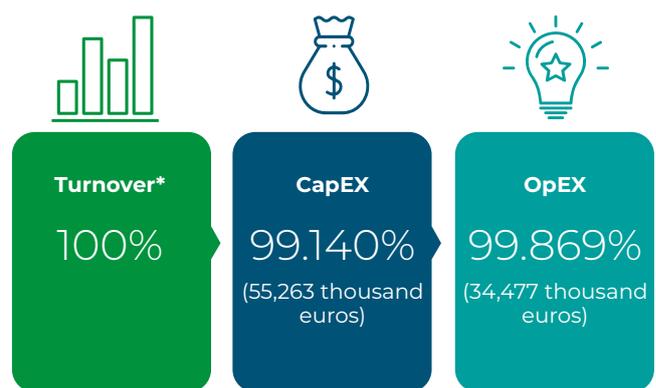
Results

The following is the proportion of eligible and non-eligible activities according to EU taxonomy:

% ELIGIBILITY

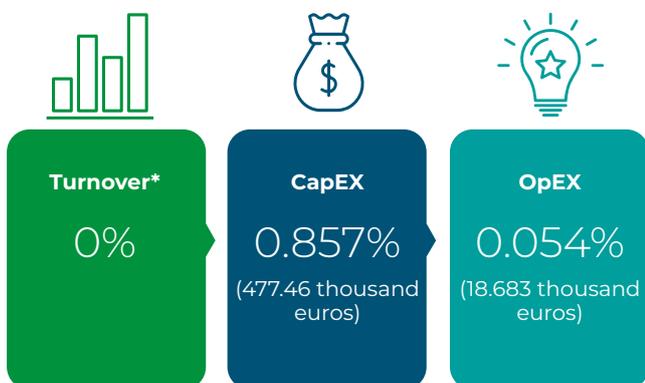


% NON-ELIGIBILITY



*ROVI does not have any of the activities included in the Taxonomy among its revenue-generating activities.

% ALIGNMENT



% NON-ALIGNMENT



*ROVI does not have any of the activities included in the Taxonomy among its revenue-generating activities.

Economic activities				Substantial contribution criteria ¹						DNSH criteria (Do Not Significantly Harm)										
	Code	Absolute CapEx	Proportion of CapEx	Climate change mitigation	Climate change adaptation	Water and marine resources	Circular economy	Pollution	Biodiversity and ecosystems	Climate change mitigation (Y/N)	Climate change adaptation (Y/N)	Water and marine resources (Y/N)	Circular economy (Y/N)	Pollution (Y/N)	Biodiversity and ecosystems (Y/N)	Minimum social safeguards	Taxonomy-aligned proportion of CapEx 2022	Taxonomy-aligned proportion of CapEx year N-1	Enabling activity (E)	Transitional activity (T)
A. TAXONOMY-ELIGIBLE ACTIVITIES																				
A1. Environmentally sustainable activities (Taxonomy-aligned)																				
Installation, maintenance and repair of energy efficiency equipment	7.3	€367,859.92	0.660%	100%	0%	N/A	N/A	N/A	N/A	N	Y	N	N	Y	N	Y	0.660%	N/A	E	
Installation, maintenance and repair of charging stations for electric vehicles in buildings (and parking spaces attached to buildings)	7.4	€15,495.90	0.028%	100%	0%	N/A	N/A	N/A	N/A	N	Y	N	N	N	N	Y	0.028%	N/A	E	
Installation, maintenance and repair of instruments and devices for measuring, regulation and controlling energy performance of buildings	7.5	€31,519.31	0.057%	100%	0%	N/A	N/A	N/A	N/A	N	Y	N	N	N	N	Y	0.057%	N/A	E	
Installation, maintenance and repair of renewable energy technologies	7.6	€62,579.57	0.112%	100%	0%	N/A	N/A	N/A	N/A	N	Y	N	N	N	N	Y	0.112%	N/A	E	
CapEx of environmentally sustainable activities (Taxonomy-aligned) (A.1)	x	€477,454.70	0.857%	100%	0%	N/A	N/A	N/A	N/A								0.857%	N/A	E	
A2. Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)																				
Installation, maintenance and repair of energy efficiency equipment	7.3	€2000	0.004%																	
CapEx of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)		€2000	0.004%																	
Total (A.1 + A.2)		€479,454.70	0.860%																	
B. TAXONOMY-NON-ELIGIBLE ACTIVITIES																				
CapEx of Taxonomy-non-eligible activities (B)		€55,263 thousand	99.140%																	
TOTAL (A+B)	x	€57,773 ² thousand	100%																	

¹⁾ Pending publication of details of the technical screening criteria associated to the other four environmental goals.

²⁾ The CapEx figure used as the denominator includes amounts recognised in relation to rights of use in accordance with International Financial Reporting Standard 16 Leases (IFRS 16).



Economic activities	Code	Absolute OpEx	Proportion of OpEx	Substantial contribution criteria ³						DNSH criteria (Does not significantly harm)						Minimum social safeguards	Taxonomy-aligned proportion of OpEx 2022	Taxonomy-aligned proportion of OpEx year N-1	Enabling activity €	Transition activity (T)
				Climate change mitigation	Climate change adaptation	Water and marine resources	Circular economy	Pollution	Biodiversity and ecosystems	Climate change mitigation (Y/N)	Climate change adaptation (Y/N)	Water and marine resources (Y/N)	Circular economy (Y/N)	Pollution (Y/N)	Biodiversity and ecosystems (Y/N)					
A. TAXONOMY-ELIGIBLE ACTIVITIES																				
A1. Environmentally sustainable activities (Taxonomy-aligned)																				
Installation, maintenance and repair of energy efficiency equipment	7.3	€6,874.7	0.020%	100%	0%	N/A	N/A	N/A	N/A	N	Y	N	N	Y	N	Y	0.020%	N/A	E	
Installation, maintenance and repair of instruments and devices for measuring, regulation and controlling energy performance of buildings	7.5	€8708.6	0.025%	100%	0%	N/A	N/A	N/A	N/A	N	Y	N	N	N	N	Y	0.025%	N/A	E	
Installation, maintenance and repair of renewable energy technologies	7.6	€3,100.0	0.009%	100%	0%	N/A	N/A	N/A	N/A	N	Y	N	N	N	N	Y	0.009%	N/A	E	
OpEx of environmentally sustainable activities (Taxonomy-aligned) (A.1)	x	€18,683.3	0.054%	100%	0%	N/A	N/A	N/A	N/A								0.054%	N/A	E	
A2. Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)																				
Renewal of waste water collection and treatment	5.4	€20,465.8	0.059%																	
Installation, maintenance and repair of energy efficiency equipment	7.3	€5,940.0	0.017%																	
OpEx of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)		€26,405.8	0.076%																	
Total (A.1 + A.2)		€45,089.08	0.131%																	
B. TAXONOMY-NON-ELIGIBLE ACTIVITIES																				
OpEx of Taxonomy-non-eligible activities (B)		€34,477 thousand	99.869%																	
TOTAL (A+B)		€34,523 thousand	100%																	

³⁾ Pending publication of details of the technical screening criteria associated to the other four environmental goals.



8

About this report





8.1. Preparation and scope

[GRI 2-3, 2-4, 3-1, 3-2]

This Integrated Report includes clear, concise and relevant information on ROVI (actions, advances and challenges) in the 2022 calendar year regarding financial, strategic and sustainability aspects that the Company has identified as material for both ROVI and its shareholders, following the annual pattern adopted by the Company. In this respect, the last Integrated Report drawn up by the Group was published in June 2022 and included the information for the 2021 calendar year.

Additionally, this document includes information that meets the requirements for the Statement of Non-Financial Information (SNFI) for 2022, in compliance with the Capital Companies Act. The previous report issued by the company was prepared in February 2022 and contained information on the 2021 calendar year. The Board of Directors of Laboratorios Farmacéuticos Rovi, S.A. approves this SNFI in accordance with Law 11/2018, which amended the Code of Commerce, the revised text of the Capital Companies Act, and the Account Auditing Act as regards disclosure of non-financial and diversity information. The external firm that checked the Integrated Report 2022 was KPMG Asesores S.L.

The information published in this document refers to the ROVI Group in its entirety (see section 3.3 "Ownership and Structure"), except when a different scope is specified. Likewise, in order to make the Group's evolution easier to understand, information on the previous year is provided.

In terms of material scope and topics, this document does not contain any significant changes when compared with the Integrated Report for 2021.

This report was drawn up using the GRI Standards as a reference. Furthermore, the structure of the information contained herein follows the IR Framework of the Integrated International Reporting Council (IIRC). Appendix III hereto contains a table showing the correlation between the GRI Standards reported and the section where the relevant information appears and also a table that sets out the correlation between

the requirements of Law 11/2018 and the content of this report.

Likewise, the information contained herein represents the expectations and beliefs of ROVI at the date of preparation hereof. This information involves known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI, or its industrial results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Therefore, ROVI wishes to state that future events or developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. Additionally, these forward-looking statements should be considered to represent the Company's expectations or beliefs at the publication date of this document and should not be relied upon at any date subsequent to the publication hereof.

The content is supplemented by the following public information on the year 2022:

- ▶ The Group's Management Report and Consolidated Annual Accounts.
- ▶ Annual Corporate Governance Report.
- ▶ Other relevant content that may be found on ROVI's corporate website: <https://www.rovi.es/es/home>.

PRINCIPLES OF THE GRI STANDARDS APPLICABLE WHEN PREPARING THE INTEGRATED REPORT OF LABORATORIOS ROVI

Accuracy

The information contained in this report is accurate in qualitative and quantitative terms, to enable the principal stakeholders to assess the organisation's performance.

Balance

This Integrated Report includes both the positive aspects of ROVI's performance and those where there is room for improvement, in order to provide a complete view of the company and its activities.

Sustainability context

ROVI, committed to sustainable development, manages all the capital flows involved in its activity responsibly, continually seeking to generate value (economic value, employment, development, etc.) for all its stakeholders.

Clarity

The information is presented in a way that is understandable, so that the principal stakeholders have a reasonable knowledge of the company and its activities.

Timeliness

The Group issues its Integrated Report annually, so that the principal stakeholders may obtain a deeper knowledge of the Company's performance and milestones in the year reported.

Comparability

The information provided contains references to previous years, so that the principal stakeholders can analyse the evolution of the organisation's performance and the performance can be analysed in comparison with that of other organisations.

Completeness

This Integrated Report provides a response to each one of the aspects identified as material, as well as the different aspects, measures and goals of ROVI, seeking to satisfy its stakeholders' information needs. This document discloses sufficient information on the activities, events and impacts in the period reported to allow their impacts to be assessed.

Verifiability

The company has processes in place to gather, record, compile and analyse the information set out in this document following recognised quality principles. Furthermore, this information is checked by a third party.



9 Appendix

Appendix I
Financial Performance

Appendix II
Our Commitment to People

Appendix III
GRI Content Index

Appendix IV
Content Index: Law 11/2018 - GRI

Appendix V
SDGs



Appendix I Financial Performance

Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries

Consolidated Statement of Financial Position as of 31 December 2022 and 31 December 2021

IN € MILLIONS	31 December, 2022	31 December, 2021
ASSETS		
Non-current assets		
Property, Plant and Equipment	215,541	181,775
Intangible assets	35,744	38,558
Investment in a joint venture	2,193	1,994
Deferred income tax assets	2,078	3,850
Equity securities	9	72
Financial receivables	65	65
	255,630	226,314
Current assets		
Inventories	311,944	245,473
Trade and other receivables	180,011	150,172
Current income tax assets	4,148	9,891
Prepaid expenses	2,025	1,791
Cash and cash equivalents	124,945	99,035
	623,073	506,362
Total assets	878,703	732,676



Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries

Consolidated Statement of Financial Position as of 31 December 2022 and 31 December 2021

IN € MILLIONS	31 December, 2022	31 December, 2021
PATRIMONIO NETO		
Equity attributed to the company	520,012	470,976
Share capital	3,241	3,364
Share premium	87,636	87,636
Legal reserve	673	673
Treasury shares	(27,561)	(66,121)
Retained earnings and voluntary reserves	256,362	292,349
Profit for the year	199,669	153,077
Accumulated other comprehensive income	(8)	(2)
Non-controlling interests	1,367	-
Total equity	521,379	470,976
LIABILITIES		
Non-current liabilities		
Financial debt	59,441	66,745
Deferred income tax liabilities	677	776
Contract liabilities	1,545	1,460
Deferred income	1,774	2,331
	63,437	71,312
Current liabilities		
Financial debt	12,725	6,417
Trade and other payables	165,776	125,173
Current tax liabilities	-	681
Contract liabilities	114,901	57,632
Deferred income	485	485
	293,887	190,388
Total liabilities	357,324	261,700
Total equity and liabilities	878,703	732,676

Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries

Consolidated income statements for 2022 and 2021

IN € MILLIONS	2022	2021
Revenue	817,698	648,677
Changes in inventories of finished goods and work in progress	38,883	782
Raw materials and consumables used	(339,824)	(264,637)
Work carried out by the Group on non-current assets	2,856	-
Employee benefit expenses	(106,522)	(89,803)
Other operating expenses	(136,482)	(93,502)
Amortisation and depreciation	(22,871)	(21,364)
Impairment of non-current assets	(2)	(95)
Recognition of government grants on non-financial non-current assets and other	2,112	1,334
Share of profits of joint venture	199	182
OPERATING PROFIT (EBIT)	256,047	181,574
Finance income	1,770	68
Finance costs	(849)	(905)
Impairment and gain or loss on measurement of financial instruments	1,820	2,069
Exchange difference	(821)	(178)
FINANCE INCOME/(COSTS) - NET	1,920	1,054
PROFIT BEFORE INCOME TAX	257,967	182,628
Income tax	(58,302)	(29,551)
PROFIT FOR THE YEAR	199,665	153,077



Laboratorios Farmacéuticos Rovi, S.A. y Sociedades Dependientes

Consolidated cash flow statements for 2022 and 2021

IN € MILLIONS	2022	2021
Cash flows from operating activities		
Profit before income tax	257,967	182,628
Adjustments for non-monetary transactions:		
Amortisation and depreciation	22,871	21,364
Finance income	(1,770)	(68)
Valuation allowance	5,160	4,885
Adjustments for changes in value of derivatives	11	(908)
Gain (or loss) on derecognition of financial assets and liabilities	(1,831)	(1,161)
Exchange differences	821	-
Finance expenses	849	905
Grants, distribution licenses and other deferred incomes	(2,904)	(6,473)
Other current assets (prepaid expenses)	(234)	(1,778)
Share of profit of joint venture	(199)	(182)
Share-based payments	-	1,403
Changes in working capital:		
Trade and other receivables	(26,820)	(74,187)
Inventories	(71,591)	(23,427)
Trade and other payables	41,672	35,358
Other collections and payments:		
Proceeds from contract manufacturing services	57,104	34,429
Proceeds from distribution licenses	385	518
Interest paid	-	(4)
Income tax cash flow	(43,889)	(23,861)
Net cash generated from (used in) operating activities	237,602	149,441
Cash flows from investing activities		
Purchases of intangible assets	(669)	(722)
Purchases of property, plant and equipment	(50,719)	(40,218)
Proceeds from sales of property, plant and equipment	78	33
Purchase of other financial assets	(5,870)	-
Proceeds from sale of other financial assets	20	-
Interest received	6	68
Net cash generated from (used in) investing activities	(57,154)	(40,839)
Cash flows from financing activities		
Repayments of financial debt	(6,768)	(6,192)
Proceeds from financial debt	1,399	1,340
Interest paid	(291)	(288)
Purchase of treasury shares	(177,008)	(78,785)
Reissue of treasury shares	77,766	42,328
Dividends paid	(51,007)	(21,132)
Capital contribution to subsidiaries	1,371	-
Net cash generated from (used in) financing activities	(154,537)	(62,729)
Net (decrease) increase in cash and cash equivalents	25,910	45,873
Cash and cash equivalents at the beginning of the year	99,035	53,162
Cash and cash equivalents at the end of the year	124,945	99,035

Tax information for 2022 by company (thousand euros)

	Country	Profit before tax	Income tax	Government grants received
Laboratorios Farmacéuticos Rovi, S.A.	Spain	44,982	(5,545)	2,109
Laboratorios Farmacéuticos Rovi, S.A. establecimiento permanente Portugal	Portugal	(132)	(20)	0
Laboratorios Farmacéuticos Rovi, S.A. establecimiento permanente Polonia	Poland	(144)	0	0
Laboratorios Farmacéuticos Rovi, S.A. establecimiento permanente Alemania	Germany	(25)	0	0
ROVI Biotech GmbH	Germany	1,014	(241)	0
ROVI Pharma Industrial Services, S.A. (*)	Spain	215,030	(53,048)	3
Pan Química Farmacéutica, S.A. (*)	Spain	512	(128)	0
Gineladius, S.L. (*)	Spain	(10)	3	0
ROVI Escúzar, S.L. (*)	Spain	(692)	173	0
Bertex Pharma GmbH	Germany	(1)	0	0
ROVI Biotech, Limited	UK	(110)	0	0
ROVI Biotech, S.R.L.	Italy	766	(334)	0
ROVI, GmbH	Switzerland	(75)	0	0
ROVI, S.A.S.	France	114	0	0
ROVI Biotech Spółka z.o.o	Poland	(104)	0	0
Glicopepton Biotech, S.L.	Spain	(9)	0	0
Total		261,116	(59,139)	2,112

This table shows the tax figures by company. The consolidated group figures at 31 December, 2022 would be:

Profit before tax: 257,967 thousand euros; Income tax: 58,302 thousand euros; Government grants received: 2,112 thousand euros.

Tax information for 2021 by company (thousand euros)

	Country	Profit before tax	Income tax	Government grants received
Laboratorios Farmacéuticos Rovi, S.A.	Spain	58,366	6,161	1,326
Laboratorios Farmacéuticos Rovi, S.A. establecimiento permanente Portugal	Portugal	357	(3)	
Laboratorios Farmacéuticos Rovi, S.A. establecimiento permanente Polonia	Poland	(68)	-	
Laboratorios Farmacéuticos Rovi, S.A. establecimiento permanente Alemania	Germany	872	-	
ROVI Biotech GmbH	Germany	(16)	-	
ROVI Pharma Industrial Services, S.A. (*)	Spain	146,891	(35,469)	4
Pan Química Farmacéutica, S.A. (*)	Spain	91	(23)	
Gineladius, S.L. (*)	Spain	(34)	9	
ROVI Escúzar, S.L. (*)	Spain	(392)	98	
Bertex Pharma GmbH	Germany	(15)	-	
ROVI Biotech, Limited	UK	91	-	
ROVI Biotech, S.R.L.	Italy	533	(98)	
ROVI, GmbH	Switzerland	747	(196)	4
ROVI, S.A.S.	France	27	-	
ROVI Biotech Spółka z.o.o	Poland	(155)	(4)	
Total		207,295	(29,525)	1,334

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

Note: There may be discrepancies in the totals due to rounding up or down.



Appendix II Our Commitment to People

Total number and distribution of employees by:

Gender

Gender	2022	2021	Variation %
Men	943	834	13%
Women	1,050	917	15%
Total	1,993	1,751	14%

Age and gender

	2022			2021			Variation %
	Men	Women	Total	Men	Women	Total	
18-30 years	200	252	452	188	251	439	3%
31-40 years	261	297	558	244	258	502	11%
41-50 years	278	305	583	252	250	502	16%
51-60 years	180	154	334	133	136	269	24%
>60 years	24	42	66	17	22	39	69%
Total	943	1,050	1,993	834	917	1,751	14%

Country and gender

Country	2022			2021		
	Men	Women	Total	Men	Women	Total
Spain	894	979	1,873	816	893	1,709
UK	5	5	10	1	1	2
Germany	20	30	50	12	14	26
Italy	5	16	21	0	3	3
France	7	3	10	4	1	5
Poland	1	2	3	0	1	1
Portugal	3	8	11	1	4	5
Chile	1	-	1	-	-	-
Romania	3	3	6	-	-	-
Venezuela	3	1	4	-	-	-
Turkey	-	1	1	-	-	-
Argentina	-	1	1	-	-	-
Morocco	-	1	1	-	-	-
Colombia	1	-	1	-	-	-
Total	943	1,050	1,993	834	917	1,751

Professional classification* and gender

	2022			2021			Variation %
	Men	Women	Total	Men	Women	Total	
1	1	6	7	1	5	6	17%
2	53	70	123	62	60	122	1%
3	185	197	382	144	151	295	29%
4	164	125	289	145	122	267	8%
5	323	335	658	287	297	584	13%
6	103	134	237	98	128	226	5%
7	64	121	185	64	124	188	-2%
8	3	1	4	3	1	4	0%
0	12	5	17	12	5	17	0%
Subsidiaries	35	56	91	18	24	42	117%
Total	953	1,050	1,993	834	917	1,751	14%

*Professional group according to the XX Collective Agreement of the Chemical Industry.

Distribution of contract types by:

Gender

	2022			2021			Variación %
	Men	Women	Total	Men	Women	Total	
Permanent full-time	828	882	1,710	632	669	1,301	31%
Permanent part-time	1	4	5	1	3	4	25%
Permanent reduced hours	7	45	52	3	36	39	33%
Total permanent	836	931	1,767	636	708	1,344	31%
Temp. specific project or service	0	0	0	1	-	1	-100%
Temp. work backlog	46	37	83	135	118	253	-67%
Temp. substitution contract	4	11	15	6	10	16	-6%
Training/apprenticeship	47	43	90	47	57	104	-13%
Temp. part-time	10	28	38	9	24	33	15%
Total temporary	107	119	226	198	209	407	-44%
Total	943	1,050	1,993	834	917	1,751	14%



Age

	2022						2021					
	18-30	31-40	41-50	51-60	>60	Total	18-30	31-40	41-50	51-60	>60	Total
Total Permanent	312	528	569	330	28	1,767	219	414	449	249	13	1,344
Temp. specific project or service	-	-	-	-	-	-	1	-	-	-	-	1
Temp. work backlog	53	18	10	2	-	83	116	74	48	15	-	253
Temp. substitution contract	8	1	4	1	1	15	4	6	5	1	-	16
Training/ apprenticeship	78	11	-	1	-	90	97	7	-	-	-	104
Temp. part-time	1	-	-	-	37	38	2	1	-	4	26	33
Total	452	558	583	334	66	1,993	439	502	502	269	39	1,751

Professional classification*

	2022										
	1	2	3	4	5	6	7	8	0	Subsidiaries	Total
Permanent	6	86	337	236	580	229	183	4	17	89	1,767
Temp. specific project or service	-	-	-	-	-	-	-	-	-	-	0
Temp. work backlog	-	32	20	3	25	1	-	-	-	2	83
Temp. substitution contract	-	5	4	1	5	-	-	-	-	-	15
Training/ apprenticeship	-	-	8	34	41	7	-	-	-	-	90
Temp. part-time	1	-	13	15	7	-	2	-	-	-	38
Total	7	123	382	289	658	237	185	4	17	91	1,993
	2021										
	1	2	3	4	5	6	7	8	0	Subsidiaries	Total
Permanent	6	28	206	226	437	191	187	4	17	42	1,344
Temp. specific project or service	0	0	0	0	0	1	0	0	0	0	1
Temp. work backlog	0	90	64	13	73	13	0	0	0	0	253
Temp. substitution contract	0	2	6	0	5	3	0	0	0	0	16
Training/ apprenticeship	0	0	9	16	61	18	0	0	0	0	104
Temp. part-time	0	2	10	12	8	0	1	0	0	0	33
Total	6	122	295	267	584	226	188	4	17	42	1,751

*Professional group according to the XX Collective Agreement of the Chemical Industry.

Number of dismissals by:

Gender

	2022	2021	Variation %
Men	18	10	80%
Women	15	11	36%
Total	33	21	57%

Age and gender

	2022			2021			Variation %
	Men	Women	Total	Men	Women	Total	
18-30 years	2	2	4	3	1	4	0%
31-40 years	5	5	10	2	2	4	150%
41-50 years	6	5	11	1	6	7	57%
51-60 years	5	2	7	4	2	6	17%
>60 years	-	1	1	0	0	0	-
Total	18	15	33	10	11	21	57%

Clasificación profesional* y género

	2022			2021			Variation %
	Men	Women	Total	Men	Women	Total	
1	-	-	0	0	0	0	-
2	2	2	4	2	1	3	33%
3	2	3	5	1	0	1	n.a.
4	3	3	6	1	1	2	n.a.
5	7	7	14	5	4	9	56%
6	3	-	3	1	3	4	-25%
7	1	-	1	0	2	2	-50%
8	-	-	0	0	0	0	-
0	-	-	0	0	0	0	-
Subsidiaries	-	-	0	0	0	0	-
Total	18	15	33	10	11	21	57%

*Professional group according to the XX Collective Agreement of the Chemical Industry.

Accident rate

Work-related accident frequency rate* by gender:

Gender	2022	2021	Variation %
Men	6.041	6.872	-12%
Women	7.903	7.132	11%
Total	7.025	7.008	0%

(*) Rate calculated as N° accidents / N° of hours worked * 1,000,000.

Work-related accident severity rate* by gender:

Gender	2022	2021	Variation %
Men	0.136	0.228	-40%
Women	0.211	0.313	-33%
Total	0.176	0.273	-36%

(*) Rate calculated as N° of working days lost / N° of hours worked * 1,000.

Work-related accident incidence rate* by gender:

Gender	2022	2021	Variation %
Men	1.591	1.799	-12%
Women	2.095	1.854	13%
Total	1.856	1.828	2%

(*) Rate calculated as N° accidents / N° workers* 100.

Number of work-related accidents* by gender:

Gender	2022	2021	Variation %
Men	15	15	-
Women	22	17	29%
Total	37	32	16%

(*) Accidents in itinere and data of ROVI Group employees are included. Information on personnel hired through temporary employment companies is excluded. In addition, a working day of 8 hours has been used to calculate the number of working days lost.

Absence rate

Summary of sick leave rates in the period

	2022	2021
Total SL rate	3.41%	3.31%
SL rate: AW & OD	0.10%	0.23%
SL rate: CC	2.21%	2.49%
SL rate: COVID-19	0.69%	0.60%

IT: Sick leave; AT: Accidents at work; EP: Occupational diseases CC: Common contingencies.

Source: FREMAP Work Accident Mutual. Annual Global Absenteeism Report ROVI GROUP.

	2022				2021			
	Days sick leave	Days worked	Absence rate	Sector absence rate	Days sick leave	Days worked	Absence rate	Sector absence rate
Total	23,122	677,998	3.41%	4.68%	18,975	573,098	3.31%	4.30%

Days sick leave: days sick leave for AW+OD+CC+COVID-19 recorded.

Notional days worked: days worked by each worker in companies with professional and common cover with a mutual society that collaborates with the Social Security. In the file of movements sent by the General Treasury of the Social Security, the days worked in the Company by each worker are calculated and the days of all the workers are added together.

Total absolute absence rate: percentage ratio between the days of sick leave (AW+OD+CC+COVID-19) and the notional days worked by each worker in companies with professional and common cover with a mutual society that collaborates with the Social Security (Days sick leave AW+OD+CC+COVID-19 / notional days) * 100.

Source: FREMAP Work Accident Mutual. Annual global Absenteeism Report ROVI Group.

Average remuneration* by:

Gender

Gender	2022	2021	Variation %
Men	38,386 €	36,868 €	4%
Women	35,647 €	34,082 €	5%
Total	37,016 €	35,475 €	4%

Age and gender

	2022			2021			Variation %
	Men	Women	Total	Men	Women	Total	
18-30 years	24,470 €	26,246 €	25,460 €	23,834 €	25,446 €	24,755 €	3%
31-40 years	31,345 €	34,217 €	32,874 €	30,369 €	33,647 €	32,053 €	3%
41-50 years	39,157 €	40,567 €	39,895 €	42,676 €	39,149 €	40,919 €	-3%
51-60 years	59,134 €	44,054 €	52,181 €	51,848 €	41,689 €	46,712 €	12%
>60 years	66,357 €	35,610 €	46,791 €	71,023 €	33,135 €	49,650 €	-6%



Professional group** and gender

	2022			2021			Variation %
	Men	Women	Wage gap***	Men	Women	Wage gap***	
1	17,035 €	18,266 €	7%	16,657 €	18,277 €	10%	-2.5 pp
2	18,207 €	18,397 €	1%	17,777 €	17,995 €	1%	-0.2 pp
3	20,084 €	21,022 €	5%	19,493 €	21,004 €	8%	-3.1 pp
4	26,989 €	26,475 €	-2%	27,118 €	26,098 €	-4%	1.9 pp
5	35,244 €	34,230 €	-3%	34,466 €	32,267 €	-6%	3.5 pp
6	46,540 €	41,051 €	-12%	43,690 €	38,127 €	-13%	0.9 pp
7	62,802 €	57,793 €	-8%	59,776 €	55,067 €	-8%	-0.1 pp
8	123,418 €	108,276 €	-12%	117,420 €	106,262 €	-10%	-2.8 pp
0	282,829 €	147,637 €	-48%	231,341 €	137,942 €	-40%	-7.4 pp
Subsidiaries	88,937 €	67,397 €	-24%	97,943 €	68,293 €	-30%	6.1 pp

* Scholarship remuneration is not included because scholarship-holders do not have a Professional Group.

**Professional Group according to the XX Collective Agreement of the Chemical Industry.

*** Wage gap calculated as the difference between the average salary of men versus that of women.

The remuneration figures shown above contain items relating to fixed remuneration and variable remuneration (commissions and bonuses).

Average executive remuneration

	2022			2021			Variation %
	Men	Women	Average	Men	Women	Average	
Fixed remuneration	245,923 €	127,336 €	186,629 €	188,400 €	117,510 €	152,955 €	22%
Variable remuneration	87,760 €	40,948 €	64,354 €	78,400 €	35,373 €	56,886 €	13%
Remuneration in kind	11,029 €	8,974 €	10,002 €	10,921 €	8,943 €	9,932 €	1%
Total average	344,711 €	177,258 €	260,985 €	277,720 €	161,826 €	219,773 €	19%

Median remuneration by:

Gender

Gender	2022
Men	28,969 €
Women	30,007 €
Total	29,488 €

Training

	2022	2021	Variation %
Total hours of training	56,885	49,393	15%
Training hours per employee	28.54	20.28	41%
% of employees who have received some kind of training	100%	52%	48.0 pp
Investment in training per employee (€)	240.30 €	221.94 €	8%
Total investment in training	478,926 €	388,629 €	23%

Training

Total training hours per professional group

	2022
1	21.86
2	18.14
3	19.59
4	21.68
5	31.74
6	37.24
7	37.16
8	25.00
0	26.76

Average hours of training by gender

	2022
Men	26.9
Women	30.02

Investment in training per employee and by gender

	2022
Men	231 €
Women	248 €

Distribution of employees by educational level:

	2022	
	Men	Women
N° studies	16	21
Bsic	69	73
Secondary	197	192
Professional training	230	244
University graduates	412	487
Doctorate	19	33



Appendix III GRI Content Index

Declaration of use ROVI has presented the information cited in this GRI Content Index for the period running from 1 January, 2022 to 31 December, 2022 using the GRI Standards as a reference.

Declaration of use GRI 1: Foundation 2021

GRI STANDARD	CONTENT	LOCATION
GRI 2: General Disclosures 2021	2-1 Organizational details	3.1. Group Profile 3.2. National and International Presence 3.3. Ownership and Structure
	2-2 Entities included in the organization's sustainability reporting	3.3. Ownership and Structure
	2-3 Reporting period, frequency and contact point	8.1. Preparation and Scope
	2-4 Restatements of information	8.1. Preparation and Scope
	2-5 External assurance	8.1. Preparation and Scope
	2-6 Activities, value chain and other business relationships	2.2. Key Milestones 2022 2.3. Our Response to the Key Challenges of 2022 3.2. National and International Presence 3.4. Business Units 6.2.3.1. Ensuring sustainability in the supply chain
	2-7 Employees	6.2.2.1. Ensuring the stability of our workforce Appendix II – Our Commitment to People
	2-8 Workers who are not employees	Appendix II – Our Commitment to People
	2-9 Governance structure and composition	6.1.1. Our corporate governance model and structure
	2-10 Nomination and selection of the highest governance body	6.1.1. Our corporate governance model and structure
	2-11 Chair of the highest governance body	6.1.1. Our corporate governance model and structure
	2-12 Role of the highest governance body in overseeing the management of impacts	6.1.1. Our corporate governance model and structure
	2-13 Delegation of responsibility for managing impacts	6.1.1. Our corporate governance model and structure
	2-14 Role of the highest governance body in sustainability reporting	6.1.1. Our corporate governance model and structure
2-16 Communication of critical concerns	6.2.3.4. Promoting active communication with our suppliers 6.1.2. Ethics and integrity in the business model	

GRI STANDARD	CONTENT	LOCATION
	2-18 Evaluation of the performance of the highest governance body	6.1.1. Our corporate governance model and structure
	2-19 Remuneration policies	6.1.4. Remuneration policy
	2-10 Process to determine remuneration	6.1.4. Remuneration policy
	2-22 Statement of sustainable development strategy	4.5. ESG Master Plan
	2-23 Policy commitments	4.2. Identity and Commitment: mission, vision and values 4.3. Corporate Strategy 6.1.2. Ethics and integrity in the business model 6.3.1. Environmental policy, goals and commitments
	2-24 Embedding policy commitments	6.1. Our Commitment to Good Governance
	2-25 Processes to remediate negative impacts	Appendix II – Our Commitment to People
	2-26 Mechanisms for seeking advice and raising concerns	6.1.2. Ethics and integrity in the business model
	2-27 Compliance with laws and regulations	6.1.3. Regulatory compliance
	2-28 Membership of associations	6.1.2. Ethics and integrity in the business model 6.2.1.3. Promoting responsible marketing 6.2.4.2. Boosting social action
	2-29 Approach to stakeholder engagement	4.4. Materiality 6.2.1.4. Maintaining active communication with our customers, patients and healthcare professionals 6.2.2.6. Achieving the well-being of our employees 6.2.3.2. Ensuring the safety and quality of the supply chain 6.2.3.4. Promoting active communication with our suppliers 6.2.4.4. Dialogue with local communities
	2-30 Collective bargaining agreements	6.2.2.7. Ensuring social dialogue
GRI 3: Material Topics 2021	3-1 Process to determine material topics	4.4. Materiality
	3-2 List of material topics	4.4. Materiality
	3-3 Management of material topics	4.4. Materiality 5.3. Tax transparency 6.1.2. Ethics and integrity in the business model 6.1.3. Regulatory compliance 6.2.1.3. Promoting responsible marketing 6.2.2.1. Ensuring the stability of our workforce 6.2.2.2. Seeking to attract and retain talent 6.2.2.3. Protecting health and safety 6.2.2.4. Promoting equal opportunities, diversity and inclusion 6.2.2.5. Boosting training, development and performance evaluation 6.2.2.6. Achieving the well-being of our employees 6.2.2.7. Ensuring social dialogue 6.2.3.2. Ensuring the safety and quality of the supply chain 6.2.4.2. Boosting social action 6.3.1. Environmental policy, goals and commitments 6.3.1. Environmental policy, goals and commitments 6.3.2. Environmental management system 6.3.3. Sustainable use of resources



GRI STANDARD	CONTENT	LOCATION
GRI 201: Economic performance 2016	201-4 Financial assistance received from government	5.3. Tax transparency
GRI 204: Procurement Practices 2016	204-1 Proportion of spending on local suppliers	6.2.3.1. Ensuring sustainability in the supply chain
GRI 207: Tax 2019	207-1 Approach to tax	5.3. Tax transparency
GRI 301: Materials 2016	301-1 Materials used by weight or volume	6.3.3. Sustainable use of resources
GRI 302: Energy 2016	302-1 Energy consumption within the organization	6.3.3. Sustainable use of resources
	302-3 Energy intensity	6.3.3. Sustainable use of resources
	302-4 Reduction of energy consumption	6.3.5. Mitigation of climate change
	303-2 Management of water discharge-related impacts	6.3.3. Sustainable use of resources
	303-3 Water withdrawal	6.3.3. Sustainable use of resources
GRI 305: Emissions 2016	305-1 Direct (Scope 1) GHG emissions	6.3.5. Mitigation of climate change
	305-2 Energy indirect (Scope 2) GHG emissions	6.3.5. Mitigation of climate change
	305-3 Other indirect (Scope 3) emissions	6.3.5. Mitigation of climate change
	305-4 GHG emissions intensity	6.3.5. Mitigation of climate change
	305-7 Nitrogen oxides (NOx), sulfur oxides (SOx), and other significant air emissions	6.3.5. Mitigation of climate change
GRI 306: Waste 2020	306-2 Waste by type and disposal method	6.3.4. Waste management and circular economy
	306-3 Waste generated	6.3.4. Waste management and circular economy
	306-4 Waste diverted from disposal	6.3.4. Waste management and circular economy
	306-5 Waste directed to disposal	6.3.4. Waste management and circular economy
GRI 308: Supplier Environmental Assessment 2016	308-1 New suppliers that were screened using environmental criteria	6.2.3.2. Ensuring the safety and quality of the supply chain
GRI 401: Employment 2016	401-1 New employee hires and employee turnover	6.2.2.1. Ensuring the stability of our workforce 6.2.2.2. Seeking to attract and retain talent
GRI 402: Labor/ Management Relations 2016	402-1 Minimum notice periods regarding operational changes	6.2.2.7. Ensuring social dialogue

GRI STANDARD	CONTENT	LOCATION
GRI 403: Occupational Health and Safety 2018	403-1 Occupational health and safety management system	6.2.2.3. Protecting health and safety
	403-4 Worker participation, consultation and communication on occupational health and safety	6.2.2.3. Protecting health and safety 6.2.2.7. Ensuring social dialogue
	403-5 Worker training on occupational health and safety	6.2.2.3. Protecting health and safety 6.2.2.5. Boosting training, development and performance evaluation
	403-6 Promotion of worker health	6.2.2.6. Achieving the well-being of our employees
	403-9 Work-related injuries	6.2.2.3. Protecting health and safety
	403-10 Work-related ill-health	6.2.2.3. Protecting health and safety
GRI 404: Training and Education 2016	404-1 Average hours of training per year per employee	6.2.2.5. Boosting training, development and performance evaluation
	404-2 Programs for upgrading employee skills and transition assistance programs	6.2.2.5. Boosting training, development and performance evaluation
GRI 405: Diversity and Equal Opportunity 2016	405-1 Diversity of governance bodies and employees	6.1.1. Our corporate governance model and structure 6.2.2.1. Ensuring the stability of our workforce 6.2.2.4. Promoting equal opportunities, diversity and inclusion
	405-2 Ratio of basic salary and remuneration of women to men	6.2.2.4. Promoting equal opportunities, diversity and inclusion
GRI 413: Local Communities 2016	413-1 Operations with local community engagement, impact assessments and development programs	6.2.4.2. Boosting social action 6.2.4.4. Dialogue with local communities
GRI 414: Supplier Social Assessment 2016	414-1 New suppliers that were screened using social criteria	6.2.3.2. Ensuring the safety and quality of the supply chain
GRI 417: Marketing and Labeling 2016	417-2 Incidents of non-compliance concerning product and service information and labeling	6.2.1.3. Promoting responsible marketing



Appendix IV Content Index: Law 11/2018 - GRI

Information required by Law 11/2018	Relationship with GRI indicators (Guidance only)	Location
General information		
Business model		
Brief description of the group's business (business environment and organisation).	2-1 2-2 2-6	3.1. Group Profile 3.3. Ownership and Structure 3.4. Business Units
Geographic presence.	2-1 2-6	3.2. National and International Presence
The organisation's objectives and strategies.	2-22	4.3.2. Strategic priorities and goals
Main factors and trends that may affect future evolution.	Company's criteria	4.1. Market Context
General		
Reference in the report to the national, European or international reporting framework used to select the key non-financial performance indicators included in each section.	GRI 1: Foundation	8. About this Report
A description of the policies applied by the Group on these issues, which will include the due diligence procedures applied to identify, assess, prevent and attenuate material risks and impact and the verification and control procedures, including the measures adopted.	3-3 103-2	6.1. Our Commitment to Good Governance
The results of these policies, including relevant key non-financial results indicators that allow the monitoring and evaluation of the progress and favour comparability between companies and sectors, in accordance with the national, European or international frameworks used as a reference for each subject.	3-3	6.1. Our Commitment to Good Governance
The key risks related to these issues linked to the group's activity, among them, when relevant and proportionate, its trading relations, goods or services that may have adverse effects in these areas, and how the group manages said risks, explaining the procedures used to detect and assess them, in accordance with the national, European or international frameworks used as a reference for each subject. Information on impacts observed should be included, providing a breakdown thereof, in particular, of the key short-, medium- and long-term risks.	205-1	6.1. Our Commitment to Good Governance

Information required by Law 11/2018	Relationship with GRI indicators (Guidance only)	Location
Environmental topics		
On the current and foreseeable effects of the company's activities on the environment and, where applicable, health and safety.	Company's criteria	6.3.2. Environmental management system
On the environmental evaluation or certification procedures.	Company's criteria	6.3.2. Environmental management system
On the resources devoted to environmental risk prevention.	Company's criteria	6.3.2. Environmental management system
On application of the precautionary principle.	3-3 102-15	6.3.1. Environmental policy, goals and commitments 6.3.2. Environmental management system
On the amount of environmental risk provisions and guarantees.	Company's criteria	6.3.2. Environmental management system
Pollution		
Measures to prevent, reduce or repair emissions that seriously affect the environment, taking into account any form of atmospheric pollution specific to an activity, including noise and light pollution.	305-5	6.3.5. Mitigation of climate change
Circular economy and waste prevention and management		
Measures for waste prevention, recycling and reutilisation and other forms of waste recovery and disposal; actions to combat food waste.	306-4 306-5	6.3.4. Waste management and circular economy
Sustainable use of resources		
Water consumption and water supply in accordance with local limitations.	303-5 303-2	6.3.3. Sustainable use of resources
Consumption of raw materials and measures adopted to enhance efficiency in using them.	301-1	6.3.3. Sustainable use of resources
Direct or indirect energy consumption.	302-1	6.3.3. Sustainable use of resources
Measures taken to improve energy efficiency.	302-4	6.3.1. Environmental policy, goals and commitments 6.3.3. Sustainable use of resources
Use of renewable energies.	302-4	6.3.3. Sustainable use of resources
Climate change		
Important elements of greenhouse gas emissions generated as a result of the company's activity, including the use of the goods and services it produces.	305-1 305-2 305-3	6.3.5. Mitigation of climate change
Measures taken to adapt to the consequences of climate change.	201-2	6.3. Our Commitment to the Environment
Medium- and long-term reduction measures fixed voluntarily to reduce greenhouse gas emissions and the means implemented for this purpose.	305-5	6.3.1. Environmental policy, goals and commitments 6.3.5. Mitigation of climate change



Information required by Law 11/2018

Relationship with GRI indicators (Guidance only)

Location

Biodiversity protection

Measures taken to conserve or restore biodiversity.	Company's criteria	6.3.3. Sustainable use of resources
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Impacts caused by the activities or operations in protected areas.	Company's criteria	6.3.3. Sustainable use of resources
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Social and employee topics

Employment

Total number and distribution of employees, employing criteria that represent diversity (gender, age, country, etc.).	2-6 2-7 405-1	6.2.2.1. Ensuring the stability of our workforce Appendix II – Our Commitment to People
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Total number and distribution of types of employment contracts, annual average of permanent contracts, temporary contracts and part-time contracts by gender, age and professional classification.	2-7	Appendix II – Our Commitment to People
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Number of dismissals by gender, age and professional classification.	401-1	Appendix II – Our Commitment to People
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Average remuneration and the evolution thereof broken down by gender, age and professional classification or equivalent.	405-2	Appendix II – Our Commitment to People
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Wage gap, remuneration for the same jobs or average remuneration in the company.	405-1 s	6.2.2.4. Promoting equal opportunities, diversity and inclusion Appendix II – Our Commitment to People
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Average remuneration of directors and management, including variable remuneration, per diems and indemnities.	405-2	6.1.4. Remuneration policy
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Payment into long-term savings schemes and any other amounts received, broken down by gender.	2-19	6.2.2.6. Achieving the well-being of our employees Appendix II – Our Commitment to People
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Implementation of disconnection-from-work policies.	Company's criteria	6.2.2.6. Achieving the well-being of our employees
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Employees with disabilities.	405-1	6.2.2.4. Promoting equal opportunities, diversity and inclusion
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Organisation of work

Organisation of working time.	Company's criteria	6.2.2.6. Achieving the well-being of our employees
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Number of hours of absence.	403-9	6.2.2.3. Protecting health and safety
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Measures aimed to facilitate reconciliation of family life and work and foster the co-responsibility of both parents.	Company's criteria	6.2.2.6. Achieving the well-being of our employees
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Information required by Law 11/2018	Relationship with GRI indicators (Guidance only)	Location
Health and safety		
Workplace health and safety conditions.	403-1	6.2.2.3. Protecting health and safety
Workplace accidents, in particular their frequency and severity, as well as occupational diseases, broken down by gender.	403-9	Appendix II – Our Commitment to People
Social relations		
Organisation of social dialogue, including procedures to inform and consult the personnel and negotiate with them.	Company's criteria	6.2.2.7. Ensuring social dialogue
Percentage of employees covered by collective agreements by country.	2-30	6.2.2.7. Ensuring social dialogue
The balance of the collective agreements, particularly in the workplace health and safety field.	403-4	6.2.2.3. Protecting health and safety
Training		
The policies implemented in the training field.	Company's criteria	6.2.2.5. Boosting training, development and performance evaluation
Total number of hours of training by professional category.	404-1	6.2.2.5. Boosting training, development and performance evaluation
Universal accessibility for persons with disabilities		
Universal accessibility for persons with disabilities.	405-1	6.2.2.4. Promoting equal opportunities, diversity and inclusion
Equality		
Measures adopted to promote equal treatment and opportunities for women and men.	405-2	6.2.2.4. Promoting equal opportunities, diversity and inclusion
Equality Plans (Chapter III of Organic Law 3/2007, of 22 March, for the effective equality between men and women), measures adopted to promote employment, protocols against sexual and gender harassment, the inclusion of universal accessibility for persons with disabilities.	Company's criteria	6.2.2.4. Promoting equal opportunities, diversity and inclusion
The policy against all kinds of discrimination and, where applicable, diversity management policy.	Company's criteria	6.2.2.4. Promoting equal opportunities, diversity and inclusion
Respect for human rights		
Application of due diligence procedures in respect of human rights; prevention of risks of violation of human rights and, where applicable, measures to mitigate, manage and provide reparation for any possible abuses committed.	2-28	4.5. ESG Master Plan 6.1.2 Ethics and integrity in the business model
Reports of cases of violation of human rights	406-1 2-27	6.1.2. Ethics and integrity in the business model



Information required by Law 11/2018

Relationship with GRI indicators (Guidance only)

Location

Promotion of and compliance with the provisions of the fundamental conventions of the World Labour Organisation related to respect for freedom of association and the right to collective bargaining; the elimination of discrimination in respect of employment and occupation; the elimination of forced or compulsory labour; and the effective abolition of child labour.

407-1

6.2.2.7. Ensuring social dialogue

Fight against corruption and bribery

Measures adopted to prevent corruption and bribery.

2-23
2-26
102-16

6.1.3. Regulatory compliance

Anti-money laundering measures taken.

2-23
2-26

6.1.3. Regulatory compliance

Contributions to non-profit foundations and entities.

413-1

6.2.4.2. Boosting social action

Information about society

Company's commitments to sustainable development

The impact of the company's activity on local employment and development.

204-1
413-1
201-1

6.2.2.1. Ensuring the stability of our workforce

The impact of the company's activity on the local population and the population of the territory.

204-1
413-1
201-1
203-16.2.4. Commitment and contribution to the environment in which ROVI operates
6.2.4.2. Boosting social action

Relations maintained with local community players and methods for dialogue with them.

2-29

6.2.4.2. Boosting social action
6.2.4.4. Dialogue with local communities

Partnership or sponsorship actions.

2-28

6.2.4.2. Boosting social action

Subcontracting and suppliers

The inclusion of social, gender equality and environmental issues in the purchasing policy.

2-6
308-1
414-1

6.2.3.4. Promoting active communication with our suppliers

In relations with new suppliers, consideration of their social and environmental activity.

308-1
414-16.2.3.1. Ensuring sustainability in the supply chain
6.3.2. Environmental management system

Oversight and Audit systems and the results thereof.

2-25

6.2.1.1. Ensuring product quality and safety
6.2.3.2. Ensuring the safety and quality of the supply chain

Consumers

Consumer health and safety measures.

2-6
308-1
414-16.2.1.1. Ensuring product quality and safety
6.2.3.2. Ensuring the safety and quality of the supply chain

Information required by Law
11/2018
Relationship with GRI
indicators (Guidance only)
Location

Complaints system, complaints received and solution thereof.

2-25

 6.2.1.4. Maintaining active communication with our customers, patients and healthcare professionals
 Appendix II - Our Commitment to People

Tax information

Tax policy.

207-1

5.3. Tax Transparency

Profits obtained by country.

Company's criteria

Appendix I – Financial Performance

Income taxes paid.

Company's criteria

Appendix I – Financial Performance

Public grants received.

Company's criteria

Appendix I – Financial Performance

Other significant information
Other useful information on preparing this document

Bases for reporting the information.

 2-1
 2-3
 2-5

8. About this Report

Scope of the report.

 2-2
 2-3
 2-4
 3-1
 3-2
 3-3
 102-54

8. About this Report

Relations with stakeholders.

 2-6
 2-29

 4.4. Materiality
 6.2.1.4. Maintaining active communication with our customers, patients and healthcare professionals
 6.2.2.6. Achieving the well-being of our workforce
 6.2.3.2. Ensuring the safety and quality of the supply chain
 6.2.3.4. Promoting active communication with our suppliers
 6.2.4.4. Dialogue with local communities

Risk management.

 2-12
 3-3
 103-2

6.1. Our Commitment to Good Governance

Corporate governance.

 2-9
 2-11
 2-19
 102-35

6.1. Our Commitment to Good Governance

Mechanisms and procedures to promote worker involvement in company management in terms of information, consultation and participation.

6.2.2. Commitment to our employees

EU Taxonomy

EU Taxonomy

Company's criteria

7. European Union Taxonomy



Appendix V SDGs

Our contribution to the SDGs regarding Good Governance:

GOALS



GOAL 5.5 "Ensure women's full and effective participation and equal opportunities for leadership at all levels of decision making in political, economic and public life."



GOAL 8.3 "Promote development-oriented policies that support productive activities, decent job creation, entrepreneurship, creativity and innovation, and encourage the formalization and growth of micro-, small- and medium-sized enterprises, including through access to financial services."

GOAL 8.7 "Take immediate and effective measures to eradicate forced labour, end modern slavery and human trafficking and secure the prohibition and elimination of the worst forms of child labour, including recruitment and use of child soldiers, and by 2025 end child labour in all its forms."



GOAL 16.5 "Substantially reduce corruption and bribery in all their forms."

GOAL 16.7 "Ensure responsive, inclusive, participatory and representative decision-making at all levels."

Our contribution to the SDGs regarding People:

GOALS



GOAL 3.4 "By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being."

GOAL 3.8 "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all."

GOAL 3.9.b "Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all."

GOALS



GOAL 4.3 “By 2030, ensure equal access for all women and men to affordable and quality technical, vocational and tertiary education, including university.”

GOAL 4.4 “By 2030, substantially increase the number of youth and adults who have relevant skills, including technical and vocational skills, for employment, decent jobs and entrepreneurship.”

GOAL 4.5 “By 2030, eliminate gender disparities in education and ensure equal access to all levels of education and vocational training for the vulnerable, including persons with disabilities, indigenous peoples and children in vulnerable situations.”

GOAL 4.7 “By 2030, ensure that all learners acquire the knowledge and skills needed to promote sustainable development, including, among others, through education for sustainable development and sustainable lifestyles, human rights, gender equality, promotion of a culture of peace and non-violence, global citizenship and appreciation of cultural diversity and of culture’s contribution to sustainable development.”



GOAL 5.1 “End all forms of discrimination against all women and girls everywhere.”

GOAL 5.2 “Eliminate all forms of violence against all women and girls in the public and private spheres, including trafficking and sexual and other types of exploitation.”

GOAL 5.c “Adopt and strengthen sound policies and enforceable legislation for the promotion of gender equality and the empowerment of all women and girls at all levels.”



GOAL 8.2 “Achieve higher levels of economic productivity through diversification, technological upgrading and innovation, including through a focus on high-value added and labour-intensive sectors.”

GOAL 8.3 “Promote development-oriented policies that support productive activities, decent job creation, entrepreneurship, creativity and innovation, and encourage the formalization and growth of micro-, small- and medium-sized enterprises, including through access to financial services.”

GOAL 8.5 “By 2030, achieve full and productive employment and decent work for all women and men, including for young people and persons with disabilities, and equal pay for work of equal value.”

GOAL 8.6 “By 2020, substantially reduce the proportion of youth not in employment, education or training.”

GOAL 8.7 “Take immediate and effective measures to eradicate forced labour, end modern slavery and human trafficking and secure the prohibition and elimination of the worst forms of child labour, including recruitment and use of child soldiers, and by 2025 end child labour in all its forms.”

GOAL 8.8 “Protect labour rights and promote safe and secure working environments for all workers, including migrant workers, in particular women migrants, and those in precarious employment.”

GOALS



GOAL 9.1 “Develop quality, reliable, sustainable and resilient infrastructure, including regional and transborder infrastructure, to support economic development and human well-being, with a focus on affordable and equitable access for all.”

GOAL 9.2 “Promote inclusive and sustainable industrialization and, by 2030, significantly raise industry’s share of employment and gross domestic product, in line with national circumstances, and double its share in least developed countries.”

GOAL 9.5 “Enhance scientific research, upgrade the technological capabilities of industrial sectors in all countries, in particular developing countries, including, by 2030, encouraging innovation and substantially increasing the number of research and development workers per 1 million people and public and private research and development spending.”



GOAL 10.2 “By 2030, empower and promote the social, economic and political inclusion of all, irrespective of age, sex, disability, race, ethnicity, origin, religion or economic or other status.”

GOAL 10.3 “Ensure equal opportunity and reduce inequalities of outcome, including by eliminating discriminatory laws, policies and practices and promoting appropriate legislation, policies and action in this regard.”

GOAL 10.4 “Adopt policies, especially fiscal, wage and social protection policies, and progressively achieve greater equality.”



GOAL 12.6 “Encourage companies, especially large and transnational companies, to adopt sustainable practices and to integrate sustainability information into their reporting cycle.”



GOAL 13.3 “Improve education, awareness-raising and human and institutional capacity on climate change mitigation, adaptation, impact reduction and early warning.”



GOAL 16.2 “End abuse, exploitation, trafficking and all forms of violence against and torture of children.”

GOAL 16.10.b “Promote and enforce non-discriminatory laws and policies for sustainable development.”



GOAL 17.17 “Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships Data, monitoring and accountability.”

Our contribution to the SDGs regarding the Environment:

GOALS



GOAL 6.3 “By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally.”

GOAL 6.4 “By 2030, substantially increase water-use efficiency across all sectors and ensure sustainable withdrawals and supply of freshwater to address water scarcity and substantially reduce the number of people suffering from water scarcity.”



GOAL 7.2 “By 2030, increase substantially the share of renewable energy in the global energy mix.”



GOAL 8.4 “Improve progressively, through 2030, global resource efficiency in consumption and production and endeavour to decouple economic growth from environmental degradation, in accordance with the 10-year framework of programmes on sustainable consumption and production, with developed countries taking the lead.”



GOAL 9.4 “By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities.”



GOAL 12.2 “By 2030, achieve the sustainable management and efficient use of natural resources.”

GOAL 12.4 “By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.”

GOAL 12.5 “By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse.”



GOAL 13.2 “Integrate climate change measures into national policies, strategies and planning.”



GOAL 15.2 “By 2020, promote the implementation of sustainable management of all types of forests, halt deforestation, restore degraded forests and substantially increase afforestation and reforestation globally.”



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ROVI



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Independent Assurance Report on the Integrated Report of Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries for 2022

(Translation from the original in Spanish. In case of discrepancy, the Spanish language version prevails.)

To the shareholders of Laboratorios Farmacéuticos Rovi, S.A.:

We have been engaged by Laboratorios Farmacéuticos Rovi, S.A. management to perform a limited assurance review of the accompanying Integrated Report for the year ended 31 December 2022 of Laboratorios Farmacéuticos Rovi, S.A. (hereinafter, the Parent) and subsidiaries (hereinafter, the Group), prepared in accordance with the Sustainability Reporting Standards of the Global Reporting Initiative (hereinafter, the Report).

In addition, pursuant to article 49 of the Spanish Code of Commerce, we have performed a limited assurance review to verify that the Consolidated Non-Financial Information Statement (hereinafter NFIS) for the year ended on 31 December 2022, included in the Report, and which is part of the Group's Consolidated Management Report for the financial year 2022, has been prepared in accordance with the contents required by prevailing mercantile legislation and following the criteria of the selected GRI standards, in accordance with what is mentioned for each matter in the table "Content Index: Law 11/2018 - GRI" of the Report.

The Report includes additional information to that required by GRI standards in its comprehensive option and prevailing mercantile legislation governing non-financial information that has not been the subject of our assurance engagement. In this regard, our work was limited only to providing assurance on the information contained in tables "GRI Content Index" and "Content Index: Law 11/2018 - GRI" included in the attached Report.

Directors' and Management responsibilities

Management of the Parent is responsible for the preparation of the Report in accordance with the GRI Standards in its comprehensive option, in accordance with each subject area in the table "Content Index: Law 11/2018 - GRI" of the aforementioned Report.

The Board of Directors of the Parent is responsible for the contents and the authorization for issue of the NFIS, included in the Report, which also is part of the Group's 2022 Management Report as well as its content. The NFIS has been prepared in accordance with the contents required by prevailing mercantile legislation and selected GRI Standards, in accordance with each subject area in the table "Content Index: Law 11/2018 - GRI" of the Report.



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This responsibility also encompasses the design, implementation and maintenance of internal control deemed necessary to ensure that the Report is free from material misstatement, whether due to fraud or error.

The directors of the Parent are also responsible for defining, implementing, adapting and maintaining the management systems from which the information necessary for preparing the Report was obtained.

Our Independence and quality management

We have complied with the independence and other ethical requirements of the International Code of Ethics for Professional Accountants (including international independence standards) issued by the International Ethics Standards Board for Accountants (IESBA), which is based on the fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behaviour.

Our firm applies current international quality standards and consequently maintains a quality system that includes policies and procedures related to compliance with ethical requirements, professional standards, and applicable legal and regulatory provisions.

The engagement team was comprised of professionals specialised in reviews of non-financial information and, specifically, in information on economic, social and environmental performance.

Our responsibility

Our responsibility is to express our conclusions in an independent limited assurance report based on the work performed. We conducted our review engagement in accordance with the requirements of the Revised International Standard on Assurance Engagements 3000, "Assurance Engagements other than Audits or Reviews of Historical Financial Information" (ISAE 3000 Revised), issued by the International Auditing and Assurance Standards Board (IAASB) of the International Federation of Accountants (IFAC), and with the Performance Guide on assurance engagements on the Non-Financial Information Statement issued by the Spanish Institute of Registered Auditors (ICJCE).

The procedures performed in a limited assurance engagement vary in nature and timing from, and are less in extent than for, a reasonable assurance engagement, and consequently, the level of assurance provided is also lower.

Our work consisted of making inquiries of management, as well as of the different units and areas of the Group that participated in the preparation of the Report, in the review of the processes for compiling and validating the information presented in the Report and in the application of certain analytical procedures and sample review testing described below:

- Meetings with the Group personnel to gain an understanding of the business model, policies and management approaches applied, the principal risks related to these matters and to obtain the information necessary for the external review.
- Analysis of the scope, relevance and completeness of the content of the Report based on the materiality analysis performed by the Group and described in the section "Materiality", considering the content required by prevailing mercantile legislation.



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- Review of the information relating to the risks, policies and management approaches applied in relation to the material aspects presented in the Report for 2022.
- Review of the information related to the risks, policies and management approaches applied in relation to the material aspects presented in the Report for the year 2022.
- Corroboration, through sample testing, of the information relative to the content of the Report for 2022 and whether it has been adequately compiled based on data provided by the information sources.
- Procurement of a representation letter from the Directors and management.

Conclusion

Based on the assurance procedures performed and the evidence obtained, nothing has come to our attention that causes us to believe that:

- a) The Integrated Report of Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries for the year ended 31 December 2022 has not been prepared, in all material respects, in accordance with the GRI Standards, as described in point 102-54 of the Table of contents GRI.
- b) The NFIS of Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries for the year ended 31 December 2022 has not been prepared, in all material respects, in accordance with the contents included in prevailing mercantile legislation and with the GRI Standards selected, in accordance with each subject area in the table "Content Index: Law 11/2018 - GRI" of the Report.

Emphasis of Matter

Regulation (EU) 2020/852 of the European Parliament and of the Council of June 18, 2020 on the establishment of a framework to facilitate sustainable investments establishes the obligation to disclose information on how and to what extent the company's activities are associated with economic activities aligned in relation to the objectives of climate change mitigation and adaptation to climate change for the first time for fiscal year 2022, in addition to the information referring to eligible activities required in fiscal year 2021. Consequently, the attached NFIS, which is included in the Integrated Report, does not contain comparative information on this matter. Furthermore, inasmuch as the information on eligible activities in 2021 was not required to be as detailed as in 2022, the disclosures on eligibility included in the attached NFIS are not strictly comparable. The directors of Laboratorios Farmacéuticos Rovi, S.A. have included information on the criteria that, in their opinion, best allow them to comply with the aforementioned obligations, which are defined in section "Taxonomy of the European Union" of the attached NFIS, included in the Report. Our conclusion is not modified in respect of this matter.

Use and distribution

In accordance with the terms of our engagement, this Independent Assurance Report has been prepared for Laboratorios Farmacéuticos Rovi, S.A. in relation to its Integrated Report and for no other purpose or in any other context.



(Translation from the original in Spanish. In case of discrepancy, the Spanish language version prevails.)

In relation to the Consolidated NFIS, this report has been prepared in response to the requirement established in prevailing mercantile legislation in Spain, and thus may not be suitable for other purposes and jurisdictions.

KPMG Asesores, S.L.

(Signed on original in Spanish)

Marta Contreras Hernández

20 February 2023