

INTEGRATED  
ANNUAL REPORT

20  
23

Antibiotice  
Science and soul





Investing responsibly  
for the health of  
future generations

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# The General Director's message to stakeholders



*Dear partners,*

In 2023, we faced significant challenges from high inflation, a tight labor market, the climate crisis, and numerous armed conflicts worldwide. However, we successfully navigated the immediate uncertainties and longer-term opportunities through resilient processes, enabling us to maintain an evolutionary trajectory and strengthen the Antibiotice business.

I am honored to present Antibiotice's third integrated report, which reflects our commitment to transparent and ethical reporting by adhering to the principles and standards of integrated reporting. This report brings together financial and non-financial information to illustrate the impact of our activities on all our stakeholders, providing a clear and comprehensive picture of our development and strategies in 2023.

We have set out on a clearly defined path and have developed a strategic development plan, The Future Together, with long-term goals for 2030. This plan integrates sustainability principles into every aspect of our operations and provides clarity and coherence to our development direction, creating an organized and effective framework for our future actions. We aim to develop sustainably by prioritizing actions to reduce the negative impacts of our business activities and relationships while maximizing the positive impacts on the social and economic environment.

In 2023, following the audit of our financial results, the total revenue amounted to 641 million lei, 23% higher than in 2022, and the net profit to 81 million lei. This is healthy and sustainable growth, in line with our business plan, based on our new strategies of maximizing returns and cost efficiency.

Responsible business practices are integral to our operations throughout the value chain. We have actively focused on the efficient allocation of capital and resources in all areas of our business, with an emphasis on operational excellence and cost competitiveness. Our actions have resulted in significant market share growth, the development of new markets, the sustainable management of resources, and the implementation of strategic investments.

Throughout 2023, we implemented a robust investment plan totaling 98 million lei, aimed at continuous improvements to meet current international regulatory requirements. These investments ensured the production of medicines under the safest conditions, the adoption of viable technologies, and the acquisition of state-of-the-art production equipment. It also supported the digital transformation of our business, increased energy efficiency, and the on-site production of green energy.

The defining moment for Antibiotice in 2023 was the signing of a consultancy agreement with the European Investment Bank (EIB) to develop a long-term strategy for the strategic and sustainable development of Antibiotice's business, identifying opportunities for growth and development at home and abroad. This partnership was followed by a €25 million financing agreement provided by the EIB under the InvestEU program. The loan will support the construction of state-of-the-art production, packaging, and storage facilities, facilitating the development of new production lines, as well as the construction of the most modern R&D and innovation center in Romania, a key pillar in ensuring a viable pharmaceutical product portfolio. The partnership with the EIB reinforces our "The Future Together" plan and contributes to strengthening our ability to respond to the needs and demands of the European pharmaceutical market.

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In addition, to support the strategic development plan, we qualified for and received state aid of 85 million lei, which will contribute in the near future to the production of valuable medicines by addressing new pharmaceutical forms, namely sterile injectable solutions and sterile topical products.

The transition to a low-carbon economy is a challenge for us as well, but we have embarked on this journey with determination and have implemented a 2.5 MW ground-mounted photovoltaic park, accessing European funding through the Ministry of Energy's National Recovery and Resilience Plan (PNRR). In 2024, we will complete a new 1.2 MW building-mounted photovoltaic plant, so that together they will provide 35% of the annual energy needs of our industrial platform from renewable sources.

The significant improvement in profitability margin, sales, and the record profit we achieved in 2023, together with the ambitious investments we have made and will make in the coming years, our consolidated businesses in more than 30 countries around the world, are important milestones that show that The Future Together business plan has put us on an upward trajectory in the transition to a low-carbon economy.

These remarkable achievements had a significant impact on the stock market and led to an accelerated stock market performance, with the company's share value increasing by 146% during 2023, demonstrating investor confidence in our company's performance and strategic direction.

Antibiotice is an integrated company with European scientific research capabilities and the most complex manufacturing infrastructure in Romania. We provide affordable therapeutic solutions in various medical areas, offer a portfolio of more than 160 medicines, 51 of which are classified as essential by the WHO, and invest in manufacturing facilities for critical medicines.

In Romania, Antibiotice has a 68-year tradition as the largest generic manufacturer with Romanian capital, of strategic importance for the local pharmaceutical industry. Our presence in more than 8,000 pharmacies and all state hospitals, as well as our partnerships with the main local distributors,

demonstrate our support for the national healthcare system and our recognition as a leading provider of affordable and valuable medicines for patients and healthcare professionals.

Externally, we benefit from the advantages of a diversified portfolio of 60 high-quality medicines that meet the requirements for registration in all international markets, confirming our presence among the top 10 sterile beta-lactam penicillin manufacturers in Europe and North America.

We believe that our most important asset is our more than 1,300 colleagues, who share our values and are the source of our success through their dedication, commitment, and expertise. We continue to invest in creating a diverse and inclusive working environment, developing a culture that enables employees to realize their potential and develop their skills and knowledge while ensuring their well-being and healthy lifestyles. In 2023, we allocated a 70% higher budget for employee development programs than in the previous year.

To adapt our HR structure to the future shape of the company in 2030, we have developed a platform called the A+ Academy, which focuses on recruitment, education, and professional skills development. Within this platform, we have partnerships with high schools and universities and run selection and career management programs.

We are confident that, together with our stakeholders, we can make this journey towards a sustainable, healthier future for present and future generations.

**Ec. Ioan Nani**

**General Director Antibiotice**

**Vice-President of the Management Board**

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# About the report

This is the third integrated annual report of Antibiotice SA (hereinafter referred to as "Antibiotice" or the "Company"). The report presents the financial indicators included in the previous reporting years in the annual report, including for the financial year 2023, and the non-financial performance indicators related to the Company's activity between January 1, 2023, and December 31, 2023.

The non-financial information contained in this report complies with the requirements of [Directive 2014/95/EU](#), [Order of the Minister of Public Finance No 1938/2016](#), [Order of the Minister of Public Finance No 3456/2018](#), [Order of the Minister of Public Finance No 1239/2021](#) and the requirements of Article 8 of [Regulation \(EU\) 2020/852](#) of the European Parliament and of the Council establishing a framework to facilitate sustainable investment and its subsequent additions ([EU Regulation 2139/2021](#), [EU Regulation 2178/2021](#) and [EU Regulation 1214/2022](#), [Regulation 2485/2023](#) - [Regulation 2486/2023](#) amending Regulation 2178/2021).

The non-financial indicators included in this report have been identified according to the methodology described in the GRI 3 Material Topics 2021 Standard, following a materiality analysis carried out between March and April 2023, and present the (positive and negative) economic, social, and environmental impacts generated by Antibiotice SA's activity and business relationships. Among the non-financial key performance indicators are environmental, social, and personnel indicators, respect for human rights, anti-corruption and anti-bribery, and risk management, as well as business-specific indicators such as patient and consumer health and safety or pharmacovigilance.

The audited\* financial statements included in the report were prepared in accordance with IFRS Financial Reporting Standards and the non-financial information has been presented in accordance with the Global Reporting Initiative (GRI) 2021 Standards, the most internationally recognized non-financial reporting standard.

Thank you to everyone who contributed to this report developed by Antibiotice's reporting team with the support of The CSR Agency's sustainability consultants.

## Suggestions and recommendations

For questions, suggestions, or recommendations on the content of this report, please use the following e-mail address: [office@antibiotice.ro](mailto:office@antibiotice.ro).

\* The independent auditor's report on the financial statements can be found on page 152 of the report.

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# 01

# Company profile





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# 1.1. History

Antibiotice is now the largest Romanian manufacturer of generic medicines and our commitment to supporting sustainable development goals is realized through investments in research, development, and innovation, the creation of new production capacities, and the sustainable partnerships we have throughout the value chain.

All this effort contributes to improving people's health and quality of life, creating long-term value for society, customers and shareholders.

Through these achievements and its ongoing commitment to quality and innovation, Antibiotice Iași continues to be one of the essential pillars of the Romanian healthcare system and a trusted supplier for patients and healthcare professionals.

With a history of more than 68 years, Antibiotice is one of the leading manufacturers of generic drugs in Romania and the company has continued its development with the mission of producing effective and high-quality medicines, contributing to ensuring patient access to essential treatments and improving the quality of medical care in hospitals.

Antibiotice has an active global presence and exports its products to all continents, succeeding in making valuable medicines more accessible to patients both in Romania and around the world.



## 1955 - 1990

The manufacturing structure is developed, especially for active substances, injection sterile powders, ointments, and suppositories.



## 1955

Only a decade after the synthesis of Penicillin, Antibiotice, the first producer of this active substance in Romania and South-East Europe, was founded.

## 1990 - 2000

- The manufacturing structure is redefined, and internal and international marketing activities are developed.
- Production of finished medicines (capsules and tablets) is developed.
- Antibiotice shares are listed on the Bucharest Stock Exchange (April 1997).
- Manufacturing technologies for Nystatin and Vitamin B12 are improved.



## 2000 - 2010

- €60 million are invested in upgrading production technologies and purchasing new equipment, developing the product portfolio, and protecting the environment to adapt to EU requirements.
- FDA approval is granted for Nystatin and injectable sterile powders.
- Certification of quality systems for compliance with EU GMP and US FDA standards is granted.
- Integrated Management System (quality, environment, occupational health and safety) is implemented.
- The Drug Evaluation Centre is authorized.

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## 2010 - 2020

- The first FDA-cleared finished products are shipped to the US.
- The company becomes the world's leading producer of Nystatin; Nystatin becomes the USP Reference Standard Release Traceability.
- Offices are opened in the Republic of Moldova, Ukraine, Serbia, and Vietnam.

## 2020 - 2022

- During the COVID-19 pandemic, the Romanian healthcare system is supported by manufacturing medicines for the treatment of COVID-related conditions and by manufacturing biocides; the company sets up the COVID Vaccination Centre for employees and the community.
- In the context of the war crisis in Ukraine, Antibiotice manufactures 65 mg potassium iodide tablets, needed in the event of a nuclear attack, and provides support to the Ukrainian population with essential medicines.
- Europe's most modern factory for solid and semi-solid topical pharmaceuticals is opened with its own funding (€20 million).

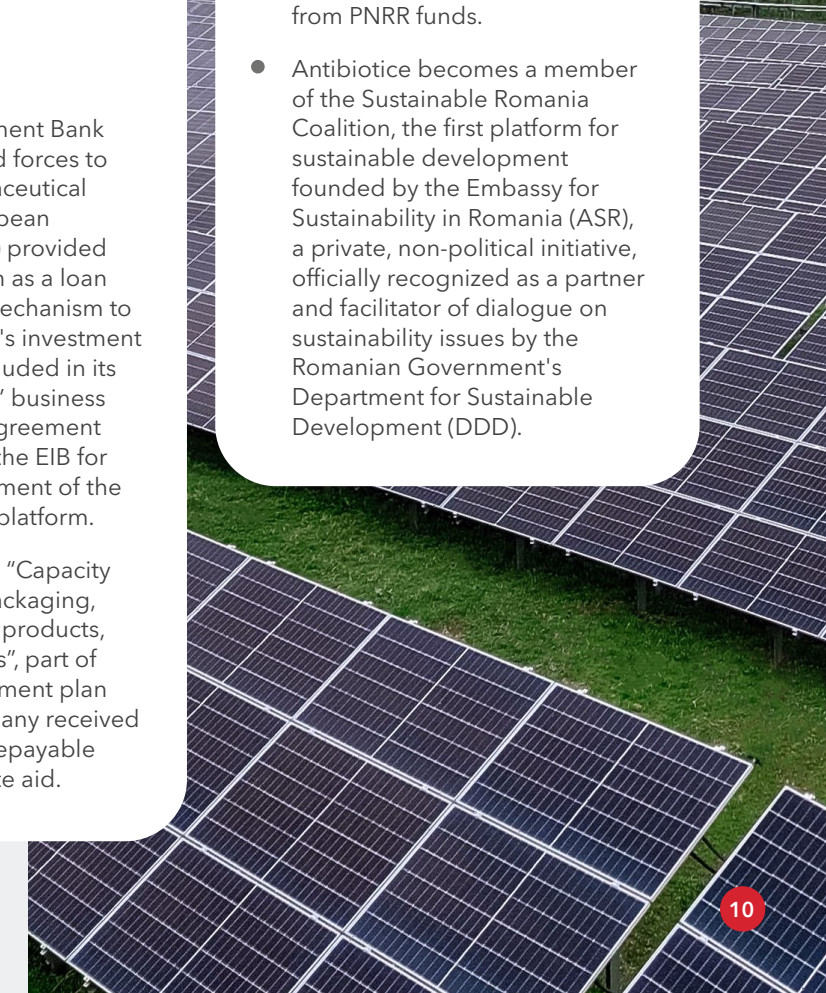


## 2023

- The European Investment Bank and Antibiotice joined forces to develop local pharmaceutical production. The European Investment Bank (EIB) provided funding of €25 million as a loan under the InvestEU mechanism to support the company's investment program, which is included in its "The Future Together" business plan. A consultancy agreement was also signed with the EIB for the strategic development of the company's industrial platform.
- To finance the project "Capacity for the production, packaging, and storage of sterile products, solutions, and topicals", part of the business development plan 2023-2030, the company received 85 million lei in non-repayable funds, secured by state aid.



- Antibiotice starts the construction of a renewable electricity production capacity, which received a grant of 4.1 million lei from PNRR funds.
- Antibiotice becomes a member of the Sustainable Romania Coalition, the first platform for sustainable development founded by the Embassy for Sustainability in Romania (ASR), a private, non-political initiative, officially recognized as a partner and facilitator of dialogue on sustainability issues by the Romanian Government's Department for Sustainable Development (DDD).



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# 1.2. Key figures in 2023


## Economic matters

**641**  
million lei  
total revenue



**122**  
million lei taxes paid  
to the state budget



**146%**   
increase in value per  
share during 2023

A **€25** million  
financing from the European  
Investment Bank as a loan  
granted under the InvestEU  
facility, to support the  
company's investment  
program, included in the  
"The Future Together"  
Business Plan




**4** commercial  
offices in 4  
countries: Vietnam,  
Republic of Moldova,  
Serbia, Ukraine



**Our partners in  
Romania:**

- ▶ 8.100 open circuit pharmacies
- ▶ 367 public hospitals
- ▶ 309 private hospital units

**85**  
million lei  
in non-reimbursable  
funds, attracted through  
state aid, for a  
production capacity  
of sterile products,  
solutions, and topicals



**28.5**  
million units (boxes)  
sold to patients and  
consumers in Romania



**4.1**  
million lei  
million lei co-financing  
for green energy  
production capacity



Sole producer on the  
Romanian market for  
**55** products

A consultancy  
agreement signed  
with the European  
Investment Bank  
on the strategic  
development  
of the company's  
industrial platform

**98.05**  
million lei investment  
value in 2023

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# Social matters

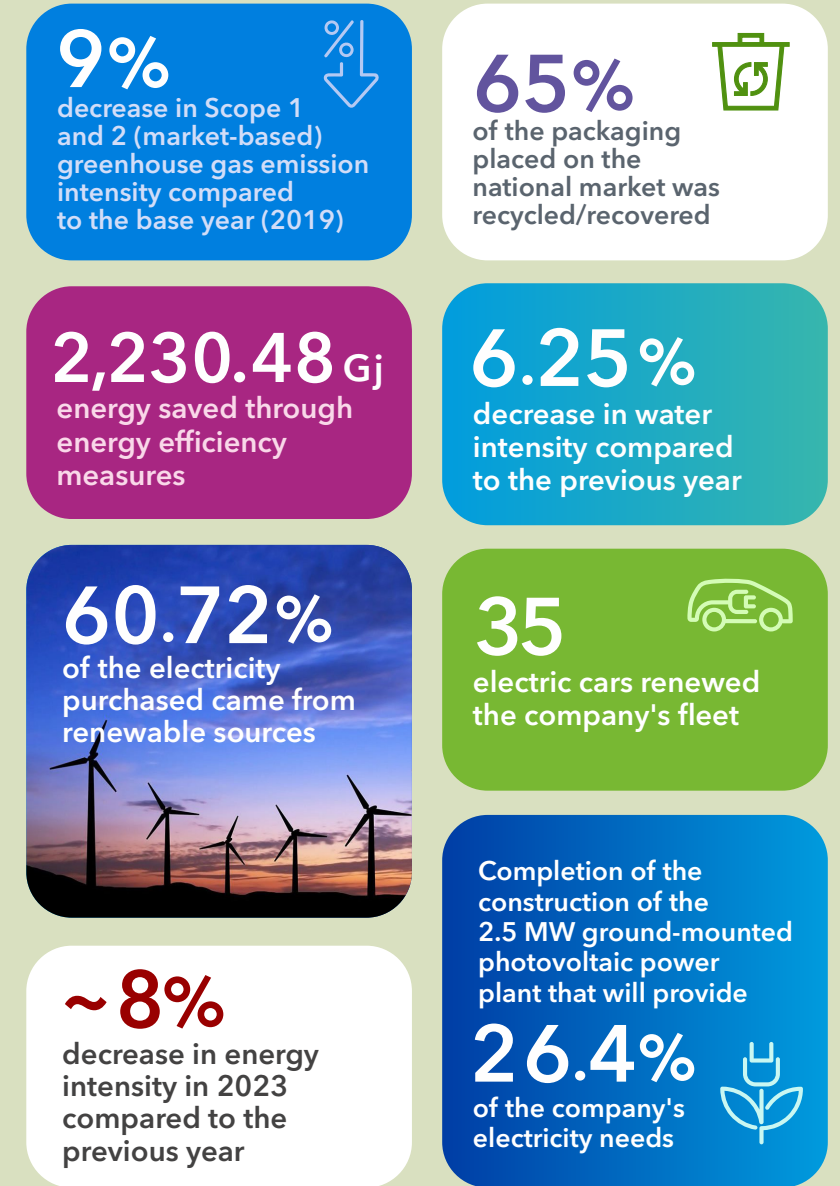
## Employees



## Community



# Environment



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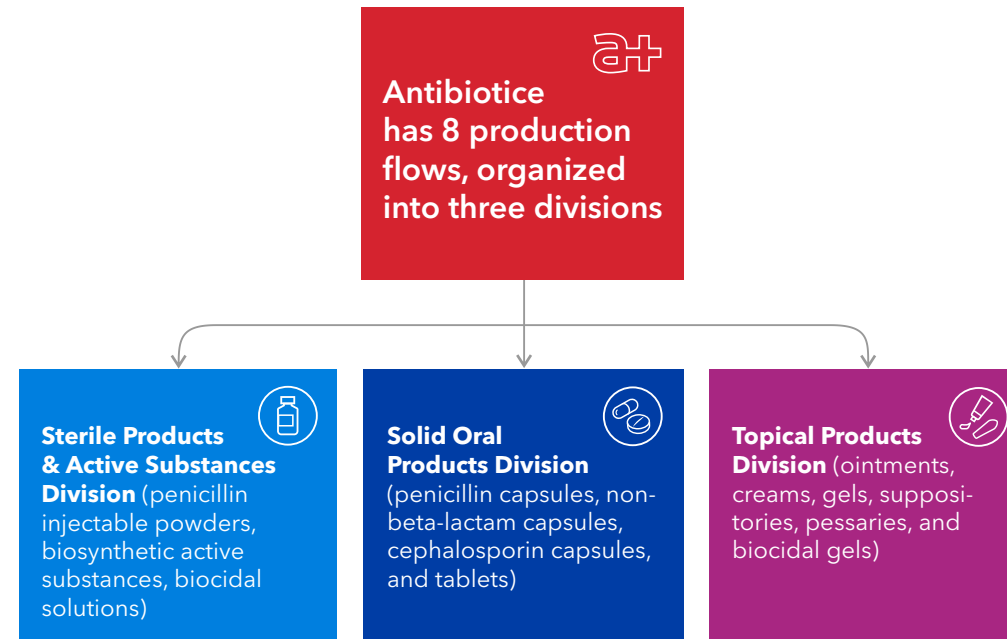
# 1.3. About us

Antibiotice's main activity is the manufacture of basic pharmaceutical products, and it is a state-owned company under the authority of the Ministry of Health, which holds 53% of the subscribed and paid-up capital. The company has been present on the capital market for 26 years and has been listed on the Bucharest Stock Exchange (BVB) in the Premium category since 1997.

With a 68-year tradition, Antibiotice SA is one of the most important Romanian manufacturers of generic medicines, the most important producer of generic anti-infective medicines, and one of the most important suppliers of medicines for hospitals in Romania.

### Antibiotice has a portfolio of 168 products in the following categories:

- medicinal products for human use;
- dermatocosmetics, food supplements, medical devices;
- active ingredients based on biotechnologies derived from streptomyces noursei for pharmaceutical use (compacted nystatin, micronized nystatin, and standard nystatin);
- veterinary products;
- biocidal products for surface and hand disinfection.



Medicines are manufactured according to Good Manufacturing Practices (GMP) in eight production flows verified and certified by the Romanian National Agency for Medicines and Medical Devices (NAMMDR). The company has a modern Research Center and its own Clinical Trials Center, which is authorized to comply with Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) for the conduct of Phase I and bioequivalence studies.

Antibiotice also has manufacturing contracts with ten partner sites. The active substance Nystatin, manufactured through a unique biosynthesis process in Romania, has been the international reference

standard for the United States Pharmacopeia (USP) since 2017. Nystatin manufactured in Iasi is exported to 55 countries around the world and places Antibiotice at the top of the world ranking in this segment.

Most of Antibiotice's medicines are prescription-based (Rx), but the portfolio also includes over-the-counter (OTC) medicines, dietary supplements, and medical devices to prevent disease and enhance the quality of life. Antibiotice's generic medicines are mainly designed for patients with infectious diseases, as well as cardiovascular, dermatological, digestive, and central nervous system pathologies.

Antibiotice products are internationally recognized and used in more than 30 countries by healthcare professionals in countries with highly regulated healthcare systems such as the USA, UK, Denmark, Norway, the Netherlands, Spain, Poland, Vietnam, and Serbia. Through the Territorial Expansion Plan, we are developing the presence of Antibiotice products in Germany, Italy, the Czech Republic, the United Arab Emirates, Australia, and other countries where we have identified potential for our products and negotiate with our partners.

The company's continuous development and expansion into international markets was possible through investment and the implementation of internationally recognized quality standards:

- **Good Manufacturing Practice (EU-GMP)**
- **Certificate of Suitability with the European Pharmacopoeia (CEP)**
- **Food and Drug Administration (FDA) authorization**
- **Good Clinical Practice (GCP)**
- **Good Laboratory Practice (GLP)**

Beyond global recognition, Antibiotice remains firmly committed to its mission of improving the health and lives of Romanians and people around the world. The company does not place on the market any products or services that have been banned or withdrawn from the market in certain regions or countries.

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# 1.4. Our mission

Antibiotice's culture, the values guiding the company and how it conducts its day-to-day business have made Antibiotice a reliable partner for suppliers, customers, and health authorities in Romania and the countries where it operates.

## Our mission

We make valuable medicines more accessible, we always put our strength into the service of those who need our support.

## Our vision

The Hippocratic spirit that guides the practice of medicine and pharmacy also guides our actions. We are honest, compassionate, and constantly concerned with modernizing our activity and enhancing our products. We believe a valuable medicine is not necessarily an expensive one, but a medicine people can afford and which brings the company a reasonable profit, a profit that satisfies our shareholders and allows us to target performance by permanently investing in people, technology, and carefully selected partnerships.

## Our values

We cherish efficiency, knowledge, and the spirit of cooperation, which allow us to focus on the ever-changing needs of our customers and consumers. In our company, we put the right people in the right place, at the right time. We mutually acknowledge our purpose and value within the company, which creates a sense of connection and gives us the strength to overcome limitations and obstacles. As human beings, we care for our fellow beings, do our best to support them, and try to improve the things they find important.



## Our value chain

Our growth and development are strongly anchored in the strong partnerships we have developed over time with all partners along our value chain. Whether we are talking about suppliers, distributors, or customers, our success is based on ethical relationships built on transparency and trust, which have allowed us to seamlessly combine research, development, and innovation processes with efficiency and rigorous quality control.

Our processes require that the selection of raw material suppliers be based on the certification of their quality system according to the international GMP requirements. Thus, in the manufacturing process of the Antibiotice medicinal products, only quality raw materials are used, purchased from authorized producers who are our partners in our mission to develop and grow sustainably our business.

Antibiotice constantly invests in Research & Development and works together with its local and international partners to create value both for Romanian society and for the consumers from over 70 countries where its products are sold.

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Regarding the indirect procurement procedure, for services or products that are not directly related to the manufacturing process of medicines, suppliers' assessment is made based on the economic selection criteria, meeting the 3E concept: Economy, Efficiency, and Effectiveness.

Throughout the value chain, optimizing the production, packaging, storage, and transport processes is constantly pursued, as a guarantee that the Antibiotice medicines reach the final consumers in the best conditions.

In the final phase of the value chain, the products arrive from the company's warehouses to the distribution partners, from where they are delivered (tender-based) to hospitals and retail pharmacies. From here, the products reach the patients/consumers.

Packaging is recycled through a partnership (service contract) concluded with an organization that meets the obligations of extended liability of the manufacturer, so that the overall objective of recycling at least 60% of the quantity of packaging placed in the market is achieved, according to the Law 249/2015 requirements on managing the packaging and packaging waste. According to the Order of the Minister of Health no. 119/2014 and Order of the Minister of Health no. 404/2009, expired medicines from the population will be deposited at pharmacies for their disposal by incineration. From 2024, according to Law No. 269/2023 amending and supplementing Law No. 95/2006 on Health Reform,

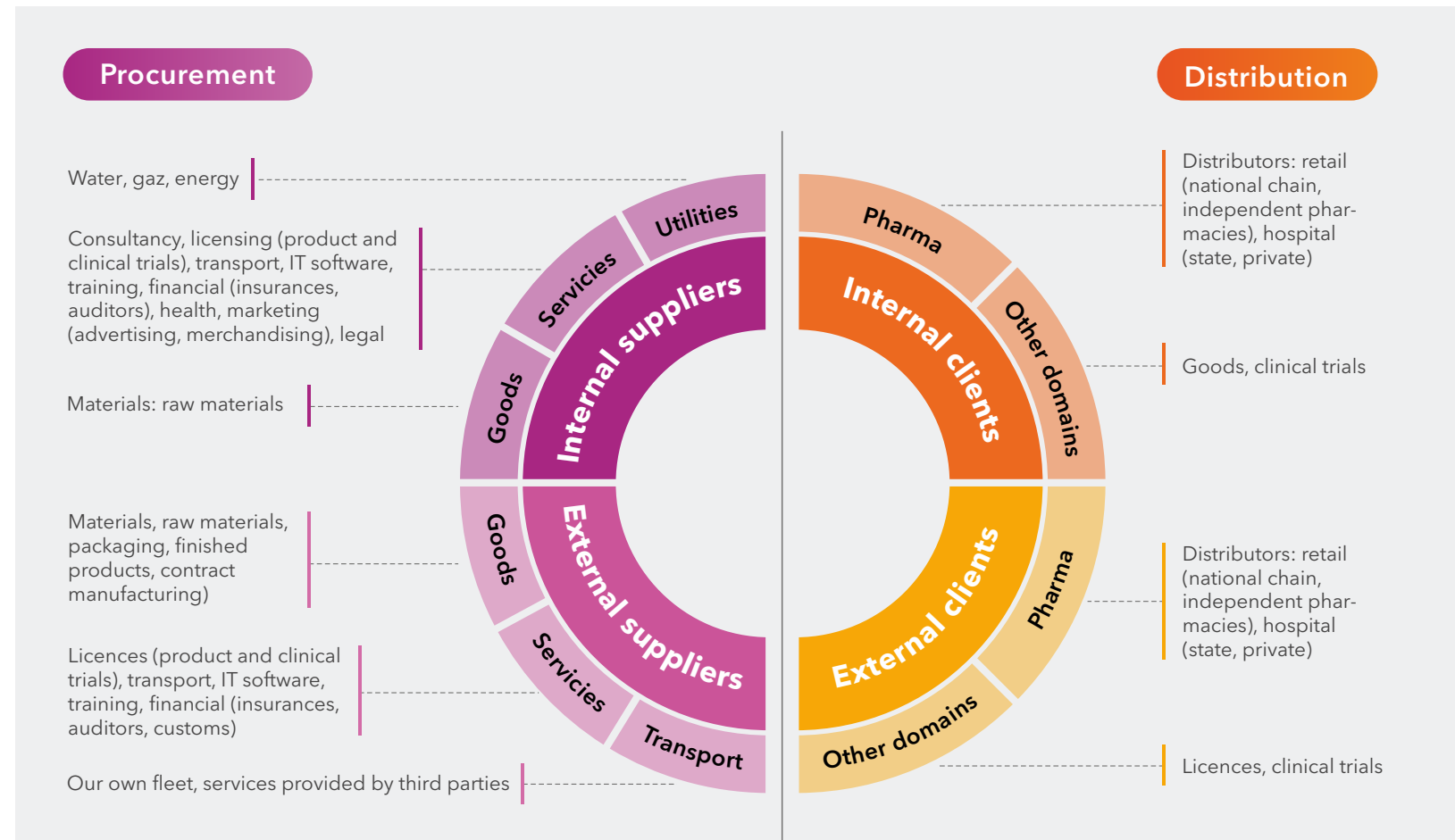
expired and/or unused medicines will be collected from the population at public or private hospitals, which will be required to receive them for final disposal.

To raise awareness of the importance of proper collection of expired medicines, Antibiotice organized an internal collection campaign of expired medicines in 2023: "Be responsible, don't treat the environment with medicines!"

At the end of the campaign, 95 kg of expired medicines were collected from company employees.

Through continuous medical training programs for health professionals, the company's promotion team, in compliance with ethical principles, aims to increase the level of accessibility and contribute to the balanced uptake of Antibiotice products.

The company's Quality Assurance teams are actively involved in self-inspection programs to identify in a timely manner any elements that could slow down the processes of the value chain and to intervene to minimize risks and constantly improve procedures.



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# 1.5. Our long-term strategy

In 2023 our strategy focused on managing the company's activities to develop and increase business profitability and generate long-term value.


Our main objectives were:

- research - development of medicines, food supplements, medical devices, and cosmetics, continuous adaptation to the internal and international market and development of market presence, modern human resources management, and upgrading of organizational culture;
- sustainability of the business through continuous improvement of the Integrated Management System, ensuring the framework governing Corporate Governance systems;
- ensuring and maintaining an effective system for evaluating professional performance and improving the risk management process.


Throughout this period, emphasis has also been placed on strategic planning and monitoring of management systems to improve organizational functionality and efficiency and to achieve specific and overall company objectives.

2023 was the year in which we implemented the strategic objectives set out in The Future Together 2023 - 2030 business plan. In the same year, we finalized the objectives of multiplying profits, increasing turnover with an impact on growing Antibiotice's market share in the local and international markets, and continuing strategic investments, all with the integration of sustainability principles in all the company's activities. At the same time, the strategy also encompasses human resources issues by improving the working conditions and well-being of employees, reflecting not only their merit but also their commitment and contribution to the company's success. Antibiotice is also committed to the sustainable development of the community, actively participating in health, education, and environmental protection projects, as well as carrying out charitable action programs in the social field.


## Our 2030 objectives include:

- 


Achieving business growth potential by adapting the business model to current market realities and coherently and sustainably anticipating the future in terms of business profit, production capacity utilization, market sales in optimal structure, and business sustainability (environmental, quality, social, governance).

**2030 target:**  
€250 million turnover, 6.5% physical market share in Romania in the generics and OTC market (boxes)
- 


Expansion of the presence in Antibiotice territories in a favorable structure, according to profitability criteria.

**2030 target:**  
Business internationalization - €80 million
- 

Strengthening the sales structure by ensuring market balance in terms of markets, territories, product quantity, the average price of the structure, and the multiplication coefficient of the active substance.

**2030 target:**  
Balanced production capacity utilization - 90% occupancy rate
- 

Continued strategic investments in the development of the R&D portfolio and infrastructure, new production sites, investments to consolidate the business by updating and streamlining business processes through digitalization, adapting to the development trends of the industrial site, implementing investments in the integrated management system, modernizing existing sites and equipment.

**2030 target:**  
Profitability - €50 million
- 

Valuable staff structure, oriented towards knowledge, innovation, and performance, complying with criteria of diversity of professions and gender and equal opportunities.

**2030 target:**  
Net average income per employee/month - €2,100



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# 1.6. Materiality analysis

A key process that underpins the development of the sustainability report is the materiality analysis, which identifies and prioritizes the material topics that form the basis for determining the non-financial indicators presented in this report. For this report, we have used the results of the materiality analysis carried out for the 2022 report.

Material topics are those that reflect the most significant impact, whether positive or negative, resulting from Antibiotice's operations and business relationships on the economy, the environment, and society, including human rights. The process was carried out in accordance with GRI Standard 3 and entailed consultation, via two online questionnaires, with both Antibiotice management (*internal analysis*) and various stakeholder groups (*external analysis*).

The stakeholder categories consulted in the process were determined by the reporting team in the company, where, together with the process coordinator and specialists from each department, they identified each stakeholder category with which they communicate and interact in their daily activities.

The questionnaire also allowed the selection of the *Other category option* for respondents who felt that they did not fit into any of the stakeholder categories identified by Antibiotice SA.

## Stakeholder categories consulted

- > Employees and employee representatives
- > Shareholders
- > Internal suppliers
- > External suppliers
- > Distributors
- > Physicians
- > Hospitals
- > Industry associations or bodies/Industry representatives
- > Business associations
- > Patient associations
- > Non-governmental organizations
- > Regulatory and supervisory authorities
- > Central and local authorities
- > International bodies
- > Academia
- > Media

The starting point for the materiality analysis was the identification of potential material topics, i.e. topics where the company could have a significant impact (positive and/or negative). The list of potential material topics was developed based on an analysis of the company's activities and business relationships, the national and European legislative context (CSRD, EU Taxonomy, Romanian Sustainability Code), the latest studies/papers in the pharmaceutical sector (*EFPIA - European Federation of Pharmaceutical Industry and Associations, OECD - Organization for Economic Co-operation and Development*) and other non-financial reporting standards such as SASB and TCFD (*Sustainability Accounting Standards Board, Task Force on Climate-Related Disclosures*).

Based on this list, two online questionnaires were developed and distributed to specialists/experts within the company and stakeholder groups. The questionnaires were structured in separate sections to allow for separate assessments of the positive impact dimension and the negative impact dimension. For each potential material topic, the positive and negative impact dimensions were rated on a scale from 0 to 3 as follows:

- 0 - no impact
- 1 - low impact
- 2 - moderate impact
- 3 - high impact

The respondents also had the option to choose N/A - don't know/don't answer. The questionnaires allowed respondents to highlight other topics/forms of impact in qualitative questions (free answer) and also the opportunity to offer suggestions to improve the consultation process.

A total of 433 responses were recorded, which were centralized and analyzed to highlight the extent of positive and negative impacts, as perceived externally (stakeholders) and assessed internally (specialists and experts in the company).

This analysis resulted in two scores for each topic evaluated, corresponding to positive and negative impact respectively. The significance threshold was set where the company's impact is at least low (score 1 on the rating scale provided in the materiality questionnaires). Therefore, the material topics for Antibiotice SA were considered to be those for which either the average of the stakeholder evaluations or the average of the internal evaluations showed at least a low impact.

The results of the materiality analysis were validated in a meeting with 7 experts from sectors relevant to the company's impact, such as patient associations, investor associations, associations relevant to sustainability, the non-governmental sector, the company's trade union, and public sector representatives. The meeting was moderated by a third party and took place in May 2023. Following this meeting, no other areas/fields were identified where Antibiotice has or could have a

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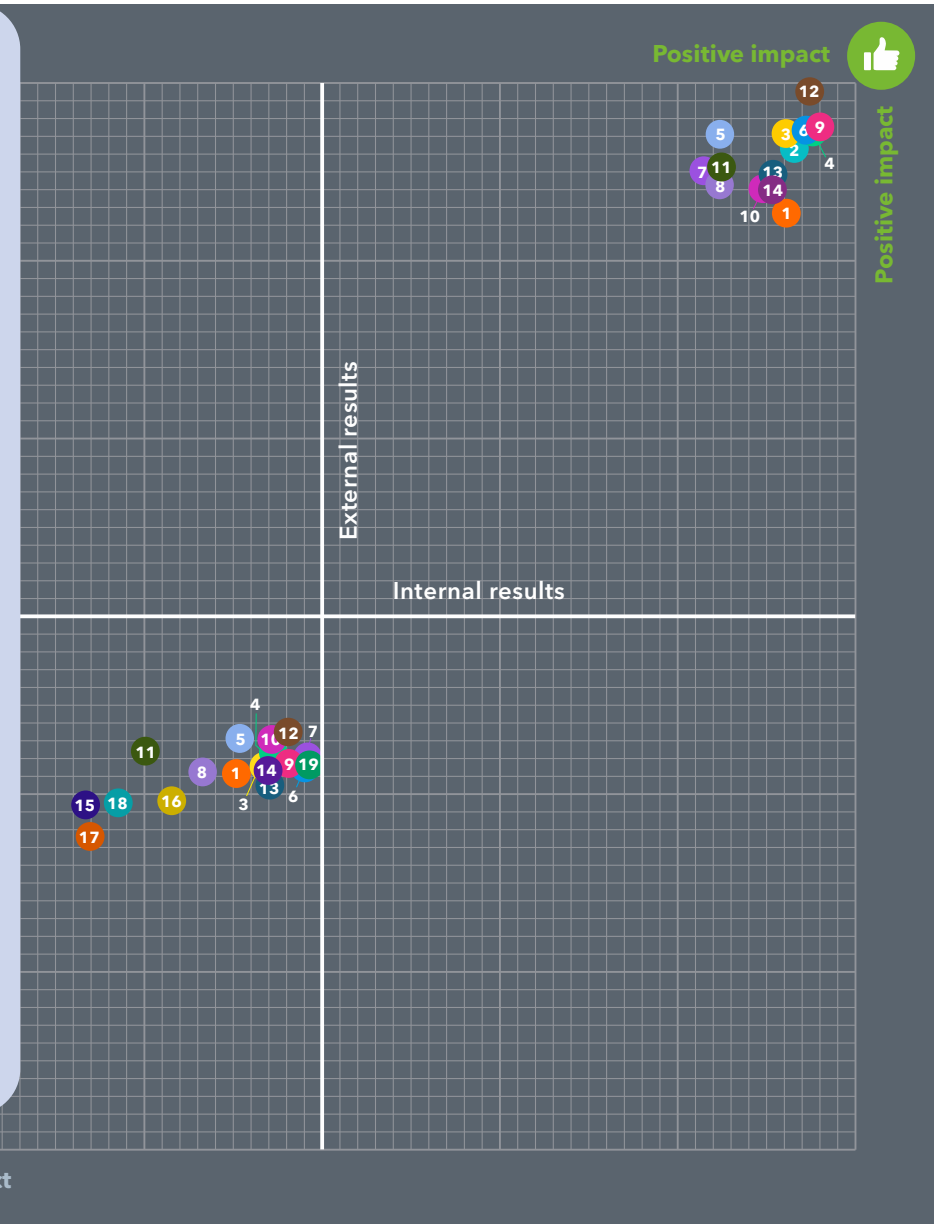
significant impact. Among the topics highlighted by the experts were resource consumption and waste management, greenhouse gas emissions, energy efficiency, responsible consumption of medicines, access to medicines, stakeholder dialogue, and employee well-being.

For a better understanding of the impact of Antibiotice SA's business activities and relationships on the economy, the environment, and society, including human rights, this is represented below in the materiality matrix. The matrix provides a visual representation of the significance and relevance of these impacts.

*Impact is defined as the effect that an organization has or could have on the economy, the environment, or people, including human rights, as a result of its activities or business relationships. Impacts may be negative or positive, actual, or potential, short or long term, intended or unintended, reversible or irreversible.*

## Material topics

- 1 Animal welfare
- 2 Volunteering and community investment
- 3 Business ethics
- 4 Impact on the local economy
- 5 Research, development, and innovation
- 6 Access to medicines
- 7 Product promotion policy
- 8 Recruitment, employee development and retention
- 9 Employee health and safety
- 10 Diversity and equal opportunities
- 11 Supply chain management
- 12 Patient and consumer health and safety
- 13 Prevention of drug abuse and self-medication
- 14 Safety of participants in clinical trials
- 15 Materials and waste
- 16 Water management
- 17 Energy consumption
- 18 Contribution to climate change
- 19 Combating counterfeit medicines and parallel trade



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## Impact assessment

Material topic*	Overview of impacts on the economy, environment, and people, including on human rights	Impact type
<b>17</b> Energy consumption	High non-renewable energy consumption (in all its forms - electricity, heat, fuel) contributes to an actual, negative impact. This contributes to the depletion of natural resources and exacerbates environmental degradation. In addition, energy-intensive transport and distribution networks associated with pharmaceuticals also contribute to the company's carbon footprint. To mitigate this impact and prevent the likelihood of its occurrence, several measures have been implemented at the company level, such as purchasing electricity from 100% renewable sources, investing in consumption efficiency, or reducing the distance traveled by the company fleet.	Actual Potential Negative
<b>15</b> Materials and waste	Pharmaceutical production requires substantial amounts of raw resources and packaging materials, which puts pressure on the components of natural capital, generating an actual, negative impact through environmental degradation, loss of habitat, and increased quantities of waste. Improper waste management, including the disposal of unused medicines and hazardous chemicals, can also contribute to water and soil pollution, posing a risk to ecosystems and human health. Through policies and measures, such as responsible waste management practices and the use of renewable materials, we can help minimize these impacts.	Actual Potential Negative
<b>18</b> Contribution to climate change	The pharmaceutical production process involves energy-intensive operations such as manufacturing, packaging, and transportation, which release carbon dioxide and other greenhouse gases into the atmosphere. In addition, the disposal of pharmaceutical waste, especially if not properly managed, can release harmful substances and contribute to environmental pollution and climate change. To reduce the likelihood of negative impacts, several internal measures have been implemented, such as measuring and monitoring greenhouse gas emissions or using electricity from renewable sources.	Actual Potential Negative
<b>16</b> Water management	The extraction and use of water resources can contribute to water scarcity and stress on local ecosystems, particularly in regions already experiencing water stress. In addition, wastewater discharges from pharmaceutical production can contain harmful chemicals and pollutants that can adversely affect water quality and aquatic life if not properly treated. To prevent these effects, the company has implemented a water resource management system, which includes effective management of water sampling, discharge, and consumption. The company also carries out water stress risk assessments in the areas where it operates.	Actual Potential Negative
<b>11</b> Supply chain management	The complex global supply chains of the pharmaceutical sector often involve extensive transport networks, which contribute to carbon emissions and air pollution. The extraction and production of raw materials, such as active pharmaceutical ingredients, can also have negative environmental impacts if not managed sustainably. To contribute to a sustainable supply chain, we have taken action to help our partners adopt responsible practices, such as the innovation of sustainable products and services and on-site visits and audits.	Actual Potential Positive Negative
<b>8</b> Recruitment, employee development, and retention	Supporting employees' professional development and providing training opportunities can increase employees' skills, engagement, and overall job satisfaction, thus generating a positive impact in the communities in which we operate. Effective retention strategies, such as competitive compensation, work-life balance initiatives, and supportive employee culture, can help retain valuable talent, leading to a more stable and productive workforce. We also recognize that there are areas where we can improve, and our efforts are focused on creating a workplace where employees feel respected and valued.	Actual Positive Negative

\* Material topics are presented in descending order of the scores resulting from the materiality analysis, giving priority to those with negative impact.

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Material topic*	Overview of impacts on the economy, environment, and people, including on human rights	Impact type
<b>1</b> Animal welfare	Animal testing is not involved when obtaining marketing authorization for the company's products. Antibiotice uses animal products in its manufacturing processes in compliance with the provisions concerning their quality and safety for human consumption. Some of them are obtained without slaughtering animals (e.g., beeswax, lanolin from sheep wool), and others are obtained as secondary processes from other industries after slaughtering (e.g., gelatine obtained from bone treatment). Currently, the company does not have animal welfare standards in place for the suppliers of these raw materials, but rather they are by-products of production processes associated with the livestock industry. In 2023, we developed the Partner Code of Conduct, which not only outlines the expected norms of behavior but also addresses animal welfare issues.	Actual Positive Negative
<b>5</b> Research, development, and innovation	Negative impacts can occur when the company fails to prioritize the development of essential medicines, including those needed for rare diseases, in the research and development process. The company also engages in collaborative research partnerships with academic and research institutions to develop new generic medicines for the benefit of public health. Clinical trials are a highly regulated area, conducted on healthy, human subjects and in accordance with best practice and industry standards.	Actual Potential Positive Negative
<b>13</b> Prevention of drug abuse and self-medication	Our national information and awareness-raising campaigns for the population and professionals on the correct use of antibiotic medicines to maintain their effectiveness and limit the phenomenon of anti-microbial resistance allow them to make informed decisions and reduce the potential negative impact of inappropriate use of medicines. Thus, to ensure only a positive impact, measures to prevent drug abuse are imperative to avoid leading to substance abuse, addiction, or potential public health problems.	Actual Potential Positive Negative
<b>3</b> Business ethics	By adhering to high ethical standards, prioritizing patient safety, accessibility, and fair pricing we contribute to improving the health of the population. As the pharmaceutical industry is heavily regulated, and despite the policies and measures in place, inadvertent violations of existing regulations can occur.	Actual Positive Negative
<b>4</b> Impact on the local economy	The economic value generated by the company can stimulate job creation and support research and development, thus generating a positive impact on the well-being of the population. Also, keeping medicines affordable is key to alleviating the barrier faced by low-income individuals in accessing needed treatments. Balancing profit and social responsibility are crucial to ensure that the economic value generated by the company benefits the society as a whole.	Actual Potential Positive Negative
<b>14</b> Safety of participants in clinical trials	By implementing rigorous safety protocols and adhering to ethical guidelines, the company ensures the well-being and protection of people involved in clinical trials. In addition, a strong focus on participant safety helps identify and mitigate any potential risks or adverse events, leading to improved patient outcomes and the development of safer and more effective treatments for public health.	Actual Positive
<b>10</b> Diversity and equal opportunities	By promoting a diverse and inclusive workplace, the company generates positive employee impacts that lead to increased innovation, creativity, and a broad range of perspectives among both employees and decision-makers.	Actual Potential Positive Negative

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Material topic*	Overview of impacts on the economy, environment, and people, including on human rights	Impact type
<b>9</b> Employee health and safety	A safe and healthy working environment reduces the risk of accidents and illness, contributing to well-being, satisfaction, and increased productivity. The policies and measures we implement prevent workplace accidents. The well-being programs conducted annually serve to maintain a balance in our employees' professional lives.	Actual Potential Positive Negative
<b>12</b> Patient and consumer health and safety	Through our concern for the health and safety of patients and consumers, we also ensure that the products and medicines we supply meet high-quality standards. This protects them from potential harm or adverse effects. Safety protocols and quality control processes prevent potential adverse effects on general well-being.	Actual Potential Positive Negative
<b>19</b> Combating counterfeit medicines and parallel trade	Counterfeit medicines pose significant risks to patient safety as they may contain incorrect ingredients, dosages, or no active ingredients at all. By actively combating counterfeit medicines, we help protect patients from potential harm and ensure the integrity and efficacy of our products. The potential impact is the opportunity to strengthen regulatory frameworks, improve supply chain security, and work with authorities and industry stakeholders to further reduce the spread of counterfeit medicines and parallel trade.	Actual Potential Negative
<b>6</b> Access to medicines	By producing and distributing generic medicines, we offer cost-effective options for patients. Measures on access to generic medicines contribute to increasing the affordability of essential medicines for the benefit of patients, healthcare systems, and the promotion of equitable healthcare.	Actual Potential Positive Negative
<b>7</b> Product promotion policy	Complying with responsible advertising practices and taking a special interest in the safety and well-being of patients and consumers enables them to make informed decisions. The policies and procedures governing the product promotion and labeling processes are aligned with national and international country-specific legislative regulations and comply with industry standards and best practices.	Actual Potential Positive Negative
<b>2</b> Volunteering and community investment	We actively participate in annual health education programs and dedicate resources to local initiatives designed to contribute to the well-being of the community. Our employees are also actively involved in the community by volunteering to support various social or environmental causes.	Actual Positive

\* Material topics are presented in descending order of the scores resulting from the materiality analysis, giving priority to those with negative impact.

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## Stakeholder engagement

Effective communication with our stakeholders is essential to us as it is a continuous and dynamic process through which we aim to stay in touch with their needs and expectations. We therefore use a variety of channels and strategies

to promote effective and transparent communication, ensuring that they are well-informed and have confidence in our actions. In doing so, we foster a transparent and collaborative relationship. Through effective communication, we ensure that

they are well informed about our activities, performance, and commitment to sustainable development. This commitment enables us to build trust, strengthen relationships, and work together for a healthier future.

Stakeholder category	Engagement method	Frequency	How we communicate	Top 3 topics in terms of negative impact	Top 3 topics in terms of positive impact
 <p><b>Shareholders</b></p>	Meetings Conferences Consultation as part of the sustainability reporting process	General Meeting of Shareholders GMS (at least half-yearly) Whenever necessary	Email Phone Videoconferencing Teleconferences Integrated report	<ul style="list-style-type: none"> <li>Recruitment, employee development and retention</li> <li>Patient and consumer health and safety</li> <li>Safety of participants in clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>Business ethics</li> <li>Access to medicines</li> <li>Impact on the local economy</li> </ul>
 <p><b>Employees and employee representatives</b></p>	Survey Consultation as part of the sustainability reporting process	Whenever necessary or requested	Email Internal magazine Notice board Social media Integrated report	<ul style="list-style-type: none"> <li>Recruitment, employee development and retention</li> <li>Energy consumption</li> <li>Materials and waste</li> </ul>	<ul style="list-style-type: none"> <li>Patient and consumer health and safety</li> <li>Safety of participants in clinical trials</li> <li>Volunteering and community investment</li> </ul>
 <p><b>Internal suppliers</b></p>	Meetings Consultation as part of the sustainability reporting process	Weekly	Email Phone Fax Integrated report	<ul style="list-style-type: none"> <li>Energy consumption</li> <li>Animal welfare</li> <li>Materials and waste</li> </ul>	<ul style="list-style-type: none"> <li>Business ethics</li> <li>Impact on the local economy</li> <li>Employee health and safety</li> </ul>
 <p><b>External suppliers</b></p>	Consultation as part of the sustainability reporting process	Weekly or Monthly	Email Phone Videoconferencing	<ul style="list-style-type: none"> <li>Contribution to climate change</li> <li>Materials and waste</li> <li>Energy consumption</li> </ul>	<ul style="list-style-type: none"> <li>Research, development, and innovation</li> <li>Volunteering and community investment</li> <li>Prevention of drug abuse and self-medication</li> </ul>

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Stakeholder category	Engagement method	Frequency	How we communicate	Top 3 topics in terms of negative impact	Top 3 topics in terms of positive impact
 <b>Distributors</b>	Meetings Consultation as part of the sustainability reporting process	Weekly or whenever necessary	Email Phone Videoconferencing	<ul style="list-style-type: none"> <li>• Contribution to climate change</li> <li>• Materials and waste</li> <li>• Water management</li> </ul>	<ul style="list-style-type: none"> <li>• Patient and consumer health and safety</li> <li>• Impact on the local economy</li> <li>• Diversity and equal opportunities</li> </ul>
 <b>Physicians</b>	Meetings Conferences Regional/national scientific events Consultation as part of the sustainability reporting process	Whenever necessary or requested	Email Phone Videoconferencing	<ul style="list-style-type: none"> <li>• Materials and waste</li> <li>• Animal welfare</li> <li>• Water management</li> </ul>	<ul style="list-style-type: none"> <li>• Safety of participants in clinical trials</li> <li>• Patient and consumer health and safety</li> <li>• Impact on the local economy</li> </ul>
 <b>Hospitals</b>	Meetings Conferences Consultation as part of the sustainability reporting process	Whenever necessary or requested	Email Phone Videoconferencing	<ul style="list-style-type: none"> <li>• Safety of participants in clinical trials</li> <li>• Contribution to climate change</li> <li>• Energy consumption</li> </ul>	<ul style="list-style-type: none"> <li>• Research, development, and innovation</li> <li>• Patient and consumer health and safety</li> <li>• Employee health and safety</li> </ul>
 <b>Industry associations or bodies/ Industry representatives</b>	Meetings Consultation as part of the sustainability reporting process	Monthly	Email Videoconferencing	<ul style="list-style-type: none"> <li>• Contribution to climate change</li> <li>• Energy consumption</li> <li>• Combating counterfeit medicines and parallel trade</li> </ul>	<ul style="list-style-type: none"> <li>• Prevention of drug abuse and self-medication</li> <li>• Safety of participants in clinical trials</li> <li>• Access to medicines</li> </ul>
 <b>Business associations</b>	Meetings Consultation as part of the sustainability reporting process	Quarterly	Email Integrated report	<ul style="list-style-type: none"> <li>• Materials and waste</li> <li>• Prevention of drug abuse and self-medication</li> <li>• Diversity and equal opportunities</li> </ul>	<ul style="list-style-type: none"> <li>• Volunteering and community investment</li> <li>• Employee health and safety</li> <li>• Patient and consumer health and safety</li> </ul>
 <b>Patient associations</b>	Patient associations were included in the list of the company's stakeholder categories in 2023, following an internal analysis conducted for the materiality analysis process. At the same time, they were included both in the online consultation and as participants during the validation phase of the material topics (meeting with experts from sectors relevant to the company's impact). Building on this initial consultation, we will keep the dialogue with patient association representatives open, both directly through traditional channels (email, phone) and by including them in future projects and stakeholder consultation processes.			<ul style="list-style-type: none"> <li>• Contribution to climate change</li> <li>• Prevention of drug abuse and self-medication</li> <li>• Access to medicines</li> </ul>	<ul style="list-style-type: none"> <li>• Patient and consumer health and safety</li> <li>• Prevention of drug abuse and self-medication</li> <li>• Safety of participants in clinical trials</li> </ul>

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Stakeholder category	Engagement method	Frequency	How we communicate	Top 3 topics in terms of negative impact	Top 3 topics in terms of positive impact
 <p><b>Non-governmental organizations - NGOs</b></p>	Consultation as part of the sustainability reporting process	Quarterly	Email Phone Integrated report	<ul style="list-style-type: none"> <li>Product promotion policy</li> <li>Recruitment, employee development and retention</li> <li>Research, development, and innovation</li> </ul>	<ul style="list-style-type: none"> <li>Access to medicines</li> <li>Diversity and equal opportunities</li> <li>Prevention of drug abuse and self-medication</li> </ul>
 <p><b>Regulatory and supervisory authorities</b></p>	Meetings Consultation as part of the sustainability reporting process	Whenever necessary or requested	Email Phone Integrated report	<ul style="list-style-type: none"> <li>Contribution to climate change</li> <li>Energy consumption</li> <li>Prevention of drug abuse and self-medication</li> </ul>	<ul style="list-style-type: none"> <li>Impact on the local economy</li> <li>Employee health and safety</li> <li>Volunteering and community investment</li> </ul>
 <p><b>Central and local authorities</b></p>	Meetings Consultation as part of the sustainability reporting process	Whenever necessary or requested	Email Phone Integrated report	<ul style="list-style-type: none"> <li>Contribution to climate change</li> <li>Materials and waste</li> <li>Animal welfare</li> </ul>	<ul style="list-style-type: none"> <li>Safety of participants in clinical trials</li> <li>Volunteering and community investment</li> <li>Access to medicines</li> </ul>
 <p><b>International bodies</b></p>	Consultation as part of the sustainability reporting process	Whenever necessary or requested	Email Integrated report		
 <p><b>Academia</b></p>	Consultation as part of the sustainability reporting process	Monthly	Email Phone Videoconferencing	<ul style="list-style-type: none"> <li>Contribution to climate change</li> <li>Energy consumption</li> <li>Materials and waste</li> </ul>	<ul style="list-style-type: none"> <li>Impact on the local economy</li> <li>Access to medicines</li> <li>Business ethics</li> </ul>
 <p><b>Media</b></p>	Consultation as part of the sustainability reporting process	Weekly	Email Phone Social media Integrated report	<ul style="list-style-type: none"> <li>Energy consumption</li> <li>Contribution to climate change</li> <li>Materials and waste</li> </ul>	<ul style="list-style-type: none"> <li>Volunteering and community investment</li> <li>Patient and consumer health and safety</li> <li>Safety of participants in clinical trials</li> </ul>



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# 1.7. Awards, ratings, and affiliations

## Our awards

### Romanian Chamber of Commerce and Industry

- First place in the ranking of the most competitive companies in Romania by awarding the National 1<sup>st</sup> place prize in the category "Industry - Very large enterprises - Manufacture of basic pharmaceutical products"

For more than 20 consecutive years, Antibiotice has held this top position, both locally and nationally, in the "National Top Companies" organized by the Romanian Chamber of Commerce and Industry.



### Iași Chamber of Commerce and Industry

Antibiotice received the following awards at the **Business Environment Gala - 2023 edition**, organized by the Chamber of Commerce and Industry Iași:

- Laureate Trophy in the Top Companies in Iași County, 2023 edition
- 1<sup>st</sup> place in the ranking of companies in Iași, Industry - Very large enterprises - Manufacture of basic pharmaceutical products
- Diploma of Excellence for having ranked among the top companies in Iași for the last 10 consecutive years

The Top Companies of Iași is the most important and comprehensive ranking of the local business community, based on a complex methodology, unitary at the level of the Romanian Chambers of Commerce System, based on the financial indicators of the companies.

### Romanian CSR Awards 2023, Sustainable Companies Gala

The 12<sup>th</sup> edition of the Romanian CSR Awards, organized in Bucharest on April 9, 2024, recognizes the best sustainability and social responsibility projects that have contributed to improving the quality of life of communities in our country.



250 companies participated in the contest, with 326 projects submitted. Antibiotice's commitment to responsible behavior towards the community has been appreciated and recognized by the awarding of the first prize in the cross-sector partnership section for the 3rd Millennium Antibiotics Project. The 2023 edition of the project, with the message "Treat antibiotics with care for a carefree future", was carried out in partnership with the Grigore T. Popa University of Medicine and Pharmacy Iași, the National Agency for Medicines and Medical Devices of Romania, the Romanian College of Pharmacists - Iași Branch and student associations from university centers across the country.

The award recognizes the contribution of this national program to efforts to limit antimicrobial resistance and the need to promote best practices of use among both specialists and patients to preserve the effectiveness of these valuable therapeutic resources for future generations.

### Randstad Romania Employer Brand Awards

Antibiotice has been named the most attractive employer in Romania in the pharma production category according to the study conducted by Randstad Romania Employer Brand Research. The study is the most comprehensive employer brand research in the world and the results were announced on May 11, 2023, at the **Randstad Romania Employer Brand Awards Gala**.

Randstad Employer Brand Research is the most in-depth independent employer brand research in the world, selecting the most attractive employers from thousands of companies. In Romania, 3,727 people took part in the research, with the analysis providing insight into job selection aspects and the motivations of potential employees.

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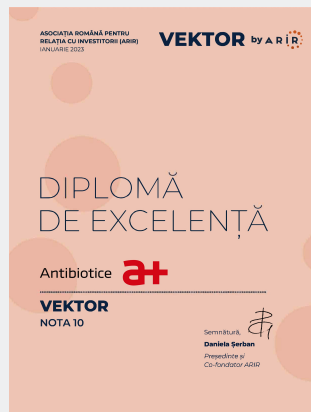
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## External assessment performance

### Antibiotice Iași - a 10 score at VEKTOR for the fifth consecutive year

Antibiotice Iași scored a 10 in the VEKTOR ranking, which reflects the quality of communication with investors in 2023, conducted among companies listed on the Bucharest Stock Exchange by the Association for Investor Relations on the Romanian Stock Exchange (ARIR).

2023 is the fifth consecutive year that Antibiotice has achieved the highest score in this ranking, which is the result of implementing best practices and standards in investor communications and corporate governance.



Evaluation criteria such as investor access to conference calls/meetings/ financial results, non-financial reporting/ sustainability reporting, and dividend policy are some of the criteria evaluated by VEKTOR, for which Antibiotice was rated as having excellent communication with investors.

### ARIR Award 2023 Antibiotice

Antibiotice was awarded by ARIR, having received the most votes from the public at the Gala organized by the association on the occasion of the 5<sup>th</sup> anniversary of its foundation, on November 23<sup>rd</sup> at the Palace of Parliament in Bucharest.

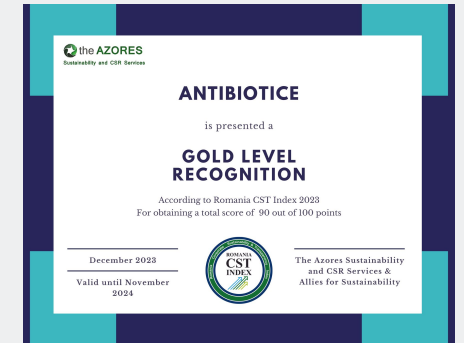
The award for the most votes from the public reflects the fact that individual investors appreciated the transparency and importance of the information communicated about Antibiotice in 2023, the quality of the financial reporting, and the responsible communication in terms of the availability and proactivity of the Antibiotice Investor Relations team.

To mark this anniversary, Antibiotice, an associate member of ARIR, responded positively to the association's initiative by participating in the launch of the anniversary NFT (Non-Fungible Token) collection, the first in the Romanian capital market. The NFT, a type of digital art created by Antibiotice and ARIR, translates the company's mission and values into the digital environment using blockchain technology.

## Sustainalytics

### EESG (Environmental, Social and Governance) assessment, Bucharest Stock Exchange, December 2023

Antibiotice ranks 28<sup>th</sup> in the top 7% of the pharmaceutical sub-industry, out of 443 companies internationally, in terms of ESG (Environmental, Social, Governance) performance, a set of non-financial criteria used by investors to assess the environmental, social, and governance activity and impact of companies. The analysis based on ESG criteria was initiated in 2021 by the Bucharest Stock Exchange, together with Sustainalytics, one of the leading providers of ESG ratings and analysis globally. The ESG score obtained by Antibiotice in 2023 can also be accessed on the [BVB website](#). ESG analysis reports are independently produced by Sustainalytics and scores are calculated based on publicly available reports and information.



### Antibiotice Iași awarded Gold in the most important sustainability ranking in Romania

Antibiotice has achieved Gold Level Recognition with 90 points (out of a maximum of 100) in the Romania Corporate Sustainability & Transparency Index Ranking 2023, the most comprehensive sustainability reporting transparency ranking in our country. The Romania CST Index Ranking 2023 was presented in December 2023, during the Best Practices in Corporate Sustainability conference, organized by The Azores - Sustainability & CSR Services. The assessment was performed after analyzing the sustainability reports of large companies in Romania, covering the year 2022. The reports were evaluated based on a scorecard with 11 categories, 78 sustainability indicators, and 201 data points.

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## Affiliations

### > Chamber of Commerce and Industry Iași (CCI)

Antibiotice SA has been a member of the CCI since 1990. Iași Chamber of Commerce and Industry is a non-governmental and apolitical organization, which supports the interests of the business environment in Iași County. Iași County Chamber is a member of the Romanian Chamber of Commerce and Industry, the national body representing the county chambers of commerce that make up the chamber system. The company is a member of the Board of Directors of the CCI Iași, and the General Director of Antibiotice SA is the First Vice-President of the Chamber of Commerce and Industry (CCI) Iași.

### > National Association of Romanian Exporters and Importers (ANEIR)

Antibiotice SA has been a member of ANEIR since 2009. ANEIR is an apolitical, non-governmental, and non-profit association, founded in 1996, aiming to promote the economic, commercial, financial, and legal interests of its members. ANEIR promotes the interests of its member companies.

### > Romanian Association of Manufacturers of Non-Prescription Drugs, Dietary Supplements and Medical Devices (RASCI)

Antibiotice SA has been a member of RASCI since 2017. RASCI is a non-governmental, non-profit, apolitical, and independent association established in 2016 to represent manufacturers, importers, and distributors of over-the-counter (OTC) medicines, dietary supplements, and personal care medical devices operating on the Romanian market.

### > Association of Generic Drug Manufacturers in Romania (APMGR)

Antibiotice SA has been a member of the Association of Generic Drug Manufacturers in Romania since 2023. Founded in 2009, APMGR is a non-governmental and independent organization that aims to actively contribute to improving access to pharmaceutical treatment for Romanian patients. Currently, APMGR brings together the most important companies in the field of generic drug manufacturing present in the Romanian market.

### > Romanian Investors Relations Association (ARIR)

Antibiotice SA has been a member of ARIR since 2019. ARIR is a non-governmental and non-profit organization that was founded in 2018 to provide current and potential issuers of listed shares with

best practices in investor relations (IR) development. ARIR provides members with the VEKTOR indicator, which evaluates, according to certain criteria, the investor communication of listed companies.

### > Romanian Medicines Serialisation Organization (OSMR)

Antibiotice SA has been a member of OSMR since its establishment in 2019. OSMR was created to implement European legislation on counterfeit medicines and the safety rules for the packaging of prescription medicines for human use (Rx). OSMR is responsible for the implementation and administration of the SNVM (National System for Verification of Medicinal Products), the verification platform through which pharmacies or other stakeholders (wholesale distributors in Romania) can verify the authenticity of an Rx medicine in the legal supply chain.

### > Sustainability Embassy in Romania

Antibiotice has been a member of the Sustainable Romania Coalition since 2023, the first platform for sustainable development founded by the Sustainability Embassy in Romania (ASR), a private, non-political initiative, officially recognized as a partner and facilitator of dialogue on sustainability issues by the Department for Sustainable Development (DDD) of the Romanian Government.



At the regional level, Antibiotice SA is also a member of the European Medicines Verification Organization (EMVO) and the Hungarian Medicines Verification Organization (HUMVO).

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# 02

# Portfolio and products



## 2.1. Our products

**Antibiotice's diverse brand portfolio reflects the company's commitment to the health and well-being of patients, helping to ensure patient access to effective treatments and improving the quality of care in hospitals. Through our manufacturing capabilities and extensive network of international partnerships, we are able to respond quickly and efficiently to critical requests for medicines, contributing to medical safety and emergency preparedness. We remain committed to our mission of making these valuable medicines more accessible as a means of healthcare for patients, physicians, and pharmacists. Partnerships with distributors facilitate the presence of Antibiotice medicines in hospitals and pharmacies in Romania, as well as in international markets where the company is present, thus contributing to and facilitating the fulfillment of the company's mission.**

Access to medicines for human use on the domestic market is provided by a network of 6 national distributors and for veterinary medicines by 4 distributors.

On the international market, we have developed sales of finished products and active ingredients in the territories where we already have registered products, but we have also opened up new territories, particularly in the European Union, in order to achieve the objectives set out in the territorial expansion plan, part of the Strategic Development Plan "The Future

Together". We currently have commercial relationships with over 100 partners, with whom we have developed solid partnerships over time.

Currently, our portfolio includes finished products (generic human and veterinary drugs, medical devices, food supplements, cosmetics, biofertilizers, and biocidal products for surface and hand disinfection), clinical and bioanalytical services for external partners and our products, and active substances based on *Streptomyces noursey* bacteria as

standard, micronized and compacted nystatin. Most of the drugs in the portfolio, as well as active substances, biofertilizers, and biocides are produced on our manufacturing sites.

Some of the Antibiotice medicines are produced in cooperation at the manufacturing sites of partners. Thus, under agreements concluded between the parties, Antibiotice acquires licenses from partners (in-licensing) and sells licenses to interested partners (out-licensing), manufacturing their products in the Iași plant.

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## Antibiotice top products

### Top 20 best-selling\* Antibiotice brands

The top 20 brands (by sales value) marketed by Antibiotice in 2023 recorded market sales of 353.89 million lei

No	Brand	International non-proprietary name (INN)	Therapeutic class and form of administration	Main competitors
1	<b>Eficef®</b> 100 mg and 200 mg	cefiximum	Antiinfectives for systemic use Other beta-lactam antibacterials Capsules	Xifia® (Alkaloid AD), Cefixima Aurobindo (Aurobindo)
2	<b>Cefort®</b> 250 mg, 1 g and 2 g	ceftriaxonum	Antiinfectives for systemic use Other beta-lactam antibacterials Injectables	Seftrion® (E.I.P.I.CO.), Medaxone® (Medochemie) Ceftriaxona-Mip (Mip Pharma)
3	<b>Colistina Atb®</b> 1,000,000 UI	colistini sulfas	Antiinfectives for systemic use Other antibacterials Injectables	Sole product
4	<b>Nidoflor®</b>	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatological preparations Corticosteroids in combination with antibiotics Ointments	Triderm® (Organon)
5	<b>Meropenem Atb®</b> 500 mg and 1 g	meropenemum	Antiinfectives for systemic use Other beta-lactam antibacterials Injectables	Archifar® (Medochemie), Meropenem Kabi (Fresenius)
6	<b>Amoxiplus®</b> 1000 mg/200 mg	amoxicillinum + acidum clavulanicum	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Injectables	Sole product
7	<b>Amoxicilina Atb®</b> 250 mg and 500 mg	amoxicillinum	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Capsules	Ospamox® (Novartis)
8	<b>AmpiPlus®</b> 1000 mg/500 mg	ampicillinum + enzyme inhibitor	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Injectables	Sole product
9	<b>Hemorzon®</b> ointment <b>Hemorzon®</b> suppositories	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoids for topical use Ointments and Suppositories	Procto-Glyvenol® (Recordati), Proctinum® (Natur Product Zdrovit), Prestogel® (Hip Pharma), Cicatridina® (Naturpharma Products)
10	<b>Kanamicina H</b> 5 mg/10 mg/g ophthalmic ointment	kanamycinum + hydrocortisonum	Sensitive organs Anti-inflammatories and anti-infectives with corticosteroids. Ointments	Betabioptal® (Farmila), Tobradex® (Novartis)
	<b>Kanamicina Atb®</b> 10 mg/g ophthalmic ointment	kanamycinum	Sensitive organs Ophthalmic antiinfectives Ointments	Sole product

\* Data source: Cegedim Romania 2023

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No	Brand	International non-proprietary name (INN)	Therapeutic class and form of administration	Main competitors
11	<b>Fluocinolon N<sup>®</sup></b> ointment	fluocinoloni acetonidum + neomycinum	Dermatological preparations Corticosteroids in combination with antibiotics Ointments	Sole product
12	<b>Paracetamol Atb<sup>®</sup></b> 500 mg tablets <b>Paracetamol Atb<sup>®</sup></b> 125 and 250 mg suppositories	paracetamolum	Central Nervous System Analgesics and antipyretics Suppositories and tablets	Paracetamol (Zentiva), Panadol <sup>®</sup> Rapid (Haleon), Paracetamol MCC (Lab. Magistra)
13	<b>Ceftamil<sup>®</sup></b> 1 g	ceftazidimum	Antiinfectives for systemic use Other beta-lactam antibacterials Injectables	Sole product
14	<b>Bisotens<sup>®</sup></b> 5 mg and 10 mg	bisoprololum	Cardiovascular system Beta-blockers Tablets	Concor <sup>®</sup> (Merck KgaA), Bisogamma <sup>®</sup> (Wörwag Pharma), Sobyc <sup>®</sup> (Krka D. D.)
15	<b>Tetraciclina Atb<sup>®</sup></b> 30 mg/g	tetracyclinum	Dermatological preparations Broad-spectrum antibiotics Ointments	Sole product
	<b>Tetraciclina Atb<sup>®</sup></b> 250 mg	tetracyclinum	Antiinfectives for systemic use Tetracyclines Capsules	Sole product
16	<b>Ampicilina Atb<sup>®</sup></b> 250 mg, 500 mg and 1 g	ampicillinum	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Capsules and injectable	Epicocillin <sup>®</sup> (E.I.P.I.Co.), Ampicilină Arena (Arena Group)
17	<b>Saliform Forte<sup>®</sup></b> cremă 100 g, 50 g and 25 g	fluocinoloni acetonidum + neomycinum	Dermatological preparations Corticosteroids in combination with antibiotics Ointments	Sindolor <sup>®</sup> (Fiterman Pharma), Deep Relief <sup>®</sup> (Laropharm), Arnigel <sup>®</sup> (Lab. Boiron) Dolorgiet <sup>®</sup> (Natur Produkt Zdrovit)
18	<b>Piafen<sup>®</sup></b> 500 mg	A3D0 combinations	Gastrointestinal tract and metabolism Antispasmodics in combination with analgesics Tablets	Algifen <sup>®</sup> (Zentiva)
19	<b>Nolet<sup>®</sup></b> 5 mg	nebolololum	Cardiovascular system Beta-blocker Tablets	Nebilet <sup>®</sup> (Menarini) Nevivolol Actavis (Teva) Nebivolol Aurobindo (Aurobindo Pharma)
20	<b>Clotrimazol Atb<sup>®</sup></b> 10 mg/g cream	clotrimazolum	Dermatological preparations Antifungals Ointments	Canesten (Bayer AG), Clotrimazol (Slavia Pharm)

\* Data source: Cegedim Romania 2023

## Top products for which Antibiotice is the sole manufacturer

Antibiotice is the sole manufacturer on the Romanian market for 55 products, among which, the best known are::

No	Product	Therapeutic indication	Therapeutic class and form of administration
1	<b>Aceclofen®</b>	Anti-rheumatic and anti-inflammatory	Musculoskeletal system Suppositories
2	<b>Colistina Atb®</b> 1,000,000 UI	Anti-infectives for systemic use	Antiinfectives for systemic use Powder for injection
3	<b>Equilibra Plus®</b>	Combination of highly absorbable magnesium and vitamin B6	Digestive tract and metabolism Tablets
4	<b>Fluocinolon N Atb®</b> 18 g	Topical corticosteroid in combination (fluocinoloni acetonidum + neomycini sulfas)	Dermatologic preparations Topical corticosteroid in combination Ointment
5	<b>Fluxiv®</b> range	Venotonic	Cardiovascular system Tablets /Cream
6	<b>Hemorzon®</b> range	Anti-hemorrhoidal	Cardiovascular system Anti-hemorrhoidal for topical use Ointment /Suppositories
7	<b>Mastoprofen®</b> 40 g	Progestogenic	Genitourinary System - Progestogenic Gel
8	<b>Moldamin®</b> 1,200,000 UI	Anti-infectives for systemic use	Antiinfectives for systemic use, broad-spectrum penicillins. Powder for injection
9	<b>Neopreol®</b> 40 g	Anti-microbial and anti-inflammatory	Dermatologic preparations Ointment
10	<b>Nidoflor®</b> 15 g	Topical corticosteroid in combination (triamcinolonum + nystatinum + neomycinum)	Dermatologic preparations Cream
11	<b>Nistatina Atb®</b> range	Antifungal	Gynecological anti-infectives/ Digestive tract and metabolism. Pessaries/Film-coated tablets
12	<b>Oxacilina Atb®</b> range	Anti-infectives for systemic use	Antiinfectives for systemic use, penicillins Powder for injection /Capsules
13	<b>Penicillin G Atb® Potassium</b> 1,000,000 UI and <b>Penicillin G Atb® Sodium</b> 400,000 UI and 1,000,000 UI	Anti-infectives for systemic use	Antiinfectives for systemic use, broad-spectrum penicillins Powder for injection
14	<b>SimbiFlora®</b> range	Probiotic	Digestive tract and metabolism Capsules
15	<b>Zifex® Complex</b>	Gynecological anti-infective	Gynecological anti-infectives Ovule

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## 2.2. Strategic development

### Company consolidation in the domestic market

The 68-year presence on the Romanian market testifies the performance of Antibiotice's business model. The company's products are sold in approximately 8,100 open-circuit pharmacies in Romania<sup>1</sup>, 367 public hospitals, and 309 private hospital units (units with beds).

Antibiotice Iași is included in the list of objectives of particular importance for the defense of the country, having a strategic role in the national economy. Its organizational structure, with branches in international territories and collaboration contracts with partners all over the world, allows the company to act in the shortest possible time, from the moment an order is received to the moment it is fulfilled. Thus, in critical periods, such as the two years of the pandemic or whenever a threat was likely to affect the entire population of the country, Antibiotice acted with maximum efficiency and responsibility and produced life-saving medicines.

One of Antibiotice's priorities is to ensure the affordability and availability of pharmaceutical products for patients, doctors, and pharmacists. This is possible by concluding contracts with the most

important distributors in Romania serving the hospital and retail segments, including the main pharmacy chains with national coverage.

The current context indicates that distributors have focused their development on setting up their own sales and communication channels with patients through pharmacy chains. Year after year, the number of independent pharmacies decreases.

Antibiotice has therefore adapted both its commercial and portfolio strategy, focusing on adapting its product portfolio to the specific needs of the Romanian pharmaceutical market. This may mean introducing new products into the portfolio, adapting existing formulations, or diversifying the product range to meet the preferences/needs of patients and health-care professionals.



**8,100**  
pharmacies

**367**  
public hospitals

**309**  
private hospital units

<sup>1</sup> According to data from the Ministry of Health 2023.

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Antibiotice provides patients with over-the-counter (Non-Rx) medicines, dietary supplements, dermato-cosmetic products, and medical devices in various pharmaceutical forms, complete and diversified product ranges that contribute to improving health and increasing the quality of life.

The consolidation of the company in the Romanian pharmaceutical market requires a well-defined strategy and the active participation of all the sales and promotion teams.

The role of the sales and promotion team is to strengthen the partnership with the distributors and the effective communication of medical and commercial information in the territory, in as many pharmacies, medical practices, and hospitals as possible.

The company has developed a strong and competitive team of medical and sales representatives, who ensure a two-way flow of information between the company and distributors, prescribers, pharmacists, and patients, which ensures increased accessibility and patient satisfaction with Antibiotice products.

There is also a permanent preoccupation of the mixed team of medical representatives, portfolio management specialists, and research and development specialists, who liaise with Key Opinion Leaders (KOLs), to define therapeutic solutions adapted to current medical trends.

Antibiotice is a trusted partner of local health authorities, both as a consultant on healthcare policies for communicable diseases (tuberculosis, syphilis) and

chronic diseases (heart disease) and as a constant supplier of medicines (for some of which Antibiotice is the sole bidder) to hospitals at affordable prices, medicines that comply with European EU GMP manufacturing and quality standards for active substances. Also, all dietary supplements produced by Antibiotice are based on the expertise of the company's researchers and are manufactured to the same quality standards as the medicines.

Antibiotice is a company that responds to the changes and needs of the Romanian market, able to adapt its strategies to strengthen its position in the domestic market and achieve long-term stability.

### Pharmaceutical market developments in Romania<sup>2</sup>

In 2023, the total value of the market in Romania (medicines dispensed from pharmacies to patients and consumers) was 29.96 billion lei, at a distribution price up 16.2% compared to 2022, representing a total consumption of medicines (in units) of 722.6 million boxes, up 2.4% compared to 2022.

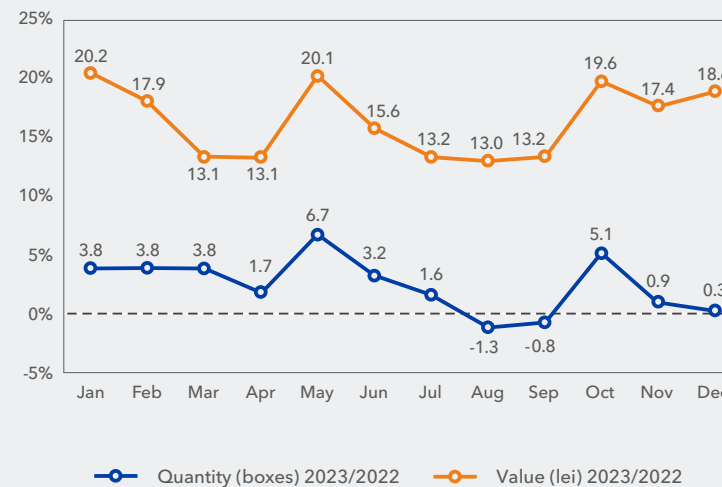
The Romanian pharmaceutical market is dominated by prescription medicines (Rx), accounting for 74.9% of total sales value and 62.5% of total quantitative medicine consumption (reported in boxes).

Prescription medicines (Rx) had a value increase of 18.2% to 22.4 billion lei in 2023 (compared to 19 billion lei in 2022), while non-prescription non-Rx products (OTC, dietary supplements, medical devices) had a value increase of 10.7% to 7.5 billion lei (compared to 6.8 billion lei in 2022).

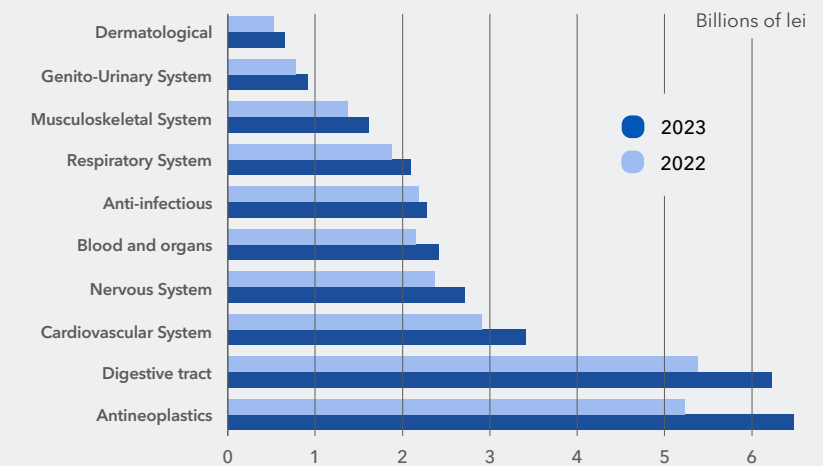
The top five therapeutic classes, grouped according to the share of value sales in 2023, account for 71% of total sales on the Romanian pharmaceutical market, namely antineoplastic medicines, for the digestive tract, cardiovascular system, central nervous system, blood and hematopoietic organs.

<sup>2</sup> According to Cegedim District Sell-Out, December 2023

Monthly evolution of the total market (2023 vs 2022)



Value evolution - Top 10 therapeutic classes (2023 vs 2022)



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## Evolution of the generic Rx and non-Rx market

**Generic Rx and non-Rx drugs recorded a value of 13.3 billion lei in the period under review, up 14% compared to 2022 (11.7 billion lei). In 2023, the quantitative medicines consumption in the generics and non-Rx market increased by 1.4% (530 million boxes were dispensed from pharmacies compared to 522.7 million boxes in 2022).**

In 2023, prescription medicines (Rx) accounted for 43.4% of total value sales and 48.9% of total medicine consumption (reported as number of boxes), with a value increase of 18.7% (from 4.9 billion lei in 2022 to 5.1 billion lei) and a 4.8% quantity increase (from 247.1 million boxes in 2022 to 259.1 million boxes in 2023).

Non-prescription medicines (non-Rx) accounted for 56.6% of total value sales and 51.1% of total medicine consumption (reported as the number of boxes), registering a value increase of 10.7% (from 6.8 billion lei in 2022 to 7.5 billion lei in 2023) and a quantity increase of 1.7% (from 275.6 million boxes in 2022 to 271.0 million boxes in 2023).



**522** million lei in sales on the Romanian pharmaceuticals market

**28.5** million boxes sold to patients and consumers in Romania

## Antibiotice on the pharmaceutical market in Romania

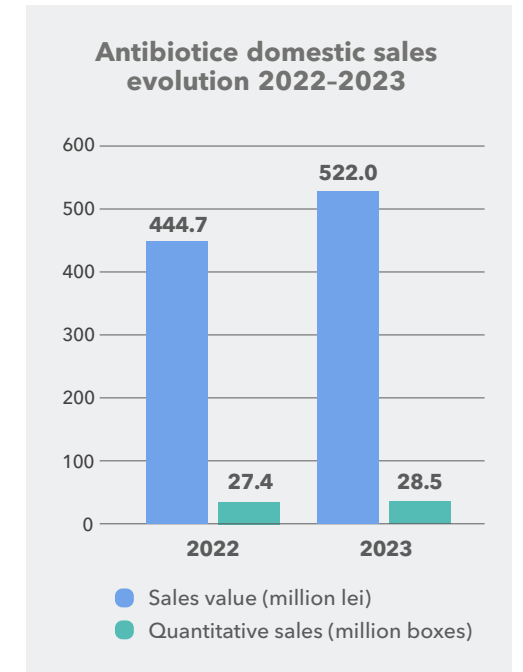
The sales value of Antibiotice's medicines to distributors in 2023 was 500.4 million lei (28.9 million boxes) and the sales value of distributors to hospitals and pharmacies was 482.4 million lei and consumption of 27.6 million boxes (162.2 million lei and 1.6 million boxes in the hospital segment and 320.2 million lei and 26.1 million boxes in the pharmacy segment).

In the retail pharmacy segment, sales reached 109.3 million lei and 9.02 million boxes in pharmacy chains and 210.8 million lei, and 17.03 million boxes in independent pharmacies and mini chains.

According to District Sell-Out, Cegedim Customer Information in 2023, Antibiotice recorded quantitative sales of 28.5 million units (boxes) and a value of 522 million lei on the domestic market in pharmacies and hospitals.

The products with significant increases in the value of sales from pharmacies to the final consumer (sell out) in 2023 are Eficef<sup>®</sup> capsules range, Amoxicillin capsules 500 mg, Colistin Antibiotice<sup>®</sup> inj 1,000,000 IU, Vancomycin Atb injectable 1g, Cefort<sup>®</sup> injectable 2 g, Nidoflor<sup>®</sup> cream 15 g, Perasin<sup>®</sup> injectable 4.5 g, Kanamicina<sup>®</sup> ophthalmic ointments, Amoxiplus<sup>®</sup> injectable 1000 mg/200 mg, and Zifex<sup>®</sup> range pessaries.

Our company has also strengthened its systemic anti-infective component, while also developing adults' and children's cold and flu products, women's health products, and ophthalmic products, areas where it holds important positions in the domestic market. Antibiotice has been in constant contact with distributors to ensure there are no gaps in the supply of medicines to hospitals and pharmacies and to build up optimal stocks so that orders can be delivered in the shortest possible time. The company has adapted to market demand, fully covering the need for treatment with injectable antibiotics such as carbapenems, cephalosporins, and penicillins.



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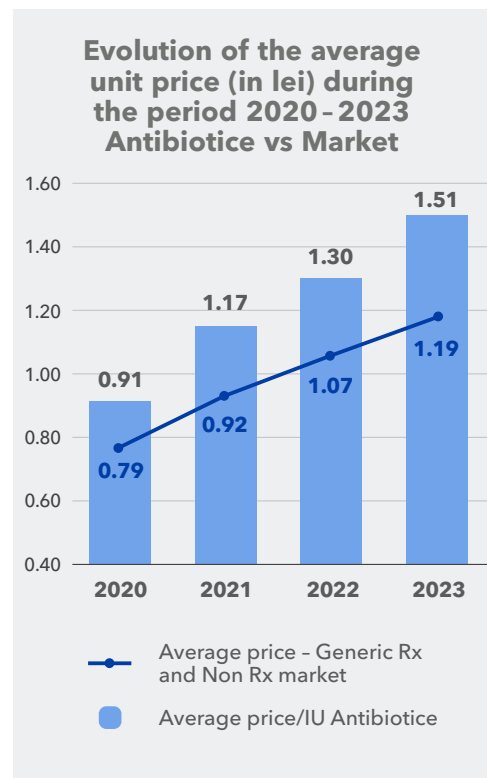
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## Price, a strategic element of market adaptation

The average market price of RX and non-Rx generics in 2023 was 1.19 lei/unit (indivisible unit), up 11.3% compared to the previous year (1.07 lei/unit). The average market price of RX and non-RX generics in 2023 was 1.19 lei/IU (indivisible unit), up 11.3% compared to the previous year (1.07 lei/IU). In terms of sales channels, the price structure is as follows: in the hospital channel - 5.78 lei/IU, of



which injectables were priced at 9.59 lei/IU, up 11.5% compared to the previous year. In the independent and mini-pharmacies (MLFI) segment - 1.13 lei/ IU (up 11.9% compared to 2022), and in the national chains channel - 1.08 lei/ UI (up 10.4% compared to 2022).

The average price of the Antibiotice portfolio in 2023 per indivisible unit was 1.51 lei/IU, up 16.0% from 1.30 lei/IU in 2022.

The product positioning strategy is the starting point for the entire marketing mix, including product and pricing policy. The implementation of strategies by market segments and promotion concepts led to an efficient value in the portfolio structure compared to the planned average price, with an achievement rate of 108.8%.

In terms of sales channels, the price structure of the Antibiotice SA portfolio in 2023 was as follows: for the hospital channel - 4.74 lei/IU, of which injectable products were priced at 9.90 lei/IU (up +17.2% compared to last year), for the mini-chain channel and independent pharmacies - 1.24 lei/IU (up +14.6% compared to 2022), and in chain pharmacies - 1.02 lei/IU (up +18.0% compared to 2022).

In the retail segment, the focus on the development projects of the non-Rx product brands in the Quality Life - Nutriensa range generated a 13.6% increase in the average unit price compared to 2022, from 0.87 lei/unit to 0.99 lei/unit.



The development of the Quality Life - Cold and Flu range through the introduction of new pharmaceutical forms: sachet (RemiFLU® ), oral spray (Faguria oral spray) and drops (Faguria drops), as well as the price increase on the current portfolio, led to an increase in the average unit price of the Quality Life - Cold and Flu range of +35.3%, from 0.78 lei/UI in 2022 to 1.06 lei/UI in 2023.

The launch of the Tinero range of dermatocosmetic products with a selling price above the portfolio average: Tinero AZ® Serum and Tinero AZ® Cream, as well as the price repositioning of the products in the current portfolio at a competitive level, led to a 6.7% increase in the average price of the Derma+ concept, from 19.47 lei/UI in 2022 to 20.77 lei/UI in 2023.

## Internal market customer satisfaction

Under the requirements of ISO 9001/2015 for the implementation of the quality management system, Antibiotice carried out a market survey on the assessment of customer satisfaction\*, which has been carried out annually since 2006, also in 2023. For 2023, the "Customer Satisfaction Assessment" research was conducted from November 2023 to January 2024. Data was collected through questionnaires sent to representative customers of Antibiotice: physicians, retail pharmacists (independent pharmacies), distributors, national chain managers, and mini-chain managers.

The average satisfaction level for the 5 customer categories in 2023 is 89.6%. All representative customers scored above 80%, which places them in the "satisfied customer" category according to the customer satisfaction categorization. Sales and promotion results are evaluated monthly and quarterly. The survey results form the basis of the action plan to correct the indicators that have not been met according to the annual plan.

\* Satisfaction level is calculated as absolute scores (from 1 to 5) and relative scores (percentages from 1 to 100%)

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## Company consolidation on the external market

### In 2023, Antibiotice SA was again one of the top 10 manufacturers of sterile beta-lactam penicillins in Europe and North America

Revenue from sales of finished products on the international market in 2023 amounted to 132.3 million lei, a 20% increase compared to the previous year. The medicines produced by Antibiotice SA have shown a strong upward trend in international exposure, with a compound annual growth rate (CAGR 2019-2023) of 9.5%, double the global pharmaceutical market growth rate reported by IQVIA (CAGR 2019-2023 = 4.03%).

The international development strategy considered the fact that the markets have a high consumption potential for the products in the company's strategic portfolio, shorter payment terms, and less exposure to the surcharge system (e.g., claw-back).

Access to highly competitive markets, with high demands regarding the quality and therapeutic efficacy of medicines, required the adaptation of the product portfolio according to the consumption profile of each territory - tender or outpatient, selection of partners who can adopt Antibiotice's long-term vision, and flexibility in accessing markets through diverse business models.



**Benefiting from a diversified portfolio of 60 products that can be registered in all international markets - mainly anti-infectives, cardiovascular medicines, and food supplements - Antibiotice confirms its status as the leading international producer of beta-lactam penicillins, among the top 10 in North America and Europe in 2023.**

**In this respect, it is worth noting the performances achieved in 2023. Some of them confirm the strategy of consolidation in established territories - Vietnam, USA, Canada, Republic of Moldova, Serbia, United Kingdom, Denmark, and Norway - while others are starting points for the company's long-term development: Poland, Hungary, and Georgia.**

Thus, according to market analyses reported by IQVIA, the "flagship" drugs that also define Antibiotice's core business such as beta-lactam penicillins (Ampicillin, Flucloxacillin, Nafcillin) and combination beta-lactam penicillins (Ampicillin/Sulbactam, Amoxicillin/Clavulanate, Piperacillin/Tazobactam) have reached significant market shares in national consumption in territories such as Vietnam (42%), UK (between 20% and 40% depending on the product), USA (between 20% and 27% depending on the product), Serbia (20%), Hungary (65%). Concretely, in these markets, at least 1 out of 5 patients benefited from Antibiotice injectable products in the treatment of acute anti-infectious diseases.

Antibiotice's presence and projects in countries with significantly lower incomes or lack of access to health insurance and territories that have difficulties in financially supporting National Communicable Disease Control Programs are representative of how the company contributes to improving access to medicines. In 2023, anti-infective drugs for acute and mild infections, as well as drugs for chronic conditions (anti-tuberculosis, syphilis treatment drugs), cardiovascular drugs (hypertension) were delivered to territories in the Middle East (Iraq, Yemen) and Africa (Tunisia), Non-EU Europe (Albania, Bosnia and Herzegovina, Kosovo) accounting for approximately 7% of the total value of drug exports.

In 2023, Antibiotice launched a pilot project in Ukraine to deliver 25,000 vials of two of the world's most prescribed anti-infective drugs to hospitals in the country.

The territorial expansion plan aimed at the sustainable development of Antibiotice in the 2030s has materialized in the 2023 phase by achieving three objectives:

- access to three new territories: Hungary (2 anti-infective medicines), Poland (3 anti-infective medicines), Georgia (4 anti-infective medicines and 2 digestive tract medicines);
- negotiating contractual terms with partners for the implementation of new projects that will generate significant growth in the coming years in countries such as Italy, Spain, Poland, Germany, Czech Republic, Bulgaria, United Arab Emirates, and Australia;
- 16 products launched in 7 territories covering the following therapeutic spheres: anti-infectives, women's health, and digestive tract disorders.

Medium- and long-term projects focus on strengthening sales of anti-infective medicines in current territories, accessing new markets mainly in the European Union, the Middle East, and Asia-Pacific,

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### Relevant statistical milestones in 2023:

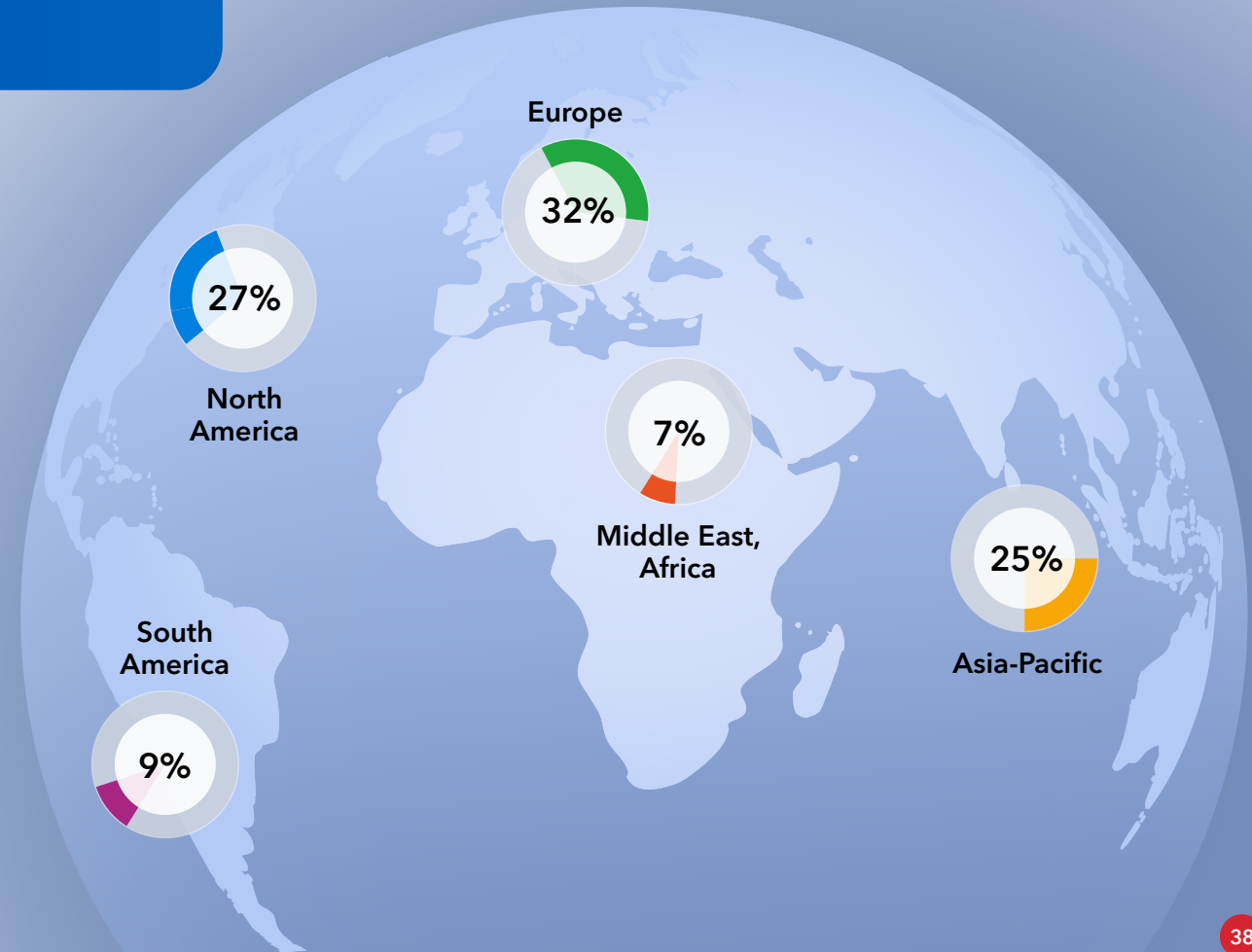
- **+22% revenue from sales** of finished products on the international market
- **\$7 million** export of medicines to the USA
- **63% of exported volumes** are capsules and tablets
- **16 new products** launched
- **30 territories** in which we exported, of which 12 to EU member states
- **3 new territories** accessed

and creating business opportunities for dermatological and women's health products.

To strengthen ties with traditional partners in the foreign market, but also to find new business opportunities and new pharmaceutical product development, in 2023 Antibiotice was represented at CPhI Worldwide, which took place in Barcelona, Spain, by a delegation of specialists in Research-Development, Procurement, International Sales, and Business Development.

*(Note: CPhI Worldwide is a pharmaceutical industry event that brings together thousands of healthcare professionals annually.)*

### Share of international sales in 2023



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## Representative territories where the Antibiotice's finished products are supplied

Territories	Sector	Customer type
<b>Romania</b>	Pharmaceutical	Medical prescription (Rx) medicines for human use, OTCs (non-prescription medicines), cosmetics, and food supplements are sold to distribution companies. Then the distribution companies sell them to hospital pharmacies to reach the beneficiaries (i.e., hospitalized patients) as well as to independent and chain pharmacies to be sold to the general public.
<b>Vietnam</b>	Pharmaceutical	Sterile injectable penicillins and cardiovascular medicines (human-use Rx medicines) are sold to drug distribution companies. They then sell them to hospital pharmacies, reaching inpatients and outpatients (who receive treatment at home).
<b>Republic of Moldova</b>	Pharmaceutical	Rx and OTC human-use medicines (from 6 therapeutic areas) are sold to drug distribution companies. They sell them to hospital pharmacies, reaching in-patients, and to independent and chain pharmacies, where they are bought by the general public.
<b>Serbia</b>	Pharmaceutical	Human-use Rx drugs (only available by prescription), food supplements, and cosmetics (available in pharmacies without prescription) are sold to drug distribution companies. They sell them in tenders organized by hospitals and in retail pharmacies, where they reach the beneficiaries (patients, general public).
<b>United Kingdom</b>	Pharmaceutical	Sterile injectable penicillins (human-use Rx medicines) are sold to drug distribution companies. They sell them to hospitals following tenders, where they reach in-patients.
<b>Denmark</b>	Pharmaceutical	Sterile injectable penicillins (human-use Rx medicines) are sold to drug distribution companies. They sell them to hospitals following tenders, where they reach in-patients.
<b>United States</b>	Pharmaceutical	Finished products for human use (sterile injectable penicillins - Rx medicines) are sold to drug distribution companies. The distributors then sell them to hospital pharmacies, health centers, private clinics, and health insurance companies, from where they reach the beneficiaries (in-patients).
<b>Iraq</b>	Pharmaceutical	Human-use Rx drugs (from 5 therapeutic areas) are sold to drug distribution companies. These sell them to independent and chain pharmacies where they are bought by the general public.

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## The impact of the war in Ukraine

In February 2023 we launched a “pilot” project in Ukraine for two beta-lactam anti-infective drugs, injectable powders – Xivulan® 1.2 g (amoxicillin/K-clavulanate) and Ampiplus® 1.5 g (ampicillin/sulbactam).

In conflict areas, the risk of infection is significantly increased due to limited access to health care, exposure to poor hygiene, and the presence of open wounds, which are susceptible to contamination.

The use of broad-spectrum antibiotics – such as the two products included in the pilot project – are anti-infective drugs of first choice in the rapid treatment of infections when a precise treatment (identified by antibiogram) is difficult to achieve in precarious conditions or when a rapid, immediate, life-saving medical decision is needed.

## Consolidation of world-leading status in the production of the Nystatin-based range of active substances

The portfolio for international markets includes, in addition to finished products, the Nystatin-based (antifungal) range of active substances. At Antibiotice, the production of Nystatin began in 1975, but interest in this active substance increased in the 2000s when, following FDA inspection (2002), the manufacturing

flow of this active substance received approval allowing export to the US market.

From that moment on, Antibiotice has become a leading international manufacturer and soon a world leader.

Nystatin manufactured through a unique biosynthesis process in Romania is, since 2017, the international reference standard certified by the United States Pharmacopeia (USP). Thus, companies that produce Nystatin, active substance or finished Nystatin-based medicines and want to sell them on the US market (or on markets that have adopted USP as their national pharmacopeia), will use the characteristics of the Nystatin produced at Antibiotice Iași as a reference standard in testing the quality of their products.

Nystatin is supplied to manufacturers all over the world and is used as raw material for the manufacture of tablets, oral suspensions, topical preparations (creams, ointments), and pessaries. The activity carried out in 2023 was in line with the growth trend of recent years and aimed at consolidating the position on the global market for the export of active ingredients based on biotechnologies derived from streptomyces noursei for pharmaceutical use, which are sold in more than 55 countries worldwide.

Good progress was made in the major consolidation and development projects in Europe, North America, and Latin

America, continuing the good development prospects in the major export markets for Antibiotice's nystatin.

## International customers' satisfaction level

The financial results of Antibiotice, the professionalism, and the reliability of how the company collaborates with the international partners have reflected also in the business partners' level of satisfaction, which is measured each year, according to the requirements of the quality management system in place. Thus, every year, during the first quarter, a market survey is conducted to evaluate the level of satisfaction of the significant customers (i.e., international customers who ensure more than 80% of the sales of the reviewed year and with sales not lower than 50,000 USD). To assess their level of satisfaction, a questionnaire is used in the form of a series of statements to which the customer gives a rating for each topic. In 2023, after analyzing the results, an overall score of 97.68% was obtained, compared to 2022 (96.07%) and compared to the operating standard of 80%.

With a satisfaction level of 100%, all customers interviewed confirmed that the organization and transport of finished products were carried out in optimal conditions of physical and qualitative integrity (goods arrived intact, without partial/total damage/destruction at the packaging or product level, in accordance with the design and specification

approved by the local authorities, transparency in the provision of all documents necessary to carry out legal import formalities).

Respondents unanimously gave Antibiotice top marks for being a company they can trust to develop sustainable collaborations with, a company that responds promptly to customer needs, and a company that produces safe, high-quality medicines according to GMP standards.

**Nystatin**  
international reference standard

**Nystatin**  
is present in 55 countries

**97.68%**  
satisfaction level of international customers



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## Investments and related activities for strategic development

### Antibiotice SA defines its strategic directions and business objectives in close connection with investment projects in order to ensure the sustainable development and long-term performance of the company.

During 2023, Antibiotice made investments totaling 98.05 million lei to implement key projects that support business objectives and sustainable growth.

Significantly, the amount of performed investments exceeded the amount originally planned. This was made possible by increasing the budget for the 2023 Investment program from 77.80 million lei to 99.02 million lei. The additional 21.21 million lei was based on a strategic reassessment and the replanning in 2023 of some investment objectives originally programmed for 2024. The replanning was generated by the approval of the financing, through the State aid scheme established by GD no. 807/2014, for the project "Production capacity, packaging and storage of sterile products, solutions and topicals", valued at 200 million lei. This strategic decision allowed the concentration of resources and efforts toward key initiatives to strengthen the company's production capacity and competitiveness in the market.

### Investment in strategic development

Investments in developing the product portfolio and expanding production capacity are fundamental pillars of Antibiotice SA's growth strategy. Through these actions, the company strengthens its position in the market and ensures its ability to meet the requirements of its customers efficiently and competitively, thus contributing to its long-term success.

As part of its development strategy, Antibiotice SA focuses its efforts and investments on expanding and improving its product portfolio. Its own Research and Development program is a central component of the strategic plan, with the main objective of ensuring a competitive portfolio of pharmaceutical products for both the national and international markets.

In 2023, the company continued to direct significant resources to research and development projects, aiming to bring quality, safe, effective, and competitive new products to the market. The Research Center prioritized the development of products in various therapeutic areas, distributed as follows: dermatology (29%), genito-urinary (23%), anti-infective (19%), digestive tract (13%), central nervous system (10%) and musculoskeletal system (10%). International collaborations also



continued to accelerate the development of the product portfolio, highlighting the company's commitment to innovation and adaptability to market requirements.

Another initiative to support Antibiotice's development strategy is the investment in new manufacturing facilities. To this end, the company has initiated the contracting process for the design and construction of three manufacturing flows. Progress is expected to lead to the signing of the design and construction contracts in the first half of 2024, thereby strengthening production capacity and increasing the company's operational flexibility and efficiency.

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## Investments for business consolidation

Antibiotice's investments in 2023 reflect the company's commitment to strengthening its business and adapting to market needs and trends. By investing in technology, infrastructure, integrated management, and equipment modernization, the company is strengthening its position in the market and ensuring a solid foundation for sustainable growth and development in the near future.

In 2023, Antibiotice directed sustained investments in information technology and the digitalization of processes. 8.31 million lei were allocated to the purchase of software aimed at optimizing human resources, quality, and research activities and strengthening data security at all levels of the company.

Antibiotice invests in digitalization for the transition to a sustainable business, choosing to sign a contract with IBM Romania Consulting in 2023, through which it benefited from consultancy to digitalize according to current needs and priorities, but also in terms of the objectives set in its strategic plan. In 2023, the feasibility phase was completed for the implementation of an ERP system, to be implemented in 2024, thus strengthening the company's digital infrastructure for greater operational efficiency.

Through this project, the company aims to take its digital transformation to the next



level by implementing the most advanced integrated software solution to help strengthen the digital foundation to anticipate and meet the complex needs of the pharmaceutical industry.

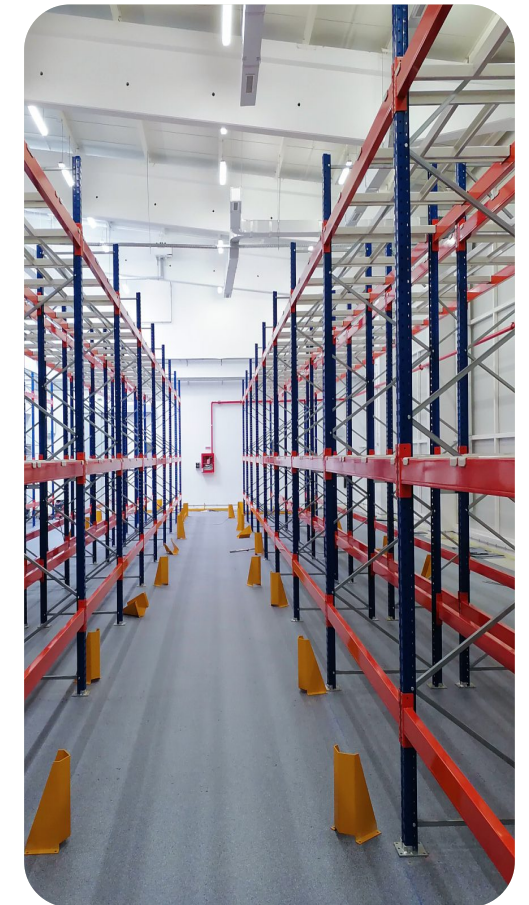
Antibiotice SA has invested in adapting to industrial developments and modernizing

its infrastructure. The investment objective of increasing the storage capacity for raw materials to accommodate the growth and diversification of production has been completed. The construction of a modern warehouse for finished products adapted to the expected production needs until 2030 has also started. Significant progress has also been made on projects to modernize production and utility distribution facilities. A key aspect of these investments is the company's commitment to green energy production and reduced energy consumption. Projects for the construction of photovoltaic power plants have been successfully launched and are scheduled to be handed over in 2024, contributing to the reduction of greenhouse gas emissions and reinforcing the company's commitment to sustainability.

To maintain high product quality standards and comply with environmental protection and occupational health and safety regulations, Antibiotice has invested 10.77 million lei in its Integrated Management System. These investments have been directed towards modern equipment and technologies to ensure accuracy and compliance in laboratory analysis and support the company's sustainability commitments.

As part of its efforts to modernize and re-engineer its production processes, Antibiotice SA has allocated 10.95 million

lei for the purchase of equipment, installations, and laboratory equipment. This investment was aimed at re-technologizing and improving production processes in order to ensure greater product efficiency and quality in all three divisions of the company.



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## Attracting funding for investment

Attracting multiple and varied sources of funding demonstrates Antibiotice's capacity and commitment to implement its strategy for sustainable growth and development. By investing in manufacturing capacity, renewable energy, and strategic expertise, the company is strengthening its market position and contributing to the consolidation of the pharmaceutical industry within the European Union.

### Financing for competitiveness:

on May 17, 2023, Antibiotice SA reached an agreement for the financing of the project "Production capacity, packaging and storage of sterile products, solutions and topicals", within the call for projects financed under GD 807/2014. The total value of the project is 200.1 million lei, of which 85 million lei is granted by the State. This initiative is integrated with "The Future Together" Business Plan and marks a significant milestone in strengthening production capacities and maintaining a competitive advantage in the market.

### Financing for green energy production:

in June 2023, Antibiotice SA received funding under the National Recovery and Resilience Plan (NRRP) for the "2.5 MW Photovoltaic Power Plant" project. This funding, amounting to 4.1 million lei, underlines the company's commitment to sustainable practices and to reducing its carbon footprint through renewable energy production.



### European Investment Bank Consultancy Grant:

Antibiotice SA benefits from the expertise of the European Investment Bank (EIB) in developing its long-term strategy. In April 2023, a grant consultancy agreement was signed, whereby EIB experts are working with the company's experts to identify the optimal solutions for growth and development, both domestically and internationally.

Financing agreement with the European Investment Bank: In November 2023, Antibiotice SA signed a financing agreement in the form of a loan granted through the InvestEU facility. The loan, amounting to €25 million, will support the implementation of the company's Investment program, included in the "The Future Together" business plan. This partnership is a first in the Romanian healthcare sector and contributes to the consolidation of the objectives included in the EU Pharmaceutical Strategy, which aims to address the shortage of medicines and strengthen the security of the supply system in the European Union.



€25 million

financing from the European Investment Bank as a loan granted under the InvestEU facility, to support the company's investment program, included in the "The Future Together" Business Plan

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## 2.3. Access to medicines

Access to medicines is essential to protect and promote people's health and it is a fundamental right that must be provided to all people, regardless of their geographical location, socio-economic status, or other barriers, in order to promote equitable access to services and products that ensure health and general well-being of the population. The right to health implies not only access to healthcare and treatment but also to the medicines needed to prevent, treat, and manage medical conditions. Access to medicines is also an important component of any healthcare system and is dependent on multiple factors such as price, availability and distribution, regulatory processes, as well as the population's education and awareness, etc.

At the same time, improving access to medicines is generally a complex issue requiring a multi-stakeholder approach and the involvement of several parties – manufacturers, local agents, distributors, and national contracting authorities (hospitals and health centers, insurance companies, etc.). The good representation of Antibiotice medicinal products in some markets, as certified by market share, is proof that this synergy has been achieved by implementing measures leading to competitive prices in different regions of the world,



increased availability of medicines, and collaboration with stakeholders to address the specific challenges of each region or vulnerable population group. In practice, in these markets, at least 1 in 5 patients have benefited from Antibiotice Romania products in the treatment of acute anti-infectious diseases.

The same applies to projects in countries with significantly lower incomes or no

access to health insurance, where healthcare systems have difficulties in financially supporting National Communicable Disease Control Programs.

As a manufacturer of generic medicines, we understand the essential role that treatments play in increasing health affordability. Generic medicines are not only modern and effective, they are essential for the budgetary sustainability

of health systems, ensuring that people from all social groups receive and can afford the medicines they need.

As a strategic partner of the Romanian healthcare system, Antibiotice is the main manufacturer of first-line anti-tuberculosis drugs, pre-qualified by the WHO to treat this disease, considered by the WHO as one of the major public health problems.

In 2023, the company supported awareness campaigns through a series of events aimed at informing people of all ages about this disease. The campaigns were carried out by medical specialists who promoted among the population at risk the correct methods of prevention of this disease, and the need to comply with the treatment of diagnosed patients and their relatives. To mark the day, Antibiotice lit up the statuary complex in front of the factory in red, the symbol of the fight against tuberculosis, along with other important local and national buildings.

Antibiotice is the market leader in the domestic segment of antibacterial drugs for systemic use and the main supplier in the Romanian hospital market, offering a wide range of antibiotics for the treatment and prophylaxis of a broad spectrum of infections.

In addition to our strategy of increasing our international presence and investing

in research, development, and innovation projects, our efforts to improve access to medicines also include targeted interventions when critical situations arise.

In the context of the humanitarian crisis caused by the devastating earthquakes in Turkey and Syria, Antibiotice quickly responded to the humanitarian appeal launched by the Ministry of Health and sent aid to the earthquake-affected areas. Antibiotice provided access to essential medicines, in particular oral and injectable antibiotics for wound infections, cardiovascular medicines, painkillers, and disinfectants worth 464,000 lei.

Also in February 2023, we launched a "pilot" project in Ukraine for two beta-lactam anti-infective drugs, injectable powders - Xivulan® 1.2 g (amoxicillin/K-clavulanate) and Ampiplus® 1.5 g (ampicillin/sulbactam). In conflict areas, the risk of infection is significantly increased due to limited access to healthcare, exposure to poor hygienic conditions, and the presence of open wounds, which are susceptible to contamination.

The use of broad-spectrum antibiotics - such as the two products included in the pilot project - are anti-infective drugs of first choice in the rapid treatment of infections when a precise treatment (identified by antibiogram) is difficult to achieve in precarious conditions or when a rapid, immediate, life-saving medical decision is needed.



The Antibiotice portfolio includes 51 medicines from the World Health Organization's list of essential medicines (molecule + pharmaceutical form for which we have marketing authorization) according to the WHO classification (medicines that meet the health needs of the majority of the population and are used to treat the most common diseases).

In 2023, Antibiotice responded positively to the European Medicines Agency (EMA) and the Health Emergency Preparedness and Response Authority (HERA) request to participate in a joint EU-wide exercise to assess the feasibility of securing the needs for a range of anti-fungal drugs used to treat respiratory infections.

# 51

WHO essential medicines  
in the Antibiotice portfolio

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## Pricing policy

The prices of medicinal products for human use are regulated at the European level with the aim of ensuring adequate supplies of medicinal products at a reasonable cost, safeguarding public health, promoting the efficient production of medicinal products, and encouraging research and development of new medicinal products.

The prices of products in the Antibiotice portfolio marketed in the Romanian market are set differently depending on the category: prescription and non-prescription medicines, medical devices, food supplements, cosmetics, veterinary medicines, biocides, and biofertilizers.

In Romania, the price of prescription medicines is approved by the Ministry of Health for all players in the pharmaceutical chain, from the manufacturer to the end consumer.

For the medicines that are issued based on medical prescription (Rx), the price is calculated in compliance with the legal requirements provided in the Order of the Minister of Health no. 368/2017 for the approval of the Norms regarding the calculation method and the procedure for approving the maximum prices of medicines for human use. The Order transposes into national law the provisions of Articles 1, 2, 3, and 4 of the European Council Directive No. 89/105/EEC of December 21, 1988, on the transparency of measures governing the pricing of medicinal products for human use and their inclusion in the scope of the national health insurance system.

According to this regulation, to determine the price of prescription medicine, the proposed price is compared with the price of the same medicine in the source catalogs of the 12 comparison countries: the Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Belgium, Italy, Lithuania, Spain, Greece, and Germany. The proposed producer price must be less than or equal to the lowest price of the same medicine in the list of countries with which the comparison is made. If the medicine is not priced in the comparison countries, the proposed price is approved.

In the case of generic medicinal products (such as medicinal products manufactured by Antibiotice), the price may not exceed the generic reference price which is the maximum producer price to be approved once, on the date of application for approval of the price of the first generic medicinal product in the international non-proprietary name (INN), strength and pharmaceutical form. Comparison with the generic reference

price does not apply between two successive corrections if that medicine is the only medicine in that INN (international non-proprietary name), dosage, and pharmaceutical form with an approved price in CANAMED (National Catalogue of Prices of Prescription Medicinal Products for Human Use Authorised for Marketing).

Rising inflation, raw material and logistics costs have led to legal regulations which, in the correction process for 2023, allowed the producer price (by packaging form) for medicines with a value of less than 25 lei to be indexed by 14%, and those with a value between 25 lei - 49.99 lei to be indexed by 7%.

The prices of over-the-counter (OTC) medicines, medical devices, food supplements, veterinary products, cosmetics, biofertilizers, and biocides under the Antibiotice brand are determined by the company's strategy, taking into account market requirements and manufacturing capabilities.

For the international market, prices of medicines are established by negotiation with external partners, under competitive conditions and according to the legislation in force in the respective countries. Participation in medicines public tenders, through distributors, ensures the access of all medical institutions to the medicinal products manufactured by Antibiotice, under competitive and transparent conditions, while the company assumes flexibility in terms of reducing the price within the limits of profitability.

Average list price increase for the company's pharmaceutical products:

Average increase calculated per indivisible unit: **+11.4%**

Average increase calculated per box: **+6.7%**

In 2023, the product with the highest price increase in the reporting year (doubling in price) was Piafen® 500mg capsules, the sole product for which the company had the opportunity to bring its price up to date, given that the product has not undergone a price change in the last 10 years except for currency updates

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## 2.4. Research, development and innovation

**Research is a key pillar of our business, with the aim of developing products that ensure effective and safe treatment for patients, as well as products that improve quality of life.**

The main goal of the R&D team is the development of generic medicines and unique combinations in the topical, tablet, capsule, and injectable sterile product categories. In addition to established pharmaceutical forms, research activities are also directed towards medical devices and cosmetic products which, in line with the medium and long-term strategic development directions, complement the product portfolio.

The mission of the R&D activity is to promote scientific excellence in medicine research and production for the benefit of public health, and the company is committed to ensuring patients access to valuable new generic medicines and innovative products.

The products and technologies developed in the research department are the basis for future growth. The research department is also laying the foundations for new areas of development, which will result in innovative products and technologies that are in demand in the pharmaceutical market in the future.

The research team can develop innovative products, which once introduced into the company's portfolio will increase its economic competitiveness.

Ongoing staff development programs and facilitating access to the latest scientific information are a priority, with particular emphasis on improving research and technical skills and increasing the capacity and speed of innovation.

Alongside the continuous and sustained professional development to achieve the intended targets, particular emphasis is placed on:

- > developing the company's innovation capacity through infrastructure improvements;
- > attracting highly qualified staff to research departments through collaboration with universities and research institutes in the country;
- > attracting funding through new national and international projects.



\* Compared to last year



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In 2023, a total of 40 new product projects were undergoing research and development, as follows:

- **23** new product projects for the Topical Products Division;
- **12** new product projects for the Oral Solid Products Division;
- **5** new product projects for the Sterile Injectables and Active Substances Division.

Due to the multi-year nature of R&D projects, a total of 24 of the above projects were continued from the previous year, and a further 16 were initiated during the reporting year. In 2023 the R&D activities for a number of 8 projects were completed and handed over to the structure responsible for their approval/ registration and will complete the company's portfolio starting with 2024.

The total value invested in Research and Development projects in 2023 amounted to approximately 13.5 million lei.

To ensure the necessary research infrastructure for the renewal of the product portfolio, the laboratories were modernized with an investment of 3 million lei.

In 2023, the actions necessary to relaunch the production of organic biofertilizers were continued by conducting field efficacy studies for two products in this category. At the same time as the field trials, a research project is being carried out in collaboration with the University of Life Sciences "Ion Ionescu de la Brad" Iași, to determine the main characteristics of the products in this category. To promote responsible agricultural production in the future, and to protect the biosphere, natural resources, and soil, Ecocert certification procedures for use in organic farming have been initiated.

In addition to the above-mentioned projects and taking into account the requirements of national and international regulatory authorities, the research laboratories continued to work on the quantification of nitrosamine impurities for the products in the company's portfolio. At the same time, efforts were made to develop new analytical methods for the qualitative support of Nystatin, thereby strengthening the company's position in the global market for this active ingredient.

In 2023, collaborations with academic partners and research institutions, which strengthen the relationship between research, development, and production, continued and will lead to increased innovation in the production of medicines and active ingredients for the pharmaceutical/cosmetics industry in the future.

The most important major project of these partnerships is the development of a new R&D Center, Inova a+.

The development of a new Drug Research Center is a significant step forward for Antibiotice, bringing many essential benefits for the company's long-term development and success. This modern research center, equipped with state-of-the-art technology, will greatly enhance our ability to develop innovative and effective medicines.

We will accelerate the development of new medicines, enabling us to bring cutting-edge therapeutic solutions to the market faster. Advanced technologies



and research equipment will facilitate complex studies, reducing the time needed for testing and validation.

The Inova a+ Center will enhance the company's competitiveness in the global pharmaceutical market. The ability to develop new medicines will strengthen our position in the industry, attracting strategic partnerships and major investments.

The Research Center will also attract and retain scientific talent. A modern and stimulating working environment will motivate researchers to explore new ideas and constantly innovate, contributing to medical progress and improving the quality of life of patients.

Through the Inova a+ Research Center, Antibiotice will make a significant contribution to accelerating the development of new medicines, which will bring significant benefits to the company, strengthening its competitive position and helping to attract new talents. These advantages will contribute to our strategic goals and long-term success.



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**28**  
new products were licensed



### In-licensing projects

Through Business Development, 28 new products were licensed in 2023, of which:

- 16 prescription products;
- 4 over-the-counter products;
- 8 veterinary nutritional supplements for pets (dogs and cats)

The 16 products that will complete the Rx portfolio are in the following pharmaceutical forms and therapeutic classes:

- **Oral Solid Forms:** Anti-infectives - 9 products, Genito-Urinary System and Sex Hormones - 1 product;
- **Injectables:** Anti-infectives - 1 product, Alimentary Tract - 2 products, Cardiovascular System - 2 products, Central Nervous System - 1 product.

Of the products contracted in 2023, 16 will be launched in 2024. The remaining products will be launched in 2025-2027, depending on the outcome of the registration process.

## 2.5. Patient and consumer health and safety

### Quality of our products

The pharmaceutical industry is highly regulated and product quality is essential to ensure patient and consumer safety. Investment in product and process quality assurance is a key element for us in delivering effective medicines and treatments that meet quality standards, ensuring regulatory compliance, and protecting the company's reputation.

Antibiotice's Quality, Environmental, and Occupational Health and Safety Policy is available for access on the company's intranet.

The policy aims to:

- continuously improve performance by strict control of the impact of all activities carried out within the company;
  - provide products and services of the highest quality per the requirements specified in standards, specified/ unspecified customer requirements, and regulatory requirements, as part of sustainable development, without affecting the safety and health of employees and environment;
  - continuously increase customer satisfaction.
- Through the analysis performed by the management, internal audit, communication, and staff training, as well as the implementation of corrective and preventative actions, and collaboration of teams responsible for root cause analysis and problem-solving, we are committed to:
- business continuity and consolidation by creating and delivering competitive, quality, safe, and effective products and services that consistently meet customer requirements;
  - compliance with applicable legal, regulatory, and other specific requirements to which the company subscribes;
  - identifying risks and opportunities to ensure business continuity and growth;

- continuous adaptation of the system, communication, and understanding by all stakeholders (Management Board, trade union, staff, suppliers, and customers) of the company policy;
- promoting a constructive attitude regarding transparency and dialogue with relevant stakeholders;
- improving the company's financial performance by reducing costs associated with non-quality (repair costs, rework, complaints/recalls);
- regularly evaluating and complying with the policy, continuously improving its performance by complying with the requirements of legal or other regulations relating to product quality, environmental, and occupational health and safety issues.



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To ensure the operation of the Integrated Management System, objectives are set, regularly monitored, measured, and evaluated by top management. In addition, all company employees are trained and informed about the methods of the management system and the necessary resources are available to ensure the effectiveness of these methods.

The production site is organized into eight dedicated production flows for the manufacture of medicines, periodically inspected and certified by the NAMMDR according to GMP requirements and has implemented a Quality Management System that integrates good manufacturing practices, as defined by European (EU GMP) and American (cGMP) legislation or the legislation of other countries where Antibiotic products are authorized.

The quality management system complies with the requirements of the ISO 9001:2015 standard, and together with the environmental standards (ISO 14001:2015) and the occupational health and safety standards (ISO 45001:2018), they form the integrated management system, which contributes to increased product quality. The functioning of the management system is permanently verified, both internally, by specialists in each field (quality, environment, occupational health and safety) and externally, by national and international bodies, certification bodies, and by business partners.



The pyramidal structure of the quality management system at Antibiotic

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Standards, licenses, authorizations, and certificates valid on December 31, 2023	Issuing organization	Date of certification	Description	Next steps
Good Manufacturing Practice Guidelines for medicinal products for human use for clinical investigation	NAMMDR	December 6, 2022	Certificate of Good Manufacturing Practice, issued on December 6, 2022	This Certificate is valid until October 2025.
Good Manufacturing Practice Guidelines for medicinal products for human use	NAMMDR	December 6, 2022	Issuance of Certificate of Good Manufacturing Practice #035/2022/RO, #036/2022/RO, #037/2022/RO	The validity period of the certificates is 3 years from the date of inspection (October 14, 2022).
ISO 45001:2018 standard - Occupational health and safety management systems	TÜV Rheinland Romania	January 10, 2023	Certificate #012131521397 (recertification)	Issuance of a certificate valid for 3 years, which opens a new 3-year cycle (2022 - recertification audit, 2023 supervisory audit 1, and 2024 supervisory audit 2).
ISO 9001:2015 Standard Quality Management systems	TÜV Rheinland Romania	January 13, 2023	Certificate #011001521397 (recertification)	Issuance of a certificate valid for 3 years, which opens a new 3-year cycle (2022 - recertification audit, 2023 supervisory audit 1, and 2024 supervisory audit 2).
ISO 14001:2015 Environmental Management Systems Standard	TÜV Rheinland Romania	January 13, 2023	Certificate #011041521397 (recertification)	Issuance of a certificate valid for 3 years, which opens a new 3-year cycle (2022 - recertification audit, 2023 supervisory audit 1, and 2024 supervisory audit 2).
Regulations and laws specific to medical devices: <ul style="list-style-type: none"> <li>• Law No 95/2006 republished, Title XX Medical devices</li> <li>• Order No. 566/2020 on the approval of activities in the field of medical devices</li> <li>• European Regulation on Medical Devices 2017/745</li> </ul>	NAMMDR	January 30, 2023	Issuance of the Operating License to the economic agent Antibiotic SA for medical devices distribution activities #8680/31.01.2023	The validity period of the Certificate is 3 years from the date of issue.
Legal basis: <ul style="list-style-type: none"> <li>• MH Order 775/2019 on the registration of manufacturers, importers, or distributors of active substances to be used as raw materials for medicinal products for human use</li> <li>• Law No 95/2006 republished, Title XVIII Medicines, Article 771</li> </ul>	NAMMDR	January 31, 2023	Agreement on the registration of manufacturers, importers, or distributors of active substances to be used as raw materials for medicinal products for human use #RO_IFA_01/2023	Annual notification to NAMMDR of changes to the information provided.
Manufacturing authorization for sterile (semi-solid, solid beta-lactam antibiotics) and non-sterile (semi-solid) veterinary medicinal products.	ANSVSA	April 26, 2023	Manufacturing authorization #RO 03/2023	Annual notification to ANSVSA of changes to the information provided.
Certificate of compliance with good manufacturing practice for veterinary medicinal products	ANSVSA	April 26, 2023	Good Manufacturing Practice Certificate #78/2023/RO	The validity period of the certificate is 3 years from the date of inspection.
Certificate of Good Laboratory Practice (GLP) for the CSC Bioanalytical Laboratory	NAMMDR	June 15, 2023	Certificate of Good Laboratory Practice No. 55	This GLP Certificate is valid until January 26, 2025.
Legal basis: <ul style="list-style-type: none"> <li>• Law 95/2006 republished, Title XVIII Medicines</li> <li>• Order 1295/2015 on the manufacturing authorization of manufacturers and importers of medicinal products for human use, including those for clinical investigation and independent control units, and on the granting of the certificate of good manufacturing practice</li> </ul>	NAMMDR	September 14, 2023	Issue of Manufacturing Authorization #30F/14.09.2023	Regular notification to NAMMDR of changes to the information provided.

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### Inspections and audits in 2023

In 2023, a total of 2 audits were performed by Antibiotice partners:

- On-site audit performed by a third-party audit company for the US partner for the parenteral product manufacturing flow;
- On-site audit carried out by a third-party audit company for the EU partner, for the parenteral product manufacturing flow.

The audits were carried out in optimal working conditions in the facilities concerned and concluded with a recommendation to continue or initiate partnerships.

To maintain high product quality, maintaining the qualification status of raw material suppliers remains a priority, therefore 2 audits were carried out in 2023:

- On-site audit at the European Union partner, for the micronization operation of the active ingredient Nystatin;
- Remote audit of a third-party manufacturer of sterile active substances.

### Quality complaints

Maintaining the quality level of our products is a commitment not only to patients and consumers but also to all our partners in the value chain. Regarding quality complaints, the internal procedure specifies that the person receiving the complaint (by email to [office@antibiotice.ro](mailto:office@antibiotice.ro), by phone, on the company's website, via the company's medical representatives, or even via social media platforms) informs the Quality Assurance structure (at [asigurarea.calitatii@antibiotice.ro](mailto:asigurarea.calitatii@antibiotice.ro)). Depending on the nature of the complaint, the Quality Assurance officer classifies the complaint according to the defect class the non-conformity falls under. An internal investigation is initiated and carried out by a multidisciplinary team (depending on the nature of the non-conformity identified). Once the documentation of the investigation is completed, the Quality Assurance Officer checks the investigation report and produces and forwards the summary of the investigation report, including the conclusion of the complaint (unjustified/justified, as well as the actions determined), to the complainant.

**In 2023, 40 complaints were received. Of these, internal investigations revealed that 24 complaints were confirmed and 16 unsubstantiated.**

### Product quality complaints

Complaint Issuer	Number	Description
Patients	2	<ul style="list-style-type: none"> <li>• Issues related to product excipients</li> <li>• Adverse reaction received via complaint form</li> </ul>
Pharmacies	2	<ul style="list-style-type: none"> <li>• Primary packaging issues (missing seals/damage/leaks/faulty tube closure)</li> </ul>
Hospital	4	<ul style="list-style-type: none"> <li>• Physical appearance issues related to product labeling - Product label damaged/detached/missing/missing text</li> <li>• Physical product appearance issues - reconstitution</li> <li>• Issues regarding the quantity of product packaged (missing blister/leaflet/ secondary packaging bottle)</li> <li>• Primary packaging issues (missing seal/damage/leaks/faulty tube closure)</li> </ul>
Distributors	13	<ul style="list-style-type: none"> <li>• Primary packaging issues (missing seal/ damage/ leaks/ faulty tube closure)</li> <li>• Issues with product secondary/tertiary packaging (damaged)</li> <li>• Issues related to the physical appearance of the product - color</li> <li>• Issues with the batch/product expiry date - illegible/incorrect/missing</li> <li>• Issues related to transportation conditions</li> </ul>
International partners	18	<ul style="list-style-type: none"> <li>• Issues related to the physical appearance of the product - taste/smell</li> <li>• Issues with the batch/product expiry date - illegible/incorrect/missing</li> <li>• Out-of-specification results</li> <li>• Issues related to product secondary/tertiary packaging (damaged)</li> <li>• Physical contamination of the product</li> <li>• Issues related to the quantity of product packaged (missing blister/ vial from secondary packaging/ missing tablet/ capsule/ suppository/ pessary from blister/ foil)</li> <li>• Primary packaging issues (missing seal/damage/leaks/ faulty tube closure)</li> <li>• Issues related to transportation conditions</li> </ul>
Regulatory agencies	1	<ul style="list-style-type: none"> <li>• Probleme legate de aspectul fizic al produsului - reconstituire</li> </ul>

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Following investigations, depending on the nature of the identified root cause, corrective actions were proposed, such as additional inspection of equipment, upgrading manufacturing equipment (e.g. installation of label data verification system), revision of modules in the Batch Master File, developing new working instructions, revision of internal documents (procedures, working instructions, etc.), including staff training.

In 2023 there was a voluntary recall of a range of tetracycline ointments due to a manufacturing defect.

### Regulations on the use of titanium dioxide (E 171)

Antibiotice is constantly concerned with patient and consumer safety and the rapid implementation of the latest requests on pharmacovigilance issues from the European pharmacovigilance regulators.

The company's action plan to comply with the authorities' requirements for the replacement of titanium dioxide included not only mandatory but also preventive measures.

Titanium dioxide (chemical formula  $TiO_2$ , food additive code E171) is a substance approved as an artificial, inorganic, insoluble, white food coloring with very good stability to light, heat, oxidation, and pH changes. Titanium dioxide is a widely used excipient in the pharmaceutical industry as an opacifier and colorant due

to its multiple functionalities in oral dosage forms such as tablets, soft gels, capsules, granules/powders for oral solution, and oral suspensions.

Due to its unique combination of physico-chemical properties, titanium dioxide imparts desirable properties to medicines such as protection of photosensitive active substances against degradation due to exposure to ultraviolet (UV)/visible light, prevention of moisture absorption, increased opacity, and enhanced contrast

to other dyes, thus improving the distinctive characteristics of oral dosage forms (product color is important for differentiation of various medicine concentrations by the patient).

Titanium dioxide (E171) was originally authorized as a food additive in the EU under Annex II of Regulation (EC) No 1333/2008. The safety of the food additive E171 was re-evaluated by the European Food Safety Authority (EFSA) in 2016 under Regulation (EU) No 257/2010

as part of the re-evaluation program of food additives authorized in the EU before January 20, 2009.

Following the re-evaluation of the safety of titanium dioxide, EFSA published a scientific opinion concluding that "E171 can no longer be considered safe when used as a food additive", so on February 7, 2022, European Commission Regulation 63/2022 came into force, bringing to the forefront the issue of banning the use of titanium dioxide in all food products, with the ban to be implemented after a six-month transition period. Thus, foods containing titanium dioxide could only be produced and placed on the market until August 7, 2022. After this date, the products could continue to be marketed until their date of minimum shelf life or use-by date.

As regards medicinal products, in 2022, the European Commission committed to review within 3 years from the date of entry into force of Regulation (EC) No 63/2022 (January 14, 2022) the need to maintain titanium dioxide (E 171) or to remove it from the Union list of food additives for use in medicinal products. This review will be based on an updated assessment by the European Medicines Agency (EMA) to be carried out before April 1, 2024.

No restrictions were imposed on the marketing of medicines containing titanium dioxide in 2023. The pharmaceutical industry, in collaboration with



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the EMA, also accelerated research and development of alternative substitutes for titanium dioxide (E171), the impact of their use on the efficacy and quality of the medicine, and the impact of removing titanium dioxide from medicines.

The final report of this research will be submitted to the EMA by the pharmaceutical industry in early 2024, and the EMA will publish an updated assessment on the possible removal of titanium dioxide from medicinal products by April 1, 2024.

The Antibiotice portfolio includes medicines and food supplements (in capsule and tablet form) containing titanium dioxide.

According to Regulation 63/2022, Antibiotice can manufacture and market medicinal products containing titanium dioxide until a final decision is taken by the EMA, but for food supplements, we are required to remove E171 from their composition.

Following the application of the legislation, Antibiotice has taken all necessary steps to remove titanium dioxide (E171) from the food supplements in our portfolio and marketed by us.

The products Silithor®, Equilibra®, Simbiflora® Forte, Simbiflora® Complex, Fezivit® C, and Lejer® have been re-notified with a new capsule that complies with current legislation.

**All food supplements that will be part of the Antibiotice portfolio will be free of titanium dioxide.**

Concerning the development of the food supplement Soriso Luna, a titanium dioxide-free capsule was identified at the formulation stage.

**Implementing the provisions on nitrosamines in 2023**

Antibiotice has complied with the EMA "Questions and answers for marketing authorization holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products", a document published on July 07, 2023, which updated the list of new nitrosamine impurities evaluated for carcinogenicity and genotoxicity. This list is updated monthly with new impurities, which also involves the re-evaluation of Antibiotice products.

The deadline for submitting declarations on the presence of nitrosamines in medicinal products was October 1, 2023, but APP holders are reminded to continue the evaluation of medicinal

products and to take into account updates to the guidelines as well as notifications from raw material manufacturers.

Following the risk assessment of all human use medicines in the Antibiotice portfolio up to December 31, 2023, the company has identified 12 medicines (in the 2019- 2023 phase) at risk for the presence of nitrosamines, mainly from the oral solid medicines class, which have a higher risk factor due to the use of active ingredients with primary, secondary or tertiary amines in their structure, which may lead to the formation of N-nitroso impurities in combination with nitrites in excipients.

In line with legislative requirements, Antibiotice has implemented appropriate control strategies to prevent or limit the presence of these nitrosamine impurities and, where necessary, to improve production processes.

Activities related to nitrosamines involved:

- Evaluation of authorized products;
- Evaluation of products in the authorization process;
- Updating of documentation in line with changes made by API manufacturers;
- Collaboration with third-party laboratories for method validation and analysis of API and finished product;

- Development of analytical methods for the analysis of nitrosamine impurities;
- Responding to regulatory observations.

The trend among regulatory authorities worldwide concerning the presence of nitrosamines in medicines is to limit the acceptable levels of these impurities as much as possible, with the list of impurities considered to be carcinogenic to humans, which can be identified in various sources of active ingredients, being updated on an ongoing basis. Acceptable limits are set for these impurities and must be respected by APP holders, finished product manufacturers, and raw material producers.



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## Pharmacovigilance

**Pharmacovigilance encompasses the totality of activities for the detection, evaluation, validation, and prevention of adverse reactions or safety problems associated with the use of medicines in the Antibiotice SA portfolio. The pharmacovigilance system is a legal obligation through which pharmaceutical companies guarantee the safety of the use of medicines, under the requirements of the European (European Medicines Agency - EMA) and national (National Agency for Medicines and Medical Devices in Romania - NAMMDR, as well as the national authorities of other non-EU member countries) regulatory authorities in the field of medicines. Pharmacovigilance thus contributes to the protection of public health and patients**

### Pharmacovigilance for medicinal products for human use

The company evaluates and communicates to regulatory authorities' information on the safety of the use of the medicines in its portfolio throughout the entire product life cycle (including pre-authorization and post-authorization phases). Any medicine can also have undesirable effects, which is why Antibiotice SA carefully monitors the occurrence of such events. Using all sources of safety information, Antibiotice SA prepares regular reports assessing the benefit-risk balance of the drug.

The pharmacovigilance specialists monitor, identify, assess, report, and

establish the potential risks associated with the use of Antibiotice medicinal products for human use. The main activities of the internal Pharmacovigilance Department are:

- identifying and collecting adverse events and other safety information from various sources such as healthcare professionals, patients, partners, literature, media, etc;
- monitoring and evaluating the safety information identified and collected for the medicines in the portfolio;
- submitting adverse reaction reports to competent authority databases;
- preparing the Risk Management Plan for the medicines in the portfolio;

\* The risk-benefit ratio refers to the balance between the benefits (positive effects) of a medicine and the associated risks (adverse effects). The benefits and risks associated with medicines are continuously monitored to confirm that the benefits outweigh the risks. (EudraVigilance Glossary, <https://www.adrreports.eu/ro/glossary.html>)

- preparing reports assessing the risk-benefit balance of medicines;
- promoting the safe and effective use of medicines, in particular by providing timely information on the safety of medicines to patients, healthcare professionals, and the public.

Antibiotice promotes good practices in the field of pharmacovigilance, both internally and through contracts with business partners, thus contributing to the creation of a network that supports patient safety.

As an integral part of the Antibiotice Quality Assurance System, the pharmacovigilance activity ensures the introduction of immediate actions and measures established by the authorities, as well as the updating of medical information on the Antibiotice medicines, through information letters and a summary of product characteristics (SPC) for healthcare professionals (physicists, pharmacists) and through the package leaflet of each medicine, which is made available to patients and consumers.

The adverse reactions received by the Pharmacovigilance Department are recorded internally, according to specific procedures. Depending on their severity, the adverse reactions received must be transmitted to the European EudraVigilance database within a



**To report suspected adverse reactions of medicinal products for human use produced by Antibiotice, several channels of communication and collection are made available to patients and consumers, as well as to physicians and pharmacists:**

- directly, through the spontaneous adverse medicines reporting form, provided by the Antibiotice medical and sales representatives, to physicians and pharmacists;
- online, on the website [www.antibiotice.ro](http://www.antibiotice.ro), through the form for collecting suspected adverse reactions, or by e-mail at [sigmedumane@antibiotice.ro](mailto:sigmedumane@antibiotice.ro);
- by phone, at +40 728 199 834 or through the phone switchboard, at +40 372 065 263.



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maximum of 15 days for severe adverse reactions and 90 days for nonsevere adverse reactions.

In 2023, 18 adverse reaction reports for human medicines were submitted to Antibiotice SA, of which 5 reports were invalidated and 13 reports were validated.

Of the 13 valid adverse reaction reports, 10 were non-severe and 3 were severe.

The 13 valid adverse reaction reports were received as follows

- 2 adverse reaction reports from competent authorities;
- 3 adverse reaction reports from patients;
- 2 adverse reaction reports from healthcare professionals (physicians and pharmacists);
- 4 adverse event reports from partners;
- 2 adverse reaction reports from clinical trials.

## Veterinary medicines



The reporting of suspected adverse reactions of veterinary medicinal products manufactured by Antibiotice is done:

- online, on the website [www.antibiotice.ro](http://www.antibiotice.ro), through the form for collecting suspected adverse reactions, or by e-mail at [sigmedveterinare@antibiotice.ro](mailto:sigmedveterinare@antibiotice.ro)
- by phone, at +40 372 065 501.

During 2023, no adverse reactions to veterinary medicinal products were reported

## Product marketing and promotion

The pharmaceutical industry benefits from a strong regulatory framework as it involves consumer health and safety. Policies and procedures that describe the internal framework for carrying out the product promotion process are based on the legislative regulations in force, both at the national and international levels (specific to each country), as well as good practice standards specific for the pharmaceutical industry

### Promotion strategies

The promotion of products from the Antibiotice portfolio is a priority activity in the company's long-term development strategy. This is achieved through:

- strengthening partnerships with healthcare professionals through promotion actions;
- identifying new consumers for the products in the portfolio through screening programs;
- identifying the prescribing habits and treatment behaviors of physicians through testing programs;
- partnerships with pharmacy chains to promote our non-RX product portfolio in their catalogs;
- accessing alternative promotion channels: online, TV, e-commerce - partner pharmacies for non-RX products.

In 2023, the promotion of the Antibiotice portfolio was focused on medical visits

to various medical specialties and pharmacists, as well as on participation in scientific events.

The promotion activity is carried out according to the Promotion Plan which contains:

- details related to the target group of health professionals: medical specialties, the number of healthcare professionals visited, and the frequency of visits;
- the promotion tactics and actions specific to promotion tools (messages, promotional materials);
- monitoring and controlling the implementation of the promotion plan by the promotion and sales teams (activity and visit reports, according to the internal CRM reporting platform);
- regular evaluation of the results and adaptation of the actions according to the set objectives.

Communication with healthcare professionals, physicists, and pharmacists aims to increase the awareness of product brands in the portfolios of therapeutic classes: anti-infectives, central nervous system, cardiovascular system, digestive system, dermatologic preparations, genito-urinary system, musculoskeletal system and Nutriensa® range of food supplements.

The direct visits of the team of medical representatives to various medical specialties and organization of local scientific events with opinion leaders and the medical and pharmaceutical community (presentations of portfolios and products or round tables) aimed to bring to attention the therapeutic solutions manufactured by Antibiotice that have proven their efficiency in administration, as well as accessibility for patients. Presentations were given in doctor's offices, dispensaries, hospitals, and round tables on topics relevant to participating physicians and pharmacists, adapted to seasonal pathologies (respiratory infections, dermatological pathologies, chronic venous disease, etc.).

In 2023, the company participated in national and regional scientific events (congresses, conferences, webinars) aiming to strengthen partnerships with representatives of the medical and pharmaceutical communities in Romania, thus supporting continuing medical education by facilitating access to conferences, as well as proposing

therapeutic solutions manufactured by Antibiotice.

The promotion of medicines to healthcare professionals involves the provision of fair, accurate, and relevant product information to physicians, pharmacists, nurses, and other healthcare professionals to help them make informed decisions regarding the treatment of patients.

Key aspects of promoting medicines to healthcare professionals include:

- **Complete and accurate information:** The promotion provided healthcare professionals with complete and accurate information about medicines, including efficacy, safety, indications, contraindications, drug interactions, and possible side effects.
- **Ethics and regulatory compliance:** Drug promotion was done ethically in compliance with local and international regulations and standards. This included compliance with laws on drug advertising, as well as professional guidelines and codes of conduct established by organizations such as the World Health Organization (WHO) and health regulators.
- **Training and ongoing education:** Antibiotice has supported training and ongoing education programs for healthcare professionals to help them better understand new medicines and therapeutic updates.



➤ **Transparent communication:** the promotion of medicines was transparent, and the information conveyed was presented clearly and understandably, without creating confusion or misrepresentation.

Promoting medicines to healthcare professionals plays a key role in ensuring access to reliable information and promoting evidence-based medical practice.

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## Communication with the general public

The population's increased interest in maintaining health and quality of life has generated a proactive, prevention-oriented attitude, evidenced by both purchasing and consumption behavior, as demonstrated by the upward trend in sales of OTC medicines, food supplements, cosmetics, and medical devices.

### Strengthening of the NON-RX portfolio through new product launches: development of new brands or brand development through range extensions

#### ➤ Food supplements portfolio - Nutriensa® range

An important ally in a healthy lifestyle is the Nutriensa® range developed by Antibiotice. Nutriensa® food supplements benefit from the expertise of Antibiotice researchers and are manufactured to high-quality standards using Good Manufacturing Practice-accredited production processes. They are innovative formulas, combining carefully selected ingredients with scientifically proven active properties, in the best formulation and optimal dosage. With a constant concern to ensure their accessibility, but also to modernize the products and diversify the range to support the proper functioning of as many devices and systems in the human body as possible, the Nutriensa®

range was completed with new products in 2023:

- Equilibra® PLUS - Equilibra® brand extension - a composition of organic magnesium salts with superior bio-availability and high ionic magnesium concentration - this new product brings added benefits to consumers;
- Lejer® Anti-Gas - complementing the portfolio for maintaining a healthy bowel transit.

#### ➤ Topical preparation portfolio Tinero® range

- Tinero® AZ - Tinero® brand extension - A to Z skin care line for acne rosacea. The line includes 3 products (cleansing foam, UV protection factor cream, and serum) containing azelaic acid.
- Zinba® - OTC medicine containing a combination of 2 antibiotics (neomycin + zinc bacitracin), recommended for the treatment of skin infections.

#### ➤ Portfolio: Cold and Flu:

- RemiFLU® - sachets containing a combination of paracetamol with antihistamines and vitamin C to help manage cold and flu symptoms (headache, fever, rhinorrhea, sneezing) and increase the body's resistance to infection.
- Faguria® - range of products (throat drops and sprays) with manuka honey with anti-inflammatory, antibacterial, and antioxidant properties.



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### Education and awareness campaigns

Antibiotice continuously promote responsible and preventive personal health behavior by encouraging the development of healthy habits. These include a balanced diet, physical activity, and emotional balance. However, in today's world, if the diet does not provide a sufficient intake of nutrients, food supplements can help to provide the optimal requirements for the body to function properly.

- **By facilitating access to accurate and truthful, scientifically documented sources of information**, the consumer is supported and guided in the process of information gathering and purchase decision-making. For example, in 2023, new websites and updates to existing websites were developed to showcase products and product ranges, to promote relevant information on the benefits of the products, their role in maintaining health, and to create an environment that facilitates access to these products. In addition, online testimonial modules were developed, and campaigns were run to encourage consumers to provide feedback and write reviews about the products they have purchased so that other potential consumers can make informed purchasing decisions.
- **Events for the general public:** promotion of a healthy lifestyle through events, conferences, interactive activities, and collaboration with

motivational speakers: Promotion of the Fluxiv® range during the *Superpietonii Tour* organized by Gașca Zurlu in 11 cities in Romania - approximately 25 shows; The "Focus on yourself" conference, an event dedicated to women, who are also the decision-makers in the purchase of pharmaceutical preparations for maintaining the family's health; Together with Nutriensa - "You feel good, you do good" at the "Inimo" International Festival of Family, Life and Good Deeds, where "You feel good, you do good!".

- **High school campaigns:** Supporting educational campaigns in high schools about maintaining healthy skin and recommending care routines in acne prevention or essential tips in treating acne-prone skin that is useful and practical for teenagers. These campaigns help promote a healthy lifestyle and raise awareness among young people about the importance of skincare.

### Collaboration with healthcare professionals

Through influencer marketing campaigns to promote the Tinero® range of dermato-cosmetic products, we worked with doctors and pharmacists who helped to build trust and loyalty to the brand through their recommendations, advice on skincare and the benefits of dermato-cosmetic products and explaining how certain ingredients work.

### Facilitating access to products

- Through promotional offers: creating promotional packages offering Fluxiv® tablets and Fluxiv® cream for combined use, with multiple benefits for the consumer.
- Providing samples to potential consumers to test and form personal opinions about the effectiveness and quality of the products.

### Strengthening partnerships to ensure product availability

Through TV, radio, online, and TV co-promotion and co-marketing projects, by accessing the sales channels developed by partner pharmacy chains and mini-chain pharmacies.

### Media promotion

- **TV campaigns:** continuation of the TV campaigns started in 2022 for Silithor®, Fluxiv®, and Clafen® rapid brands as well as the launch of new brands:
  - SimbiFlora® - the range of symbiotics recommended in combination with antibiotics or cases of intestinal dysbiosis. The campaign developed around the message "Symbiotics from the antibiotic experts!"
  - Saliform® is a brand with a strong history in the company's portfolio. This media communication campaign to the general public

aims to strengthen its market position by attracting the interest of the target audience. The campaign is built around the idea of sharing the experience of people who have already used the product, thus boosting trust and awareness of its benefits.

- **Radio:** through a mix of national radio stations selected according to the target consumer profile, linked to the listener profile of the radio stations
- **Online and social media networks:** dedicated to different target audiences and used to promote products that are addressable to these consumer profiles.



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## Legislative framework for product promotion

Antibiotice takes all the measures to ensure that the promotion of the products in the company's portfolio is carried out responsibly and ethically, in line with the legislation in force. In our company, the Promotion Manager coordinates the promotional activity. The Medical Department ensures the proper registration of materials used in promotional activities under the applicable laws, and the National Sales Department ensures that company employees involved in promotional activities as well as representatives of companies contracted for promotional activities are trained and familiar with the applicable laws and with the provisions of the Code of good practice for the promotion of prescription drugs and interactions with medical professionals.

The training of the promotion team is part of the induction process of new employees. The issues related to ethical behavior in drug promotion activities are addressed in quarterly areas or regional meetings. These meetings are attended by approximately 50 members of the promotion department team, depending on the area for which it was organized.

There are some general principles that aim to protect public health and ensure the fair promotion of medicines. Here are some key aspects of the regulatory

framework for the promotion of medicines as applied within Antibiotice:

- 1 Regulatory approval:** Before a medicine can be marketed to healthcare professionals or the general public, it must be approved by regulatory authorities such as the FDA (Food and Drug Administration) in the United States, and NAMMDR (National Agency for Medicines and Medical Devices) in Romania. These organizations evaluate the safety, efficacy, and quality of the drug before authorizing its use and promotion.
- 2 Balanced and fair information:** All advertising for medicines provides fair and balanced information about the benefits, risks, and uses of the medicine.
- 3 Compliance with medical ethics:** The promotion of medicines is consistent with ethical standards and respects the integrity of healthcare professionals and patients.
- 4 Supervision and regulation of promotion activities:** Antibiotice monitors and adapts drug promotion activities to ensure compliance with applicable laws and regulations.

## Code of Good Practices for the promotion of prescription drugs

The Code of Good Practice for the promotion of prescription drugs and interactions with medical professionals defines and implements specific ethical standards for the promotion of prescription drugs aiming to ensure that these activities are carried out following the strictest ethical principles of professionalism and responsibility.

The Code of Good Practice applies to all types of communication and interaction (digital or traditional).

The legislation that formed the basis for the drafting of the Code includes the following categories of normative acts: laws, emergency ordinances, orders, instructions, or any similar document issued by the Romanian Parliament, the Government of Romania, or by any other competent authority, as well as any applicable normative act issued by the competent bodies of the European Union and directly applicable to the activities carried out by Antibiotice. The legislation taken into account can be consulted in full in the [Code of Good Practice](#), available on the company's website here.

The behavior that the company expects from the people responsible for promoting the products in the Antibiotice portfolio is included in the provisions of this Code. All the employees involved in

In 2023, the company did not receive any fines, warnings, or penalties for non-compliance with applicable laws or voluntary codes relating to product promotion.

promotion activities participate regularly in training programs, but also when significant changes take place in the applicable laws and regulations. The code of good practice for the promotion of prescription drugs is brought to the attention of each new medical or sales representative employed, and it can be accessed online here. The Code stipulates, inter alia, that the promotion of prescription-only medicines should be directed only to those professionals who can reasonably be expected to need or be interested in the information. The company's medical or sales representatives are not allowed to leave promotional materials in places accessible to the general public, such as pharmacies, waiting rooms, hospital halls, and medical clinics. All promotional materials and information (whether printed, digital, or oral) should be clear, legible, accurate, up-to-date, balanced, fair, correct, and sufficiently complete to enable the recipient to form an independent opinion.

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They should not be misleading and should promote the rational use of medicines by presenting them objectively and without exaggeration. Promotion should encourage the rational use of medicines by presenting them objectively and without exaggerating their properties.

The promotion activity includes:

- promoting medicines to healthcare professionals through visits of medical representatives to individuals qualified to prescribe drugs, provision of promotional materials and samples, organization of group presentations, round tables, webinars, and participation in scientific events organized by specialized medical societies (according to Order 194/2015 on the approval of the Norms for the evaluation and approval of advertising for medicinal products for human use);
- promoting products to individuals qualified to distribute medicinal products.

### “Treat antibiotics with care for a care-free future!” campaign

The national campaign “Treat antibiotics with care for a care-free future!” aimed to inform and raise awareness among the population and healthcare professionals on the correct use of antibiotic drugs to preserve their effectiveness and limit antimicrobial resistance.

In 2023, the campaign took place as part of **European Antibiotic Awareness Day** (EAAD), a European initiative to promote

good health and the prudent use of antibiotics, which takes place on November 18. EAAD is organized in partnership with **World Antimicrobial Resistance Awareness Week**, an annual event organized by the World Health Organization from 18 to 24 November.

The events organized as part of this campaign, as part of the Corporate Social Responsibility program “Antibiotics of the Third Millennium”, were developed around two components:

#### Communication with and for healthcare professionals

##### ➤ Events organized around the week of 18-24 November:

- Webinar for pharmacists: “Guide for pharmaceutical counseling in antimicrobial prescriptions”. Course credited with 8 EFC points, organized in partnership with the College of Pharmacists Iași on September 13, 2023, with the topic: “Guide for pharmaceutical counseling in antimicrobial prescriptions. Optimizing patient counseling by pharmacists”. The webinar, part of the Pharmaceutical Continuing Education Program, was held on the IT platform of the Romanian College of Pharmacists and featured lecturers specialized in infectious diseases, pharmacy, and communication. The video recording of the webinar has been uploaded and can be viewed on the CFR National platform, in the

Professional/Educational-Scientific section.

- Project competition with the theme “Pharmacists - Guardians of the efficacy of antibiotics”, addressed to pharmacy residents, for ideas for information campaigns to the general public, in partnership with UMF “Grigore T. Popa” and the College of Pharmacists Iași. Teams of pharmacists participated in the competition, whose projects tried to surprise through inspiration and creativity, developing campaigns that would lead the general public to adopt responsible behavior concerning the use of antibiotics. The award ceremony and showcase of the winning projects took place on November 14th at the UMF Iași. The winning project was published on the Antibiotics for the Third Millennium website, LinkedIn, and YouTube.
- A workshop for students of UMF Iași and four other university centers was organized in partnership with the University of Medicine and Pharmacy “Grigore T. Popa” Iași and the College of Pharmacists Iași. The aim was to inform them about the important role they have in promoting the appropriate and responsible use of antibiotics as part of the campaign “Treat antibiotics with care for a care-free future”. The workshop, which was attended by 200 medical and pharmacist



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students, was held in a hybrid format on 16 November 2023. It was delivered by the university's teaching staff and provided information for the general public on 18 November 2023.

➤ **Events organized during the week 18-24 November:**

- A series of workshops was held for resident physicians of varying specialties. The workshops focused on clinical cases of antimicrobial resistance, therapeutic strategies, and antibiotic stewardship. The sessions were led by specialists in the field of infectious diseases. A total of 100 resident physicians from different specialties from the university centers in Iași and Bucharest attended the workshops.

**Information activities for the general public**

- From 18-24 November 2023, in collaboration with the National Agency for Medicines and Medical Devices in Romania and the College of Pharmacists Iași, pharmacists distributed 100,000 prescription-like flyers to the public in 300 pharmacies in Iași County. The campaign's messages, conveyed by pharmacists through the flyers, advised patients to take antibiotics only when prescribed by a doctor, not to interrupt treatment before the recommended period, never to share antibiotics with other people, and not to use them in case of viral infections.

- On the 18<sup>th</sup> of November 2023, a flyer distribution campaign was conducted in shopping centers in Iași, Bucharest, Cluj, Timisoara, and Oradea. Student volunteers provided counseling based on the flyers.

- 20-24 November 2023 - National awareness campaign with the support of Radio Europa FM as part of the Health Minute show with renowned doctors and involvement in awareness and information programs.

- Tableta de sănătate, a TVR Iași program, brought together a doctor specializing in infectious diseases and a pharmacist, both lecturers at the UMF "Grigore T. Popa" Iași, and focused on good practices in the use of antibiotics by health professionals, but also on communication with the general public in awareness campaigns.

**Antibiotics of the Third Millennium**

The [www.antibioticelemileniuluiitrei.ro](http://www.antibioticelemileniuluiitrei.ro) platform aims to support the development and dissemination of best practices in the field of antibiotic stewardship, targeting a community of patients and the general public, doctors, nurses, pharmacists, manufacturers, environmental experts, academics, and entrepreneurs. In addition to the website, the program includes a LinkedIn page and a bi-monthly newsletter with the most relevant news and studies on the topic, which is sent to subscribers of the platform.



Episodes 3 and 4 of the podcast Antibiotics of the Third Millennium were broadcast on this platform in the same year, covering topics such as:

- The need for information about antibiotic therapy;
- Principles of correct use of antibiotics;
- Challenges of antibiotic use in general practice;
- Maintaining the effectiveness of antibiotics

It is the responsibility of all of us, and even more so of Antibiotice as a recognized manufacturer in this field, to prevent the growth of antimicrobial resistance to preserve the value of these irreplaceable therapeutics for future generations.

**27,674**  
visits to  
antibioticelemileniuluiitrei.ro  
in 2023

**1,854**  
subscribers of the  
"antibioticelemileniuluiitrei"  
newsletter

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## Transparency in the relationship with medical and pharmaceutical professionals and organizations

Transparency in dealings with medical and pharmaceutical professionals and organizations is essential to maintain integrity and trust in pharmaceutical companies and the healthcare system.

In compliance with the obligations established in 2015, by Law no. 95/2006 on healthcare reform, Article 814 and Order of the Minister of Health no. 194/2015 on the approval of the Norms for the evaluation and endorsement of the advertising of medicinal products for human use, Antibiotice reported also in 2023, to the Romanian National Agency for Medicines and Medical Devices, all sponsorship activities and any other expenses incurred by the company in 2022, prior to the reporting, for healthcare professionals, professional organizations, patient organizations and any other type of organizations that carry out activities related to human health, healthcare or pharmaceutical.

The main objectives of the promotion plan are to ensure:

- accessibility of all categories of patients to Antibiotice medicines, through a complex distribution system, which facilitates the presence of our medicines both in hospitals and pharmacies in Romania and in international markets where we are present;

- access to accurate, factual, and real-time information, while complying with all existing legal regulations and ethical standards in this industry.

By implementing these practices and promoting transparency in its dealings with healthcare professionals and medical organizations, Antibiotice ensures that medical decisions are made in the best interests of patients and public health.

## Product labeling

The labeling of pharmaceutical products is subject to strict regulations to ensure patient safety and provide clear and accurate information about the medicines. Antibiotice's product packaging complies with the national legislation of the country in which the medicines are registered and/or marketed. The labeling of medicines (primary packaging, leaflet, secondary packaging) is subject to

approval by the national medicinal product regulatory authority, NAMMDR, or by other European or non-European authorities before being placed on the market, and the information shall be reviewed regularly, and aligned with relevant legislative requirements. The information included in the leaflet, addressed to both healthcare professionals and patients or users, explains the correct way to use the medicine. Information on the composition of the products, indications,





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dosage, route of administration, mode of action, warnings of possible adverse effects, recommendations for pregnant or lactating women, the possible interactions with other medicinal products, packaging, and storage are provided.

The labeling of other pharmaceutical products (medical devices, food supplements, cosmetics) manufactured and marketed by Antibiotice is carried out following the relevant legislation. If the pharmaceutical products contain ingredients that could affect the natural environment, then the packaging and leaflet may also contain information on the proper disposal of the product. All this information is regularly checked and updated, to ensure that all our products contain the latest information on quality, safety, and efficacy, as appropriate.

We carefully and systematically monitor the legislative changes, constantly checking and updating the information on the packaging and leaflet to ensure that all our products contain the latest information on quality, safety, and efficacy, as appropriate.

In 2023, the company did not receive any fines, warnings or sanctions for:

- non-compliance with the regulations in force or voluntary codes regarding product labeling
- incidents reported by the regulatory authorities in the field (NAMMDR) regarding non-compliance with labeling



## Pharmaceutical serialization

Serialization aims to ensure patient safety by identifying and tracking each pharmaceutical product from the manufacture to the end user. This reduces the risk of counterfeiting or substandard medicines being used. The Antibiotice portfolio includes serialized products with applied security features consisting of a unique identifier to verify the authenticity of the medicine, identification of each package, and tamper-evident protection in accordance with national and international requirements.

Production sites and finished product warehouses are equipped with dedicated equipment to ensure compliance with these requirements (printing, print verification, sealing, and aggregation).

The serialization equipment is connected to a serialization line management software solution provided by Advanco, which interfaces with Tracelink.

Tracelink, a cloud-based solution, provides connectivity to Antibiotice partners (Europe, USA, Asia) and data reporting to regulatory HUBs (EMVS).

The following information is printed on each complete commercial unit or collective box:

- 1** = DMC Code, 2D data matrix code
- 2** = PC Product Code, GTIN-14, globally unique trade number consisting of 14 digits
- 3** = SN Serial Number, a series of characters assigned to a commercial unit/ complete collective box which together with the GTIN forms the Unique Identifier
- 4** = EXP expiry date consisting of 7 characters, as follows: for the Romanian market, MM.YYYY, for the US market, MM/YYYY
- 5** = LOT product lot/batch in accordance with the batch number assignment procedures specific to each manufacturing site

Print quality must be at least C grade (1.5) according to ISO/IEC 15415:2011, in compliance with the legislative requirements of Commission Delegated Regulation (EU) 2016/161. Printing is checked for all the serialized commercial units and is carried out by Bosch serialization equipment and Microscan LVS 9510 equipment in the Quality Control Department.

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## Reducing the risk of introducing counterfeit products

Preventing and reducing the risk of counterfeit products entering the supply chain plays an extremely important role in terms of the significant impact it has on several topics: the health and well-being of patients and consumers, public health, trust in the healthcare system, and the pharmaceutical industry.

According to the definition stipulated by Law No. 95/2006 republished - Title XVIII, Medicinal product, a "falsified medicinal product" is any medicinal product for which the following is falsely represented:

- **identity**, including packaging and labeling, name or composition in respect of any of its ingredients, including excipients and concentration of those ingredients;
- **source**, including the manufacturer, country of manufacture, country of origin, or marketing authorization holder;
- **history**, including records and documents relating to the distribution channels used.

The European Union has established a series of measures under Directive 2011/62/EU (also known as the Falsified Medicines Directive - FMD) to prevent falsified medicines from entering the legal medicines distribution chain. The European Commission has published further technical details for the definition

of safety features in the Commission Delegated Regulation (EU) 2016/161 in the Official Journal of the EU.

The probability that the batch number can be guessed must be negligible and in any case less than one in ten thousand.

The character sequence must be unique for a particular drug packaging at least one year after the expiry date of the drug or five years from the time the packaging was placed for sale or distribution.

In Romania, the authenticity of a unique identifier is verified by scanning the barcode and verifying the existence of that unique identifier in the SNVM (National Drug Verification System - a verification platform through which pharmacies or wholesalers in Romania can verify the authenticity of a medicine).

The tamper-evident device must be placed on the packaging in such a way that, once it has been torn open, the batch number and expiry date information remain visible.

Counterfeit medicines can come from inside or outside the legal distribution chain. It is important for regulatory agencies to secure the supply chain and to raise awareness among healthcare professionals and patients about the risks associated with medicines from illegal sources.

For all the batches of medicinal products in the Antibiotice portfolio, qualified personnel also check how serialization activities are carried out according to

internal procedures. By certifying and issuing the batch they confirm that the product batch is in stock for sale. For products manufactured under contract for Antibiotice, specific details are established with the partners (within the technical capabilities of the equipment) according to agreements between the parties.

Antibiotice has developed procedures to manage, document, and report falsification complaints/alerts for medicines in its portfolio. Falsified medicines can be identified by checking the characteristics of the packaging and/or by checking the unique identifier (of serialized products) and by physicochemical testing.

Procedures are in place at Antibiotice describing how falsification alerts are handled and how the investigation takes place to determine the root cause of the occurrence of falsification alerts/cases. Suspected counterfeit products may be identified either internally or from external sources.

Within Antibiotice, counterfeit alerts can be submitted in writing, by phone, fax, email, social networks, and on the company website. We also ask the entity that submitted the alert to send evidence of the suspected counterfeit product. Antibiotice's specialists carry out a series of activities to assess a suspected counterfeit product according to criteria described in the company's procedures, such as packaging integrity, whether or not secondary packaging corresponds to the product batch code and expiry date by scanning barcodes, checking holograms, testing physicochemical

parameters, etc. Depending on the characteristics that do not meet the criteria checked, one or more appropriate detection techniques and/or additional tests may be identified to confirm the counterfeit suspicion. If the investigation confirms the falsification of the product, the following measures are taken: quarantine the product and inform the regulatory agency - the decision to block or withdraw is taken together with the regulatory agency.

For the products manufactured by Antibiotice for the Romanian market but delivered to customers in Europe as parallel or special needs imports, the company delivers the products with the safety features included as required. Agreements are concluded with such customers where responsibilities are defined between Antibiotice SA (manufacturer) and the customer on how to decommission the serialized products in case of parallel import or special needs, and each customer is requested the authorization for parallel or special needs import, issued by the competent authority, specifying the name of the product, quantity and the deadline for delivery. Under these agreements, customers must confirm one of the decommissioning options (by Antibiotice or by the customer) to comply with Antibiotice SA policy.



**In 2023, 6 counterfeit alerts were recorded.**

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## Clinical Trials Centre

From idea to authorization, a key step in the development of generic medicines is clinical bioequivalence trials, which alongside research, development, and innovation activities play an essential role in protecting patients' health and promoting access to quality treatments. Clinical trials are an essential component of the regulatory and approval process for generic medicines, as they are rigorous tools through which data and evidence are collected to help inform decisions on the approval and widespread use of generic medicines, ensuring that they meet the necessary standards of patient safety and therapeutic value.

Since 2006, Antibiotice has operated its own Clinical Trials Center for Phase I clinical trials and bioequivalence studies.

The Antibiotice Clinical Trials Center is authorized to conduct clinical trials by the National Agency for Medicines and Medical Devices in Romania (NAMMDR). Compliance with Good Laboratory Practices (GLP) and Good Clinical Trial Practices (GCP) is reassessed by inspection every two years by NAMMDR and documented by the issuance of the corresponding certificate of compliance.

In January 2023, the Bioanalytical Testing Activity of the Center for Clinical Studies was audited by the NAMMDR for compliance with the rules of good laboratory practice. As a result of this inspection,

the laboratory of the Center for Clinical Studies received the GPL recertification, being one of the three laboratories at the national level to hold this certification.

Through the Clinical Trials Center, Antibiotice conducts clinical trials for the development of its portfolio, as well as for external partners. It provides comprehensive services at a high scientific level, covering all stages of a clinical trial, from the design and obtaining of study authorizations from the NAMMDR and the National Commission of Bioethics of Medicines and Medical Devices, to the reporting of clinical trial results and the preparation of documentation that forms part of the product authorization file.

Through clinical trials, the company authorizes affordable generic products, ensuring that they are similar to innovative products in both efficacy and safety during administration.

No animal testing is involved in the process of receiving marketing authorization for Antibiotic products. Generic Antibiotice products are authorized based on clinical trials conducted on healthy human subjects following good clinical trial practice.

Subjects' participation in clinical trials is voluntary and confidential. Studies are conducted according to a study protocol authorized by the NAMMDR and the National Bioethics Commission for Medicines and Medical Devices, in compliance with the ethical principles

for medical research involving human subjects outlined in the Declaration of Helsinki. The inclusion of subjects in the study is carried out after informing and obtaining the informed consent of each subject, in the presence of specialized medical personnel.

The company does not encourage over-volunteering; by implementing inclusion/exclusion criteria in/out of clinical trials, participation in trials is limited to people who are materially or medically vulnerable.

Participation in bioequivalence clinical trials does not provide therapeutic benefits. Depending on the complexity of the study, volunteers are rewarded with financial compensation, and the amount and method of payment are reviewed and approved by the National Bioethics Commission to avoid problems of coercion or undue influence on the volunteers. Another benefit of participating in clinical trials is the medical evaluation, which includes a clinical examination, ECG, and a wide range of laboratory tests before and at the end of the study.

The informed consent process is carried out by specialized medical personnel, after obtaining the favorable opinion of the national regulatory authorities for clinical trials, NAMMDR or CNBMDM, for the conduct of the clinical trial. The debriefing takes place at the Clinical Trials Center, in the investigating physician's office. Subjects are assured of confidentiality and information sessions are



Portfolio and products

individualized. The company processes the personal data of trial subjects in accordance with Regulation 2016/679 of the European Parliament and other legislation governing the processing of personal data. Personal data will remain strictly confidential and may only be disclosed at the express request of the competent regulatory authorities, provided that all the rights of the trial subjects are respected and in accordance with applicable laws.

Potential subjects are given sufficient time, at their discretion, to inform themselves about the details of the study and to decide whether or not to participate in the study.

The general informed consent form for participation in bioequivalence studies ensures that the subject has been provided with all data about the study that are relevant to him/her, including the fact that the subject may withdraw at any time during the conduct of the study without any repercussions for him/her and without being required to motivate his/her decision. By signing this form, the subject certifies that he/she has received all the information he/she needs to make a fully informed decision to participate in the study.

The medical team of the clinical trials consists of licensed medical staff, emergency physicians, primary care physicians, and nurses. The medical analysis laboratories are RENAR accredited.



Antibiotice SA's Clinical Trials Centre has a clinical unit with 2 investigators and a clinical monitor. An internal quality assurance unit with permanently trained monitors and auditors operates within the Clinical Trials Centre to ensure that the conduct of clinical trials complies with the harmonized European legislation (ICH), the Integrated Management System, the Good Clinical Practice and Good Laboratory Practice guidelines and the Declaration of Helsinki.

Quality Assurance Specialists have developed and periodically updated a set of Standard Operating Procedures (SOPs) focused on increasing quality, improving efficiency, lowering costs, increasing compliance, and improving responsiveness and problem correction. Our SOPs are designed to ensure strict quality assurance control covering every step of the process.

The clinical monitor, a highly experienced clinical trial specialist, liaises with the sponsor's site, the Project Manager, Data Management, and the Pharmacovigilance Departments and also efficiently and promptly resolves issues associated with the conduct of the clinical phases for trials being conducted within the Antibiotice SA Clinical Trials Centre.

**Antibiotice's clinical trial plan for 2023 included bioequivalence clinical trials for two generic products, one developed in-house, and one developed by an external partner. Two clinical trials are also underway for products with local application and action in the company's research plan (one topical product and one pessary). These studies are subcontracted to companies specialized and authorized to carry out this type of clinical trial.**

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## 3.1. Corporate governance

**Antibiotice is committed to implementing robust corporate governance practices designed to promote trust and accountability and bring long-term value to its relationship with shareholders, employees, customers, and other stakeholders.**

Corporate governance refers to the system of rules, policies, practices, and processes by which a company is governed, controlled, and managed including the relationships and responsibilities between the company's management, management board, shareholders, and other stakeholders. The primary objective of corporate governance is to ensure that a company operates in an ethical, transparent, and accountable manner while maximizing long-term shareholder value.

Antibiotice SA has been listed on the Bucharest Stock Exchange in the Premium category since 1997. The company has adhered to the corporate governance rules of the BVB and ensures compliance with the capital market legislation (Law no. 24/2017, respectively ASF Regulation no. 5/2018, on issuers of financial instruments and market operations).

Antibiotice SA is a company that is majority-owned (53.0173%) by the Romanian State, through the Ministry of Health (public supervisory authority) and is a public enterprise as defined by the

Emergency Ordinance no. 109/2011 on the corporate governance of public enterprises, as subsequently amended and supplemented, which regulates its organization and operation.

**Antibiotice's Corporate Governance Code** is the basis of the company's good governance practices. The Code outlines the general framework for the management of the company and the responsibilities of the Management Board, the risk management and internal control system, the fair reward and remuneration of management, and the building of transparent investor relations.

**The General Meeting of Shareholders (GMS)** is the highest decision-making body of Antibiotice SA, the governing body where shareholders participate directly and make decisions. Among other duties, the GSM selects and appoints the company's directors, decides on the distribution of profits, elects, and sets the remuneration of the members of the Management Board, and appoints the financial auditor.

### Management Board

The company is managed under the unitary management system by a Management Board consisting of five members, elected by the General Meeting of Shareholders (GMS) for a renewable term of 4 years. The unitary board groups executive and non-executive members. The Board elects a President and a Vice-President from among its members. The President of the Board cannot also be appointed as a General Director and does not hold executive positions in the organization. A majority of the members of the Board must be non-executive members and at least two of the members must be independent.

The Board has the powers to perform all the necessary administrative actions for the company, except those reserved by law for the General Meeting of Shareholders and those delegated by the Board to the company General Director. The establishment, revocation of directors, terms of office, duties, and role of the Board are clearly defined in our company's Articles of Incorporation prepared according to Law no. 31/1990

on the trading companies and GEO 109/2011 on the corporate governance of public enterprises.

Three Committees (Audit Committee, Nomination and Remuneration Committee, Risk Management Committee) are established and function within the Management Board.

Decisions concerning the company's activity are taken by the Management Board, in compliance with the provisions of the Board's Organization and Operation Regulation, which is an integral part of Antibiotice's Corporate Governance Code.

During 2023, the Management Board held 11 meetings to review the results achieved in the implementation of the company's strategy, according to the business plan, performance criteria, and the Income and Expenditure Budget for 2023. Three Ordinary General Meetings of Shareholders and two Extraordinary General Meetings of Shareholders were also convened, the resolutions of which are published on the company's [website](#).

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## Membership of the Management Board of Antibiotice SA on December 31, 2023

In 2023, the Management Board consisted of four non-executive and independent members and one executive member, appointed by the Management Board as General Director.

Membership of the Board of Directors	Position	Role	Term of office	Number of other significant positions and commitments and the nature of these commitments	Age (on Dec. 31, 2023)	Competences relevant to the impact of the organization	Shares owned*
<b>Lucian Timofticiuc</b>	President	Non-executive director**, independent***	Sep 16, 2020 - Apr 18, 2024	General manager and administrator of Vremea Nouă local newspaper, Vaslui.	49	Experience in business management and administration	Does not own ATB shares
<b>Ioan Nani</b>	Vice-President	Executive, non-independent administrator, holding the office of General Director	Jun 1, 2020 - Apr 18, 2024	-	64	Experience in management and business administration in the pharmaceutical industry, financial control, accounting, and economic studies	Owns 1,513 ATB shares
<b>Ionel Damian</b>	Member	Non-executive independent administrator	Apr 21, 2021 - Apr 18, 2024	Member and then President of the Board of Directors of the Autonomous Administration Iași Airport, as representative of the trustee body, Iași County  Council Executive Director of Tax Inspection, Iași Regional Directorate of Public Finance (DGRFP Iași), National Tax Administration Agency (ANAF), Ministry of Finance	53	Experience in business management and administration, public finance, tax audit, and legal studies	Does not own ATB shares
<b>Mihai Trifu</b>	Member	Non-executive independent administrator	Aug 26, 2021 - Apr 18, 2024	Vice-President of the Board of Directors of SIF Oltenia SA  Deputy General Manager of SIF Oltenia SA	40	Experience in business management and administration, including in the pharmaceutical industry, finance, internal audit, economic studies	Does not own ATB shares
<b>Cătălin Codruț Popescu</b>	Member	Non-executive independent administrator	Aug 26, 2021 - Apr 18, 2024	General Manager of Medimfarm SA  General Manager of Medimfarm TopFarm SA	49	Experience in business management and administration (pharmaceutical retail and distribution)	Does not own ATB shares

\* Number of Antibiotice shares owned as of December 31, 2023, according to the latest company database for 2023

\*\* A non-executive director in the Management Board, as defined by the updated Law no. 31/1990, is a director who has not been appointed manager of the company.

\*\*\* An independent director on the Management Board as defined by Law no. 31/1990 updated, is a director who has not been a director or employee of the company in the last 5 years, has not been additionally remunerated, and has not received other benefits, is not a significant shareholder of the company, has not had business relations with the company in the last year, either personally or as a partner, shareholder, director, manager or employee of a company that has such relations with the company, if, by their substantial nature, they are such as to affect his/her objectivity, who has not been a financial auditor of the company during the last 3 years, nor a director of another company in which one of the directors of the company is a non-executive director, who has not been a non-executive director of the company for more than 3 terms and who has no family relationship with the director or significant shareholder of the company.

All members of the Management Board are Romanian nationals, do not belong to minority or vulnerable groups, and represent the interests of all shareholders



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## Management Board - Gender and age diversity

Age group	Women		Men		Total	
	Nr.	%	Nr.	%	Nr.	%
< 30 years	0	0	0	0	0	0
30-50 years	0	0	3	60	3	60
> 50 years	0	0	2	40	2	40
<b>Total</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>100</b>	<b>5</b>	<b>100</b>

## Membership of the Advisory Committees of the Management Board of Antibiotice SA on December 31, 2023

Advisory Committees of the Management Board	Members of the Advisory Committees	Total number of members	Number of executive members	Number of independent members	Number of non-executive members
<b>Nomination and Remuneration Committee</b>	Lucian Timofticiuc, președinte Ionel Damian Mihai Trifu	3	0	3	3
<b>Audit Committee</b>	Ionel Damian, președinte Mihai Trifu Cătălin Codruț Popescu	3	0	3	3
<b>Risk Management Committee</b>	Lucian Timofticiuc, președinte Ionel Damian Cătălin Codruț Popescu	3	0	3	3

## Management Board Committees

The Management Board has set up advisory committees with the following duties:

- **The Nomination and Remuneration Committee** makes recommendations on the selection and remuneration of administrators and the General Director;
- **The Audit Committee** monitors the financial reporting process, effectiveness of Antibiotice SA's internal control, internal audit, where applicable, and risk management systems, monitors the statutory audit of the annual financial statements, reviews and monitors the independence of the statutory auditor or audit firm and, in particular, the provision of additional services to the audited entity.
- **The Risk Management Committee** ensures the alignment of control activities with the risks generated by the activities and processes subject to control, identifies, analyzes, evaluates, monitors, and reports on the risks identified, the measures planned to mitigate or anticipate such risks and other measures taken by the management. The Risk Management Committee was established in accordance with the legal obligations imposed by the amendments to the Emergency Ordinance No. 109/2011 on the Corporate Governance of Public Enterprises.

Specialized advisory committees carry out analyses, draw up recommendations, and report regularly to the Board on their activities. The duties and responsibilities of the advisory committees are set out in detail in the [Rules of Organization and Operation of the Management Board](#), annexed to the Company's Corporate Governance Code available on the Company's website.

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## Management team

At Antibiotice SA, the management team is made up of the executive management, which includes the General Director\* (a director mandated by the Management Board with the executive management of the company, according to Law no. 31/1990) and the Executive Directors\*\*.

### Executive management: General Director

The Management Board of Antibiotice SA has delegated the executive management to a member of the Management Board, who has thus become an executive administrator and director of the company, within the scope of Law no. 31/1990 on companies. Antibiotice SA is legally represented by the General Director, who ensures the operational management of the company, in accordance with the prerogatives established by law and the company's Articles of Association.

Member	Position	Age (on Dec. 31, 2023)	Details and competencies	Shares owned***
<b>Ioan Nani</b>	General Director, mandated by the Management Board (executive management)	64	Economist, in office since 1998 (1998-2008 and 2009 to present)	Owns 1,513 ATB shares

\* Director, as defined by Article 143 of Law no. 31/1990 on companies, republished, with subsequent amendments and additions, is the director to whom the Management Board delegates executive and managerial powers of the company, and who, to fulfill this mandate, cannot conclude an employment contract with the company, but a management contract.

\*\* Irrespective of the technical title of the position held within the company, any other person who is not in the situation described above is excluded from the application of Law no. 31/1990, as regards directors of public limited companies.

\*\*\* Number of Antibiotice SA shares held on December 31, 2023, according to the latest company database for 2023.

All members of the management team are Romanian nationals, hold Romanian citizenship, and do not belong to minority or vulnerable groups

## Executive Directors

On December 31, 2023, there were nine executive directors in the company.

Member	Position	Age (on Dec. 31, 2023)	Details and competencies	Shares owned***
<b>Cornelia Moraru</b>	Executive Director Technical and Production Division	58	Engineer, Head of the Technical and Production Division since May 1, 2003.	Owns 1,513 ATB shares
<b>Ovidiu Băţaga</b>	Executive Director National Sales Division	46	Economist, Head of National Sales since May 5, 2008.	Does not own ATB shares
<b>Paula Luminiţa Coman</b>	Executive Director Finance Division	56	Economist, Head of Finance since June 6, 2011	Does not own ATB shares
<b>Liviu Vatavu</b>	Executive Director Legal and Corporate Governance Division	52	Lawyer, head of the Legal and Corporate Governance Division since September 1, 2019.	Does not own ATB shares
<b>Darius Giorgiani Agafitei</b>	Executive Director International Business Development and Sales Division	44	Economist, Head of Business Development and International Sales since September 2, 2020	Does not own ATB shares
<b>Daniela Pascariu</b>	Executive Director Quality Assurance Division	49	Pharmacist, Head of Quality Assurance since October 8, 2021	Does not own ATB shares
<b>Mihaela Murariu</b>	Executive Director Human Resources Division	45	Psychologist, Head of Human Resources since Sep. 7, 2022	Does not own ATB shares
<b>Gianina Gabriela Macovei</b>	Executive Director Research Development and Portfolio Management Division	43	Engineer, Head of Research Development and Portfolio Management since June 01, 2023	Does not own ATB shares
<b>Ştefania Alexandru</b>	Executive Director Strategic Planning and Performance Management Division	41	Economist, Head of Strategic Planning and Performance Management since June 01, 2023	Does not own ATB shares

### Executive management\* - Gender and age diversity

Age group	Women		Men		Total	
	Nr.	%	Nr.	%	Nr.	%
< 30 years	0	0	0	0	0	0
30-50 years	4	40	2	20	6	60
> 50 years	2	20	2	20	4	40
<b>Total</b>	<b>6</b>	<b>60</b>	<b>4</b>	<b>40</b>	<b>10</b>	<b>100</b>

\* General Director and Executive Directors

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## Nomination, selection, remuneration, and performance evaluation of the organization's management

The criteria for the nomination and selection of the members of the Management Board are stipulated in the Antibiotice SA Corporate Governance Code, prepared in accordance with the provisions of the applicable legislation in force. The Nomination and Remuneration Committee assesses the independence of the members of the Management Board and monitors the number of mandates held by administrators in other companies (it is mandatory that they do not hold more than three mandates concomitantly). The majority of Board members must not hold executive positions in the company and at least two members must be independent as stipulated in Article 1382 of Law No. 31/1990 on legal entities.

Antibiotice SA's Remuneration Policy was developed by the Nomination and Remuneration Committee of the Management Board and includes the principles and mechanisms applied by the company in determining the remuneration of administrators and directors, as well as the method of payment and the maximum limits thereof.

According to the Remuneration Policy, non-executive administrators receive remuneration consisting of a fixed monthly fee and a variable component. The fixed compensation is paid once a month and the variable component is

paid once a year, is established by the mandate contracts approved by the GMS and is granted according to the degree of achievement of financial and non-financial performance indicators.

The General Director receives a remuneration consisting of a fixed monthly allowance and a variable component. The fixed allowance is paid once a month and the variable component is paid quarterly/annually, is set by the mandate contract approved by the Board and is granted according to the degree of achievement of financial and non-financial performance indicators.

The objectives and performance indicators of the Management Board set for the year 2023 and approved by the GMS on April 27, 2023, are as follows:

### ➤ Non-executive administrators

- **Financial indicator:** turnover, gross profit, arrears, and total expenses per 1,000 lei income
- **Non-financial indicators:** government social policies, setting risk management policies and monitoring risk, monitoring transparency and communication processes, reviewing, evaluating, and reporting on administrator and director performance.

### ➤ Executive Administrator (General Director)

- **Financial indicator:** turnover, gross profit, arrears, and total expenses per 1,000 lei income
- **Non-financial indicators:** government social policies, capacity utilization  $\geq 60\%$ , achievement of at least 80% customer satisfaction rate in the domestic market, average number of continuing training hours per employee, monitoring of transparency and communication processes.

Evaluation of the Management Board covers all the activities that this management body carries out and coordinates, including managing the impact that Antibiotice SA has on the environment, economy, and people, and is carried out in accordance with the provisions of the Regulation on the Evaluation of the Management Board, annexed to the Corporate Governance Code of the company.

The evaluation activity of the Management Board members can be carried out in two ways:

**a)** Self-evaluation - when the Management Board members will be evaluated using a methodology and a questionnaire

designed by the Board members and/or by an interview, each member of the Board discussing with the President of the Board and/or the Nomination and Remuneration Committee relating to the activities carried out within this body;

**b)** External evaluation is carried out by an independent natural or legal person, specialized in the recruitment of human resources, using a questionnaire designed by the expert and/or an interview; each member of the Board discusses with the expert the activities carried out within this body.

Aspects of the remuneration of the Management Board can be found in the [2023 Report of the Nomination and Remuneration Committee of the Management Board](#)

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## Managing economic, social, and environmental impacts

Within the company, the Sustainability Task Force was established in 2022 by a decision of the CEO and delegated responsibility for managing economic, social, and environmental impacts with the following objectives:

- Integrate financial and sustainability reporting;
- Monitor sustainability targets and report regularly on progress;
- Set sustainability targets (environmental, social, governance) and communicate results appropriately to stakeholders.

The working team is coordinated by the Quality Assurance Executive Director and consists of representatives of the following structures: Communication and Public Relations (reporting and communication), CSR (collection of reporting information), Environmental Protection (implementation and reporting of environmental objectives), Quality (implementation of patient and consumer safety measures), Financial (financial reporting and management reporting), Strategic Planning (planning sustainability objectives and monitoring), Risk Management (risk identification), Legal (implementation of anti-corruption measures).

The working team meets weekly and compiles progress reports according to the objectives and deadlines set for 2023.



## Management's role in sustainability reporting

Sustainability information is included in the integrated report. The report is sent to the management team for verification and then presented to the Management Board for review and approval.

In May, the entire management team participated in the course "Management Awareness and Involvement in Sustainability Programs and Initiatives". A total of 54 hours of training was provided to 18 members of management and employees directly involved in impact areas. The project will continue next year as reporting standards evolve.

## 3.2. Business ethics

**Business ethics refers to the moral principles and values that guide business behavior and decisions. For us, integrity, professionalism, accountability, and transparency are the core ethical values shared by the entire company team. These ethical principles are applied in all aspects of the business, from relationships with employees, customers, and business partners to the way the company conducts its activities and fulfills its social responsibilities.**

In our company, the [Code of Ethics](#) sets out the principles and rules aimed at determining professional, honest conduct and creating an organizational culture based on standards of integrity, in accordance with the legislation in force. Any violation of the Code is considered an ethical incident and the non-compliance with the Code of Ethics may lead to disciplinary sanctions. Compliance with the provisions of the Code is mandatory for everybody in the organization (i.e., *employees, members of the executive management, and the Management Board*).

Antibiotice has an Ethics and Integrity Committee that monitors compliance with the provisions of the Code of Ethics and applies the ethical principles and rules specific to the promotion of medical prescription medicinal products, supporting the company management in making decisions related to business conduct and ethical promotion of

prescription medicines by promotion and sales personnel.

The Ethics and Integrity Council also investigates all ethical incidents that are reported to it by referral or in which it takes action.

In 2023, 25% of Sales and Promotion employees were trained on the provisions of the company's Code of Ethics.

## Reporting incidents/ Public interest whistleblowers

Whistleblowers play a vital role in ensuring transparency and integrity within the company. By reporting suspicious or unethical activities, whistleblowers help protect the interests and values of the organization and promote an ethical and responsible working environment. Whistleblowers

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can identify deficiencies in internal policies and procedures, thereby facilitating continuous improvement of practices and risk management within the company. Antibiotice SA recognizes the importance of public interest whistleblowers in strengthening a healthy and sustainable corporate culture and provides the necessary legal and organizational framework for their protection.

Any interested natural or legal person can report an incident of violation of the Code of Ethics. The notification must be addressed to the CEO and should contain personal identification data and contact information. It can be submitted in writing to the company registry office or online, by completing an ethics form which can be accessed on [www.antibiotice.ro](http://www.antibiotice.ro).

Any person who has learned of or knows of possible violations of laws within the company or by the company or its employees has the right to make a report to the company's Ethics and Integrity Council. The Ethics and Integrity Board examines the facts of which it has been informed and the related evidence, if submitted, and gives its opinion in a written report proposing the measures it deems necessary.

In 2023, Antibiotice SA ensured compliance with the requirements of Law no. 361/2022 on the protection of public interest whistleblowers and implemented the following measures at the company level:

- It implemented the Procedure for receiving, investigating, and resolving

reports of violations of the law, established in accordance with the provisions of Law No. 361/2022 on the protection of public interest whistleblowers, which is available online on the Company's [website](#). The procedure ensures secure and confidential communication channels for whistleblowers and protection mechanisms for those acting as whistleblowers.

- Campaigns were conducted to educate management and employees on the importance of reporting public interest alerts and the appropriate reporting process.

**In 2023, over 600 employees participated in public interest warning training sessions.**

There were no public interest whistleblower reports or reports of breaches of the Company's ethical principles during the reporting period.

## Conflict of interests

The company has implemented a procedure to prevent, remedy, and sanction conflicts of interest and incompatibilities identified in the company's current activities. Conflicts of interest are managed in accordance with the provisions of Chapter 2 of the Code of Ethics, detailing the types of conflicts of interest that may arise, how they are resolved, and incompatibilities (situations that may

arise in the performance of the duties of employees and administrators and that could present a personal interest of a financial nature, influencing the objective performance of duties).

Regarding members of the Management Board, potential conflicts of interest arise in the situations described in the provisions of the Code of Ethics and the Corporate Governance Code. The latter specifies that Antibiotice's transactions with any of its affiliates will be approved in advance by the Management Board following a binding opinion received from the Audit Committee.

Members of the Management Board and/or persons who have been informed of the occurrence of a conflict of interest at Antibiotice must immediately report the matter to the Ethics and Integrity Board in writing. The solutions to manage the conflict of interest are determined by the Management Board in the case of administrators and by the General Director in the case of employees.

**In 2023 there were no reports of conflicts of interest.**

## Internal policy commitments

Through its [governance documents](#), the company has made several commitments to responsible business conduct, which are applicable both inside and outside

the company. The governance documents are the Code of Ethics, Code of Corporate Governance, Operating Regulations of the Advisory Committees of the Management Board, [Code of Good Practice](#) for the promotion of prescription medicines and interactions with healthcare professionals, Sponsorship and Patronage Policy, Forecasting Policy, Dividend Policy, Remuneration Policy, Environmental Quality Policy, [Internal Regulation and its annexes](#) (Code of Good Practice for Sales Activities, Policy on Workplace Harassment and Equal Opportunities, Procedure on the Protection of Public Interest Whistleblowers).

All these governance documents were approved by the company's Management Board, and their contents were communicated to all employees through regular training sessions during which the importance of compliance with the provisions of these commitments by employees during the performance of specific activities was stressed. The governance documents were communicated to the employees also on the company's [website](#).

## Communication of critical issues

Critical issues relate to concerns about potential and actual negative impacts of the organization on stakeholders, raised through the complaints and grievance mechanisms. In 2023, at Antibiotice no critical events were recorded and consequently, no such communications to management were required. In the event of such events, stakeholders may

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communicate a detailed complaint in writing to the company's management via the ethics form on the company's website. Shareholders can approach the management to raise critical issues at the General Meetings of Shareholders.

Potential negative impacts of the organization on stakeholders that can be reported through the complaints and other referral mechanisms relate to:

- the social impact of the company or the effects the company has on the community around it;
- employee well-being, which is a concern for both individual employees and other stakeholders;
- employee health and safety, other common interests of employees and other stakeholders;
- job security is another common concern of employees and other stakeholders.

In 2023 the company recorded no significant cases of non-compliance with the provisions of the laws and regulations in force, including fines or non-monetary sanctions.

## Anti-corruption and anti-bribery policy

Antibiotice is an ethical partner that cultivates respect and fairness in its relations with its internal (*employees*) and external (*suppliers, customers, etc.*) collaborators and, consequently, has implemented measures to prevent the occurrence of situations of abuse in the administration of its assets and management of its funds. As an entity that complies with the principles of corporate governance established by GEO no. 109/2011 on corporate governance of public companies, Antibiotice SA adopted the **Declaration of adherence to the fundamental values, principles, objectives, and monitoring mechanism of the National Anti-Corruption Strategy (SNA)**, thus complying with the provisions of GD no. 1269/2021 on the approval of the National Anti-Corruption Strategy 2021-2025 (SNA) and its related documents.

The national anti-corruption strategy meets the requirements of the Treaty on the Functioning of the European Union on the fight against fraud and any illegal operations affecting the financial interests of the Union. Member States are required to take the same measures to combat fraud affecting the Union's financial interests as they take to combat fraud affecting their financial interests.

In this respect, the 2021-2025 SNA aims to promote integrity by applying the

legal and institutional framework to prevent corruption in Romania. It is distinguished from other such strategies by the definition of very detailed and tangible objectives and deadlines and a monitoring mechanism supervised by the Ministry of Justice.

Subsequently, Antibiotice SA prepared the Integrity Plan containing the measures to implement the 2021-2025 National Anti-Corruption Strategy, appointing a member of the management team as coordinator. The plan includes anti-corruption and transparency measures for Antibiotice SA's activities, including measures relating to the conduct of periodic self-assessment at the company level on the degree of compliance with the provisions and dispositions of the plan, as well as recommendations on the conduct of periodic training aimed also at increasing the level of education of employees on good anti-corruption practices.

In April 2023, 100% of the company's management attended a training session on anti-corruption policies and procedures.

Integrity is a key factor in business. Combating bribery and other corrupt practices is vital for the protection of contractual parties as well as other entities indirectly affected by commercial transactions. There is a need to maintain confidence in the binding nature of contractual commitments as it is a key component of successful business

relationships. Integrity must prevail throughout the lifecycle of commercial contracts from their negotiation to their implementation, including the related payments.

To prevent the occurrence of corruption incidents in contractual relationships with business partners, Antibiotice selects its partners (suppliers, distributors, etc.) responsibly taking into consideration both the compatibility of the trade objectives and the integrity of such partners. In addition, the company's procedures for contract negotiation and preparation include clauses that discourage and sanction the attraction of the company and its employees to corruption acts or deeds.

By including anti-corruption clauses in contracts, the company ensures that, during contract negotiations and preparation (pre-contract period), no bribe, gift, or other improper advantage is offered or promised, in connection with the contract, by an employee (or no indication to this effect is given for the future), to an external or national partner, political party, party member, candidate for political office or director, either directly or indirectly through a subcontractor, agent, or other third party.

In conclusion, corruption-deterrent clauses and procedures are designed to strike a balance between the interests of the contracting parties, to avoid corruption, and the need to ensure that the objectives of the contract are achieved.

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In 2023, at the company level, there were no:

- corruption incidents;
- employees dismissed or disciplined as a result of their involvement in acts of corruption;
- contractual relationships terminated following suspicions of corruption;
- legal actions taken against the company on suspicion of corruption.

Our company did not financially support political causes during the reporting period. Antibiotice does not undertake and is completely against making any direct or indirect representations of any kind against political representatives. The company also does not finance political parties, their representatives, or candidates and does not sponsor events aimed at political propaganda.

### Audit on anti-corruption procedures and measures

In 2023, the Internal Audit Department of Antibiotice carried out an audit assignment on "Evaluation of the Corruption Prevention System, 2023". The objective of the mission was to assess the implementation of corruption prevention measures: declaration of assets, declaration of gifts, corruption risk assessment, and assessment of integrity incidents. The mission was reported to the Technical Secretariat of the National Anti-Corruption Strategy of the Ministry of Justice.

In the Audit Report dated September 14, 2023, it was established that the company's activities comply with the relevant legal provisions regarding the declaration of assets, declaration of gifts, assessment of corruption risk, and integrity incidents.

It should also be mentioned that, in December 2023, a questionnaire was submitted by the Integrity Structure of the Ministry of Health to identify the anti-corruption and integrity measures implemented. Based on the answers provided by Antibiotice SA, the company received the highest score.

In today's complex business environment, ensuring compliance with legal and ethical standards is essential to maintaining a company's integrity and reputation. To this end, our company implemented rigorous measures to monitor and verify our business partners' compliance with relevant commercial, civil, and criminal laws. In this regard, we took the following actions:

#### Monitoring business partner compliance

Concerning the measures taken by the company to monitor the compliance of business partners with the relevant commercial, civil, and criminal legislation, we established the Supplier/Partner Risk Analysis Procedure, identified by Code SOP-AR.003. In accordance with the provisions of this procedure, the Risk Management Department conducts a comprehensive risk analysis prior to entering into a business relationship with

internal or external partners/suppliers. This analysis focuses in particular on verifying that the third parties in question are structured and operate in compliance with the relevant civil and criminal laws and that they are financially sound. In addition, business partners are required to provide criminal record certificates issued by the relevant authorities to show that they have no previous convictions.

#### External evaluations and audits

Concerning third-party assessment of the company's compliance with national, European, and international anti-corruption and integrity legislation, it is an ongoing practice for our business partners, particularly external ones, to conduct audits using specific questionnaires. The purpose of these audits is to identify the measures implemented by our company to ensure that our employees comply with the relevant anti-corruption, integrity, and ethics legislation.

Similar audits are also carried out by national and international banks with which the company does business. For example:

- In 2023, the European Investment Bank carried out due diligence before granting the requested financing to Antibiotice SA to improve the company's profitability both domestically and internationally.

- In the same year, one of our contracting partners in Asia carried out a due diligence audit before signing collaboration contracts with our company.

Through these rigorous procedures and external assessments, we ensure that our business operations meet the highest standards of legal and ethical compliance.

### Competition policy

Anti-competitive or monopoly practices have a significant negative impact on consumers, the price of products, and other elements essential for an effective market. At Antibiotice, the internal framework regulating competition-related aspects, policies, and procedures is represented by the Corporate Governance Code, Code of Good Practice for Promotion of Prescription Medicinal Products and Interaction with Healthcare Professionals, Sponsorship, and Patronage Policy. The documents are available on the company website and are also communicated to the employees. The purpose of such documents is to highlight the fundamental elements of the company policy on fighting unfair competition. Embracing these values is essential and consequently, all the decisions taken by the management of the company follow the provisions of the internal regulations.

In 2023 there were no court actions (pending or completed) relating to anti-competitive behavior and antitrust and monopoly violations in which Antibiotice was identified as a participant.

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## Personal data protection

Antibiotice's policy on the protection of personal data is detailed in an internal system procedure: "Procedure for the processing of personal data at Antibiotice". In developing the procedure and related internal regulations, the company takes into account compliance with the requirements of the EU Regulation 2016/679 (GDPR) and national legislation, as well as the recommendations stipulated in the best practice guidelines issued by the A29 Working Group, the European Data Protection Supervisor (EDPS), the European Data Protection Board (EDPB) or the national personal data supervisory authorities of the European Union states.

How the company processes personal data depends on the capacity that each individual has in relation to Antibiotice and is described in detail on the company's website, under the section Personal Data Processing. The main objective of personal data protection is to ensure that all the company's activities comply with the requirements of the GDPR Regulation and related legislation. Our company is also concerned with the continuous improvement and streamlining of technical and organizational measures for the protection and security of personal data implemented at the organizational level.

The Information Governance Department is the internal structure responsible for managing the legal aspects of personal data protection.



In 2023, a variety of projects and measures were initiated and implemented to protect confidential and personal data, including:

- updating internal procedures on the protection of confidential information and personal data in line with the new guidelines developed by the relevant authorities;
- 95% of employees were trained on the data protection policy (in 2023,

Antibiotice SA employees completed a total of >1000 hours of training on personal data protection) and tested on their acquired knowledge (compared to 2022, the average score per company improved by about 17%);

- continuing the process of signing confidentiality agreements with all employees and updating access rights to information for employees who have changed function or job;

- improving technical security measures for confidential information and personal data by operationalizing the new Data Center within Antibiotice SA;
- conducting an internal audit of technical IT security measures by the Cyber Security Audit Department;
- creation of an Incident Rapid Response Team with specialists from various departments (Information Governance, Information Technology, Cyber Security Audit).



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Periodically (at least annually), personal data security policies, regulations, forms, and measures are reviewed to make them more effective and updated to correspond to changes in the organization.

Antibiotice SA ensures the protection of personal data, and confidential information, as well as of the information systems and networks used in the processing of such data through a series of technical and organizational measures, including:

- the general procedure for personal data processing at Antibiotice SA;
- procedures for handling security incidents, i.e., personal data breaches;
- regular employee training on the processing and protection of personal data, confidential information, and cyber security;
- implementing strict rules on the obligations of Antibiotice SA employees to keep personal data and information designated as trade secrets confidential;
- regulations on how to handle requests by which data subjects exercise their rights under the GDPR;
- procedures for the management of relations with Antibiotice SA's contractual partners in terms of processing and protection of personal data;

- regulations for the establishment and record-keeping of personal data processing activities and the identification, analysis, and management of risks related to personal data processing activities;
- procedures and measures to ensure physical security on Antibiotice SA premises;
- strict rules on information security, including ensuring access and access control of employees and collaborators to information on the computer network, remote access, and working.

**In 2023, there were no incidents of personal data or confidential information security incidents, and no complaints received from regulators or third parties regarding breaches of customer data security and privacy policies and regulations, leaks, thefts, or data loss.**

## Cybersecurity

↑ In 2023, Antibiotice took a decisive step towards supporting robust cybersecurity measures with the creation of the Cybersecurity Audit Department. The new structure was created in the context of the company's digitalization plan and the implementation of the European NIS Directive, to increase preparedness for cybersecurity incidents. Antibiotice is classified as an operator of essential services in the national economy, with the obligation to comply with the national strategy on network and information systems security, subject to the provisions of Law No. 362/2018 on ensuring a high common level of network and information systems security. Also in 2023, Antibiotice passed its first NIS audit with no major non-conformities, and the auditor found reasonable compliance with the security requirements imposed by Order no. 1323/200 on the approval of the Technical Norms on the minimum requirements for ensuring the security of networks and information systems applicable to operators of essential services.

The company's cybersecurity strategy is aligned with industry best practices, an important component of which is cyber threat risk management, along with a set of rules for securing the information system to comply with legal requirements. Continuous monitoring of the internal IT infrastructure highlights any missing or inadequate safeguards and defenses, allowing security teams to implement



the necessary mitigating controls and prioritize risk remediation. As of 2023, 23 system procedures were developed and are being implemented that regulate the way the company operates and ensure cybersecurity in accordance with the requirements of the National Cybersecurity Directorate, the national authority responsible for monitoring the implementation of Law No. 362 of 28 December 2018 on ensuring a high common level of security of networks and information systems ("NIS Law").

In 2023, a new data infrastructure was inaugurated, together with a new data center, designed to meet current and future digitalization requirements by ensuring the necessary redundancy and a minimum infrastructure speed of 10 Gbits between any two main points in the company. The new infrastructure, together with the new data center, forms the basis for obtaining ISO 27001 certification (Information Security Management System Certification).

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# 3.3. Financial developments

## Domestic market performance\*



- **value leader** in the market of generic and non-RX medicines marketed in hospitals, with a 14% market share;
- **leader** in the generic anti-infectives segment with a 32.2% value market share;
- **value leader** in the topicals segment - ointments, suppositories, and pessaries (market share: 14.6%) and injectable powders (market share: 18.6%);
- **quantitative leader** (indivisible unit) in the topical segment (ointments, suppositories, and pessaries) with a 31.3% market share, and injectable powders with a 57% market share;
- **4<sup>th</sup> place** in the prescription generics segment with a 7.8% market share;
- **4<sup>th</sup>** in consumption (boxes) in the prescription and non-Rx generic segment (5.4% market share);
- manufacturer of the **full range** of essential anti-tuberculosis medicines.

## External market performance



- consolidation of the world leadership status in the production of the Nystatin range of active substances (compacted, micronized, and standard);
- reference standard in the American Pharmacopoeia (USP) for the Nystatin range of active substances for over 5 years;
- the main Romanian exporter of medicines to Vietnam;
- leading international manufacturer of beta-lactam penicillins, among the top 10 in North America and Europe;
- continued dynamic territorial expansion plan, with three new territories accessed in 2023: Poland, Hungary, and Georgia, through anti-infective drugs and sterile powders;
- partner of health systems in various disadvantaged countries in support of National Communicable Disease Control Programs (Iraq, Yemen, Tunisia);
- representative offices in the Republic of Moldova, Ukraine, and Vietnam, and a commercial office in Serbia.

\* According to District Sell-Out, Cegedim Customer Information, December 2023.

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## Stock market performance

Antibiotice SA is a commercial company in which the Romanian State is the majority shareholder, holding 53.0173% of the subscribed and paid-up share capital through the Ministry of Health.

The shares issued by Antibiotice have been listed on the PREMIUM category of the Bucharest Stock Exchange (BVB), under the symbol ATB, since 1997.

The first transaction was recorded on April 16, 1997, at a reference price of 0.3500 lei/share. The historical maximum was reached on July 10, 2007, with a price of 2.1700 lei/share, and the historical minimum of 0.0650 lei/share was recorded on June 8, 2000.

### Antibiotice's main shareholders as of December 31, 2023, extracted from the Shareholders Register:

- Ministry of Health · **53.0173%**
- Infinity Investment Capital SA **29.4153%**
- Other individual and corporate shareholders (44,916 shareholders) **17.5674%**

### Shareholder categories:

- Legal entities **86.7086%**
- persoane fizice **13.2914%**

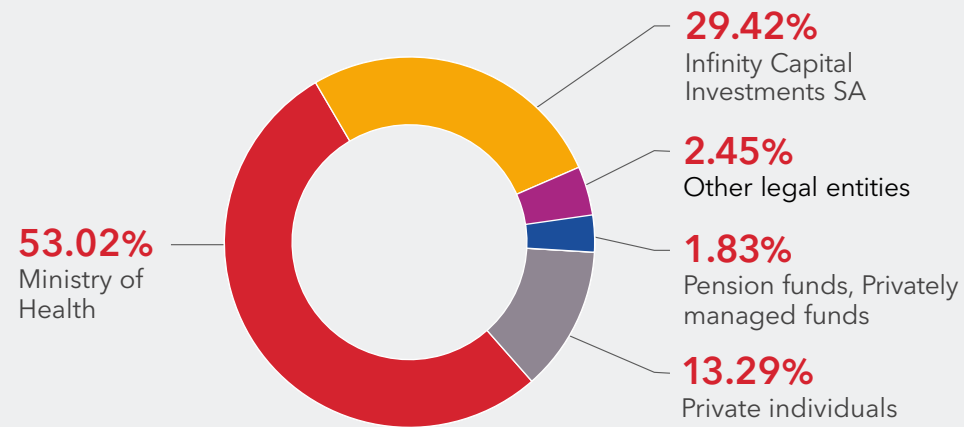
## Antibiotice SA on the capital market

The shares of Antibiotice SA are included in the BET-Plus index, which includes Romanian companies listed on the BVB market that meet the minimum selection criteria, except for financial investment companies, and in the BET-BK index, which is designed to be used as a benchmark by fund managers and other institutional investors. This reflects the fact that Antibiotice SA is a solid company, developed on a sound economic basis.

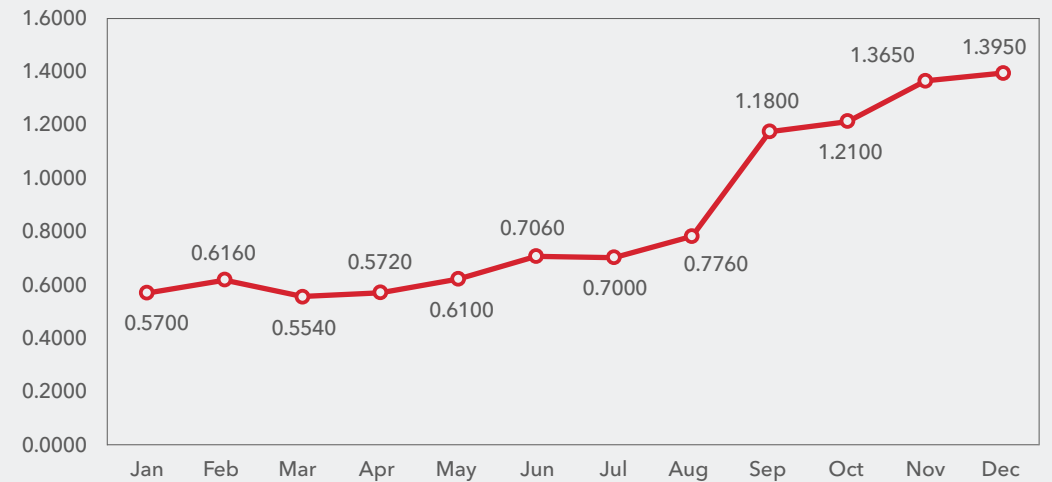
As of December 4, 2023, Antibiotice has been included in the MSCI Frontier IMI and MSCI Romania IMI (investable market indices) in the Small-Cap category. These indices include companies in the Small Cap, Mid Cap, and Large Cap size categories. The inclusion of Antibiotice SA in these indices increases the number of Romanian companies in the MSCI Frontier IMI and MSCI Romania IMI indices from 22 to 23.

In 2023, the lowest share price was 0.5400 lei. The share price increased to the maximum value of 1.5500 lei/share.

**Shareholding Structure**  
December 31, 2023

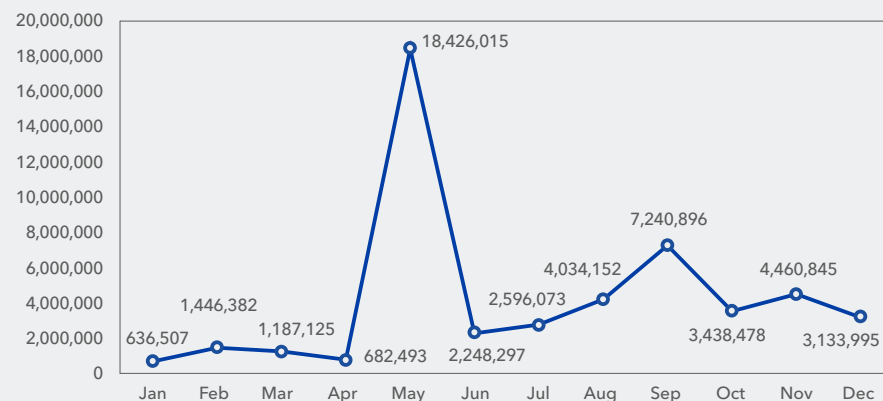


**Share price evolution in 2023**  
(Lei/share)



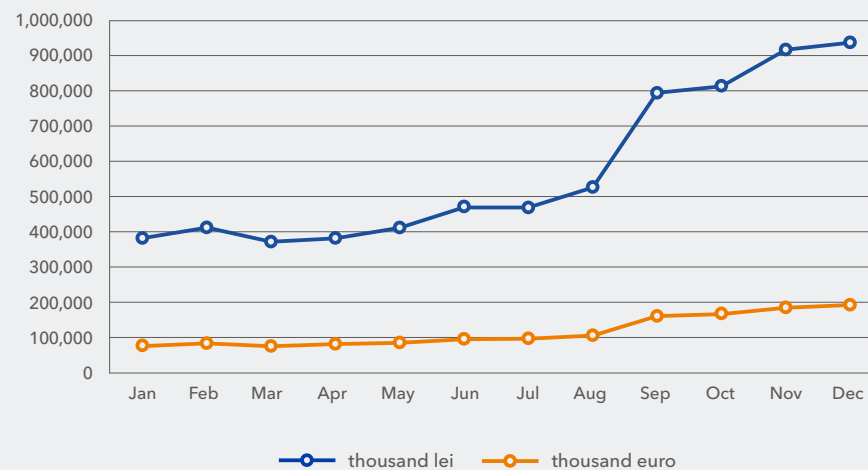
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### Number of shares traded in 2023



During 2023, 49,531,258 shares were traded, worth 41.12 million lei (€8.3 million/\$8.95 million), with an average price of 0.8301 lei/share.

### Stock market capitalization



The market capitalization of Antibiotice SA as of December 31, 2023, was 936,517 thousand lei (188,260 thousand euro).

### Antibiotice SA shares - (ATB)/Regular Market

	2019	2020	2021	2022	2023
Number of shares	671,338,040	671,338,040	671,338,040	671,338,040	671,338,040
Stock market capitalization (thousand LEI)*	341,040	326,270	406,831	379,977	936,517
Stock market capitalization (thousand EUR)*	71,370	66,935	82,211	76,803	188,260
Stock market capitalization (thousand USD)*	79,873	82,163	93,022	81,987	208,309
Total traded value (million LEI)	15	14	44	8	41
No. of traded shares	30,364,292	27,085,005	80,534,368	14,651,742	49,531,258
Opening price (LEI/share)	0.4800	0.5120	0.4940	0.6060	0.5660
Maximum price (LEI/share)	0.5260	0.5550	0.6080	0.6100	1.5500
Minimum price (LEI/share)	0.4500	0.4130	0.4800	0.4800	0.5400
Price at the end of the period (LEI/share)	0.5080	0.4860	0.6060	0.5660	1.3950
Average price (LEI/share)	0.4851	0.5079	0.5913	0.5408	0.8301
Earnings/share (LEI/share)***	0.0459	0.0418	0.0446	0.0574	0.1214
Gros dividend/share (LEI/share)**	0.029879738	0.00330631	0.003198092	0.00792224	0.04606825
Dividend yield****	6.20%	6.5%	0.65%	1.31%	8.1%
Dividend distribution rate*****	65%	8.4%	7.2%	13.8%	38.1%

\* Calculation based on the share price on the last trading day of that year  
 \*\* Dividend proposed and approved (\*)  
 \*\*\* Calculation of the earnings per share is based on the net profit of each year  
 \*\*\*\* Dividend per share/price of the share on the first trading day of each year  
 \*\*\*\*\* Dividend distribution rate = (total number of shares x gross dividend per share)/total net profit

(\*) At the date of this report, the distribution as dividends of 50% of the net profit remaining after the creation of reserves for tax incentives and the date of payment of dividends was not approved by the Annual General Meeting of Shareholders (on April 16, 2024). If the memorandum prepared by the Ministry of Health regarding the amount of these dividends receives a negative opinion from the Ministry of Finance and the Romanian Government, the amount of dividends may reach up to 90% of the net profit remaining after the creation of reserves for tax incentives.

These topics were also submitted for approval at the GSM meeting of May 28, 2024, but as they were not approved, they will be new items on the agenda of the General Meeting of Shareholders of July 01/02, 2024.

The two variants of the calculation of the distribution of the net profit of the Company can be consulted by following [this link](#).

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## Dividends

In 2023, 49,531,258 shares were traded, valued at 41,116,948.60 million lei (€8,288,763.40 million, \$8,949,596.51 million), with an average price of 0.8301 lei/share.

In 2023, dividends were paid for the financial years 2019, 2020, 2021 and 2022, amounting to 4,617,419.12 lei.

For the years 2019, 2020, 2021 and 2022, dividends will be paid through the Central

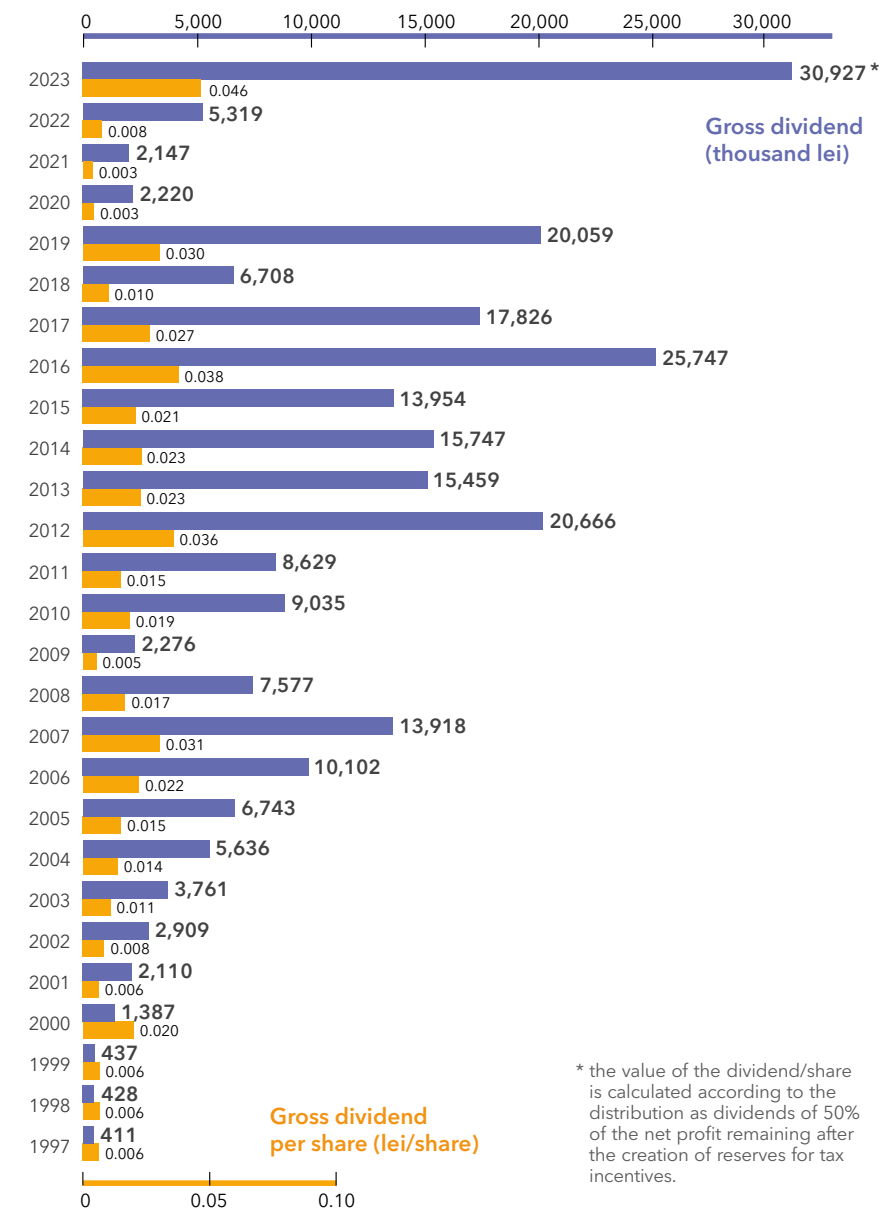
Depository in Bucharest and implicitly through the paying agent - CEC Bank. Dividends are at the disposal of the shareholders during the entire payment period and are recognized as income according to the legislation after the shareholders' approval.

The net profit for the year 2023, based on the audited financial statements, amounted to 81,088,596 lei.

### Dividend history 2019 - 2020 - 2021 - 2022

Time period	Net dividends								Dividend payment cut-off date
	Due	Paid (lei)				Unclaimed on 31.12.2023			
		Until 31.12.2022	01.01÷31.12 2023	Total	%	lei	%		
2019	19,811,039.75	18,214,252.34	13,552.12	18,227,804.36	92.01	1,583,235.39	7.99	20.09.2023	
2020	2,208,009.98	2,020,069.54	3,238.65	2,023,308.19	91.63	184,702.23	8.37	in progress	
2021	2,136,257.01	1,949,195.32	4,908.57	1,954,103.89	91.47	182,153.11	8.53	in progress	
2022	5,025,047.00	–	4,595,719.78	4,595,719.78	91.46	429,327.22	8.54	in progress	

### Gross dividend volume and gross dividend per share



\* the value of the dividend/share is calculated according to the distribution as dividends of 50% of the net profit remaining after the creation of reserves for tax incentives.

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## Investor relations

The activities of the Investor Relations Department include meeting with shareholders and investors, organizing conferences, private meetings with shareholders, teleconferences, and videoconferences, managing the Investor Relations section of the company's website, facilitating access to relevant information on the company's activities and reports, communicating the company's corporate governance policies, communicating information with an impact on the company, shareholders and investors.

Maintaining relationships with investors is based on effective communication, adapted to market feedback, which enables shareholders to understand and assess, based on objective and timely information, changes in trading patterns, the direction of the company's development, and information that affects risk management strategies.

In 2023, communication with shareholders and investors consisted of:

- Organization of meetings with investors to present annual financial results;
- Organization of conference calls based on the Company's financial calendar. These events are attended by interested investors and analysts, who have the opportunity to present their questions, opinions, and suggestions, thus ensuring a dialogue with the representatives of the Romanian

capital market and providing them with a sufficient basis for investment decisions.

- Publication of presentations and audio recordings of investor conference calls on the Company's website;
- Prompt transmission of information upon request by shareholders, potential investors, and capital market participants;
- Participating in conferences organized by third parties on the Romanian capital market and presenting the Company's financial results and growth opportunities;
- Participation of the Company's representatives in informative seminars organized by the competent authorities to improve corporate governance and increase transparency towards shareholders;
- Organization of General Meetings of Shareholders, changes in the Company's structure, resolutions of the General Meetings, as well as actions related to the guarantee of shareholders' rights - distribution of dividends for the financial year 2022, were carried out in compliance with legal regulations;
- Gathering of information, preparation, and verification of current reports, their submission to the competent authorities (BVB and ASF), and their publication on the Company's website in compliance with the deadlines established by the legislation in force;

- Participation in training and discussion sessions on corporate governance standards, investor communication platforms, and other tools made available by the capital market authorities;
- Regularly updating the Company's website to improve access to relevant information for shareholders and investors.

The events agenda, which aimed to maintain an ongoing dialog between the company's management, investors, and analysts, included four conference calls during 2023 to present individual financial statements on March 2, May 15, August 23, and November 21.

All documents related to the successful conduct of the above-mentioned events were published in accordance with the legislation in force, namely Law no. 31/1990 on commercial companies, republished, with subsequent amendments and additions, Government Emergency Ordinance no. 109/2011 on corporate governance of public enterprises, Law no. 24/2017 on issuers of financial instruments and market operations, Regulation no. 5/2018 on issuers of financial instruments and market operations.

The first place for the best company in terms of Investor Relations activity - Main Market - public vote, awarded by the Association for Investor Relations at the Romanian Stock Exchange during the ARIR Gala on November 23rd, 2023,

as well as a rating of 10, achieved for the fourth consecutive year, in the evaluation of the VEKTOR indicator based on 15 criteria of good practices in Investor Relations, motivate us to perform in our communication with investors, to fulfill our mission of providing information transparently and responsibly, to develop relationships based on ethics and trust with current and potential investors. This recognition supports the company's orientation towards sustainable development, in line with the transparency of the company's activities towards its stakeholders.



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## Optimizing operating costs and increasing operating efficiency

The activities of 2023, part of the business plan "The Future Together" for 2023-2030, resulted in the following economic and financial indicators, which reflect increased profitability and maintained financial balance, creating the conditions for a resilient business in the long term.

The Business Plan 2023-2030 "The Future Together" is the strategic tool for the continuous adaptation to the national and international markets, for the development and growth of the company, with the following objectives:

- business sustainability and durability;
- optimal utilization of production capacity;
- maximizing the market potential for the products in the portfolio;
- optimizing the distribution structure in Antibiotice territories;
- maximizing long-term returns;
- managing corporate costs to balance activities;
- diversifying funding sources to support current activities and investment programs;
- standardizing and streamlining processes.

## Indicators from the 2023 Comprehensive Income Statement

Indicators	M.U.	2021	2022	2023	Δ 2023/ 2022	Δ 2022/ 2021
Total income	thousand lei	388,925	522,227	<b>640,727</b>	23%	34%
Total expenditure	thousand lei	358,622	480,324	<b>549,203</b>	14%	34%
Net turnover	thousand lei	368,422	483,724	<b>600,781</b>	24%	31%
- domestic	thousand lei	225,974	299,192	<b>382,398</b>	28%	32%
- export	thousand lei	142,448	184,532	<b>218,382</b>	18%	30%
Export share in turnover	%	39%	38%	<b>36%</b>	-4%	-3%
Gross profit	thousand lei	30,303	41,903	<b>91,524</b>	118%	38%
Clawback	thousand lei	28,669	31,333	<b>37,013</b>	16%	12%
Gross profit + clawback	thousand lei	58,972	73,236	<b>128,537</b>	74%	25%
Net profit	thousand lei	29,939	38,513	<b>81,089</b>	111%	29%
Total assets (TA)	thousand lei	895,388	856,474	<b>1,139,172</b>	33%	-4%
Equity capital	thousand lei	604,992	641,431	<b>846,964</b>	32%	6%
Total liabilities (TL)	thousand lei	290,397	215,044	<b>292,208</b>	36%	-26%
Indebtedness (TL/TA*100)	%	32%	25%	<b>26%</b>	-2%	29%
Global solvency (AT/DT*100)	no. of times	3.08	3.98	<b>3.90</b>	-2%	29%
Total expenses per 1,000 lei income	lei	922	920	<b>857</b>	7%	0,3%
Operating income	thousand lei	383,826	511,529	<b>629,266</b>	23%	33%
Average number of employees	no.	1,410	1,355	<b>1,350</b>	-0.37%	-4%
Work productivity (operating income/ average no. of employees)	thousand lei	272	378	<b>466</b>	23%	39%
Taxes and fees, of which:	thousand lei	89,078	100,497	<b>122,033</b>	21%	13%
- clawback	thousand lei	28,669	31,333	<b>37,013</b>	18%	9%
- taxes and fees related to salaries	thousand lei	47,358	52,023	<b>61,380</b>	18%	10%
- other taxes and fees to state budget	thousand lei	11,438	15,159	<b>19,976</b>	32%	33%
- local taxes and fees	thousand lei	1,613	1,982	<b>3,665</b>	85%	23%
Added value	thousand lei	184,594	259,211	<b>330,793</b>	28%	40%
Profitability of gross profit	%	8.22%	8.66%	<b>15.23%</b>	76%	5%
Profitability of gross profit + clawback	%	16.01%	15.14%	<b>21.39%</b>	40%	-5%

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Activities in 2023 were guided by the following principles: strategic planning, identification of activities by operating divisions (Oral Solid Products Division, Sterile Products and Active Ingredients Division, Topical Products Division), accountability through performance management and decentralization of budgets and activities down to portfolio, product group and product level.

In 2023, the total revenue amounted to 640,727 thousand lei, an increase of 23% compared to the amount of 522,227 thousand lei in 2022.

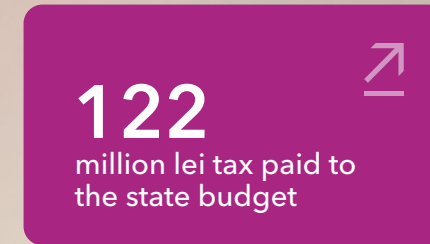
The activities carried out in 2023, focused on actions aimed at strategic adaptation of human resources, strategic adaptation of the product portfolio, business sustainability through continuous improvement of the Integrated Management System (quality, environment, occupational health and safety), strategic planning and performance management, improvement of the corporate governance system generated total expenses amounting to 549,203 thousand lei, 14% higher compared to the amount recorded in 2022. The efficiency of the whole activity is reflected by the total expenses per 1,000 lei total revenue indicator, amounting to 857 lei as of December 31, 2023, lower compared to the amount of 920 lei reported in 2022.

Gross profit amounted to 91,524 thousand lei, above the level of 41,903 thousand lei recorded in 2022.

Gross profit, consolidated with the amount of the clawback tax, gives a return on sales of 21.3%. The clawback tax is paid quarterly by pharmaceutical manufacturers as a state budget tax since 2011 on prescription medicines included in national health programs, with or without personal contribution, used in outpatient treatment, through open-circuit pharmacies and, on those used in hospital treatment, paid from the National Single Fund for Social Health Insurance and the budget of the Ministry of Health.

The net profit amounted to 81,089 thousand lei, above the level recorded in 2022 (38,513 thousand lei), as a result of the cumulative effect of:

- increased sales on the international market by entering new territories with products that define Antibiotice's strategic portfolio;
- optimization of the sales structure in the domestic market of systemic anti-infectives and dermatological products;
- increased sales in an optimal structure in both the hospital and retail segments;
- renegotiating partnerships with distributors in each market segment - hospitals, national chains, mini-chains, and independent pharmacies - to improve market share and profitability.





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## Economic performance

The economic impact of our business is reflected in our spending on procurement, salaries, operational investment, payments to the national budget, and community investment.

### Indicators presented according to Regulation 852/2020 (Taxonomy Regulation)

The European Taxonomy is a classification system for economic activities based on sustainability and environmental impact criteria and plays a crucial role in redirecting capital flows towards sustainable investments and promoting transparency in capital markets.

The legislative framework governing the reporting of the indicators set out in Regulation 852/2020 (on establishing a framework to facilitate sustainable investment) and underlying the reporting of the indicators presented below is completed by:

- **Commission Delegated Regulation (EU) 2021/2139** of 4 June 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining

whether that economic activity causes no significant harm to any of the other environmental objectives;

- **Commission Delegated Regulation (EU) 2021/2178** of 6 July 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and the Council by specifying the content and presentation of information to be disclosed by undertakings subject to Articles 19a or 29a of Directive 2013/34/EU concerning environmentally sustainable economic activities, and specifying the methodology to comply with that disclosure obligation;
- **Commission Delegated Regulation (EU) 2022/1214** of 9 March 2022 amending Delegated Regulation (EU) 2021/2139 as regards economic activities in certain energy sectors and Delegated Regulation (EU) 2021/2178 as regards the publication of specific information concerning those economic activities.



### Economic performance

Description	Value (lei)
Directly generated economic value	614,162,676
Revenue	614,162,676
Economic value distributed	604,135,943
Operating costs	393,322,739
Employee salaries and benefits	146,360,002
Payments to shareholders	5,433,706
Payments to government/state budget	27,766,919
Clawback tax	30,193,335
Community investment (sponsorships)	1,059,242
Economic value retained	10,026,733
Tax exemptions and credits	3,077,417

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### The proportion of turnover from products or services associated with taxonomy-aligned economic activities - information provided for 2023

Economic activities	Code(s)	Turnover	Proportion of turnover, 2023	Substantial contribution criteria						DNSH criteria - Do no significant harm						Minimum safeguards	Proportion of turnover aligned to the taxonomy (A.1.) or taxonomy eligible (A.2.) turnover, 2022	Enabling activity category	Transitional activity category	
				Climate change mitigation	Climate change adaptation	Water and marine resources	Pollution	Circular economy	Biodiversity and ecosystems	Climate change mitigation	Climate change adaptation	Water and marine resources	Pollution	Circular economy	Biodiversity and ecosystems					
		lei	%	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	Y;N; N/EL	%	Enabling	Transitional
<b>A. Taxonomy - eligible activities</b>																				
<b>A.1 Environmentally sustainable activities (Taxonomy-aligned)</b>																				
Turnover of environmentally sustainable activities (Taxonomy-aligned) (A.1.)		0	0%	0%	0%	0%	0%	0%	0%									0%		
Of which enabling		0	0%	0%	0%	0%	0%	0%	0%									0%	Enabling	
Of which transitional		0	0%	0%														0%		Transitional
<b>A.2. Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)</b>																				
Turnover of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)		0	0%	0%	0%	0%	0%	0%	0%									0%		
<b>A. Turnover of Taxonomy-eligible activities (A.1+A.2)</b>		<b>0</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>									<b>0%</b>		
<b>B. Taxonomy non-eligible activities</b>																				
<b>Turnover of Taxonomy-non-eligible activities</b>		<b>600,780,825</b>	<b>100%</b>																	
<b>Total</b>		<b>600,780,825</b>	<b>100%</b>																	

D - Yes, taxonomy-eligible activity and taxonomy-aligned activity to the relevant environmental objective  
 N - No, taxonomy-eligible but taxonomy-not aligned to the relevant environmental objective  
 N/EL - not eligible, activity not taxonomy-eligible for the relevant objective

Proportion of turnover/Total turnover	CCM	CCA	WTR	CE	PPC	BIO
Taxonomy aligned by objective	0%	0%	0%	0%	0%	0%
Taxonomy eligible per objective	0%	0%	0%	0%	0%	0%

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### The proportion of CapEx from products or services associated with taxonomy-aligned economic activities - information provided for 2023

Economic activities	Code(s)	CapEx	Proportion of CapEx, 2023	Substantial contribution criteria						DNSH criteria - Do no significant harm						Minimum safeguards	Proportion of CapEx aligned to the taxonomy (A.1.) or taxonomy eligible (A.2.) CapEx, 2022	Enabling activity category	Transitional activity category
				Climate change mitigation	Climate change adaptation	Water and marine resources	Pollution	Circular economy	Biodiversity and ecosystems	Climate change mitigation	Climate change adaptation	Water and marine resources	Pollution	Circular economy	Biodiversity and ecosystems				
		lei	%	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	%	Enabling	Transitional
<b>A. Taxonomy - eligible activities</b>																			
<b>A.1 Environmentally sustainable activities (Taxonomy-aligned)</b>																			
Urban and suburban transport, road passenger transport	6.3	5,174,650	8%	Y	N/EL	N/EL	N/EL	N/EL	N/EL		Y	N/A	Y	Y	N/A	Y	*)		Transitional
Installation, maintenance, and repair of energy-efficiency equipment	7.3	345,412	1%	Y	N/EL	N/EL	N/EL	N/EL	N/EL		Y	N/A	Y	N/A	N/A	Y	0.48%	Enabling	
Installation and operation of electric heat pumps	4.16	1,360,815	2%	Y	N/EL	N/EL	N/EL	N/EL	N/EL		Y	Y	N/A	Y	N/A	Y	**)		
Construction, extension, and operation of wastewater collection and treatment	5.3	3,997,855	6%	Y	N/EL	N/EL	N/EL	N/EL	N/EL		Y	Y	Y	N/A	Y	Y	4.7%		
Production of heat/cool using waste heat	4.25	2,580,263	4%	Y	N/EL	N/EL	N/EL	N/EL	N/EL		Y	N	N	Y	Y	Y	***)		
CapEx of environmentally sustainable activities (Taxonomy-aligned) (A.1.)		13,458,995	21%	0%	0%	0%	0%	0%									5.18%		
Of which enabling		345,412	1%	1%	0%	0%	0%	0%	0%		Y	Y	Y	Y	Y	Y	0.48%	Enabling	
Of which transitional		5,175,650	8%								Y	Y	Y	Y	Y	Y			Transitional

\*) Activity with code 6.3 Urban and suburban transport, road passenger transport was not performed in 2022

\*\*\*) Activity code 4.16 Installation and operation of electric heat pumps was not performed in 2022

\*\*\*) Activity code 4.25 Production of heat/cool using waste heat was not performed in 2022

D - Yes, taxonomy-eligible activity and taxonomy-aligned activity to the relevant environmental objective

N - No, taxonomy-eligible but taxonomy-not aligned to the relevant environmental objective

N/EL - not eligible, activity not taxonomy-eligible for the relevant objective

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The proportion of CapEx from products or services associated with taxonomy-aligned economic activities - information provided for 2023 (continuation)

Economic activities	Code(s)	CapEx	Proportion of CapEx, 2023	Substantial contribution criteria						DNSH criteria - Do no significant harm						Minimum safeguards	Proportion of CapEx aligned to the taxonomy (A.1.) or taxonomy eligible (A.2.) CapEx, 2022	Enabling activity category	Transitional activity category
				Climate change mitigation	Climate change adaptation	Water and marine resources	Pollution	Circular economy	Biodiversity and ecosystems	Climate change mitigation	Climate change adaptation	Water and marine resources	Pollution	Circular economy	Biodiversity and ecosystems				
		lei	%	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	%	Enabling	Transitional
<b>A.2. Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)</b>																			
CapEx of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)			0	0%	0%	0%	0%	0%	0%	0%							5.18%		
<b>A. CapEx of Taxonomy-eligible activities (A.1+A.2)</b>		<b>13,458,995</b>	<b>21%</b>	<b>21%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>									
<b>B. Taxonomy non-eligible activities</b>																			
CapEx of Taxonomy-non-eligible activities		<b>50,994,847</b>	<b>79%</b>																
<b>Total</b>		<b>64,453,842</b>	<b>100%</b>																

D - Yes, taxonomy-eligible activity and taxonomy-aligned activity to the relevant environmental objective  
 N - No, taxonomy-eligible but taxonomy-not aligned to the relevant environmental objective  
 N/EL - not eligible, activity not taxonomy-eligible for the relevant objective

In 2022, activity code 5.9 Water supply, sewerage, waste management and remediation were also performed with a CapEx proportion of 0.22%

Proportion of CapEx/Total CapEx	CCM	CCA	WTR	CE	PPC	BIO
Taxonomy aligned by objective	21%	0%	0%	0%	0%	0%
Taxonomy eligible per objective	0%	0%	0%	0%	0%	0%

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### The proportion of OpEx from products or services associated with taxonomy-aligned economic activities - information provided for 2023

Economic activities	Code(s)	OpEx	Proportion of OpEx, 2023	Substantial contribution criteria						DNSH criteria - Do no significant harm						Minimum safeguards	Proportion of OpEx aligned to the taxonomy (A.1.) or taxonomy eligible (A.2.) OpEx, 2022	Enabling activity category	Transitional activity category
				Climate change mitigation	Climate change adaptation	Water and marine resources	Pollution	Circular economy	Biodiversity and ecosystems	Climate change mitigation	Climate change adaptation	Water and marine resources	Pollution	Circular economy	Biodiversity and ecosystems				
		lei	%	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y;N;N/EL	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	%	Enabling	Transitional
<b>A. Taxonomy - eligible activities</b>																			
<b>A.1 Environmentally sustainable activities (Taxonomy-aligned)</b>																			
Water supply, sewerage, waste management, and remediation activities	5.5	441,449	4%	Y	N/EL	N/EL	N/EL	N/EL	N/EL		Y	N/A	N/A	Y	N/A	Y	3.58%		
OpEx of environmentally sustainable activities (Taxonomy-aligned) (A.1.)		441,449	4%	4%	0%	0%	0%	0%	0%		Y	N/A	N/A	Y	N/A		3.58%		
Of which enabling		0	0%	0%	0%	0%	0%	0%	0%	Y	Y	Y	Y	Y	Y	Y	4%	Enabling	
Of which transitional		0	0%	0%						Y	Y	Y	Y	Y	Y	Y			Transitional
<b>A.2. Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)</b>																			
OpEx of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)		0	0%	0%	0%	0%	0%	0%	0%								0%		
<b>A. OpEx of Taxonomy-eligible activities (A.1+A.2)</b>		<b>441,449</b>	<b>4%</b>	<b>4%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>										
<b>B. Taxonomy non-eligible activities</b>																			
OpEx of Taxonomy-non-eligible activities		<b>12,084,200</b>	<b>96%</b>																
<b>Total</b>		<b>12,525,649</b>	<b>100%</b>																

Proportion of OpEx/Total OpEx	CCM	CCA	WTR	CE	PPC	BIO
Taxonomy aligned by objective	4%	0%	0%	0%	0%	0%
Taxonomy eligible per objective	0%	0%	0%	0%	0%	0%

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## 3.4. Supply chain

In the pharmaceutical industry, where innovation and regulatory compliance are of paramount importance, effective supply chain management through efficient procurement practices is a vital component for business success.

A strategic procurement approach brings significant benefits in terms of product quality, cost, and competitiveness in an industry as complex and dynamic as pharmaceuticals.

Through the adoption of best practices, Antibiotice strives to ensure efficiency, cost savings, and product quality.

In 2023, the geopolitical factor continues to be at the forefront: the war in Ukraine and other challenges such as the situation between China and Taiwan or the tensions between the US and China.

Supply chains have not fully recovered from the pandemic and changing behaviors in the global economy have disrupted the availability of certain raw materials. In such a risk-sensitive industry, assessing and managing supply risk is critical.

Security of supply is a top priority for Antibiotice. We always consider the human factor and the impact on the supply chain. We constantly seek to understand which elements are most at

risk and implement mitigation measures that have helped to eliminate, reduce, or control the risk of stock-outs.

In 2023, we initiated actions to ensure the viability of the entire supply chain, beyond the financial aspects.

In particular, we are focusing on key elements such as driving the digital transformation process, ensuring continuity of supply, and strengthening relationships with our suppliers.

We carried out analyses to understand the elements most at risk to sustainability to find solutions to mitigate potential disruptions. Each year we conduct a risk analysis and define a criticality index for procurement and implement mitigation measures such as increasing safety stocks as much as possible, taking into account the shelf life of components. We also work with our suppliers to maintain a safety stock of raw materials at their premises as well as our own, to ensure prompt delivery while benefiting from our suppliers' expertise. Sometimes even a difference of a few days can have an impact on the supply chain.

Several of these approaches required change management in terms of forecasting and planning activities, such as IT tools that need to be flexible to support implementation.

In times of recession, procurement tends to revert to traditional ways of working, focusing on savings, negotiations, and working capital improvements. While this has been and remains a key priority for us, we need to be careful that these short-term priorities do not prevent us from making progress on future procurement priorities.

We have taken steps to minimize the impact of inflation and manage commodity price volatility. All these challenges make it difficult to discuss and agree on a long-term strategy with our suppliers. We intend to strengthen our supplier risk assessment tools and extend supplier relationship management to new categories to be perceived as a key customer.

Purchasing managers buy from suppliers in Romania and on international markets, machinery, and equipment, materials for logistics, vehicles for the fleet and consumables for fleet maintenance, raw materials, and materials for the production process.

Procurement is carried out in accordance with the annual investment and repair programs approved at the company level. Overall, there are long-standing partnerships with nationally and internationally recognized suppliers

that comply with occupational health, employee, and environmental protection standards, as noted during visits to their sites. The relationships with the suppliers are defined in clauses of the supply and procurement contracts and orders, while the requirements pertaining to occupational health and safety, environmental protection, consumption of utilities for the equipment operation, and compliance with the standards specific to the pharmaceutical industry are included in the procurement procedure.

The Procurement department makes purchases only from authorized suppliers included on the List of Authorized Suppliers, in conformity with the appropriate procedures.

The approved suppliers that meet the requirements of the company are selected based on criteria formulated by the R&D and Regulatory Affairs departments, then audited and authorized by the Quality Assurance and afterward, included on the List of Authorized Suppliers.

With growing environmental and ethical concerns in the pharmaceutical industry, adopting sustainable procurement practices will lead to stronger relationships with stakeholders and operational efficiencies in the long term.

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**74.93%**  
of our suppliers are local

In 2023, the company finalized the Code of Conduct for Partners, and in 2024 will begin the process of assessing suppliers for social and environmental impact.

Implementing sustainability due diligence throughout the value chain is essential to ensure ethical and sustainable business practices. This is a major challenge that requires collaboration not only within the company but also across the industry. This means joining forces to persuade our suppliers to adopt sustainable practices and ensuring that our business partners make sustainable choices.

Change in the pharmaceutical industry can be slow - for example, the process of qualifying new suppliers is extensive and time-consuming. By properly assessing and managing the environmental, social, and governance (ESG) risks associated with our value chain activities, and through a continued commitment to promoting best practice, we can help improve our environmental and community impacts.

### Supplier expenditure

Year	Local suppliers' expenditure	Other suppliers' expenditure	Total
2023	43.61%	56.39%	100%
2022	45.13%	54.87%	100%
2021	48.95%	51.05%	100%

### Evolution of the number of suppliers

Year	Number of local suppliers	Other suppliers	Total	Of which new suppliers
2023	831	278	1,109	39
2022	842	269	1,111	43
2021	831	237	1,068	N/A

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# 3.5. Risk management

**Antibiotice's risk management process aims to identify the risks facing the organization to anticipate and manage them so that they do not impair the effective achievement of the company's objectives. The identification, assessment, management, and reporting of risks comply with applicable legal and regulatory requirements.**

Antibiotice SA seeks to understand the risks to which the company is exposed and their causes and to improve the company's risk profile by managing the process of identifying, assessing, and managing risks and implementing the necessary control measures to keep risk exposure within the tolerable range.

Specific risks are identified at the level of Antibiotice SA's internal organizational structures, and significant risks that may affect the achievement of the company's overall objectives are analyzed and prioritized annually by establishing the risk profile and tolerance limit. These are then approved by the company's management.

The "Plan for the implementation of control measures for significant risks at the company level" is also prepared annually.

The cyclical review of the key risks involves an assessment of the likelihood of their occurrence and their potential consequences to confirm the level of exposure and assess strategies for their management.

The Internal Audit Office conducts an annual risk management assessment, making recommendations for improvement where necessary, and the findings are presented to the Audit Committee.

In 2023, the General risk register was developed and approved, aiming to minimize significant risks to which the company is exposed, impacting its objectives. Relevant risks were summarized according to their magnitude using impact and probability of occurrence criteria.

The main risk categories identified were:

- business risks (economic, legislative, partner-generated), integrity risks;
- financial risks (currency, liquidity, interest rate, commercial);
- operational risks (personnel, information technology, and information security);
- occupational health and safety risks;
- environmental risks;
- climate change risks.

## Business risk

Business risk is the possibility that an event or action could adversely affect the company's ability to achieve its stated objectives or proposed strategies.

Geopolitical and macroeconomic issues, rising inflation, energy crisis, supply chain disruptions, raw material crises, raw material price increases due to a reduction in the number of producers, implementation of European GMP requirements, environmental policies, increases in energy and methane gas

prices, increases in transport costs, changes in local market conditions (decrease in consumption, decrease in prices, entry of new competitors) are just some of the circumstances that can lead to business risks.

Measures to mitigate these risks include renegotiation of prices and contracts, development in regulated markets (US, Europe) with high price levels, trading relationships with several suppliers, authorization of at least one additional source of raw materials where economically justified, meetings with partners to





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ensure supply by maintaining constant and proactive contact with them, informing them of the organization of production in campaigns to reduce costs and manufacturing time, the overhaul period, the correlation of the quarterly procurement plan with the production plan, the creation of safety stocks for certain raw materials.

### Financial risks

Financial risks reflect the impact that financial sources and/or resources have on the company: liquidity risk, currency risk, interest rate risk, and commercial (default) risk.

Circumstances conducive to financial risks include tax unpredictability (clawback tax), rising inflation, rising prices for raw materials and utilities, and currency exchange rate fluctuations, which are reflected both in the cost of imported raw materials and in the prices of finished products for export, the increase in the monetary policy interest rate, and the increase in the ROBOR index.

A number of measures have been taken to mitigate the impact of financial risks, such as: optimizing the turnover rate of inventories in distribution to ensure demand for products in the Antibiotice portfolio and to improve the time of collection of receivables from distributors; improving relations with suppliers; organizing rigorous cost management at company level to identify measures to optimize and reduce costs; ensuring

an optimal balance between external receipts and payments; covering external payments from foreign receipts through a permanent analysis of the structure of receipts and payments in order to achieve the best possible correlation between currency and time of payment/receipt; reducing the amount of operating loans used; reducing the level of loans to an optimal level; covering the temporary gap between receipts and mandatory payments to be made; permanent analysis of the structure of assets and liabilities in order to determine the sensitivity to changes in interest rates.



### Legislative risks

Regulatory risks are one of the main challenges facing the pharmaceutical industry. These risks stem from legislative and regulatory changes that can affect the way products are developed, tested, manufactured, marketed, and sold.

Adapting to these regulations results in additional costs being incurred in updating the documentation to meet the latest quality standards.

Antibiotice SA's strategy for managing these risks includes constant efforts to obtain international certifications for production processes, updating the authorization documentation for the products in its portfolio, continuous monitoring of legislative changes at national and international levels, continuous adaptation of policies, rules, and procedures to the changes, continuous training of staff on current legislative requirements or identified trends.

### Operational risk

Operational risk is the risk of loss resulting either from inadequate internal processes, people or systems that fail to perform their function properly, or from external events, such as those arising from legal and regulatory requirements and generally accepted standards of organizational behavior.

Operational risks can arise from equipment failure, human error, and operational process failures, which can ultimately lead to unplanned shutdowns.

The company continuously monitors operational risks to take measures to keep them at an acceptable level that does not jeopardize the financial stability of the company or the interests of its creditors, shareholders, employees, and partners.

### Human resource risk

The shortage of pharmaceutical specialists on the labor market, the loss of specialists due to retirement and voluntary departure, the emergence of new companies in the field of drug production that are currently attracting existing staff, the migration of staff due to socio-economic conditions, the inability to reward performance at the level offered by competitors, restrictive regulations on increasing the salary budget are just some of the circumstances that give rise to human resources risks.

Measures to mitigate the impact of this risk include seeking internal training solutions through assigned mentors, continuing and expanding collaboration programs with academic institutions, providing scholarships and internship opportunities, implementing professional training projects for employment, continuous analysis of the organizational climate, identifying financial and non-financial motivational opportunities to retain employees in the organization, implementing career management projects, improving the compensation and benefits system to increase the attractiveness of the employer brand.

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### Occupational accidents and illnesses

To reduce the likelihood of risks and impacts, emphasis was placed on verifying compliance with OHS procedures and instructions and equipment operating instructions; ongoing training of personnel in OHS according to the training program; use of collective means of protection available at the workplace (ventilation systems for personnel protection, guards and protection systems for equipment); verification of the presence of devices and means of signaling hazards; provision of personal protective equipment; verification of the use of personal protective equipment; compliance with the maintenance and preventive maintenance program, periodic medical check-ups.



### Risks to confidential information and personal data security

Digitalization and technological innovation have not only made economic activities more efficient but have also created security risks for confidential information and personal data.

To mitigate risks to the security of confidential information and personal data, the following steps have been taken:

- Implementing security requirements imposed by legislation on the protection of personal data and business secrets;
- Securing IT systems in accordance with the requirements of NIS legislation;
- Organizing training and awareness courses for employees, strict rules on data access, use of personal devices, and disclosure to third parties;
- Developing and implementing specific working procedures.

### Cyber risks

Antibiotice SA is classified as an operator of essential services in the national economy and is obliged to comply with the national strategy on the security of networks and information systems and is subject to the provisions of Law No. 362/2018 on ensuring a high common level of network and information systems security.



An important component of corporate governance is the management of cyber threat risks, in addition to the set of rules for securing the information system to comply with regulatory requirements. Continuous monitoring of internal IT infrastructure highlights any missing or inadequate defenses and safeguards, allowing security teams to implement the necessary mitigating controls and prioritize remediation.

During 2023, there were no information security incidents.

In 2023, 23 system procedures were developed and are being implemented that regulate the way the company operates and ensure cybersecurity in accordance with the requirements of the National Cybersecurity Directorate, the national authority responsible for monitoring the implementation of Law No. 362 of 28 December 2018 on ensuring a high common level of security of networks and information systems ("NIS Law").

### Integrity risks

Antibiotice has adhered to the National Anti-Corruption Strategy 2016-2020 and 2021-2025 and has an Organizational Integrity Agenda in accordance with G.D. No. 1269/2021, on the approval of the National Anti-Corruption Strategy.

The company's Integrity Plan includes measures to prevent and combat corruption and procedures to ensure ethics and integrity in business activities.

In 2023, the procedure for receiving, investigating, and resolving reports of violations of the law was developed and implemented in accordance with the provisions of Law No. 361/2022 on the Protection of Public Interest Whistleblowers. According to this procedure, any employee of Antibiotice, as well as any director, shareholder, volunteer, trainee, or person working under the supervision or management of the Company, hereinafter referred to as "Public Interest Whistleblowers", who has received or is

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aware of information regarding possible cases of violations of law within or by the Company, has the right to make a report to the Company's Ethics and Integrity Council.

In 2023, there were no reports of possible violations of the law at the company level.

Following the entry into force of Law no. 202/2002 on equal opportunities and equal treatment between men and women, Antibiotice has developed a nd implemented a policy on harassment in the workplace and equal opportunities, which commits Antibiotice to provide a safe environment for its employees, based on the principle of exclusion of discrimination for any reason.

**During 2023, there were no integrity incidents within the company**

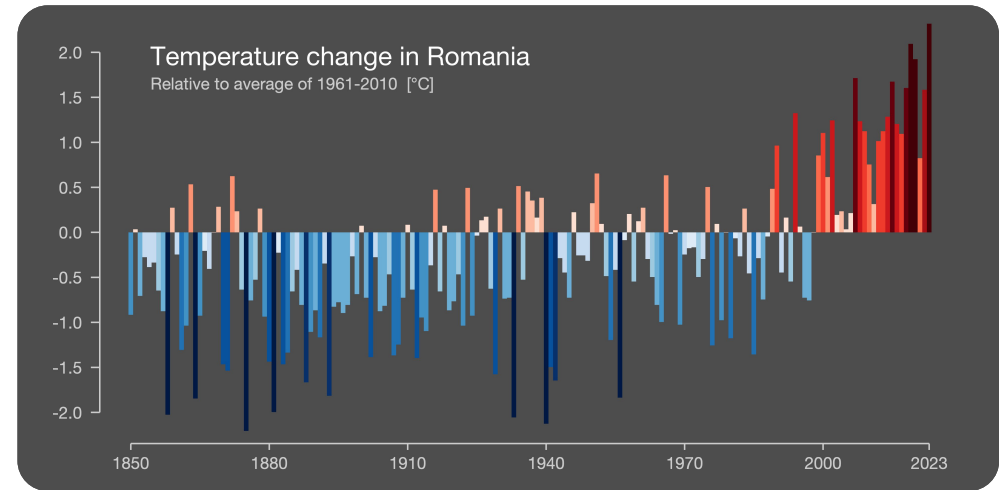
**There were no incidents of discrimination (on any grounds) in 2023**

### Anti-competitive practices risks

Violation of competition law is one of the risks to which the company is exposed, given the high level of fines that can be imposed by the Competition Council. Through its internal framework, which includes internal policies, the Corporate Governance Code, Antibiotice SA's Code of Good Practices for the Promotion of Prescription Medicines and Interactions with Healthcare Professionals, the Sponsorship and Patronage Policy and the Code of Good Practices in Sales, the Company's management aims both to prevent the risk of infringement and to provide means to detect and manage infringements that could not be avoided in the first place.

To reduce the likelihood of the risk of unfair competition occurring and to minimize its impact, Antibiotice has carried out the following: identification of potential areas of exposure to unfair competition and risk assessment, review of the main commercial contracts, updating of the Integrity Plan, revision of the Code of Good Practice in Sales, training to educate employees in this area, implementation of specific procedures, monitoring, and control.

In 2023, there were no court actions (pending or finalized) relating to anti-competitive behavior and antitrust and monopoly violations in which Antibiotice was identified as a participant.



### Environmental risks

The pharmaceutical industry has a significant impact on the natural environment, from resource consumption to waste generation and emissions. Awareness and management of environmental risks is vital for long-term business sustainability. Environmental regulations are becoming increasingly stringent, and non-compliance can lead to significant fines, penalties, and loss of reputation.

Maintaining and improving the environmental management system in accordance with ISO 14001 and carrying out internal audits to verify compliance with the requirements of the standard, continuous monitoring of the quality of environmental factors, compliance with operating procedures, staff training, compliance with the maintenance program, monitoring of legislative changes

and harmonization with existing legislation, emergency preparedness and response are some of the measures taken to prevent and monitor environmental risks.

### Climate change risks and opportunities

Climate change risks are one of the most important global challenges of our time. Antibiotice is focused on assessing the company's potential vulnerability to climate change, environmental impacts, and mitigation actions that will ensure a transition to a low-carbon economy. To this end, Antibiotice conducted a rigorous assessment of the associated risks and finalized a detailed report in accordance with the Task Force on Climate-Related Financial Disclosures (TCFD).

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## Risks and opportunities generated by climate change

Summary of risks identified as a result of climate change	Risk type	Impact	Financial implications	Management method	Costs of management measures	Benefits resulting from implemented actions
<b>Legal or regulatory risk</b>	transition	<ul style="list-style-type: none"> <li>Increased reporting obligations on emissions and environmental performance indicators and value chain management;</li> <li>The expected penalties for non-compliance with specific legislation will impose an upward trend in CO<sub>2</sub> emission taxes and thus higher energy and fuel prices.</li> </ul>	Costs related to penalties and other forms of penalties for the company; increased energy prices.	Monitoring changes in ESG regulations; continuous employee training on upgrading legislative requirements; working with experts in the field; investing in human resources; streamlining and monitoring resource consumption; optimizing operations, and processes; planned investments in new, more efficient technologies and renewable energy sources.	Training costs; costs of new equipment and technology.	Efficient use of human resources; process efficiency; waste minimization and separate collection and gradual transition to a circular economy model; energy sourced from low carbon producers.
<b>Market risk</b>	transition	<ul style="list-style-type: none"> <li>Increased prices for raw materials, energy, and other services;</li> <li>Changing consumer behavior towards low carbon footprint products.</li> </ul>	Impact on production cost; decrease in profitability rate; decrease in market share.	Negotiating long-term contracts in advance; adapting contractual relationships with main raw material and service suppliers; scientific demonstrations of the efficacy and health benefits of marketed products; investing in new capabilities to increase the pace of product innovation in the portfolio.	Expenditure on raw materials, and services.	Development of new products or expansion of the current range of medicines; new markets.
<b>Reputational risk</b>	transition	Damaging image generated by specific litigation associated with the 3 areas of sustainability (environmental, social, and governance); stakeholder pressures to increase ESG performance.	The increasing cost of financing; decreasing share price.	Ensuring access to accurate, factual and real-time information while complying with all existing legislative regulations and industrywide ethical standards.	Service costs	Improved company image; access to lower-cost sources of finance; increase in share price.
<b>Technological risk</b>	transition	Large up-front investments in decarbonization by replacing current equipment and machinery with more energy-efficient or lower-emitting new ones.	Increased cost of production; decreased profitability rate	The company focuses its investments in two key directions: <ul style="list-style-type: none"> <li>Strategic development investments - expanding the product portfolio through R&amp;D and license acquisitions, investing in new manufacturing sites;</li> <li>Investments to strengthen the business - investments in information technology, telecommunications, and digitalization of processes; investments in the Integrated Management System (quality, environment, sustainability, occupational health and safety); investments in the modernization of existing sites and equipment.</li> </ul>	Costs of new equipment and technology	Efficient use of resources by optimizing consumption and conserving energy and water through state-of-the-art technical solutions; reduction of waste and its selective collection, gradual transition to a circular economy model.

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Summary of risks identified as a result of climate change	Risk type	Impact	Financial implications	Management method	Costs of management measures	Benefits resulting from implemented actions
<b>Heavy rainfall and storms that can lead to flooding and even landslides</b>	physical - acute	Damage to fixed assets or other property owned by the company, disruption of the supply chain of raw materials or other (logistical) services, damage to the health and safety of employees; interruption of activities	Significant costs to repair damage or replace goods; financial losses due to supply chain disruption	Diversifying the range of suppliers and collaborators and engaging in a dialogue with the supply chain to find solutions to adapt to these types of risks, impact analysis, complex insurance for goods and products, and afforestation actions carried out by company employees; emergency response plan.	Expenditure on raw materials, insurance, and repairs	Resilience by diversifying the supply chain and ensuring a predictable and balanced business environment in the short, medium, and long term by assessing climate risks and preparing and implementing measures to mitigate these risks.
<b>Average temperature increases of 1.7°C and maximum temperature increase of 2.2°C by 2040</b>	physical - chronic	Increased energy consumption associated with air-conditioning systems; decreased work productivity or increased employee absenteeism due to discomfort from increased temperatures or illnesses caused by climate change; decreased quality or product expiry due to increased temperatures	High energy costs; increased cost of production	Digital automation solutions for air temperature management in cold storage rooms, LED lighting (replacement of fluorescent lighting in the Raw Materials warehouse with LED lighting), re-engineering of certain production lines, optimization of certain processes, adaptation of working hours to specific situations, regular monitoring and assessment of the health status of all employees according to workplace and exposure factors, extensive internal studies on the organizational climate.	Energy costs, refurbishment.	Resilience by diversifying the supply chain and ensuring a predictable and balanced business environment in the short, medium, and long term by assessing climate risks and preparing and implementing measures to mitigate these risks.
<b>Drought that can lead to high water stress, water scarcity, and even high-risk vegetation fires</b>	physical - chronic	Increased energy consumption associated with air conditioning installations (production areas, storage, and refrigerated transport), increased water supply prices, interruptions in water supply, decreased work productivity, increased employee absenteeism due to discomfort caused by high temperatures or deterioration of pre-existing medical conditions or the development of new ones.	High energy and water costs, high manufacturing costs.	Constant monitoring of consumption; water recovery/recycling within the steam production and distribution system, the resulting condensate being recovered and reintroduced into the feed water circuit of the steam boilers; technological (industrial) wastewater is treated locally in pre-purification plants existing in each manufacturing plant and is directed via internal piping to the factory's main pre-purification station; regular determinations of quality indicators for discharged water are made in the company's laboratory as well as in third-party RENAR accredited laboratories.	Energy, water, and refurbishment expenditure.	Resilience by diversifying the supply chain and ensuring a predictable and balanced business environment in the short, medium, and long term by assessing climate risks and preparing and implementing measures to mitigate these risks.

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### Integrating climate risks

Climate change risks and opportunities are integrated into Antibiotice SA's risk management process, which aims to identify, assess, and manage business risks.

Risk assessment is determined by exposure to inherent risk, the risk that exists without taking control measures. To this end, the likelihood and impact of inherent risk is assessed using rating scales. Following the assessment of the likelihood and impact of the risk, the exposure to the inherent risk is determined as the product of the level of likelihood and the level of impact.

### Integrating transition risks

Identified regulatory risks have a significant place in the company's materiality matrix and are addressed through a reporting system adapted to current and future regulatory requirements by continuously optimizing data management, identifying trends and aligning documentation with new legislative requirements, collaborating with subject matter experts, investing in human resources, streamlining and monitoring resource consumption, optimizing operations, processes and planned investments

in new, better-performing technologies and renewable energy sources.

Market risks are addressed through effective management of the partners involved in the supply chain. Antibiotice works with partners with whom it has been working for over 30 years and with whom it has built relationships of trust and mutual respect. Thus, identifying the optimal conditions to develop our business and that of our partners has become a common goal that ensures stability and predictability in the supply business. The reduction of purchasing costs, especially for raw materials that have a significant share in the value of purchases and therefore in products with a significant share in the company's turnover and profitability, is an objective pursued through performance indicators. In this respect, we are constantly monitoring the evolution of raw material prices by liaising with various suppliers and companies that collect and report information on raw material prices, to identify the optimal conditions to ensure the most favorable quality-price ratio. We also seek to identify new potential suppliers in order to increase flexibility in negotiations and to secure the supply of raw materials. In this way, we ensure the sustainability of the projects that the company aims to develop in the future.

Growing demand for sustainably produced products may require adjustments to the product portfolio and production processes.

Changes in consumer behavior can be addressed through scientific evidence of the efficacy and health benefits of marketed products, and through investment in new production capacity that will increase the pace of product portfolio renewal.

Reputational risks can be mitigated through transparent, ethical, and honest communication, by supporting sound sustainability policies that can be qualitatively and quantitatively verifiable. Our priorities include ensuring access to accurate, factual, and real-time information while complying with all existing legislative regulations and industry-wide ethical standards.

Technological risks require the early development of a well-thought-out investment strategy:

- Strategic development investments, i.e. investments in product portfolio development;
- Investments to strengthen the business - investments in information technology, telecommunications, and digitalization of processes; investments in the Integrated Management System (quality, environment, sustainability, occupational health and safety); investments in the modernization of existing sites and equipment.

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### Integrating physical risks

Acute physical risks associated with climate change can have a significant impact on production, the supply chain, and distribution, driving the need for effective adaptation and mitigation strategies, namely a series of initiatives aimed at diversifying the range of suppliers and collaborators and engaging in dialogue with the supply chain to find solutions to adapt to these types of risks, impact assessments, complex insurance for goods and products, and reforestation activities carried out by company employees.

The chronic physical risks identified prompted the company to take several measures: digital automation solutions for air temperature management in cold storage rooms, LED lighting (replacement of fluorescent lighting in the Raw Materials warehouse with LED lighting), refurbishment of certain production lines, streamlining of certain processes, regular monitoring and assessment of the health status of all employees according to workplace and exposure factors and extensive internal studies targeting the organizational climate.

### Climate change opportunities

Adaptation or mitigation measures to climate risks also present several

opportunities from which the company could benefit:

- Efficient use of resources by optimizing consumption and conserving energy and water through state-of-the-art technical solutions (purchase of a variable speed compressor for the compressed air system, replacement of old transformers with new, dry, more efficient ones), involvement of human resources, process efficiency, reduction of waste and its selective collection and gradual transition to a circular economy model.
- Purchasing energy from low-carbon producers, investing in green/renewable energy production equipment and reducing associated costs (building a photovoltaic panel park to partially cover electricity needs), and accessing financial incentives offered by the government or other European bodies in the transition to a "net zero" goal, which implies a balance between the amount of greenhouse gases produced and the amount removed from the atmosphere.
- Developing new products or expanding the current range of medicines used for climate change-related conditions through research, innovation, and reengineering with the lowest possible carbon footprint.

- New markets driven by increased demand for medicines in geographical areas affected by notable changes in multiannual average temperatures or other changes in climatic conditions.
- Resilience by diversifying the supply chain and ensuring a predictable and balanced business environment in the short, medium, and long term by assessing climate risks and preparing and implementing measures to mitigate these risks.

Proactively addressing these environmental risks and implementing mitigation strategies not only reduces the negative impact on the planet but also improves operational efficiency, innovation, and long-term sustainability. Adopting responsible, sustainable business practices can enhance a company's image with consumers, investors, and other stakeholders who are increasingly aware of environmental issues



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# 04

# Our people and communities





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The highly regulated environment of the pharmaceutical industry and the ever-changing economic context demand fast and viable resilience solutions from the professionals involved in the company's business.

Attracting and retaining these professionals is a constant concern that drives us to develop professional and personal development programs, specific recruitment models and reward systems that are dynamically adapted to the needs of our employees.

With our social responsibility as a leading manufacturer focused on caring for people's health, we believe it is vital to ensure a healthy work-life balance for our employees. For our employees and their families, we have put in place a range of measures, including diversified benefits packages, with easy access to solutions that promote their well-being.

Our people, in their diversity and uniqueness, are what drive business to success and define our impact on the society and community of which we are a part. As they are a vital resource for business growth, we are committed to creating an attractive working environment with desirable opportunities for growth and development.

## 4.1. The Antibiotice team

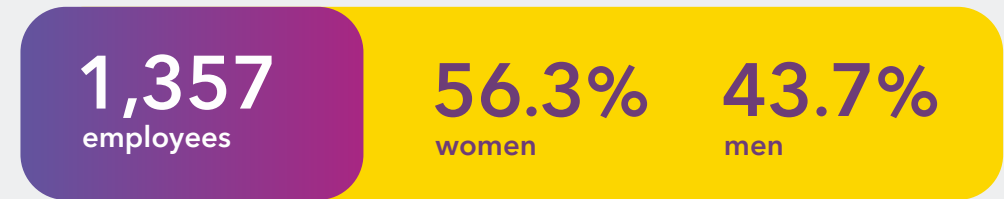
The company's mission to make valuable medicines more accessible to patients, physicians, and pharmacists, and to put our strength behind those who need our help, can only be achieved with a team of high-performing, motivated, and determined people who are committed to achieving their goals.

All positions are part of structures that are interlinked in the company's value chain.

As of December 31, 2023, Antibiotice had 1,357 employees, of which 764 were women and 593 men.

		Women	Men	Total
By type of contract	Permanent	736	566	1,302
	Fixed-term	28	27	55
	<b>Total</b>	<b>764</b>	<b>593</b>	<b>1,357</b>
By working hours	Full-time	760	591	1,351
	Part-time	4*	2**	6
	<b>Total</b>	<b>764</b>	<b>593</b>	<b>1,357</b>

\* one 2hr/day part-time employee and 3 4hr/day part-time employees,  
 \*\* two 2hr/day part-time employees



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### Third-party activities

Workers who are not directly employed work on our premises, providing activities such as construction (repairs, new and ongoing investments), installation of new equipment in manufacturing and laboratory departments, maintenance of existing equipment, catering, and waste collection. The workers carrying out these activities are employed by companies under contract to Antibiotice SA. These contracts also include annexes covering occupational health and safety, environmental protection, and emergency situations, which regulate the responsibility for competence, qualification, and training in these areas.

We do not tolerate the exploitation of child labor, forced labor, or human trafficking in our operations or those of our subcontractors. The company's internal regulations, policies, and procedures are drawn up in accordance with the provisions of the Forced Labour Convention, the Abolition of Forced Labour Convention, and the Minimum Age Convention. All our partners must therefore comply with these guidelines.

We do not currently monitor data on their number/fluctuation.

#### Employees benefiting from the provisions of the collective bargaining agreement

	Number	% of total employees
December 31, 2022	1,341	100
December 31, 2023	1,357	100

Starting in 2023, the company employs 12 young people under internship contracts, subject to all the legal requirements for training and work supervision.

### Collective Bargaining Agreement

Collective bargaining between the trade union (*representing the interests of the employees*) and the employer (*representing the interests of the employer*) to determine the terms and conditions of work and employment is a legal obligation. The Free Antibiotice Trade Union operates within the company and is the social dialogue partner of the company's employers.

Any company employee can join the union, based on the right to freedom of association guaranteed by the Constitution and respected by the company through the collective agreement.

The trade union, as the representative of the employees, participates in the negotiations with the employer on the clauses of the Collective Bargaining Agreement concluded between the parties at the company level. All Antibiotice SA employees benefit from the provisions of the Collective Bargaining Agreement,



regardless of the type of employment contract, working hours, or whether or not they are union members.

The Collective Bargaining Agreement is valid for two years and can be extended once for a maximum of 12 months. The current Collective Bargaining Agreement is concluded in 2022 and is valid until 2024.

Antibiotice, through its management, initiates discussions with trade union

representatives in advance of decisions that may affect employees' rights or create new obligations for them, which are finalized using mutually agreed notifications (in accordance with the methods required by applicable legislation).

The Antibiotice Free Trade Union is part of the Federation of Free Trade Unions in the Chemical and Petrochemical Industry (itself a member of the "Cartel ALFA" National Trade Union Confederation).

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# 4.2. Employee recruitment, retention and development

## Recruitment at Antibiotice

**The digital transformation accelerated scientific and technological progress, and a constantly changing regulatory environment have made the pharmaceutical industry a sector in constant transformation. As a result, the process of identifying and recruiting the right candidates is extremely important and involves a careful balance between the technical and personal competencies of potential employees.**

It is essential for us to attract and recruit professionals with pharmaceutical expertise, who are willing to engage in a continuous learning process, given the scientific nature of the industry, and who can thus contribute to an innovative and collaborative working environment.

In 2023, we continued to apply best practices in recruitment, finding creativity and innovation in our projects.

The success of the recruitment process lies in attracting, preparing, and developing young people, and improving learning through educational programs based on work experience (internship program). More and more young people are working online, so in 2023 recruitment through social media channels becomes common practice, with the HR strategy focusing on the concept of employer

branding. As a result, in 2024 we plan to implement a series of promotional campaigns focusing on key concepts such as diversity and equal opportunities, based on a close collaboration with LinkedIn.

Identifying young talent led to aligning the recruitment process with the Future Together Business Plan objectives.

We ensure transparency through continuous communication with our candidates and our recruitment and selection strategy is based on the following principles:

- principle of transparency, through equal and fair access to information for all candidates;
- principle of equal opportunities, through the use of a common set of criteria for assessing candidates;

- principle of non-discrimination, by avoiding any form of direct or indirect discrimination based on gender, sexual orientation, genetic characteristics, age, nationality, race, color, ethnicity, religion, political choice, social origin, disability, family situation, or responsibility, trade union membership or activity, membership of a disadvantaged group;
- principle of respect for lawfulness and protection of personal data;
- principle of efficiency and effectiveness, by ensuring that the quantity and quality of human resources needed to achieve the company's strategic and operational objectives are provided in good time and at optimum cost.

We have continued to develop projects and partnerships with pre-university and university educational institutions, facilitating young people's access to the information they need to make the best choices for their professional future.



For the second year in a row, Antibiotice was named the most attractive employer in the Romanian pharmaceutical industry, according to the ranking carried out by Randstad Romania Employer Brand Research.

This recognition confirms the company's constant concern for the professional and personal development of its employees, the improvement of the working environment, and how it attracts and trains talented young people.

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## Recruitment programs (internal and external)

### a+ Academy

In 2022, the a+ Academy was set up, a platform focused on recruitment, education, and professional skills development programs in order to adapt the human resources structure to the future configuration of the company in 2030. The two components of the a+ Academy are the a+ Technical College and the a+ Business School (project presented in more detail in the Professional Development section) aimed at attracting and training employees on an ongoing basis, as well as internal on-the-job qualification to acquire skills specific to the pharmaceutical industry.

Under the a+ Academy umbrella, new partnerships with academia are established and the selection and on-the-job qualification, induction, and career management programs are carried out. Also, under the a+ Academy framework, already traditional Antibiotice activities continue to be organized: internships, student visits during the "Different School" week, career workshops for primary and secondary school students, school scholarships, sponsorship of school Olympiads, collaboration with the County School Inspectorate, and other initiatives through which Antibiotice, as an employer, strengthens its relationship with the university and pre-university environment.

### a+ Technical College

The two sessions of the A+ Technical College, scheduled for 2023, provided the Antibiotice team with valuable candidates eager to retrain in the pharmaceutical industry.

The first session, dedicated to employees with secondary education, brought 16 participants to the platform; the training program was diversified and designed for all production sites and ran from May to October 2023. At the end of the program, 11 participants were validated in terms of the skills they had acquired and accepted the job offer.

The second session of a+ Technical College 2023, named "Turning Talent into Performance", includes an internship program for high school and university graduates interested in developing their skills and competencies. As of September 2023, the program has 12 participants working in manufacturing, research laboratories, information technology, and human resources.

### a+ Technical College project participants

	No. of participants	Women	Men	Employment offer accepted
Session 1 - 2023	16	10	6	11
Session 2 - 2023	12	9	3	Possible employment in 2024



In 2023 the a+ Academy included:

- two new editions of the a+ Technical College
- the eighth edition of the Performa+ program



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## Sustainable partnerships with academia

### In 2023, cooperation with the academic sector resulted in:

- conclusion of cooperation protocols with 5 academic institutions in Iași: "Al.I.Cuza" University, "Gr.T.Popa" University of Medicine and Pharmacy, "Gh. Asachi" Technical University and "Ion Ionescu de la Brad" University of Life Sciences, Petru Poni Institute of Macromolecular Chemistry;
- didactic visits and internship programs organized for more than 200 students from the Faculties of Biology, Chemistry, Pharmacy, Chemical Engineering and Environmental Protection, Electrical Engineering, Energetics and Applied Informatics, Mechanical Engineering, and Industrial Management;
- participation in events organized for the promotion of the company and career guidance of young graduates;
- implementation of the 8th edition of the a+ Perform project.

### Collaboration with the pre-university sector consisted in:

- educational visit programs carried out in the three editions of the "Different Week" program for 500 students of theoretical and vocational education;
- collaboration agreements signed with three technical colleges to provide

internships for students in the 2023-2024 school year for the following qualifications: pharmaceutical and cosmetics operator, laboratory technician, mechatronics and automation technician, mechanical maintenance and repair technician, electromechanical technician;

- projects to obtain European funding for the organization of internships in secondary and higher education - a new call for projects to obtain funding through the Managing Authority of the Education and Employment Program (PEO) - "Promoting the development of quality, flexible and labor market relevant tertiary study programs - Student/pupil internships". These projects involve establishing partnerships with higher or pre-university education institutions in order to organize internships for students/pupils.

Two projects have been drafted: one for higher education and one for secondary education, with a submission date of January 2024 set by the contracting authority.

a+ Perform program	2023	2022	2021	2020
Number of participants	35	35	21	22
Number of participants/applicants employed by Antibiotice	7	2	7	12

## a+ Perform program

Our program is aimed at students in their final years of university, including residents and doctoral students, and offers the opportunity to supplement the knowledge acquired during their undergraduate studies with theoretical and practical sessions, supported by mentors appointed from among the company's employees. At the end of the course, a project is presented to colleagues and company representatives to demonstrate the integration and application of the knowledge acquired.

a+ Perform started in 2016, through a partnership with the Faculty of Pharmacy of the "Grigore T. Popa" University of Medicine and Pharmacy Iași. In 2020, the collaboration program was extended to other faculties in Iași, such as the Faculties of Chemistry and Biology of the "Alexandru Ioan Cuza" University or the Faculty of Chemical Engineering and Environmental Protection of the "Gheorghe Asachi" Technical University.

As of 2023, another specialization was included in the a+ Perform program, that of Medical Bioengineer, through the Faculty that is part of the "Grigore T. Popa" University of Medicine and Pharmacy Iași.



**8** editions  
**250** participants  
**46** participants in all editions of the project were employed by Antibiotice

Following the eight editions of the program, Antibiotice employed 46 university graduates (applicants/ participants in the project) in the R&D, Regulatory Affairs, Portfolio Management, Quality, and Manufacturing departments. The a+ Perform program represents a successful cooperation with academia and a way to attract and support the development of university graduates in the generic pharmaceutical industry.

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**95.83%**  
staff retention in key positions (strategic retention) in 2023

**65%**  
women in the management team (13 women and 7 men in the top management team)



## New employees and staff turnover

Category	New employees		Employees who left the company	
	No.	Rate (%)*	No.	Rate (%)*
<b>Gender</b>				
Women	69	5.10	41	3.03
Men	40	2.96	52	3.85
<b>Total</b>	<b>109</b>	<b>8.06</b>	<b>93</b>	<b>6.88</b>
<b>Age group</b>				
< 30 years	44	3.25	13	0.96
30 - 50 years	63	4.66	48	3.55
> 50 years	2	0.15	32	2.37
<b>Total</b>	<b>109</b>	<b>8.06</b>	<b>93</b>	<b>6.88</b>

\* The ratios were calculated with reference to the average number of employees in 2023, i.e. 1,352 employees

## Employee remuneration and motivation policy

The employee reward and motivation system encompass both financial and non-financial aspects and is a strategic element aimed at increasing employee satisfaction and improving staff retention.

Regarding financial aspects, particular attention has been paid to the complexity of Antibiotice SA's activities. Starting from the national minimum base, it was acknowledged that the nature of work at Antibiotice requires a higher level of expertise and qualification compared to jobs with lower training requirements in the general economy. Therefore, the minimum salary level within the company

was set to be higher than the general economy minimum wage, reflecting the high degree of training and specialization required by positions within Antibiotice.

The remuneration methodology is based on hierarchical coefficients assigned to each position in the company. The base salaries for each position are structured in salary bands. The 7 salary bands implemented are correlated with the skills level demonstrated by the employee on the job, through periodic evaluations, following which the transition from one salary band to another is documented.

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In 2023, the following measures were taken concerning the remuneration system and motivational elements:

- Salary increases
  - general salary increases given to all employees to bring salaries up to date, usually in line with inflation;
  - net minimum wage increase within Antibiotice;
  - strategic salary increases (Antibiotice professions have a high level of complexity of activities and are difficult to identify/train; the labor market, through competitiveness, approaches well-trained professionals, and therefore active measures have been taken to increase the salaries of these categories of staff in order to keep them in the company).
  - granting a complexity coefficient for certain production activities;
  - exceptional salary increases for deserving employees who have excelled in terms of results and attitude and who should be encouraged.
- Motivational incentives such as meal vouchers, employee profit sharing, and various employee well-being initiatives (recreational activities, modernization of workspaces)

Category	Ratio of the basic salary of women to men	Ratio of basic remuneration of women to men
Senior management	1.03	0.99
Middle management	0.92	0.92
Line managers	0.97	0.92
Higher education specialists	0.86	0.80
Secondary education specialists	0.93	0.85
Qualified workers	0.97	0.86
Low-skilled workers	0.81	0.69
2023	Women	Men
The ratio of the minimum wage in the company to the nationally regulated minimum wage	1.14	1.22
2023	2022	
Ratio of the annual total compensation for the organization's highest-paid individual to the median annual total compensation for all employees (excluding the highest-paid individual)	4.09	4.63
Ratio of the annual total compensation of the highest-paid person in the organization to the median annual total compensation for all employees (excluding the highest-paid person)	7.09	8.11
Ratio of the percentage increase in annual total compensation for the organization's highest-paid individual to the median percentage increase in annual total compensation for all employees (excluding the highest-paid individual)	1.67	1.27

Through a more dynamic increase in salaries, Antibiotice aims to keep pace with the growth trends in average net salaries, both nationally and in the pharmaceutical industry in particular, and to reach a level in line with the targets of the business plan "The Future Together 2030".

The motivational component of the remuneration system (benefits) promotes professional performance and competitiveness, employee loyalty and commit-

ment to the organization, and contributes to strengthening the employer brand. In 2023, the remuneration system was reviewed and updated to include variable salary packages and other benefits linked to performance indicators and criteria derived from company-wide objectives.

These benefits consisted of changes in the value of meal vouchers and an increase in the number of private health insurance packages.

## Strategy to update organizational culture

The plan to improve the organizational climate in 2023 included more than 15 projects for employees. The largest project was "A team for tomorrow, a company for the future", which brought together more than 700 employees in non-formal meetings and included more than 40 meetings with teams from different working environments. Employees had meetings dedicated to them, where they talked about the current state of their team, how they communicate, how to improve team communication, as well as what they expect from the company.

In line with the company's business strategy "The Future Together 2023-2030" and what it means to develop a sense of belonging, we practice an appreciation-based culture where all Antibiotice team members frequently recognize and thank others for their contributions.

With a particular focus on human capital, we continually align the company's goals with what motivates our people. The constant objective is to create a context in which people can excel, an experience of collaboration, and autonomy, a space for initiative, where people can trust, express themselves, and rely on each other.

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At the beginning of each year, we draw up a plan to optimize the organizational climate, and during the months we carry out people-oriented projects.

Hobby-oriented projects (fishing, cycling in the open air, making handicrafts) have been designed to strengthen teamwork, as well as projects related to medical recovery.

At the end of 2023, the company organized a special evening at the National Theatre of Iași for 708 employees, a project that the company developed out of a desire to show gratitude for all the efforts made in the year that was ending. As this project was highly appreciated by the employees, at the end of 2023 the idea was born to offer theatre and opera tickets to deserving employees on a monthly basis in 2024.

## Increase brand loyalty and improve internal communication

Turning employees into brand ambassadors for our company and products helps to increase their commitment and involvement in achieving long-term goals, as well as promoting an attractive employer brand in the labor market, with a direct impact on the recruitment process. Here are the key projects that made a significant contribution to promoting the company's brand values and fostering open communication among employees in 2023:

## Building the future together

Our company's development projects up to 2030, under the umbrella of "The Future Together", became the subject of an extensive internal communication campaign launched in 2023, as the involvement of employees (as the main stakeholders) in the company's strategic objectives is essential. The company's internal magazine and other communication channels have been used to publish materials and articles on the organization's 2030 objectives, on each of the five business pillars, the status of project implementation, and how the achievement of the objectives is reflected in the level of financial and non-financial benefits for employees.

## Guests in our home

In the 2023 internal communication evaluation survey (38% of employees participated), one of the wishes expressed by employees was to get to know the company's production sites and laboratories. In response to this need (identified among newly recruited employees as well as those with more than 10 years' service), we developed the "Guests in our home" project in 2023.

This internal communication and brand values nurturing project allows employees to get to know their factory, their second "home", and to create a healthy emotional bond with the organization, making them part of the success of Antibiotice products on their journey from idea to market.

During the first two editions in 2023, a total of 180 colleagues visited parenteral, capsule, and tablet manufacturing sites, API biosynthesis facilities, and R&D laboratories. The full picture of the medicines' journey from inception to finished product was complemented by workshop sessions dedicated to presenting the role of each department.

## One by One on December 11

The assimilation of Antibiotice's brand values by young employees is a constant challenge in our organization, given that three generations of employees work together. For this reason, we have developed an internal communication project aimed at increasing the level of cohesion and identification of employees with our brand values. As part of this project, our colleagues have the opportunity to nominate employees who exemplify certain values and behaviors that they would like to see manifested at Antibiotice. The timing of the project - around Factory Day on 11 December - is not coincidental, as it provides a memorable and direct link to our history and brand.

In 2023, we organized the 5th edition of this project under the slogan **"One by One on December 11"**, celebrating tenacious people who have given unconditional help to other colleagues.

In total, 177 colleagues chose to send a big thank you to 165 colleagues who demonstrated tenacity and collegiality.



## Event to recognize 2023 performers

Every December, we hold a now traditional event to recognize valued employees. In 2023, which marked the launch of our multi-year development plan "The Future Together", a total of 140 colleagues, representing 10% of the total workforce, were nominated by managers as the year's performers and people who exemplify the spirit of cohesion, dedication, and innovation.

Other events dedicated to employees that contribute to strengthening the image of our brand (some of which have become a tradition) are events on March 8, the Tradition from Generation-to-Generation project, held on Day of the Romanian Blouse on June 24 or "Challenge your boss", a project initiated in 2023 to promote fair play, collegiality and the commitment to common goals.



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## Employee benefits

### a+ Club

The a+ Club is a dynamic and inclusive platform designed to centralize cultural, educational, and sports activities for Antibiotice employees, promoting a sense of cohesion and alignment with company values. Aiming to become a valuable tool for non-financial motivation and to increase employee engagement, a+ Club offers a wide range of services that seamlessly combine sports, relaxation, and wellness activities.

In 2023, around 1,000 Antibiotice employees took part in a+ Club activities free of charge:

- First aid course in case of cardio-respiratory arrest within the "Plus for Life" project. The event was organized by the a+ Club in October, in partnership with SMURD Iași, and was supported by 10 doctors, accredited by the European Resuscitation Council,



and was attended by over 100 of our colleagues and their children;

- The handicraft workshop where the ornaments exhibited at the Christmas Fair were made and donated to the "Give from the Heart Be Santa Claus" campaign;
- Educational cooking workshop, "Masterchef at a+ Club" where employees' children learned about healthy eating and baked Christmas cookies;
- **Adventure in nature** - two editions were organized with over 100 company employees participating;
- **Friendship Cup Volleyball**;
- **Skin health and beauty, from A to Z** - an event for women employees of the company on Women's Day (March 14, 2023), featuring dermatology specialists.

### Bookster books at the a+ Library

Starting in 2020, Antibiotice SA offers employees with a passion for reading free access to the online platform [Bookster.ro](https://bookster.ro). By the end of 2023, 272 employees had an active account on Bookster.ro, with an average of 16 loans per "active bookster".

### Benefits package

Benefits are provided to employees whether they work full or part-time. Several benefits are granted to all employees (and are included in the company-wide Collective Bargaining Agreement), others are granted by the employer as part of a personalized

motivational package, based on the following principles:

- Legality;
- Continuous adaptation to market dynamics;
- Fair reward (principle of equal opportunities);
- Predictability (career management and professional development);
- Boosting professional performance and competitiveness;
- Employee loyalty;
- Increasing the attractiveness of the employer brand.

Benefits granted by contract type	Full-Time	Part-Time
Meal vouchers	✓	✓
Support in case of personal events (marriage, birth, death, social benefits)	✓	✓
Compensatory wages	✓	✓
Private health insurance	✓	✓
Holiday rewards (8 March, Easter, Christmas)	✓	✓
Performance bonuses	✓	✓
Accident insurance	✓	✓
Profit sharing	✓	✓
Additional rest days	✓	✓
Free medical services within the in-house medical practice	✓	✓

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Parental leave, 2023	Women	Men
Total no. of days	8,694	710
No. of employees entitled to parental leave	764	593
No. of employees who took parental leave	16	4
No. of employees who returned to work (in 2023) at the end of the parental leave	12	4
No. of employees who returned to work (2022) at the end of the parental leave and were still employed after 12 months (in 2023)	13	4
Return to work rate	100%	100%
Retention rate	81.25%	66.67%

## Employee professional development

Professional development and employee training are crucial elements of the human resources policy. Working in a complex industry with a direct impact on the well-being of the population, but also an industry that is experiencing rapid progress and change, it is very important that our team has access to training programs that allow them to acquire the skills and knowledge needed to be effective in this dynamic field. At the same time, professional development is also a key aspect that facilitates innovation and

enables our employees to seek and develop new solutions to complex problems and challenges. Last but not least, as an industry subject to stringent regulatory rigor, employee training helps us maintain the quality and compliance so vital to the sector in which we operate, to uphold the highest safety and effectiveness standards.

The general policy on ongoing vocational training of employees is carried out in compliance with the principles of human

	2023	2022
Total number of training hours	58,891	56,986
Average training hours/employee	43.6	42.5

Note: the average number of hours was calculated in relation to the total number of employees at December 31, 2023.

rights and equal opportunities. This policy is included in the Internal Regulations and the Collective Bargaining Agreement set at Antibiotice SA. Our company has also established a Regulation dedicated to postgraduate training for employees, which is incorporated in the Internal Regulations.

Employee training is carried out according to the system procedure and an Annual Training Plan which includes:

- statutory topics (occupational health and safety, emergency situations, etc.);
- topics in areas of activity requiring regular certification/re-certification (ISCIR, transport, ANRE);
- topics relating to good practice rules (manufacturing, storage, logistics, labeling, packaging, laboratory work, etc.);
- topics relating to the implementation of rules, regulations, and legislative provisions by area of activity (corporate governance, taxation, labor relations, etc.);
- topics delivered by external lecturers to develop and acquire new skills.

Antibiotice upholds the principles of the internal procurement policy and complies with the provisions of the applicable legislation in dealing with partners providing training services. This commitment ensures that the company maintains a transparent and compliant approach when engaging with partners for training services.

Continuous vocational training offered to employees includes various procedures aimed at acquiring qualifications, specializations, or certifications. These efforts are undertaken to achieve the following objectives:

- adapting employees to the requirements of the job or workplace;
- gaining professional qualifications;
- updating and improving knowledge and skills relevant to the specific job or workplace, thus improving professional competence;
- facilitating retraining in response to possible socio-economic restructuring;
- acquiring advanced knowledge, modern methods, and procedures necessary to carry out professional activities;
- reducing the unemployment risk;
- promoting career development and advancement.

Through these comprehensive training initiatives, employees are equipped with the tools to adapt, grow, and develop while fostering a supportive work environment that encourages career development.

In the year 2023, the annual training budget amounted to 948.000 lei, an increase of about 70% compared to the previous year.

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## a+ Business School

It includes professional and personal development programs for employees, both with internal trainers and external providers: classroom and online courses, e-learning courses, management, and leadership programs to train and develop management skills, and access to specialized conferences and seminars depending on the job.

The implementation of the e-learning platform provided employees with learning alternatives by including topics in different areas, grouped by different types of skills: critical thinking, strategic thinking, project management, change

management, etc. In addition to soft skills and management topics, in 2023 the company provided employees with specialized training topics on diversity and equal opportunities, first aid, compliance, and cybersecurity. The company's goal is to ensure that all employees have access to these programs by the end of 2025.

New to the professional development projects are courses for employees with secondary education, launched as a pilot project in September 2023. The aim is to develop communication and team spirit. 45 employees have taken part in the project, but we aim to extend it to all structures in 2024-2030.

Training categories available on the platform	Number of certifications in 2023
Personal development (9 topics)	150
Team management (10 topics)	132
Compliance, health, safety (3 topics)	86
MS Office (3 topics)	62
Customer service (5 topics)	61
Sales skills (7 topics)	59
Marketing and communication (4 topics)	43
<b>Total</b>	<b>593</b>

**472**  
employees registered as platform users in 2023

**3,443**  
training hours registered on the platform in 2023

Topic	Women	Men	Total no. of participants	Training hours
Digital skills, Microsoft Excel, etc.	21	16	37	1.386
Contamination control strategy	39	21	60	597
Problem-solving & Decision-making	21	25	46	552
Impact management in the organizational context	22	21	43	516
Me as manager	19	13	32	384
Legislation applicable to cosmetics	28	1	29	377
Time management	12	18	30	360
Retail team onboarding	13	5	18	342
Team management	18	10	28	336
Promotion skills - advanced	13	5	18	324
Key account management	4	14	18	324
Communication and feedback	14	12	26	312
Extractables & leachables	10	6	16	255
Communication and time management skills	3	15	18	216
Introduction to good manufacturing and distribution practice	13	7	20	216
Territory business planing	7	3	10	180
Pharmacovigilance vs. cosmetovigilance	7	0	7	168
Growth and development feedback culture	10	2	12	144
General and strategic marketing in the medical pharmaceutical sector	14	1	15	270
Finance for non-financiers	8	3	11	132
Territory business planning. Coaching & Performance management skills	2	5	7	126
Strategic and critical thinking	9	1	10	120
Effective management	7	2	9	108

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## Performance evaluation and career development plan

Regular evaluations are critical to our company as they serve such purposes as fostering employee growth and driving the success of our organization. By providing feedback, guidance, and tailored development plans, we empower our employees to enhance their skills and expertise within the pharmaceutical industry, allowing them to reach their full potential. This, in turn, contributes to our overall success in providing high-quality pharmaceutical products and services to our partners and patients. We believe that investing in the growth and development of our employees is not only beneficial to

them but also essential to the continued progress and prosperity of our company.

Employee performance evaluation is carried out once a year by the Human Resources Department, for the previous year. The results of this evaluation are important because they are taken into account when the next plans are established:

- individual development plan;
- remedial performance improvement plans;
- career plans.

### Performance evaluation and career development plan

Employee categories	Women		Men	
	No.	% of total number of employees/gender and category	No.	% of total number of employees/gender and category
Senior management	13	100.00	7	100.00
Middle management	49	94.23	21	100.00
Line managers	145	84.30	109	92.37
Higher education specialists	181	88.73	100	91.74
Secondary education specialists	31	93.94	18	100.00
Qualified workers	263	96.34	306	96.23
Low-skilled workers	16	94.12	2	100.00
<b>Total</b>	<b>698</b>	<b>91.36</b>	<b>563</b>	<b>94.94</b>



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# 4.3. Diversity and equal opportunities

**Diversity in the workplace is an important factor for the long-term success and sustainable development of an organization. Promoting an inclusive and diverse work environment means recognizing and valuing different skill sets and being aware of the unique potential that each team member brings to internal operations.**

The company has implemented since 2022 the Regulation and Policy on Equal Opportunities and Equal Treatment between Women and Men and Workplace Harassment as part of the Internal Regulations, all employees are aware of and comply with the measures to prevent and combat discrimination and harassment in the workplace in their daily activity.

The principle of equal treatment and equal opportunity for all employees is consistently and unreservedly respected in our company. We actively promote an organizational culture that has a zero-tolerance approach to discrimination and harassment. To ensure a respectful working environment, the following actions are strictly prohibited:

- requiring information about race, nationality, ethnicity, religion, social or disadvantaged status, age, sex, sexual orientation, or personal beliefs as a condition of participation in a job advertisement or competition;
- discrimination against any employee on the grounds of race, nationality, ethnicity, religion, social or disadvan-

taged category, beliefs, age, gender, or sexual orientation;

- engaging in any conduct designed to create an atmosphere of intimidation, hostility, or discouragement that adversely affects the employee's position in terms of promotion, remuneration, access to training, and opportunities for further development.

Employees can report any case they consider to be harassment or discrimination in physical or electronic format (at [resurse.umane@antibiotice.ro](mailto:resurse.umane@antibiotice.ro)) to the Human Resources Department. Reports will be forwarded to the Commission and the Secretary-General for consideration and the employee will receive a reply within 30 days.

45  
 years - average age of employees at Antibiotice

Employees by age, gender, and category

December 31, 2023	Women			Total	Men			Total
	<30	30-50	>50		<30	30-50	>50	
Senior management	0	8	5	13	0	4	3	7
Middle management	0	22	30	52	0	10	11	21
Line managers	29	96	47	172	12	70	36	118
Higher education specialists	44	121	39	204	10	67	32	109
Secondary education specialists	2	19	12	33	2	6	10	18
Qualified workers	6	109	158	273	11	149	158	318
Low-skilled workers	0	6	11	17	0	0	2	2
Total	81	381	302	764	35	306	252	593

Employees with disabilities by gender and category

December 31, 2023	Women	Men
Senior management	0	0
Middle management	0	2
Line managers	0	1
Higher education specialists	1	1
Secondary education specialists	0	0
Qualified workers	1	2
Low-skilled workers	0	0
Total	2	6

Employees in senior management positions\* recruited from the local community\*\*, 2023

Number	% of total
20	100

\* senior management = directors and executive managers with at least 15 years of work experience either within Antibiotice or in their specific field of professional activity.  
 \*\* local community = Romania

In 2023, there were no incidents of discrimination.

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## 4.4. Employee health and safety

**Our employees are at the heart of the company's business, and the quality of their working environment directly impacts their well-being and business performance. Thus, providing an optimal working environment is the first step in ensuring the health and safety of all our colleagues. For Antibiotice, employee health and safety is not just a legal obligation, but a firm commitment that we uphold. Year after year, we implement rigorous measures to ensure a safe working environment, enabling our employees to perform their daily tasks safely.**

Since 2007, the company has been certified with the Integrated Management System (quality/environment/occupational health and safety) according to international standards 9001/14001/18001.

Our company creates a safe, healthy, and modern working environment, enabling our workforce to perform their daily tasks safely. The occupational health and safety (OHS) activities within our company strictly comply with the provisions of Law No. 319/2006, as amended and supplemented, together with the corresponding methodological rules of application.

Our activities are conducted in accordance with the SR ISO 45001/2018 Standard for Occupational Health and Safety Management Systems. Compliance with the standard was successfully confirmed following the audit conducted by TÜV Rheinland Romania in December 2023. All company employees are covered by the Occupational Health and Safety Management System.

100% of our employees are aware of occupational health and safety activities.

### Occupational Health and Safety Committee

According to legislation in force and the specific procedure for consultation and participation of employees, an Occupational Safety and Health Committee (OHSC) operates within the company. The Committee is composed of employee representatives with specific responsibilities for the safety and health of employees, on one hand, and the employer or his legal representative and his representatives in equal numbers as the representatives of the employees and the occupational physician, on the other. The manager of the Occupational Health and Safety activity is the secretary of the OHSC. The employer or his legal representative is the President of the OHSC.

The responsibilities of the OSHC, according to legislation in force, are:

- analyzes and makes proposals regarding the occupational safety and health policy and the prevention and protection plan, according to the internal regulation;
- monitors the implementation of the prevention and protection plan, including the allocation of the necessary means to achieve its provisions and their efficiency in terms of improving working conditions;
- analyzes the introduction of new technologies, and the choice of equipment, taking into account the consequences on the safety and health of workers, and makes proposals when certain deficiencies are found;
- analyzes the selection, purchase, maintenance, and use of work equipment, collective and individual protection equipment;
- proposes measures for the arrangement of workplaces, taking into account the presence of groups sensitive to specific risks;
- analyzes the requests made by the workers regarding the working conditions and how the designated persons fulfill their attributions;
- monitors how the legal regulations on labor safety and health are applied and observed as well as the measures ordered by the labor inspector and the health inspectors;
- analyzes workers' proposals for the prevention of occupational accidents and illness, as well as for the improvement of working conditions, and proposes their inclusion in the prevention and protection plan;
- analyzes the causes of occupational accidents, illness, and events and may propose technical measures in addition to the measures ordered following the investigation;
- performs its checks regarding the application of its own instruction and work instructions and makes a written report on the findings;
- discusses the written report on the occupational safety and health status, the actions that have been taken and their effectiveness in the past year, as well as the proposals for the Prevention and Protection Plan to be implemented in the following year, which is presented to the Occupational Safety and Health Committee by the General Director of Antibiotice SA at least once a year.

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**For the activity carried out in 2023 the following was prepared:**

- **Prevention and Protection Plan - according to the specific procedure;**
- **Annual training program in occupational health and safety - according to the staff training procedure;**
- **Annual schedule of periodic medical check-ups - according to the procedure for carrying out periodic medical check-ups and other types of medical check-ups;**
- **Annual schedule for monitoring exposure to harmful substances - in accordance with the procedure for monitoring and measuring occupational exposure to noxes.**

Antibiotice has also the following obligations with regard to the successful operation of the OHSC, namely:

- ensuring that all necessary information is provided to the Committee so that its members can give an informed opinion;
- submitting a written report to the Committee at least once a year, covering the occupational safety and health status, the actions taken and their effectiveness in the past year, and proposals for the following year's Prevention and Protection Plan;

- submitting to the Territorial Labor Inspectorate, through the Committee's secretary, within 10 days of the meeting of the Occupational Health and Safety Committee, the report on the state of occupational safety and health, endorsed by the members of the Committee;
- submission to the Committee for examination of the documentation on the characteristics of work equipment, collective and individual protective equipment, to select the best equipment;
- informing the Committee of the assessment of occupational health and safety risks and prevention and protection measures at both company and workplace levels, by type of job, as well as first aid, fire prevention, and extinguishing measures, and worker evacuation;
- communication to the OHSC of the employer's or, where appropriate, the occupational physician's point of view on the internal prevention and protection service regarding workers' complaints about working conditions and how the designated staff of the internal prevention and protection service carries out their duties;
- presentation of and reasons for decisions rejecting the proposals submitted by the OHSC members and their recording in the minutes.

## Identifying risks

At Antibiotice SA, occupational health and safety risk assessment is carried out according to internal procedures. The assessment is carried out by a team comprised of an assessor, who has the necessary expertise (postgraduate specialist studies), an occupational health physician, a chief technologist, a process coordinator who is familiar with the job, and an employee who is familiar with the job being evaluated.

The Occupational Health and Safety Coordinator, together with the Heads of plants/departments, are responsible for nominating workplaces and jobs to be assessed for occupational health and safety risks. Appointment of staff responsible for the occupational health and safety management system is done through an internal decision-making process. Personnel who are part of the assessment team are trained by the assessor to identify risks associated with the assessment methodology. Once the committee members have acquired competence in the methodology, the actual evaluation of the job description under review takes place. This assessment involves a comprehensive analysis of the workplace and the job being assessed, focusing on the following aspects:

- 1.** Identifying and describing the components of the system and how it works - the purpose of the system (workstation), means of work used (work equipment, utilities, raw materials, etc.) ;

- 2.** Specification of the workload of the contractor in the system ( based on the job description, written or verbal orders, and instructions given on a routine basis, operations carried out during routine work, but also during occasional work or preventive or corrective maintenance, etc.);
- 3.** Description of current environmental conditions;
- 4.** Specification of security requirements for each component of the system, based on applicable legal requirements. The information required at this stage is taken from existing documents (technology sheet, equipment technical books, job description for the worker, specifications, analysis bulletins on exposure to harmful substances, working rules, work instructions, and procedures). An additional source of information for the definition of the system is the discussions with the workers at the job under analysis.
- 5.** Job description in terms of the level of training and occupational health and safety risks and measures to manage them for all staff, including risk-sensitive groups.

Any occurrence of an incident on Antibiotice premises involving Antibiotice personnel or employees of other companies conducting operations on Antibiotice premises, or incidents involving Antibiotice personnel while performing their job duties or while traveling to/from work, including traffic

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accidents, must be reported promptly to the OHS and Antibiotice management. Any person with knowledge of such incidents is required to report them immediately to the Occupational Health and Safety Office or the medical practice.

Under Law No 346/2002 on insurance for work-related accidents and occupational diseases, as amended, the coordinator of the OHS activity or his/her substitute is responsible for the prompt reporting of all incidents leading to temporary incapacity for work, disability, or death to the Territorial Labor Inspectorate and the insurer, once their occurrence has been confirmed.

Employees are required to inform their employer or designated personnel immediately of any work situation that they reasonably consider to pose a risk to their health and safety. In addition, employees must report any deficiencies they observe in the protection systems.

### Workers operating on the Antibiotice site

At the beginning of the activity, the provider's workers are briefed and trained by Antibiotice representatives on the specific risks regarding occupational health and safety, environmental protection, emergency situations, and the measures established within the company according to the applicable procedures and regulations. Any unsafe situation and/or activity resulting in a hazardous



situation will be immediately reported to the Antibiotice representative. Upon entering the company's premises, workers must notify the Antibiotice representative of any allergies to chemical agents, medicinal products, etc.

The company enters into agreements with all external partners who perform various activities on the Antibiotice premises in accordance with internal procedures.

## Occupational health and safety training

Within the company, all employees benefit from training, the frequency and manner of which is described in the specific personnel training procedure.

Periodic training is carried out on a monthly, quarterly or half-yearly basis, depending on the position held, according to the annual *Occupational Health and Safety training programs*, which are carried out annually for both supervisors and executive staff, depending on the specific activities carried out.

In 2023, all training for personnel involved in all activities related to manufacturing and support processes has been completed.

In addition, the following trainings were held for the staff involved:

- on overhaul and repair work;
- on the authorization/re-licensing of trades in accordance with the legislation in force (abrasive stone fitters, working at height);
- on authorization according to ISCIR (State Inspection for the Control of Boilers, Pressure Vessels, and Lifting Installations).

Our company also carries out OHS training and concludes agreements in this respect with all external partners carrying

out various works on the Antibiotice site according to internal procedures. In 2022, 1,209 general introductory training courses on occupational health and safety were carried out for staff from other companies working on our company's premises. At the same time, 56 trainees and 49 students undergoing internships within the company received general introductory training on Occupational Health and Safety.

Type of training in 2023	Number of employees	Total number of hours
General introductory training instructions, on hiring	94	752
Dedicated OHS training	325	650
Authorization instructions according to ISCIR	141	282
Instructions on authorization/reauthorization for each type of job according to the legislation in force - abrasive stone installers	39	78
Instructions on authorization/ reauthorization for each type of job according to the legislation in force - working at height	17	34
Work instructions during the industrial site review period	138	276



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## Promoting employee health

The company operates an Occupational Medical Office with a team of specialist physicians and nurses. The Occupational Medical Office operates on a 24-hour basis and has the necessary medical equipment for:

- compulsory medical examination on recruitment - according to the specific procedure. In 2023, 119 pre-employment medical examinations were carried out in the Medical Practice;
- periodic medical examinations (in accordance with the legislation on occupational medicine and the requirements for the quality of medicine) in accordance with the annual program for periodic medical examinations. Employees who are found to be suffering from various diseases are referred for specialist consultations by the family doctor, after which the employee submits the results of the examinations to the Medical Office;
- providing first aid in medical emergencies.

The Occupational Medical Office also provides:

- a dental surgery, which provides specialist care for emergencies;
- a psychological practice, which carries out psychological assessments of



employees at risk, in accordance with the legislation in force.

In 2023, with the support of medical staff (physicians, nurses), the following activities were carried out within the Occupational Medical office, 100 employees were vaccinated against the flu, free of charge, as part of the flu vaccination incentive campaign conducted between October and December (the campaign has been running annually since 2013).

Screening activities were also carried out with the support of the medical staff as follows:

- In January 2023, as part of the ONCOFEM program for the early detection, diagnosis, and treatment of breast cancer, a breast cancer screening was carried out on the company's platform in cooperation with the Regional Oncology Institute of Iași. The screening carried out with the mobile unit was addressed to Antibiotice employees over 50 years of age, and a total of 102 people were examined;
- In the second quarter of 2023, in cooperation with Preventis Iași, a screening program was launched to assess the health of the musculo-skeletal system of employees who constantly exert physical effort in the performance of their work. A total of 253 employees were identified and scheduled for assessment, of which 224 were assessed;
- Employees in visually demanding jobs undergo a specialized eye examination every six months. In 2023, 56 employees received an ophthalmological examination.

Employees (including new hires) working in controlled atmosphere areas undergo standard pulmonary X-rays as part of the *Annual Health Examination Program*. In 2023, 75 pulmonary radiographs were performed.

## Work-related accidents

The reporting, investigation, and recording of work-related accidents are carried out in accordance with the legislation in force and internal procedure.

Events leading to temporary incapacity for work are investigated by a committee appointed by written decision of the General Director and composed of at least three persons, one of whom must be a representative of the OHS activity. The persons nominated must have adequate technical training and must not be involved in the management and organization of the activity where the event occurred.

Events resulting in apparent or confirmed disability, death, collective accidents, or dangerous incidents are investigated by the Territorial Labor Inspectorate. The investigation of collective accidents caused by special events, such as accidents and explosions, is the responsibility of the Labor Inspectorate.

During 2023, Antibiotice did not register:

- fatalities caused by work-related accidents;
- work-related accidents causing serious injuries;
- illnesses caused by exposure to occupational hazards.

**Zero work-related accidents**

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## 4.5. Community investment

We believe that active involvement in projects that address pressing community needs is essential to building a more prosperous and equitable environment for all. We believe in supporting the growth and development of people in the communities in which we operate by actively participating in projects that address their pressing needs, and by investing and redirecting funds to make a positive impact. **The main directions of community involvement are centered on four pillars:**

- healthcare
- education
- environment
- social area

We run our own charitable and humanitarian projects, as well as educational and cultural programs through the Antibiotice - Science and Soul Foundation. By focusing on these pillars, we aim to improve access to healthcare, promote the development of knowledge and skills, protect the natural environment, and support social initiatives. Through our commitment to the community, we strive to create a better future for all.

Antibiotice has a Sponsorship and Patronage Policy that outlines the criteria and guidelines for granting sponsorships. This policy applies to all employees, members of the Management Board,

and executive management, in accordance with the regulations laid down in Law No. 32/1994 on sponsorship. The provisions of this policy ensure that sponsorship decisions are made in a transparent and accountable manner, promoting fairness and consistency throughout the organization. By adhering to these guidelines, we demonstrate our commitment to responsible sponsorship practices in accordance with the applicable legal framework.

Responsibility for the implementation of the Sponsorship and Patronage Policy lies with:

- The General Director and the Financial Director - for sponsorships up to 20,000 lei;
- Management Board - for sponsorships above 20,000 lei.

At least once every 12 months, the Finance Director reports to the Management Board on sponsorships and grants made by the company.

**In 2023, the total sponsorship budget amounted to 1,523,288 lei, an increase of 64% compared to 2022.**

**The total number of projects supported in 2023 was 11, with 6 partner organizations.**

**More than 500 participants from the Antibiotice team provided more than 800 hours of involvement in social projects (300 hours more than last year).** Volunteer hours were given by employees in their free time as well as during working hours.



\* Compared to the previous year



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## Healthcare

### Donate blood! Give for life! (Donează sânge! Pune suflet pentru viață!)

More than 140 Antibiotice employees donated blood in the two editions of the "Give blood! Give for life!" campaign, organized by the Antibiotice - Science and Soul Foundation in cooperation with the Iași Regional Blood Transfusion Centre (CRTS Iași). For more than 12 years, Antibiotice has been carrying out this campaign, providing CRTS Iași doctors with access to a constant supply of donors, including people with rare blood types. Thanks to the voluntary contributions of Antibiotice employees, both regular and new donors, a total of 64 liters of blood have been donated.



### Plus for Life

Antibiotice recognizes the critical importance of first aid training in saving lives, and health education plays a vital role in increasing the chances of survival before professional medical help arrives. In a remarkable initiative, 100 Antibiotice employees and their children participated in the fourth edition of the first aid course, which was held on 30-31 October 2023 at the a+ Club Sports Hall. The 2023 edition, organized by a+ Club and the Iași Mobile Emergency, Resuscitation and Rescue Service, was held under the aegis of the National Sustainability Day events.

In the 4 editions of this project, more than 400 employees were trained in first aid. Another 400 were trained in the use of the automatic defibrillator.

### Health Cup at the a+ Club

On World Health Day, the a+ Club organized the first edition of the Health Cup on 7-9 April 2023. During this sports competition, Antibiotice employees competed in badminton, volleyball, basketball, and field tennis. For three days, Antibiotice employees exercised, learned about sports nutrition, and were ultimately all winners. The a+ Club is one of the most appreciated benefits offered to Antibiotice employees, as it is the place where they feel motivated to exercise and where they always leave with a smile on their face and full of energy.



## Education

### Science and Soul Scholarships

Now in its 22nd year, the "Science and Soul Scholarships" program is the longest-running community involvement program of the "Antibiotice - Science and Soul" Foundation. Through this initiative, Antibiotice actively collaborates with the "Pro Ruralis" Association to provide valuable support to five deserving rural students each year. Through these scholarships, Antibiotice aims to help students who have exceptional ability and high IQ, but lack the necessary financial resources.

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## Environment

### We plant oxygen in the community

On 31 March 2023, 150 Antibiotice employees planted 600 maple and sycamore trees in the western area of the company's industrial platform. The trees were planted as part of the fourth action of the "Planting Oxygen in the Community" project to increase the green area on the Antibiotice platform.

The voluntary participation of Antibiotice employees in such projects demonstrates responsible behavior aimed at improving the company's impact on the environment, thus contributing to limiting the effects of climate change.



### Donate an hour to the Earth. Connect with nature!

For the 14th consecutive year, Antibiotice has actively participated in the global environmental event Earth Hour by symbolically switching off the lights. At Antibiotice, this event consisted of symbolically switching off the lights for one hour in areas where this was possible (Administration and Quality Pavilions, Gate 1, Friendship Park, etc.). For this edition, Antibiotice launched a communication campaign called "Donate an hour to the Earth. Connect with nature!", which ran from 23 to 31 March, mainly online (Antibiotice lași Facebook page), encouraging fans to behave responsibly towards natural resources.

### European Mobility Week

Antibiotice took an active part in the European Mobility Week from 16 to 22 September by encouraging employees to use public transport to reduce carbon emissions and ease congestion in cities.

Around 50 Antibiotice employees took part in the internal campaign "One car down, nature is up", choosing to leave their cars at home and opt for car sharing instead.

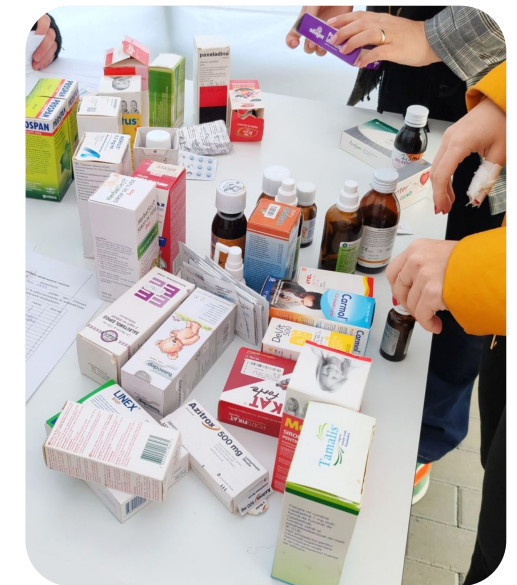
### First collection campaign for expired medicines at Antibiotice

From 27 October to 3 November, Antibiotice conducted an internal collection campaign of expired medicines "Be responsible, don't treat the environment with medicines! At the end of the campaign, 95 kg of expired medicines were collected from the company's employees.

Launched on National Sustainability Day on October 27, the project aimed to raise awareness among employees about the importance of proper collection of expired medicines.

For one week, the company's employees responded to this initiative by bringing their expired medicines from home to the collection point at Antibiotice. The collected medicines were handed over to a specialized company, which destroyed them without harming the environment.

Antibiotice has launched such a campaign in response to stakeholder requests following the consultation process for the Sustainability Report. The consultation process identified a need for the company to be involved in sustainability projects aimed at the general public on the collection of expired medicines. To meet this stakeholder expectation, the company organized a pilot project in 2023 to collect unused and expired medicines, targeting its employees.



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## Social area

### "The Power of Deed" Easter charity program

In an effort to bring joy and alleviate the hardships of the less fortunate during the Easter holidays, the "Antibiotice - Science and Soul" Foundation launched the "Power of Deed" initiative. 100 vulnerable elderly people from Iași Municipality and Miroslava Municipality received packages with traditional Easter products from the volunteers of the "Antibiotice - Science and Soul" Foundation.

Also, as part of the "Respect for the Elderly" program, whose beneficiaries are former employees of Antibiotice, currently retired people in old age and poor health, the Foundation provided help during the holidays to 50 people who had worked "a lifetime" at Antibiotice.



### Magic and fun for children in the a+ Friendship Park

The a+ Friendship Park in the vicinity of Antibiotice was once again a place of fun, good spirit, and celebration for 150 children from the community and of the employees on International Children's Day in 2023.

For more than 16 years, Antibiotice has supported events dedicated to the children of its employees on the occasion of International Children's Day. In 2023, the a+ Friendship Park was a creative and magical space, staged by professional actors and our enthusiastic colleagues from the research departments, who performed several fun experiments in front of the little ones

### Antibiotice, partner of the INIMO 2023 Festival

Antibiotice was a partner of the INIMO 2023 Festival, which took place from 18 to 20 August in Iași, at the "Emil Alexandrescu" stadium in Copou. The event, organized by the "Glasul Vieții" Association, aimed to raise funds for 10,000 children who do not have the material means to start school. Antibiotice had a stand that attracted participants to the event with a variety of surprises and activities, including a raffle with prizes sponsored by Nutriensa®. Employees of the company provided product information for those interested in a healthy lifestyle, and the highlight of the festival days were the fun experiments and workshops for children organized by the company's researchers.



### "Give from the heart! Be Santa Claus"

100 children from disadvantaged families experienced the joy and excitement of Christmas during the 11th edition of the "Give from the heart! Be Santa Claus!" project, which took place on 19 December at the Antibiotice headquarters.

The project was organized by the "Antibiotice - Science and Soul" Foundation in partnership with the "Pro Vita" Association. In the 10 years of its existence, this project has managed to turn the holidays into unforgettable moments for more than 900 children from the counties of Moldova.

Also, during the holidays, 100 pensioners, former employees of the company, received food packages from Antibiotice as part of the four-year project "Respect for the Elderly".

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# 05

# Respect for the Environment



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**The pharmaceutical industry is a sector with significant environmental impacts due to high energy consumption, greenhouse gas emissions, consumption of natural resources, and generation of waste and wastewater. The manufacture of medicines can involve complex processes and the use of chemicals that can have a negative impact on air, water, and soil quality.**

Antibiotice SA recognizes the importance of protecting the environment and accepts its responsibility to minimize the environmental impact of all its activities. The company believes that environmental protection is an integral part of its corporate responsibility and is essential to ensure a sustainable future.

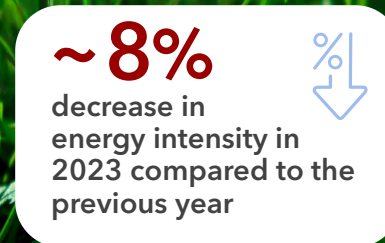
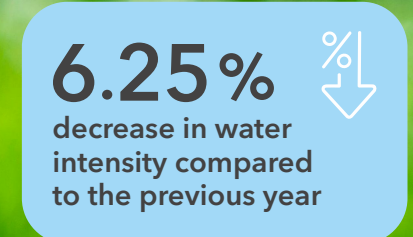
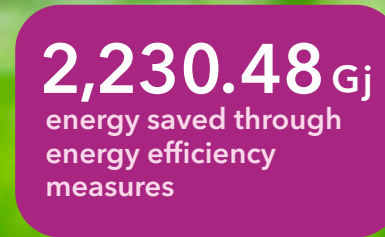
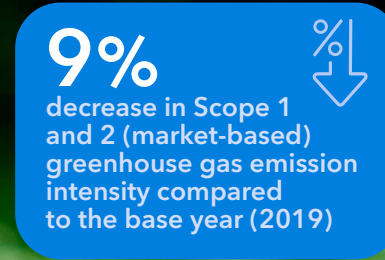
Antibiotice SA has developed an integrated management policy, the main objective of which is to reduce the impact on the environment by identifying and implementing sustainable practices and technologies in all areas of activity. This policy is based on compliance with legislation and environmental standards such as ISO 14001, promoting efficiency in the use of natural resources and reducing emissions and waste.

All activities related to environmental protection are governed by environmental management system operating procedures and specific working instructions that are implemented and monitored throughout the organization. These procedures and instructions ensure that all employees are aware of their

responsibilities and act in accordance with the environmental objectives and standards set by the company.

Antibiotice SA regularly monitors the quality of environmental factors in accordance with the requirements of the integrated environmental authorization. This monitoring is carried out both through its own laboratories and in collaboration with laboratories authorized by the Romanian Accreditation Association (RENAR). The data obtained from this monitoring is used to assess the environmental performance and to identify opportunities for improving environmental protection practices.

Therefore, Antibiotice demonstrates a strong commitment to environmental protection through its integrated environmental management policies, procedures, and practices in accordance with the GRI Sustainability Reporting Standards. The company is dedicated to continuing its efforts to reduce environmental impacts and promote sustainable practices throughout its operations.



# 5.1. Energy consumption

**We have implemented a robust Energy Management System to manage energy consumption. This system covers compliance with relevant legislation, monitoring, and control of energy consumption. Through the Energy Management activity, the company ensures a responsible approach to the use of energy resources.**

Energy consumption is regularly monitored, and energy efficiency measures are systematically reported. Reports on energy consumption and energy efficiency are submitted annually to competent authorities, such as the Energy Efficiency Directorate of the Ministry of Energy and the National Statistics Institute.

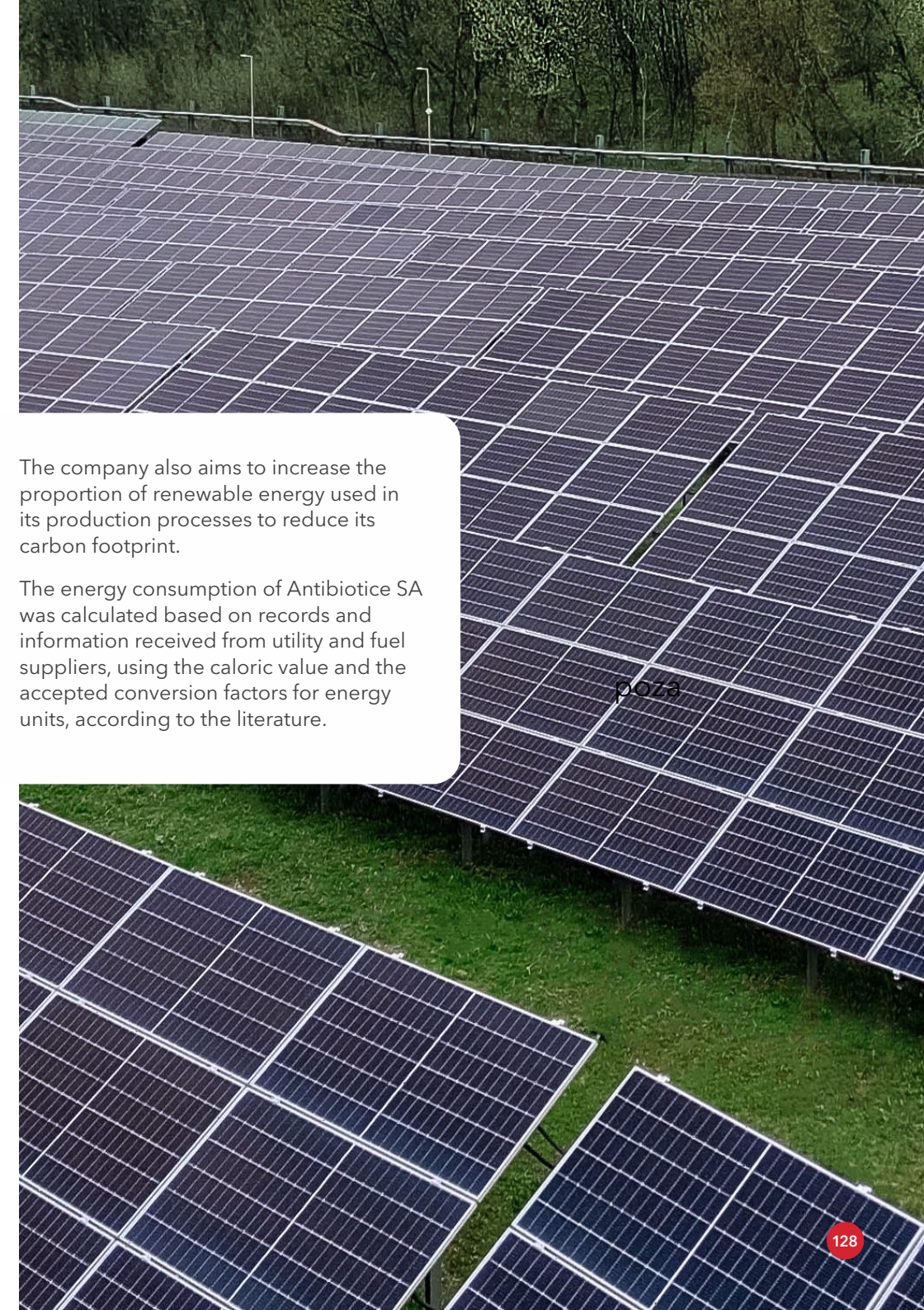
At Antibiotice SA, energy consumption is monitored using an intelligent system. Data on consumption of electricity, natural gas, compressed air, heat (steam), drinking water, demineralized water, and sewage water are recorded by each plant and each user via meters that transmit this data in real-time via a fiber-optic network to a central server. In addition, other methods are used, such as (non-invasive) measurement of utilities using state-of-the-art meters, and consultation of fiscal documents issued by utility suppliers (invoices, receipts). Analysis of this data helps determine the desired energy performance of the equipment and identify measures to reduce energy consumption and thereby

costs. The Energy Management activity also implements energy efficiency measures, including those resulting from the Complex Energy Audit. The audit takes place every 4 years (according to Law 121/2014, Annexes 2 and 3 on companies with an energy consumption of more than 1,000 toe\*/year).

In 2023, the procurement of the Complex Energy Audit service was initiated and will run throughout 2024. A list of measures will result at the end of 2024 that will be analyzed and considered in the following investment plans.

All the company's activities involve energy consumption generated from different sources: fossil fuels, electricity, and heat. Part of the energy required is produced by the company (steam, heat, cooling energy) and part is purchased from external suppliers (natural gas, electricity). The end goal is to reduce consumption by improving energy efficiency.

\* toe = ton of oil equivalent (toe) is a unit of energy; it measures the chemical energy released by burning one ton of oil (1 toe = 41.868 GJ)



The company also aims to increase the proportion of renewable energy used in its production processes to reduce its carbon footprint.

The energy consumption of Antibiotice SA was calculated based on records and information received from utility and fuel suppliers, using the caloric value and the accepted conversion factors for energy units, according to the literature.

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## Energy consumption from conventional sources (fossil fuels)

Fuel from conventional sources refers to fuels needed for combustion in boilers, furnaces, heaters, incinerators, generators, vehicles, etc. At Antibiotice SA, fuel consumption occurs in all drug production processes, but also in fueling the company's fleet of vehicles, as follows:

- ▶ natural gas is used in the thermal power plant, in the production of thermal energy, in the waste incinerator, and in the production of the active substance Nystatin by industrial biosynthesis;
- ▶ the steam required for the production process is generated by the combustion of natural gas (methane gas);
- ▶ diesel is used to fuel the car fleet and forklift trucks;

- ▶ petrol is used to fuel the car fleet, power tillers, and lawnmowers.

In 2023, Antibiotice SA consumed no fuel from renewable sources.



### Total conventional fuel consumption

Fuel consumption (Gj*)	2023	2022	2021
Diesel**	11,548	12,821	19,970
Gasoline**	375	204	570
Natural gas***	151,694	159,511	171,420
<b>Total</b>	<b>163,617</b>	<b>172,536</b>	<b>191,960</b>

\* 1Gj=10<sup>9</sup> Joules.

\*\* Calorific value of fuels (CVF): diesel - 42.50 Gj/ton and gasoline - 43.96 Gj/ton; the values used are the conversion values published by the Directorate of Energy Efficiency in Annexes 2 and 3 for reporting the energy analysis questionnaire. Annexes 2 and 3 can be found on <https://energie.gov.ro/eficienta-energetica>, in the chapter: "Reporting obligations and deadlines as set out in Law 121/2014 on energy efficiency".

\*\*\* The gross calorific value (GCV) of natural gas is 38.43 GJ/thousand Nmc, according to information from the supplier.

## Total electricity consumption

In the year 2023, Antibiotice SA recorded an increase in electricity consumption of only 2.11% compared to the previous year. Also in 2023, 60.72% of the total energy consumed came from renewable sources.

### Total electricity consumption at Antibiotice SA

Electricity consumption (Gj*) (Gj*)	2023	2022	2021
From non-renewable sources	22,086**	0	30,865
From renewable sources	34,146	55,070	14,575
<b>Total</b>	<b>56,232</b>	<b>55,070</b>	<b>45,440</b>

\* 1Gj=10<sup>9</sup> Joules.

\*\* The 2022 electricity supplier's energy label has been used, as the 2023 energy label will be published after July 2024.

The total energy consumption includes the consumption of the headquarters, the industrial production platform, the a+ Club, and other sites owned by Antibiotice in the Iași area. In the calculation of the total energy consumption, the consumption of the Antibiotice representative office in Bucharest was not included and the consumption of third-party users was subtracted.

## Energy intensity

In calculating energy intensity, we included the following types of energy: electricity, natural gas, gasoline, and diesel.

Energy intensity (Gj*/ 1.000 lei)	2023	2022	2021
(1) Total energy consumption (Gj)	219,849	227,606	237,400
(2) Goods production by registration price (thousand lei)	518,251	493,618	381,259
Energy intensity (GJ) per 1,000 lei of goods production = (1) : (2)	0.424	0.461	0.622

\* 1Gj=10<sup>9</sup> Joules.

Energy intensity by registration price decreased in 2023 by 8.03% compared to 2022.

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## Energy efficiency measures

In 2023, we implemented energy efficiency measures, which were identified and recommended following the Complex Energy Audit conducted in 2020. As a result of the implementation of these measures, we have recorded significant savings in electricity and natural gas, totaling 2,230 GJ, which corresponds to a total saving of approximately 223,135 lei.

### Energy saved by Antibiotice SA in 2023

Energy saved	Reduction achieved (Gj)	Amount saved (lei)	Description of the initiative that led to the reduction in energy consumption
Fuel (natural gas)	1,597.07	95,490	Reduction of thermal energy consumption through heat pump systems. Measurements and calculations during the two months of operation in 2023 showed a natural gas saving of <b>443.63 MWh</b> .
Fuel (natural gas)	193.82	11,589	Recovery and reintroduction of clean condensate into the feed water circuit of the boilers of two production sections (Capsule and Parenteral). Measurements and calculations carried out during the 4 months of operation in 2023 showed a natural gas saving of <b>53.84 MWh</b> .
Electricity	264.38	69,736	Reducing electricity consumption by using LED lighting for interior lighting in 12 buildings. In 2023, a total of 515 fluorescent luminaires in the 12 buildings were replaced with LED luminaires. Given that each building has a certain operating time, the estimated number of operating hours per year was calculated for each building, to which a simultaneity coefficient was applied. The calculations showed an electricity saving of approximately <b>73.44 MWh</b> in 2023.
Electricity	5.50	1,453	Upgrade of outdoor lighting by replacing 37 mercury vapor lamps with LEDs. A total of 4380 operating hours/year have been estimated, resulting in electricity savings of approximately <b>1.53 MWh</b> in 2023.
Electricity	170.10	44,867	Optimization of the operation of the ethylene glycol recirculation pumps at the ICS Compressed-Topical cooling station. According to the Complex Energy Audit estimates, 6 months of operation resulted in electricity savings of <b>47.25 MWh</b> .
<b>Total quantity saved 2023</b>	<b>2,230.87</b>	<b>223,135</b>	



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## 5.2. Carbon footprint

**Global climate change is creating significant challenges not only through the disruption of environmental factors but also through its potential negative impact on human health, including the spread of disease and increased illness caused by temperature change.**

We recognize that our activities, particularly our manufacturing processes and consumption of non-renewable energy, are often associated with negative environmental impacts through greenhouse gas emissions. We therefore focus on prioritizing investments in energy efficiency projects and reducing greenhouse gas emissions.

To monitor and report our greenhouse gas emissions, we comply with the procedures set out in our ISO 14001-certified Environmental Management System, an integral part of our integrated management system.

When implementing new processes and procedures, we follow Best Available Techniques (BAT), i.e. those techniques that are considered to be the most efficient and economically viable to prevent or reduce air emissions, as required by the [European Commission's Implementing Regulation \(EU\) 2018/2066](#).

In implementing new processes and procedures, we adopt the best available techniques (BAT), the most effective techniques to prevent or reduce air emissions when technically feasible and economically viable within the sector, in accordance with Commission Implementing

Regulation (EU) 2018/ 2066 on monitoring and reporting of greenhouse gas emissions.

Our greenhouse gas emissions footprint is calculated annually in accordance with the standards and guidelines of the GHG Protocol. We are committed to continually updating our methodology and improving the transparency and accuracy of our data to ensure accurate and transparent reporting of our greenhouse gas emissions as required by Directive 2003/87/EC of the European Parliament and Council.

To achieve this goal, we have implemented a greenhouse gas emissions monitoring and inventory system to collect emissions data in accordance with the Greenhouse Gas Emissions Protocol and the ISO 14064-1 standard for greenhouse gas emissions accounting. This system enables us to collect and analyze relevant data to assess and manage our environmental impacts.

We use the [GHG Protocol Calculation Tools and Guidance](#) to calculate our greenhouse gas emissions. This set of tools and guidance helps us make accurate calculations and report our emissions transparently according to international standards.



### Emissions

GHG emissions (tons CO <sub>2</sub> eq)		2023	2022	2019
Scope 1	from natural gas combustion	8,432.68	8,947.85	9,141.90
	from diesel and gasoline combustion	899.587	807.534	1,029.92
	from fugitive refrigerant emissions	161.124	181.86	749.02
	<b>Total Scope 1</b>	<b>9,493.39</b>	<b>9,937.24</b>	<b>10,920.80</b>
Scope 2	electricity consumption - national data (location-based)	5,370.10	5,259.21	4,996.69
	electricity consumption - suppliers (market-based)	3,782.35	0	3,604.07
<b>Total Scope 1 + Scope 2 greenhouse gas emissions (tons CO<sub>2</sub>eq) - (location-based)</b>		<b>14,863.50</b>	<b>15,196.50</b>	<b>15,917.50</b>
<b>Total Scope 1 + Scope 2 greenhouse gas emissions (tons CO<sub>2</sub>eq) - (market-based)</b>		<b>13,275.70</b>	<b>9,937.24</b>	<b>14,524.90</b>

### Annual variation of Scope 1 and 2 greenhouse gas emissions compared to base year 2019

GHG emissions evolution	2023	2022	2019
Total GHG emissions (t CO <sub>2</sub> eq) - (location-based)	↓ 6%	↓ 5%	base year
Total GHG emissions (t CO <sub>2</sub> eq) - (market-based)	↓ 9%	↓ 32%	base year

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## Setting organizational boundaries for GHG inventory

The company has adopted the operational control approach to define the organizational boundaries of its GHG inventory. Accordingly, we have only calculated GHG emissions for our headquarters and production platform, as these are representative of our operations. Sales offices are excluded from the calculation as their emissions are insignificant.

### Operational boundaries

- 1. Headquarters and production platform:** Emissions from activities and operations at these sites over which the company has full operational control are included in the inventory.
- 2. Sales offices:** These are excluded from the inventory as their emissions are considered insignificant and do not have a significant impact on the total emissions reported.
- 3. Specific exclusions:** If some other facilities or activities cannot be properly monitored or reported, they will be excluded, and the reasons will be clearly documented in the report.

This approach ensures that our GHG inventory accurately reflects the significant emissions over which we have direct control and the ability to implement reduction and management strategies. This methodology helps us to provide accurate and credible reporting, which is essential to our sustainability and compliance strategy.

## Greenhouse gases included in the inventory

Emissions data are reported in tons (t) for each GHG and aggregated to total emissions in thousands of t CO<sub>2</sub>e. The company reports emissions of all applicable GHGs under the Kyoto Protocol: carbon dioxide (CO<sub>2</sub>), methane (CH<sub>4</sub>), nitrous oxide (N<sub>2</sub>O) and hydrofluorocarbons (HFCs).

### Converting emissions to CO<sub>2</sub>e

To convert the gases to CO<sub>2</sub>e, we used the Global Warming Potentials from the Fifth Assessment Report (AR5) of the Intergovernmental Panel on Climate Change (IPCC) over a 100-year time horizon.

**Scope 1 emissions** represent the amount of direct greenhouse gas emissions resulting from the activity of Antibiotice SA (from sources owned or controlled by the company, including from the generation of electricity, heat, cooling agent, and steam, chemical or physical processes, transportation on behalf of the company of materials, products, waste, employees, or other isolated emissions).

**Scope 2 emissions** are the amount of indirect greenhouse gas emissions from the production of electricity purchased from third parties for own consumption.

**Scope 2 - Location-based:** Location-based method calculates greenhouse gas emissions in the local grid area where electricity consumption takes



place, according to their intensity (ANRE emission factor)

**Scope 2 - Market-based:** Market-based method calculates emissions based on the electricity the organization has chosen to procure, often through contracts or instruments such as renewable energy certificates.

The emission factors and Global Warming Potential factors used can be found at [ghgprotocol.org](https://www.ghgprotocol.org).

Following our efforts to inventory **Scope 3** indirect emissions, we have focused the calculation on specific categories that include related energy or fuel-consuming activities, upstream transport and distribution, waste

generated in operations, business travel, employee commuting, and downstream transport and distribution.

It is important to emphasize that, given the complexity of our supply chain and the diversity of our operations, these partial calculations do not provide a complete picture of the impacts associated with indirect emissions. As a result, the partial Scope 3 GHG results are not currently published but are used as an informative tool for internal decision-making.

We are continuing our efforts to complete a full inventory of our Scope 3 emissions, working with our supply chain partners to collect and analyze relevant data. We are committed to being transparent about our progress and to taking a responsible approach to managing and reducing our carbon footprint as we move forward.

In the context of ever-evolving greenhouse gas (GHG) emissions reporting regulations and increasingly stringent requirements for transparency and data accuracy, we reaffirm our commitment to sustainable and responsible practices. To ensure that our GHG emissions reporting is accurate and credible we will begin working with third-party auditors to obtain limited assurance under the ISAE 3000 standard. As we develop our internal capabilities and optimize our reporting systems, we will also consider transitioning to reasonable assurance opinions under ISAE 3000 or ISO 14064

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## Greenhouse gas (GHG) emissions intensity

Scope 1 + Scope 2 (market-based) emissions intensity in 2023 is 6% lower than in 2019.

This reduction was mainly achieved by implementing effective measures to optimize and improve energy efficiency as a result of the company's Energy Audit. It should be noted that the decrease in emission intensity is mainly related to Scope 1 emissions from natural gas combustion.



Scope 1 and 2 greenhouse gas (GHG) emission intensity (tons CO <sub>2</sub> eq / 1,000 lei)		2023	2022	2019
1.	Total GHG emissions (t CO <sub>2</sub> eq) - (location based)	14,863.50	15,196.45	15,917.53
	Total GHG emissions (t CO <sub>2</sub> eq) - (market based)	13,275.74	9,937.24	14,524.91
2. Revenue from sales (thousand lei)		600,781	482,667	390,000
3. Goods production (thousand lei)		518,250	493,618	394,418
GHG emission intensity per 1,000 lei sales revenue (1:2) (location-based)		0.025	0.031	0.041
GHG emission intensity per 1,000 lei sales revenue (1:2) (market-based)		0.022	0.021	0.037
GHG emission intensity per 1000 lei of goods production (1:3) (location-based)		0.029	0.031	0.040
GHG emission intensity per 1000 lei of goods production (1:3) (market based)		0.026	0.020	0.037

## Other emissions

The activity carried out by the company has an impact on air quality through the amount of air emissions resulting from the production process, such as volatile organic compounds (VOC), carbon oxides (CO), organic substances expressed as total organic carbon (TOC), sulfur dioxide (SO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>) and particulate emissions. The industrial biosynthesis plant uses the organic solvents acetone (C<sub>3</sub>H<sub>6</sub>O) and methanol (CH<sub>3</sub>OH), which belong to the group of volatile organic compounds (VOCs).

The 11% decrease in total non-methane volatile compound (VOC) emissions in 2023 compared to 2022 was driven by both the production structure and the implementation of solvent recovery techniques in the dedicated facility.

The emission target value for fugitive emissions (15% of annual solvent consumption) was met.

In addition, activity-specific air pollutants are generated by the combustion of fuels (natural gas) in the thermal power plants and the on-site incinerator.

The air quality in the Antibiotice perimeter is monitored by regular determinations, with the frequency established by the company's operating regulations, in its own laboratory and a third-party laboratory. Thus, the measurements carried out show that the concentrations of gaseous pollutants emitted into the air are within the maximum permitted limits for the protection of human health: nitrogen oxide (NO), sulfur oxide (SO), carbon monoxide (CO), hydrochloric acid (HCl), organic substances expressed as total organic carbon (TOC), volatile organic compounds (nmVOC), dust, etc.

There were no exceedances of the maximum permissible concentrations set out in the regulatory acts and legal requirements in force for the activities carried out by the company.

Other significant air emissions (tons nmVOC*/year)	2023	2022	2021
Non-methane volatile organic compounds (VOCs) (t nmVOCs/year)**	318,694	357,289	285,476

\* nmVOC = non-methane volatile organic compounds

\*\* According to the solvent balance prepared by taking into account the values measured by a RENAR-accredited third-party laboratory.

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## Reducing greenhouse gas emissions

To reduce our greenhouse gas emissions, we have committed to a series of ambitious goals and targets to help combat and mitigate the effects of climate change. These targets are defined below, along with their key performance indicators (KPIs).

In 2023, we successfully completed an in-depth climate risk analysis, initiated in 2022, to identify and implement measures to prevent and mitigate the impact of these risks on the company's operations.

This analysis was critical in ensuring that we are prepared to proactively and effectively manage and mitigate climate risks. We are committed to aligning with the Science Based Targets Initiative (SBTi), which will strengthen our commitment to reducing greenhouse gas emissions and meeting global climate goals. We look forward to continuing this journey and implementing the necessary measures to align with SBTi and continuously improve our environmental performance.

We recognize that our business activities and relationships have a significant impact on the environment. Adapting to the effects of climate change is a topic of

interest to our stakeholders who are directly or indirectly affected by it. As a responsible business, we are committed to meeting the expectations of all our stakeholders and to continuing to develop sustainably.

Although the effects of climate change in Romania - such as excessive rainfall leading to massive flooding, droughts causing significant water stress, and extreme temperature changes leading to severe storms - have not yet had a significant impact on our operations, we recognize the importance of addressing these risks. At the same time, given the global nature of our value chain, it is

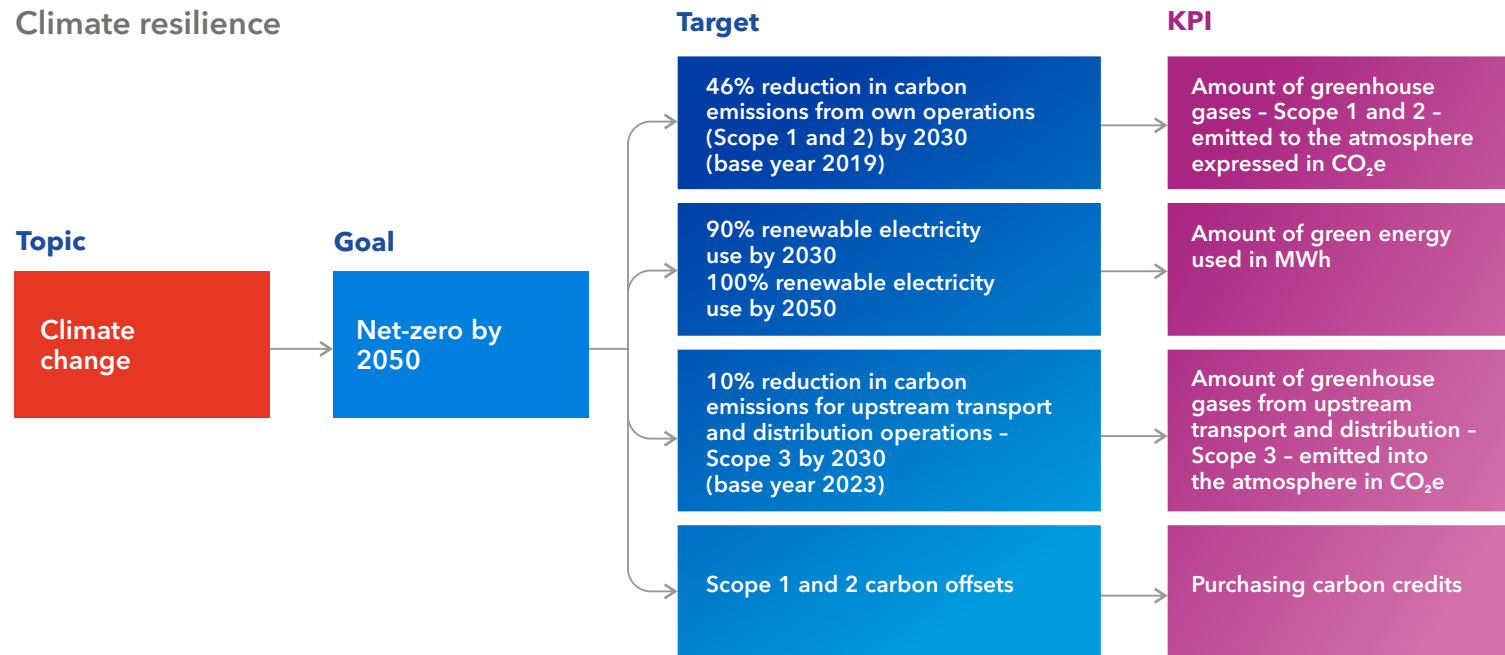
critical to strategically address potential climate-related challenges.

In 2023, a more detailed analysis of the climate risks that could affect our performance was completed to define measures to prevent and reduce the impact of these risks on our activities. Action plans have been developed that include concrete and effective climate change adaptation measures to ensure the transition to a low-carbon economy, with the aim of achieving the climate neutrality target set by the European Union through the European Green Deal and the objectives of the Paris Agreement.

We have taken concrete and effective action to adapt to climate change and help mitigate its effects:

- In 2023, Antibiotice Iași started the construction of a 2.5 MW photovoltaic plant, financed by PNRR, which will cover more than 25% of its electricity needs, based on 2021 consumption. The new plant will produce an average of 3,500 MWh/year, reducing the carbon footprint by more than 2,000 tons per year, thus contributing to climate resilience by reducing greenhouse gas emissions.
- Also in 2023, a project was launched to reduce thermal energy consumption through a heat pump system. The system consists of a heat pump that takes the heat generated when air is compressed by air compressors

### Climate resilience



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### Amount of emissions reduced (tons CO<sub>2</sub> eq)

Initiative	Reduction achieved in 2023 (tons)	Brief description of the initiative
Optimize consumption by using renewable energy and reducing carbon footprint	88.78	Reducing heat consumption with heat pump systems
	10.77	Recovery and reintroduction of clean condensate into the boiler feed water circuit of two production sections (Capsule and Parenteral)
	18.15	Reducing electricity consumption by using LED fixtures for indoor and outdoor lighting
Optimize equipment operation and adjust parameters	11.45	Optimizing the operation of the ethylene glycol recirculation pumps of the ICS cooling station in the Tablet-Topics section
<b>Total</b>	<b>129.15 tons CO<sub>2</sub> eq</b>	

in a production area and transfers/ uses it to the company's district heating system and/or preheats demineralized water to feed the company's steam boilers.

- A project was launched to upgrade the exterior and interior lighting by replacing the existing lighting with LED fixtures.
- In 2024, a 1.2 MW photovoltaic array will also be installed on the company's buildings, so that green energy production will ensure energy autonomy for around 35% of the industrial platform's needs.

The company is currently focusing on measures to reduce carbon emissions through energy efficiency, renewing its fleet with electric cars, and increasing the percentage of electricity purchased from renewable sources. Investment in renewable generation capacity is an important part of 'The Future Together 2020-2030' business plan, through which Antibiotice's shareholders have set ambitious targets for the next few years to achieve sustainable business growth.

## Managing odor impact

Antibiotice SA is committed to improving the technological performance of its installations and equipment as far as is technologically possible, and to find appropriate solutions to prevent odor nuisance to the community living in the vicinity of our factory.

In 2023, specific actions to implement the requirements of Law 123/2020 ("Odour Law") continued. The collaboration with a company specialized in the supply of technological solutions for odor neutralization was continued, and specific equipment is in the industrial testing phase, in parallel with the monitoring of odor emissions. The cost of the industrial testing phase is approximately €15,000.

## Company fleet in 2023

Within the company, we manage a variety of means of transport to meet the needs of people and goods. The fleet consists of the following types of vehicles: company cars, buses for employee transport, minibuses, vans, trucks, and tractors. On the factory platform, the transport of goods is carried out by forklifts and electro cars. The fleet also includes a fire-fighting vehicle, which is used to extinguish any fires that may occur inside or outside the company's premises.

As part of our ongoing efforts to reduce our environmental impact and help combat climate change, our company has decided to invest in a fleet of electric cars. As of December 2023, 35 electric cars have been purchased.

Antibiotice car fleet (vehicles in circulation)	2023	2022	2021
Number of cars	224	168	164
Distance traveled (km)	2,958,909	3,219,701	3,427,850

Number of cars in the fleet, by type of fuel used	2023	2022	2021
Diesel	179	163	161
Gasoline	10	5	3
Electric	35	0	0

## 5.3. Consumption of natural resources

**In 2023, Antibiotice continued to prioritize sustainable supply chain management. We worked closely with our suppliers to promote ethical and environmental practices throughout the supply chain. We strengthened partnerships with suppliers who share our sustainability values and implemented measures to ensure compliance with ethical and environmental standards.**

We continued to optimize the use of raw materials and consumables to reduce resource consumption and waste. We implemented new technologies and processes to improve material use efficiency in pharmaceutical manufacturing. The new topical manufacturing site was completed at the end of 2022. As a result, we have reduced material consumption and optimized our operating processes.

In 2023, we have focused on estimates of inputs of raw materials, materials, and packaging used exclusively in the direct activity of producing medicines, active ingredients, and biofertilizers.

### Materials used in 2023

In 2023, we estimate that the total weight of raw and auxiliary materials used in the production of active ingredients and finished products, such as human and veterinary generics, medical devices, food supplements, and cosmetics, reached 5,198.17 tons. Of this total, 4,658.66 tons are non-renewable materials, and 539.51 tons are renewable materials.

In addition, 65% of the total raw materials and materials purchased in 2023 were sourced from internal Romanian suppliers, and the remaining 35% from external international suppliers. These details reflect our commitment to sustainable and responsible sourcing of materials and working with local suppliers to support the local economy and community

i. Non-renewable materials 2023		tons
<b>i.1) Non-renewable virgin materials</b>		
Raw materials (active substances in bulk, excipients, organic and inorganic chemical substances, etc.)		1,955.12
Materials used in the manufacturing process, but which are not part of the final product or packaging of the product (diesel and gasoline*, industrial lubricants, solvents, gas, aluminum, polyethylene, etc.)		1,012.88
Products or semi-finished parts, including all the types of materials and components, other than the raw materials entering the final product (typewriter ink, paint, electrodes, parts of various metals, glass, and plastic, other than packaging, etc.)		368.24
Materials used as packaging (glass, plastic of different types, rubbers, aluminum/plastic caps, blisters of aluminum foil, composite materials)		1,322.42
<b>Total non-renewable virgin materials</b>		<b>4,658.66</b>
<b>i.2) Recycled non-renewable materials</b>		
<b>Total recycled non-renewable materials</b>		<b>0</b>
<b>Total non-renewable materials used in 2023</b>		<b>4,658.66</b>
ii. Renewable materials 2023		tons
<b>ii.1) Virgin renewable materials</b>		
Raw materials (natural resources transformed into products and services)		0
Materials used in the manufacturing process, but which are not part of the final product or packaging of the product (paper and paperboard, other than packaging, natural rubber)		0
Materials used as packaging (paper and cardboard, wood)		539.51
<b>Total virgin renewable materials</b>		<b>539.51</b>
<b>ii.2) Recycled renewable materials (recycled cardboard)</b>		
<b>Total recycled renewable materials</b>		<b>0</b>
<b>Total renewable materials used in 2023</b>		<b>539.51</b>
<b>Total non-renewable and renewable materials used in 2023</b>		<b>5,198.17</b>

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## Recycled materials used at Antibiotic

Due to the specific nature of the pharmaceutical industry and the drug manufacturing process, the use of recycled materials in production is limited. No recycled materials were used in 2023.

The ratio of the total amount of materials used to manufacture Antibiotic products in 2023 to the amount of waste generated in the same period was 9.34.

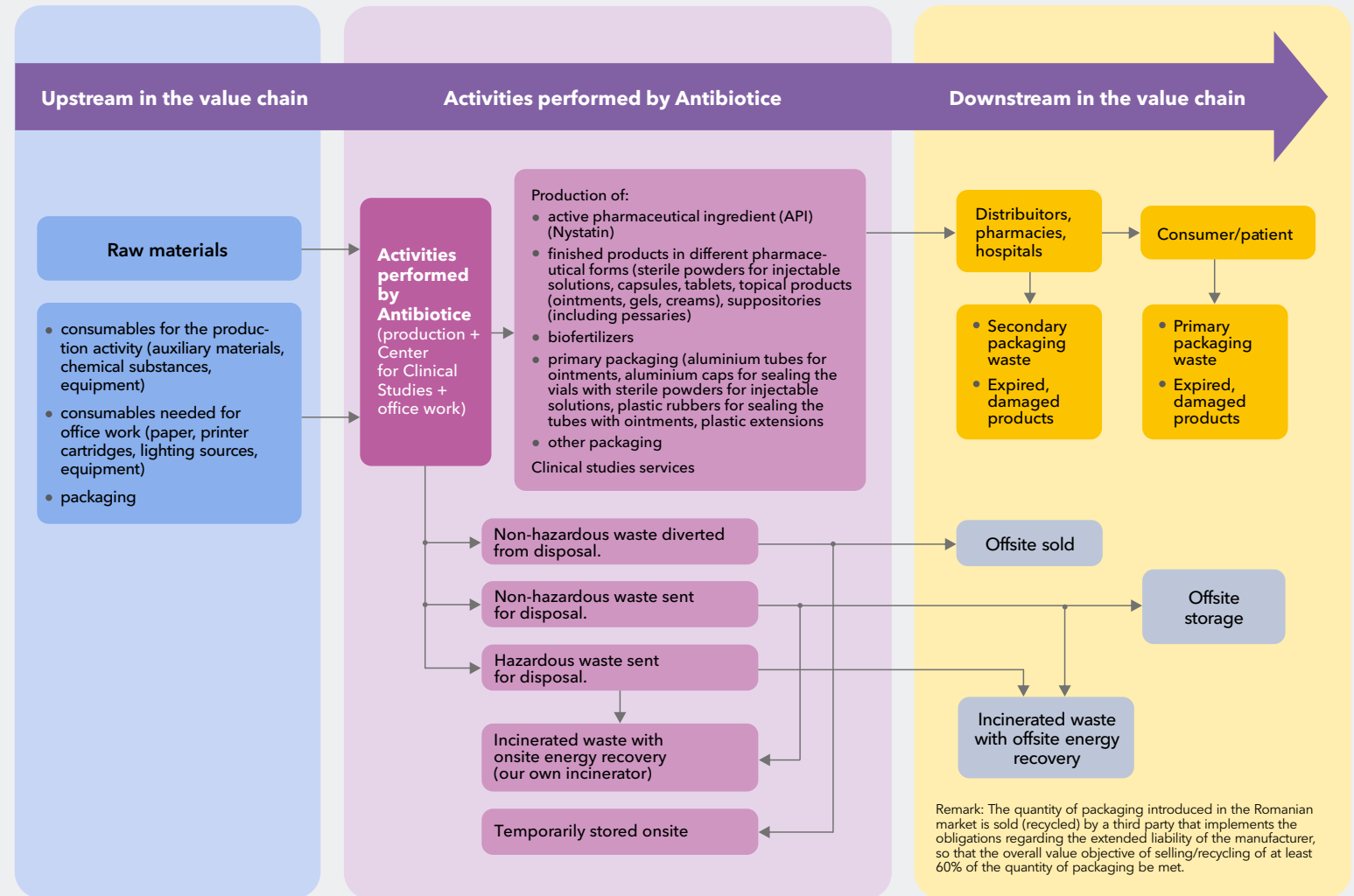
This data reflects our focus on material efficiency and responsible waste management in our production process.

### The flow of input materials and waste from operations

Within Antibiotic SA's operations, we carefully monitor the quantities and characteristics of the materials and raw materials used in the production phase, as well as the amount of waste generated in subsequent stages, including packaging waste associated with our products intended for the domestic market.

This monitoring is essential to assess the impact of our activities on the environment and to identify opportunities to improve the efficiency of material use and waste management.

## Materials and waste flow



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By keeping a close eye on these issues, we ensure that we fulfill our commitment to sustainability and contribute to the protection of the environment.

## Upstream

### *Raw materials and supplies*

Antibiotice SA purchases renewable raw materials (wood, water, plant fibers) and derived materials (paper, cardboard), non-renewable raw materials (minerals, oil, natural gas), and derived materials (plastics, films, synthetic resins, synthetic fibers), auxiliary materials and packaging from upstream in the value chain. These arrive at the company and are stored appropriately, according to their nature, characteristics, and type, to be used for the manufacture of Antibiotice products.

### *Waste*

Upstream, hazardous, or non-hazardous waste, depending on its nature, comes from raw materials and materials damaged during transport or expired.

### *Packaging waste*

Packaging waste results from primary, secondary, and tertiary packaging (paper, cardboard, plastic, composites, wood, and glass).

## Downstream

Downstream in the value chain, the active substances produced by Antibiotice reach manufacturers who produce medicines using Nystatin as the active pharmaceutical ingredient (pharma grade).

The finished pharmaceutical products manufactured at Antibiotice reach distributors' warehouses, and from there, pharmacies, where they are purchased by patients and the general public, by prescription (Rx) or over-the-counter (OTC, medical devices, food supplements, cosmetics). Prescription medicines are also purchased, by tender, by pharmacies in hospitals, where physicians prescribe them as treatment for in-patients.

Biocides reach stores, where they are bought by the general public, and fertilizers are sold through distributors.

### *Waste*

Finished medicines can expire in the warehouses of medicines distributors, pharmacies, and consumers. According to the Orders of the Minister of Health No. 119/2014 and 444/2019, expired pharmaceuticals must be handed over to community pharmacies, which are required to store them in specially designated areas and subsequently hand them over to the relevant organizations for destruction by incineration. On 14 October 2023, the Company took note of the entry into force of Law No. 269/2023 amending and supplementing Law No. 95/2006 on Health Reform. According to the provisions of this law, expired and/or unused medicines must be collected from the population at public or private hospitals, which are required to receive them for final disposal.

Downstream, non-hazardous waste comes from biofertilizers in the event of damage or expiry.

### *Packaging waste*

Packaging waste comes from primary, secondary, and tertiary (transport) packaging of active substances, medicines, biocides, and biofertilizers (paper, cardboard, plastic, composite materials, wood, and glass).

## Operations on the Antibiotice production site

Antibiotice SA inputs raw materials, materials, and packaging purchased upstream into its production flows. The end result is active substances, finished pharmaceutical products (human and veterinary medicines, medical devices, food supplements, cosmetics), hand and surface biocides, and biofertilizers for agriculture.

Production waste and packaging waste are the result of the manufacturing flow. Waste from all other activities on the industrial site and at the company's headquarters is also added.

The main production operations carried out on the site to manufacture end products and the flow of raw materials and materials, water used, packaging, and waste generated in the operations are as follows:

### 1) Manufacture of pharmaceuticals

Antibiotice produces active substances on an industrial scale in the biosynthesis flow through chemical and biological

processes and manufactures generic human and veterinary drugs, medical devices, food supplements, and cosmetics in seven manufacturing flows. All 8 production flows are GMP-certified.

### 1.1) Manufacture of the active substance

Industrial biosynthesis processes to obtain an active substance involve several main steps: selection of the producer micro-organism, inoculation of biosynthetic media with the producer micro-organism, biosynthesis, filtration-atomization, isolation-purification.

At the end of the industrial biosynthesis process of the active substance, a yellowish powdery substance is obtained. The active substance Nystatin is an antifungal. Antibiotice produces Nystatin for pharmaceutical use (pharma grade), available as micronized (micron-sized crystals) and non-micronized (standard and compacted) Nystatin.

### *Raw materials and materials*

The nature of industrial-scale biosynthesis processes makes the Nystatin production stream the largest consumer of raw materials and materials.

The largest quantities of materials and raw materials used are the organic and inorganic substances that make up the nutrient medium, as well as water, the major component of the biosynthesis fluid.

The extraction of Nystatin is done using the organic solvents acetone

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and methanol, which are then recovered to 95% and reintroduced into the technological process.

#### *Water*

Water is only used in the production process and is not found as such (in liquid form) in the composition of the final product (the active substance is available as a crystallized powder).

The nature of the industrial-scale biosynthesis processes of active substances makes this flow the largest consumer of resources, with electricity and water consumption accounting for about 50-60% of the total electricity and water consumption recorded at the company level.

#### *Waste*

The industrial biosynthesis flow is the largest generator of hazardous and non-hazardous waste. The main hazardous waste generated is residues with traces of acetone and methanol, left after recovery of organic solvents. The main non-hazardous waste is the dehydrated mycelial pellets remaining after filtration.

#### *Packaging*

The active substance produced is stored and transported in bulk. The powder is first placed in the primary packaging, a plastic bag (polyethylene-PE), and then in the secondary, insulating packaging, a bag made of triple-layered PET-ALU-PE (polyethylene terephthalate-aluminum polyethylene) composite material.

Tertiary transport packaging consists of grouping in cardboard boxes, which are then sealed and labeled. The boxes are transported on wooden pallets. For transport integrity, the pallet is sealed by wrapping it in stretch plastic film (polyvinyl chloride-PVC).

#### *Packaging waste*

The main packaging wastes are paper, and cardboard, wood waste (pallets), and packaging made of stretch film (PVC), polyethylene (PE), and composite materials (PET-ALU-PE).

### **1.2) Manufacture of finished pharmaceuticals**

At Antibiotice, formulation and packaging of finished pharmaceutical products in various dosage forms such as parenteral products, capsules, tablets, ointments, creams, gels, suppositories, and pessaries take place on the seven production flows.

Each manufacturing flow has operations specific to the pharmaceutical form obtained, but as a general description, the main operations in manufacturing finished pharmaceuticals are weighing of active substances and excipients, their mixing until homogenization, filling into finished forms, and primary, secondary, and tertiary packaging.

#### *Raw materials and materials*

The main raw materials and materials used are active pharmaceutical ingredients (active substances), excipients, and other organic and inorganic substances.



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*Waste*

The main hazardous wastes generated in the production process are grease-containing wastes, mineral substances for the maintenance of industrial equipment, and used filter absorbents.

*Water*

Water is only used in production processes and is not found as such (in liquid form) in the composition of the final products manufactured by Antibiotice (generic medicines for human and veterinary use, medical devices, food supplements, and cosmetics, in the form of capsules, tablets, ointments, creams, gels, suppositories, pessaries, and sterile powders for injection).



*Packaging*

The primary packaging of finished products manufactured at Antibiotice takes place as follows:

- parenteral products (sterile injectable powders) are placed in labeled glass vials sealed with rubber stoppers and aluminum caps, with or without plastic flip-off;
- capsules, tablets, suppositories, and pessaries are packaged in labeled blisters made of aluminum foil, plastic (polyethylene-PE, polyvinyl chloride-PVC, polyvinylidene chloride-PVcD), or composite materials (aluminum-plastic);
- ointments, creams, and gels are placed in plastic or aluminum tubes, labeled, and sealed with plastic (PE) caps

In secondary packaging, each unit (tube of ointment, tube of cream, tube of gel, vial of sterile powder for injections, tablet, capsule, suppository, ovule) is placed, together with the leaflet, in its own box, which is then sealed.

Tertiary transport packaging involves grouping several units of medicines into cardboard boxes, which are then sealed and labeled. They are transported on wooden pallets. For transport integrity, the pallet is sealed by wrapping it in plastic (PVC) stretch film.



*Packaging waste*

The main packaging waste is paper and cardboard, glass, aluminum, and polyethylene.

**2) Primary packaging manufacture**

In 2023, Antibiotice reinforced its commitment to sustainability by outsourcing and streamlining the production process of the primary packaging material - aluminum tubes - produced on the platform. In doing so, we improved operational efficiency and strengthened the supply chain, while maintaining our focus on socially, economically, and environmentally responsible practices.

**3) Manufacture of biocides and fertilizers**

**3.1) Biocides**

In 2023 the company did not manufacture biocides.

**3.2) Biofertilizers**

In 2023, Antibiotice SA also produced agricultural biofertilizers (biological fertilizers for crop fertilization) in the quantities necessary to continue the additional tests carried out to verify their influence on agricultural production. Biofertilizers are liquid concentrates in the form of a bacterial suspension, beige to dark brown in color.

*Water*

Water used in the production process is present as such (in liquid form) in the composition of the final product (>50%).

*Packaging*

Biofertilizers are packaged primarily in plastic drums or cube drums (1,000 l). Transport of the drums is done on wooden pallets. For transport integrity, the pallet is sealed by wrapping it with stretch plastic film (PVC).

*Packaging waste*

The main packaging wastes are paper, cardboard, wood, and plastic.

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# 5.4. Water consumption

**Access to clean water is critical to the sustainability of our business and the well-being of the communities in which we operate. We recognize our responsibility to protect water resources and manage their use responsibly and sustainably.**

We comply with environmental legislation and maintain close cooperation with the competent environmental protection authorities. We comply with all legal requirements and regulations relating to water management and work with the authorities to ensure continued compliance.

To ensure effective water management, we have implemented an environmental management system according to ISO 14001:2015. This system provides a robust framework for identifying,

assessing, and managing the impact of our activities on water resources and the environment.

To improve water management, we carried out a diagnostic analysis of water consumption and quality. Based on the results of this analysis, we have developed a specific water management policy that effectively addresses the issues identified and promotes sustainable practices in water use and conservation. This policy will be published on the company website in 2024.

Antibiotic SA owns water collection, treatment, storage, and distribution facilities to ensure efficient management of water resources. This infrastructure allows us to responsibly manage the extraction, consumption, and discharge of water while ensuring that it remains of high quality.

To carefully monitor water consumption and quality, we have implemented an advanced water consumption monitoring system. This system, which is expanded each year, allows us to monitor water consumption and discharge in accordance with the requirements of the Water Management Permit.

We are committed to complying with all Water Management Permit requirements issued by the relevant authorities. We are committed to not discharging untreated or inadequately treated wastewater into the environment as required by the Permit.



into the feed water circuit of the steam boilers, reducing freshwater consumption.

### Recirculation in manufacturing flows

In all our manufacturing processes, we provide some level of water recirculation to minimize the use of freshwater resources and reduce environmental impact. In 2023, we recycled 8.44 MI (mega liters) of water from steam condensate for heating and pre-heating.

### Accidental Pollution Prevention and Control Plan

Within our company, we have developed and implemented an Accidental Pollution Prevention and Control Plan in accordance with legal requirements. This plan sets out the actions to be taken in the event of an accidental pollution incident or any event that may lead to the imminent pollution of water sources. It also specifies the phone numbers to report such an event and the persons responsible for intervention.

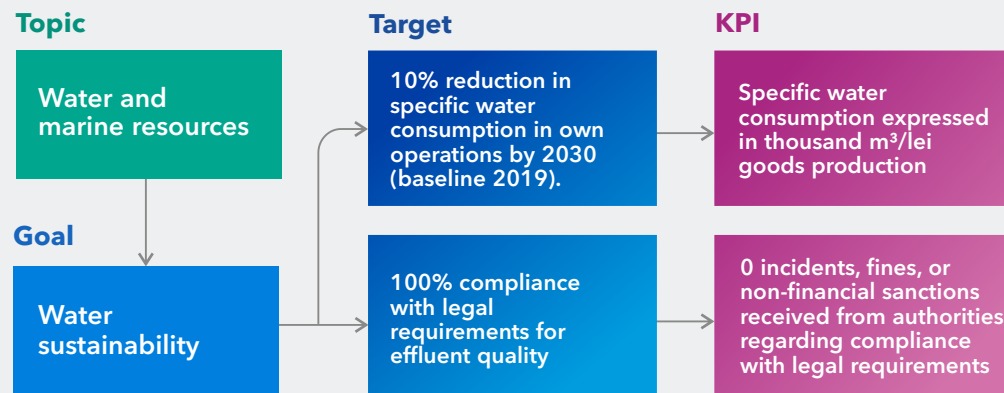
### Recovered (recycled) water

Antibiotic SA is committed to improving its water management system by implementing innovative water recovery and recycling practices. We focus our efforts on designing and implementing solutions that allow us to recover a significant portion of the water used in our processes.

### Recovery in production and distribution

Water recovery and recycling take place within our steam generation and distribution system. The condensate from these processes is recovered and re-introduced

### Responsible water resources management



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### Water collected (extracted)

Antibiotice SA does not extract water directly from any source. The entire volume of water abstracted and used in its activities in Iași comes from the regional public water and sewerage operator in Iași County. The operator supplies the municipality of Iași with drinking water from the Timisesti source (since 1911) and from the Prut River (since 1957).

Valea Lupului commune, located in the immediate vicinity of our company, also relies on water from the water supply system of Iași municipality, coming from the Timisesti source.

In 2023, the volume of drinking water abstracted from the municipal network decreased by 3% compared to 2022, due to the implementation of internal

measures to improve the management of water use by monitoring consumption. These measures have led to a more efficient use of water, contributing to maintaining equity in the use of water resources and minimizing environmental impact.

### Water stress and drought risk

Water stress and drought risk are fundamental issues in assessing the sustainability and environmental impacts of our operations. Water stress refers to the ability of an area to meet human and environmental water needs, taking into account availability, quality, and access. This concept is expressed by a specific indicator, the Water Stress Reference (BWR), which is calculated as the ratio between the total amount of water abstracted in an area and the total renewable water resources available in that area.



### Water stress risk assessment

To assess the water stress of the source area of the water used by Antibiotice, we performed a risk analysis based on data provided by the [Aqueduct Water Risk Atlas](#) tool. This map is based on the BWR indicator and gives us an insight into the level of water stress in the area. In our case, the Timisesti area has a medium to high level of water stress, with a BWR value between 20-40%.

### Forecasts and prospects

Simulations carried out for the years 2030 and 2050, using the same BWR indicator, indicate that the Timisesti area is likely to be affected by significant water stress. These projections show that the available water resources in the area will be under increased pressure in the future, which may affect water availability and access.

### Drought risk

In addition to water stress, drought risk is another important aspect to consider. It indicates the likelihood of drought in a given area and exposes communities and assets to the negative impacts of water scarcity. We also use data from the [Aqueduct Water Risk Atlas](#) tool to assess drought risk.

Antibiotice recognizes its responsibility to manage its impact on water resources and address the risk of water stress. A comprehensive analysis has been undertaken to assess the impact of our operations on water availability and quality, particularly in the context of climate change and increasing global water demand.

To improve the security and sustainability of our water supply, we undertook a detailed hydrogeological study in 2023

Total volume of captured (extracted) water, by source (MI*)	2023		2022		2021	
	Total operating areas	Water-stressed areas	Total operating areas	Water-stressed areas	Total operating areas	Water-stressed areas
Water from suppliers** (from public water supply systems)	153.8	0	158.5	0	149.0	0
Total water captured (extracted) = Water (total) + Groundwater (total) + Seawater (total) + By-product water (total) + Water from suppliers	153.8	0	158.5	0	149.0	0

\* 1 MI (megalitre) = 1,000,000 litres = 1,000 cubic metres

\*\* Municipal suppliers, treatment plants, public or private suppliers, or other organizations engaged in the supply, transport, treatment, or management of water and effluents

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to assess the potential and impact of drilling for groundwater extraction. This initiative is justified for the following reasons:

**1. Diversifying water sources:**

Groundwater abstraction allows us to diversify our water sources and reduce our dependence on surface water resources, which are more vulnerable to fluctuations caused by climate change.

**2. Conservation of water resources:**

By extracting water from groundwater sources, we can contribute to the conservation of surface water resources, which

are essential for natural ecosystems and the sustainability of water supplies for local communities.

**3. Reduce pressure on surface water:**

By using groundwater sources, we can reduce pressure on surface water ecosystems, helping to maintain hydrological balance and protect biodiversity.

By implementing this science-based groundwater extraction project to the highest standards of sustainability, we are committed to ensuring that our operations remain in harmony with the environment and the communities in which we operate.



**Water discharged**

The wastewater from the Antibiotice site, which is discharged through the company's sewer system, includes both industrial (technological) wastewater and domestic wastewater. Rainwater is also managed and introduced in a controlled manner in order to optimize the treatment processes.

In 2023, we successfully completed work on the sewer modernization project, a key initiative for our business. Over a five-year period from 2019, this project demonstrated our strong commitment to providing a safe working environment and protecting the environment. The sewer modernization has significantly contributed to improved resource efficiency and reduced environmental impact, reflecting our ongoing commitment to sustainability.

We have implemented effective measures to treat the industrial wastewater generated by our technological processes. This water is treated at the treatment plant before being discharged into the municipal sewerage system.

The in-house treatment plant is equipped with advanced technologies for efficient wastewater treatment. The two-stage treatment process ensures the removal of pollutants and compliance with quality standards for discharge into the public sewage network.

Industrial wastewater is water discharged after being used in technological processes.

Domestic wastewater is water discharged from administrative facilities and staff areas, including use for personal hygiene, food preparation, and other domestic activities.

Wastewater quality monitoring: The influent flow at the inlet of the treatment plant is quantified using specialized measuring equipment and the records are documented according to protocols established in cooperation with the regional water and wastewater service provider of Iași County. Antibiotice monitors the quality of the wastewater discharged from the treatment plant both in its own laboratory and in third-party laboratories accredited according to RENAR (Romanian Accreditation Association) standards.

The analyses are carried out before the wastewater is discharged into the public sewerage system in Iași.

**Rainwater (meteoric water)**

In addition to the water we use, the site also collects rainwater from atmospheric precipitation, including rain, snowfall, and snowmelt. Some of this water is absorbed into the ground, some evaporates, and the rest runs off onto paved surfaces. Rainwater from the Biosynthesis area is routed through the company's sewer network to the treatment plant. The remaining rainwater, which is considered conventionally clean and is estimated to be 132.45 MI in 2023, is discharged into the Cantacuzoaia natural outfall, a tributary of the Bahlui

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River. We also analyze rainwater that is considered conventionally clean in our laboratory before it is discharged into the natural outfall.

The amount of pollutants in the pre-treated effluent is determined using the mass flow method, based on the values determined by laboratory analysis.

The quality of the wastewater discharged from the treatment plant into the public sewerage system and of the rainwater discharged into the outfall complies with the parameters established by environmental legislation.

There were no exceedances of the maximum permissible discharge limits established by Government Decision 352/2005 (NTPA 001-2005 and NTPA 002-2005), the Integrated Environmental Permit, and the Water Management Permit.

### Water consumed

All the water used by Antibiotice in its activities in Iași is drinking water, purchased from the regional public operator of water and sewage services in Iași County. The amount of water entering Antibiotice

premises is measured on entry to the company using water meters.

Water consumed by an organization is the sum of all water abstracted (incorporated into products, used in construction, generated as waste, evaporated, consumed by personnel, or polluted to the point of being unusable by other users and therefore not discharged back to the surface water, groundwater, or to a third-party) during the reporting period.

Water is not present in its natural form in Antibiotice end products, except for biofertilizers.

Total water consumption at Antibiotice in 2023 was 31.1 megalitres of potable water, a decrease of 13.5 megalitres (30%) compared to the previous year. This decrease was mainly due to the completion of simulations and production tests on the four streams of the new topical products unit, which was inaugurated at the end of 2022.

### Water consumption intensity

Water consumption intensity related to the value of goods production decreased by 6.25% in 2023 compared to 2022.

Water consumed (MI*)	2023	2022	2021
(1) Total water collected	153.7	158.5	149.0
(2) Total water discharged	122.6	113.9	109.3
Water consumed (MI) = (Total water collected/abstracted) - (Total water discharged/ spilled) = (1) - (2)	31.1	44.6	39.7

\* 1 MI (megaliter) = 1,000,000 liters = 1,000 cubic meters

Water consumption intensity (specific water consumption)	2023	2022	2021
(1) Water consumption (MI)	153,779	158,472	149,000
(2) Revenue from sales (thousand lei)	600,781	482,667	366,209
(3) Goods production (thousand lei)	518,250	493,618	381,259
Water consumption intensity per 1000 lei sales revenue (1:2)	0.26	0.33	0.41
Intensity of water consumption per 1000 lei of goods produced (1:3)	0.30	0.32	0.39

Water discharged by Antibiotice SA (MI*), by water source	2023		2022		2021	
	Total operating areas	Water-stressed areas	Total operating areas	Water-stressed areas	Total operating areas	Water-stressed areas
Water discharged to suppliers or other organizations (total)	122.6	0	113.9	0	109.3	0
Total water discharged	122.6	0	113.9	0	109.3	0

\* 1 MI (megaliter) = 1,000,000 liters = 1,000 cubic meters





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## 5.5. Packaging and waste

Antibiotice SA is constantly aware of its responsibility towards the environment and the community in which it operates. To this end, in 2023 the company once again focused on preventing the generation of waste, reducing its quantity, and managing it safely and responsibly, in compliance with the applicable legal regulations. Each year, Antibiotice SA develops and implements a program for the prevention and reduction of waste from its activities. The main objective of this program is to reduce the negative impact of waste generated by the company's activities.

Waste is collected separately and handled by authorized companies with whom the company has service contracts. These companies are responsible for either the recovery of waste or the safe disposal of non-recoverable waste.

Throughout the year, waste management records are kept monthly, including types of waste generated, quantities, and methods of recovery or disposal.

This data is used for internal performance analysis and evaluation and to ensure reporting to environmental authorities as required by the Integrated Environmental Permit.

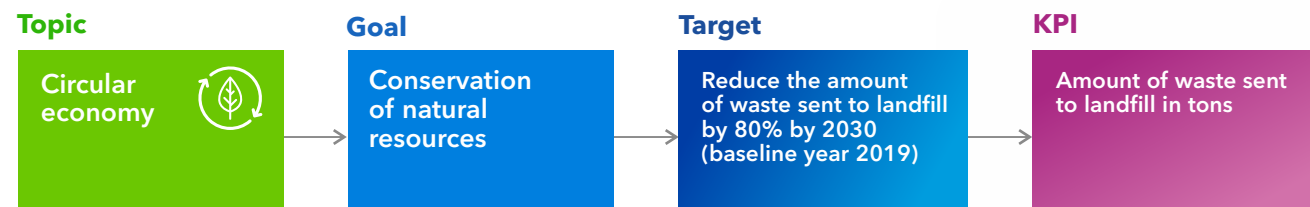
We regularly assess our authorized waste management contractors and verify compliance with contract terms. This assessment begins before service contracts are concluded and includes the establishment of specific authorization requirements. This is followed by checks on how the contracted services are performed, including audits of the service providers.

The data on the quantities of waste generated by Antibiotice SA in 2023 and how it is managed has been extracted from the records of the Environmental Protection structure and the Waste Audit carried out for 2023.

The target for 2030 is to reduce the amount of waste sent to landfills by 80% compared to the reference year 2019.



### Implementing circular economy principles



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## Waste generated by Antibiotice SA in 2023

In 2023, the total amount of waste generated decreased significantly compared to the previous year, from 817.04 tons in 2022 to 556.67 tons in 2023, due to the specific implementation stages of the measures included in the Waste Management Project:

- 1. Compliance with waste management policy:** The implementation of waste management policy is a key factor in reducing the amount of waste generated. This includes guidelines and regulations designed to reduce waste at source, promote recycling, and manage waste disposal responsibly and sustainably. This policy will be published on the company's website in 2024.
- 2. Increased selective collection:** The implementation of specific stages of selective collection under the Waste Management Project has contributed

to an increase in the amount of recyclable waste collected separately from other types of waste. This has reduced the total amount of waste that would have been sent to landfills, contributing to an overall reduction in the amount of waste generated.

- 3. Landfill modernization:** The modernization of the company's landfill in 2023 has had a positive impact on waste management. By investing in infrastructure, the landfill has helped to reduce the amount of waste sent to permanent landfills and, in turn, increased the amount of waste sent for recycling or other more sustainable management methods

Of this, 63.46 tons of depleted mycelium filter cake (from Nystatin biosynthesis) are temporarily stored on-site in concrete composting basins at the pre-treatment plant before being handed over to authorized operators for collection and transport for final disposal. The remaining 479.21 tons of waste, which includes the initial 2022 stockpile, has been disposed of or diverted from disposal.

### The total amount of waste generated by Antibiotice SA in 2023

Waste (tons)	2023	2022	2021
Total waste generated	556.67	817.04	1132.76
- hazardous waste	10.26	20.62	16.22
- non-hazardous waste	546.41	796.42	1116.54

### Hazardous waste

The significant reduction of 50% in the amount of hazardous waste in 2023 compared to 2022 is due to the implementation of energy efficiency measures within the company. These measures have resulted in the generation of hazardous waste, mainly waste oil, due to the gradual replacement of old, inefficient equipment. In 2022, the significant increase in hazardous waste, mainly waste oil, was related to the replacement of the company's old transformers. This specific activity was completed in that year, which explains the absence of specific waste oil generation in 2023.

The industrial biosynthesis flow of the active substance Nystatin generates the largest amount of hazardous waste, 14.68 tons, representing 71% of the total hazardous waste (7.2 tons of residues from solvent distillation and recovery and 0.74 tons of filter material absorbents).

Of the total 10.26 tons of hazardous waste, 83% was disposed of (7.3 tons disposed of internally by incineration on the site and 1.23 tons disposed of externally by authorized operators). The remaining 16% (1.65 tons) was recovered by authorized operators and 0.08 tons remained in stock.

### Non-hazardous waste

The amount of non-hazardous waste generated in 2023 was 546.41 tons, almost 31% less than in 2022. Of this, 0.2 tons were disposed of internally (by incineration on the site), 26.78 tons were disposed of externally (by authorized operators), and 420.11 tons were recovered (by authorized operators). The remaining 71.13 tons remained in the waste stockpile, stored on the company's site.

The amount of 32.33 tons of mixed municipal waste, representing 6% of the total non-hazardous waste generated in 2023, decreased by 75% compared to 2022.



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## Types of waste generated 2023 (tons)

No.	Type of waste	Waste code	Total waste generated	Waste diverted from disposal	Waste directed to disposal (incineration with or without energy recovery, landfill)
1	Distillation and solvent recovery residue	07 05 08*	7.20	0.00	7.20
2	Sludge - mycelial filter cakes	07 05 12	63.46	0.00	0.00
3	Solid waste containing hazardous substances	07 05 13*	1.00	0.00	1.00
4	Printer toners	08 03 18	0.50	0.00	0.50
5	Absorbents, filter materials, PPE	15 02 03	2.01	2.00	0.00
6	Engine, transmission, and lubricating oils	13 02 08*	0.94	0.85	0.09
7	Paper and cardboard packaging	15 01 01	109.24	109.24	0.00
8	Plastic packaging	15 01 02	66.86	66.92	0.00
9	Wood packaging	15 01 03	37.99	37.92	0.00
10	Metal packaging (including aluminum)	15 01 04	19.97	20.36	0.00
11	Glass packaging	15 01 07	27.99	28.18	0.00
12	Absorbents, filter materials, PPE	15 02 02*	0.74	0.65	0.01
13	Scrap tires	16 01 03	1.90	1.90	0.00
14	Discarded electrical and electronic equipment (WEEE)	16 02 14	4.11	4.05	0.00
15	Chemicals (laboratory reagents)	16 05 09	2.02	0.00	2.02
16	Lead batteries	16 06 01*	0.15	0.15	0.00
17	Aluminum from construction and demolition	17 04 02	1.62	1.62	0.00
18	Iron and steel from construction and demolition	17 04 05	113.36	113.25	0.00
19	Cables from construction or demolition	17 04 11	0.03	0.00	0.00
20	Sharp objects (medical waste)	18 01 01	0.04	0.00	0.04
21	Infectious medical waste	18 01 03*	0.23	0.00	0.23
22	Ashes, burning slag	19 01 12	0.03	0.00	0.00
23	Sludges from biological treatment of industrial wastewater	19 08 12	4.44	0.00	0.00
24	Paper and cardboard	20 01 01	0.35	0.35	0.00
25	Medicines disposed of internally	20 01 32	0.20	0.00	0.20
	Medicines disposed of by external operators		49.51	25.88	24.00
27	Plastics (including rubber)	20 01 39	7.67	7.64	0.00
28	Metals	20 01 40	0.80	0.80	0.00
29	Mixed municipal waste	20 03 01	32.33	0.00	32.33
<b>Total, tons</b>			<b>556.67</b>	<b>421.76</b>	<b>67.63</b>

\* Hazardous waste



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### Waste management by type and disposal/recovery method (tons)

	2023	2022	2021
<b>Total waste generated</b>	<b>556.67</b>	<b>817.04</b>	<b>1,132.76</b>
<b>Total hazardous waste generated, by recovery/disposal method (where applicable)</b>	<b>10.26</b>	<b>20.62</b>	<b>16.22</b>
Hazardous waste for reuse	0.00	0.00	0.00
Hazardous waste for recycling	1.65	3.62	0.38
Hazardous waste for compost	0.00	0.00	0.00
Hazardous waste for recovery, including energy recovery	0.00	0.00	0.00
Hazardous waste for incineration	8.53	17.00	15.84
Municipal waste landfill	0.00	0.00	0.00
On-site storage	0.08	0.00	0.00
<b>Total non-hazardous waste generated, by recovery/disposal method (where applicable)</b>	<b>546.41</b>	<b>690.19</b>	<b>998.01</b>
Non-hazardous waste for reuse	0.00	0.00	0.00
Non-hazardous waste for compost	0.00	0.00	0.00
Non-hazardous waste for recycling	0.00	0.00	0.00
Non-hazardous waste for recovery, including energy recovery	420.11	486.15	769.86
Non-hazardous waste for incineration	26.78	80.09	34.70
Municipal waste landfill	32.33	129.32	188.50
On-site storage*	67.90	106.23	118.53

\* This non-hazardous waste is temporarily stored on the company's site before recovery or disposal by authorized economic operators.



## Waste diverted from disposal

Location >	Waste code	Waste diverted from disposal 2023 (tons)			Waste diverted from disposal 2022 (tons)			
		Onsite	Offsite	Total	Onsite	Offsite	Total	
<b>Hazardous waste</b>								
<b>Prepare for reuse</b>		0	0	0	0	0	0	
<b>Recycling (downcycling, upcycling, composting, anaerobic digestion)</b>		0	1.65	1.65	0	3.62	3.62	
	Engine, transmission, and lubricating oils	13 02 08*	0	0.85	0.85	0	3.52	3.52
	Absorbents, filter materials, PPE	15 02 02*	0	0.65	0.65	0	0	0
	Lead batteries	16 06 01*	0	0.15	0.15	0	0	0
	Fluorescent tubes	20 01 21*	0	0	0	0	0.10	0.10
	Abandoned equipment containing CFCs	20 01 23*	0	0	0	0	0	0
<b>Another recovery method (repurposing, refurbishment)</b>		0	0	0	0	0	0	
<b>Total hazardous waste diverted from disposal</b>		0	1.65	1.65	0	3.62	3.62	
<b>Non-hazardous waste</b>								
<b>Prepare for reuse</b>		0	420.11	420.11	0	486.15	486.15	
	Printer toners	08 03 18	0	0	0	0	0.46	0.46
	Paper and cardboard packaging	15 01 01	0	109.24	109.24	0	100,85	100.85
	Plastic packaging	15 01 02	0	66.92	66.92	0	23.09	23.09
	Wood packaging	15 01 03	0	37.92	37.92	0	36.55	36.55
	Metal packaging	15 01 04	0	20.36	20.36	0	21.57	21.57
	Glass packaging	15 01 07	0	28.18	28.18	0	14.5	14.5
	Absorbents, filter materials, PPE	15 02 03	0	2	2	0	0	0
	Scrap tires	16 01 03	0	1.9	1.9	0	2.00	2.00
	Discarded electrical and electronic equipment	16 02 14	0	4.05	4.05	0	30.73	30.73
	Aluminum	17 04 02	0	1.62	1.62	0	2.13	2.13
	Iron and steel	17 04 05	0	113.25	113.25	0	247.55	247.55
	Aluminum cables	17 04 11	0	0	0	0	2.74	2.74
	Paper	20 01 01	0	0.35	0.35	0	0.88	0.88
	Medicines	20 01 32	0	25.88	25.88	0	0	0
	Discarded WEEE	20 01 36	0	0	0	0	1.85	1.85
	Plastics	20 01 39	0	7.64	7.64		0	0
	Metal	20 01 40		0.8	0.8	0	1.25	1.25
<b>Recycling (downcycling, upcycling, composting, anaerobic digestion)</b>			0	0	0	0	0	0 0
<b>Another recovery method (repurposing, refurbishment)</b>		0	0	0	0	0	0	0
<b>Total non-hazardous waste diverted from disposal</b>		0	420.11	420.11	0	486.15	486.15	

\* Hazardous waste

In 2023, compared to 2022, the amount of paper and cardboard packaging recycled increased by 8% and wood packaging by 4%. In addition, the amount of plastic packaging collected doubled, and the amount of metal packaging decreased by 6%. In contrast, the amount of recycled paper decreased by 60% in 2023. At the same time, the amount of scrapped waste electrical and electronic equipment (WEEE) was seven times lower in 2023 than in 2022.

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## Waste directed to disposal

Location >	Waste code	Waste directed to disposal 2023 (tons)			Waste directed to disposal 2022 (tons)		
		Onsite	Offsite	Total	Onsite	Offsite	Total
<b>Hazardous waste</b>							
<b>Incineration (with energy recovery)</b>		<b>7.30</b>	<b>1.23</b>	<b>8.53</b>	<b>16.31</b>	<b>0.69</b>	<b>17.00</b>
	Other residues from the bottoms of reaction columns	07 05 08*	7.20	0.00	7.20	13.60	0.00
	Solid waste containing hazardous substances	07 05 13*	0.00	1.00	1.00	0.00	0.00
	Medical waste subject to special measures	18 01 03*	0.00	0.23	0.23	0.00	0.06
	Waste from paint or varnish removal containing organic solvents or other hazardous substances	08 01 17*	0.00	0.00	0.00	0.14	0.00
	Other engine, gear, and lubricating oils	13 02 08*	0.09	0.00	0.09	0.24	0.00
	Depleted absorbents	15 02 02*	0.01	0.00	0.01	2.26	0.18
	Chemicals (expired reagents, laboratory substances)	16 05 06*	0.00	0.00	0.00	0.00	0.45
	Spent activated carbon	19 01 12*	0.00	0.00	0.00	0.07	0.00
<b>Incineration (without energy recovery)</b>		<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Landfilling</b>		<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>Total hazardous waste directed to disposal</b>		<b>7.30</b>	<b>1.23</b>	<b>8.53</b>	<b>16.31</b>	<b>0.69</b>	<b>17.00</b>
<b>Non-hazardous waste</b>							
<b>Incineration (with energy recovery)</b>		<b>0,20</b>	<b>26,58</b>	<b>26,78</b>	<b>15,25</b>	<b>64,84</b>	<b>80,09</b>
	Printer toners	08 03 18	0,00	0,50	0,50	0,00	0,00
	Paper and cardboard packaging	15 01 01	0,00	0,00	0,00	0,77	0,00
	Plastic packaging	15 01 02	0,00	0,00	0,00	8,67	6,46
	Expired chemicals	16 05 09	0,00	2,02	2,02	0,00	1,98
	Medical waste, sharp objects	18 01 01	0,00	0,04	0,04	0,00	0,02
	Wax paper	20 01 01	0,00	0,00	0,00	0,00	0,00
	Medicines (expired), non-compliant products	20 01 32	0,20	24,02	24,22	5,51	55,78
	Plastics	20 01 39	0,00	0,00	0,00	0,30	0,60
<b>Incineration (without energy recovery)</b>		<b>0,00</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00</b>
<b>Landfilling</b>		<b>0,00</b>	<b>32,33</b>	<b>32,33</b>	<b>0,00</b>	<b>129,32</b>	<b>129,32</b>
	Mixed municipal waste	20 03 01	0,00	32,33	32,33	0,00	129,32
<b>Total non-hazardous waste directed to disposal</b>		<b>0,20</b>	<b>58,91</b>	<b>59,11</b>	<b>15,25</b>	<b>194,16</b>	<b>209,40</b>

\* Hazardous waste

The amount of non-hazardous waste incinerated is reduced by 66% compared to 2022. Essentially, we stopped disposing of paper and cardboard packaging and plastics. The amount of printer cartridges incinerated in 2023 is also 100% higher than in the previous year.

The 60% reduction in waste from expired medicines and non-compliant products in 2023 compared to 2022 is due to the completion of the testing phases required for the technological transfer of the production of topical medicines from the old Ointments unit to the new Topicals unit (which came on stream at the end of 2022).

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## Packaging

The quantity of packaging placed on the Romanian market has been recovered (recycled) through a service contract with an organization that implements extended producer responsibility obligations (OIREP) so that the overall recovery/recycling target of at least 60% of the total quantity of packaging placed on the market by Antibiotice SA in 2023 was achieved (according to Law 249/2015 on packaging and packaging waste management, updated and GEO 196/2005 on the Environment Fund).

**We have no outstanding amounts due to the Environmental Fund Administration in 2023**

tons	2023	2022	2021
1. Total packaging recycled/recovered	529	452	360
2. Total packaging placed on the market	814	745	597
Percentage of packaging recycled/recovered from packaging placed on the market (1:2)	65%	60%	60%

## Pharmaceuticals in the environment

Our company recognizes the significant impact that pharmaceutical substances have on the environment (Pharmaceuticals in the Environment - PIE) and the importance of their responsible management to minimize the environmental impact.

We are committed to addressing the entire life cycle of our medicines, from manufacturing to patient use. This strategic approach comprises several initiatives or programs organized around three main pillars:

- 1. Assess and minimize the environmental impact of production activities:**
  - We focus on assessing and reducing the environmental impact of pharmaceutical manufacturing processes. We use innovative technologies and practices to minimize resource consumption and emissions from waste management.
- 2. Improve our understanding of how our products interact with the environment and assess their potential**

### impacts before and after market launch:

- We are committed to better understanding how our products interact with the environment, both during the manufacturing process and after use by patients. Through research and collaboration with experts in the field, we aim to assess and minimize the environmental impact of our medicines.

### 3. Promote responsible use and correct disposal of unused medicines:

- We focus on educating patients and healthcare professionals about the importance of responsible use and proper disposal of unused medicines. This includes awareness campaigns, training, and facilitating the collection and safe disposal of expired or unused medicines.

În 2023, we developed a robust policy for the responsible management of pharmaceuticals and chemicals in the environment. This policy represents our firm commitment to protecting the environment and promoting responsible practices in the pharmaceutical industry. We intend to publish this policy in 2024, reflecting our transparency and responsibility to society and the environment.

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# 06

## Report on the audit of the Individual Financial Statements



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To Antibiotice SA shareholders

## Report on the audit of the Individual Financial Statements

### Opinion

- We audited the individual financial statements of Antibiotice SA ("The Company"), with its registered office in Iași, 1 Valea Lupului St., identified by the tax identification number RO1973096, comprising the financial position statement as of December 31, 2023 and statement of comprehensive income, statement of changes in equity and cash flow statement for the financial year ended on this date as well as notes to the individual financial statements that include material information on the accounting policies.
- The individual financial statements as of December 31, 2023 are identified as follows:
  - ▶ Net assets/Total equity: **846,964,120 Lei**
  - ▶ Net profit of the fiscal year: **81,088,596 Lei**
- In our opinion, the attached individual financial statements give a true and fair view, in all material respects, of the financial position of the Company on December 31, 2023, as well as of its financial performance and cash flows for the fiscal year ended on the above-mentioned date in accordance with the Order of the Minister of Public Finance (OMPF) no. 2844/2016 for approving the Accounting Regulations in accordance with the International Financial Reporting Standards, with the subsequent amendments.

### Basis for opinion

- We conducted our audit in accordance with International Standards on Auditing ("ISA"), Regulation (EU) no. 537 of the European Parliament and of the Council (hereinafter referred to as the "Regulation") and Law no. 162/2017 on the statutory audit of annual financial statements and annual consolidated financial statements and amending some normative acts (hereinafter referred to as "Law 162/2017"). Our responsibilities under these standards are described in detail in our report section "Auditor's responsibilities in an audit of financial statements". We are independent of the Company, according to the International Code of Ethics for Profes-

sional Accountants issued by the Ethics Committee of the International Federation of Accountants (including the International Independence Standards) (IESBA code), according to the ethical requirements that are relevant for the audit of financial statements in Romania, including the Regulation and Law 162/2017, and we fulfilled our ethical responsibilities according to these requirements and according to the IESBA Code. We believe that the audit evidence we obtained is sufficient and appropriate to provide a basis for our opinion.

### Other matters

- The Antibiotice SA's financial statements for the year ended December 31, 2022 were audited by another auditor who issued an unmodified opinion on those statements on March 17, 2023.

### Highlighting some matters

- As described in Note 23, during 2023 the Company restated the financial statements for 2022. Our opinion is not modified in respect of this matter.

### Key audit matters

- Key audit matters are those matters that, based on our professional judgment, were of greatest importance to the audit of the individual financial statements of the current period. These matters were addressed in the context of the audit of the individual financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Key matters	How our audit addressed the key matter
<p>Revenue recognition, including discounts granted</p> <p>The revenues generated from the sale of finished products and traded goods represent the Company's core activity.</p>	<p>Our audit procedures performed to address the risk of material misstatement of revenue recognition included the following:</p> <ul style="list-style-type: none"> <li>• We evaluated the Company's accounting policies on revenue recognition, including discounts granted</li> </ul>

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Key matters	How our audit addressed the key matter
<p>Recognition of revenues resulting from the sale of finished products and goods depends on the appropriate assessment of the amount of the contractual counterperformance, including discounts granted in some sales transactions and their registration in the period to which they refer, in accordance with the commercial clauses of the contracts with customers.</p> <p>We believe that revenue recognition is a significant audit area, as the Company's management may incorrectly account the revenue from the sale of finished products and goods due to the nature of the sales transactions and contractual clauses regarding the manner and date when control over the sold goods is transferred.</p> <p>In addition, revenue is one of the Company's most important key performance indicators. The Company's presentations of revenue are included in the Note 3 to the individual financial statements.</p>	<ul style="list-style-type: none"> <li>• We assessed the development and implementation of existing key internal controls regarding the sales transactions of finished products, goods and discounts granted.</li> <li>• We confirmed the revenue and discounts granted to the customers selected on the basis of a random sample on December 31, 2023 in order to evaluate the completeness of the transactions made by the Company with them.</li> <li>• We selected a random sample of revenue including the discounts granted, which we compared with the relevant supporting documents to ensure the accuracy and completeness of the recorded transactions, also validating the financial period in which they had to be recorded depending on the date on which the transfer of control over the finished products or goods sold was made from the Company as the seller to the customer as the buyer.</li> <li>• We performed analytical procedures that consisted in the analysis of revenue and discounts granted, comparing the current period with the previous one for: sales, customer volumes and margin.</li> <li>• We evaluated whether the information presented in the Explanatory Notes is appropriate.</li> </ul>

**Other information**

8. Administrators are responsible for the preparation and presentation of other information. That other information includes the Management Report and Remuneration Report, but does not include the individual financial statements and the auditor's report thereon, nor the non-financial statement, which is presented in a separate report.

Our opinion on the individual financial statements does not cover this other information and, unless expressly stated in our report, we do not express any assurance conclusion about them.

In connection with the audit of the individual financial statements for the financial year ended 31 December 2023, our responsibility is to read that other information and, in doing so, to consider whether that other information is materially inconsistent with the individual financial statements, or with our knowledge obtained during the audit, or if they appear to be materially misstated.

**Other reporting responsibilities on other information - Management Report**

Regarding the Management Report, we read it and report whether it was prepared, in all material respects, in accordance with the Order of the Minister of Public Finance no. 2844/2016, with the subsequent amendments, for the approval of the Accounting Regulations in accordance with the International Financial Reporting Standards, with the subsequent amendments.

Based exclusively on the activities to be carried out during the audit of the individual financial statements, in our opinion:

- a) The information presented in the Management Report and in the Remuneration Report for the financial year for which the individual financial statements were drawn up is consistent, in all material respects, with the individual financial statements;
- b) The Management Report was prepared in all material aspects, in accordance with the Order of the Minister of Public Finance no. 2844/2016, for the approval of the Accounting Regulations in accordance with the International Financial Reporting Standards adopted by the European Union, with subsequent amendments.

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In addition, based on our knowledge and understanding of the Company and its business environment, acquired during the audit of the individual financial statements for the financial year ended 31 December 2023, we are required to report whether we identified material misstatements in the Management Report and in the Remuneration Report. We have nothing to report on this matter.

#### **Reporting responsibilities regarding other Information - Remuneration Report**

As regards the Remuneration Report, we have read it to determine whether it presents, under all material respects, the information required by article 107, para. (1) and (2) of Law 24/2017 on issuers of financial instruments and market operations, as republished. We have nothing to report on this matter.

#### **Responsibilities of the management and of the persons responsible for governance for the individual financial statements**

- The management is responsible for the preparation and fair presentation of the individual financial statements in accordance with the Order of the Minister of Public Finance no. 2844/2016 for the approval of the Accounting Regulations in accordance with the International Financial Reporting Standards, with subsequent amendments and for that internal control that the management considers necessary to allow the preparation of financial statements free of material misstatements, due to fraud or error.
- In preparing the individual financial statements, the management is responsible for assessing the Company's ability to continue its activity, presenting, if necessary, the aspects related to the continuity of the activity and using the going concern accounting principle, unless the management either intends to liquidate the Company or cease operations, or has no other realistic alternative.
- Those charged with governance are responsible for overseeing the Company's financial reporting process.

#### **Auditor's responsibilities in an audit of individual financial statements**

- Our objectives are to obtain reasonable assurance about whether the individual financial statements, taken as a whole, are free from material

misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with International Standards on Auditing will always detect a material misstatement, if any. Misstatements can be caused either by fraud or error and are considered material if they can reasonably be expected, individually or cumulatively, to influence the economic decisions of users, taken on the basis of these individual financial statements.

- As part of an audit in accordance with International Standards on Auditing, we exercise professional judgment and maintain professional skepticism throughout the audit. Also:
  - We identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures in response to those risks, and obtain sufficient appropriate audit evidence to provide a basis for our opinion. The risk of not detecting a material misstatement due to fraud is higher than that of not detecting a material misstatement due to error, because fraud may involve collusions, forgery, intentional omissions, misrepresentations and avoidance of internal control.
  - We understand the internal control relevant to the audit, with a view to designing audit procedures appropriate to the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
  - We evaluate the appropriateness of the accounting policies used and the reasonableness of the accounting estimates and of the related information presentations made by the management.
  - We form a conclusion on the appropriateness of management's use of going concern accounting and determine, based on the audit evidence obtained, whether a material uncertainty exists regarding events or conditions that could cast significant doubt on the ability Company to continue its activity. If we conclude that a material uncertainty exists, we must draw attention in the auditor's report to the related presentations in the individual financial statements or, if those presentations are inadequate, we have to change our opinion. Our conclusions are based

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on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the Company to stop operating on a going concern basis.

- We evaluate the presentation, structure and overall content of the individual financial statements, including the information presentations, and the extent to which the individual financial statements reflect the core transactions and events in a manner that achieves fair presentation.

14. We communicate to those charged with governance, among other things, the planned scope and timing of the audit, as well as the main audit findings, including any significant deficiencies in the internal control, that we identify during the audit.
15. We also provide those charged with governance with a statement that we complied with the relevant ethical requirements regarding independence and that we disclosed to them all the relationships and other matters that could reasonably be expected to affect our independence and, where applicable, the actions taken to eliminate risks or protective measures applied.
16. Among the issues communicated with the persons responsible for governance, we determine which are the most important matters for the audit of the individual financial statements for the current period and which therefore represent key audit matters. We describe these matters in the auditor's report unless laws or regulations prohibit public disclosure of the matter or unless, in extremely rare circumstances, we determine that a matter should not be communicated in our report because it is reasonably expected that the public interest benefits are outweighed by the negative consequences of this communication.

#### Report on other legal and regulatory provisions

17. We were appointed by the General Meeting of Shareholders held on April 27, 2023 to audit the individual financial statements of Antibiotice SA for the financial year ending December, 31 2023. The total uninterrupted term of our commitment is 1 year, covering the financial year ending 31 December 2023.

We confirm that:

- Our audit opinion is consistent with the additional report submitted to the Company's Audit Committee, which we issued on the same date as this report. Also, in conducting our audit, we maintained our independence from the audited entity.
- Prohibited non-audit services referred to in Article 5 para.(1) of Regulation (EU) no. 537/2014 were not provided.

The engagement partner of the audit for which this independent auditor's report was prepared is Alina Mirea.

#### Report on compliance with Law no. 162/2017 on the statutory audit of annual financial statements and annual consolidated financial statements and amending some normative acts ("Law 162/2017") and Delegated Regulation (EU) 2018/815 of the Commission on the Regulatory Technical Standard regarding the European Single Electronic Format ("ESEF").

We performed a reasonable assurance mission on compliance with Law 162/2017 and Delegated Regulation (EU) 2018/815 of the Commission applicable to the individual financial statements included in the annual financial report of Antibiotice SA as presented in the digital files that include this audit report (the "Digital Files").

- (I) *Responsibility of the management and those charged with governance for the Digital Files prepared in accordance with the ESEF*

Management is responsible for the preparation of Digital Files in accordance with ESEF. This responsibility entails:

- designing, implementing and maintaining the relevant internal control for the application of ESEF;
- ensuring compliance between the Digital Files and the individual financial statements that will be submitted in accordance with the Order of the Minister of Public Finance no. 2844/2016 for the approval of the Accounting Regulations compliant with the International Financial Reporting Standards, with subsequent amendments.

Those charged with governance are responsible for overseeing the preparation of Digital Files in accordance with the ESEF.

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## (II) Auditor's Responsibility for Auditing the Digital Files

We have the responsibility to express a conclusion on the extent to which the individual financial statements included in the annual financial report comply with the ESEF requirements, in all material respects, based on the evidence obtained. Our reasonable assurance engagement was performed in accordance with International Standard on Assurance Engagements (ISAE 3000 Revised), Assurance Engagements Other Than Audits or Reviews of Historical Financial Information (ISAE 3000) issued by the International Auditing and Assurance Standards Board.

Our company applies the International Standard on Quality Management 1 ("ISQM 1") and, accordingly, maintains a comprehensive quality control system, including documented policies and procedures on the compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

A reasonable assurance engagement in accordance with ISAE 3000 involves performing procedures to obtain evidence about compliance with the ESEF. The nature, timing and extent of the procedures selected depend on the auditor's judgment, including the assessment of the risk of material deviations from the ESEF requirements, whether due to fraud or error. A reasonable assurance engagement involves:

- obtaining an understanding of the Company's process of preparing the Digital Files in accordance with ESEF, including the relevant internal controls;
- reconciliation of the Digital Files with the audited individual financial statements of the Company that will be submitted in accordance with the Order of the Minister of Public Finance no. 2844/2016 for the approval of the Accounting Regulations in accordance with the International Financial Reporting Standards, with subsequent amendments;
- evaluating whether the individual financial statements included in the annual report were prepared in a valid XHTML format.

We believe that the evidence obtained is sufficient and adequate to provide a basis for our conclusion. In our opinion, the individual financial statements for

the financial year ended December 31, 2023 included in the annual financial report in Digital Files comply, in all significant matters, with the ESEF requirements.

Alina Mirea, Partner

*Registered in the Electronic Public Register of Financial Auditors and Audit Firms under number AF 1504*

On behalf of:

DELOITTE AUDIT S.R.L.

*Registered in the Electronic Public Register of Financial Auditors and Audit Firms under number FA 25*

The Mark Building, 84-98 and 100-102 Calea Griviței, 9<sup>th</sup> floor, Sector 1  
Bucharest, Romania

March 15, 2024

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## GRI content index

<b>Statement of use</b>	Antibiotice SA reported in accordance with the GRI Standards for the period January 1 <sup>st</sup> - December 31 <sup>st</sup> , 2023
<b>GRI 1 used</b>	GRI 1: Foundation 2021
<b>Applicable GRI Sector Standard(s)</b>	Currently not available

GRI Standard	Disclosure	Page number(s) and/or direct response	Omission		
			Requirement(s) omitted	Reason	Explanation
<b>General Disclosures</b>					
GRI 2: General Disclosures 2021	2-1 Organizational details	7, 11, 13			
	2-2 Entities included in the organization's sustainability reporting	7			
	2-3 Reporting period, frequency and contact point	7			
	2-4 Restatements of information	There was no updated information during the reporting period.			
	2-5 External assurance	The non-financial information has not been subject to external verification.			
	2-6 Activities, value chain and other business relationships	13-15, 33, 37, 38			
	2-7 Employees	105			
	2-8 Workers who are not employees	106			
	2-9 Governance structure and composition	71-74			
	2-10 Nomination and selection of the highest governance body	75			
	2-11 Chair of the highest governance body	71			
	2-12 Role of the highest governance body in overseeing the management of impacts	76			
	2-13 Delegation of responsibility for managing impacts	76			
	2-14 Role of the highest governance body in sustainability reporting	76			
	2-15 Conflicts of interest	77			
	2-16 Communication of critical concerns	77			
	2-17 Collective knowledge of the highest governance body	76			
	2-18 Evaluation of the performance of the highest governance body	75			
	2-19 Remuneration policies	75			
	2-20 Process to determine remuneration	75			
	2-21 Annual total compensation ratio	111			
	2-22 Statement on sustainable development strategy	5, 6			
	2-23 Policy commitments	77, 78			

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GRI Standard	Disclosure	Page number(s) and/or direct response	Omission		
			Requirement(s) omitted	Reason	Explanation
GRI 2: General Disclosures 2021	2-24 Embedding policy commitments	16			
	2-25 Processes to remediate negative impacts	All negative impacts are remediated in accordance with applicable national legislation.			
	2-26 Mechanisms for seeking advice and raising concerns	76, 77			
	2-27 Compliance with laws and regulations	78			
	2-28 Membership associations	27			
	2-29 Approach to stakeholder engagement	22-24, 86			
	2-30 Collective bargaining agreements	106			
<b>Material topics</b>					
GRI 3: Material topics 2021	3-1 Process to determine material topics	17, 18			
	3-2 List of material topics	18			
<b>Impact on the local economy</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	16, 20, 33-38, 82, 89			
GRI 201: Economic Performance 2016	201-1 Direct economic value generated and distributed	89			
	201-4 Financial assistance received from government	89			
GRI 202: Market Presence 2016	202-1 Ratios of standard entry level wage by gender compared to local minimum wage	111			
	202-2 Proportion of senior management hired from the local community	117			
<b>Business ethics</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 76-81			
GRI 205: Anti-corruption 2016	205-2 Communication and training about anti-corruption policies and procedures	77, 78	Incomplete information. Data has not been monitored in accordance with the provisions of this requirement		
	205-3 Confirmed incidents of corruption and actions taken	79			
GRI 206: Anti-competitive Behavior 2016	206-1 Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	79			
GRI 418: Customer Privacy 2016	418-1 Substantiated complaints concerning breaches of customer privacy and losses of customer data	81			
GRI 415: Public Policy 2016	415-1 Political contributions	79			
<b>Product promotion policy</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 57-65			
GRI 417: Marketing and Labeling 2016	417-2 2 Incidents of non-compliance concerning product and service information and labeling	65			
	417-3 Incidents of non-compliance concerning marketing communications	61			

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GRI Standard	Disclosure	Page number(s) and/or direct response	Omission		
			Requirement(s) omitted	Reason	Explanation
<b>Supply chain management</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	15, 19, 94, 95			
GRI 204: Procurement Practices 2016	204-1 Proportion of spending on local suppliers	95			
<b>Combating counterfeit medicines and parallel trade</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 65-67			
Organization specific topic: <i>Combating counterfeit medicines and parallel trade</i>	Counterfeit alerts generated by the serialization system	67			
<b>Research, development, and innovation</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 47-49			
Organization specific topic: <i>Research, development, and innovation</i>	Active research projects at the end of the reporting period	47			
	Value of investment in R&D activity	47			
<b>Animal welfare</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 68			
Organization specific topic: <i>Animal welfare</i>	Number of animal-tested products	Zero generic products			
<b>Safety of clinical trial participants</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	13, 20, 57, 68, 69			
Organization specific topic: <i>Safety of clinical trial participants</i>	Number of clinical trials started during the reporting period	69			
<b>Access to medicines</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 44, 46			
Organization specific topic: <i>Access to medicines</i>	Number of essential medicines in the company's portfolio	45			
<b>Patient and consumer health and safety</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 50-56			
GRI 416: Customer Health and Safety 2016	416-1 Assessment of the health and safety impacts of product and service categories	51-53			
	416-2 Incidents of non-compliance concerning the health and safety impacts of products and services	53-55			
<b>Preventing drug misuse and self-medication</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 56, 57, 60			
Organization specific topic: <i>Preventing drug misuse and self-medication</i>	Initiatives to promote responsible consumption of medicines	52, 63			



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GRI Standard	Disclosure	Page number(s) and/or direct response	Omission		
			Requirement(s) omitted	Reason	Explanation
<b>Recruitment, employee development and retention</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 105, 107-110, 113-116			
GRI 401: Employment 2016	401-1 New employee hires and employee turnover	110			
	401-2 Benefits provided to full-time employees that are not provided to temporary or part-time employees	113			
	401-3 Parental leave	114			
GRI 402: Labor/Management Relations 2016	402-1 Minimum notice periods regarding operational changes	106			
GRI 404: Training and Education 2016	404-1 Average hours of training per year per employee	114			The information was not presented in accordance with this requirement
	404-2 Programs for upgrading employee skills and transition assistance programs	115			
	404-3 Percentage of employees receiving regular performance and career development reviews	116			
<b>Diversity and equal opportunities</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 110, 111, 117			
GRI 405: Diversity and Equal Opportunity 2016	405-1 Diversity of governance bodies and employees	73, 74, 117			
	405-2 Ratio of basic salary and remuneration of women to men	111			
GRI 406: Non-discrimination 2016	406-1 Incidents of discrimination and corrective actions taken	117			
<b>Employee health and safety</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 118-121			
GRI 403: Occupational Health and Safety 2018	403-1 Occupational health and safety management system	118			
	403-2 Hazard identification, risk assessment, and incident investigation	119			
	403-3 Occupational health services	118-120			
	403-4 Worker participation, consultation, and communication on occupational health and safety	118, 119			
	403-5 Worker training on occupational health and safety	120			
	403-6 Promotion of worker health	121			
	403-7 Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	120, 121			
	403-8 Workers covered by an occupational health and safety management system	118, 120			
	403-9 Work-related injuries	121			

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			Requirement(s) omitted	Reason	Explanation
<b>Volunteering and community investment</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 122-125			
Organization specific topic: <i>Volunteering and community investment</i>	Number of projects supported	122			
	Total sponsorship budget	122			
<b>Materials and waste</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 127, 136-141, 145-151			
GRI 301: Materials 2016	301-1 Materials used by weight or volume	136			
	301-2 Recycled input materials used	137			
GRI 306: Waste 2020	306-1 Waste generation and significant waste-related impacts	145			
	306-2 Management of significant waste-related impacts	146, 151			
	306-3 Waste generated	146, 147			
	306-4 Waste diverted from disposal	148, 149			
	306-5 Waste directed to disposal	150			
<b>Water management</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 139-144			
GRI 303: Water and Effluents 2018	303-1 Interactions with water as a shared resource	139-144			
	303-2 Management of water discharge-related impacts	142, 144			
	303-3 Water withdrawal	144			
	303-4 Water discharge	144			
	303-5 Water consumption	144			
<b>Energy consumption</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 128-130			
GRI 302: Energy 2016	302-1 Energy consumption within the organization	129			
	302-3 Energy intensity	129			
	302-4 Reduction of energy consumption	130			
<b>Climate change contribution</b>					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 131-135			
GRI 305: Emissions 2016	305-1 Direct (Scope 1) GHG emissions	131			
	305-2 Energy indirect (Scope 2) GHG emissions	131			
	305-4 GHG emissions intensity	133			
	305-5 Reduction of GHG emissions	134			

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