

# INTEGRATED ANNUAL REPORT 2022

Antibiotice   
Science and soul

Investing responsibly  
for the health of  
future generations







Investing responsibly  
for the health of  
future generations



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# Message of the General Director of Antibiotice

Dear partners,

It is my great pleasure to present Antibiotice's second integrated report - *"Investing responsibly for the health of future generations"*. The report outlines the company's in terms of business objectives and through the lens of sustainability indicators describing our business and our economic, social, and environmental impact.

We are the largest Romanian-owned pharmaceutical manufacturer, of strategic importance to the Romanian pharmaceutical and defense industries, and our history of almost seven decades attests to our commitment and responsibility to be a reliable partner in solidarity with the national healthcare system and to generate a positive impact on the environment, society, and the economy at large.

2022 was the year we redefined our goals and updated our Strategic Development Plan, "The Future Together 2020-2030". The plan aims to multiply profit and turnover targets, with an impact on increasing Antibiotice's market share in the local and international market, achieved by integrating sustainability principles into all aspects of the company's business. Because as proud as we are of our financial performance in the previous year and our plans for the future, we are aware that social and environmental aspects must continue to be at the forefront of our strategy.

During this year we continued our efforts to consolidate the business which resulted in total revenues of 522 million lei, 34% higher compared to 2021. The advantages offered by a diversified portfolio of around 50 products registered on foreign markets confirm our status as an international manufacturer and supplier of highly regulated healthcare systems.





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Thus, 2022 is an important milestone on our path to sustainable financial growth. In a constantly changing and dynamic environment, our ability to adapt and respond to the challenges that may arise remains a vital quality. As such, in line with our commitment to reducing our contribution to climate change, we have undergone an extensive climate risk assessment process, updated our greenhouse gas emissions calculation methodology, and committed to setting science-based targets to reduce these emissions.

Improving energy efficiency is a primary objective in our action plan to reduce our carbon footprint. That is why in 2022 we succeeded in purchasing 100% of our electricity from renewable sources and undertook a major investment to build a photovoltaic plant that will provide more than 25% of the company's energy consumption.

Because research, development, and innovation are key to ensuring a sustainable product portfolio and increasing access to medicines, we continued to invest in new product research and licensing acquisitions, new manufacturing sites, and quality assurance equipment. To support the business, we have also invested in upgrading manufacturing technologies and infrastructure, as well as digitizing processes. The total value of investments made in 2022 exceeded 47 million lei.

All the progress we have made was possible with the dedication, commitment, and expertise of our employees. We are constantly working to develop an organizational culture that ensures the well-being and healthy lifestyles of our 1,300+ employees, enabling them to reach their potential and enhance their skills and knowledge. In 2022, the budget allocated to training and professional development programs saw an increase of approximately 93% over the previous year.

The health of a company depends to a large extent on the health of its people, which is why we have developed health education and prevention campaigns in our company and encouraged practicing a healthy lifestyle, as part of the "Healthy living in a healthy company" program. In 2022, screenings to identify heart, liver, or cancer disorders

were available to all employees, and our internal evaluation studies show that at least three-quarters of employees value these screening programs and wish to continue them.

Caring for the people around us, but also for the generations to come, has always been an important topic on our agenda, and last year the budget invested in community projects reached 925,000 lei. Being a company that provides the population with access to anti-infective medicines, it is our duty to contribute to the education effort to preserve the efficacy of these valuable products for future generations. That is why, operating under the umbrella of the "Antibiotics of the Third Millennium" program, we have launched the national campaign *"Treat antibiotics with care for a care-free future!"* which brought together the voices of the most renowned specialists in the field in Romania, to inform and raise awareness of both the general public and healthcare professionals on the correct and appropriate use of antibiotics in order to preserve their efficacy, given the increasing resistance to antimicrobial drugs.

We recognize the essential role that our suppliers and partners play and that is why we continued to develop collaborations that improve supply chain resilience and help us build strong partnerships based on ethics, integrity, and mutual respect.

In closing, I would like to extend my sincere gratitude to all those who are part of the Antibiotice ecosystem and who have contributed directly or indirectly to our success and progress. I am confident that with your support, collaboration, and trust we will be able to shape a healthier future for ourselves, those around us, and those who will follow!

**Ec. Ioan Nani**  
**General Director Antibiotice**  
**Vice-President of the Management Board**



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# About the report

This is the second 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 of the annual report, including for the financial year 2022, and the non-financial performance indicators related to the Company's activity between January 1, 2022, and December 31, 2022.

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 1.938/2016](#), [Order of the Minister of Public Finance No 3.456/2018](#), [Order of the Minister of Public Finance No 1.239/2021](#) 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 2.139/2021](#), [EU Regulation 2.178/2021](#) and [EU Regulation 1.214/2022](#)).

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 have been 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 140 of the report.

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# 01

## Company profile

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# 1.1. History

Access to healthcare and medicines is a global sustainability goal and Antibiotice is committed to contributing to its achievement through investment in research, development, and innovation, the development of new manufacturing capabilities, and sustainable partnerships with players across the value chain. All of these are designed to promote the long-term well-being of society by embedding sustainability and inclusion principles in every aspect of our operations.

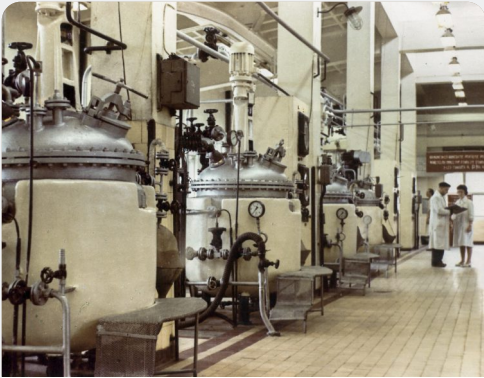
With more than six and a half decades of activity, Antibiotice is the most important producer of generic medicines in Romania, making an important contribution to the sustainable growth of the country. Over the years, the company has maintained its dedication to the mission of producing reliable, effective, and high-quality medicines, thereby providing patients with the prospect of a healthy life and ensuring access to essential treatments.

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

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



## 1955 - 1990

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

## 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 has become the world's leading producer of Nystatin; Nystatin becomes 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 own funding (€20 million).





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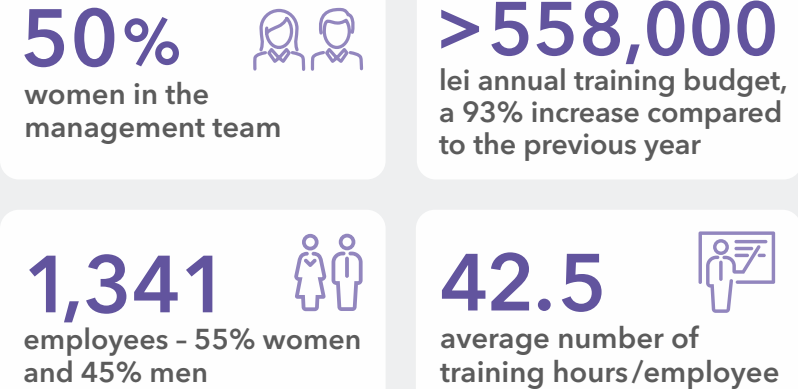
## 1.2. Key figures in 2022

### Economic



### Social

#### Employees



We launched **a+ Academy** - a knowledge management platform for employees



**100%** of employees in senior management positions are recruited from Romania

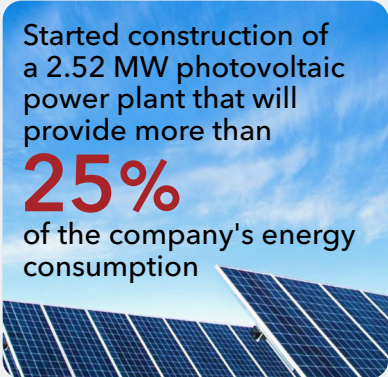
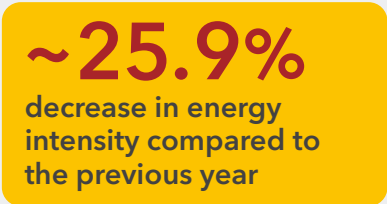
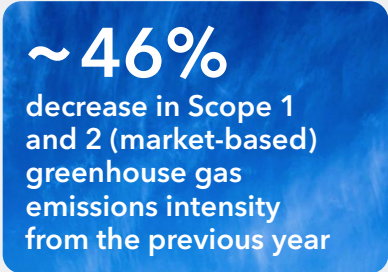
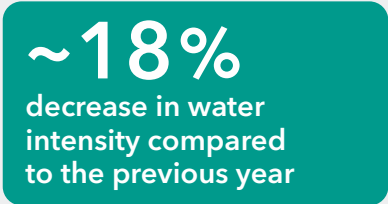
#### Community





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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 25 years and has been listed on the Bucharest Stock Exchange (BVB) in the Premium category since 1997.

With a 67-year tradition, Antibiotice Iasi 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 develops and manufactures generic drugs for human use (150 products in 11 therapeutic classes), veterinary drugs, active substances, and biocidal products, on eight production flows verified and certified by the Romanian National Agency for Medicines and Medical Devices (NAMMDR), according to Good Manufacturing Practice (GMP) requirements.

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 70 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 produces valuable and affordable medicines for both the Romanian and foreign markets on all continents. Over the years it has developed strong commercial relationships with over 70 partners worldwide and has opened branches in Vietnam, the Republic of Moldova, Ukraine, and an office in Serbia.

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 (COS)**
- > **Food and Drug Administration (FDA) authorization**

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's headquarters and Research and Development Centre, which includes its own Clinical Studies Centre, are located in Iasi, in the same location as the drug factory (production site).

The company does not market products or services that are prohibited/withheld from the market in certain regions or countries.

## Antibiotice has 8 production flows, organized into three divisions:

- Sterile Products & APIs Division**  
(penicillin injectable powders, biosynthetic active substances, biocidal solutions);
- Solid Oral Products Division**  
(penicillin capsules, non-beta-lactam capsules, cephalosporin capsules, and tablets);
- Topical Products Division**  
(ointments, creams, gels, suppositories, pessaries, and biocidal gels).

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# 1.4. Our mission

Antibiotice is one of the companies with a rich tradition in Romania. Its organizational culture, values, and the way it conducts its business day to day have made the company a trusted partner for suppliers, customers, and healthcare authorities in Romania and the countries where it operates.

## Our mission

We make our valuable medicines more accessible, we always put our strength to 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 the Romanian society and for the consumers from over 70 countries where its products are sold.

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.

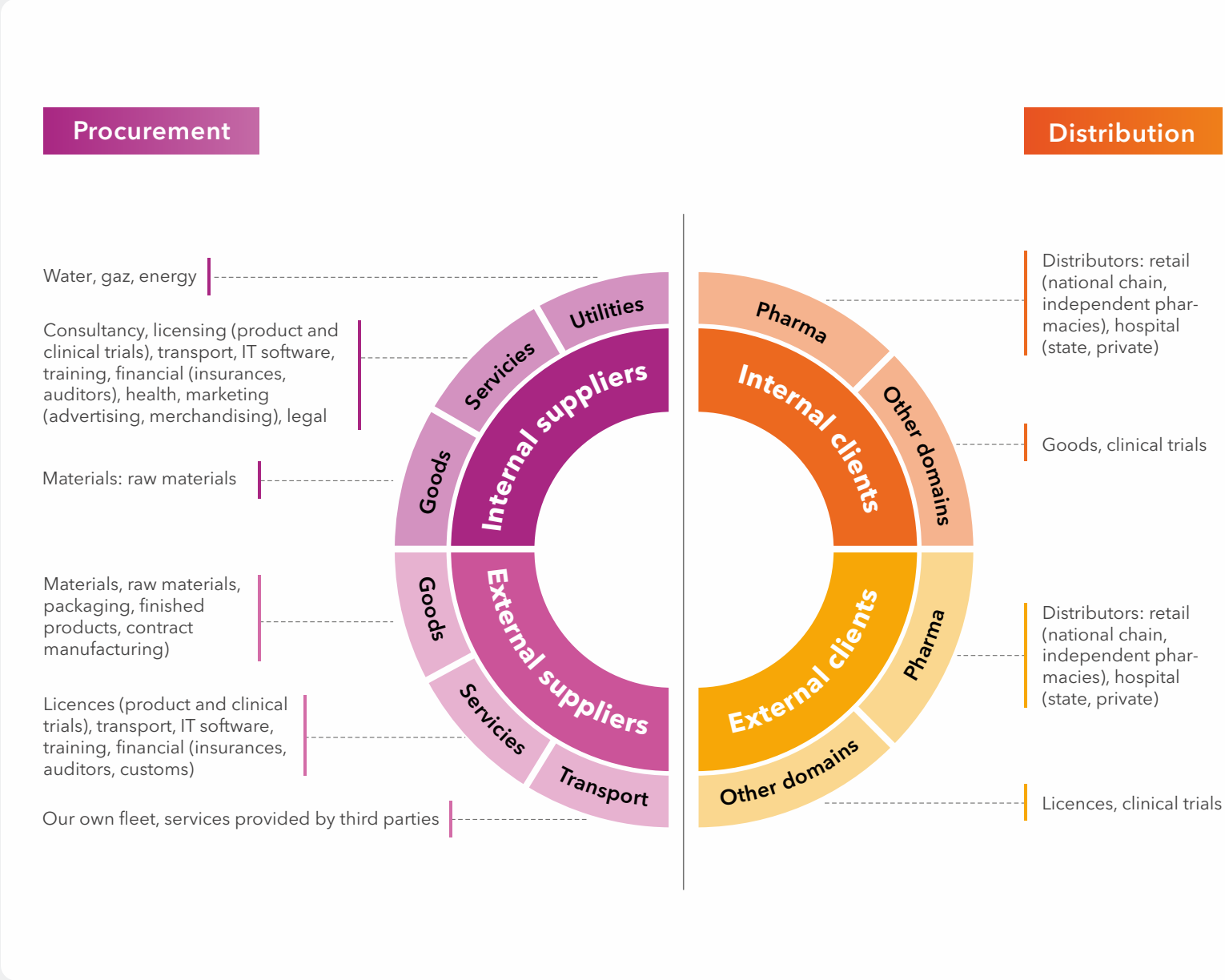
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Throughout the value chain, optimizing the production, packaging, storage, and transport processes is constantly pursued, as a guarantee that the Antibiotice medicines reach the final consumers in the best conditions.

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.

By running continuous medical education programs dedicated to healthcare specialists, the company's promotion team, following ethical principles, aims to increase accessibility, contributing to the balanced uptake of Antibiotice products. The company's teams of specialists in the Quality Assurance Department are actively involved, through self-inspection programs, in the early identification of elements that could slow down processes in the value chain, intervening so that risks are minimized and procedures are constantly improved.





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# 1.5. Our long-term strategy

In 2022 our strategy focused on managing the company's activities to develop and increase business profitability.

Our main objectives were:

- modern human resources management and updating the organizational culture, continuous adaptation to the internal and international market, and development of market presence;
- redefining the Integrated Management System to support business sustainability, ensuring the internal corporate regulatory framework;
- ensuring and maintaining an effective system for evaluating professional performance and improving the risk management process.

At the same time, throughout this period, emphasis has been placed on strategic planning and monitoring of management systems to improve organizational functionality and efficiency and to achieve specific and overall company objectives.

2022 was also when we defined our strategic objectives that will underpin our business until 2030. The company's Strategic Development Plan, *The Future Together 2020-2030*, aims to multiply profits, turnover, and impact on increasing Antibiotice's market share in the local and international market, all this with the integration of sustainability principles in all company activities. At the same time, the strategy also integrates team aspects, by improving working conditions and the well-being of employees, reflecting not only their merits but also their commitment and contribution to the company's success.

## The 2030 targets entail:

	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).	 <b>2030 target:</b> €250 million turnover, 6.5% physical market share in Romania in the generics and OTC market (boxes)
	Expansion of products in Antibiotice territories, to develop a structure favorable to international markets, according to profitability criteria;	 <b>2030 target:</b> Business internationali- zation - €60 million
	Strengthening the sales structure through "compliance" in terms of markets, territories, product quantity, the average price of the structure, and the multiplication coefficient of the active substance;	 <b>2030 target:</b> Balanced production capacity utilization - 90% occupancy rate
	Continued strategic investments, equipping the new topical products unit for the manufacture of sterile topical products, investment in research pilots, technology transfer and small-scale production for sterile injectable solutions, upgrading the sterile penicillin powder flow, equipping production flows, investment in research and development of new products and acquisition of state-of-the-art laboratory equipment, reduction of electricity consumption, process digitization.	 <b>2030 target:</b> Profitability - €50 million
	Valuable staff structure, oriented towards knowledge, innovation, and performance, complying with criteria of diversity of professions and gender and equal opportunities.	 <b>2030 target:</b> Net average income per employee/month - €2,100

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## 1.6. Materiality analysis

The materiality analysis is the process of identifying and prioritizing material topics that underpin the determination of the non-financial indicators presented in this 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. In 2022, following an internal analysis, three further categories of stakeholders were identified and included separately in the consultation: patient associations, hospitals, and international bodies.

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 potentially material topics, i.e. topics where the company could have a significant impact (positive and/or negative). The list of potentially 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 potentially material topic, the positive and negative impact dimensions were rated on a scale from 0 to 3 as follows:

-  - no impact
-  - low impact
-  - moderate impact
-  - high impact

At the same time, 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



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Antibiotice has or could have a 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, or 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, it 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



Negative impact

Positive impact



Positive impact

External results

Internal results

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Impact assessment

Material topic*	Overview of impacts on the economy, environment, and people, including on human rights	Impact type
17 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
15 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
18 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
16 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
11 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
8 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.  At the same time, we 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
1 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. We are considering introducing such provisions in the Supplier Code of Conduct under development at the time of publication of the report (June 2023).	Actual Positive Negative
5 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
13 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
3 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
4 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. At the same time, keeping medicines affordable is key to alleviating the barrier faced by low-income individuals in accessing needed treatments. Balancing profit and social responsibility is crucial to ensure that the economic value generated by the company benefits the wider society.	Actual Potential Positive Negative
14 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
10 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 Positive Potential Negative
9 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. At the same time, the well-being programs conducted annually serve to maintain a balance in our employees' professional lives.	Actual Positive Potential 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	
12	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 Positive	Potential Negative
19	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 Negative	Potential
6	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 Positive	Potential Negative
7	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 Positive	Potential Negative
2	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. At the same time, our employees are 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







As a pharmaceutical company, maintaining a strong relationship with stakeholders is important to us. We recognize that their needs and expectations evolve over time, and it is essential that we stay connected.

We use a variety of channels and strategies to promote effective and transparent communication, ensuring they are well-informed and can trust 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 sustainability. This commitment allows us to build trust, strengthen relationships and work collectively 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
 Shareholders	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>
 Employees and employee representatives	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>
 Internal suppliers	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>
 External suppliers	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
 <b>Non-governmental organizations - NGOs</b>	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>
 <b>Regulatory and supervisory authorities</b>	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>
 <b>Central and local authorities</b>	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>
 <b>International bodies</b>	Consultation as part of the sustainability reporting process	Whenever necessary or requested	Email Integrated report		
 <b>Academia</b>	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>
 <b>Media</b>	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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## Local community consultation: Open Day

During June 23-27, 2022, the company organized an engagement and dialogue event with the local community designed to raise awareness in the nearby communities that Antibiotice complies with environmental standards and does not pollute the environment and is concerned with developing a dialogue between the company and the nearby communities on environmental issues and promoting the company as a friendly and responsible brand.

Because we want ongoing dialogue and feedback to be at the heart of our relationship with local communities, we distributed a series of consultation questionnaires to visitors to find out the main issues they face and how Antibiotice can support them.

The main issues faced by the respondents, as members of the local community, are those related to road infrastructure and

public transport (11 respondents, approx. 24%) and pollution and air quality (8 respondents, approx. 17.5%). Most respondents (approx. 30%) believe that the most important projects Antibiotice could support for the well-being of the community are those related to environmental protection. Also important are sports or educational projects - including partnerships with universities.

The main positive aspects of Antibiotice's presence in the vicinity of the community where the respondents live include providing jobs for people in the local community (approx. 40% of respondents), closely followed by the importance of providing access to life-saving medicines (15 respondents, approx. 33%).

At the same time, Antibiotice is considered by 7 respondents as a symbol of Iasi, bringing national and world prestige to the city, and 6 respondents positively appreciate the a+ Friendship Park in the area, donated by the company to the local community.

Overall, respondents did not note any negative aspects of Antibiotice's presence in the local community. The most important negative aspect that emerges from the survey is related to air quality (smell) - 3 respondents.

Number of visitors:

270

Number of completed questionnaires:

46 (17%)



Among the topics related to Antibiotice's business about which respondents would like to know more information, those related to the company's products, manufacturing technologies and product quality control concerned 20 respondents (43.5%).

Another topic of interest for the local community is related to the jobs offered by the company and the programs dedicated to students (13 respondents).

## Consultations with local community representatives

As part of the dialogue processes with our stakeholders, in April 2022, a meeting was held at Antibiotice's headquarters with representatives of the institutions we are constantly in contact with, on the topic of *Environmental protection - opportunities and challenges*. In addition to the feedback we received from the participants, the meeting also included a visit to the production site, followed by a presentation of the company's activity and the main investment projects undertaken to reduce our environmental impact.



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# 1.7. Awards, ratings, and affiliations

## Our awards

### Romanian Chamber of Commerce and Industry

- **1<sup>st</sup> prize, 1<sup>st</sup> place in the category "Industry - Very large enterprises - Manufacture of basic pharmaceutical products"**

### Iasi Chamber of Commerce and Industry

- 1<sup>st</sup> place in the category "Industry - Very large enterprises - Manufacture of basic pharmaceutical products"**

Antibiotice has been among the elite of Romanian companies for over two decades, ranking first in its field for business excellence. For the ranking, which aims to compile the National Top Companies 2022, several indicators are considered, such as net turnover, operating profit rate, operating profit, human resources efficiency, and employed capital efficiency.

In the 2022 edition, of the 3,319 companies ranked at the top of Iasi County, 383 companies were ranked in the National Top (33 more than in the previous edition). 40 companies were ranked 1<sup>st</sup> nationally, 99 companies were ranked 2<sup>nd</sup>-3<sup>rd</sup> and 244 companies were ranked 4<sup>th</sup>-10<sup>th</sup>.

### Romanian CSR Awards 2022, Sustainable Companies Gala

At the 11<sup>th</sup> edition of the Romanian CSR Awards competition, held on April 5, 2023, in Bucharest, the only one in Romania that annually rewards the best sustainability and social responsibility projects that have contributed to improving the quality of life of our country's communities, 250 companies attended the competition and entered 300 projects. Antibiotice's focus on responsible behavior towards the community and its employees was appreciated and recognized by the granting of two awards for the campaigns carried out in 2022.

- **3<sup>rd</sup> place in the Cross-Sector Partnership category, *Solidarity without Borders* campaign**

Through the *Solidarity without Borders* project, a total of 5,000 people benefited from medicines sent to hospitals in Ukraine and 1,000 people benefited from aid sent through the Red Cross.

- **Honorable mention in the Employee Support category, *Plus for Life!* campaign**

Through the *Plus for Life!* project, which consisted of first aid courses organized at Club a+ with SMURD, 100 employees and their children learned first aid measures

in various emergency situations, learning essential life-saving maneuvers. In addition, 400 employees were trained in first aid using an automatic defibrillator.

## Performance confirmed by the external evaluations

### Romanian Investors Relations Association (ARIR), Score 10 on the VEKTOR 2022 indicator

- **Diploma of Excellence in the category Excellent Investor Communication**

For the fourth consecutive year, Antibiotice Iasi received a score of 10 in the VEKTOR ranking, compiled by the Association for Investor Relations on the Romanian Stock Exchange (ARIR), which includes over 100 listed companies. The VEKTOR indicator assesses the quality of investor communication of listed companies based on 15 criteria in line with international best practices in the field.

## Sustainalytics

- **ESG (environmental, social and governance) assessment, Bucharest Stock Exchange, August 2022**

Antibiotice ranks 19<sup>th</sup> in the top 5% of the pharmaceutical sub-industry out of 452 companies worldwide in terms of ESG (Environmental, Social, Governance) performance, a set of non-financial criteria used by investors to assess the environmental, social, and governance performance and impact of companies. The ESG analysis was initiated in 2021 by the Bucharest Stock Exchange, together with Sustainalytics, one of the leading global providers of ESG ratings and analysis, and Antibiotice's ESG score for 2022 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.

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## Affiliations

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

Antibiotice SA has been a member of the CCI since 1990. Iasi Chamber of Commerce and Industry is a non-governmental and apolitical organization, which supports the interests of the business environment in Iasi County. Iasi 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.

Antibiotice SA is a member of the Board of Directors of the CCI Iasi, and the General Director of Antibiotice SA is the First Vice-President of the Chamber of Commerce and Industry (CCI) Iasi.

### > 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.

### > Romanian Association of Industrial Drug Manufacturers (PRIMER)

Antibiotice SA has been a PRIMER member since its foundation in 2017. PRIMER is a non-governmental association founded in 2017, which brings together the major pharmaceutical manufacturers with production facilities in Romania.

### > 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.

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



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## 2.1. Our products

Throughout the years we have remained true to our mission of making medicines so valuable to people more accessible as a means of health care for patients, doctors, and pharmacists. Partnerships with distributors facilitate the presence of Antibiotice medicines both in hospitals and pharmacies in Romania and in international markets where the company operates, thus contributing to and facilitating the achievement of the company's mission. Access to medicines for human use is ensured on the domestic market through a network of 7 national distributors, and for veterinary use through 4 distributors. On the international market, our medicines reach the 40 commercial and business branches in the territories where we export products for which we hold marketing authorizations, as well as through tenders in which we participate either directly or through our external partners.

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 nursery bacteria as standard, micronized and compacted nystatin. The majority 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 Iasi plant.





# Antibiotice top products

## Top 20 best-selling\* Antibiotice brands

The top 20 brands (by sales value) marketed by Antibiotice in 2022 recorded market sales of 303.66 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	Zinnat® (Glaxosmithkline), Xifia® (Alkaloid AD)
2	<b>Cefort®</b> 250 mg, 1 g and 2 g	ceftriaxonum	Antiinfectives for systemic use Other beta-lactam antibacterials Injectables	Medaxone® (Medochemie)
3	<b>Meropenem Atb®</b> 500 mg and 1 g	meropenemum	Antiinfectives for systemic use Other beta-lactam antibacterials Injectables	Meropenem Kabi (Fresenius)
4	<b>Nidoflor®</b>	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatological preparations Corticosteroids in combination with antibiotics Ointments	Triderm® (Organon)
5	<b>Colistină Atb®</b> 1,000,000 IU	colistini sulfas	Antiinfectives for systemic use Other antibacterials Injectables	Sole product
6	<b>Amoxiplus®</b> 1000 mg/200 mg	amoxicillinum + acidum clavulanicum	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Injectables	Sole product
7	<b>Amoxicilină 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	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoids for topical use Ointments	Procto Glyvenol (Recordati), Proctinum (Natur Product Zdrovit), Prestogel (Hip Pharma)
	<b>Hemorzon®</b> suppositories	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoids for topical use Suppositories	Cicatridina (Naturpharma Products), Prosto Glyvenol (Recordati)
10	<b>Paracetamol Atb®</b> 125 mg and 250 mg suppositories 500 mg tablets	paracetamolum	Central Nervous System Antipyretic analgesics Suppositories and tablets	Paracetamol (Zentiva), Paracetamol (Terapia), Paracetamol LPH (Labormed)

\* Data source: Cegedim Romania 2022

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Brand	Denumire comună internațională (DCI)	Clasă terapeutică și formă de administrare	Principalii competitori
11 Kanamicina H 5 mg/10 mg/g ophthalmic ointment	kanamycinum + hydrocortisonum	Sensitive organs Anti-inflammatories and anti-infectives with corticosteroids. Ointments	Tobradex (Novartis) Betabioptal (Farmila)
Kanamicina Atb® 10 mg/g ophthalmic ointment	kanamycinum	Sensitive organs Ophthalmic antiinfectives Ointments	Sole product
12 Ceftamil® 1 g	ceftazidimum	Antiinfectives for systemic use Other beta-lactam antibacterials Injectables	Sole product
13 Bisotens® 5 mg and 10 mg	bisoprololum	Cardiovascular system Beta-blockers Tablets	Concor® (Merck Kgaa), Bisogamma® (Wörwag Pharma), Sobyc® (Krka D. D.)
14 Nolet® 5 mg	nebivololum	Cardiovascular system Beta-blockers Tablets	Nebilet® (Menarini) Nevivolol Actavis (Teva)
15 Ampicillin Atb® 250 mg, 500 mg and 1 g	ampicillinum	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Capsules and injectables	Ampicilină® (Novartis), Ampicilină® (Farmex Company), Standacillin (Novartis)
16 Tetracycline Atb® 30 mg/g	tetracyclinum	Dermatological preparations Ointments	Sole product
Tetracycline Atb® 250 mg	tetracyclinum	Tetracycline Capsules	Sole product
17 Glycerin suppositories for adults and Glycerin suppositories for children	glycerolum	Digestive tract and metabolism Laxatives Suppositories	Dulcolax® (Sanofi), 4Lax® (Solacium Pharma), Glycerin suppositories (Dr. Max)
18 Clotrimazol Atb® 10 mg/g cream	clotrimazolum	Dermatological preparations Antifungals Ointments	Canesten (Bayer AG), Clotrimazol (Slavia Pharm) Clotrimazol MK (Fiterman Pharma)
19 Fluxiv® tablets	food supplement	Cardiovascular system Tonic for venous capillaries Tablets	Detralex® (Servier), Endolex® (Sun Wave Pharma), Devaricid® (Biofarm)
Fluxiv® cream	cosmetic product	Cardiovascular system Varicose veins therapy Ointments	Ruscoven (Aboca), Endolex® (Sun Wave Pharma), Troxevasin (Teva)
20 Saliform Forte® cream 100 g, 50 g and 25 g	fluocinoloni acetonidum + neomycinum	Dermatological preparations Corticosteroids in combination with antibiotics Ointments	Sindolor® (Fiterman Pharma), Deep Relief® (Laropharm), Dolorgiet® (Natur Produkt Zdrovit)



Top products for which Antibiotice is the sole manufacturer

The products for which Antibiotice is the sole producer on the Romanian market recorded sales of 173.7 million lei in 2022.

No	Product	International non-proprietary name (INN)	Therapeutic class and form of administration
1	Aceclofen®	diclofenacum + paracetamolum	Musculoskeletal system Suppositories
2	Amoxiplus® 1000 mg/200 mg	amoxicillinum + acidum clavulanicum	Antiinfectives for systemic use Powder for injection
3	Ampiplus® 1000 mg/500 mg	ampicillinum + sulbactamum	Antiinfectives for systemic use Powder for injection
4	Cicloserină Atb® 250 mg	cycloserinum	Antiinfectives for systemic use, tuberculosis treatment. Capsules
5	Clo-Ekarzin® 15 g	bethametasonum + clotrimazolum	Dermatological preparations Cream
6	Colistina Atb® 1,000,000 IU	sodium colistimethate	Antiinfectives for systemic use Powder for injection
7	Cutaben Bebe® 40 g and 100 g	zinc oxide + ichthammol + Vital ET®	Dermatological preparations Emollient and protective cream
8	Cutaden® 40 g	ichthammol + zinc oxide + extractum hamamelis	Dermatological preparations Protective cream
9	Fezivit®	vitamina C + fier + zinc	Dermatological preparations Other dermatological preparations Capsules
10	Fluocinolon N Atb® 18 g	fluocinoloni acetonidum + neomycini sulfas	Dermatological preparations Topical corticosteroid in combination Ointments
11	Fluxiv®	diosminum + hesperidinum + troxerutin + acidum ascorbicum	Cardiovascular system Food supplements with a role in the normal functioning of blood vessels Coated tablets
12	Fluxiv® tonic cream 40 g and 100 g	troxerutin + D-pantenol	Cardiovascular system Varicose vein therapy, topical product Cremă
13	Hemorzon® suppositories	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoid product for topical use Suppositories

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No	Product	International non-proprietary name (INN)	Therapeutic class and form of administration
14	Hemorzon® 18 g ointment	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoid product for topical use Ointments
15	Hidrocortizon Atb® 20 g ointment	hydrocortisonum	Dermatological preparations Ointments
16	Lejer®	senna + rhubarb + ginger + hibiscus	Digestive tract and metabolism. Laxatives Capsules
17	Lisinopril Atb® 40 mg	lisinoprilum	Cardiovascular system Angiotensin converting enzyme inhibitors Tablets
18	Moldamin® 1,200,000 IU	benzathini benzylpenicillinum	Antiinfectives for systemic use, broad-spectrum penicillins. Powder for injection
19	Nidoflor® 15 g	triamcinolonum + nystatinum + neomycinum	Dermatological preparations Cream
20	Nystatin Atb® Pessaries 100,000 IU	nystatinum	Gynecological antiinfectives Pessaries
21	Nystatin Atb® 500,000 IU	nystatinum	Intestinal anti-infectives Coated tablets
22	Oxacillin Atb® 1 g	oxacillinum	Antiinfectives for systemic use, penicillins Powder for injection
23	Penicillin G Atb® potassium 1,000,000 IU and Penicillin G Atb® sodium 400,000 IU and 1,000,000 IU	benzylpenicillinum	Antiinfectives for systemic use, broad-spectrum penicillins Powder for injection
24	Piafen®	metamizolum natricum + pitofenonum + fempipramidum	Digestive tract and metabolism. Antispasmodics in combination with analgesics. Tablets
25	Pyrazinamide Atb® 500 mg	pyrazinamidum	Antiinfectives for systemic use, tuberculosis treatment. Tablets
26	Saliform Forte® 25 g, 50 g and 100 g	methylis salicylas + levomentholum	Musculoskeletal system Cream
27	Silithor®	silimarinum + L-methioninum + L-cisteinum	Digestive tract and metabolism Hepatoprotective food supplement Capsules
28	Sinerdol® Capsiles 300 mg	rifampicinum	Antiinfectives for systemic use, tuberculosis treatment. Capsules





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No	Product	International non-proprietary name (INN)	Therapeutic class and form of administration
29	Sinerdol® ISO	rifampicinum + isoniazidum	Antiinfectives for systemic use, tuberculosis treatment. Capsules
30	Soriso®	rhodiola rosea + ocimum basilicum	Central Nervous System Adaptogen food supplement Coated tablets
31	Tetracycline Atb® HCL 30 mg/g	tetracyclinum	Dermatological preparations Ointment
32	Tinero® Gel 40 g	nicotinamidum	Dermatological preparations, anti-acne products. Ointment
33	Triamcinolon S Atb® 15 g	triamcinolonum + chlorquinaldolum	Dermatological preparations Cream
34	Zifex® Complex	metronidazolum + nystatinum + neomycini sulfas + hydrocortisonum	Gynecological antiinfectives Pessaries

\* Data source: Cegedim Romania 2022



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## 2.2. Strategic development

### Company consolidation in the domestic market

The 67-year presence on the Romanian market is a testament to the performance of Antibiotice's business model. The company's products are sold in Romania's 8,100 open-circuit pharmacies, 367 public hospitals, and 309<sup>1</sup> private hospital units (units with beds).

Antibiotice Iasi 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 the priorities behind the way Antibiotice does business is to ensure continuity in the distribution process so that patients, physicians, and pharmacists have access to the company's products. 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, and the number of independent pharmacies decreased year on year. Thus, Antibiotice has adapted its commercial and portfolio strategy, focusing on tailoring its product portfolio to the therapeutic trends and market segment evolution of each partner distributor's (patients) specific addressability segment. Long-term contracts have been concluded with the main distributors on a differentiated basis, by product portfolio, so that patients can be guaranteed continuity of treatment with the medicines recommended by the prescriber.

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 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. The role of this team is to also support our partner distributors in the effective communication of medical and commercial information in the field, in as many pharmacies and medical offices as possible.

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.

8,100

pharmacies

367

public hospitals

309

private hospitals

<sup>1</sup> According to the Ministry of Health



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

In 2022, the total value of the market in Romania (medicines dispensed from pharmacies to patients and consumers) was 25.78 billion lei, at distribution price, up 21.88% compared to 2021, representing a total consumption of medicines (in units) of 705.82 million boxes, up 7.17% compared to 2021.

The Romanian pharmaceutical market is dominated by prescription medicines (Rx), accounting for 73.6% of total sales value and 60.9% of total quantitative medicine consumption (reported in boxes).

Prescription medicines (Rx) had a value increase of 21.5% to 19 billion lei in 2022 (compared to 15.6 billion lei in 2021), while non-prescription non-Rx products

(OTC, dietary supplements, medical devices) had a value increase of 23.0% to 6.8 billion lei (compared to 5.5 billion lei in 2021).

The top five therapeutic classes, grouped according to the share of value sales in 2022, account for 70.2% of total sales on the Romanian pharmaceutical market, namely the digestive tract, antineoplastic drugs, cardiovascular system, central nervous system, and systemic anti-infectives.

Evolution of the generic and non-Rx market

Generic and Non-Rx drugs recorded a value of 11.7 billion lei in the period under review, up 21.4% compared to 2021 (9.6 billion lei). In 2022, the quantitative medicines consumption in the generics and non-Rx market increased by 7.4%

(522.7 million boxes were dispensed from pharmacies compared to 486.6 million boxes in 2021).

In 2022, prescription medicines (Rx) accounted for 41.7% of total value sales and 47.3% of total medicine consumption (reported as number of boxes), with a value increase of 19.1% (from 4.1 billion lei in 2021 to 4.9 billion lei) and a 5.5% quantity increase (from 243.2 million boxes in 2021 to 247.1 million boxes in 2022).

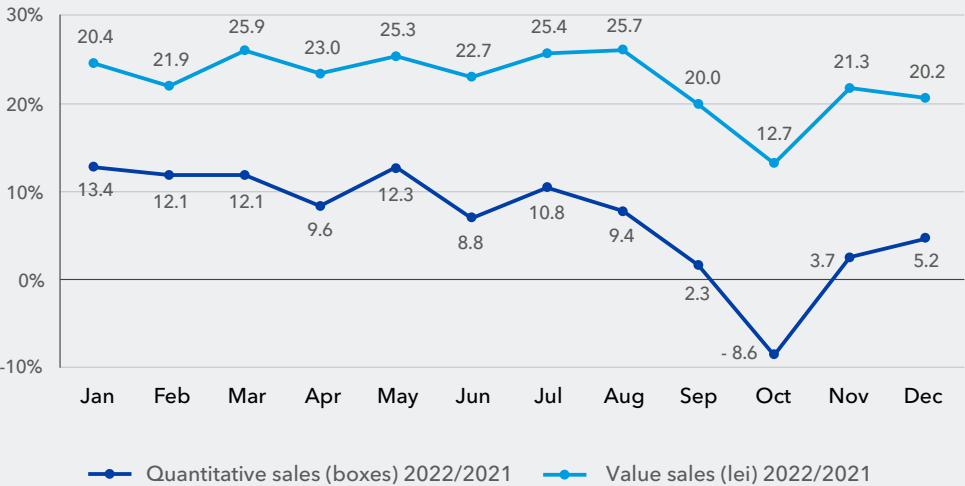
Non-prescription medicines (non-Rx) accounted for 58.3% of total value sales and 52.7% of total medicine consumption (reported as number of boxes), registering a value increase of 23.0% (from 5.5 billion lei in 2021 to 6.8 billion lei in 2022) and a quantity increase of 9.2% (from 252.5 million boxes in 2021 to 275.6 million boxes in 2022).

Antibiotice on the pharmaceutical market in Romania

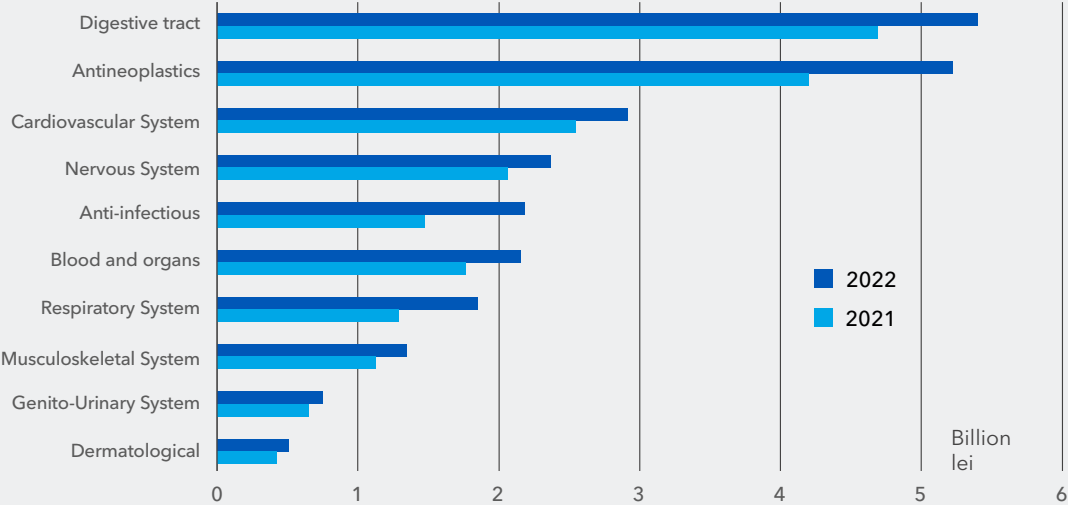
The sales value of Antibiotice's medicines to distributors in 2022 was 413.7 million lei (25.4 million boxes) and the sales value of distributors to hospitals and pharmacies was 432.3 million lei and consumption of 28.9 million boxes (133.5 million lei and 1.48 million boxes in the hospital segment and 298.7 million lei and 27.4 million boxes in the pharmacy segment). In the retail pharmacy segment, sales reached 99.4 million lei and 9.1 million boxes in pharmacy chains and 199.3 million lei, and 18.29 million boxes in independent pharmacies and mini chains.

According to District Sell-Out, Cegedim Customer Information in 2022, Antibiotice recorded quantitative sales of 27.4 million

Monthly evolution of the total market (2022 vs 2021)



Value evolution - Top 10 therapeutic classes (2022 vs 2021)

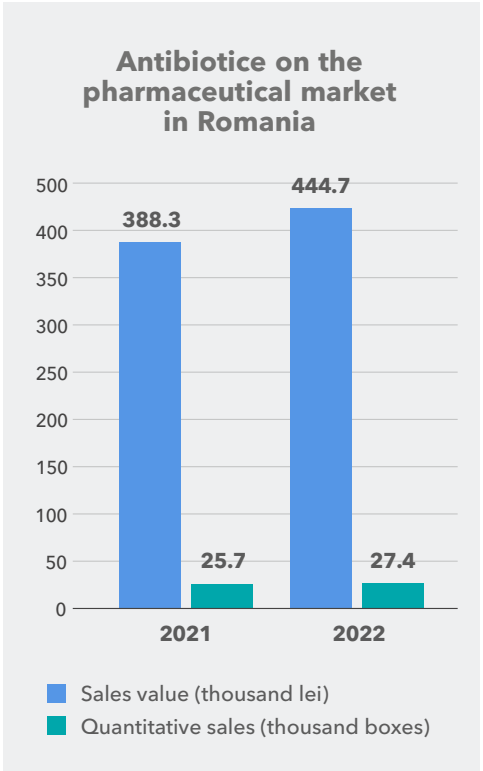


<sup>2</sup> According to Cegedim District Sell-Out, December 2022

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units (boxes) and a value of 444.7 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 2022 are Eficef® cps range, Amoxiplus® for injection 1,000mg/200mg, Ceftamil® for injection 1gr, Amoxicillin cps 500 mg, Ampiplus® for injection 1,000mg/500mg, Kanamycin® ophthalmic ointments, Paracetamol sup. range, Tigecycline Atb® inj 50 mg, Perasin® inj range and Novocalmin® suppositories.



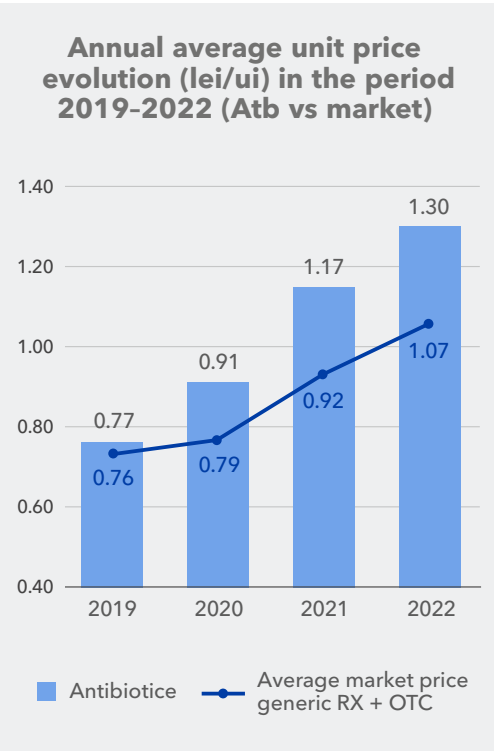
Our company has also strengthened its systemic anti-infective component, while also developing children's cold and flu products, women's health products, and ophthalmic products, where it holds important positions in the domestic market. Antibiotice has been in constant contact with distributors to ensure 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.

**Price, a strategic element of market adaptation**

The average market price of generics and non-Rx products in 2022 was 1.07 lei/unit (indivisible unit), up 16.5% compared to the same period last year (0.92 lei/unit).

In terms of sales channels, the highest price of medicines in the generics and non-Rx market was recorded in 2022 in the hospital channel: 5.32 lei/IU, of which injectables recorded a price of 8.6 lei/IU, an increase of 28.6% over last year. The independent pharmacy segment (MLFI) ranked second, with an average price in 2022 of 1.01 lei/IU (up 17.0% from 2021), and national chains recorded an average price in 2022 of 0.98 lei/IU (up 13.6% compared to 2021).

The average price of the Antibiotice portfolio in 2022 per indivisible unit was 1.3 lei/IU, up 11.3% from 1.17 lei/IU in 2021.



In terms of sales channels, the highest price was recorded by Antibiotice in 2022 in the hospital channel: 4.38 lei/IU, of which injectables recorded a price of 8.44 lei/IU, up +10.4% from last year. On the MLFI channel (mini-chain and independent pharmacies) in 2022 the recorded price was 1.08 lei/IU, up 10.0% compared to 2021, and in chain pharmacies, the average price in 2022 reached 0.87 lei/IU (up 12.4% compared to 2021).

**444.7**  
million lei in sales  
on the Romanian  
pharmaceuticals market

**27**  
million boxes sold  
to patients and  
consumers in Romania

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 104.6%.

In the retail segment, the focus on the development projects of the non-Rx product brands in the Nutriensa range resulted in the achievement of an optimal structure, with an average price of 0.73 lei/IU compared to 0.69 lei/IU in 2021.



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## Company consolidation on the external market

In 2022 also, Antibiotice placed Romania on the world map of sterile injectable penicillin manufacturers in the UK and USA.

Revenue from sales of finished products on the international market in 2022 amounted to 108.4 million lei, a 22% increase compared to the previous year. The growth rate far exceeds that of the global pharmaceutical market which, according to IQVIA analysts, was up 5%.

The international development strategy considered the fact that the markets have a high consumption potential for the products in the company's 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.

Benefiting from a diversified portfolio of around 50 products registered on foreign markets - mostly anti-infectives and cardiovascular drugs - Antibiotice confirms its status as an international manufacturer and supplier to healthcare systems in 2022.

Several performances achieved throughout 2022 are noteworthy in this regard, some of them confirming the consolidation strategy in established territories - Vietnam, USA, Canada, Moldova, Serbia, and the UK,

while others are starting points in the long-term development of the company: Germany, Italy, Spain, Poland, Czech Republic, Australia, Saudi Arabia, and South Africa.

Thus, according to market analyses reported by IQVIA, the "flagship" drugs that also define Antibiotice's core business such as penicillins (Ampicillin, Flucloxacillin, Nafcillin) and combination penicillins

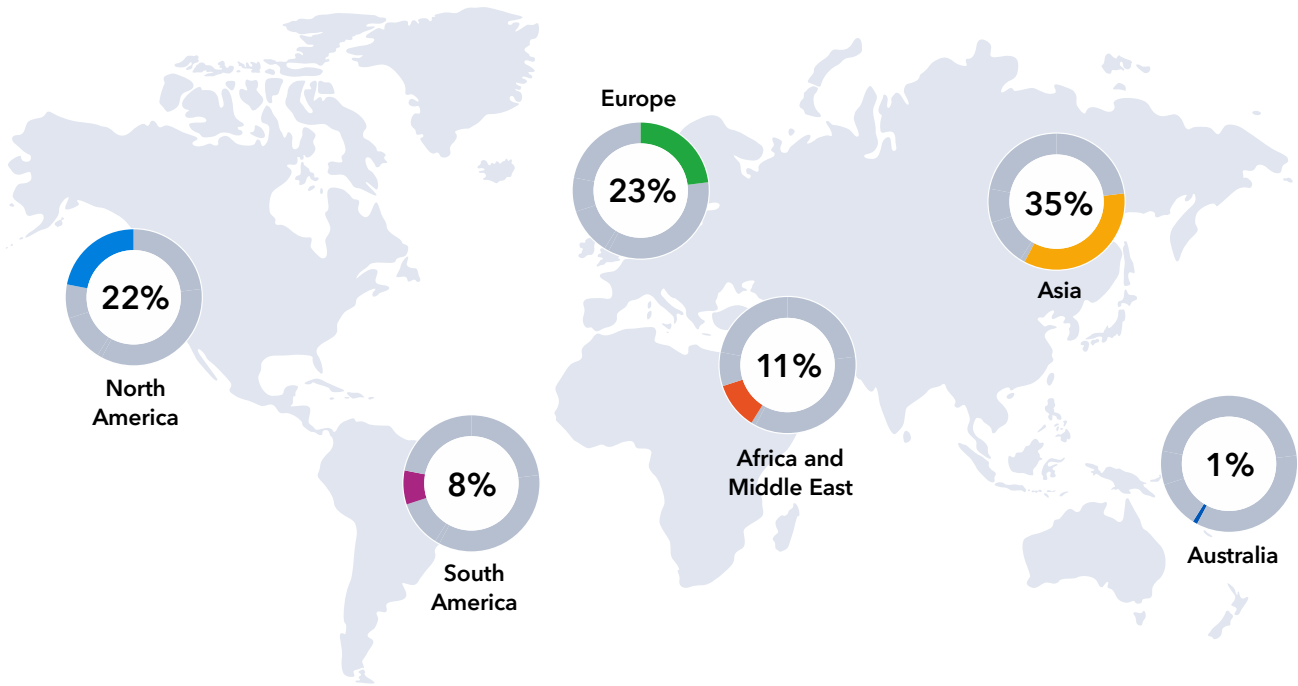
(Ampicillin/Sulbactam, Amoxicillin/Clavulanate, Piperacillin/Tazobactam) have reached significant market shares in national consumption in territories such as Vietnam (60%), UK (27%), USA (18%). Concretely, in these markets, at least 1 out of 5 patients benefited from Antibiotice products in the treatment of acute anti-infectious diseases.

Antibiotice's presence and projects in countries with significantly lower incomes or lack of access to health insurance, 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 2022, 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) accounting for approximately 7% of the total value of drug exports.

In 2022, Antibiotice responded to requests from the national health authorities of the Republic of Moldova and Malta to provide an emergency stock of a drug used in case of unintentional exposure to radioactive iodine. In addition, Antibiotice has initiated a donation project for Ukraine, delivering approximately 600,000 therapeutic units of anti-infective, anti-inflammatory, analgesic, anti-thermal, and disinfectant drugs.

Share of sales on the international market in 2022



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The territorial expansion plan aiming for the sustainable development of Antibiotice in the 2030s came to life in the 2022 stage by achieving three objectives:

- access to three new territories: Saudi Arabia (1 anti-infective medicine), Albania (3 anti-infective medicines and 2 topical products), and South Africa (6 cardiovascular medicines);
- contract negotiation with partners for the implementation of new projects that will generate significant growth in the coming years in countries such as Germany, Italy, Spain, Poland, Czech Republic, Bulgaria, United Arab Emirates, and Australia.
- 25 products launched in 5 territories covering various conditions: anti-infectives, anti-inflammatories, and dermatologicals.

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, 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 2022 Antibiotice was represented at CPhI Worldwide, which took place in Frankfurt, Germany, by a delegation of specialists in Research-Development, Procurement, Export, Marketing-Sales, and Business Development. CPhI Worldwide is a pharmaceutical industry event that brings together thousands of healthcare professionals annually.

Representative territories where the Antibiotice's finished products are supplied

Territories	Sector	Customer type
Romania	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.
Vietnam	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).
Republic of Moldova	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.
Serbia	Pharmaceutical	Human-use Rx drugs (only available by prescription), nutritional 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).
United Kingdom	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.
Denmark	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.
United States	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).
Irak	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

The war in Ukraine has delayed, only temporarily, the start of a new national project to market 25 products, mainly anti-infective and cardiovascular medicines. During the first half of 2022, we aimed to test this market, under its new conditions and selected 2 top products both in Antibiotice's international sales and in anti-infective therapeutics in hospitals. The products are Ampiplus 1.5 g (ampicillin/sulbactam) and Amoxiplus 1.2 g (amoxicillin/clavulanic acid).

We also maintained solidarity with our team in the Antibiotice representative office in Kiev and since the outbreak of the conflict, we have been in almost daily contact with them, having them visit Romania in 2022.

We will assess the economic and military conditions in this country, taking calculated and as far as possible, insured risks, and at the end of this pilot program we will decide whether to access the market with other products.

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 became 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.

Antibiotice 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 production and sales achieved in 2022 were in line with the trend of the last 3 years of strengthening the position on the international market, with the active substance Nystatin being sold on almost all continents: North America, South America, Europe, Asia, Africa, and Australia. In the United States, Antibiotice is the market leader for this product.

International customers' satisfaction level

The financial results of Antibiotice, professionalism, and reliability of how the company collaborates with the international partners are 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). The survey contains a series of statements that the customers are invited to grade. In 2022, following the analysis of the results, values greater than or equal to 91.25% were scored for all 20 topics in the questionnaire, resulting in a total score of 96.07%. With a satisfaction level of 100%, all customers interviewed confirmed also in 2022 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).

+22%

revenue from sales of finished products on the international market

1 in 5

patients benefited from Antibiotice products in countries like Vietnam and the UK

7.2

million lei sales in the Middle East and Africa

ATB Nystatin, international reference standard

ATB Nystatin is present on 6 continents

## Investments and related activities for strategic development

### Investments in sustainable development

A company of Antibiotice's complexity can only define ambitious business goals in close relation to sustainable investment projects.

In 2022, the company continued to invest in new product research and license acquisitions, new manufacturing sites, quality assurance equipment, upgrading of manufacturing technologies and infrastructure, and digitization of operations. By doing so, Antibiotice continues to develop sustainably so as to remain a strategic partner of the national healthcare system and a producer of essential and affordable medicines for the population.

In 2022, the investment value reached 47.48 million lei, according to the contracts concluded with the partner companies and the agreed project schedules. Antibiotice implemented the investment policy set out in the management plan approved at the General Meeting of Shareholders in April 2022, following the strategic directions.

### Investments in the strategic development of the company

An important component of strategic investments is product portfolio development, which includes in-house research and development of new, quality, safe and

efficient products, and licensing of new products. In 2022, the value of these investments was 12.36 million lei.

The development of new production sites, another direction in the strategic development, entailed allocating and spending 7,86 million lei in 2022.

In 2022 the new factory for the production of topical products (topical preparations), considered one of the most modern in Europe, was commissioned. Thus, the construction, installation, and equipment qualification operations were completed, including those related to the documentation required to receive the operating permit from the Romanian National Agency for Medicines and Medical Devices (NAMMDR).

This investment objective amounting to 100 million lei, financed from own sources, consists of 4 new production lines built to the highest manufacturing standards, where 56 topical products will be manufactured for both the Romanian and foreign markets. The capacity of the new manufacturing site is 50% higher than the current capacity.

In October 2022 the NAMMDR audit to authorize the four new manufacturing lines was carried out and resulted in the granting of authorization under the GMP good manufacturing practice regulations.

**47.48**  
million lei invested  
in 2022  
—  
The investment in  
the new plant for  
the production  
of topical products  
has been completed

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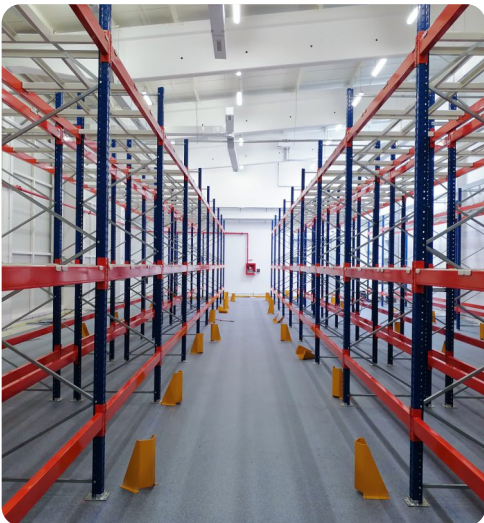
Investments for business consolidation

To consolidate the business, in 2022 investments were made in information technology, telecommunications, digitization of processes, and upgrading the infrastructure of the industrial platform, totaling 15.62 million lei.

As part of the plan to digitize and computerize the company's processes, priority was given to the purchase of software to streamline human resources activities, quality assurance, and research, and to secure data and information at all company levels.

Investments were also made to expand raw material storage capacity by 60% in order to increase and diversify the company's production.

In 2022, investments in utility production and transport infrastructure continued, which will lead to reduced utility consumption, and increased energy efficiency with a beneficial impact on the environment, while design and authorization activities were planned for the construction of a modern warehouse for finished products, adapted to the production estimated for 2030.



Important steps have also been made toward the transition to green energy, the implementation of new sustainable technologies, and the optimization of manufacturing processes, which will help maximize business returns and optimize costs.

Thus, in 2022, an important investment in renewable energy was initiated for the construction of a 2.52 MW photovoltaic plant that will provide more than 25% of the company's energy consumption. In 2023, it is planned to complete the photovoltaic park with an additional capacity for the production of renewable electricity, with an installed capacity of about 1.2 MW, which will provide for increased energy autonomy for about 35% of internal energy consumption.

Other investments were directed towards the re-engineering of the medicine manufacturing flows of the three divisions, as well as the maintenance of the Integrated Management System, namely the procurement of equipment to maintain the quality standards of the manufactured products and to comply with the legal requirements regarding the protection of the environment and employees. The investments amount to 11.63 million lei.



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## 2.3. Access to medicines

Access to medicines 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. 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 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 – manufacturer, local agent, distributor, 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.

In addition to our strategy to increase our international presence and our investment in research, development, and innovation stimulation projects, our efforts to improve access to medicines also include timely interventions when critical situations arise, and we are requested to help.

In 2022, amid the military conflict on our border, the company provided access to oral and injectable antibiotic medicines for 5,000 Ukrainian patients (600,000 therapeutic units of anti-infective, anti-inflammatory, analgesic, anti-thermal and disinfectant products worth 0.6 million lei) and manufactured, at the request of the Ministry of Health and the National Administration of State Reserves and Special Problems, 30 million tablets of potassium iodide needed to cover the needs of all Romanians in the event of a special situation. Our company responded also to requests received from the national health authorities of the Republic of Moldova and Malta to provide emergency stocks of the medicine used in case of unintentional exposure to radioactive iodine.

The Antibiotice portfolio provides, from the World Health Organization's list of

essential medicines, **49 medicines considered essential** (molecule + pharmaceutical form, for which we have marketing authorisation) according to the WHO classification (medicines that meet the health needs of the majority of the population, used in the treatment of the most common diseases).

**600,000**  
therapeutic units aid  
for 5,000 Ukrainian  
patients

We manufactured  
**30**  
million potassium  
iodide tablets





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## Pricing policy

The cost of medicines is a barrier to access, especially for people from vulnerable backgrounds or without adequate financial resources. Pricing policy thus significantly influences access to medicines, with a direct impact on health equity, sustainability of healthcare systems, but also on innovation and competition.

In Romania, as in the European Union as a whole, the healthcare system is facing increasing problems due to the very high cost of medicines, and thus access for the population, especially the elderly, can be limited. However, generic medicines bring significant savings to the healthcare system. Without generic medicines, the medicines financing system would not function and would be unsustainable. Off-patent medicines currently account for 92% of treatment volume in the EU, which means a 61% reduction in their cost during their market exclusivity phase. Thus, as the largest producer of generic medicines, Antibiotice generates a positive impact on the health of the population by facilitating access to affordable products and medicines.

The Antibiotice pricing policy complies with the specific legislation in force (Law no. 21/1996, republished), by observing the competitive practices and the ethical conduct in business, according to the company's internal codes: the Code of Ethics and the Code of Good Practice for the promotion of medicines issued on prescription and for interactions with the medical professionals.

- On the Romanian market, Antibiotice's products are priced differently depending on the category, i.e., prescription and non-prescription medicines, medical devices, food supplements, and cosmetics.

- For the medicines in the Antibiotice portfolio that are issued based on medical prescription (Rx), the establishment of prices is done 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 order, in order to determine the price of a prescription medicinal product, the proposed price is compared with the price of the same medicinal product authorized in 12 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 medicinal product in the list of countries with which the comparison is made. If the medicinal product 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).

- The prices of Antibiotice over-the-counter (OTC) medicines, medical devices, food supplements, and cosmetics are set and changed freely, taking into account the market requirements and trends.

- For the international market, prices of medicines are established by negotiation with external partners, in conditions of competitiveness 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, in conditions of competitiveness and transparency, 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:

**+5.5%**

➤ Average increase calculated per box:

**+12.6%**

In 2022, the product with the highest price increase in the reporting year (30%) was **Tetracycline ATB 250 mg capsules**, a unique 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

The focus of the R&D activity is the development of generic medicines and unique combinations in the topical, tablet, capsule, and 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.

In order to meet the highest standards, 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 patient access to valuable new generic medicines and innovative products.

Research activities are permanently focused on responding to the most pressing demands and needs in the market in a sustainable way so that people benefit from the best treatments. Research and development is also extremely important to ensure the economic sustainability of the company. The products and technologies developed in the research department, which will fund the company's future development, 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 has the ability to develop innovative products, which once introduced into the company's portfolio will increase its economic competitiveness.

The company is constantly developing its research and development sector, so refresher courses for staff in this sector and facilitating access to information are a priority, with a particular focus on improving research and technical skills and increasing innovation capacity.

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R&D projects for a new product in 2022





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Portfolio and products

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

- developing the company's innovation capacity, including 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.

New product R&D projects and/or product updates of the current portfolio with a focus on going international, specific to each of the company's three divisions, are multi-year projects and are quantified in research phases.

**In 2022, activities were carried out for the following projects:**

- 17** new product projects for the Topical Products Division;
- 7** new product projects for the Oral Solid Forms Division;
- 3** new product projects for the Sterile Injectables and Active Substances Division.



Alongside the new product projects, we upgraded 10 products in the company's portfolio: 7 topical products and 3 sterile injectable products, required in order to comply with the current legislation requirements for the registration of products in new markets.

At the end of 2022, there were 37 active research projects in various research stages in the R&D activity.

In 2022, the total value of R&D projects amounted to approximately 9 million lei.

To ensure portfolio renewal, additional funds of up to 12.36 million lei were invested for the purchase of product licenses and upgrading of research laboratories.

Partnerships and collaboration are extremely important elements in R&D. Thus, the company has various collaborations with academic partners and research institutions, which strengthen the relationship between research, development, and production, and in the future will lead to increased innovation in the production of medicines and materials for the pharmaceutical/cosmetic industry.

Thus, a large-scale project is underway within the company to develop a new Inova a+ Research and Development Centre, with two main objectives:

- 1)** partnerships with academia (universities and research centers in the country and abroad) based on experimental and applied research;
- 2)** development of the portfolio of added-value generic medicines through innovative solutions in their development (e.g., nano-structured medicines, soft capsules, duo-caps, etc.).

The advantages of such added-value generic medicines are:

- the possibility to administer several medicinal substances at the same time, thus reducing the number of medicines prescribed to patients;
- increasing the effectiveness of the active substance, which will reduce the doses required for treatment and thus reduce the toxicity associated with treatment;

To this end, various collaboration contracts have been concluded with academic partners and research institutions. New/innovative projects agreed with academic partners such as the University of Life Sciences “Ion Ionescu de la Brad” Iasi, “Alexandru Ioan Cuza” University Iasi, “Gheorghe Asachi” Technical University Iasi, and “Petru Poni” Institute of Macromolecular Chemistry Iasi are of major interest for both basic and applied scientific research that will lead to the improvement of the healthcare system.

Currently, fundamental research projects containing innovative medicine formulations are being carried out in collaboration with the “Gheorghe Asachi” Technical University of Iasi and the “Petru Poni” Institute of Macromolecular Chemistry of Iasi.

At the same time, with the increasing emphasis on environmental protection, Antibiotice has relaunched the production of biofertilizers. Ecofertil P is a 100% natural product that successfully replaces

soil-damaging pesticides and is used to remediate eroded soils and improve crops. Currently, a research project is being carried out in collaboration with the “Ion Ionescu de la Brad” University of Life Sciences Iasi, where the biofertilizers developed within Antibiotice are being analyzed and tested to demonstrate their effectiveness on different crops. Such products aim to support responsible production in order to protect the biosphere, natural resources, agriculture, and soil.

37  
active research  
projects

34  
in-licensing  
projects for  
new products

In-licensing projects

Through Business Development, 34 new products were licensed in 2022, of which:

- 26 prescription products
- 8 over-the-counter products

These products will complement the portfolio of prescription medicines (Rx) of the following pharmaceutical forms:

- Oral solid forms from the following therapeutic classes: Cardiovasculars – 8 products, Anticoagulants – 2 products, Antidiabetics – 2 products, Systemic hormonal preparations – 1 product, Musculoskeletal system – 1 product, Central nervous system – 1 product;
- Injectable products in the following therapeutic classes: Antiinfectives – 10 products, Alimentary tract – 1 product.

Of the products contracted in 2022, 6 will be launched for sale in 2023, the others to be launched in 2024–2026, depending on the progress of registration procedures.

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# 2.5. Patient and consumer health and safety

## Quality of our products

The quality of products and manufacturing processes is a key element in the pharmaceutical industry and is essential to protect the safety of patients and consumers, provide effective medicines and treatments, ensure regulatory compliance, and protect the company's reputation.

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

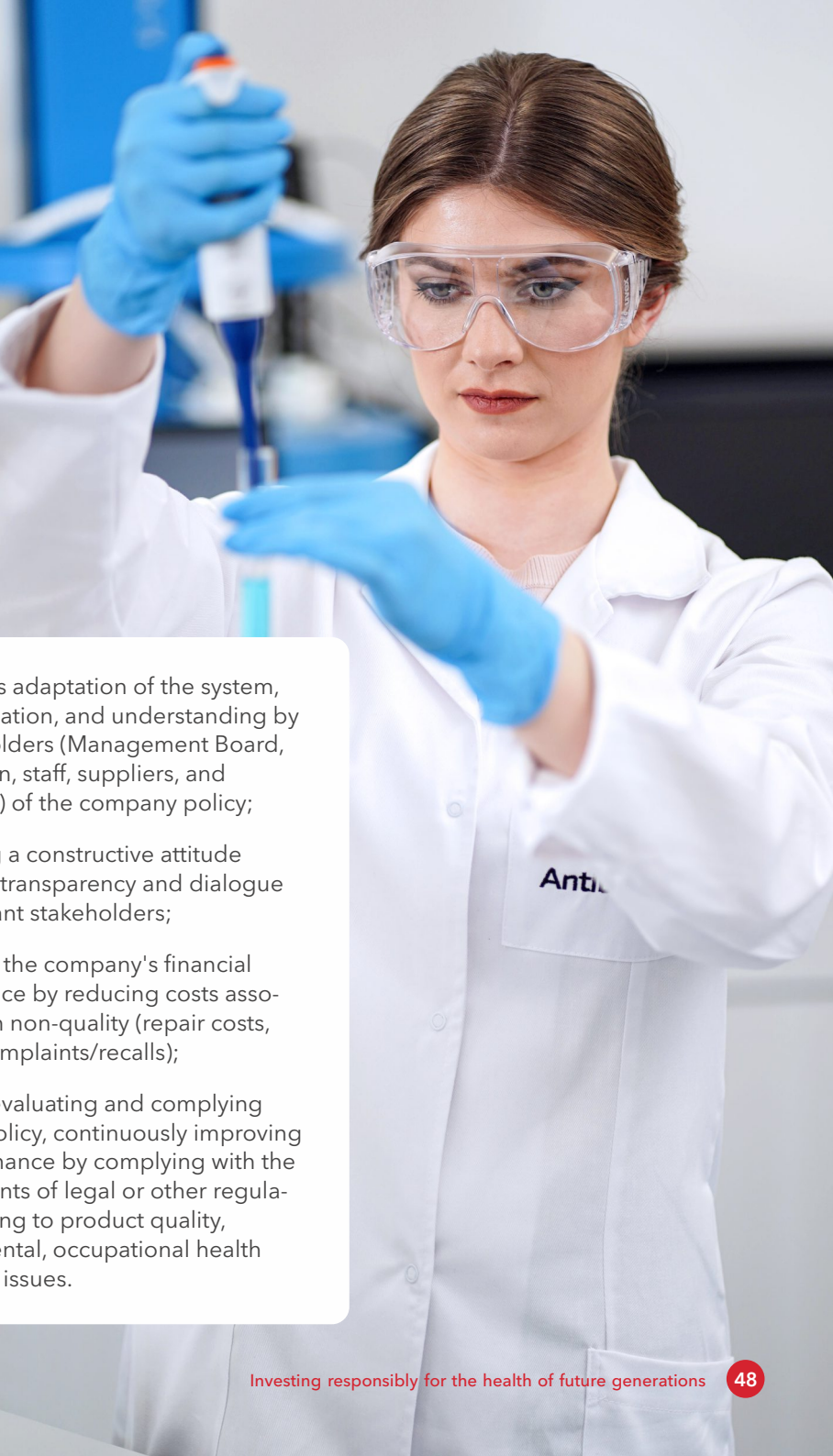
The policy is implemented aiming:

- continuous performance improvement by strict control of the impact of all activities carried out within the company;
- providing products and services of the highest quality in accordance with 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;
- continuous improvement of 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, occupational health and safety issues.





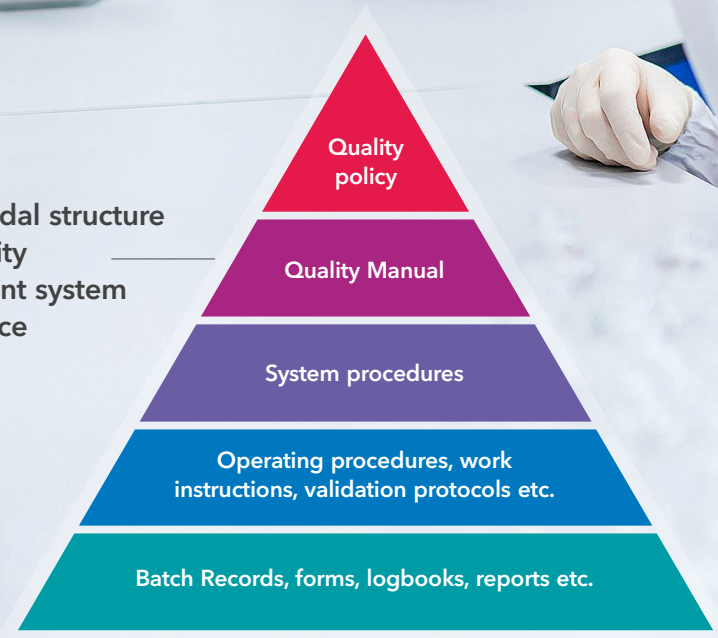
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To ensure the operation of the Integrated Management System, objectives are set, regularly monitored, measured, and evaluated by top management. In addition, all company employees are trained and informed about the methods of the management system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

The production site is organized into eight dedicated manufacturing 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 Antibiotice products area uthorized.

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 the growth of the 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 (NAMMDR, ANSVSA) and international bodies (US-FDA), by certification bodies (TÜV Rheinland, SRAC) and by business partners.

The pyramidal structure of the quality management system at Antibiotice





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Standards, licenses, authorizations, and certificates valid on December 31, 2022	Issuing organization	Date of certification	Description	Next steps
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 Good manufacturing Practice certificate</li></ul>	NAMMDR	December 6, 2022	Issuance of Manufacturing Authorization #30F / Dec. 6, 2022	Annual notification to NAMMDR of changes to the information provided.
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	Validity period of the certificates is 3 years from the date of inspection (October 14, 2022).
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.
Regulations, and laws specific to the medical devices field: <ul style="list-style-type: none"><li>• Law No 95/2006 republished, Title XX Medical devices</li><li>• Order #566/2020 on the approval of activities in the field of medical devices</li><li>• European Medical Devices Regulation 2017/745</li></ul>	NAMMDR	January 30, 2023	Issuance of the Operating License to the economic agent Antibiotice SA for medical devices distribution activities #8680 / 31.01.2023	Validity period of the Certificate is 3 years from the date of issue.
ISO 9001:2015 Standard Quality Management systems	TUV Rheinland Romania	January 12, 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 45001:2018 Occupational health and safety management systems Standard	TUV 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 14001:2015 Environmental management systems Standard	TUV 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).
Certificate of Good Laboratory Practice (GLP) for the CSC Bioanalytical Laboratory	NAMMDR	Extended	Certificate of Good Laboratory Practice, issued on July 5, 2017	This GLP Certificate has been successively extended, as a result of the pandemic, by an NAMMDR letter of August 11, 2020, and an NAMMDR letter of February 17, 2022, until the next NAMMDR inspection.
Certificate of Good Manufacturing Practice for human use medicines flow for clinical investigation	NAMMDR	December 6, 2022	Certificate of Good Manufacturing Practice, issued on December 6, 2022	This Certificate is valid until October 2025

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Inspections and audits in 2022

In 2022, a total of 6 audits were conducted by the Antibiotice's partners, i.e., customers of the active substance Nystatin:

- Onsite audit manufacturing and testing flow partner for parenteral products manufactured under contract;
- On-paper audit manufacturing and testing flow partner for parenteral products manufactured under contract;
- Onsite audit partner for Nystatin manufacturing flow;
- Onsite audit partner for Nystatin manufacturing flow;
- Diapharm/Blue inspection onsite audit for Nystatin manufacturing flow;
- Remote audit partner specialized in Pharmacovigilance & QA for oral products manufactured under contract

The audits were carried out under optimal working conditions at the facilities concerned, concluding with several minor observations and/or recommendations, with no major or critical non-conformities identified.

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**, 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**). 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, 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, 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 2022, 49 complaints were received. Of these, internal investigations revealed that 29 complaints were justified and 20 unjustified.

Product quality complaints

Complaint Issuer	Number	Description
Pacients	1	<ul style="list-style-type: none"><li>Issues related to the physical appearance of the product</li></ul>
Pharmacies	2	<ul style="list-style-type: none"><li>Issues with the quantity of packaged product (missing blister/leaflet/vial from secondary packaging)</li><li>Physical appearance issues related to product labeling - Product label damaged / removed / missing / missing text</li></ul>
Hospitals	4	<ul style="list-style-type: none"><li>Physical contamination of the product</li><li>Issues related to the physical appearance of the product - reconstitution</li></ul>
Distributors	13	<ul style="list-style-type: none"><li>Issues with primary packaging (missing seal / damage / leaking / faulty tube closure)</li><li>Issues with the quantity of packaged products (missing secondary packaging from tertiary packaging)</li><li>Issues with secondary/tertiary product packaging (damaged)</li></ul>
International partners	24	<ul style="list-style-type: none"><li>Issues related to the physical appearance of the product - taste/smell</li><li>Issues related to product/batch expiry date - illegible/incorrect/missing</li><li>Out-of-specification results</li><li>Issues with secondary/tertiary product packaging (damaged)</li></ul>
Regulatory agencies	5	<ul style="list-style-type: none"><li>Physical contamination of the product</li><li>Out-of-specifications results</li><li>Missing the leaflet</li><li>Issues with the quantity of packaged product (missing blister/ leaflet vial from secondary packaging)</li><li>Issues with lot/product expiry date - illegible/incorrect/missing</li><li>Issues with a product closure system (tamper evidence)</li></ul>



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At the same time, there was an incident of non-compliance with legislative regulations on the impact of products on the health and safety of patients, which resulted in a warning. The incident consisted of an error in a product leaflet (identical sodium content for both concentrations of the product). As a result of the incident, approval was received for a variation to change the incorrect leaflet (as a corrective measure) and a Caution in Use Notice to healthcare professionals (immediate correction) was published on the MHRA website for the batch in question.

As a result of the investigations, depending on the nature of the identified root cause, corrective actions were proposed, such as the purchase of new external vial decontamination equipment, upgrade of manufacturing equipment (e.g., sensor fitting), proofreading of leaflets, vial labels, change of secondary packaging sizes, relabeling of vials, revision of internal documents (procedures, work instructions, etc.), including staff training.

**In 2022 there were no cases of recalled/withdrawn products. There was one case of 13 batches of product being recalled from the market and relabeled with revised vial labels approved by the competent authority.**

**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  $\text{TiO}_2$ ; 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 physicochemical 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, the Commission mentions a 3-year period during which it undertakes, based on scientific evidence, to re-examine the need to maintain titanium dioxide or remove it from the list of food additives used in the European Union. This review must be carried out by April 1, 2024. The European Medicines Agency (EMA) also



declared that a 10-year transition period may be needed to phase out titanium dioxide from medicines, as many products need to be individually assessed, reformulated, and tested.

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. Antibiotice has taken all necessary actions to replace titanium dioxide in food supplements while ensuring that their properties are preserved.

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Thus, Silithor®, Equilibra®, SimbiFlora® Forte, or SimbiFlora® Complex food supplements manufactured after August 7, 2022 do not contain titanium dioxide, and Fezivit® C and Lejer® will also enter the production flow with the new titanium dioxide-free formula. In order to reduce the visual impact on patients, who are used to a certain appearance and color of the capsule, the aim was to identify vegetable capsules with natural pigments, so that the color of the new product is close to the color of the previous product on the market. As regards the develop-

ment of new medicines through in-house research, the company is already considering replacing titanium dioxide in the formulation phase with other compounds considered safe.

Implementing the provisions on nitrosamines in 2022

During 2022, the European Medicines Agency revised the information on nitrosamines by updating the document on the presence of nitrosamine impurities in medicinal products for human use

(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).

The updated information is presented below as follows:

- **March 24, 2022:** new risk factors have been identified that may lead to the formation of nitrosamines (the most significant would be the formation of N-nitroso impurity, NO-API, on the finished product, e.g., n-nitroso ramipril).
- **June 23, 2022:** DAPP must maintain product quality by continuously assessing the risk of nitrosamine formation, even if it has submitted the Step 1-No Risk declaration. In this case, manufacturers and collaborating partners are continuously assessed to reduce the risk of nitrosamines occurrence in Antibiotice products.
- **July 29, 2022:** the deadline to submit step 3 declarations (submission of variations) is extended to October 1, 2023, but without affecting the deadline for step 2 which remained September 26, 2022, deadlines that Antibiotice managed to meet.
- **October 10, 2022:** Temporary limit of 178 ng/day is set for marketed medicines identified as containing one or

more nitrosamines exceeding the threshold of theoretical concern (TTC) of 18 ng/day. The adoption of the temporary acceptable intake (t-AI) is not automatic and is assessed by the relevant authorities at the time of notification. Use of t-AI beyond 12 months will require further consultation with the competent authorities.

- **December 5, 2022:** 6 additional nitrosamines with calculated acceptance limits were introduced.

E171  
replaced from all dietary  
supplements in the  
Antibiotice portfolio



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## Pharmacovigilance

Pharmacovigilance covers all the activities of detection, evaluation, validation, and prevention of adverse reactions or any problems associated with the use of medicinal products for which there are marketing authoriza-tions. Pharmacovigilance is the legal obligation by which each manufacturer of medicines guarantees the safe use of the medicines that the company manufactures, according to the requirements of the regulatory authorities in the field of medicines at the European level (European Medicines Agency – EMA) and at national level (National Agency for Medicines and Medical Devices in Romania – NAMMDR). Thus, pharmacovigilance contributes to the protection of public health and patients.

### Pharmacovigilance for medicinal products for human use

At Antibiotice, all the information on the safety of the use of medicines is evaluated, maintained, and communicated to the regulatory authorities throughout the life cycle of the products (including in the pre-authorization and post-authorization stages). Any medicine can also have side effects, so Antibiotice closely monitors the occurrence of such events, by using all sources and by observing the obligation to report to the authorities the information on the safety of our medicines and to implement appropriate measures if the benefit- risk ratio\* of a medicine changes.

The pharmacovigilance specialists monitor, identify, assess, report, and establish, through risk management plans, the potential risks associated with the use of Antibiotice medicinal products for human use. The main activities of the Scientific and Pharmacovigilance Department, the internal pharmacovigilance structure of Antibiotice are:

- collection of adverse reactions from physicians, pharmacists, and patients to monitor the frequency of known adverse reactions to the medicines in the portfolio;
- analysis and dissemination of information necessary for the correct prescription of the company's

medicines for the rational and safe use of medicinal products;

- evaluation and communication of the risk – benefit ratio for all the company's medicines on the market and their transmission to the competent authorities of the territories where they are placed on the market.

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.

Antibiotice is connected to the European Pharmacovigilance database, EudraVigilance, providing patients with access to reporting of suspected adverse reactions, through available forms, promoted to healthcare professionals through medical and sales representatives, or on the company's website.

Thus, for the reporting of suspected adverse reactions on 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 +40728 199 834 or through the phone switchboard, at +40 232 209 501;

\* The benefit-risk ratio refers to the weighting of the benefits of a medicine (positive effects) in relation to the associated risks (adverse reactions). Sometimes known as the risk- benefit ratio, it must be considered favorable for a medicinal product to be authorized. The benefits and risks associated with medicines are constantly monitored to confirm that the benefits outweigh the risks (Eudra Vigilance Glossary, <https://www.adrreports.eu/ro/glossary.html>).

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The adverse reactions received by the Scientific and 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 maximum of 15 days for severe adverse reactions and 90 days for non-severe adverse reactions.

During 2022, for the medicines for human use, 10 adverse reactions were reported to Antibiotice, of which 7 were non-severe and 3 severe.

The 10 adverse reaction reports were received as follows:

- 4 adverse reaction reports from health professionals (physicians and pharmacists);
- 6 adverse reaction reports from pharmaceutical companies.

In 2022, Antibiotice's Scientific and Pharmacovigilance Department responded to a questionnaire to assess the potential risk of the company's pharmacovigilance activities requested by an external partner. Furthermore, an external partner conducted a pharmacovigilance audit at Antibiotice, which found no critical or major deficiencies.

## Product marketing and promotion

Pharmaceutical industry benefits from a strong regulatory framework, both in terms of promoting pharmaceutical products and their labeling. Policies and procedures that describe the internal framework for carrying out product promotion and labeling processes are based on the legislative regulations in force, both at the national and international level (specific to each country), as well as good practice standards specific for the pharmaceutical industry.

### Promotion strategies

The promotion of the products from the Antibiotice portfolio is a priority activity from the long-term development strategy of the company, which is achieved through:

- strengthening partnerships with health 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 for promoting our non-RX product portfolio in their catalogs;
  - accessing alternative promotion channels: online, TV; e-commerce - partner pharmacies for non-RX products
- In 2022, 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 health 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 to the health professionals, physicists, and pharmacists aims to increase the awareness of product brands in the portfolios of therapeutic classes: antiinfectives, dermatological preparations, genitourinary system, musculoskeletal system, and the range of Nutriensa® 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 2022, 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.



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**Communication with healthcare professionals** was also achieved through participation in national congresses and conferences organized by the main professional, academic, and scientific societies, and associations in Romania, of the medical specialties in the focus of communication and partnership development actions: ICU, infectious diseases, obstetrics-gynecology, urology, dermatology, ENT, family medicine and pharmacy. Communication was also continued through multiple information channels, i.e., online. Webinars dedicated to health professionals were organized through communication platforms.

**Communication with the general public** was carried out through numerous actions, including TV and radio promotion campaigns, social media platforms, product and product range websites, trade magazines, or other special online and offline communication projects dedicated to the general public.

- Integrated communication campaigns to the general public: TV and radio
  - Silithor® food supplement – national TV promotion campaign: “Silithor® – no half measures”
  - continued TV promotional campaigns for the Fluxiv® range of tablets and cream, with the promoted message “Fluxiv®, boost your blood ”

- the market launch of the OTC medicine Clafen® rapid (gel, diclofenac diethylamine 11.6 mg/gram), the newest product developed under the Clafen® brand. Clafen® rapid brings additional benefits to consumers both through its rapid action in relieving pain and inflammation, being active in joint, muscle, and back pain, but also due to its special formula designed for absorption by massage. Clafen® Rapid has also been promoted since October through a TV campaign.

- TV communication through co-branding projects with partners, chain pharmacies, and regional and national mini chains to promote the Nutriensa® range of food supplements by continuing previously started campaigns and initiating new partnerships.

- Radio promotion campaigns on top ranked national channels: Radio ZU, DIGI FM and PRO FM.

- Online communication channel: Social Media

- Active Facebook and Instagram pages: Nutriensa®, Cutaden®, Tinero®
- Tik Tok Channel – @coolonia.tinero
- Metaverse Nutriensa® – a virtual space to promote the Nutriensa® range dedicated to the general public and health professionals.

Cum ar fi ca tot ce primești să fie pe jumătate?  
La fel e și cu sănătatea ficatului tău.



**Silithor® acționează fără jumătăți de măsură!**  
Silithor®, formulă unică cu acțiune complexă, intervine în ambele faze de detoxifiere hepatică.

Antibiotice **a+** Nutriensa®

**Fluxiv®**  
Circulație sănătoasă la activ



**Fluxiv® comprimate** contribuie la sănătatea circulației vasculare

**Fluxiv® cremă tonică** contribuie la menținerea elasticității, hidratării și tonicității pielii

Când tu stai, circulația ta nu trebuie să stea și ea

Antibiotice **a+**

Durerea îți face probleme?  
Când durerea nu cedează, **Clafen® rapid** acționează.

➤ Conține diclofenac dietilamină  
➤ Formula creată pentru absorbție prin masaj  
➤ Reduce durerea și inflamația  
➤ Activ în dureri articulare, musculare și de spate



Acest medicament conține diclofenac dietilamină și se poate elibera fără prescripție medicală. Se recomandă citirea cu atenție a prospectului sau a informațiilor de pe ambalaj. Dacă apar senzații neplăcute, adresați-vă medicului sau farmacistului.  
Foaie de publicitate numărul 5357/16.10.2022

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On this platform, a LIVE webinar dedi-cated to the Simbiflora® range of symbiotics, the newest products in the Nutriensa® range, was held in September. During the webinar, national opinion leaders addressed topics related to the benefits of symbiotic administration in various therapeutic areas. The format of the webinar was a first, as it was broad-cast LIVE in a virtual environment where healthcare professionals could log in and visit the presen-tation booths of each Nutriensa® product.

- Product and product range sites: active sites: Nutriensa®, Tinero®, Cutaden®.
- Special online and offline communication projects dedicated to the general public:
  - Promotional campaigns across communities and communication platforms for targeted audiences. Websites: [desprecopii.com](https://desprecopii.com) and [clubulbebelusilor.ro](https://clubulbebelusilor.ro). Campaign objectives focused on increasing the visibility of product brands in mommy communities, with over 3.5 million views.
  - Editorial project in online women's lifestyle magazines. The promotio-nal project called "Everyday thera-pies" is an editorial project that aims to inspire the female audience to choose a healthy lifestyle by raising awareness of proven

effective ways to maintain everyday health, and advice given by medical professionals. The campaign is targeted at women because of the important role women play, inclu-ding as a deciding factor in the purchase of medicines to maintain family health. Articles were publi-shed about the Nutriensa® range of food supplements, including Imunofix® for immunity support, Equilibra® capsules for energy every day, Soriso® for well-being, and the Fluxiv® range contributing to vascular health.

- In the October issue of Psychologies - the ecosystem of well-being, Soriso®, the Nutriensa® brand adaptogenic food supple-ment, was promoted.
- Promotion of the Fluxiv range of tablets and creams as part of the Super Pietonii Tour - Zurli Gang - in two cities (Timisoara and Oradea), five shows. A raffle with prizes consisting of Nutriensa kits was organized at each concert. In 2023, the campaign will continue nationwide in 11 cities and over 25 performances. The campaign will also be promoted on social media, on the Nutriensa and Zurli Gang Facebook and Instagram pages.





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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 accordance with the legislation in force. In our company, the coordinator of the promotion activity is the promotion manager. The Medical Department ensures the proper registration of materials used in promotional activities in accordance with the applicable laws, and the Marketing 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 42 members of the promotion department team, depending on the area for which it was organized.

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. They will ensure the correct transmission of information on generic medicines to medical professionals. 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 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 read online, on [www.antibiotice.ro](http://www.antibiotice.ro), Corporate



In the year 2022, the company did not record fines, warnings or penalties for non-compliance with legislative regulations in force or the codes undertaken voluntarily, related to the promotion of products.

Governance, Reference Documents section. The Code stipulates, inter alia, that the promotion of prescription-only medicines should be directed only to medical or pharmaceutical professionals. At the same time, 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.

The promotion activity includes:

- promoting products to health professionals: visits of medical representatives to persons qualified to prescribe drugs, provision of promotional materials and samples, organization of group presentations, round tables, webinars,

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 people qualified to distribute medicinal products;
- promoting products intended for the general public (according to the RASCI Code of Ethics 2021 and Law no. 56/31.03.2021 on food supplements).

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“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.

The campaign was launched in 2022 as part of the “European Antibiotic Awareness Day” on November 18 and the “World Antimicrobial Awareness Week” (November 18-24) and is part of the “Antibiotics of the Third Millennium” project.

The campaign was developed based on two components:

1 Communication with and for healthcare professionals:

- Workshop sessions for resident physicians with discussions of clinical cases under the guidance of academics specialized in infectious diseases (100 resident physicians of different specialties from the university centers of Iasi and Bucharest participated);
- Training sessions on the correct use of antibiotics conducted by academics working in Infectious Diseases and Pharmacy (200 medical students and pharmacists from the two university centers in Iasi and Bucharest participated).

2 Information actions addressed to the general public

As part of the campaign, on November 18, 2022, an action was organized in which student volunteers, together with Antibiotice representatives, offered passers-by information materials on the responsible use of antibiotics. In addition, medical students from Iasi organized a flashmob on Stefan cel Mare și Sfânt Boulevard, attended by 60 young people, to draw attention in a unique way to the importance of responsible and correct use of life-saving antibiotics.

Also, as part of the campaign “Treat antibiotics with care for a care-free future!”, a national awareness-raising campaign with the support of Radio Europa FM took place from November 18-24, 2022, during the “Health Minute” broadcast with renowned physicians from different medical specialties.

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 antibiotic use, targeting a community of patients and the general public, physicians, nurses, pharmacists, manufacturers, environmental experts, academics, and entrepreneurs. 13,500 people accessed the platform in 2022.

On this platform, in the same year, the first two episodes of the podcast *Antibiotics of the Third Millennium*, moderated by

Dr. Stefan Busnatu, were launched, bringing into the debate topics such as:

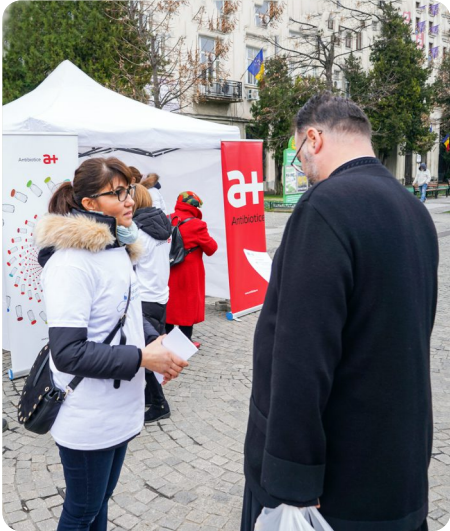
- The need for information on antibiotic therapy;
- Principles of correct antibiotic use;
- Challenges in the use of antibiotics in the family doctor's office;
- Maintaining antibiotic effectiveness

Also, as part of the *Antibiotics of the Third Millennium* project, the company has set an objective to facilitate training in antibiotics, over the next five years, for future generations of healthcare specialists, namely medical residents (4 workshops – 100 residents per year) and medical students (2 annual sessions held in November - 200 students per year) from the Iasi and Bucharest university centers.

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

13,500

people accessed the [antibioticelemileniuluiitrei.ro](http://antibioticelemileniuluiitrei.ro) platform in 2022





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Transparency in the relationship with medical and pharmaceutical professionals and organizations

According to the duties established starting in 2015, by the Law no. 95/2006 on healthcare reform, article 814, and the Order of the Minister of Health no.194/2015 on the approval of the Norms for the evaluation and approval of advertising for medicines for human use, Antibiotice reported, also in 2022, to the National Agency for Medicines and Medical Devices in Romania, all sponsorship activities and any other expenses incurred by the company during 2021, before reporting, for health professionals, professional, patient organizations and any other type of organizations carrying out activities related to the human health, medical or pharmaceutical assistance.

The main objectives of the promotion plan are to ensure:

- > accessibility of all categories of patients to Antibiotice medicines, through a complex distribution, 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.

In the year 2022, the company has not record fines, warnings or penalties for:

- non-compliance with regulations in force or voluntarily undertaken codes in terms of labeling products
- incidents reported by regulatory authorities from the field (ANMDMR) with regard to non-compliance regarding labelling

Product labeling

Packaging of the Antibiotice pharmaceutical products is done in accordance with the national legislation of the country where the medicines are registered and/or marketed. The labeling of medicines (primary packaging, leaflet, secondary packaging) is subject to the 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, 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 in accordance with 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.



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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.

Serialization of medicines

Antibiotice’s portfolio includes serialized products with tamper-evident sealing systems in accordance with national and international requirements. Thus, at each production department dedicated equipment has been purchased to ensure compliance with these requirements (packaging, serialization, and aggregation lines, equipped with hardware devices – cameras, printers, visual inspection stations with which printing, print verification, and rejection are carried out, as well as software handling it – which assigns serial numbers to the serialization lines, verifies the information transmitted to the Tracelink global network, which allows the management of serialized and regulatory data, the liaison with partners, customers or any regulatory authority. Tracelink communication ensures data reporting to the EU HUB, and to US partners.

Product details must be entered in all 3 systems (Bosch, Advanco, TraceLink).

The common element these systems use to communicate with each other is the GTIN-14 code, which is utilized by all 3 systems. The following information is printed on each secondary packaging of commercial units:

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

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 issues: the health and well-being of patients and consumers, public health, confidence in the healthcare system and the pharmaceutical industry.

According to the definition of the falsified medicinal product (from Law No. 95/2006 republished - Title XVIII, Medicinal product) “Falsified medicinal product” - is any medicinal product for which it is falsely presented:

- a) **identity**, including packaging and labeling, name or composition in respect of any of its ingredients, including excipients and concentration of those ingredients;
- b) **source**, including the manufacturer, country of manufacture, country of origin, or marketing authorization holder;
- c) **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 (Delegated Regulation - DR) in the Official Journal of the EU. As of February 9, 2019, prescription-only medicines (with very few exceptions) can only be placed on the market by manufacturers if they carry the new safety features. The safety features consist of a unique identifier allowing the authenticity of the medicine to be verified and identifying each individual packaging, and a tamper-evident device to check whether the secondary packaging has been tampered with. The unique identifier consists of a sequence of numeric or alphanumeric characters that is unique to a particular packaging of the medicinal product. The unique identifier consists of the following data elements:

- a) **product code** allowing identification of at least the name, common name, pharmaceutical form, strength, package size, and type of medicinal product packaging showing the unique identifier;
- b) **batch number**;
- c) **expiry date**;
- d) **serial number** - a numeric or alphanumeric sequence of up to 20 characters generated by a deterministic or non-deterministic randomization algorithm.

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

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The sequence of characters 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.

Verification of the authenticity of a unique identifier is done by scanning the barcode and comparing the unique identifier with the unique identifiers entered in the repository system by the marketing authorization holder by querying the SNVM (National Drug Verification System - a verification platform through which pharmacies or wholesale distributors 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 health-care 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. Thus, only after the certification of the batches, the managers of the Finished Product Warehouse constantly make sure that any batch is released, respectively entered into the stock for sale before carrying out any delivery operations. In the case of 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 SN (or 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.

Internal identification consists of reporting suspected counterfeit product on receipt, testing, or following an investigation (on reception of products manufactured under contract, testing of finished products, or, where appropriate, investigation of quality complaints, after comparison of the reported sample with the reference specimen).

Products suspected of being falsified may be identified externally in the following situations: along the distribution chain (by the distributor, pharmacy, hospital, physician), following quality complaints received from the market, following routine inspections carried out by the NAMMDR in the territory (pharmacy, distribution, etc.), following notifications by the authorities (police, customs authority, etc.), by the contract supplier, by generating an alert in the serialization system of serialized pharmaceutical products (distributor, pharmacy, hospital).

Within Antibiotice, the ways to receive a counterfeit alert are: 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 import, 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.

No counterfeiting alerts were registered in 2022.



## Clinical Trials Centre

Clinical trials, together with research, development, and innovation activities, play a key role in advancing and improving population health. Clinical trials are essential for assessing the safety and efficacy of new medicines and are rigorous tools through which data and evidence are collected, contributing to decisions on their approval and widespread use, ensuring that they meet the necessary standards for patient safety and therapeutic value.

To conduct Phase I clinical trials and bioequivalence studies, the company founded its own Clinical Trials Centre in 2006. It is authorized to conduct clinical trials by the Romanian National Agency for Medicinal Products and Medical Devices (NAMMDR), an authorization that is renewed every two years in accordance with the law. Compliance with Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) is reassessed by inspection every two years by the NAMMDR and the corresponding certificate of compliance is issued. By conducting clinical trials, the company authorizes generic products, with similar efficacy and safety in administration as the innovators, but affordable in price.

No animal testing is involved in the process of receiving marketing authorization for Antibiotic products. Generic Antibiotic products are authorized based on clinical trials conducted on

healthy human subjects in accordance with 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 principles of the Declaration of Helsinki regarding the safety of study participants. The inclusion of subjects in the study is done after informing and gaining informed consent from each subject. The company does not encourage over-volunteering by implementing inclusion/exclusion criteria in/from clinical trials that limit participation in the trial to vulnerable individuals.

Participation in bioequivalence clinical trials is without therapeutic benefit. Subjects are rewarded according to the complexity of the study with monetary compensation that is approved by the National Bioethics Commission. Participants in clinical trials also benefit from a clinical examination, including an EKG, and laboratory tests before and at the end of the trial.

Informed consent is collected after receiving favorable opinions from the national regulatory authorities in the field of clinical trials, NAMMDR and CNBMDM respectively, at the Clinical Trials Centre in the investigator's office. Subjects are assured confidentiality, as the information sessions are individual.



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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.

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 update 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 Department 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 2022 included the conduct of clinical trials for two local application and action products in the company's research plan (a topical product and a pessary). These trials are ongoing, and their conduct is subcontracted to companies specialized and authorized in conducting these types of clinical trials.



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## Our performance



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# 3.1. Corporate governance

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 is a company that is majority-owned (>50%) by the Romanian State, through the Ministry of Health (public supervisory authority) and is a public enterprise as defined by the Emergency Ordinance (EGO) no. 109/2011 on the corporate governance of public enterprises, as subsequently amended and supplemented, which regulates its organization and operation. Also, as a listed company, Antibiotice is subject to capital market legislation (Law no. 24/2017, respectively ASF Regulation 5/2018, on issuers of financial instruments and market operations) and has adhered to the BVB's corporate governance rules.

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 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. 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 administrators to the company directors. The establishment, revocation of directors, terms of office, duties, and role of the Board are clearly defined in the our company's Articles of Incorporation prepared according to the 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, Trade Policy Committee) are established and function within the Management Board with the following main tasks:

- managing the company by overseeing the operation of prudent and effective control systems to assess and manage risk;
- endorsing the company's development strategy, ensuring that the necessary financial and human resources are in place to achieve the strategic objectives, and overseeing the company's executive management;
- ensuring that the company meets its legal obligations to stakeholders;
- monitoring executive management performance;
- ensuring that the financial information reported by the company is accurate and that financial control and risk management systems are effective;



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- setting and approving the remuneration of the Directors and fulfilling the legal provisions concerning the recruitment, appointment, evaluation, and, where appropriate, dismissal of other Directors of the company holding mandate contracts;
- preparation of annual reports and other reports as required by law.

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

During 2022, the Management Board held 10 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 2022. 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.

Composition of Antibiotice SA Management Board as of December 31, 2022

In 2022, the Management Board consisted of four non-executive and independent members and one executive member, appointed by the Management Board as General Director.

Composition of the Management Board	Position held	Role	Term of office	Number of other significant positions and commitments and the nature of these commitments	Age (on Dec. 31, 2022)	Competences relevant to the impact of the organization	Shares owned*
Lucian Timofticiuc	President	Non-executive director**, independent***	16.09.2020 – 18.04.2024	General manager and administrator of Vremea Nouă SRL, Vaslui.	48	Experience in business management and administration	Does not own ATB shares
Ioan Nani	Vice-President	Executive, non-independent administrator, holding the office of General Director	1.06.2020 – 18.04.2024	-	63	Experience in management and business administration in the pharmaceutical industry, financial control, accounting, and economic studies	Owns 1,513 ATB shares
Ionel Damian	Member	Non-executive independent administrator	21.04.2021 – 18.04.2024	Member and then President of the Board of Directors of the Autonomous Administration Iasi Airport, as representative of the trustee body, Iasi County Council Executive Director of Tax Inspection, Iasi Regional Directorate of Public Finance (DGRFP Iasi), National Tax Administration Agency (ANAF), Ministry of Finance	52	Experience in business management and administration, public finance, tax audit, and legal studies	Does not own ATB shares
Mihai Trifu	Member	Non-executive independent administrator	26.08.2021 – 18.04.2024	Vice-President of the Board of Directors of SIF Oltenia SA Deputy General Manager of SIF Oltenia SA	39	Experience in business management and administration, including in the pharmaceutical industry, finance, internal audit, economic studies	Does not own ATB shares
Cătălin Codruț Popescu	Member	Non-executive independent administrator	26.08.2021 – 18.04.2024	General Manager of Medimfarm SA General Manager of Medimfarm TopFarm SA	48	Experience in business management and administration (pharmaceutical retail and distribution)	Does not own ATB shares

\* Number of Antibiotice shares owned as of December 31, 2022, according to the latest company database for 2022

\*\* A non-executive director in the Management Board, within the meaning of 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 within the meaning of 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.

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

Management Board – Gender diversity

	Men	Women	Total
President	1	0	1
Vice-President	1	0	1
Members	3	0	3
<b>Total</b>	<b>5</b>	<b>0</b>	<b>5</b>
<b>%</b>	<b>100%</b>	<b>0%</b>	<b>100%</b>

Management Board – Age diversity

	30-39 years	40-49 years	50-59 years	>60 years	Total
Members of the Management Board	1	2	1	1	5
<b>%</b>	<b>20%</b>	<b>40%</b>	<b>20%</b>	<b>20%</b>	<b>100%</b>



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, the 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 Trade Policy Committee** provides support to the Board in fulfilling its responsibilities for approving the company's development strategy, ensuring that the necessary financial and human resources are in place to achieve the strategic objectives, and overseeing executive management.

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.

Membership of the Advisory Committees of Antibiotice SA  
Management Board as of December 31, 2022

Name of the Advisory Committee 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
Nomination and Remuneration Committee	Lucian Timofticiuc, preşedinte Ionel Damian Mihai Trifu	3	0	3	3
Audit Committee	Ionel Damian, preşedinte Mihai Trifu Cătălin Codruţ Popescu	3	0	3	3
Trade Policy Committee	Ionel Damian, preşedinte Mihai Trifu Cătălin Codruţ Popescu	3	0	3	3



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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 (at Dec. 31, 2022)	Details and competencies	Shares owned***
Ioan Nani	General Director, mandated by the Management Board (executive management)	63	Economist, in office since 1998 (1998-2008 and 2009-present)	Owens 1,513 ATB shares

\* Director, within the meaning of 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, in order 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, 2022, according to the latest company database for 2022.

### Gender diversity

	Men	Women	Total
General Director (Executive management)	1	0	1
Executive Directors	3	4	7
Total	4	4	8
%	50%	50%	100%

### Executive Directors

On December 31, 2022, there were seven executive directors in the company.

Member	Position	Age (at Dec. 31, 2022)	Details and competencies	Shares owned***
Cornelia Moraru	Executive Director Production and Industrial Strategies Unit	57	Engineer, Head of Production, and Industrial Strategies Unit since May 1, 2003.	Owens 1,513 ATB shares
Ovidiu Bățağa	Executive Director Marketing and Sales Unit	45	Economist, Head of Marketing and Sales Unit since May 5, 2008.	Does not own ATB shares
Paula Luminița Coman	Executive Director Financial Unit	55	Economist, Head of the Financial Unit since June 6, 2011.	Does not own ATB shares
Liviu Vătavu	Executive Director Legal and Corporate Governance Unit	51	Lawyer, Head of the Legal and Corporate Governance Unit since September 1, 2019	Does not own ATB shares
Darius Giorgiani Agafiței	Executive Director International Affairs Unit	43	Economist, Head of International Affairs Unit since September 2, 2020.	Does not own ATB shares
Daniela Pascariu	Executive Director Quality Assurance Unit	48	Pharmacist, Head of Quality Assurance Unit since October 8, 2021.	Does not own ATB shares
Mihaela Murariu	Executive Director Human Resources Unit	44	Psychologist, Head of Human Resources Unit since September 7, 2022.	Does not own ATB shares

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

### Age diversity

	40-49 years	50-59 years	>60 years	Total
General Director (Executive management)	0	0	1	1
Executive Directors	4	3	0	7
Total	4	3	1	8
%	50%	40%	10%	100%

## 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 within the meaning of Article 1382 of the Companies Act No 31/1990.

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 a 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 2022 and approved by the GMS on April 27, 2022, are as follows:

### ➤ Non-executive administrators

- **Financial indicators:** 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 indicators:** 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.

The 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, the 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 performed by two methods:

**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 having a discussion 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 regarding the activities carried out within this body.

Aspects of the remuneration of the Management Board can be found in the **2022 Report** of the Nomination and Remuneration Committee of the Management Board.

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## Managing economic, social, and environmental impacts

In March 2022, the General Director decided to set up the Sustainability task force delegating responsibility for managing economic, social, and environmental impacts with the following objectives:

- unified financial and sustainability reporting starting with 2021 reporting;
- monitoring sustainability objectives and regular reporting on progress;
- identifying sustainability objectives for 2022 (environmental, social, governance) and adequately communicating the results 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, Quality, 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 2022.

## 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.



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## 3.2. Business ethics

The fundamental ethical values assumed by the company are integrity, professionalism, responsibility, and transparency. 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 medicines.

The Ethics and Integrity Board also examines all ethical incidents about which it has been informed or has taken notice.

### Reporting incidents

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).

At the same time, 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 2022, there were no recorded incidents of violation of the company's ethical principles.**

In 2022, the company developed the Procedure for receiving, reviewing, and resolving reports of violations of the law, regarding the protection of public interest whistleblowers. The implementation of the procedure will take place in 2023.

### 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*).

About 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 2022 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 Regulations.

All these governance documents have been approved by the company's Management Board, and their contents have been communicated to all employees through regular training sessions during which the importance of compliance with



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the provisions of these commitments by employees during the performance of specific activities has been stressed. At the same time, the governance documents were communicated to the employees 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 2022, at Antibiotice no critical events were recorded and consequently, no such communications to management were required. In the event of such events, stakeholders may 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 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 2022 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 positions as 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 has 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 own 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 S.A. 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.

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 integrity of such partners. In addition, the company's procedures for contract negotiation and preparation have 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

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the contracting parties, to avoid corruption, and the need to ensure that the objectives of the contract are achieved.

In 2023, we plan to organize information sessions for employees on anti-corruption topics.

In 2022, 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 action taken against the company on suspicion of corruption.

At the same time, the 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.

In 2022 there were no incidents of corruption within the company

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 are in accordance with the provisions of the internal regulations.

In 2022 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.

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 person 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. At the same time, the company is 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 Security Management department is the internal structure responsible for managing the legal aspects of personal data protection.

In 2022, 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;
- training employees in data protection and testing their acquired knowledge (in 2022, Antibiotice SA employees completed a total of >1,000 hours of training in personal data protection);
- concluding confidentiality agreements with all employees and granting access rights to information;
- improving technical measures for the protection of personal data through the purchase and implementation of IT solutions;
- external audit of IT security measures by an auditor accredited by the National Cyber Security Directorate.

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

Antibiotice SA implemented a series of technical and organizational measures to ensure the protection of personal data, confidential information, as well as computer systems and networks used in the processing of such data.



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- Technical and organizational data protection measures include:
- 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, access, and access control of employees and collaborators to information on the computer network, remote access and working.

In 2022, there were no substantiated complaints received from regulators or third parties regarding breaches of customer data security and privacy policies and regulations, leaks, thefts, or losses of personal data.



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# 3.3. Financial evolution

## Domestic market performance\*

- **leader** in the relevant\*\* market of generic and non-RX medicines marketed in hospitals, with a 13.6% market share;
- **leader** in the generic anti-infectives segment with a 30.1% value market share;
- **value leader** in the topicals segment – ointments, suppositories, and pessaries (market share: 14.5%) and injectable powders (market share: 17.6%);
- **quantitative leader** in the topical segment (ointments, suppositories, and pessaries) with a 31.7% market share, and injectable powders with a 60.1% market share.
- **3<sup>rd</sup> place** in the prescription generics segment with a 7.6% market share;
- **4<sup>th</sup> place** in the prescription generics (Rx) and over the counter (OTC) segment, with a 4% market share;
- Romanian manufacturer of **the full range** of essential anti-tuberculosis medicines.

\*According to District Sell-Out, Cegedim Customer Information, December 2022.  
\*\* According to the competition rules, the relevant market of a product includes all the products/services that the consumer considers to be interchangeable or substitutable taking into account the characteristics, use and price of the product (according to Order No. 388 of the Competition Council for the implementation of the instructions on the defining of the relevant market, published in the Official Gazette 553/5 August 2010).

## Performance on the external market

- 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;
- the leading supplier of sterile injectable antibiotics to the UK NHS healthcare system for a total of 5 injectable anti-infective products; in 2022, approximately 1 in 3 vials used in treatments with these medicines were made by the Antibiotice Iasi;
- territorial expansion plan continues to gain momentum, with three new territories accessed in 2022: Saudi Arabia and Albania (anti-infective medicines) and South Africa (cardiovasculars);
- expanding access to therapeutically effective and price-competitive generic medicines for the populations in 5 countries with the launch of 25 products in these countries covering various conditions: anti-infectives, anti-inflammatories, and dermatological;
- partner of the healthcare systems in the Republic of Moldova and Malta to ensure the emergency stock of a medicine used in case of involuntary exposure to radioactive iodine;
- representative offices in the Republic of Moldova, Ukraine, and Vietnam, and a commercial office in Serbia.



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## Stock market development

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

Antibiotice's main shareholders as at December 31, 2022, extracted from the Shareholders Register:

- **\*Ministry of Health** **53.0173%**
- **S.I.F. Oltenia\*** **27.0379%**
- **Other shareholders (42,563 shareholders)** **19.9448%**

Shareholder classes:

- **egal entities** **87.4988%**
- **private individuals** **12.5012%**

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 (ATB) shares are included in the BET-Plus index (comprising Romanian companies listed on the BVB that meet the minimum selection criteria, excluding financial investment companies).

\* Significant shareholders, according to the Law no. 297 of 28.06.2004, Art. 2, Par. 1

## Antibiotice on the capital market in 2022

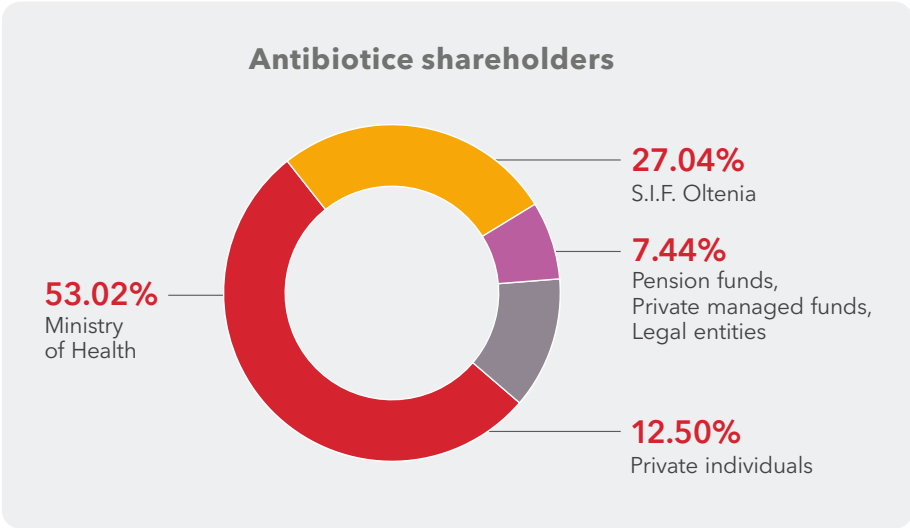
The market capitalization of Antibiotice as of December 31, 2022, was 379,977 thousand lei. In 2022, the minimum price of ATB shares was 0.4800 lei.

The share price increased to the maximum value of 0.6100 lei/share. Antibiotice (ATB) shares are included in the BET-Plus index (comprising Romanian companies listed on the BVB that meet the minimum selection criteria, excluding financial investment companies)

### Antibiotice shares - ATB/ Regular Market

	2018	2019	2020	2021	2022
Number of shares	671,338,040	671,338,040	671,338,040	671,338,040	671,338,040
Stock market capitalization (thousand LEI)*	326,942	341,040	326,270	406,831	379,977
Stock market capitalization (thousand EUR)*	70,100	71,370	66,935	82,211	76,803
Stock market capitalization (thousand USD)*	80,259	79,873	82,163	93,022	81,987
Total traded value (million LEI)	9	15	14	44	8
No. of traded shares	17,109,263	30,364,292	27,085,005	80,534,368	14,651,742
Opening price (LEI/share)	0.5780	0.4800	0.5120	0.4940	0.6060
Maximum price (LEI/share)	0.5780	0.5260	0.5550	0.6080	0.6100
Minimum price (LEI/share)	0.4550	0.4500	0.4130	0.4800	0.4800
Price at the end of the period (LEI/share)	0.4870	0.5080	0.4860	0.6060	0.5660
Average price (LEI/share)	0.5028	0.4851	0.5079	0.5913	0.5408
Earnings/share (LEI/share)***	0.0511	0.0459	0.0418	0.0446	0.0574
Gros dividend/share (LEI/share)**	0.0099991506	0.029879738	0.00330631	0.003198092	0.00792224
Dividend yield****	2.05%	6.20%	6.5%	0.65%	1.31%
Dividend distribution rate*****	20%	65%	8.4%	7.2%	13.8%

\* Calculation based on the share price on the last trading day of that year  
\*\* Proposed dividend  
\*\*\* 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



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Dividends

As a result of the activity carried out in the financial year 2022, the company obtained a net profit of 38,513,427 lei. Of this amount, the sum of 33,194,927 lei will be allocated to other reserves, of which:

- 30,523,566 lei representing reserves for fiscal facilities related to the profit reinvested in technological equipment, electronic computers, and peripheral equipment, as well as in computer programs, according to Art. 22, para. 5 of Law no. 227/2015 on the Fiscal Code;
- 2,671,361 lei representing fiscal facilities for research & development activities, according to Art. 20, of Law no. 227/2015 on the Fiscal Code.

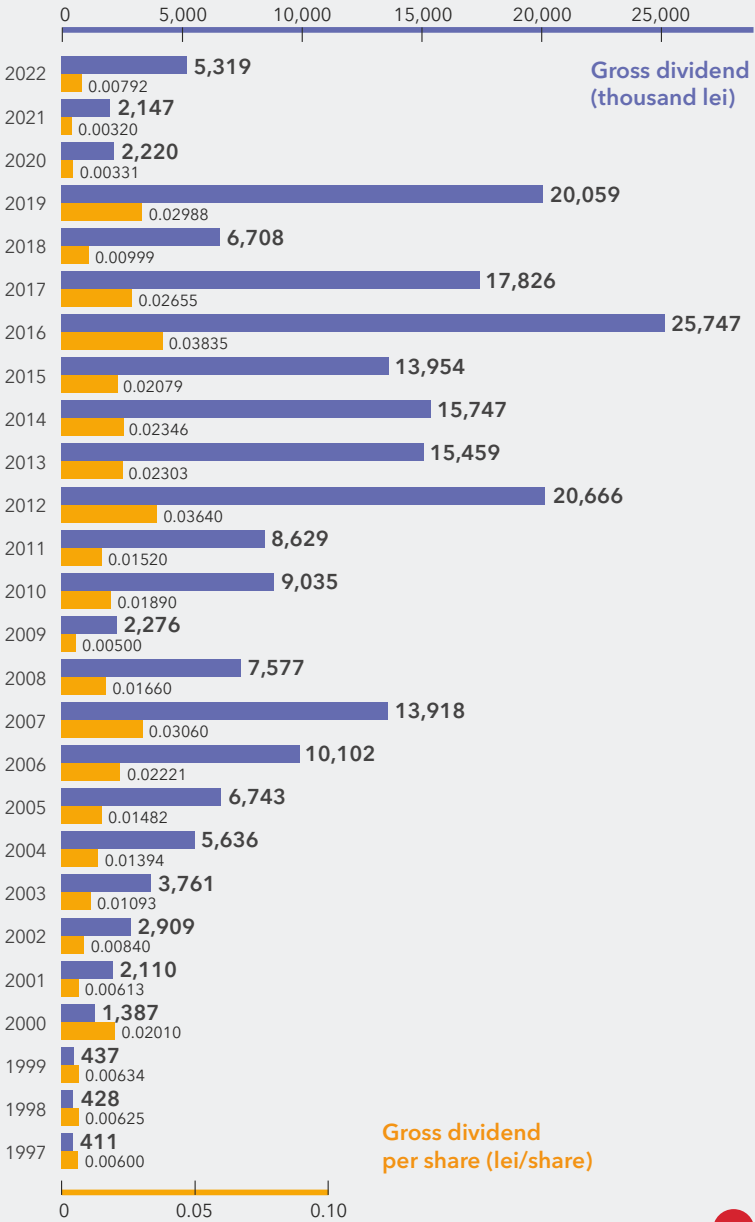
The difference of 5,318,500 lei between net profit and other profit reserves provided for by law represents the amount to be distributed as dividends for the financial year 2022. Dividends will be paid starting October 2, 2023. During 2022, 14,651,742 shares were traded, worth 7.92 million lei (€1.60 million, \$1.69 million), with an average price of 0.5408 lei/share.

In 2022, dividends were paid for the financial years 2018, 2019, 2020, and 2021, amounting to 2,003,111.99 lei. Payment of the dividends for the fiscal years 2018, 2019, 2020, and 2021 has been made through the Central Depository Bucharest and, implicitly, through the CEC Bank – the Paying Agent.

Dividend history (2018 - 2019 - 2020 - 2021)

Time period	Net dividends							Dividend payment cut-off date
	Due	Paid (Lei)				Unclaimed on 31.12.2022		
		Until 31.12.2021	01.01+31.12 2022	Total	%	Lei	%	
2018	6,612,624.05	6,083,476.66	6,434.79	6,089,911.45	92.10	522,712.60	7.90	19.09.2022
2019	19,811,039.75	18,174,724.85	39,527.49	18,214,252.34	91.94	1,596,787.41	8.06	in progress
2020	2,208,009.98	2,012,114.71	7,954.39	2,020,069.10	91.49	187,940.88	8.51	in progress
2021	2,136,257.01	—	1,949,195.32	1,949,195.32	91.24	187,061.69	8.76	in progress

Volume of gross dividends and gross dividend per share





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## Investor Relations

The constant communication between our company and its investors is maintained through the Investor Relations Department. This process allows the knowledge of the operational activity, strategy, and the perspectives of the business, in order to carry out, in an informed way, a fair evaluation of the company. Being a listed company, Antibiotice makes available to the public and submits to the Financial Supervisory Authority (ASF), respectively BVB, annual, half-yearly, quarterly, and current reports, as well as documents related to the proper conduct of general meetings.

Oriented towards developing and increasing transparency towards shareholders, the company organizes immediately after the periodic, annual, and half-yearly financial reports, its own meetings and presentation events, attended by interested investors and analysts, who can send questions, opinions and suggestions. This ensures a dialogue with the exponents of the Romanian capital market so that they gain a sufficient basis for the investment decision-making process.

On May 17 and November 15, 2022, our company organized teleconferences for the presentation of financial statements, on April 15, the event organized together with the Bucharest Stock Exchange, entitled - "Antibiotice celebrates 25 years

since listing on the Bucharest Stock Exchange", and on December 14, the "Antibiotice SA Iasi Investor Day" conference, to maintain a permanent dialogue between management, investors, and analysts. All the documents related to the smooth running of the mentioned events were published in accordance with the legislation in force.

The maximum grade obtained in the evaluation of the VEKTOR indicator of the Romanian Investor Relations Association (ARIR) for the fourth year in a row in 2022 is a recognition of the active, transparent, and constant communication of our company with the investors.

Also, at the ARIR Gala on November 17, Antibiotice Iasi was awarded first place for "Best Company in Investor Relations - Main Market - public vote", an award that complements the strategy to improve investor relations and create value for its shareholders.



**25**  
years of presence on the  
Romanian capital market

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## Operating costs optimization and increase of operating efficiency

The Strategic Organization and Development Plan of the company is based on sustainable development, as a comprehensive approach that links three directions: environment, social, and governance. Their integration requires compliance between environmental and economic development over a long period of time.

The indicators planned for 2022, part of the multiannual business plan, were achieved, creating the premises for achieving the 2030 targets:

- doubling of turnover;
- increasing the export share to 50% of turnover;
- maintaining world leadership for the active substance Nystatin;
- adapting human resources and motivating employees to achieve objectives;
- streamlining activities by digitizing and computerizing the site, for sustainable development of the company.

The total income resulting from the operations carried out by Antibiotice in 2022 amounted to 522,227 thousand lei, 34% higher than the income of 2021.

## Indicatorii din situația rezultatului global în 2022

Indicators	U.M.	2020	2021	2022	2022/ 2021	2021/ 2020
Total income	thousand lei	380,393	388,925	<b>522,227</b>	134%	102%
Total expenditure	thousand lei	352,064	358,622	<b>480,324</b>	134%	102%
Turnover	thousand lei	341,048	368,422	<b>483,724</b>	131%	108%
- domestic	thousand lei	182,773	225,974	<b>299,192</b>	132%	124%
- international	thousand lei	158,275	142,448	<b>184,532</b>	130%	90%
Export share in turnover	%	46%	39%	<b>38%</b>	99%	83%
Gross profit	thousand lei	28,329	30,303	<b>41,903</b>	138%	107%
Clawback	thousand lei	27,767	28,669	<b>31,333</b>	109%	103%
Gross profit + clawback	thousand lei	56,096	58,972	<b>73,236</b>	124%	105%
Total assets (TA)	thousand lei	863,000	895,388	<b>856,474</b>	96%	104%
Equity	thousand lei	577,272	604,992	<b>641,431</b>	106%	105%
Total liabilities (TL)	thousand lei	285,728	290,397	<b>215,044</b>	74%	102%
Indebtedness (TL/TA*100)	%	33%	32%	<b>25%</b>	77%	98%
Solvability (TA/TL*100)	%	3.02	3.08	<b>3.98</b>	129%	102%
Total expenses per 1,000 lei income	lei	926	922	<b>920</b>	99.7%	99.6%
Average no. of employees		1,415	1,410	<b>1,355</b>	96%	100%
Work productivity (operating income/ total no. of employees)	lei	264,342	272,217	<b>377,512</b>	139%	103%
Taxes and fees, of which:	thousand lei	89,447	89,078	<b>100,497</b>	113%	100%
- clawback	thousand lei	27,767	28,669	<b>31,333</b>	109%	103%
- taxes and fees related to salaries	thousand lei	44,682	47,358	<b>52,023</b>	110%	106%
- other taxes and fees to state budget	thousand lei	15,458	11,438	<b>15,159</b>	133%	74%
- local taxes and fees	thousand lei	1,540	1,613	<b>1,982</b>	123%	105%
Added value	thousand lei	200,200	184,594	<b>259,211</b>	140%	92%
Profitability of gross profit	%	8.31%	8.22%	<b>8.66%</b>	105%	99%
Profitability of gross profit + clawback	%	16.45%	16.01%	<b>15.14%</b>	95%	97%



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**34%**  
increase in total income  
achieved in 2022

**>100**  
million lei taxes paid  
to the state budget

The activities performed during 2022, focused on measures aiming at the strategic adaptation of human resources, strategic adaptation of the product portfolio, business sustainability by 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 expenses amounting to 480,324 thousand lei, 34% higher than in the previous year.

The efficiency of the entire activity is reflected by the indicator Total expenses per 1,000 lei of total income, which by the end of December 2022, amounted to 920 lei, lower than in the previous year (922 lei).

On December 31, 2022, the gross profit was 41,903 thousand lei, 38% higher compared to the gross profit of 2021. The gross profit consolidated with the clawback value resulted in a profitability of the business of 15.14%, a significantly higher level compared to the 8.66% obtained by registering this tax.

The clawback tax is paid quarterly by drug manufacturers as a state budget tax, since 2011 for prescription drugs included in national health programs, with or without personal contribution, used in outpatient treatment, through open circuit pharmacies, for those used in hospital treatment, borne by the Unified National Health Insurance Fund and the Ministry of Health budget.

## Economic performance

The economic impact generated by our activity is manifested in the expenditure we make on purchases, salary payments, operational investments, payments to the state budget, as well as community investments.

### 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 of 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

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Economic performance

Description	Value (lei)
Direct economic value generated	497,503,277
Revenue	497,503,277
Economic value distributed	494,880,313
Operating costs	314,810,251
Employee salaries and benefits	121,488,906
Payments to shareholders	5,699,668
Payments to government/state budget	20,239,994
Clawback tax	31,716,036
Community investment (sponsorships)	925,458
Economic value retained	2,622,964
Tax exemptions and credits	5,311,188.76

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 of 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 specific public disclosures for those economic activities

Proportion of turnover generated by products or services associated with Taxonomy-aligned economic activities

Economic activities	Code(s)	Absolute turnover, in lei	Proportion of turnover
A. Taxonomy-eligible activities			
A.1 Environmentally sustainable activities (Taxonomy-aligned)			
Turnover of environmentally sustainable activities (Taxonomy-aligned) (A.1.)	0	0	0%
A.2 Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)			
Turnover of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)	0	0	0%
Total (A.1+A.2)	0	0	0%
B. Taxonomy non-eligible activities			
Turnover of Taxonomy-non-eligible activities (B)	482,666,811	0	100%
Total (A+B)	482,666,811	0	100%





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Proportion of CapEx from products or services associated Taxonomy-aligned economic activities

Economic activities	Code(s)	Absolute CapEx, in lei	Proportion of CapEx	Substantial contribution criteria						DNSH criteria - Do no significant harm						Minimum safeguards	Taxonomy aligned proportion of CapEx
				Climate change mitigation	Climate change adaptation	Water and marine resources	Circular economy	Pollution	Biodiversity and ecosystems	Climate change mitigation	Climate change adaptation	Water and marine resources	Circular economy	Pollution	Biodiversity and ecosystems		
A. Taxonomy-eligible activities																	
A.1 Environmentally sustainable activities (Taxonomy-aligned)																	
Installation, maintenance, and repair of energy efficiency equipment	7.3	493,959	0.48%	100%							✔	N/A	N/A	✔	N/A		
Construction, expansion and operation of wastewater collection and treatment	5.3	4,869,790	4.7%	100%							✔	✔	N/A	✔	✔		
Water supply, sewerage, waste management and remediation	5.9	232,043	0.22%	100%							✔	N/A	N/A	N/A	✔		
CapEx of environmentally sustainable activities (Taxonomy-aligned) (A.1)		5,595,792	5.4%														5.4%
A.2. Taxonomy-Eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)																	
CapEx of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)																	0%
Total (A.1+A.2)		5,595,792	5.4%														
B. Taxonomy non-eligible activities																	
CapEx of Taxonomy-non-eligible activities (B)		97,934,300															
Total (A+B)		103,530,092															

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Proportion of OpEx from products or services associated Taxonomy-aligned economic activities

Economic activities	Code(s)	Absolute CapEx, in lei	Proportion of CapEx	Substantial contribution criteria						DNSH criteria - Do no significant harm						Minimum safeguards	Taxonomy aligned proportion of CapEx
				Climate change mitigation	Climate change adaptation	Water and marine resources	Circular economy	Pollution	Biodiversity and ecosystems	Climate change mitigation	Climate change adaptation	Water and marine resources	Circular economy	Pollution	Biodiversity and ecosystems		
A. Taxonomy-eligible activities																	
A.1 Environmentally sustainable activities (Taxonomy-aligned)																	
Generating electricity using solar photovoltaic technology	4.1	270,560	1.9%	100%								✔	N/A	✔	N/A	✔	
Construction, expansion, and operation of water collection, treatment and supply systems	5.1	1,130,792	7.95%	100%								✔	✔	N/A	N/A	✔	
Construction, expansion, and operation of wastewater collection and treatmente	5.3	2,459,230	17.29%	100%								✔	✔	N/A	✔	✔	
Water supply, sewerage, waste management, and remediation	5.5	509,676	3.58%	100%								✔	N/A	✔	N/A	N/A	
Professional services related to energy performance of buildings	9.3	38,100	0.27%	100%								✔	N/A	N/A	N/A	N/A	
Engineering activities and related technical consultancy	9.1	93,547	0.66%		100%						✔		✔	N/A	N/A	N/A	
OpEx of environmentally sustainable activities (Taxonomy-aligned) (A.1)		4,501,905	31.66%														31.66%
A.2. Taxonomy-Eligible but not environmentally sustainable activities (not Taxonomy-aligned activities)																	
OpEx of Taxonomy-eligible but not environmentally sustainable activities (not Taxonomy-aligned activities) (A.2)		0	0%														
Total (A.1+A.2)		4,501,905	31.66%														
B. Taxonomy non-eligible activities																	
OpEx of Taxonomy-non-eligible activities (B)		9,718,538															
Total (A+B)		14,220,443															



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## 3.4. Supply chain

In 2022, the pharmaceutical industry faced rising costs of raw materials and finished products and a shortage of skilled professionals. To combat these issues and maintain their competitive position in the global market, pharmaceutical supply chain leaders considered different approaches to procurement and operations management taking into account new global trade policies and competition from emerging markets. Pharmaceutical supply chain professionals have regularly reassessed business strategies and continually evaluated how to optimize operations.

Starting in 2022 to meet the challenges of global pharmaceutical expansion, the supply business has taken steps to evolve while providing a sustainable business model. Changing regulatory requirements across the supply chain means businesses need to adapt their procurement policies and practices promptly.

The need for robust compliance capabilities in procurement is essential. Procurement compliance allows companies to control spending and comply with a set of procurement standards within an approved framework. Compliance is an important part of an organization's risk management strategy.

Antibiotice has undertaken careful procurement management actions to create and deliver value and address long-term sustainability challenges by:

- Encouraging collaboration with suppliers for innovation: regular videoconferences were held to identify solutions that can increase profitability or reduce environmental impact or improve quality.
- Sustainable sourcing and supplier diversity: actions to include sustainability criteria in the selection process for suppliers are currently being finalized. Consideration is being given to suppliers' environmental practices, waste management systems, and compliance with ethical sourcing principles. In addition, supplier diversity will be promoted to foster innovation, inclusiveness, and social responsibility in the supply chain. Factors beyond price, such as suppliers' track record in sustainable production, commitment to regulatory compliance, and ability to adapt to emerging regulatory standards are taken into account. This approach makes it easier to identify suppliers that align with long-term sustainability challenges and value-creation goals.
- Early involvement of healthcare providers such as hospitals and clinics

in the procurement planning phase. Information on patient needs, treatment protocols, and sustainability requirements are identified and centralized. Collaboration with healthcare providers helps align procurement decisions with long-term sustainability challenges and ensures the delivery of value-based pharmaceutical solutions.

- Evaluation and selection: careful evaluation techniques were used when selecting suppliers:
  - Collaborative evaluation: Cross-functional teams were appointed consisting of representatives from procurement, quality assurance, regulatory affairs, and other relevant departments. This encouraged collaboration and facilitation of a joint evaluation process to benefit from diverse perspectives and expertise.
  - Visits and audits: On-site visits and audits were conducted to assess suppliers' equipment, production processes, quality control systems, and sustainability practices. This hands-on assessment helps to validate information provided by suppliers and ensures transparency and compliance with established standards.

- Agile negotiations: beyond price criteria, the procurement team focused on flexibility, sustainability commitments, and mutual value creation.

These supply chain actions indicate that Antibiotice is taking steps to transform its relationship into a strategic partnership in which each party shares responsibility for adding value.

Supplier relationships are based on long-term partnerships, characterized by transparency, mutual respect, and reliability.

The company is aware of the impact it has on the players in its supply chain and of the importance such players have for the continuity of the production process.

A fundamental element for trustworthy relationships with suppliers is the timely payment of contractual obligations. Thus, in general, the standard payment term in relation to the suppliers is 60 days from the date of invoice, except for the utility suppliers, which have an average payment term of 30 days. Taking into account the long-term partnerships, Antibiotice is always receptive to suppliers facing

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## Our performance

difficulties, which require the payment of the invoice before the due date and supports them in this regard.

Procurement officers buy from suppliers in Romania and international markets tools and equipment, logistics materials, fleet and maintenance supplies, 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, compliance with the standards specific to the pharmaceutical industry are included in the procurement procedure.

The Procurement Department is an important link within Antibiotice and supports the company's objectives through efficient inventory management techniques and robust procurement management. Building trust along the entire supply chain is a strategic objective of the department and the procurement policy is an important pillar in achieving company-wide sustainability goals.

**75.79%**  
of our suppliers  
are local

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

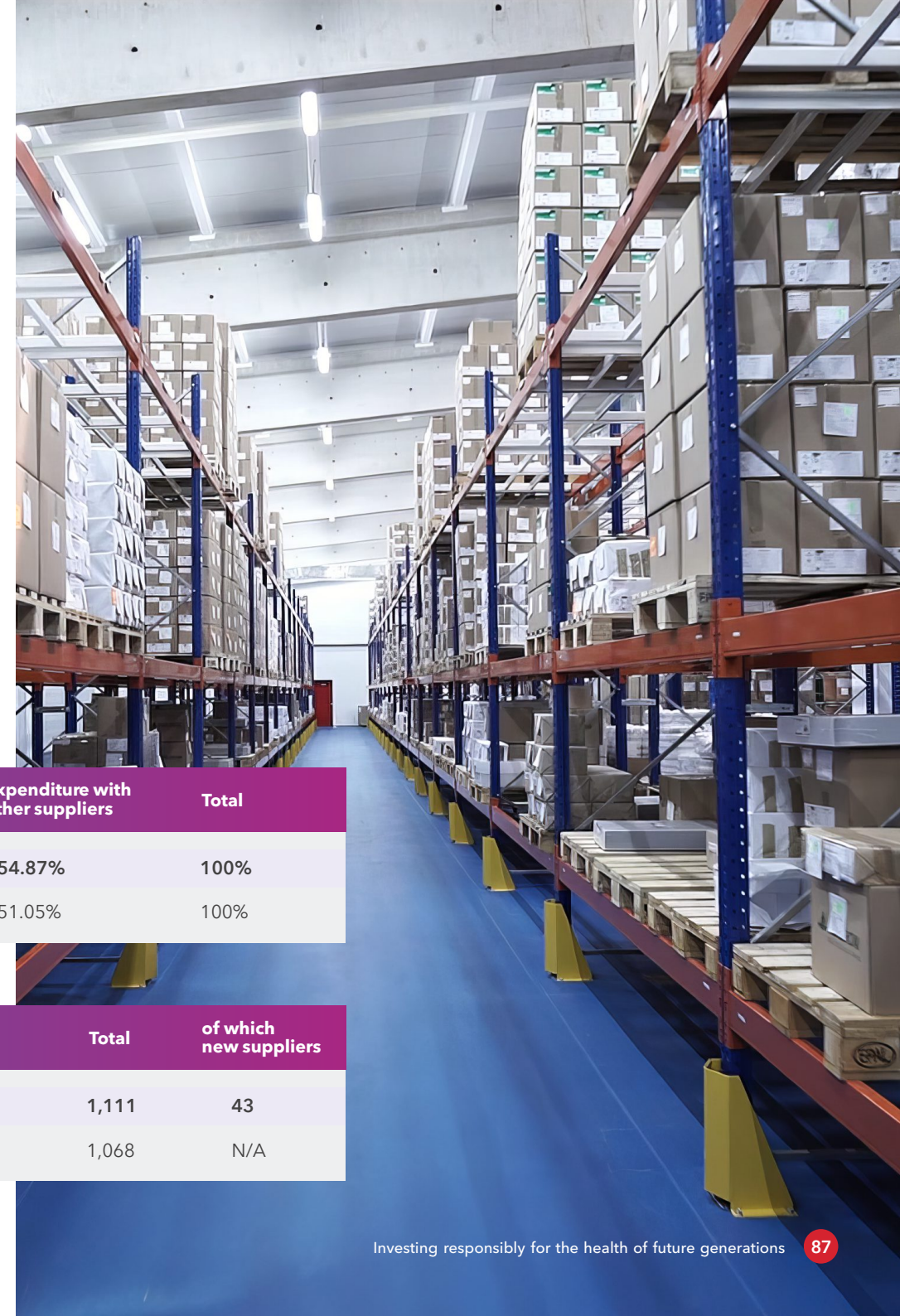
The approved suppliers which meet the requirements of the company are selected based on criteria formulated by the R&D and Regulatory Affairs departments, then audited and authorized by the Quality Assurance and afterward, included on the List of Authorized Suppliers.

### Expenditure with suppliers

Year	Expenditure with local suppliers	Expenditure with other suppliers	Total
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
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 in order 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 main 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 2022, 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.

The geopolitical situation (war in Ukraine), rising inflation rate, energy crisis, raw material crisis (plastic, aluminum, paper), rising prices of raw materials and utilities, rising transport costs (sea and air), changing local market conditions (decreasing consumption, falling prices, new competitors) are just some of the circumstances that create 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 secure sourcing;
- creating safety stocks for certain raw materials.



### Legislative risks

Pharmaceutical market is a highly regulated one, with clear legislative requirements created to control the quality and therapeutic efficiency of the medicinal products in the market and to prevent counterfeiting. The adaptation to such requirements results in additional costs generated by the documentation updating and alignment to the latest quality standards.

The company strategy for managing such risks involves the constant concern for obtaining the international quality certifications for the manufacturing lines, updating the documentation for the marketing authorization of the products, continual monitoring the international legislative changes, and adaptation of the policies, rules, and procedures to such changes.

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Integrity risks

Integrity risks are the likelihood of an integrity incident occurring concerning an employee, professional group, or area of activity, which is fostered by specific vulnerabilities and which may adversely affect the achievement of a structure's objectives. Several measures have been taken to control integrity risks, such as:

- the development and implementation of the Integrity Plan;
- implementation of warning tools;
- transparent communication of the Code of Ethics and the Integrity Plan to raise awareness;
- monitoring the implementation of ethics and integrity measures through the Ethics and Integrity Board.

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 are:

- tax unpredictability (clawback tax);
- rising inflation;
- rising prices for raw materials and utilities;
- 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;
- the increase in the ROBOR and EURIBOR indices.

Several measures have been taken to mitigate the impact of financial risks such as:

- optimizing stock turnover speed in distribution to ensure demand for the products in the Antibiotice portfolio and to improve the collection of receivables from distributors, improving relations with suppliers;
- organizing rigorous cost management at the company level in order to identify cost optimization and reduction measures;
- ensuring an optimal balance of external receipts and payments;
- covering external payments from foreign receipts through a permanent analysis of the structure of receipts and payments, to achieve the best possible correlation between currency and time of payment/receipt;
- decreasing the amount used from operational credits, reducing the credit level to an optimal level, and covering the temporary gap between receipts and payments to be made;

Operational risk

The operational risk is the risk of loss due either to inadequate processes, people, or internal systems that have not operated or functioned properly or to external events.

Operational risks include equipment malfunctions, human errors, and defective operational processes, which may ultimately result in unplanned shutdowns.

The company constantly monitors such risks to be able to take measures to maintain them at an acceptable level that does not jeopardize the financial stability of the company or the interests of the creditors, shareholders, employees, and business partners.

Human resource risk

The lack of candidates specialized in the pharmaceutical field on the labor market, the decrease in the number of specialists due to retirements and voluntary departures, the emergence of new companies in the field of drug production, the development of an industrial park in the vicinity of the company, the migration of the labor force due to socio-economic conditions are just some of the circumstances leading to this risk.

Measures to mitigate the impact of this risk include an inventory of specific positions with a pharmaceutical profile, continuous market research to update the database of potential candidates, continuity and expansion of collaboration programs with academic institutions, improvement of the compensation and benefits system to increase the attractiveness of the employer brand, continuous analysis of the organizational climate, training programs.

Environmental risks

Failure to comply could have a negative impact on the environment and the reputation of the company. Several measures have been taken to monitor this risk, such as:

- maintaining and improving the ISO 14001 environmental management system and conducting internal audits to assess compliance with the requirements of the standard;
- compliance with operating procedures;
- staff training;
- compliance with the maintenance schedule, monitoring legislative changes and their harmonization with current ones;
- emergency preparedness and response.

Internal control

Specialized internal control is exercised within Antibiotice SA through Preventive financial control, Financial management control, and Management control which are periodically evaluated by the Internal Audit Office.

In 2022, a total of 9 audit assignments and two reporting and planning topics were carried out, resulting in the following auditable objectives tailored to the specific audited area:

- examination of compliance with all specific principles, procedural and methodological rules, internal notes, and decisions;



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- > examination of the organization and conduct of audited activities;
- > assessing the management and control system of the activity;
- > other activity-specific objectives.

Details of the areas audited, the assignments, the structures audited and the findings of the audit assignments can be found in full in the [Audit Committee Report](#), available on the company's website.

Antibiotice began the process to identify, analyze, and assess climate risks

Climate change risks and opportunities

In 2022, Antibiotice began the process to identify, analyze, and assess climate risks, and subsequently develop plans to mitigate the impact of these risks and adopt a strategy for the transition to a low-carbon economy.

Summary of risks identified as a result of climate change	Risk type	Impact	Financial implications	Management method	Costs of management actions	Benefits resulting from implemented actions
Legal or regulatory risk	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
Market risk	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; promotional campaigns for the general public (TV and radio campaigns, social media); communicating to healthcare professionals through participation in national congresses and conferences.	Expenditure on raw materials, services	Development of new products or expansion of the current range of medicines; new markets
Reputational risk	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 industry-wide ethical standards.	Service costs	Improved company image; access to lower-cost sources of finance; increase in share price

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Summary of risks identified as a result of climate change	Risk type	Impact	Financial implications	Management method	Costs of management actions	Benefits resulting from implemented actions
Technological risk	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 important directions: <ul style="list-style-type: none"><li>investments for strategic development - expansion of the product portfolio through R&amp;D and licensing acquisitions; investments in new manufacturing sites; Investments to strengthen the business</li><li>quality assurance equipment, modernization of manufacturing technologies and capabilities, digitization of activities, investments in the Integrated Management System (Quality, Environment, Sustainability, Occupational Health and Safety).</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.
Heavy rainfall and storms that can lead to flooding and even landslides	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.
Average temperature increases of 1.7°C and maximum temperature increase of 2.2°C by 2040	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.
Drought that can lead to high water stress, water scarcity, and even high-risk vegetation fires	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

To integrate climate risks into the overall business risk management process, the Risk Management procedure has been revised.

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, companies that collect and report information on raw material prices, in order 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.

Changes in consumer behavior can be addressed through scientific demonstrations of the efficacy and health benefits of marketed products, but also by investing in new capabilities such as the completion of the investment in a modern R&D Centre that allows for an increased pace of product innovation in the portfolio.

Promotion campaigns for the general public are also used: investment in TV and radio campaigns, investment in social media campaigns, product and product range websites, special online and offline communication projects, and communication to healthcare professionals.

**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 – expansion of the product portfolio through research, development, and licensing; investments in new manufacturing sites.
- Investments to strengthen the business – quality assurance equipment, modernization of manufacturing technologies and capabilities, digitization of activities, investments in the Integrated Management System (Quality, Environment, Sustainability, Occupational Health and Safety); initiation of a major investment in renewable energy – construction of two photovoltaic power plants.

Integrating physical risks

Acute physical risks relevant to Antibiotice are addressed through a series of initiatives aimed at diversifying the range of suppliers and collaborators and engaging in a dialogue with the supply chain in finding solutions to adapt to these



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types of risks, impact analyses, complex insurance for goods and products and afforestation actions 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

Measures to adapt or mitigate climate risks also present several opportunities that the company can take advantage of:

- 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, diversified by investing in green energy production equipment and reducing the associated costs (construction of a photovoltaic panel park to cover part of the electricity needs - planned for 2023) and accessing financial incentives provided by the state or other European bodies in the transition towards the “net-zero” objective which requires 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 re-engineering 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.





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## Our people and communities

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In the dynamic field of the pharmaceutical industry, particularly in drug development and clinical trials, it is essential to have highly qualified professionals who are adaptable to changing contexts and responsive to community needs. So, to meet this need, we have implemented a number of professional development programs and specialized recruitment initiatives designed to boost talent within our workforce.

At the same time, as a responsible pharmaceutical company, we understand the importance of maintaining a healthy work-life balance for our employees. To support our employees, we have implemented various measures, including comprehensive benefits packages, programs for employees and their children, and facilitating access to solutions that promote their well-being. At Antibiotice, we believe that our employees play an important role in our success and the impact we have on society. Because our people are a critical resource, we strive to create a positive work environment and provide them with growth and development opportunities.

# 4.1. Antibiotice team

Our employees make a vital contribution to our mission to improve healthcare services and products. Whether we are talking about colleagues working in the research and development of new medicines or administrative departments, they all contribute to improving patient outcomes. These roles are interlinked and collaboration between our employees is essential.

On December 31, 2022, the Antibiotice SA team consisted of 1,341 employees - 55% women and 45% men.

		Women	Men	Total
By contract type	Permanent	718	571	1,289
	Fixed-term	20	32	52
	Total	738	603	1,341
By working hours	Full-time	736	601	1,337
	Part-time	2*	2**	4
	Total	738	603	1,341

\* 2h/day part-time, \*\* 4h/day part-time





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Third-party activities

Within Antibiotice SA there are **several** workers who are not directly employed but work on the Antibiotice site. The activities they carry out are construction (repairs and new investments), installation of new equipment in manufacturing and laboratory departments, maintenance of current equipment, waste collection, and catering/bistro. The workers carrying out these activities are employed by companies under contract to Antibiotice SA. These contracts are accompanied by an agreement on occupational health and safety, environmental protection and emergency situations which regulates responsibility for competence, qualification, and training in these areas. We do not currently monitor data on their number/fluctuation. At the same time, there are no temporary or internal employees in the company.

Collective labor agreement

In Romania, the collective negotiations between the trade union (*representing the interests of employees*) and the employer (*representing the interests of employers*) to establish the working conditions, employment, etc., is a legal obligation. The **Antibiotice Free Trade Union** operates at Antibiotice SA, which is the social dialogue partner of the company's

management and can be joined by any employee of the company.

As the employees' representative, the Trade Union participates in the negotiation with the management on the clauses of the Collective Bargaining Agreement, which is concluded between the parties at Antibiotice. Every Antibiotice SA employee benefits from the provisions of the Collective Bargaining Agreement, regardless of the type of employment contract, working hours, membership, or non-membership of the union.

The Collective Bargaining Agreement is valid for two years, with the possibility to extend it once for a maximum of 12 months. The current Collective Bargaining Agreement is concluded in 2022 and is valid until 2024.

The company's management engages in advance discussions with union representatives about decisions that may affect employees' rights or create new obligations for them, which are concluded by mutually agreed notifications (in compliance with the methodologies required by the applicable legislation).

The Free Antibiotice Union is part of the Federation of Free Trade Unions in Chemistry and Petrochemistry (which is a member, in turn, of the National Trade Union Confederation "Cartel ALFA").

December 31, 2022	Number	% of total employees
Employees covered by the provisions of the collective bargaining agreement	1,341	100



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## 4.2. Employee recruitment, retention, and development

### Recruitment at Antibiotice

The pharmaceutical industry is a constantly changing sector as a result of scientific and technological advances and a rapidly changing regulatory landscape. The process of identifying and recruiting the right candidates is therefore extremely important and involves a careful balance between the technical and personal skills of potential employees. For us, it is essential that Antibiotice team members are individuals with excellent technical skills and a willingness to engage in a continuous learning process, given the scientific nature of the industry, but who can contribute to an innovative and collaborative working environment.

Recruitment and selection for vacancies are carried out according to the specific internal procedure, which provides in detail the methods and channels of recruitment. The objectives of the recruitment process are set out in the annual staff recruitment plan.

The company ensures its necessary workforce through a transparent process, from internal and/or external sources through the Human Resources Unit and/or specialized recruitment firms. The selection process is based on competition (written examination, practical test, interview).

The candidate recruitment and selection policy is based on the following principles:

- 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.
- 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;

Within Antibiotice, three generations of employees actively collaborate, sharing experience through internally established induction and mentoring programs in all areas of the company. This gives young people the opportunity to develop a successful career in the company.

To this end, we are developing our own vocational training projects and partnerships with pre-university and university institutions to facilitate their access to the information they need to make the best decisions about their future.





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In 2022 the **Academia a+** the knowledge management platform for employees - was founded.

## Recruitment programs (internal and external)

### Academy a+

In 2022 the Academy a+ was set up, a platform focused on recruitment, education, and professional skills development programs, in order to adapt our human resources to the future structure of the company, looking forward to the 2030s. The two components of the Academy a+ are the Technical College a+ and the Business School a+ (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 Academy a+ 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 Academy a+ 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.

### Technical College a+

It includes programs for further training and internal qualification, addressed to people with secondary/higher education, mainly technical. The programs are aimed both at employees seeking to undergo development programs aiming for professional retraining, and especially at external candidates, aiming to undergo professional training programs, leading to internally recognized qualifications, followed by the opportunity to access vacancies in the company.

In 2022, the first pilot program of its kind was launched, where 12 externally identified candidates (mostly from rural areas) were trained as flow operators in the pharmaceutical industry and became part of the future drug manufacturing team.

Two further sessions are planned for 2023 aiming to encourage people from disadvantaged backgrounds or those who want to retrain to join a competitive and stable industry offering promising opportunities. These sessions provide an avenue for unemployed people to explore a stable market industry with solid prospects.

Other initiatives aimed at recruiting workforce are part of the dual education category, developed through partnerships with pre-university education institutions – “Petru Poni” Technological High School Iasi and the Technological High School of Mechatronics and Automation.



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Partnerships for dual education

Other workforce recruitment initiatives in 2022 fall under the dual education category and are developed in partnership with pre-university education institutions. These included educational and practical visit programs for 120 students from Iasi in theoretical and vocational education. As of 2020, Antibiotice supports, as part of dual education, 15 students in the chemical operator specialty at the "Petru Poni" Technological High School and 10 students in the low-voltage network electrician specialty at the Mechatronics and Automation Technological High School, for the entire three-year education cycle (2020-2023).

Perform a+ Program

Perform a+ introduces senior students, including residents and PhD students, to what it means to work in the pharmaceutical industry and offers the opportunity to complement the knowledge acquired during their undergraduate years with theoretical and practical sessions, supported by mentors appointed from among the company's employees. At the end of the course, the knowledge acquired is integrated and applied by presenting a project to colleagues and company representatives.

The collaboration with academia resulted in 2022 in educational visits and internship programs organized for 215 students from the Faculties of Pharmacy, Biology, Chemistry, Chemical Engineering, and Environmental Protection, the Faculty of Electrical Engineering, Energetics and Applied Informatics, and the Ion Ionescu de la Brad University for Life Sciences in Iasi.

The Perform a+ program started in 2016 via a partnership with the Pharmacy Faculty of the Grigore T. Popa University of Medicine and Pharmacy Iasi. In 2020, the collaboration program was extended to other Iasi universities, such as the Chemistry and Biology faculties of "Alexandru Ioan Cuza" University or the Faculty of Chemical Engineering and Environmental Protection of "Gheorghe Asachi" Technical University.

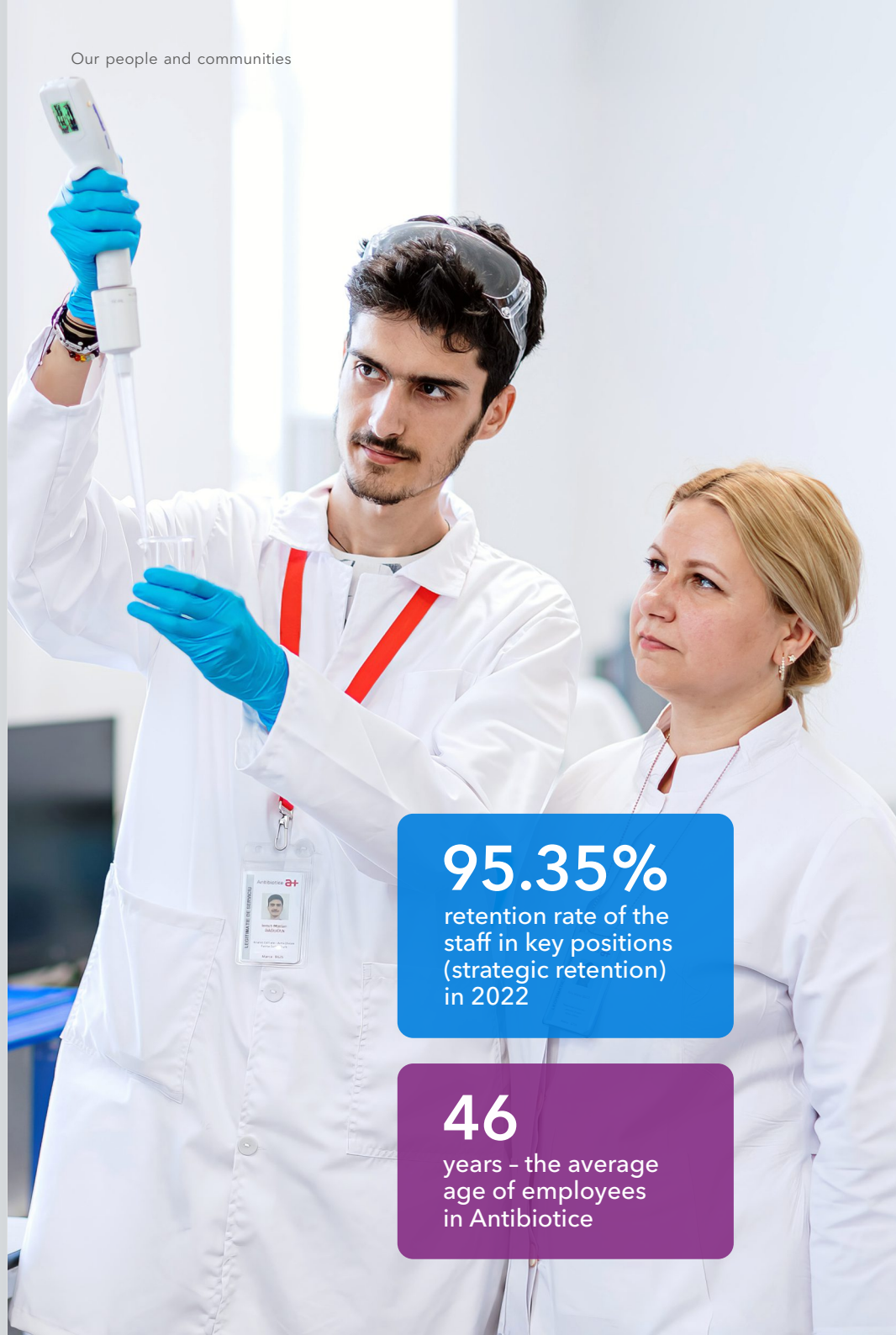
Following the seven editions of the program, Antibiotice has hired 37 graduates in the Research & Development, Regulatory Affairs, Portfolio Management, Quality, and Production departments.

The Perform a+ program is a successful cooperation with academia and a way to attract and support the development of graduates in the generic drug industry.





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# 95.35%

retention rate of the staff in key positions (strategic retention) in 2022

# 46

years - the average age of employees in Antibiotice

## New employees and staff turnover

Category	New employees		No. of employees who left the company	
	No.	Rate (%)*	No.	Rate (%)*
<b>Gender</b>				
Women	53	3.91	56	4.13
Men	36	2.66	58	4.28
Total	89	6.57	114	8.41
<b>Age group</b>				
< 30 years	31	2.29	19	1.40
30–50 years	52	3.84	61	4.50
> 50 years	6	0.44	34	2.51
Total	89	6.57	114	8.41

\* rates were calculated by reference to the average number of employees in 2022, i.e. 1,355 employees

## Employee remuneration and motivation policy

Adapting the remuneration system and establishing a comprehensive employee motivation policy, covering both financial and non-financial aspects, are strategic measures 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 2022, as a key component of our Remuneration and Motivation Policy, we conducted a thorough review of our incentive packages for various staff categories, ensuring they are up-to-date and aligned with our goals of fostering employee loyalty, encouraging performance, and promoting long-term engagement.

**50%** women in the management team

The pay adjustment in 2022 took place over at least two stages, as the remuneration and motivation policy were refined and the effects of inflation in Romania were taken into account. At the same time, in 2022, we undertook a review of internal employee categories. This review aimed to enhance our ability to monitor HR issues efficiently and clearly. The objective of this review was to increase the traceability of human resources issues. Accordingly, the following categories of employees were established:

Category	Ratio of basic salary of women to men	Ratio of basic remuneration of women to men
Senior management	0.99	0.93
Middle management	0.94	0.94
Line managers	0.91	0.84
Higher education specialists	0.90	0.85
Secondary education specialists	1.05	1.02
Qualified workers	0.96	0.89
Low-skilled workers	0.83	0.76
2022	Men	Women
Ratio of the minimum wage in the company to the nationally regulated minimum wage	1.37	1.26
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)		4.63
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)		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)		1.27%

As for the motivational component of pay (benefits), it encourages job performance and competitiveness, promotes employee loyalty and commitment to the organization, and contributes to employer branding. Thus, in 2022, the positions for which salary packages with a variable component and other benefits correlated with the objectives, indicators, and performance criteria arising from company-wide objectives will be applied from 2023 were established. These include changes in the value of meal vouchers and an increase in the number of health insurance packages.

### Strategy to update organizational culture

Organizational culture and work climate are constant concerns within the company. The employee retention policy has made Antibiotice SA an employer brand that is “worth working for”, an aspect that has been noticed both by the internal audience of employees and potential employees in the community.

An organizational climate survey is conducted regularly to assess the motivation and retention prerequisites.

In 2022, 963 employees participated in the organizational climate survey (72% of the total number of employees) and 87% of the respondents were executives. The survey consisted of 16 topics, including teamwork, rewards and benefits, career development opportunities, performance management, etc. In doing so, it tracks the evolution of employees' perceptions

of the workplace atmosphere, managers' concern for ensuring a climate conducive to collaboration and improved results, and last but not least, the desired/practiced value system at the company level. The results showed in a detailed way in which activities and workplaces improvement and optimization measures have to be taken in the topics surveyed.

The resulting findings were the starting point for an updated Climate Improvement Implementation Plan for 2023.

### Employee benefits

#### Club a+

The Club a+ 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, Club a+ offers a wide range of services that seamlessly combine sports, relaxation, and wellness activities.

In 2022, 70 Antibiotice employees participated free of charge in the activities offered by Club a+: aerobics and pilates classes, ballroom dancing lessons, self-defense training, Club a+ Runners meetings for joggers, and Club a+ Bikers meetings for cyclists. The Club a+ Holiday program, organized during children's holidays, provided recreational activities for employees and their children. Club a+



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also offered access to the gym for team sports: volleyball, field tennis, basketball, table tennis, and badminton.

Club a+ aims to centralize cultural, educational and sports activities for Antibiotice SA employees, with the objective of becoming a valuable tool for non-financial motivation and increasing employee engagement.

Bookster books at Library a+

Antibiotice SA is offering employees who love reading free access to the online platform Bookster.ro from 2020. At the end of 2022, 225 employees had an account on Bookster.ro.

The objective of the project “Bookster books on the shelves of the a+ Library” is to encourage reading. Bookster is a public library that lends books to company employees directly in their workplace.

Benefits package

Antibiotice provides the same benefits to employees whether they work full-time 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 customized motivational package.

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	✓	✓
Gift vouchers and bonuses for employees and employees' minor children	✓	✓
Holiday rewards (8 March, Easter, Christmas)	✓	✓
Performance bonuses	✓	✓
Accident insurance	✓	✓

Parental leave, 2022	Men	Women
Total no. of calendar days	404	2,786
No. of employees entitled to have a parental leave	603	738
No. of employees who took parental leave	6	18
No. of employees who returned to work (in 2022) at the end of the parental leave	6	16
No of employees who returned to work (2021) at the end of the parental leave and were still employed after 12 months (in 2022)	4	18
Return to work rate	100%	106.66%*
Retention rate	100%	79.16%

\* Employee return-to-work rate exceeded 100%, as employees who were originally scheduled to return to work in 2023 returned earlier, in 2022.

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, in order to uphold the highest safety and effectiveness standards.

In 2022, the annual training budget amounted to 558,400 lei, a

93% increase over the previous year.

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The general policy on ongoing vocational training of employees is carried out in compliance with the principles of human rights and equal opportunities. This policy is included in the Internal Regulations and the Collective Bargaining Agreement set at the 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, 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.

**Continuing 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 2022, our employees completed a total of 56,986 hours of training, an average of 42.5 hours of training per employee.**

Examples of training offered to employees	Total hours	Number of participants
Project Manager	960	22
EU - Manager	504	42
Team management	468	39
Trainer (team of internal lecturers)	378	21
Practical approaches for impurity risk assessment	242	14
English	23	26
Extractable and leachable substances in pharmaceutical production (interaction with packaging)	228	19
Legislation on the promotion of non-prescription medicinal products for human use	108	18
Legal requirements applicable to medical devices	72	9
Excellence in clean room service and maintenance (production facilities)	45	4
Good Laboratory Practice	36	6
International Sustainability Carbon Certification (ISCC)	36	2
Auditor for SSM CF14001:2015	36	2
Waste management	22	3

42.5

is the average number of training hours per employee

*Note: the average number of hours were calculated in relation to the total number of employees on December 31, 2022.*



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In 2022, as part of the company's Digital Transformation Plan, we carried out a project to train and assess the digital skills of our employees. The project is vitally important to our employees as it equips them with the essential skills and knowledge needed to thrive in today's digital landscape. By improving digital competence, employees gain a competitive advantage in their roles, adapt quickly to technological advances and increase their productivity through the effective use of digital tools. 56 employees participated in the project and completed a total of 3,360 hours of training. The project will continue in 2023.

In June 2022, we also launched a comprehensive training project for the company's management team (senior management, middle management, and line managers), with the following objectives:

- increasing job performance;
- creating a unified vision for the management system in the company;
- creating a professional development plan.

Results: 8 training sessions, 4 management/leadership topics, 108 participations (60 people), and a total of 1,290 training hours.

In 2022, we set up the **Academy a+**, a broad professional development initiative for our employees, but also for those who want to be part of the Antibiotice SA team. Thus, as part of this initiative, we launched the e-learning platform dedicated to our employees. The platform aims to encourage employees to invest in themselves and prioritize their personal and professional development. The platform was created out of the need to make soft skills easier for as many employees as possible. It was launched in August 2022, and by the end of October, accounts had been created for our employees. The first results of the e-learning platform were quick to follow:

- 87 employees completed a total of 1,793 participations
- 54 trainees completed 47 modules
- 20 topics available

Month-Year	Time spent in classes (h)	No. of unique active users
Nov-2022	498	129
Dec-2022	528	61

The Academy a+ consists of two components: the **Technical College a+** (more details in the Recruitment sub-chapter) and the **Business School a+**.



Business School a+

It includes professional and personal skills development programs for employees with both internal company trainers and external providers.

The implementation of the e-learning platform in 2022, as a component of the Academy a+ initiative focused on training and skills development, greatly improved the accessibility of professional and personal training programs for a substantial number of employees.

In 2023, the company plans to take further steps by implementing specialized training programs in the field of human rights, diversity, and equal opportunities. The company's goal is to ensure that all employees have access to such programs by the end of 2025. In addition, starting with the implementation phase, these programs will be incorporated as a standard component of the induction and getting acquainted period for new employees, helping them learn about the company's internal policies, procedures, and regulations.

## Performance evaluation and career development plan

At Antibiotice we understand the importance of regular career development and performance reviews. These evaluations are critical to our company as they serve two vital purposes: 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. 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 2022

Employee categories	Men		Women	
	No.	% of total employees/gender and category	No.	% of total employees/gender and category
Senior management	6	100	9	100
Senior management	17	100	46	93.88
Line managers	96	97.96	119	90.84
Higher education specialists	113	91.87	192	87.67
Secondary education specialists	16	100	34	97.14
Qualified workers	337	98.83	275	98.92
Low-skilled workers	2	100	16	94.12
Total	587	97,35	691	93.63

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## 4.3. Diversity and equal opportunities

Workplace diversity means acknowledging and appreciating different skill sets and being aware of the unique potential each team member brings to internal operations.

In 2022, Antibiotice implemented the Regulation and Policy on equal opportunities and treatment between women and men and on workplace harassment, which were communicated to all employees through training on hiring and re-training of those already employed, based on signature. These documents are part of Antibiotice SA's Internal Regulations and establish measures to prevent and combat discrimination and harassment in the workplace.

100% of the company's employees are aware of the new provisions in the Regulation and Policy on equal opportunities and equal treatment between women and men and workplace harassment.

The principle of equal treatment and equal opportunities for all employees is firmly respected in employment relations. We actively support this principle by promoting an organizational culture that adopts a “zero tolerance” approach to discrimination and harassment. To ensure a respectful working environment, the following actions are strictly prohibited:

- requiring race, nationality, ethnicity, religion, social, or disadvantaged category, age, gender, sexual orientation, or personal beliefs as

requirements for employment through advertisements or competitions.

- discrimination against any employee on the grounds of race, nationality, ethnicity, religion, social or disadvantaged 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.

Our employees have the right to report any case they consider to be harassment or discrimination. They can submit their requests/complaints physically or electronically ([resurse.umane@antibiotice.ro](mailto:resurse.umane@antibiotice.ro)) to the Human Resources Department. They will be forwarded to the Commission and the General Secretary for consideration and the employee will receive a response within 30 days.

By enforcing these rules, Antibiotice is committed to ensuring a fair and inclusive workplace for all employees, where everyone is treated with respect and given equal opportunities for personal and professional development.

### Employees by age, gender, and category

December 31, 2022	Men				Women			
	<30	30-50	>50	Total	<30	30-50	>50	Total
Senior management	0	5	1	6	0	3	6	9
Middle management	0	13	4	17	1	34	14	49
Line managers	14	60	24	98	19	91	21	131
Higher education specialists	9	87	27	123	26	131	62	219
Secondary education specialists	2	8	6	16	1	16	18	35
Qualified workers	5	142	194	341	4	122	152	278
Low-skilled workers	0	0	2	2	0	6	11	17
Total	30	315	258	603	51	403	284	738

### Employees with disabilities by gender and category

December 31, 2022	Men	Women
Senior management	1	0
Middle management	1	1
Higher education specialists	0	1
Secondary education specialists	1	0
Qualified workers	2	0
Low-skilled workers	0	0
Total	5	2

### Employees in senior management positions\* recruited from the local community\*\*, 2022

No.	% of total
15	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 2022, there were no incidents of discrimination

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## 4.4. Employee health and safety

The achievements we have made over the years are a direct result of the contribution, dedication, and active involvement that our team demonstrates in their daily activities. This is why, 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.

Occupational health and safety (OHS) operations within our company strictly comply with the provisions of Law 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, which was successfully recertified for another 3 years following the full audit conducted by TÜV Rheinland Romania at the end of 2022. 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, there is an Occupational Safety and Health Committee (OHSC) within the company. The Committee is composed of worker representatives with specific responsibilities for the safety and health of workers, on one hand, and the employer or his legal representative and his representatives in equal numbers as the workers' representatives and the occupational physician, on the other. The coordinator of the occupational health and safety activity is the secretary of the Occupational Safety and Health Committee. The employer or his legal representative is the President of the Occupational Safety and Health Committee.

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;

- pursues 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 labour 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 accidents at work and occupational diseases, as well as for the improvement of working

- conditions, and proposes their inclusion in the prevention and protection plan;
- analyzes the causes of work accidents, occupational diseases, 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.

For the activity carried out in 2022 the following was prepared:

- Prevention and Protection Plan;
- Annual training program in occupational health and safety;
- Annual schedule for periodic medical examination;
- Annual schedule for monitoring exposure to harmful substances.



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- 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 level, 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 carry 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, who is familiar with the workplace, and the employee representative.

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. Designated staff and employee representatives in the workplaces are

trained by the coordinator of occupational health and safety activities on the methodology of occupational health and safety risk assessment. 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, 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 accidents, must be reported promptly to the OHS and Antibiotice management. Any person with knowledge of such incidents is required to report them immediately.

In accordance with 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.



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## Workers operating on the Antibiotice site

At the beginning of the activity, the provider's workers will be briefed and trained by Antibiotice's 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 recording and subsequent investigation of work-related accidents is carried out in accordance with the legislation in force and internal procedure.

Events resulting in temporary incapacity for work are investigated by a committee appointed by written decision of the General Manager, consisting of at least three members, one of whom must be a representative of the OHS activity. The persons nominated must have appropriate technical training and must not be involved in the management and organization of the activity in which the event occurred.

Events resulting in evident or confirmed invalidity, 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, falls under the scope of the Labor Inspectorate.

## Occupational health and safety training

In our company, all employees are informed and receive regular training (monthly, quarterly, or half-yearly, depending on the position held) on occupational health and safety, depending on the specific activities carried out. Additionally, in 2022, the following training took place 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 trainings 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.



Training type in 2022	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;
  - first aid in case of medical emergencies;
  - medical examinations to assess the health of employees in accordance with occupational health legislation and the requirements of the quality and safety of the manufacture of medicines.
- Also, 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 2022, with the support of physicians and medical staff, the following activities were carried out within the Occupational Medicine office:

- 776 employees were tested with rapid tests as part of the screening program (preventive examination) for hepatitis



B, C, and D, within the European LIVE(RO) project carried out in collaboration with the Institute of Gastroenterology and Hepatology Iasi and the University of Medicine and Pharmacy Iasi;

- blood pressure measurement for 780 employees. They received information on hypertension prevention and how to monitor blood pressure;
- 200 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);
- 15 employees were vaccinated against COVID-19.

## Work-related accidents

In 2022, there were two work-related accidents, one on the way to work following a road accident and the other due to improper use of work equipment, totaling 91 days of temporary incapacity for work. In these cases, according to the law and internal procedures, the occupational accidents were reported to the Territorial Labor Inspectorate of Iasi, and the investigation files prepared were forwarded to and approved by the same institution. According to Antibiotice SA's internal procedures, in order to eliminate the risks and hazards underlying the recorded occupational accidents, the company ordered the reassessment of the risks related to occupational safety and security, and additional training of the employees took place.

In 2022, no deaths caused by diseases due to exposure to existing workplace hazards and no illnesses caused by exposure to existing workplace hazards were recorded.

Through the Medical Office, all employees undergo a regular annual examination in which medical staff screen for various conditions and refer employees with a medical letter to the family physician for specialized investigations. The employee is asked to submit the results of the investigations within 30-60 days to the Medical Office. In addition, all new employees are asked to submit preventive pulmonary radiography upon hiring. Once every two years, all employees in the production plants have a pulmonary X-ray examination and, in addition, employees in departments where extra visual effort is required have an ophthalmological examination twice a year.

**In 2022, there were no deaths from illnesses due to exposure to workplace hazards.**

Work-related accidents 2022	Employees		Workers	
	Men	Women	Men	Women
No. of deaths due to work-related accidents	0	0	0	0
No. of work accidents causing serious injury e.g. employee will not recover within 6 months	0	0	0	0
No. of registered work-related accidents	2	0	0	0

Rate of recorded work accidents

=

No. of recorded work accidents

Total no. of hours worked by employees

× 1,000,000

=

2

2,259,469

× 1,000,000

=

0.88

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**925**  
thousand lei total amount  
of the Community  
investment budget

**500**  
hours of involvement in  
social projects provided  
by our employees

## 4.5. Community investment

Within our company, we believe in promoting the growth and development of people in our community. That is why we actively engage ourselves in projects that address their urgent needs, investing and redirecting funds to make a positive impact. **The main directions of our community involvement center around four pillars:**

- healthcare
- education
- environment
- social

Not only do we carry out our own charitable and humanitarian projects, but we also run educational and cultural programs through the “Antibiotice - Science and Soul” Foundation. 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 2022, the total sponsorship budget was 925,458 lei, an increase of ≈27% compared to 2021.**

**In 2022, we supported a total of 11 projects and had 8 partner organizations.**

**More than 500 participants from the Antibiotice team volunteered more than 500 hours of involvement in social projects.** Volunteering hours were carried out by employees both in their free time and during working hours.



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## Healthcare

### "Donate blood! Put soul for life!" (Donează sânge! Pune suflet pentru viață!)

More than 140 Antibiotice employees donated blood in the two editions of the campaign organized in April and October 2022, by the Antibiotice Science and Soul Foundation, in partnership with the Regional Blood Transfusion Centre Iasi (CRTS Iasi).

The donation campaign, supported by Antibiotice Iasi, is the longest-running initiative in Iasi County dedicated to blood collection within a company. Antibiotice has been running this campaign consistently for more than 11 years, giving CRTS Iași doctors access to a constant supply of donors, including people with rare blood types. Through the voluntary contributions of Antibiotice employees, both recurring donors and new donors, a total of 64 liters of blood were donated. This significant contribution played a crucial role in solving the blood shortage that persists in hospitals in Iasi, helping to meet the persistent demand for blood transfusions.

Over **140**  
Antibiotice employees  
donated 64 liters of  
blood in 2022.



## 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 a unique first aid course organized by Club a+ and the Iasi Mobile Emergency, Resuscitation and Rescue Service. The project, called "Plus for Life!", took place at the Club a+ Sports Hall on October 25 and 26, 2022. The training focused on promoting essential first aid techniques in scenarios such as cardio-respiratory arrest, accidents, trauma, and airway obstruction. Following the recommendations of the European Resuscitation Council to train the younger generation in first aid techniques, Antibiotice organized a specialized course for the first time in 2022 for employees and their children over 12 years old. This year's course was delivered by eight SMURD-accredited doctors, providing comprehensive training. Furthermore, on November 8, 2022, 400 of the company's employees were trained by SMURD Iași doctors on the use of defibrillators, thus aligning with Antibiotice's commitment to safety. In 2022, the company installed two defibrillators on its premises, further underlining its dedication to employee and community well-being



## Call for life

In 2022, 7 Antibiotice employees actively participated in the "Call for Life" campaign, responding to the request of the Iasi Public Health Directorate (DSP) to provide volunteer cars and drivers. Between January 28 and February 26, 2022, they contributed a total of 268 volunteering hours. This enabled DSP medical staff to travel to various locations for COVID-19 testing, providing timely assistance to the community. The commitment and support of the Antibiotice team were essential in ensuring the smooth running of the campaign and facilitating community access to essential testing services.



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## Education

### “Science and Soul” scholarships

Now in its 21st year, the “Science and Soul Scholarships” program is the longest-running community involvement program run by 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 possess exceptional abilities and a high IQ but lack the necessary financial resources. The scholarships ensure that these talented individuals can continue their studies at the secondary and high school levels, opening doors to professional success and personal development. Through its commitment to education, Antibiotice embraces the opportunity to nurture young talent, enabling them to thrive and have a positive impact on their communities.

## Environment

### Earth hour

For 13 consecutive years, Antibiotice has actively participated in the global environmental event known as Earth Hour by symbolically turning off the lights. This initiative aligns with Antibiotice's environmental program, “Be Pro Nature, Put Your Heart and Soul”. The company has consistently promoted the Earth Hour message, encouraging individuals to join



this collective effort by turning off the lights and embracing the opportunity to spend quality time with loved ones. Antibiotice recognizes the importance of mitigating the effects of global warming and continues to advocate for sustainable practices that protect and conserve our planet. By actively participating in Earth Hour, Antibiotice is expressing its commitment to being an environmentally responsible company and encouraging others to join this impactful movement.

### Antibiotice volunteers planted 200 trees

In 2022, more than 50 dedicated Antibiotice employees volunteered to participate in the third edition of the “Plant oxygen in the community” project. This initiative entailed the planting of 200 trees, including oak, lime, and maple varieties.

The timing of the tree planting was World Health Day, which is celebrated annually on April 7. This year, World Health Day was held under the slogan “Our Planet, Our Health”, highlighting the crucial link between environmental well-being and human health. The World Health Organization stressed the urgent need to create sustainable societies that meet the needs of today without compromising

the well-being of future generations. In addition, they expressed concern about the negative effects of air, water, and food pollution on human health. By actively engaging in this tree-planting initiative, Antibiotice employees demonstrated their commitment to creating a sustainable and healthier future for both the community and future generations.





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European Mobility Week

Antibiotice actively participated in the European Mobility Week, held on September 16-22, promoting responsible environmental behavior and making tangible investments to reduce CO<sub>2</sub> emissions from urban transport. Around 50 Antibiotice employees enthusiastically embraced the internal campaign “One car down, nature up”, choosing to leave their cars at home and opt for car-sharing instead. This initiative aimed to encourage the use of public transport among employees, thereby reducing carbon dioxide emissions and alleviating urban congestion.

In 2022, we inaugurated a new car park in the southern area, towards the Miroslava commune, with a 150-space capacity. By using this new car park, the travel distance to Antibiotice is shortened by 7 km, which leads to significant fuel and time savings for employees. As a result, each vehicle using the new car park contributes, on average, to a reduction of approximately 22% in CO<sub>2</sub> emissions compared to the emissions generated by the main car park. Through these initiatives, Antibiotice actively contributes to promoting sustainable transport practices and minimizing its environmental footprint.

Social

Open Days

Antibiotice has embraced its commitment to being a friendly and responsible brand by organizing the Open Days event as part of its sustainability strategy. It took place from June 24-27, 2022, and aimed to promote dialogue with members of the surrounding communities and identify projects that address their specific needs.

Over the three days, more than **100 community members** actively participated in interactive discussions with Antibiotice experts from various departments, including quality assurance, production, control laboratories, and environmental protection. In addition, they had the opportunity to visit the company's production site and learn about its operations and practices. This engagement aimed to promote transparency and open communication between Antibiotice and its community members, strengthening the company's relationship with the local community.

In addition, more than **70 university and dual education students** were invited to visit the company during the event. This gave them a valuable opportunity to explore potential career prospects within the company, which could pave the way for a successful career path in the future.





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By opening its doors and actively engaging with the community, Antibiotice has demonstrated its commitment to fostering positive relationships, understanding local needs, and creating opportunities for collaboration. The Open Days event illustrated Antibiotice's commitment to being a responsible and community-oriented brand in line with its sustainability strategy.

“Solidarity without borders”

The conflict in the neighboring country has prompted us to step forward and support those directly affected by the war, be it those on the frontline or displaced people seeking refuge. In February and March, Antibiotice organized the “Solidarity without Borders” campaign to provide assistance in various forms. As part of this initiative, two truckloads of oral and injectable antibiotics, enough to treat 5,000 patients, were sent to Ukraine. In addition, Antibiotice employees generously contributed donations, both monetary and in kind. These donations were directed to the Romanian Red Cross - Iasi Branch for centralized distribution, according to the specific needs of the affected individuals and families. Through the “Solidarity without Borders” campaign, Antibiotice and its employees demonstrated their firm commitment to stand by those affected by the conflict, offering much-needed support and help in these difficult times.



“The power of deed”,  
Easter charity program

In an effort to bring joy and alleviate the hardships faced by the less fortunate during the Easter holidays, the “Antibiotice - Science and Soul” Foundation has launched the “The Power of Doing” initiative. Through this initiative, the lives of **20 families** living in Iasi and neighboring localities such as Dumești, Mogoșești, Iepureni, Andrieșeni, Traian, Bivolari, and Dancu were influenced. These families, each consisting of 8 to 12 children, face difficult situations and have limited material resources.

The “Antibiotice - Science and Soul” Foundation, in collaboration with dedicated volunteers and Antibiotice employees, has partnered with the “Pro Vita” Department of the Metropolitanate of Moldavia and Bucovina to implement this compassionate initiative. Traditional Easter dishes, essential food items, hygiene, and cleaning products were offered to these families.

“Give from the heart! Be Santa Claus”

The 10<sup>th</sup> edition of the event “Give from the heart! Be Santa Claus” brought the spirit of Christmas and fulfilled the wishes of **100 children** from disadvantaged families. Organized by the “Antibiotice - Science and Soul” Foundation, this touching initiative aimed to distribute gifts to children aged between two months and 15 years from disadvantaged rural backgrounds.

In the heartfelt letters written by these little ones, Santa discovered their simplest wishes: sweets, toys, clothes, shoes, school books, backpacks, stationery,

skateboards, bicycles, and scooters to make their way to school easier. These letters reached the compassionate “elves”, the dedicated employees of Antibiotice, who embraced the opportunity to grant every wish, from the boldest to the most innocent.

Over ten years, this project has been based on an extraordinary effort by Antibiotice volunteers, transforming the lives of over **800 children** in the counties of Moldova. The generosity and kindness shown by Antibiotice employees created a profound impact, bringing joy and hope to these young hearts during the holiday season.





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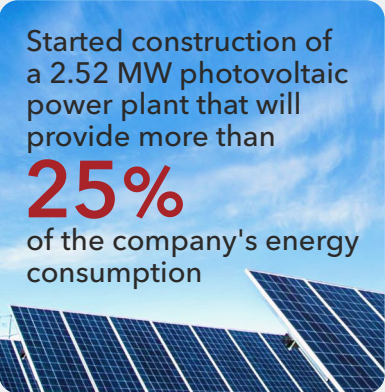
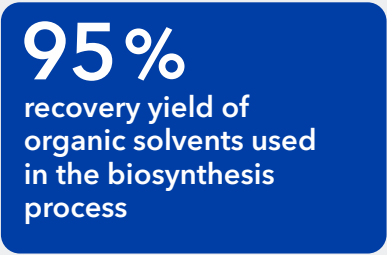
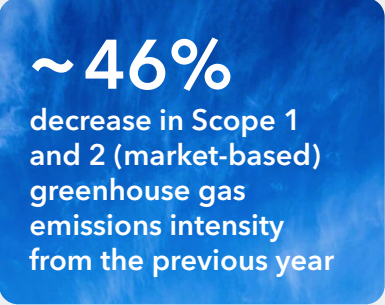
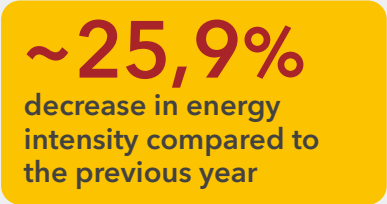
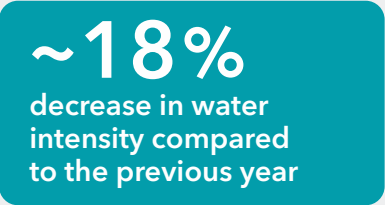
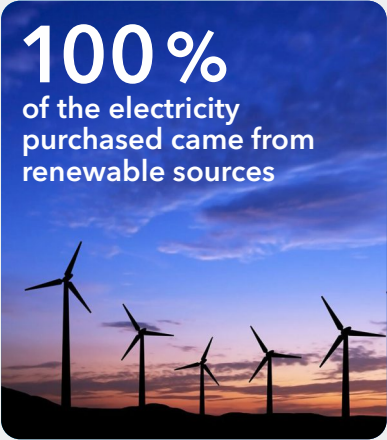
# 05

# Environment



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Environmental protection in the pharmaceutical industry is of significant importance given the impact that the production of medicines has, both through energy consumption and greenhouse gas emissions, as well as through the consumption of natural resources and generation of waste and wastewater. Antibiotice SA pays particular attention to environmental protection aspects, as reflected in its management commitment and integrated management system policy. All environmental protection activity is governed by environmental management system operating procedures and specific working instructions. Monitoring of the quality of environmental factors is also carried out in accordance with the requirements of the Integrated Environmental Authorisation, both by our own laboratories and by laboratories authorized by the Romanian Accreditation Association (RENAR).





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# 5.1. Energy consumption

Antibiotice SA manages energy consumption through the Energy Management activity, which ensures compliance with the legislation in this field by keeping energy consumption under control and monitoring. Energy consumption and energy efficiency measures adopted are reported weekly to the management team and annually to the authorities (Energy Efficiency Directorate of the Ministry of Energy and the National Institute of Statistics).

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 (an audit that lasts one year and tracks the company's entire energy consumption).

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). The last audit took place during the entire year 2020.

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 ultimate aim is to reduce consumption by improving energy efficiency. To this end, the company aims to increase the proportion of renewable energy used in production processes.

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

\* toe = tonnes of oil equivalent (toe) is a unit of energy; it measures the chemical energy released by burning one tonne of oil (1 toe = 41.868 GJ)

## 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 fuelling 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 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 2022, Antibiotice SA consumed no fuel from renewable sources.

### Total conventional fuel consumption at Antibiotice SA

Total fuel consumption (Gj*)	2022	2021	2020	2019
Diesel**	12,821	19,970	18,539	16,213
Gasoline**	204	570	596	425
Natural gas***	159,511	171,420	170,331	162,960
Total	172,536	191,960	189,466	179,598

\* 1 Gj =109 Jouli.  
\*\* Calorific value of fuels (NCV): diesel - 42.50 Gj/tonne and gasoline - 43.96 Gj/tonne; 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 energie.gov.ro/eficiență-energetică, 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.

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## Total electricity consumption

The 21.19% increase in electricity consumption in 2022 compared to 2021 was due to the 3.58% increase in production, but mainly to the simulations and production tests carried out on the 4 manufacturing lines of the new topical products plant inaugurated at the end of 2022.

In 2022, Antibiotice SA did not consume any electricity from non-renewable sources, all electricity being 100% green energy.

### Total electricity consumption at Antibiotice SA

Total electricity consumption (Gj*)	2022	2021**	2020	2019
- from non-renewable sources	0	30,865	33,339	25,930
- from renewable sources	55,070	14,575	22,183	26,400
<b>Total</b>	<b>55,070</b>	<b>45,440</b>	<b>55,522</b>	<b>52,930***</b>

\* 1Gj =10<sup>9</sup> Jouli.  
\*\* In the calculations for the 2021 reporting, the 2020 energy labels were used, because, by June 30, 2022, when the report was published as required by law, suppliers had not published the 2021 energy labels. Therefore, in this report (2022), we have recalculated the fuel consumption values using the corresponding 2021 energy label values.  
\*\*\* Calculation error (amount calculated incorrectly - under Total Electricity (Gj), the correct amount is 52,330, not 51,970 - see 2020 Sustainability Report, pg.70, table Electricity consumption, total 2019; in the 2019 Non-Financial Report, page 64, the amount was reported rounded to 52 TJ.

### Total energy consumption at Antibiotice SA

Total energy consumption (Gj*)	2022	2021	2020	2019
Fuel consumption from conventional sources	172,536	191,960	189,466	179,598
Electricity, heat, cooling, and steam purchased for consumption	55,070	45,440	55,522	52,330
<b>Total energy consumption</b>	<b>227,606</b>	<b>237,400</b>	<b>244,988</b>	<b>231,928</b>

\* 1Gj =10<sup>9</sup> Jouli.

Total energy consumption includes consumption at headquarters and on the industrial production site. The total energy consumption does not include the consumption of the Antibiotice representative office in Bucharest, Club a+, and other locations owned by Antibiotice, which are used (rented) by third parties.

## Energy intensity

The energy intensity calculation includes the following types of energy: electricity, natural gas, gasoline, and diesel.

Energy intensity (Gj*/ 1,000 lei)	2022	2021	2020	2019
(1) Total energy consumption (Gj)	227,606	237,400	244,988	231,928
(2) Goods production (thousand lei)	493,618	381,259	360,779	394,418
Energy intensity per 1,000 lei of goods production = (1) : (2)	0.461	0.622	0.679	0.588

\* 1Gj =10<sup>9</sup> Jouli.

Energy intensity decreased in 2022 by 25.9%.

## Energy efficiency measures

In 2022, consumption efficiency measures were taken at Antibiotice SA, derived from the 2020 Complex Energy Audit. As a result of these measures, electricity and natural gas savings of 1,500 GJ (total value of almost 362,000 lei) were achieved.

Energy saved in 2022	Reduction achieved (Gj)	Investment value (lei)	Description of the initiative that led to the reduction of energy use
Fuel (natural gas)	1,151.28	236,414	Replacement of the heating source of the buildings at the Wastewater Treatment Plant with several sources for the production of heating thermal agent (hot water). The measurement and calculation of energy savings were done by a certified thermal and electrical energy auditor.
Electrical energy (electricity)	201.60	64,553	Replacement of the interior fluorescent lighting in the Parenteral Products Plant (317 fluorescent luminaires, 100 W/lamp) with LED lighting (31 W/lamp). The energy saved was calculated considering the average number of hours of use (2561 hours/year).
Electrical energy (electricity)	147.60	61,100	Introduction of an adiabatic cooling system for the water-cooling unit in the Parenterals and Capsules Plants. Measurement and calculation of energy savings were done by a certified thermal and electrical energy auditor.
<b>Quantity saved</b>	<b>1,500.48</b>	<b>361,967</b>	



# 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.

Antibiotice is aware that the negative impact on the environment also derives from greenhouse gas emissions generated by its activities, especially the production and consumption of energy produced from non-renewable sources, which is why we prioritize investments in energy efficiency projects and the reduction of greenhouse gas emissions.

Monitoring of greenhouse gas emissions is carried out in accordance with the procedures of the ISO 14001 certified Environmental Management System – part of the Integrated Management System.

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 pursuant to



Directive 2003/87/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 601/2012.

Our greenhouse gas footprint calculation is done for each fiscal year according to the GHG Protocol standard guidelines. We are continuously working to update the methodology, improve the visibility and accuracy of the data presented, and update the information as necessary each reporting year.

GHG emissions (tons CO <sub>2</sub> e)	2022	2021	2020	2019
<b>Scope 1</b>				
– from natural gas combustion	8,947.85	9,626.41	9,558.26	9,141.90
– from diesel and gasoline combustion	807.534	1,270.79	1,183.45	1,029.92
– from fugitive emissions of refrigerants	181.86	493.841	202.06	749.02
<b>Total Scope 1 emissions</b>	<b>9,937.24</b>	<b>11,391</b>	<b>10,943.80</b>	<b>10,920.8</b>
<b>Scope 2</b>				
<b>Scope 2 – location-based:</b>				
– electricity consumption (based on national emission factors)	5,259.21	4,339.51	5,302.29	4,996.69
<b>Scope 2 – market-based:</b>				
– electricity consumption (based on emission factors from suppliers)	0	2,772.95	3,031.91	3,604.07
<b>Total greenhouse gas emissions Scope 1 + Scope 2 (location-based)</b>	<b>15,196.50</b>	<b>15,730.50</b>	<b>16,246.10</b>	<b>15,917.50</b>
<b>Total greenhouse gas emissions Scope 1 + Scope 2 (market-based)</b>	<b>9,937.24</b>	<b>14,164</b>	<b>13,975.70</b>	<b>14,524.90</b>

## Annual variation in greenhouse gas emissions compared to the base year 2019

	2022	2021	2020	2019
<b>Scope 1 + Scope 2 (location-based)</b>				
Total greenhouse gas emissions (tons CO <sub>2</sub> e)	15,196.50	15,730.50	16,246.10	<b>15,917.50</b>
Change compared to the base year	↘ 4.53%	↘ 1.17%	↗ 2.06%	<b>base year</b>
<b>Scope 1 + Scope 2 (market-based)</b>				
Total greenhouse gas emissions (tons CO <sub>2</sub> e)	9,937.24	14,164	13,975.70	<b>14,524.90</b>
Change compared to the base year	↘ 31.58%	↘ 2.48%	↘ 3.78%	<b>base year</b>

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**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). The following greenhouse gases have been included in the calculation of Scope 1 emissions: carbon dioxide CO<sub>2</sub>, methane CH<sub>4</sub>, and nitrous oxide N<sub>2</sub>O.

**Scope 2 emissions** are the amount of indirect greenhouse gas emissions from the production of electricity purchased from third parties for own consumption. The following greenhouse gases were included in the calculation of Scope 2 emissions: carbon dioxide CO<sub>2</sub>, methane CH<sub>4</sub>, and nitrous oxide N<sub>2</sub>O.

*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 that calculates emissions based on the electricity the organization has chosen to purchase, often through contracts or instruments such as renewable energy certificates.

In 2022 we procured the services of an external expert to calculate the carbon footprint of Scope 1 and Scope 2 as well as limited Scope 3 in accordance with the methodology of the GHG Protocol standard. Thus, the emission values for the years 2019, 2020, and 2021 were recalculated.

*Note: Due to the complexity of the information required for a complete inventory of indirect Scope 3 emissions, only the following categories have been calculated: related energy or fuel-consuming activities (not included in Scope 1 and 2), upstream transport and distribution, waste generated in operations, business travel, employee commuting, downstream transport, and distribution. Because it does not provide a complete picture of the impacts associated with indirect emissions, the company does not currently publish partial results on the amount of Scope 3 GHGs, rather these are intended to guide decision-making.*

The change in methodology resulted in differences in reporting in 2020, 2021, and 2022 respectively. The emission factors and global warming potential factors used can be found at [ghgprotocol.org](https://ghgprotocol.org).

Greenhouse gas (GHG) emissions intensity

Scope 1 + Scope 2 (market-based) emissions intensity decreased by almost 46% in 2022 compared to 2021. The decrease in GHG emissions intensity is mainly due to the 100% purchase of green energy from the electricity supplier, which also implied a decrease in specific electricity consumption per 1,000 lei of goods production. At the same time, measures to optimize and improve energy efficiency were also implemented following the company's Energy Audit.

Scope 1 and Scope 2 greenhouse gas (GHG) emission intensity (tons CO <sub>2</sub> e/ 1,000 lei)	2022	2021	2020	2019
Location-based Total GHG emissions (t CO <sub>2</sub> e)	15,196.45	15,730.55	16,246.07	15,917.53
Market-based Total GHG emissions (t CO <sub>2</sub> e)	9,937.24	14,163.98	13,975.69	14,524.91
Goods production (thousands lei)	493,618	381,259	360,779	394,418
Location-based GHG emissions intensity per 1,000 lei goods production	0.030	0.041	0.045	0.040
Market-based GHG emissions intensity per 1,000 lei goods production	0.020	0.037	0.039	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).

Other significant air emissions (tons NMVOCs*/year)	2022	2021	2020	2019
Non-methane volatile organic compounds (VOCs) (t nmVOCs/year)**	357,289	285,476	382,977	310,583

\* 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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The 25% increase in total emissions of non-methane volatile compounds (VOCs) in 2022 compared to 2021 was generated by the production structure. However, by applying solvent recovery techniques, the emission target value for fugitive emissions (15% of annual solvent consumption) was met.

Also, the combustion of fuels (natural gas) in the thermal power plant and its own incinerator results in activity-specific air pollutants.

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<sub>x</sub>), sulfur oxide (SO<sub>x</sub>), carbon monoxide (CO), hydrochloric acid (HCl), organic substances expressed as total organic carbon (TOC), volatile organic compounds (VOC<sub>nm</sub>), dust, etc.

There were no exceedances of the maximum permissible concentrations laid down in the regulatory acts held and the legal requirements in force applicable to the activities carried out in the company.

Managing odor impact

In 2022, specific actions continued in order to implement the requirements of Law 123/2020 („Odour Law”). Antibiotice SA is constantly concerned with improving the technological performance of the installations/equipment, as far as technologically possible, as well as identifying applicable solutions in order to prevent odor nuisance for the neighboring community.

Thus, the collaboration with a company specialized in providing solutions for neutralizing technological odors was initiated, and specific equipment was installed and commissioned, together with monitoring of odor emissions. Expenditure amounts to approximately €15,000 during the industrial testing phase.

Company fleet in 2022

The fleet, transporting people and goods outside the company, consists of means of transport such as company cars, buses for employee transport, minibusses, vans, and tractors. On the factory site, goods are transported by forklift trucks and electric trucks.

The fleet also includes a fire brigade, which is used to help extinguish any fires that may occur on the company's premises and beyond.

In 2022, in order to renew its fleet of vehicles, the purchase of 8 new Euro 6

Antibiotice fleet (vehicles in circulation)	2022	2021	2020	2019
Number of vehicles	168	164	151	153
Distance traveled (km)	3,219,701	3,427,850	2,683,276	3,299,008

Number of fleet vehicles by type of fuel used	2022	2021	2020	2019
Diesel	163	161	145	148
Gasoline	5	3	6	5

cars was initiated (16 vehicles were handed over for scrapping, following access to the classic Rabla Program). The request has been approved and the new vehicles are to be purchased during 2023.





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## Reducing greenhouse gas emissions

Climate change adaptation is a topic of interest to stakeholders who are directly or indirectly affected by the impact of Antibiotice activities on the environment, people and communities. Antibiotice SA is a responsible company that wants to ensure that the expectations of all its stakeholders are met and will continue to develop itself based on sustainability principles in the future.

Even if in Romania the effects of climate change (such as excess rainfall, which could cause massive flooding, or lack of rainfall, which could cause significant water stress, or changes in temperature values to an extreme level, which could cause severe storms, etc.) have so far not been so significant as to endanger the activities carried out by the company, the global nature of Antibiotice SA's value chain shows that they cannot be excluded and must be addressed strategically.

Thus, in 2022 a more detailed analysis of the climate risks that may influence the performance of Antibiotice SA was initiated in order to establish measures to address and reduce the impact of these risks on the company's activities. Details of this process are presented in detail in the Risk Management sub-chapter.

Action plans have been developed that include concrete and effective climate change adaptation measures to ensure the transition to a low-carbon economy in order to achieve the climate neutrality goal set by the European Union through the European Green Deal and the objectives of the Paris Agreement.

### Reduced emissions (tons CO<sub>2</sub>e)

Initiative	Reduction achieved in 2022 (tons)	Brief description of the initiative
Consumption monitoring	13% reduction in Scope 1 emissions, amounting to 1,518 tons CO <sub>2</sub> e.	Monitoring consumption through the development of the utility consumption monitoring system, a previously implemented measure.
Optimizing equipment operation and adjusting parameters		Adjustment of equipment operations in relation to the average outdoor temperature (higher compared to 2021).
Optimizing transport routes		Optimization of transport routes following the end of the pandemic phase.
Optimizing utility procurement procedures	100% reduction of Scope 2 emissions amounting to 2,772.95 tons CO <sub>2</sub> e (market-based) and 4,339.51 tons CO <sub>2</sub> e (location-based) due to the exclusive use of green energy from the utility provider.	Using the opportunity to contract green energy.





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## 5.3. Natural resource consumption

For the year 2022, raw materials, materials, and packaging inputs were estimated for production operations carried out on the industrial site in Iași, exclusively in the production process of medicines and biofertilizers. The estimates do not include materials used in other departments, except for those used in direct production activity (consumables, office supplies, printer cartridges, including writing paper), materials and spare parts used for motor vehicles (spare tires, etc.), computing technology and consumables, spare parts, and consumables for production and laboratory equipment, software applications for production and laboratory equipment, mechanical, electrical, and automation materials, oils and vaseline, laboratory glassware, air conditioning equipment).

In some cases, the quantities consumed were measured directly, but due to the very large number of products purchased, the different characteristics and units of measurement, and the lack of necessary data in the calculations, estimates were made in many cases.

The data were provided by the procurement departments, and the context data were taken from the [Integrated Environmental Authorisation no. 3/ 29.09.2021](#), which can be found on the Iași Environmental Protection Agency website, in the section Regulations, Integrated Environmental Authorisations (IEA), respectively from the [Antibiotice 2022 Annual Environmental Report](#), which can be consulted on the Antibiotice website in the section Responsibility, Environmental Protection.

### Materials used in 2022

In 2022, the total estimated weight of raw and auxiliary materials used for the production and packaging of the active substance and finished products (generic human and veterinary medicinal products, medical devices, food supplements, cosmetics) was 6,583.13 tons, of which 4,027.90 tons were non-renewable materials and 2,550.40 tons were renewable materials. Of the total amount of raw materials and supplies purchased in 2022, 65% were purchased from domestic suppliers (Romania) and 35% from foreign suppliers (international).

### Recycled materials used in Antibiotice activity

Due to the specifics of the pharmaceutical and medicine industry, there is a limit to recycled materials that can be used in production. Therefore, the percentage of recycled materials used in the manufacture of the main Antibiotice products in 2022 is very small, only 0.073% (the cardboard used to separate the products in their shelf on the pallet, in the tertiary packaging).

**The ratio of the amount of materials used to make the Antibiotice products in 2022 and the waste generated in the same period was 8.06.**

i) Non-renewable materials 2022	tonnes
i.1) Non-renewable virgin materials	
Raw materials (active substances in bulk, excipients, organic and inorganic chemical substances, etc.)	2,185.50
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.)	784.30
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.)	398.30
Materials used as packaging (glass, plastic of different types, rubbers, aluminum/plastic caps, blisters of aluminum foil, plastic or composite materials	659.80
Total non-renewable virgin materials	4,027.90
i.2) Recycled non-renewable materials	0
Total recycled non-renewable materials	0
Total non-renewable materials used in 2022	4,027.90
ii. Renewable materials 2022	tonnes
ii.1) Virgin renewable materials	
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)	2.30
Materials used as packaging (paper and cardboard, wood)	2,548.10
Total virgin renewable materials	2,550.40
ii.2) Recycled renewable materials (recycled cardboard)	
Total recycled renewable materials	4.83
Total renewable materials used in 2022	2,555.23
Total non-renewable and renewable materials used in 2022	6,583.13

Materials and waste flow

The quantities, specifics of raw materials, materials used, and waste generated upstream, in operations on the production site, and downstream (including quantities of packaging waste for Antibiotice SA products placed on the national market) are monitored along the value chain.

Upstream

Raw materials and supplies

Antibiotice SA purchases upstream, in the value chain, renewable raw materials (wood, water, plant fibers) and derived materials (paper, cardboard), non-renewable raw materials (minerals, oil, natural gas), and derived materials (plastics, foils, synthetic resins, synthetic fibers), auxiliary materials and packaging. 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.

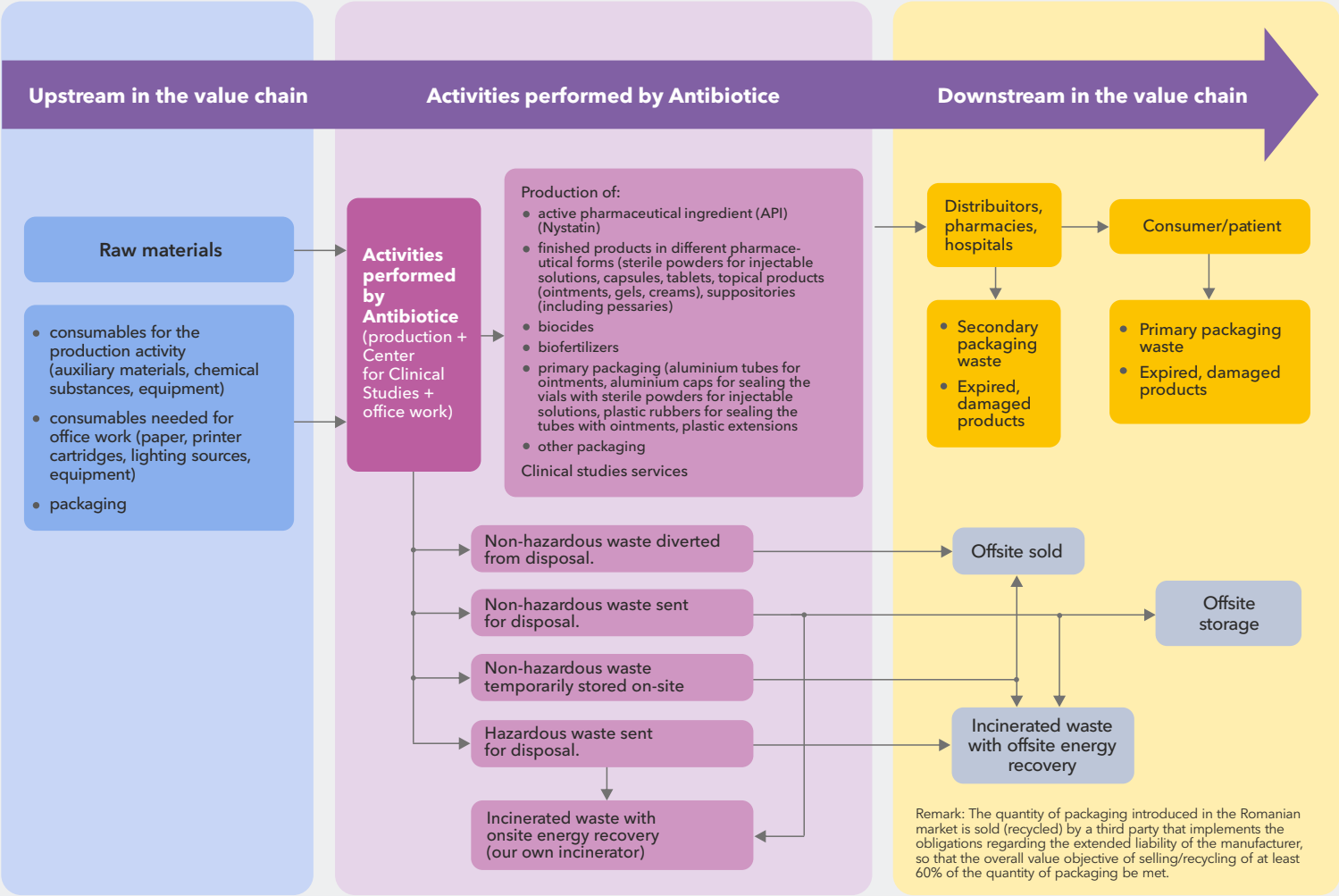
Waste

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 the primary, secondary, and tertiary packaging (paper, cardboard, plastic, composites, wood, and glass).

Materials and waste flow





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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, on 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 a treatment for in-patients.

Biocides reach stores, where they are bought by the general public, and fertilizers are sold through distributors.

Waste

Downstream, hazardous waste comes from active substances, finished pharmaceuticals, and biocides deteriorated during transport or expired.

Finished pharmaceuticals can expire in the warehouses of drug distributors, pharmacies, and consumers. According to the Orders of the Minister of Health 119/2014 and 444/2019, expired medicines can be handed over to community pharmacies, which are required to store them in specially designated areas and then hand them over to the relevant organizations for destruction by incineration.

Downstream, non-hazardous waste comes from biofertilizers in case of spoilage 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. Some of the primary packaging for Antibiotice SA's medicines are also produced in the company's Microproduction Department.

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

In its Iași factory, 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: seeding on a nutrient medium of microorganisms (in the case of Nystatin,

Streptomyces noursey), their fermentation in bioreactors (where the active substance is biosynthesized), filtration, extraction, and crystallization.

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 supplies

The industrial biosynthesis flow is the largest consumer of raw materials and supplies (including chemicals and hazardous products).

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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 the active substance is done using the organic solvents acetone 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 wastes generated are residues with traces of acetone and methanol, left after recovery of organic solvents. The main non-hazardous wastes are 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 waste is 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, the formulation and packaging of finished pharmaceutical products (generic human and veterinary drugs, medical devices, food supplements, and cosmetics) in various dosage forms (capsules, tablets, sterile powders for injections, ointments, creams, gels, suppositories, and pessaries) take place on seven flows.

Each individual 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 material*

The main raw materials and materials used are active pharmaceutical ingredients (active substances), excipients, and other organic and inorganic substances.

*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.





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In secondary packaging, each individual unit (tube of ointment, tube of cream, tube of gel, vial of sterile powder for injections, tablet, capsule, suppository, pessary) individually packaged 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**

Some of the primary packaging for Antibiotice SA medicines is produced in the factory, in the Microproduction department: aluminum tubes for ointments, aluminum caps for sealing sterile powder vials for injectable solutions, plastic sleeves for sealing aluminum ointment tubes and plastic pins (elongated tips used to apply certain ointments).

*Raw materials and material*

The raw materials and materials used are aluminum (tape and discs), polyethylene (plastic granules), organic solvents (acetone), and typographic paints (inks) for the inscription of aluminum tubes.

*Waste*

Hazardous waste generated in the production process comes from solvent-containing waste used to remove printing inks. Non-hazardous waste is plastic and aluminum waste.

**3) Manufacture of biocides and fertilizers**

**3.1) Biocides**

Antibiotice SA manufactures two types of alcohol-based biocides for surface and hand disinfection.

*Raw materials and materials*

Biocides for surface disinfection are clear, liquid solutions and those for hand disinfection are translucent gels. The active substance used in the manufacture of biocides is denatured ethanol.

*Water*

Water used in the production process is found as such (in liquid form) and in the composition of the final product (26.77% purified water in surface biocides and 17.35% purified water in hand disinfection biocides).

*Packaging*

Biocides are primarily packaged in plastic containers/bottles. Secondary packaging involves grouping several units in cardboard boxes. Tertiary packaging, for the transport of the boxes/bottles, is done on wooden pallets. For transport integrity, the pallet loaded with boxes of biocides/bottles is sealed by wrapping it in stretch plastic film (PVC).

*Packaging waste*

The main packaging wastes are paper, cardboard, wood, and plastic.

**3.2) Biofertilizers**

In 2022, Antibiotice SA produced biofertilizers for agriculture, and biological fertilizers for the fertilization of crops, in the quantities required for 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) and 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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## Water consumption

Access to clean water supplies is essential both to ensure the continuity of the company's business and to ensure a good quality of life for the community around the plant. Antibiotice SA complies with environmental legislation and maintains close contact with the relevant environmental authorities and other relevant stakeholders that may be affected by the company's activities.

Thus, the company has established specific procedures related to water management, based on the ISO 14001:2015 environmental management system. In order to improve water management, a diagnostic analysis of water consumption and quality has been carried out and, in the future, Antibiotice will develop a water management policy based on the findings of this analysis.

For efficient management of water sampling, discharge and consumption, Antibiotice SA owns collection facilities, treatment plants, storage facilities, and water distribution networks.

Both water consumption and discharged water volume are closely monitored with the help of a utility consumption monitoring system implemented in 2018 and expanding every year by adding new sensors and diversifying the type of utilities monitored. Currently, the system monitors electricity, heat, methane gas, steam, and water.

The management of water supply and discharge, as well as the monitoring of water quality, are carried out according to the requirements of the Water Management Permit no. 20/31.03.2021, issued by the "Apele Române" National Association, Prut Bârlad Water Basin Administration (valid until April 1, 2026). According to the Authorisation, Antibiotice SA is required not to discharge untreated or insufficiently treated wastewater resulting from its activities into surface and/or groundwater or on land.

## Recovered (recycled) water

A certain degree of water recirculation is ensured in all manufacturing flows. In 2022, 7,438 liters of water from steam condensate were reused for heating and pre-heating.

In our company, the Accidental Pollution Prevention and Control Plan has been developed and implemented, establishing, in accordance with legal requirements, the measures to be taken in the event of accidental pollution or an event that may lead to imminent pollution of water sources, the phone numbers to report the event and the persons notified for intervention.

## 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 a third party: the regional public water and sewerage



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Total volume of captured water, by source (MI*)	2022		2021		2020		2019	
	Total operating areas	Water-stressed areas	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)	158.5	0	149.0	0	159.6	0	146.7	0
Total water captured (extracted) = water (total) + Groundwater (total) + Seawater (total) + By-product water (total) + Water from suppliers	158.5	0	149.0	0	159.6	0	146.7	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

operator in Iași County. The ApaVital operator supplies the municipality of Iași with drinking water from the Timișești source (since 1911) and from the Prut River (since 1957).

Also, the water supply of Valea Lupului, located in the immediate vicinity of the factory, is also made from the water supply system of the municipality of Iași, the Timișești source.

The over 6% increase in the volume of drinking water captured in 2022 from the municipal network compared to 2021 was partly due to the 3.58% increase in the production of medicines (but not proportionally due to the implementation of internal measures to improve water use management by ensuring consumption monitoring). Most of the water was used in the production simulation processes and manufacturing tests carried out on the 4 flow lines of the new topical products plant inaugurated at the end of 2022.

Water risks

Water is a vital resource for industry, agriculture, and communities alike, and therefore the Timișești, Neamt area, from which the water used in Antibiotice SA's activities originates, has been assessed to see if it is an area affected by water stress and drought risk, as part of a global assessment of such risks.

The World Resources Institute (WRI) has produced, based on the available dataset, risk rankings of the (average) exposure of countries and/or provinces for some of the Aqueduct 3.0 water risk indicators (from highest to lowest risk). Risk scores are also available for the (average) exposure of industrial, agricultural, and domestic water users, which allows tracking an organization's entire value chain, regardless of the location of its operations.

The two indicators we monitor in the analysis are baseline water stress and

drought risk. For this, we used the tools provided by the World Resources Institute (WRI) Aqueduct Water Risk Atlas. Aqueduct 3.0 uses the risk element terminology used by the United Nations Office for Disaster Risk Reduction (hazard, exposure, and vulnerability), with each indicator assigned a risk element.



Water stress risk

Water (drinking and non-residential) is captured for domestic, industrial, irrigation, and livestock use, and renewable water supplies available in the natural environment include surface and groundwater supplies and take into account the impact that water consumers, i.e. large upstream dams on rivers, have on water availability downstream.

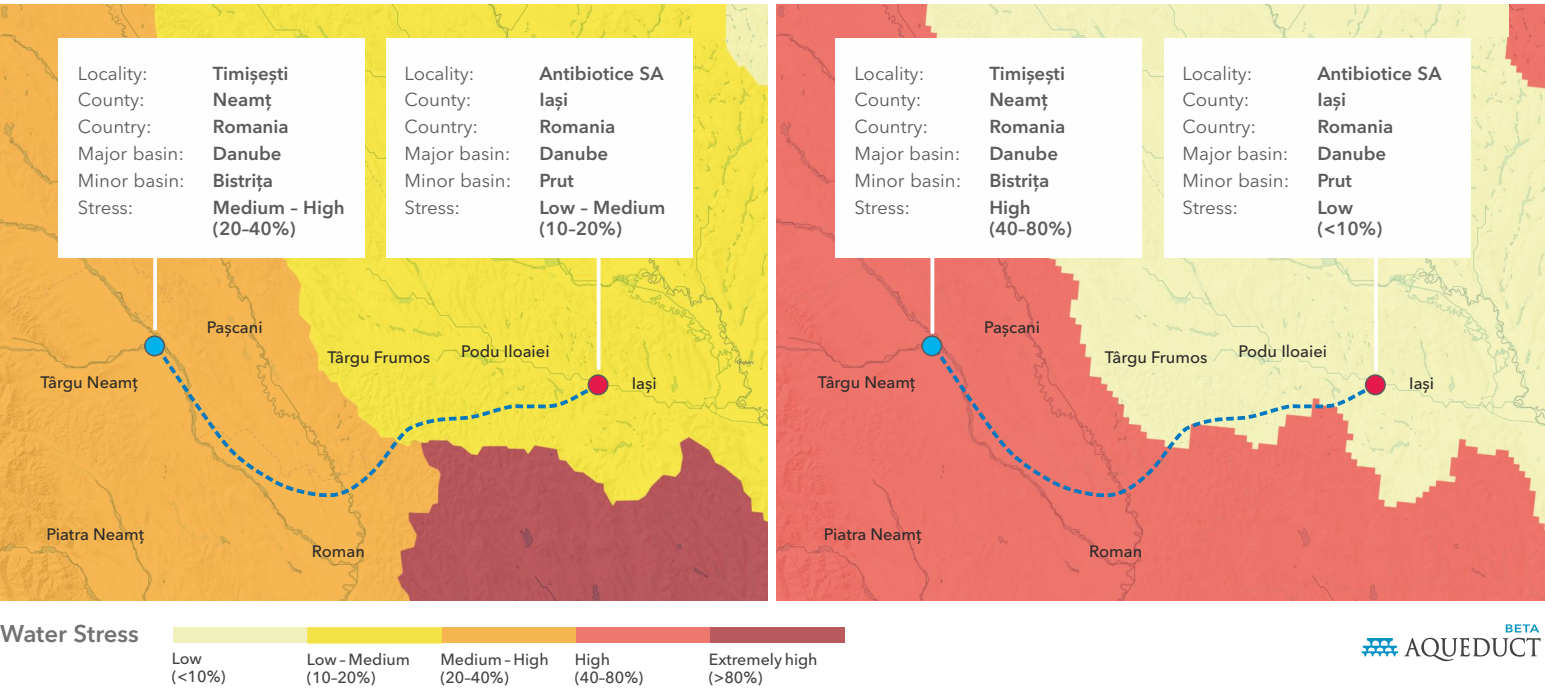
An area is said to be under water stress if it does not have the capacity to meet ecological and human water demand (i.e. water availability, quality, or access).

In order to assess the water stress of the area of origin of the water used by Antibiotice SA, we follow the map based on the reference water stress (baseline water stress)\* (BWR) from the Aqueduct atlas. Baseline water stress is an indicator in the category of physical hazards affecting water.

The baseline water stress, BWR, is calculated as the ratio of the total water captured (extracted) from an area in a year to the total renewable water resources available in that area. The higher the values of this indicator, the greater the competition between users for the same water sources. If the BWR indicator values are high or extremely high, we define the area as being under water stress.

\* Baseline Water Stress (BWR) is an indicator used in the Aqueduct Water Risk Atlas, a page accessed on May 9, 2023.

Evaluation of water stress in the Timișești area, Neamț County, in the present and in the future (2030)



As can be seen on the left side of the risk map, the baseline water stress (BWR) in the Timisesti area has a medium to high value (20-40%).

Based on these observations, we can say that the water collected by Antibiotice SA in 2022, which comes from water extracted directly by its supplier, ApaVital, from the Timișești source, does not originate from an area under water stress.

In the global ranking of exposure to water stress risk (starting with the highest risk), Romania ranks 71st out of 167 countries

monitored, with a total score of (1.85), between low and medium (10-20%).

In detail, the score for agricultural water users (1.21) is in the same risk range as that for industrial water users (1.98). The score for domestic water users (population) (2.03), however, is in the medium to high-risk range (20-30%).

The Aqueduct 3.0 tool and the Aqueduct atlas have also allowed a projection into the future, by simulating scenarios of water stress in the Timișesti area in the 2030 and 2050 horizon, based on the

same indicator, BWR. Unfortunately, in all three scenarios allowed by the simulation, pessimistic, business as usual (BAU), and optimistic, the values of the indicator are high (40-80%), so the area will probably be in water stress (see risk map on the right).

Although the Timișești, Neamt area, where the water used by Antibiotice SA originates from, is not currently under water stress, available information, and simulations show that the water resources available in that area will decrease in the future.

Drought risk

Another phenomenon affecting available natural water resources, especially with global warming, is drought. 2022 was a dry year all over Europe, including Romania. The north-eastern region of Moldova was one of the regions strongly affected by soil drought throughout the year (see the 2022 reports for Europe, in particular, the August report; these detailed reports are produced by the European Drought Observatory (EDO) only in cases of severe drought. The EDO provides relevant drought information and issues timely drought warnings for both Europe and globally.

Drought risk is another indicator in the category of physical risks related to water.

Drought risk indicates where drought is likely to occur, which communities and assets will be at risk, and their vulnerability to the adverse effects of drought. The higher the indicator values, the greater the risk of drought occurring. If the drought risk indicator values are medium-high (60-80%) or high (>80%), we define the area as being at risk of drought.

In order to assess the drought risk of the area of origin of the water used by Antibiotice SA, we follow the map based on this risk, from the Aqueduct atlas.

\* Drought risk is an indicator used in the Aqueduct Water Risk Atlas (<https://www.wri.org/data/aqueduct-water-risk-atlas>), page accessed May 9, 2023

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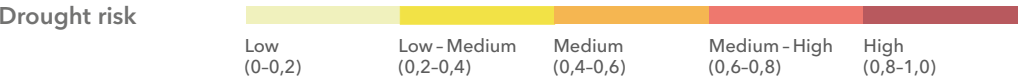
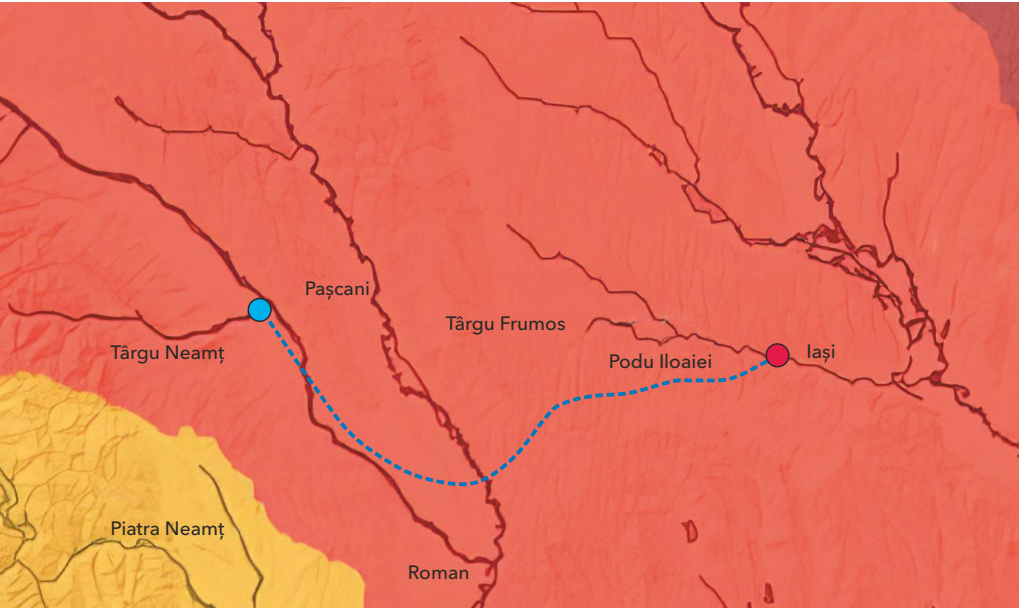
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Evaluation of drought risk in the Timișești area, Neamț County



As shown on the risk map, in the Timisesti area, as in the whole northeastern area of Moldova, the drought risk indicator is in the medium to high range (60-80%). Based on these observations, we can say that the water abstracted by Antibiotice SA, in 2022, from water extracted directly by its supplier, ApaVital, from the Timisesti source, comes from an area exposed to a medium risk of drought.

In the global drought risk exposure ranking (starting with the highest risk), Romania ranks a worrying 7th out of 138 countries monitored, with a total score of (0.73),

between medium and high (60-80%). It is worth noting that the top two places (highest risk exposure) are occupied by two neighboring countries, the Republic of Moldova and Ukraine, so the entire geographical area of the region is affected.

In detail, the scores for the industrial sector of (0.70) and the household sector (population) of (0.72) are in the same medium to high range ( 60-80%). The risk level for the agricultural sector, however, is (0.82), so it falls into the high-risk group (80-100%).

Water discharged

From the Antibiotice SA site, the factory's sewage system discharges (polluted) wastewater from its own activity: industrial (technological) wastewater and domestic wastewater.

Industrial (technological) wastewater is water that is discharged after being used in technological processes (as process water, wash water, cooling water, etc.). At Antibiotice SA, industrial wastewater is initially treated locally in pre-treatment facilities within the structures that used it (production, storage, auxiliary, etc.). Then, this partially pre-purified industrial wastewater, together with domestic wastewater and rainwater from the active substance production area, is directed via the plant's sewerage network to the plant's pre-purification plant.

The pre-treatment plant is a construction and installation system designed to clean polluted water. The wastewater entering the treatment plant is called influent. The purification process takes place inside the plant; through various treatment methods (physical, chemical, biological), wastewater is cleaned (reducing the quantity and concentration of specific pollutants, removing certain substances from the water, etc.). The process takes place until the water leaving the treatment plant (called effluent) has the quantitative and qualitative characteristics suitable for discharge into the sewage network.

Antibiotice SA's wastewater pre-treatment plant, in operation since 2006, treats

influent in two stages of treatment: the first stage, mechanical, retains floating coarse solids, fats, etc., and the second stage, biological, using active sludge, reduces the load of organic substances and other pollutants (ammoniacal nitrogen NH4-N, sulfides, etc.). The treated wastewater is discharged into the public sewage network of the Iași municipality, which is managed by the Iași County water and sewerage operator.

Domestic wastewater is water discharged after being used for food preparation, washing clothes, personal hygiene, and sanitary facilities. Through Antibiotice SA's sewage network, it is directed to the company's pre-treatment plant. After treatment, they are discharged into the public sewage network of the municipality of Iași.

The flow rate of the influent at the inlet of the pre-treatment station is measured using measuring equipment and the records are based on the reports concluded with the water supplier (regional public operator of water and sewage services in Iași County).

Antibiotice SA monitors the quality of the wastewater leaving the pre-treatment plant in its in-house laboratory and third-party laboratories accredited by RENAR (Romanian Accreditation Association). Analyses are carried out before the effluent is discharged into the public sewerage network of the municipality of Iași.

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Rainwater (meteoric water)

In addition to the water used by Antibiotice SA, there is also rainwater on the site, coming from rain, snow, snow melt, and street washing. Some of this evaporates, some is absorbed into the ground and the rest ends up on the streets, pavements, and asphalt around buildings. Rainwater from the Biosynthesis section area is directed through the sewer network to the pre-treatment plant. The rest of the conventionally clean rainwater, estimated at 134 MI in 2022, is discharged into the Cantacuzoia Stream, a tributary of the Bahlui River.

In its in-house laboratory, Antibiotice also analyzes conventionally clean rainwater before it is discharged into the Cantacuzoia natural outfall.

The determination of the amounts of pollutants in pre-cleaned wastewater is carried out using the mass flow method (calculation based on values determined by laboratory analysis).

In 2022, the quality of the wastewater discharged from the pre-treatment plant into the public sewer system and the rainwater discharged into the outfall is within the parameters set by environmental legislation. There were no

exceedances of the maximum permitted discharge limits set by GD 352/2005 (NTPA 001-2005 and NTPA 002-2005), the Integrated Environmental Permit, and the Water Management Permit.

Water consumed by Antibiotice SA

All the water used by Antibiotice in its activities in Iasi is drinking water, purchased from the regional public operator of water and sewage services in Iasi County. The amount of water entering Antibiotice premises is measured on entry to the company using water meters.

Water consumed is the sum of all water abstracted (incorporated into products, used in construction, generated as waste, evaporated, consumed by humans, or polluted to the point of being unusable by other users and therefore not discharged back to surface water, groundwater or to a third-party during the reporting period).

The quantity of water consumed at Antibiotice in 2022 was 44.6 megalitres of drinking water, up by 4.9 megalitres (12.34%) from 2021. The increase was mainly due to simulations and production tests carried out on the 4 manufacturing lines of the new topical products plant inaugurated at the end of 2022.

Water discharged by Antibiotice SA (MI*), by water source	2022		2021		2020		2019	
	Total operating areas	Water-stressed areas	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)	113.9	0	109.3	0	123.4	0	115.2	0
Total water discharged	113.9	0	109.3	0	123.4	0	115.2	0

\* 1 MI (megaliter) = 1,000,000 liters = 1,000 cubic meters

Water consumed (MI*)	2022	2021	2020	2019
(1) Total water collected	158.5	149	159.6	146.7
(2) Total water discharged	113.9	109.3	123.4	115.2
Water consumed (MI) = (Total water collected/abstracted) - (Total water discharged/ spilled) = (1) - (2)	44.6	39.7	36.2	31.5

\* 1 MI (megaliter) = 1,000,000 liters = 1,000 cubic meters

Water consumption intensity

Water consumption intensity related to the value of goods production decreased by 18% in 2022 compared to 2021

Water consumption intensity (specific water consumption per 1,000 lei of goods production)	2022	2021	2020	2019
(1) Water consumption (MI)	158.472	149	159.600	146.700
(2) Goods production (thousand lei)	493,618	381,259	360,779	394,418
Intensity of water consumption per 1,000 lei of goods production (1):(2)	0.32	0.39	0.44	0.37

\* 1 MI (megaliter) = 1,000,000 liters = 1,000 cubic meters





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# 5.4. Packaging and waste

Antibiotice is constantly concerned with the accountability of all employees, to prevent the generation of waste in the company, reduce its quantity, and dispose of it safely, in compliance with the legal requirements. To this end, the Waste Prevention and Reduction Program is carried out every year.

To reduce the negative impact of the waste generated, it is collected selectively and handled by authorized companies contracted by Antibiotice for recovery or disposal.

During the year, records on waste management (types of waste and quantities generated, methods of recovery or disposal) are prepared monthly, both for internal analysis and evaluation and reporting to the environmental authorities as required by the integrated environmental permit held.

Recyclable waste is recovered by authorized economic operators, and non-recyclable waste is either incinerated in the company's incineration plant, with energy recovery or disposed of (by landfilling at the municipal landfill or by authorized economic operators under a service contract).

Antibiotice regularly evaluates the authorized waste management operators and

verifies compliance with the contractual terms agreed upon. The assessment is carried out prior to contracting the services, by establishing specific authorization requirements, followed by checks on the implementation of the contracted services, including audits of the service providers. These steps are set out in the Integrated Management System documents applicable to the company.

Data on the quantities of waste generated by Antibiotice from manufacturing operations in 2022, and how it was managed, were extracted from the records of the Environmental Protection structure and the Internal Environmental Audit conducted in 2022.

## Waste generated by Antibiotice SA in 2022

The total amount of waste generated in 2022 was 817.04 tonnes, a decrease of almost 28% compared to 2021, due to specific stages of implementation of investment projects in 2022. Of these, 97.38 tonnes of depleted mycelium filter cakes (resulting from the biosynthesis of Nystatin) are temporarily stored on the company's site in the concrete composting tanks at the pre-treatment

### Total waste generated by Antibiotice SA in 2022

Waste (tonnes)	2022	2021	2020	2019
Total waste generated, of which:	817.040	1,132.758	1,400.910	1,760
- hazardous waste	20.620	16.218	21.714	17
- non-hazardous waste	796.420	1,116.540	1,379.196	1,743

plant, after which they are handed over to authorized operators for collection and transport for final disposal. The remaining 716.17 tonnes of waste, which includes the initial stockpiles from 2021, were disposed of or diverted from disposal.

### Hazardous waste

The more than 27% increase in hazardous waste in 2022 compared to 2021 is due to the implementation of energy efficiency measures. These measures generated hazardous waste (waste oil), stemming from the process of gradually replacing old, inefficient equipment.

The industrial biosynthesis flow of the active substance Nystatin generates the largest amount of hazardous waste, 14.68 tonnes, representing 71% of the total hazardous waste (13.6 tonnes of residues from solvent distillation and recovery and 1.08 tonnes of filter material absorbents).

Of the total 20.62 tonnes of hazardous waste, more than 82% was disposed of (16.31 tonnes disposed of internally by incineration on the site and 0.69 tonnes disposed of externally by authorized operators). The remaining almost 18% (3.62 tonnes) was recovered by authorized operators.

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Non-hazardous waste

The amount of non-hazardous waste generated in 2022 was 796.42 tonnes, almost 29% less than in 2021. Of this, 15.25 tonnes were disposed of internally by incineration on the site, 194.16 tonnes were disposed of externally by authorized operators, and 486.15 tonnes were recovered by authorized operators. The remaining 100.86 tonnes remained in the waste stockpile, stored on the company's site.

The amount of 129.32 tonnes of mixed municipal waste, representing 16% of the total non-hazardous waste generated in 2022, decreased by 31.4% compared to 2021.



Types of waste generated 2022 (tonnes)

No.	Type of waste	Waste code	Total waste generated	Waste diverted from disposal	Waste directed to disposal (incineration, landfill)
1	Other residues from the bottoms (blaz)* of reaction columns (distillation and solvent recovery residues)	07 05 08*	13.60	0	13.60
2	Sludges from on-site effluent treatment other than those containing dangerous substances (mycelia, filter cake)	07 05 12	97.38	0	0
3	Acetone mixture with interior varnish, enamel, inks	08 01 17*	0.14	0	0.14
4	Waste printer toners other than those containing dangerous substances	08 03 18	0.46	0.46	0
5	Other (used) engine, gear and lubricating oils	13 02 08*	3.76	3.52	0.24
6	Paper and cardboard packaging	15 01 01	101.57	100.85	0.77
7	Plastic packaging	15 01 02	38.10	23.09	15.13
8	Wood packaging	15 01 03	36.55	36.55	0
9	Metal packaging (including aluminum)	15 01 04	20.76	21.57	0
10	Glass packaging	15 01 07	11.88	14.50	0
11	Exhausted absorbents (filter media,contaminated protective equipment)	15 02 02*	2.44	0	2.44
12	Scrap tires	16 01 03	2.00	2.00	0
13	Discarded electrical and electronic equipment (WEEE) other than transformers and capacitors containing printed/integrated circuit boards (PCBs) and those containing hazardous components	16 02 14	30.17	30.73	0
14	Expired non-hazardous laboratory chemicals	16 05 09	1.98	0	1.98
15	Hazardous chemicals (expired reagents, laboratory substances)	16 05 06*	0.45	0	0.45
16	Aluminum (from construction and demolition)	17 04 02	2.05	2.13	0
17	Iron and steel (construction and demolition)	17 04 05	245.57	247.55	0
18	Cables, other than those containing oil, tar or other dangerous substances (from construction or demolition)	17 04 11	2.74	2.74	0
19	Sharp objects except for waste whose collection and disposal are subject to special infection prevention measures	18 01 01	0.02	0	0.02
20	Wastes whose collection and disposal are subject to special infection prevention measures	18 01 03*	0.06	0	0.06

\* Blaz = Tank at the bottom of a distillation column where distillate mash is introduced.



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Types of waste generated 2022 (tonnes)

No.	Type of waste	Waste code	Total waste generated	Waste diverted from disposal	Waste directed to disposal (incineration, landfill)
21	Spent activated carbon from flue gas cleaning	19 01 10*	0.07	0	0.07
22	Ash, slag, other than those containing dangerous substances	19 01 12	0,12	0	0
23	Sludges from biological treatment of industrial wastewater other than those containing dangerous substances	19 08 12	8.85	0	0
24	Paper and cardboard	20 01 01	0.88	0.88	0
25	Fluorescent tubes and other mercury-containing waste	20 01 21*	0.10	0.10	0
26	Drugs other than cytotoxic and cytostatic (expired, non-compliant)	20 01 32	61.97	0	61.29
27	Other discarded electrical and electronic equipment	20 01 36	1.85	1.85	0
28	Plastics (including rubber)	20 01 39	0.96	0	0.90
29	Metals	20 01 40	1.25	1.25	0
30	Mixed municipal waste	20 03 01	129.32	0	129.32
Total			817.04	489.77	226.40



Waste management by type and disposal/recovery method (tonnes)	2022	2021	2020	2019
Total waste generated	817.04	1,132.76	1,400.91	1.760
Total hazardous waste generated, by recovery/disposal method	20.62	16.22	21.71	17
Hazardous waste for recycling	3.62	0.38	0	0
Hazardous waste for incineration	17.00	15.84	21.71	17
Total non-hazardous waste generated, by recovery/disposal method	690.19	998.00	1,000.63	1.743
Non-hazardous waste for recovery, including energy recovery	486.15	769.86	710.92	1112
Non-hazardous waste for incineration	80.09	34.70	54.21	36
Municipal landfill	129.32	188.50	213.50	215
On-site storage*	106.23	118.53	400.22	407



\* This non-hazardous waste is temporarily stored on the company's site before recovery or disposal by authorized economic operators.

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Waste diverted from disposal 2022		Waste diverted from disposal 2022 (tonnes)		Waste diverted from disposal 2021 (tonnes)	
Location >	Waste code	Offsite	Total	Offsite	Total
Hazardous waste					
Recycling		3.62	3.62	0.38	0.38
Other (used) engine, gear and lubricating oils	13 02 08	3.52	3.52	0	0
Lead batteries	16 06 01	0	0	0.25	0.25
Fluorescent tubes and other mercury-containing waste	20 01 21	0.10	0.10	0	0
Abandoned equipment containing CFCs	20 01 23	0	0	0.13	0.13
Total hazardous waste diverted from disposal		3.62	3.62	0.38	0.38
Non-hazardous waste					
Preparing for re-use		486.15	486.15	769.86	769.86
Waste printer toners other than those containing dangerous substances	08 03 18	0.46	0.46	0	0
Paper and cardboard packaging	15 01 01	100.85	100.85	71.13	71.13
Plastic packaging	15 01 02	23.09	23.09	7.29	7.29
Wood packaging	15 01 03	36.55	36.55	21.88	21.88
Metal packaging	15 01 04	21.57	21.57	8.50	8.50
Glass packaging	15 01 07	14.5	14.5	7.19	7.19
Scrap tires	16 01 03	2	2	0	0
Discarded electrical and electronic equipment (WEEE) other than transformers and capacitors containing printed/integrated circuit boards (PCBs) and those containing hazardous components	16 02 14	30.73	30.73	1.28	1.28
Copper, bronze, brass	17 04 01	0	0	2.39	2.39
Aluminum (from construction and demolition)	17 04 02	2.13	2.13	0	0
Cables. other than those containing oil, tar or other dangerous substances (from construction or demolition)	17 04 11	2.74	2.74	2.90	2.90
Paper and cardboard	20 01 01	0.88	0.88	5.26	5.26
Other discarded electrical and electronic equipment	20 01 36	1.85	1.85	0	0
Metals	20 01 40	1.25	1.25	0	0
Total non-hazardous waste diverted from disposal		486.15	486.15	769.86	769.86



In 2022, compared to 2021, the recycled quantities of paper and cardboard packaging increased by 41.8% and wood packaging by 37%. The collected quantities of plastic and glass packaging also doubled, and metal packaging almost tripled. In contrast, the amount of paper for recycling in 2022 was 6 times lower than in 2021 (83.2% decrease). At the same time, the amount of discarded electrical and electronic equipment (WEEE) in 2022 was 24 times higher than in 2021, due to modernization works and investments.



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Waste directed to disposal (tonnes)	Waste code	Waste directed to disposal 2022 (tonnes)			Waste directed to disposal 2021 (tonnes)		
		Onsite	Offsite	Total	Onsite	Offsite	Total
Hazardous waste							
Incineration (with energy recovery)		16.31	0.69	17.00	15.42	0.42	15.84
Other residues from the bottoms* of reaction columns (distillation and solvent recovery residues)	07 05 08	13.60	0	13.60	12.00	0	12.00
Solid waste containing dangerous substances	07 05 13	0	0	0	0	0.04	0.04
Wastes whose collection and disposal are subject to special infection prevention measures	18 01 03	0	0.06	0.06	0	0.29	0.29
Waste from paint or varnish removal containing organic solvents or other dangerous substances	08 01 17	0.14	0	0.14	0.22	0	0.22
Other (used) engine, gear and lubricating oils	13 02 08	0.24	0	0.24	0.58	0	0.58
Exhausted absorbents (filter media, contaminated protective equipment)	15 02 02	2.26	0.18	2.44	2.61	0.00	2.61
Hazardous chemicals (expired reagents, laboratory substances)	16 05 06	0	0.45	0.45	0	0.09	0.09
Spent activated carbon from flue gas cleaning	19 01 10	0.07	0	0.07	0	0	0
Total hazardous waste directed to disposal		16.31	0.69	17.00	15.42	0.42	15.84
Non-hazardous waste							
Incineration (with energy recovery)		15.25	64.84	80.09	18.39	16.31	34.70
Paper and cardboard packaging	15 01 01	0.77	0	0.77	1.75	0	1.75
Plastic packaging	15 01 02	8.67	6.46	15.13	9.13	0	9.13
Expired non-hazardous laboratory chemicals	16 05 09	0	1.98	1.98	0	0	0
Sharp objects except for waste whose collection and disposal are subject to special infection prevention measures	18 01 01	0	0.02	0.02	0	0.06	0.06
Drugs other than cytotoxic and cytostatic (expired, non-compliant)	20 01 32	5.51	55.78	61.29	7.28	16.25	23.52
Plastics (including rubber)	20 01 39	0.30	0.60	0.90	0.23	0	0.23
Storage		0	129.32	129.32	0	188.50	188.50
Mixed municipal waste	20 03 01	0	129.32	129.32	0	188.50	188.50
Total non-hazardous waste directed to disposal		15.25	194.16	209.41	18.39	204.81	223.20

The amount of non-hazardous waste incinerated more than doubled in 2021 (2.3 times higher). The amount of paper and cardboard packaging incinerated decreased by 56% compared to 2021, but the amount of plastic packaging increased by 65.7% compared to the same period. The amount of plastics (including rubber) incinerated in 2022 also increased threefold compared to the previous year.

The almost threefold increase in 2022 compared to 2021 in the amount of waste consisting of expired medicines and non-compliant products was due to the testing steps required for the technological transfer of topical medicines production from the old Ointments Plant to the new Topical Products Plant (which was commissioned at the end of 2022). According to the technological steps of the specific production flows, the tests carried out generated significant quantities of non-hazardous waste, which were subsequently disposed of by authorized operators.

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Packaging

Antibiotice is constantly looking for opportunities to reduce, reuse and recycle used materials. Thus, in 2022, the packaging sizes of suppositories for the domestic market were reduced, thus achieving a reduction of 5,800 kg of paperboard packaging for these products.

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 (OIREF) 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 2022 was achieved (according to Law 249/2015 on packaging and packaging waste management, updated and GEO 196/2005 on the Environment Fund).

Antibiotice Iasi did not record in 2022, any outstanding amounts to be paid to the Environmental Fund Administration.



Types and quantities of packaging placed on the Romanian market by Antibiotice (tonnes)	2022		2021		2020		2019	
	Packaging quantity (tonnes)	% recovered from total (OIREF)	Packaging quantity (tonnes)	% recovered from total (OIREF)	Packaging quantity (tonnes)	% recovered from total (OIREF)	Packaging quantity (tonnes)	% recovered from total (OIREF)
Glass packaging	365.671	60.90%	271.012	60.11%	272.111	60.58%	418.995	60.00%
Aluminum packaging	40.654	20.34%	35.933	20.76%	37.203	21.93%	47.886	60.00%
Plastic packaging	84.271	47.68%	67.680	43.77%	60.150	55.82%	98.548	60.00%
Paper and cardboard packaging	254.762	66.54%	222.261	70.62%	240.024	66.07%	306.660	60.00%



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# 06

## Independent auditor's report to the Antibiotice shareholders

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## Report on the audit of Financial Statements

### Our opinion

We audited the attached individual financial statements of Antibiotice SA ("The Company") with its registered office in Iași, 1 Valea Lupului St., tax identification number RO1973096, comprising the financial position statement as of December 31, 2022, statement of comprehensive income, statement of changes in equity and cash flow statement for the financial year ended on the above-mentioned date as well as a summary of the significant accounting policies and other explanatory notes.

The individual financial statements as of December 31, 2022, are identified as follows:

- Net assets/total equity: **641,430,601 lei**
- Net profit of the fiscal year: **38,513,427 lei**

In our opinion, the attached individual financial statements give a true and fair view, in all significant aspects, of the financial position of Antibiotice company on December 31, 2022, as well as of the 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 compliant with the International Financial Reporting Standards adopted by the European Union ("IFRS-EU").

We conducted our audit in accordance with the International Standards on Auditing (ISAs), Regulation (EU) no. 537 of the European Parliament and of the Council („ The Regulation”) and Law no. 162/2017. Our responsibilities are described in detail in the section *Auditor's responsibilities in an audit of financial statements* in our report. We are independent of the Company, in accordance with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants (the IESBA code), according to the relevant ethical requirements for the audit of financial statements in Romania, including the Regulation and Law no. 162/2017 and we fulfilled our ethical responsibilities according to these requirements and to the IESBA code. We believe that the audit evidence we obtained is sufficient and appropriate to provide a basis for our audit opinion.

### Key issues

Key audit issues are those issues that, based on our professional judgement, had the greatest importance for auditing the financial statements of the current

period. The following key issue was approached in the context of the audit of the financial statements as a whole and in forming our opinion on them and we do not offer a separate opinion on this key issue.

### Key issue - value of trade receivables

Presentation value of trade receivables according to IFRS depends significantly on the calculation and estimation process of the trade discounts as well as on the process of estimating their recoverability. The company presented in the financial statements, in the explanatory note no. 4 - "Sales Income" the value of the granted trade discounts and, in the explanatory note no. 15 - "Trade and other receivables" the company presented the trade receivables in net value of 193 million LEI, adjusted with the estimated depreciation.

During our mission, we conducted the following audit procedures that included, but were not limited to these:

- We assessed the compliance of the policies for recognizing the income and trade receivables;
- We conducted analytical review procedures and detail tests for verifying the amount of granted discounts, including through

- extending the verifications on the discounts granted in the next fiscal year related to the sales in the audited fiscal year;
- We conducted procedures for direct confirmation of trade receivable balances;
- We evaluated the internal procedures and methods used by the management for estimating the probable amount to be collected;
- We verified the consistency of applying the accounting policies related to the adjustment of trade receivables.

### Other information - Management Report

The administrators are responsible for drafting and submitting other information. This other information includes the Management Report and Remuneration Report but it does not include the financial statements and auditor's report related to these statements. The Management is responsible for this other information.

Our audit opinion on the financial statements does not cover other information and we do not express any form of assurance conclusion thereon.



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In connection with our audit on the financial statements, our responsibility is to read this other information and, in this approach, to evaluate whether this information is significantly inconsistent with the financial statements or with the knowledge we gained from the audit or if it appears to include significant errors. If, based on the performed activity, we come to the conclusion that there are significant errors in this information, we must report this. We have nothing to report on this matter.

Additionally, in accordance with the provisions of OMPF no. 2844/2016, we read the Management Report and Remuneration Report and report the following:

- In the Management Report we did not identify information that is not consistent in all significant aspects with the information presented in the financial statements as of December 31, 2022;
- The above-identified Management Report includes, in all the significant aspects, the information requested by OMPF no. 2844/2016 to the para 15-19 of the Annex no. 1;
- The Management Report does not include the non-financial declaration specified to the paragraphs 39-42 from OMPF no. 2844/2016 which will be subsequently presented in a separate report;
- Based on our knowledge and our understanding gained during the

audit of the financial statements drafted on December 31, 2022 about the Company and its environment, we did not identify significant erroneous information presented in the Management Report;

- The Remuneration Report, identified above, includes, in all material respects, the information required by Article 107, para. (1) and (2) of Law 24/2017 (republished) on issuers of financial instruments and market operations.

**Responsability of the management and other persons responsible for the governance related to the financial statements**

The Management team is responsible for drafting and fair presentation of these financial statements in accordance with OMPF no. 2844/2016 and for the internal control which is considered relevant by the management for elaborating the financial statements without significant misstatements due to fraud or error.

When drafting the financial statements, the management is responsible for assessing the company's ability to continue its activity, presenting, if needed, the aspects related to continuity of the activity and using the accounting based on the going concern principle, unless the management plans to either liquidate the company or stop the operations or has no realistic alternative except for these.

The persons responsible for administering the company are also responsible for supervising the financial reporting process.

**Auditor's responsibility**

Our objectives are to obtain reasonable assurance that the financial statements as a whole do not include material misstatements, whether due to fraud or error, and to issue an auditor's report that includes our opinion. The reasonable assurance represents a high level of assurance but it is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement, if any. Misstatements can arise from either fraud or error and are considered material if they reasonably can be expected, individually or cumulatively, to influence the users' economic decisions based on these financial statements.

As part of an audit in accordance with the ISA standards, we exercise our professional judgement and maintain our professional skepticism during the audit. Moreover:

- We identify and evaluate the risks of material misstatements in the financial statements caused either by fraud or by error, establish and perform audit procedures to respond to these risks and we get enough and appropriate audit evidence to form a basis for our opinion. The risk of not detecting a material misstatement caused by fraud is greater than the risk of not detecting

ing a material misstatement caused by error, as fraud may include complicity, forgery, intentional omissions, false statements, or avoidance of internal control.

- We consider the internal control as relevant to the audit to establish the audit procedures appropriate in the given circumstances, but not to express an opinion on the effectiveness of the Company's internal control.
- We assess the appropriateness of the used accounting policies and reasonableness of accounting estimates and of the related information presented by the management.
- We formulate a conclusion on the appropriateness of using the going-concern principle by the company and determine, based on the obtained audit evidence, whether there is a significant uncertainty related to events or conditions that could raise significant doubts about the Company's ability to continue its activity. If we conclude that there is a significant uncertainty, we need to draw attention in the audit report on the related presentations from the financial statements or, if these presentations are inappropriate, we must change our opinion. Our conclusions are based on the audit evidence obtained by the date of our audit report. However, future events or conditions may determine the Company not to continue operating on the going-concern principle.

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- We evaluate the presentation, structure and overall content of the financial statements, including the information submissions and the extent to which the financial statements reflect the transactions and basic events in a manner that lead to the accurate presentation.

We communicate to those responsible for the administration, among other things, the planned objectives and timing of the audit, as well as the significant audit findings, including any significant internal control deficiencies identified during our audit.

**Report on other legal and regulatory requirements**

We were appointed by the General Meeting of Shareholders held on April 9, 2020, to audit the financial statements

of Antibiotice SA Iași for the fiscal years 2020-2022. The uninterrupted total duration of our commitment is 6 years, covering the financial exercises 2017-2022. We confirm that:

- Our audit opinion is in accordance with the additional report submitted to the Audit Committee of the Company which we issued on the same date to which we issued this report. Also, in conducting our audit, we remained independent of the audited entity.
- We did not provide for the Company the non-audit services that are prohibited according to the article 5, para. (1) from the Regulation (EU) no. 537/2014.

In the name of,  
  
Accounting, Expertise & Accounting  
Consultancy Company - SOCECC Ltd.  
headquartered in Bucharest, registered in the  
Electronic Public Register with the no. FA227  
  
through **Zegrea Laurențiu**, registered in the  
Electronic Public Register with the no. AF2666

Bucharest, March 17, 2023





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Statement of use	Antibiotice SA reported in accordance with the GRI Standards for the period January 1 <sup>st</sup> - December 31 <sup>st</sup> , 2022
GRI 1 used	GRI 1: Foundation 2021
Applicable GRI Sector Standard(s)	Currently not available

Standard GRI	Disclosure	Page number(s) and/or direct response	Omission			
			Requirement(s) omitted	Reason	Explanation	
General Disclosures						
GRI 2: General Disclosures 2021	P 2-1 Organizational details	13, 38				
	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	120, 121				
	2-5 External assurance	The content of the non-financial information has not been externally verified.				
	2-6 Activities, value chain and other business relationships	13-15, 29, 35, 38, 39				
	2-7 Employees	95				
	2-8 Workers who are not employees	96				
	2-9 Governance structure and composition	67-70				
	2-10 Nomination and selection of the highest governance body	71				
	2-11 Chair of the highest governance body	70				
	2-12 Role of the highest governance body in overseeing the management of impacts	72				
	2-13 Delegation of responsibility for managing impacts	72				
	2-14 Role of the highest governance body in sustainability reporting	71				
	2-15 Conflicts of interest	73				
	2-16 Communication of critical concerns	74				
	2-17 Collective knowledge of the highest governance body	No steps were taken to improve the collective knowledge, skills and experience of the highest governance body on sustainable development during the reporting period.				
	2-18 Evaluation of the performance of the highest governance body	71, 72				
	2-19 Remuneration policies	71				
	2-20 Process to determine remuneration	71				
	2-21 Annual total compensation ratio	101				
	2-22 Statement on sustainable development strategy	5, 6				
	2-23 Policy commitments	73, 74				

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Standard GRI	Disclosure	Page number(s) and/or direct response	Omission		
			Requirement(s) omitted	Reason	Explanation
GRI 2: General Disclosures 2021	2-24 Embedding policy commitments	71, 72			
	2-25 Processes to remediate negative impacts	47, 73, 74, 105			
	2-26 Mechanisms for seeking advice and raising concerns	73, 74			
	2-27 Compliance with laws and regulations	74-76			
	2-28 Membership associations	27			
	2-29 Approach to stakeholder engagement	17, 18, 22-25			
	2-30 Collective bargaining agreements	96			
Material topics					
GRI 3: Material topics 2021	3-1 Process to determine material topics	17, 18			
	3-2 List of material topics	18			
Impact on the local economy					
GRI 3: Material topics 2021	3-3 Management of material topics	11, 16, 20, 35-38			
GRI 201: Economic Performance 2016	201-1 Direct economic value generated and distributed	83			
	201-4 Financial assistance received from the government	83			
GRI 202: Market Presence 2016	202-1 Ratios of standard entry level wage by gender compared to local minimum wage	101			
	202-2 Proportion of senior management hired from the local community	106			
Business ethics					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 73-76			
GRI 205: Anti-corruption 2016	205-2 Communication and training about anti-corruption policies and procedures	No communication and training sessions on anti-corruption policies and procedures were conducted during the reporting period.			
	205-3 Confirmed incidents of corruption and actions taken	75			
GRI 206: Anti-competitive Behavior 2016	206-1 Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	75			
GRI 418: Customer Privacy 2016	418-1 Substantiated complaints concerning breaches of customer privacy and losses of customer data	76			
GRI 415: Public Policy 2016	415-1 Political contributions	75			
Product promotion policy					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 55-58			
GRI 417: Marketing and Labeling 2016	417-2 Incidents of non-compliance concerning product and service information and labeling	During the reporting period, there were no incidents of non-compliance with regard to product and service information and labelling.			
	417-3 Incidents of non-compliance concerning marketing communications.	During the reporting period, there were no incidents of non-compliance related to marketing communications.			



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Standard GRI	Disclosure	Page number(s) and/or direct response	Omission		
			Requirement(s) omitted	Reason	Explanation
Supply chain management					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 86, 87			
GRI 204: Procurement Practices 2016	204-1 Proportion of spending on local suppliers	87			
Combating counterfeit medicines and parallel trade					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 60-63			
Organization specific topic: <i>Combating counterfeit medicines and parallel trade</i>	Counterfeit alerts generated by the serialization system	63			
Research, development, and innovation					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 45-47			
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	46			
Animal welfare					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 64			
Organization specific topic: <i>Animal welfare</i>	Number of animal-tested products	Zero generic products			
Safety of clinical trial participants					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 64, 65			
Organization specific topic: <i>Safety of clinical trial participants</i>	Number of clinical trials started during the reporting period	65			
Access to medicines					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 43, 44			
Organization specific topic: <i>Access to medicines</i>	Number of essential medicines in the company's portfolio	43			
Patient and consumer health and safety					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 48-54			
GRI 416: Customer Health and Safety 2016	416-1 Assessment of the health and safety impacts of product and service categories	50, 51			
	416-2 Incidents of non-compliance concerning the health and safety impacts of products and services	51, 52			
Preventing drug misuse and self-medication					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 54, 55			
Organization specific topic: <i>Preventing drug misuse and self-medication</i>	Initiatives to promote responsible consumption of medicines	59			

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Standard GRI	Disclosure	Page number(s) and/or direct response	Omission		
			Requirement(s) omitted	Reason	Explanation
Recruitment, employee development and retention					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 97-99			
GRI 401: Employment 2016	401-1 New employee hires and employee turnover	100			
	401-2 Benefits provided to full-time employees that are not provided to temporary or part-time employees	102			
	401-3 Parental leave	102			
GRI 402: Labor/Management Relations 2016	402-1 Minimum notice periods regarding operational changes	96			
GRI 404: Training and Education 2016	404-1 Average hours of training per year per employee	103			The information has not been presented in accordance with this requirement.
	404-2 Programs for upgrading employee skills and transition assistance programs	98, 99			
	404-3 Percentage of employees receiving regular performance and career development reviews	105			
Diversity and equal opportunities					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 106			
GRI 405: Diversity and Equal Opportunity 2016	405-1 Diversity of governance bodies and employees	68-70, 106			
	405-2 Ratio of basic salary and remuneration of women to men	101			
GRI 406: Nedisdiscriminare 2016	406-1 Incidents of discrimination and corrective actions taken	106			
Employee health and safety					
GRI 3: Material topics 2021	3-3 Management of material topics	20, 107			
GRI 403: Occupational Health and Safety 2018	403-1 Occupational health and safety management system	107			
	403-2 Hazard identification, risk assessment, and incident investigation	108			
	403-3 Occupational health services	110			
	403-4 Worker participation, consultation, and communication on occupational health and safety	107, 108			
	403-5 Worker training on occupational health and safety	109			
	403-6 Promotion of worker health	110			
	403-7 Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	109, 110			
	403-8 Workers covered by an occupational health and safety management system	107, 109			
	403-9 Work-related injuries	110			



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			Requirement(s) omitted	Reason	Explanation
Volunteering and community investment					
GRI 3: Material topics 2021	3-3 Management of material topics	21, 111-115			
Organization-specific topic: <i>Volunteering and community investment</i>	Number of projects supported	111			
	Total sponsorship budget	111			
Materials and waste					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 124-128, 134, 139			
GRI 301: Materials 2016	301-1 Materials used by weight or volume	124			
	301-2 Recycled input materials used	124			
GRI 306: Waste 2020	306-1 Waste generation and significant waste-related impacts	125-128			
	306-2 Management of significant waste-related impacts	134, 139			
	306-3 Waste generated	135, 136			
	306-4 Waste diverted from disposal	37, 139			
	306-5 Waste directed to disposal	138			
Water management					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 129-133			
GRI 303: Water and Effluents 2018	303-1 Interactions with water as a shared resource	127-130			
	303-2 Management of water discharge-related impacts	132, 133			
	303-3 Water withdrawal	129, 130			
	303-4 Water discharge	131-133			
	303-5 Water consumption	133			
Energy consumption					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 118, 119, 122			
GRI 302: Energy 2016	302-1 Energy consumption within the organization	119			
	302-3 Energy intensity	119			
	302-4 Reduction of energy consumption	119			
Climate change contribution					
GRI 3: Material topics 2021	3-3 Management of material topics	19, 120-123			
GRI 305: Emissions 2016	305-1 Direct (Scope 1) GHG emissions	120, 121			
	305-2 Energy indirect (Scope 2) GHG emissions	120, 121			
	305-4 GHG emissions intensity	121			
	305-5 Reduction of GHG emissions	123			

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# INTEGRATED ANNUAL REPORT 2022

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Investing responsibly  
for the health of  
future generations