

Antibiotice  
Science and soul



# NON-FINANCIAR REPORT

2018



## Responsible for a better life





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## About this report

Development of a sustainable business, ethics and transparency, economic, social and environmental impact of Antibiotice SA Iași represent strategic directions presented in this second non-financial report for 2018.

Annually, Antibiotice SA will present relevant data that will help the stakeholders understand its economic, social and environmental performance, as well as the impact of its activities developed in the local and international markets.

This way, our company assumes the responsibility of improving the comparative indicators which outline its fingerprint profile on the natural, economic and social environment.

The report was made, having as the main reference the Global Reporting Initiative (GRI) Standards for sustainability reporting. .

### Purpose

Along with providing an overview of the actions and directions in which Antibiotice SA invests to achieve sustainable results, this report is prepared to meet the provisions of O.M.F.P. no. 1938/2016. At the same time, the purpose of this document is to meet, not only the legal, mandatory requirements, but also to comply with the currently best international practices..

### Reporting period

All the information in this report is related to the financial year 2018, which corresponds to the calendar year.

### Acknowledgement

The Antibiotice's management team wants to thank to all those who contributed to the sustainability objectives of the company, as well as to the employees, partners and institutions that participated in preparing this report.

### Suggestions and comments

We will be happy to receive your suggestions and comments to the phone number: **0232 209.000** or to the mail address: **office@antibiotice.ro**.

## Message of Antibiotice's General Director

Dear friends,

I consider myself a supporter of sustainable development principles and I strongly believe that it is the responsibility of our entire Antibiotice's team to make a commitment to permanently improve our practices and activities so that our impact on the community, on the economic and natural environment be a positive one.

Starting with the last year, we added non-financial information in the process of enhancing the transparency of our actions and financial results. In this way we underline another dimension of our performance, that one of the value and impact that we create by assuming good practices in all our fields of activity. I am honored to present you the second non-financial report which reflects a performing company responsible for all the categories of stakeholders.

Working in a company with a tradition of over 60 years in the pharmaceutical company in Romania, we learned to act responsibly because we are aware of the importance of our activity on the Romanian health system. We are a leader in the production of generic anti-infective medicines and a leader in the production of topical medicines. Through our distribution partners, the 158 products from our portfolio reach over 8,000 pharmacies and all the hospitals in the country, ensuring in this way a continuous and active presence of our products in the entire Romanian pharmaceutical system.

We continue to actively communicate with the healthcare professionals and we use their recommendations in order to meet the higher and higher expectations of having a sustainable medicine portfolio that offers a variety of treatment options. We do this by investing in new medicinal products in line with the therapeutic trends but also in programs for supporting the therapeutic efficacy addressed to both specialists and the general public.

We permanently focus on continuously improving our market position and customer-oriented policy and therefore we are able to reach significant economical performances. We are proud that, for five years in a row, we have maintained ourselves as the number 1 worldwide producer of the active substance Nystatin, our product being chosen by the United States Pharmacopeial Convention (the American body that annually develops a compendium of quality standards for testing active substances and finished products), as the international reference standard for this product.

In 2018, we inaugurated the fourth representative office abroad, in Ukraine. This representative office joins those opened in the previous years in Vietnam, Republic of Moldova and Serbia which are successful models of implementing a growth strategy in the respective territories. The medicinal products from the Antibiotice portfolio are delivered in more than 70 countries in Europe, Asia, North America

**Ec. Ioan Nani,**  
Director General,  
Vicepreședinte al Consiliului  
de Administrație



and Africa, our desire being to join the communities and health systems in these countries, providing therapeutically effective medicines, at prices adapted to the local economic context.

Since 1995, we follow our mission of making our valuable medicines more accessible to patients, doctors and pharmacists.

At the same time, we are responsible for offering to our customers the certainty that our medicinal products are not counterfeit. So, in 2018 we took some important steps in implementing the medicine verification system in order to combat counterfeiting. For this purpose, we heavily invested in serialization equipment and software for the finished product warehouse and for all our manufacturing flows.

We put a special stress on business integrity and we develop commercial relationships both in the country and internationally, in an ethical, transparent and competitive way.

The honest behaviour is part of our identity, this is why we implemented throughout our company codes of ethics and integrity, a good practice code in dealing with the healthcare professionals, irregularity reporting systems, anticorruption policies and procedures, risk management, assuming all of these in the most professional manner.

We succeeded in doing all of these possible, by involving the entire team of over 1,400 Antibiotice employees who contribute to the development of a business that meets the highest standards in its field of activity. This reflects a confirmation of the conduct and values that underpin our activities. I appreciate and thank them for their hard work and dedication.

We are open and permanently interested in the satisfaction, occupational safety and security of our employees, we offer them opportunities for career growth, a correct motivation and loyalty system in a stable, safe and pleasant environment so that their commitment to the company's mission and values as well as their satisfaction level be high.

We have thus assumed the responsibility of developing a sustainable business that meets the needs of shareholders, investors, community and, last but not least, of our employees and their families.

The future belongs to those who build responsibly! This belief guides all our activities and we are convinced that Antibiotice is and will remain a reliable partner for all its stakeholders, a company that contributes to creating a better world, governed by responsibility, transparency, ethics and integrity.

Ioan Nani



# 2018 versus 2017 Highlights

2018

2017



## Economic matters

**365.3** million LEI/  
**337.6** million LEI  
net turnover

**35.1** million LEI/  
**35.3** million LEI  
gross profit



**83.9** million LEI/  
**74.4** million LEI  
contributions to the consolidated  
state budget and local budget

+13%



Zero incidents of corruption/ Zero incidents of corruption



## Social matters

**1415**,  
**1420**  
average  
number of  
employees

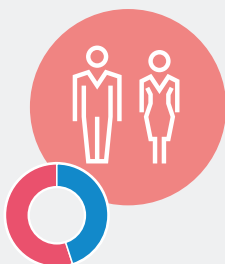
**77%**,  
**83.4%**  
of our  
employees  
are union  
members

**665**,  
**580**  
employees  
participated  
in professional  
training courses

+15%



**55.06% / 54.8%**  
of our employees  
are women



**61.5%**   
of the staff with  
management positions  
are women



**36% / 45%**  
ponderea achizițiilor  
de la furnizorii  
din România

**46 / 37** Antibiotic  
medicines are considered  
essential according to  
the WHO classification



**Zero** clinical bioequivalence trials prematurely ended  
because of the safety of volunteers/  
**Zero** clinical bioequivalence trials prematurely ended  
because of the safety of volunteers



## Environment



**60% / 60%**   
recycling / recovery  
rate for  
packaging waste

**Zero** sanctions for  
environmental incidents/  
**Zero** sanctions for  
environmental incidents



# 02

## About Antibiotice

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## Brief presentation

Antibiotice SA is currently the most important Romanian manufacturer of generic medicines and an internationally recognized brand of reference in the Romanian industry, which continues its mission of making quality, safe and efficient products, to give people the hope of a healthy life. Antibiotice SA was established in 1955 and has the most complex manufacturing structure in Romania, with its eight manufacturing flows, from which that one manufacturing active substances by biosynthesis is unique in our country.

Since 1991 Antibiotice has become a joint-stock company and, starting with 1997, it has been listed on the Bucharest Stock Exchange (BVB) under the symbol ATB.

Our company has a rich portfolio, comprising more than 150 generic medicines for patients with infectious diseases, for those suffering from cardiovascular, dermatological, digestive, central nervous system diseases as well as for women's health. It has become an important partner in the hospital pharmaceutical market, having also a self-medication portfolio for prophylaxis and improving the quality of life (food supplements, medical devices, over-the counter medicines (OTCs)).

Antibiotice SA has an active international presence, exporting its products in all the continents, making its valuable medicines more accessible not just in the Romanian market but also in a considerable number of countries worldwide. Antibiotice SA is also the world leading manufacturer of the active substance Nystatin, our product being the international reference standard.

Enjoying the recognition gained internationally, Antibiotice brand remains firmly dedicated to its mission of giving to the people, with science and soul, a better health and life. All of these underline our company's orientation towards a sustainable development.

Within the large team comprising more than 1,400 employees, there is a diversity of generations and professions, from doctors, pharmacists, chemists and biologists to economists, engineers and technicians. Employees specialized in specific areas such as medicine research, quality assurance and control, production and marketing. They contribute together to the total value created by our company.

For 63 years, Antibiotice SA has proven itself to be a competitive and modern company, demonstrating that the performance of the global pharmaceutical industry can be achieved in Romania as well.

Antibiotice SA is a Romanian company what makes a genuine Romanian brand known globally.



Peste **150**  
medicamente  
generice  
în portofoliu



Peste  
**1400**  
de angajați  
în 2018



**365,3**  
milioane lei  
cifra de afaceri  
în 2018



# Mission, Vision, Values



## Our mission

We make our valuable medicines more accessible to patients, physicians and pharmacists. 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. Profit that satisfies our shareholders and allows us to target performance, permanently investing in people, technology and carefully selected partnerships.



## Our values

We cherish efficiency, knowledge and 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, which creates a sense of connection and gives us the strength to overcome limitations and obstacles.

As human beings, we care about our fellows, we seek to be close to them, and we always think about how to improve things that are important to them.



Efficiency



Knowledge



Cooperation spirit



# Corporate governance

Since 2012, Antibiotice SA has adopted the principles and recommendations of the Corporate Governance Code of the Bucharest Stock Exchange, principles that underpin the fulfillment of our company's good corporate governance standards.

Corporate governance plays an important role in protecting the shareholders' interests, through maximizing the value of their shares in the company in the long term, but also in stimulating the investors' interest by making the company's activities and processes more transparent and efficient.

The corporate governance represents the premise for the transparency of the company's activities in order to protect the social partners' interests while the efficient control system implemented at the entity level is the guarantee of achieving its objectives.

The corporate governance system of Antibiotice SA is based upon:

- **Management Board**
- **Code of Ethics**
- **Advisory committees**
- **Corporate Governance Code**
- **Executive management**
- **General Meeting of Shareholders**

## Management Board

Antibiotice SA is administered by a Management Board responsible for fulfilling all the tasks necessary to achieve the company's object of activity, except those provided by law for the General Meeting of Shareholders. There is a clear division of responsibilities between the Management Board and Executive Management.

The Management Board aims as its own decisions, those of the company's management and of the General Meeting of Shareholders as well as the internal regulations be compliant with the legal requirements and properly implemented. The Board is responsible for monitoring the company's management on behalf of the shareholders.

During 2018, the Management Board met in 10 sessions and adopted decisions that enabled it to carry out its tasks in an effective and efficient manner.

The five members of the Management Board guarantee the ability of efficiently

supervising, analyzing and assessing the directors' activity, as well as the fair treatment of the shareholders..

### Management Board of Antibiotice SA on December 31, 2018

**Ionuț Sebastian Iavor**, Legal Adviser  
President of the Management Board and representative of the Ministry of Health

**Ioan Nani**, Economist  
Vice President of the Management Board and General Director

**Dan-Octavian Alexandrescu**, Physician  
Member of the Management Board and representative of the Ministry of Health

**Nicolae Stoian**, Economist  
Member of the Management Board and representative of the SIF Oltenia shareholder and other shareholders legal entities

**Elena Calițoiu**, Engineer  
Member of the Management Board and representative of the shareholder SIF Oltenia and other shareholders - legal entities



Valorile noastre  
fundamentale  
de etică:

**Integritatea**

**Profesionalismul**

**Responsabilitatea**

**Transparența**

## Advisory Committees

The specialized advisory committees conducted investigations and analyzes, elaborated recommendations for the Management Board and submitted periodic reports on their activity to the Board.

In 2018, they had the following structure:

- **Audit Committee:** **Mr. Ionuț Sebastian Iavor**, President, **Mr. Nicolae Stoian** and **Ms. Elena Calîtoiu**;
- **Nomination and Remuneration Committee:** **Mr. Ionuț Sebastian Iavor**, President and **Ms. Elena Calîtoiu**;
- **Trade Policy Committee:** **Mr. Dan Octavian Alexandrescu**, President and **Mr. Nicolae Stoian**.

## Executive Management

Antibiotice is represented by the General Director, according to the powers provided by law and by the company's Articles of Association. The Management Board represents the company in relationship with the appointed directors.

The executive management of Antibiotice is ensured by the General Director who is also the Vice President of the Management Board and nine specialty executives.

### Antibiotice's Executive Management on December 31, 2018

**Ioan Nani**, Economist

General Director and Vice-President of the Management Board

**Cornelia Moraru**, Engineer

Specialty Director of the Technical & Production Unit

**Paula Luminița Coman**, Economist

Specialty Director of the Financial Unit

**Vasile Chebac**, Economist

Specialty Director of the Commercial and Logistics Unit

**Gica Rusu**, Economist

Specialty Director of the Human Resources Management Unit

**Ovidiu Bățaga**, Economist

Specialty Director of the Marketing and Domestic Market Sales Unit

**Mihaela Moșneguțu**, Physician

Specialty Director of the Medical Unit

**Mihai Stoian**, Economist

Specialty Director of the International Business Unit

**Mihaela Stoenescu**, Engineer

Specialty Director of the Communication Unit

**Cristina Diaconescu**, Engineer

Specialty Director of the Research & Development Unit

## General Meeting of Shareholders

General Meeting of Shareholders (GMS) represents the highest decision-making body of the company, where the shareholders participate directly in the decision-making process. Among other attributions, GMS decides the distribution of profit, elects the Management Board, appoints the auditors and sets the remuneration for the Management Board members.

During 2018, the Board convened three Ordinary General Meetings and three Extraordinary General Meetings of Shareholders, on *March 5, 2018, April 26, 2018 and September 25, 2018*.

All the necessary documents relating to the smooth conduct of the General Meetings were published in due time and as required by the law.

## Code of Ethics


The Code of Ethics of Antibiotice SA is applicable to all its employees and establishes principles and rules designed to determine an honest professional conduct and to create an organizational culture based upon integrity standards, in accordance with the legislation in force and in line with the corporate values.

The fundamental values of ethics assumed throughout the organization:

- **Integrity**
- **Professionalism**
- **Responsibility**
- **Transparency**

Also, the Code of Ethics regulates the business responsibilities and obligations of the organization members and how the organization operates.

The Code of Ethics is a fundamental commitment to strive to comply with high ethical standards and applicable legal requirements, wherever Antibiotics operates.

 The Code of Ethics is presented extensively on the company's website ([www.antibiotice.ro/Investors/Corporate Governance/Reference documents/Code of Ethics](http://www.antibiotice.ro/Investors/Corporate%20Governance/Reference%20documents/Code%20of%20Ethics)).

## Corporate Governance Code

The Corporate Governance Code of Antibiotice SA and its annexes outline the general framework on which the Management Board operates according to the corporate governance rules and principles established by the Bucharest Stock Exchange, based upon the best practices and transparency and confidence principles.

The Corporate Governance Code of Antibiotice SA is divided into four chapters:

**Chapter I** – Responsibilities of the Management Board

**Chapter II** – Risk management system and internal control

**Chapter III** – Fair reward and motivation

**Chapter IV** – Investor Relations

It also has two annexes:

**Annex I** – Management Board's Rules of Procedure

**Annex II** – Rules for evaluating the Antibiotice's administrators

## Economic performance

The economic performance of Antibiotice SA results from the consistent application of the strategies included in the business plan. The main diagnostic indicators highlight the upward trend that Antibiotice experienced during the reporting period, as well as the continuous concern of the management for the constant streamline of the business and maintenance of the financial balance.

In 2018, the economic performance of Antibiotice SA is reflected by the following indicators:

### Economic indicators

	2016	2017	2018
Net turnover (LEI)	334,990,734	337,629,448	<b>365,304,988</b>
Gross profit (LEI)	34,881,646	35,361,430	<b>35,088,611</b>
Average number of employees	1449	1420	<b>1415</b>
Taxes on wages	29,965,651	34,169,838	<b>36,123,811</b>
Other taxes to the state budget	15,448,356	9,241,601	<b>10,258,105</b>
Claw-back tax	22,398,133	29,923,031	<b>36,484,839</b>
Local taxes and fees	1,072,087	1,106,741	<b>1,125,783</b>
Total taxes and fees	<b>68,884,227</b>	<b>74,441,211</b>	<b>83,992,538</b>

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Approximately one quarter of the sales value (**83,99 million.LEI**) is transferred to the state budget as taxes and fees.

## Our products

For over six decades Antibiotice SA has been the most important Romanian manufacturer of generic medicines that contribute to maintaining the health and well-being of Romanians and people around the world.

By investing in knowledge, technology and human resources, the company has reached important internal and international standards that certify the safety, quality and efficiency of the 158 products in our portfolio.

Thus, Antibiotice SA is continuously concerned with ensuring a sustainable portfolio through investments in the development of new products in line with the therapeutic trends and also through programs meant to support the therapeutic effectiveness, addressed to both specialists and the general public.

### The therapeutic classes that make up the structure of the Antibiotice SA portfolio are as follows:



systemic anti-infective medicinal products, including drugs for the treatment of tuberculosis;



medicinal products for cardiovascular use;



medicinal products for dermatological use;



medicinal products for the disorders of the central nervous system;



products intended for self-medication (prophylaxis, adjuvants in certain diseases with high incidence and for maintaining health) in the category of

- dietary supplements,
- dermatological cosmetics,
- medical devices and
- non-prescription medicines (OTCs).

Antibiotice SA is a reliable partner for hospital physicians through its complex portfolio of anti-infectives (beta-lactam antibiotics, penicillins, cephalosporins, carbapenems and polymyxins) and supports the National Program of Prevention, Surveillance and Control of Tuberculosis through the production of the full range of first line anti-tuberculosis medicinal products and part of the of second line anti-tuberculosis medicinal products.

Antibiotice SA is concerned with the judicious use of antibiotics so that their effectiveness be maintained for the future

generations. That is why we launched the education and social responsibility program **"Antibiotics of the Third Millennium"**, intended for both health professionals and the general public.

Another important category of medicines that represents the company is the category of topical products: ointments, creams, gels, suppositories and pessaries from the following therapeutic classes: dermato-corticosteroids, anti-inflammatories, antifungals, vasoprotectives, dermato-cosmetics and corticosteroids for dermatological use, antibiotics and products for the disorders of the genitourinary system.

Besides the traditional topical medicines - **Nidoflor® cream** (triamcinolone acetonide, neomycin, nystatin), **Fluocinolon® N ointment** (fluocinolon acetonide, neomycin sulfate), **Clafen® gel, cream** (diclofenac sodium), **Hemorzon® suppositories, ointment** (tetracycline, hydrocortisone acetate, benzocaine), **glycerin suppositories** (for adults and children), Antibiotice SA has created a new portfolio, represented by the range for women's health: **Zifex® complex, pessaries** (nystatin, neomycin, metronidazole, hydrocortisone acetate), **Zifex® duo** (metronidazole, clotrimazole), **Nistatină Atb®** and the dermato-cosmetics range **Cutaden®**, **Cutaden® Bebe**, **Tinero®** (nicotinamide, dexpanthenol) and **Fluxiv® cream** (troxerutin, dexpanthenol).

Maintaining the cardiovascular health is an important component of the quality of life, therefore Antibiotice SA has developed a complex portfolio of medicinal products that can provide the complete therapeutic scheme in the treatment of cardiovascular diseases. This portfolio is intended for chronic conditions such as high blood pressure, angina and heart failure.


The cardiovascular medicines from the our portfolio provide the access of patients to the main subclasses of medicinal products used in cardiovascular disease therapy: beta-blockers (**Bisotens®** - bisoprolol,

**Nolet®** - nebivolol, **Gladycor®** - carvedilol), conversion enzyme inhibitors (**Lisinopril Atb®**, **Ramipril Atb®**), calcium channel blockers (**Almacor®** - amlodipine), statins (**Rosuvastatină Atb®**), sartans (**Candesartan Atb®**) and diuretics (**Indapamida Atb®**).

The **Nutriensa®** range is intended to maintain the health of each system of the human body: **Equilibra®**, **Soriso®**, **Fluxiv®**, **Silithor®**, **Sprinten®**, **Lejer®** - are combinations of standardized extracts of plants, vitamins, minerals and amino acids that can be administered without a prescription, for personal care, prophylaxis or in the case of mild symptoms.

Antibiotice SA supports the quality of life through its portfolio dedicated to:

- > **the dermatological health,**
- > **the cardiovascular health,**
- > **women's health and**
- > **the well-being,** with the range of standardized extracts - **Nutriensa®**.

 Topul produselor pentru care compania Antibiotice este unic producator, il puteti accesa la <https://bit.ly/2VRCTcM>



A complex portfolio of medicinal products, **158** products from **12** therapeutic areas.



A partner of the hospital physicians, through its **anti-infectives portfolio**.



**"Antibiotics of the Third Millennium"** - an education and social responsibility program.





## Domestic market

Antibiotice SA has had a continuous presence in the Romanian pharmaceutical market since 1955. Initially, only active substances were obtained on our industrial site, thus Antibiotice becoming the first company in South-East Europe to produce penicillin. Subsequently, it has become one of the leaders in the pharmaceutical market in Romania, a major manufacturer of finished medicinal products and active substances with a portfolio of 158 products from 12 therapeutic classes (source: Cegedim SO).

The products manufactured by Antibiotice are sold almost entirely in those over 8,000 pharmacies (according to market research firm IQVIA), in over 360 public hospitals, as well as in over 160 private hospitals (units with beds).

True to its mission to make valuable medicines more accessible to patients, doctors and pharmacists, Antibiotice SA is highly concerned with ensuring continuity in distribution, by concluding commercial contracts with the most important distributors in Romania, which provide distribution services for both the hospital and retail segments, the latter including also the main chains of pharmacies with national coverage.

The prescription products (Rx) have a share of 84% of the total sales, while the products without prescription (OTCs) have a share of 16%.

The company's activity reflects a constant interest for performance, with the aim of providing patients with quality, safe and efficient products. Thus, in a fiercely competitive market, Antibiotice SA has consolidated its position as a leader in traditional market segments, recording notable performances:

- **Antibiotice SA is a leader in the segment of generic prescription medicines for hospitals** (source: Cegedim SO);
- **Antibiotice SA is a leader in the production of injectable beta-lactam antibiotics in Romania, the anti-infective medicinal products manufactured by Antibiotice are distributed to all the hospitals across the country** (source: Cegedim SO);
- **Antibiotice SA is a leader in the market of suppositories, both in terms of quantity (market share of 42.08%) and value (market share of 24.75%) and it is also a leader in the market of ointments from a quantitative viewpoint of (26.29% market share)** (source: Cegedim SO);
- **Antibiotice SA ranks 4<sup>th</sup> among the 128 generic manufacturers of prescription medicines in the Romanian market** (source: Cegedim SO);
- **Antibiotice SA ranks 13<sup>th</sup> among the OTC companies in Romania (out of a total of 221 companies), one position upwards compared to 2017** (source: Cegedim SO).



**44,55%**  
cotă de piață pe  
segmentul hospital  
antiinfecțioase



**8,58%**  
cotă de piață în  
producerea de  
medicamente generice

## External markets

One of the strategic pillars of the medium and long-term development of Antibiotice SA is the expansion and consolidation of its presence in foreign markets. The company runs its business on all continents of the world, with a portfolio of over 70 finished products from various therapeutic classes and with the active substance Nystatin which is a USP international reference standard, Antibiotice being the world leader manufacturer of Nystatin.

Antibiotice SA promotes the Romanian values to more than 200 international business partners, through its diversified and accessible product portfolio delivered both in mature, highly developed markets and also in emerging markets.

In 2018, Antibiotice SA inaugurated the fourth representative office in the international markets, this time in Ukraine – an emerging market with an annual growth rate of over 15%. Through this strategy of territorial expansion, the company expands its development area in the Russia-CIS area for the finished product portfolio. Starting with 2020, the first products with their own

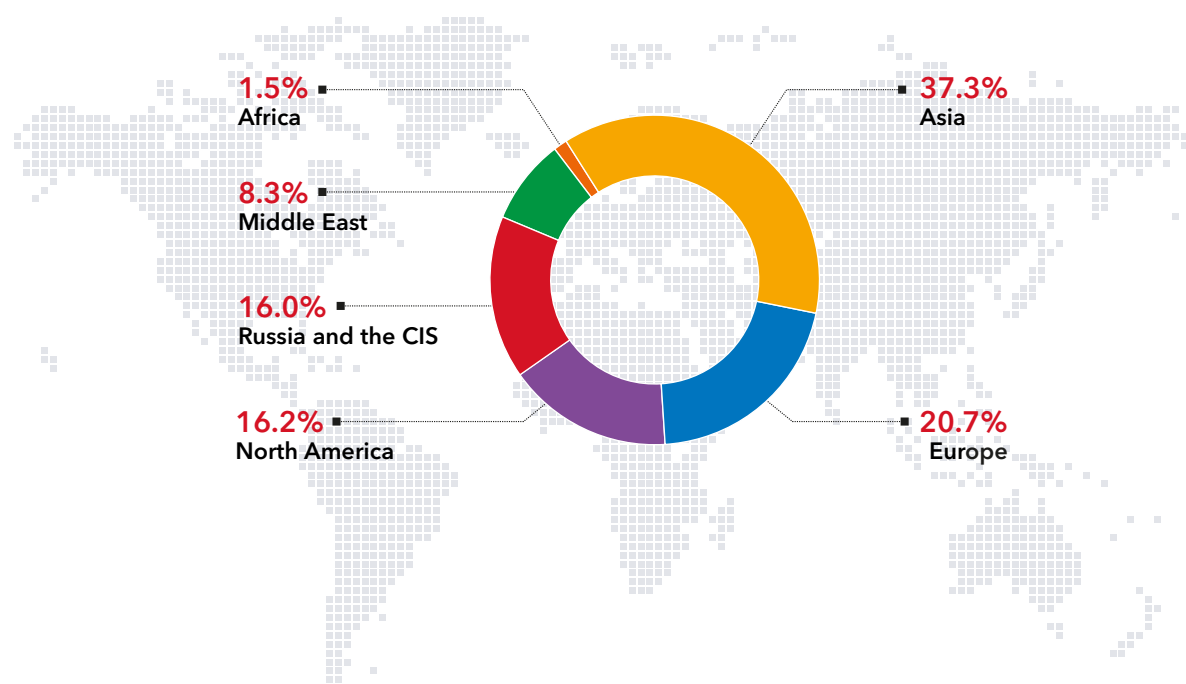
brand will be launched, within the partnerships with the local distributors and pharmacy chains.

This representative office joins the offices opened in the previous years in Vietnam, the Republic of Moldova and Serbia which are successful models of implementing an organic growth strategy in the respective territories, by transforming the market opportunities into product, promotion and distribution policies.

The main destination market where Antibiotice SA is present through its medicinal products is Southeast Asia, where Vietnam is the most important market. As a result of opening its own representative office in Hanoi, the company has succeeded in providing a greater degree of accessibility of its products to patients in Vietnam. Also, Antibiotice SA analyzes the potential of developing trade relations in the Philippines.

At the same time, important markets where Antibiotice SA delivers finished products are: Europe, North America, Russia & CIS.

Finished product sales breakdown in the international markets



The main growth pole for Nystatin, the product for which Antibiotice SA obtained the US FDA (Food and Drug Administration) certification in 2007, is North America (USA). Also, this active substance, which accounts for half of the export value, is delivered to most markets in South East Asia, South America, Europe, the Middle East and recorded significant sales growth during the reporting period.

Antibiotice SA places a special emphasis upon business integrity, developing commercial relations with partners in international markets in a transparent, ethical, competitive and mutually advantageous manner, on a non-exclusive business model and in compliance with the national legislation specific to the countries in which its own products are registered and marketed.

In 2018, Antibiotice SA adapted its external expansion policies to the new legal regulations in the field of health, taking into account both the consumption trends and the specificity of each market.



Export - **34%** of the company's turnover



**World leader** in the production of Nystatin (active substance), USP International Reference Standard



**Operational representative** offices in Vietnam, Ukraine, Republic of Moldova and Serbia



Internationally recognized **certifications and authorizations**

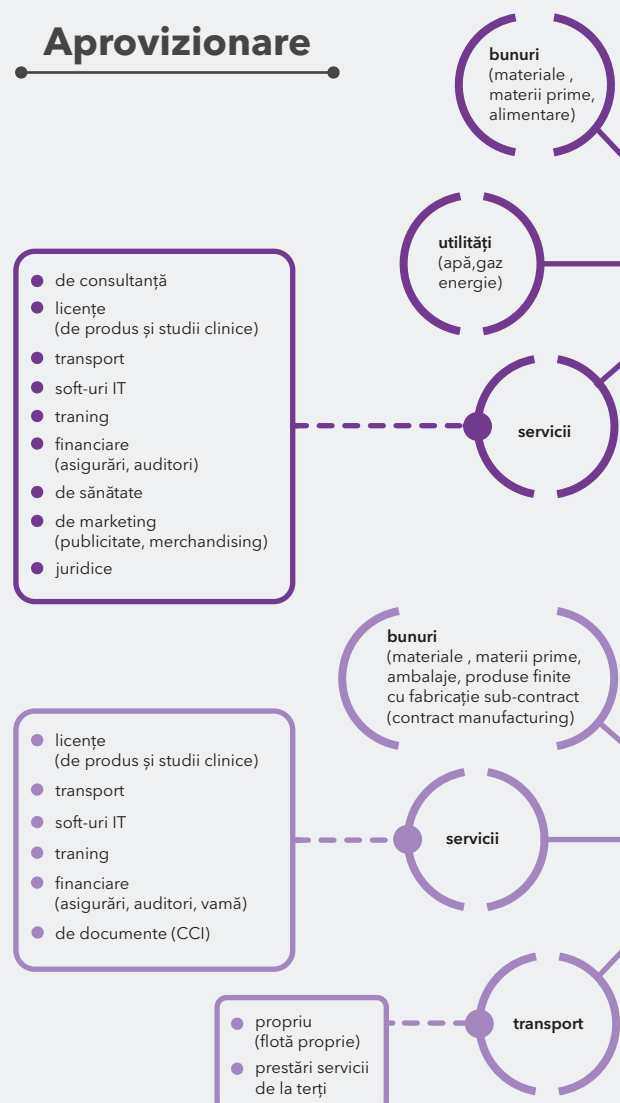
## Value chain

The value chain plays a fundamental role in the activity of Antibiotice SA and involves going through precise steps and rigorous procedures by which the company creates value both for itself and for its partners. Minimizing the impact upon the environment and ensuring the compliance with the principles of sustainable development are constant concerns throughout all the activities integrated in the value chain.

The process begins with identifying long-term viable therapeutic solutions, followed by the research and development of new pharmaceutical products; the company permanently considers the assurance of quality, safety and efficiency standards.

Selection of the suppliers of raw materials is based upon the compliance of their

### Aprovizionare



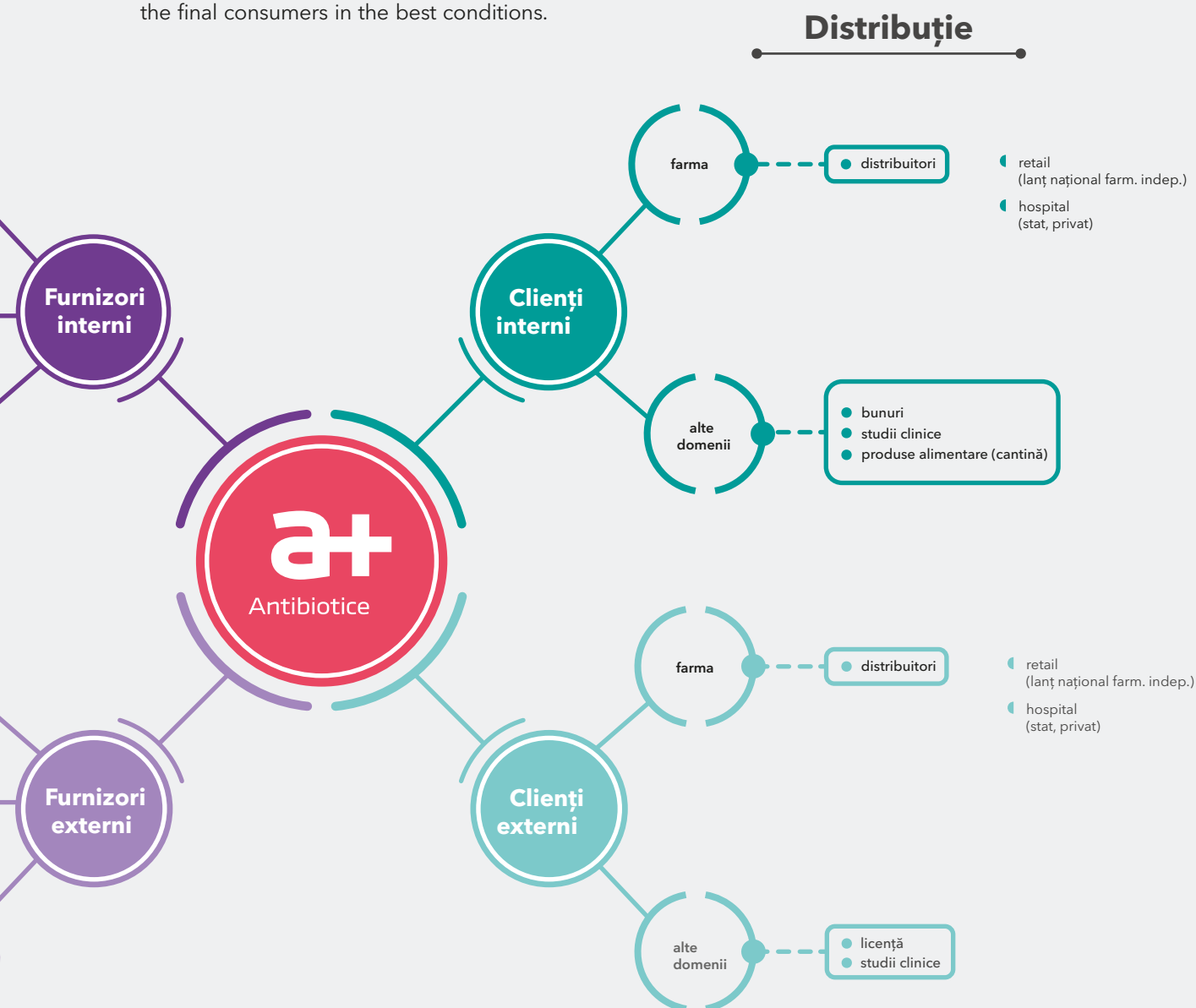
quality system with the international requirements of good manufacturing practice (GMP). Thus, in the process of manufacturing the Antibiotice medicines, we use only quality raw materials, purchased from authorized producers which are our partners in the mission of developing a sustainable a business.

Regarding the indirect procurement procedure, for services or products that are not directly related to the manufacturing process of medicinal products, the evaluation of the suppliers is made upon the basis of the economic selection criteria, respecting the 3Es concept: Economy, Efficiency and Effectiveness.

Throughout the value chain, the optimization of the production, packaging, storage and transport processes is constantly pursued, as a guarantee that the medicinal products the company manufactures reach the final consumers in the best conditions.

In the final phase of the value chain, the product arrives from the company's warehouses to the distribution partners, from where it is delivered to the hospital pharmacies (following the auctions) and the retail pharmacies. The company's promotion team, through an ethical promotion and the development of continuous medical education programs dedicated to health professionals, aims to increase the degree of accessibility, contributing to the balanced absorption in consumption of the Antibiotice medicinal products.

The teams of specialists within the company are actively involved in the identification and timely intervention upon the elements that could slow down the processes along the value chain, so that the risks are minimized and the procedures are constantly improved.



## Licenses and certifications


All the eight manufacturing flows of Antibiotice SA are GMP verified and certified by the National Agency for Medicines and Medical Devices of Romania (NAMMDR). In addition, the quality of the products manufactured by Antibiotice SA is also confirmed by the obtaining of the US FDA (Food and Drug Administration) approval for sterile injectable finished products and the active substance Nystatin.

In order to carry out Phase I clinical studies and bioequivalence studies, our company established in 2006 its own Center for Clinical Studies, which is periodically authorized by NAMMDR. Also, the Bioanalytical Laboratory within the Center for Clinical Studies is GLP (Good Laboratory Practice) certified by NAMMDR.

These certifications and authorizations demonstrate the continuous concern of Antibiotice SA for quality, which ultimately translates into the commitment and responsibility assumed with regard to the health of consumers, employees, as well as the environment.

In this regard, the company's processes are carried out according to the Integrated Management System (quality, environment, occupational health and safety). This framework governs all the processes, from research, development, supply, production and control, to the distribution of medicinal products to patients.

The initial certification of the Integrated Management System was made in 2007 by Lloyd's Register Quality Assurance and the latest recertification audit was carried out in 2017.

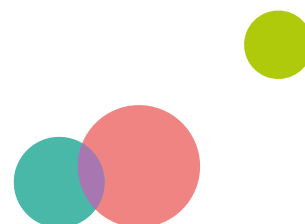
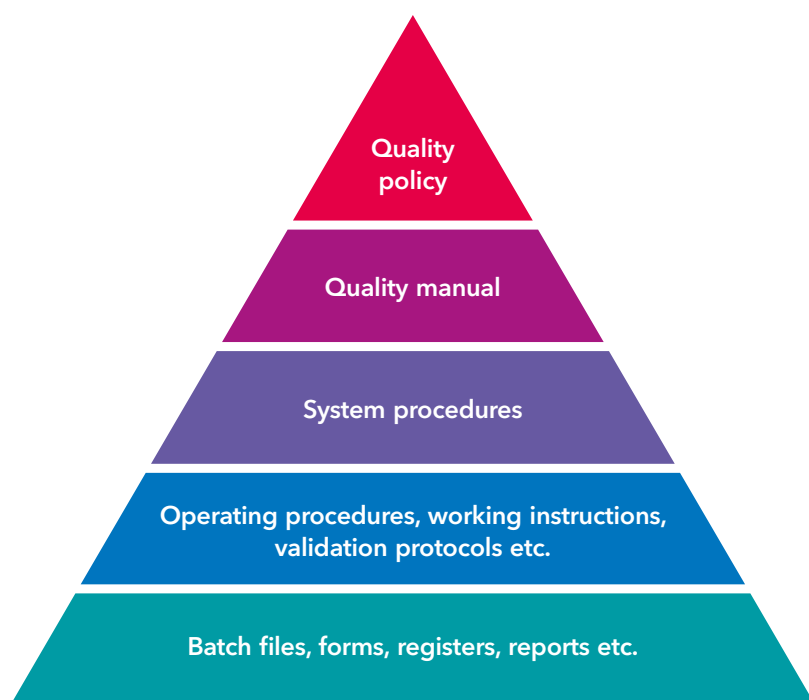
 Our quality, environment, occupational health and safety policy can be accessed here - <https://bit.ly/2nGZSLi>.

Adherence to the rigors of the Quality Management System - implemented according to EU GMP and ISO requirements - is monitored internally through strict policies and procedures, by the specialists of dedicated structures, and externally by business partners (through periodic audits), by the authorities in the field - NAMMDR, the National Veterinary Sanitary and Food Safety Authority and other equivalent authorities in the countries where our company's products are authorized.

The Quality Management System within Antibiotice SA is also aligned with the GMP requirements of the US FDA (CFR 210&211 requirements), a fact attested by the acceptance letter obtained in 2017.

This recognition has increased the confidence of international partners in the robustness and performance of the quality system implemented within Antibiotice SA, making it possible for the company to communicate in a common language and to open to the entire world.

**Pyramidal structure of the Quality Management System of Antibiotice SA**





Standards/licenses/authorizations/certificates valid on December 31, 2018	Name/description	Recertifications	Date of the latest certification
<b>Authorization 30 F</b>	Manufacturing authorization issued by the NAMMDR for the production of medicinal products for human use, including medicinal products for clinical investigation.	Recertification when changing the certification conditions	-
<b>GMP Certificate 23/2018/RO</b>	Certificate on the compliance with the good manufacturing practice (GMP - Good Manufacturing Practice) issued by NAMMDR (National Authority for Medicines and Medical Devices), following the inspection of the manufacturing, packaging and testing operations for the quality control of ointments (medicines for human use).  The manufacture of medicines is carried out in accordance with the Good Manufacturing Practice (GMP) guideline, issued and used by the NAMMDR in assessing the applications for the manufacturing authorization and for the inspection of the manufacturers of medicinal products for human use, based upon the principles of quality risk management.  The manufacturing authorization system guarantees that all authorized medicinal products are manufactured only by authorized manufacturers, whose activities are regularly inspected by the competent authority.	Recertification every 3 years	June 5, 2018
<b>GMP Certificate 40/2017/RO</b>	A certificate regarding the conformity with the good manufacturing practice (GMP) issued by the NAMMDR, following the inspection of the manufacturing, packaging and testing operations for the quality control of suppositories, capsules and tablets (medicines for human use).	Recertification every 3 years	August 11, 2017
<b>GMP Certificate 41/2017/RO</b>	A certificate regarding the conformity with the good manufacturing practice (GMP) issued by the NAMMDR, following the inspection of the manufacturing, packaging and testing operations for the quality control of ointments, suppositories, capsules and tablets (medicines for human use).	Recertification every 3 years	August 11, 2017
<b>GMP Certificate 46/2016/RO</b>	A certificate regarding the conformity with the good manufacturing practice (GMP) issued by the NAMMDR, following the inspection of the manufacturing, packaging and testing operations for the quality control of sterile products, powders for injectable solutions/suspensions (medicines for human use).	Recertification every 3 years	December 16, 2016
<b>GMP Certificate 43/2016/RO</b>	A certificate regarding the conformity with the good manufacturing practice (GMP) issued by the NAMMDR, following the inspection of the manufacturing, packaging and testing operations for the quality control of the Nystatin active substance.	Recertification every 3 years	November 29, 2016
<b>US FDA EIR Acceptance</b>	The US FDA EIR (Establishment Inspection Report) is a unit inspection report (Antibiotic SA) issued by the FDA (US Medicines Regulatory Authority) after the inspection of the manufacturing flows for the sterile products (powder for injectable solutions/suspensions) and the Nystatin active substance.	Periodic recertification correlated with risk analysis	June 2, 2017
<b>GLP 49 Certificate</b>	The Bioanalytical Laboratory within the Center for Clinical Studies is certified by the NAMMDR, in accordance with the Good Laboratory Practice. The GLP consists of a set of principles that ensure the quality and integrity of the non-clinical studies.	Recertification every 3 years	June 2, 2017
<b>ISO 9001:2015</b>	Quality management system. An international standard that specifies the requirements that a quality management system must meet, so that the organization can provide quality products.	Annual supervision and recertification every 3 years	December 3, 2017
<b>ISO 14001:2015</b>	Environmental management system. An international standard specifying the requirements that an environmental management system must meet, in order for the organization to increase its environmental performance.	Annual supervision and recertification every 3 years	December 8, 2017
<b>OHSAS 18001:2007</b>	Occupational health and safety management system. The international standard that establishes the requirements that an occupational health and safety management system must meet, in order for the organization to control the risks and improve their OHSAS performance.	Annual supervision and recertification every 3 years	January 10, 2018
<b>Authorization 861/2018</b>	The authorization for clinical studies in the field of the medicinal product.	Reauthorization every 2 years	July 12, 2018
<b>GMP 58/2019/RO Certificate</b>	The certificate regarding the conformity with the good manufacturing practice (GMP) issued by the NAMMD, following the inspection of the manufacturing, packaging and testing operations for the quality control of veterinary medicinal products.	Recertification every 3 years	April 11, 2019
<b>Authorization RO 03</b>	The manufacturing authorization issued by NAMMDR, for the manufacture of veterinary medicinal products.	Recertification at each change of information in the Active Substance Master File (ASMF), containing complete information about an active substance	April 11, 2019
<b>Authorization 861/2018</b>	The authorization for the performance of clinical studies in the field of the medicinal product.	Reauthorization every 2 years	July 12, 2018
<b>Authorization 71/3262252</b>	The authorization for operations with substances classified in category 1 (precursors of drugs).	—	April 27, 2018
<b>Authorization 7Fsp/2019</b>	The authorization to manufacture preparations containing narcotic substances and psychotropic substances.	Annual Reauthorization	February 4, 2019
<b>Authorization 1/2011</b>	The integrated Environmental Authorization	Annual targeting, review/reauthorization upon the change of the authorization/annual endorsement conditions	March 30, 2018
<b>Authorization 303/2010</b>	The authorization of water management	Review / reauthorization when changing authorization conditions	December 20, 2010
<b>Certificate R1-CEP 2003-096-Rev 01</b>	Certificate of conformity with the European Pharmacopoeia (CEP - Certification of suitability of European Pharmacopoeia monographs) for Nystatin active substance, issued by the European Directorate for the Quality of Medicines (EDQM). CEP confirms that a pharmaceutical substance or an active substance is produced according to the requirements of the corresponding monograph in the European Pharmacopoeia.	Recertification at each change of information in the Active Substance Master File (ASMF)	September 25, 2018
<b>Certificate no.10</b>	The certificate of conformity for aluminum tubes used in the packaging of ointments, creams and gels.	Recertification every 3 years	March 21, 2018
<b>Certificate no.11</b>	The certificate of conformity for threaded caps and membrane penetration device used for closing aluminum tubes filled with ointments, creams and gels.	Recertification every 3 years	March 21, 2018
<b>Certificate no. 12</b>	The certificate of conformity for the metal cap for closing the vials containing antibiotic products.	Recertification every 3 years	March 21, 2018

# Awards and affiliations

## Awards

The recognition of the economic and social results that the company obtained during the reporting period resulted in obtaining honorary awards for Antibiotice SA, a proof of its performance, transparency and integrity.



- The National Association of Exporters and Importers in Romania (ANEIR) - **Jubilee Trophy of excellence;**
- The Chamber of Commerce and Industry of Romania - **National Prize 1<sup>st</sup> place** in the category - "Industry, very large companies, the manufacturing of basic pharmaceutical products, for the special financial results recorded during the reporting period".
- The Chamber of Commerce of the City of Iași:
  - **1<sup>st</sup> place** in the Top of companies from Iași County, in the category "Industry, very large companies, manufacturing of basic pharmaceutical products"
  - **Diploma of excellence** for ranking first in the top of the companies from the City of Iași, 10 years in a row, in the same category.
- CSR Media - **Third place** at the Gala "Romanian CSR Awards 2018", in the category of Intersectoral Partnership, for the project "Science and Soul Scholarships" which has been carried out by the company since 2001 and dedicated to children from rural areas in financially unfavorable situations.

## Affiliations

The 63 years of continuity and expertise both in the domestic and international pharmaceutical field make Antibiotice SA an important partner of some national professional entities, contributing to the development of the economy, of the Romanian pharmaceutical market for the benefit of the society and the patient. At the same time, the membership of these organizations facilitates the continuous improvement of the company's own business procedures and practices in line with market trends, legislative requirements and not least with the integration of sustainability principles into business plans.

- Antibiotice SA is part of **the Patronage of Industrial Manufacturers of Medicines in Romania (PRIMER)** alongside the main manufacturers of medicines with production facilities in Romania. Established as an independent professional organization, PRIMER aims to work together for Romania to become a European hub for the manufacture of medicinal products, for the benefit of patients and the Romanian economy;
- Antibiotice SA is a member of **the Romanian Association of Self-Care Industry (RASCI)**, a non-governmental, non-profit, apolitical and independent association. The mission of RASCI is to generate a common approach at the level of the main entities in the industry, in order to increase the public awareness of these product categories, but also to draw the authorities' attention to the need for involvement and dialogue in the development and implementation of a legislative framework favorable to the well-being and health of Romanian citizens;
- Antibiotice SA complies with the Community code for preventing the entry of counterfeit drugs into the legal supply chain

and is a member of both **the Romanian Organisation for Serialising Medicines (OSMR)** and **the European Medicines Verification Organization**, organizations set up to implement European directives on the new rules for the safety and manufacture of packaging, in order to eliminate the risk of the occurrence of counterfeit drugs;

- In order to better represent and support the business interests of the company, in the dialogue with the local and central public authorities, with the national and international bodies, with investors and members, the diplomatic corps accredited in Romania, Antibiotice SA is a member of both **the Chamber of Commerce and Industry of Romania, and the Chamber of Commerce and Industry of the City of Iași**;
- Antibiotice SA is part of **the International Chamber of Commerce**, the most representative business organization in the world, which brings together 6 million members from over 100 countries;
- With an important activity internationally, Antibiotice SA is a member of **the National Association of Exporters and Importers of Romania (ANEIR)**, which acts to create a legislative, economic, financial and banking framework that can expand the export-import volume of Romania, in conditions of efficiency and fair competition;
- At the same time, Antibiotice SA is a partner of **the Ministry of Health in the National Program for the Prevention, Surveillance and Control of Tuberculosis** by providing the necessary essential TB drugs, as Antibiotice SA is the main supplier.

## Risk management

The risk management is a company-wide activity that aims to facilitate the efficient and effective achievement of the organization's objectives. The risk management process focuses upon the identification, assessment, management, monitoring and systematic reporting of risks.

The risk management involves assessing the probability of their occurrence and the impact upon the objectives if a risk is materialized and it is a continuous and cyclical process, based upon the analysis of the internal and external environment in which the company's activity is carried out.

By ensuring a global control of risks, the maintenance of an acceptable level of the risk exposure with minimum costs is achieved. Knowing the threats will allow the ranking thereof according to the probability of their materialization, the extent of the consequences upon the objectives, but also according to the expected costs for implementing actions to reduce the likelihood of occurrence or to limit the effects on the objectives.

The objectives of Antibiotice SA regarding the risk management:

- Understanding the risks to which the company is exposed, the causes, as well as the general and specific objectives;
- Improving the risk profile of the company, by managing the process of identifying, evaluating and managing the risks and implementing the control measures necessary to maintain the risk exposure within the tolerable area.



The main risks identified within the company Antibiotice SA:

## Financial risks

From the viewpoint of the financial risk the management the company is exposed to, the currency risk, the liquidity risk and the commercial (non-payment) risk are considered.

**Currency risk**, a component of the financial risk, frequently occurs under the current conditions of the market economy, where monetary exchange rates fluctuate under the rule of the demand and supply law. The fluctuations of the exchange rate are reflected both in the costs of the imported raw materials and in the selling prices of the finished products for export. The company's policy regarding the currency risk is based upon the synchronization of the import activity with the export activity, by correlating the payment and collection terms, as well as on a better correlation between the currency and the time of payment/collection.

**Liquidity risk** is the risk in which the company may have difficulties to meet the short-term payment obligations at any time. The circumstances of the liquidity risk are the lack of cash flow generated by the gap between receipts and payments, determined by the collection of receivables on terms exceeding 300 days, the unpredictability and lack of transparency

for calculating the claw-back tax, the raising of the price for utilities, raw materials and services.

In 2018, the company's need for cash was higher than in 2017, both for the payment of the claw-back tax, the dividends to the shareholders and for supporting the acquisitions in the investment plan that led to a greater use of the credit lines.

The company's policy regarding the liquidity risk is to maintain, to the extent possible, sufficient liquid resources to meet the obligations as they mature, as well as the availability of financing through financing lines.

**Commercial (non-payment) risk** takes into account the risk of recording losses or of not achieving the estimated profits due to the lack of financial liquidity of the debtors and of the non-fulfillment of the payment obligation when its maturity is fulfilled.

The circumstances of occurrence of the non-payment risk are the large exposures on the main distributors, the long payment terms due in large part to the delays with which the medical services bills are settled by the National Health Insurance House.

The measures used by the company to keep under control and reduce the commercial (non-payment) risk include monitoring the quality of customers, diversifying the customer portfolio and requesting guarantees.

## Legislative risks

The legislative changes related to the pharmaceutical market lead to the emergence of legislative risk, which must be managed continuously.

The pharmaceutical market is a regulated market, with clear legislative provisions, developed in order to control the quality and therapeutic efficiency of the medicines present on the market, as well as to avoid counterfeiting. The adaptation to these provisions is reflected both in the additional costs related to updating the documentation, aligning to the latest quality standards and the delays in marketing the products. The company's strategy for managing these risks involves the permanent concern for obtaining

international certifications of the manufacturing flows, the updating of the authorization documentation for the portfolio products, the conducting of bioequivalence and stability studies, the constantly monitoring of the legislative changes at international level, the continuous adapting of policies, rules and procedures to any occurred changes.

## Human resources related risks

The main risk of human resources is the lack on the labor market of candidates trained in fields specific to the pharmaceutical industry. The measures used to control and reduce this risk have resulted in two programs for attracting future specialists, from their very university years. This is the "Summer School a+" project which reached the tenth edition and the "Perform a+" project at its fourth edition, which involved promoting the company within the specialty faculties, organizing student study visits and establishing partnerships with the pre-university education units.

## Reputational risk

Reputational risk is defined as the current or future risk of adversely affecting profits and capital, as determined by the unfavorable perception of the company's image.

In order to efficiently manage events that may give rise to the reputational risk, measures are being taken to monitor the image of the company in the media, to identify any rumors or news that could generate image risks, periodic press releases in the media with positive information.

The company also carries out a permanent surveillance of operational risks in order to take measures to maintain them at an acceptable level that does not threaten its financial stability, the interests of creditors, shareholders, employees and partners.

# Dialogue and consultations

The process of dialogue and consultation of the interested parties to identify risks, opportunities and issues that require an increased attention from the company, the management team and the employees, took place during the first part of 2018, through a comprehensive methodological approach (one on one interviews, in Iași and Bucharest, an extended meeting organized at the company headquarters in the City of Iași and an online questionnaire) and aimed at identifying the needs and expectations of the stakeholders regarding:

- **the economic, social and environmental impact generated by the activity of Antibiotice SA;**
- **the identification of potential risks and opportunities.**

The aim was for all data providers and those with legal responsibility for the correct reporting thereof to have a common understanding of the role and importance of the non-financial reporting.

The consultation process was based upon the AA1000 SES standard of the Account Ability organization and the GRI 101 standard of the Global Reporting Initiative (GRI) organization. Thus, in determining the stakeholder groups to be consulted, the characteristics recommended in the AA1000 SES standard were taken into consideration, namely:

- **the role** and the legal, commercial, operational or ethical **responsibility** that the company has in relation with the respective stakeholder group;
- **the influence** of the activity of Antibiotice SA Iași on the stakeholder group (or a stakeholder) or the activity of the stakeholder group upon the activity of the Antibiotice SA company;
- **the representativeness** of the stakeholder group / of a particular stakeholder;



- › **the diversity of opinions**, which provides a broader and more balanced picture;
- › a better understanding of the context in which the company operates.

The stakeholder proposals prior to the initiation of the consultative process included:

- › **domestically:** responsible managers (quality, marketing, human resources, economic, medical, CSR, the union and the "Antibiotice Science and Soul" Foundation);
- › **externally:** local authorities, the academic environment, regulatory bodies (the Environmental Agency, the National Environmental Guard, the Ministry of Health, TLI (Territorial Labor Inspectorate), etc.), business partners, NGOs.

Finally, a list of 37 representative persons for all initial proposals resulted.

In order to have a correct and complete understanding of the context in which the company operates and to identify those areas relevant to the activity of Antibiotice SA, the topics included by the representative operators in the pharmaceutical industry in Romania, a number of international standards, as well as European and local legislation on the non-financial reporting were analyzed.

Starting from this document and from the preliminary themes, a questionnaire was prepared with the objective of collecting qualitative and quantitative data, including the identification of risks and opportunities.

The preliminary themes were evaluated by the stakeholders, who appreciated the relevance of each topic for Antibiotice SA in the context of the legislation regarding the non-financial reporting as well as the potential risks and opportunities.

## Methodology used in the reporting process

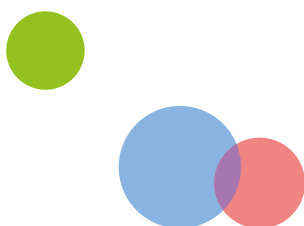
Antibiotice SA decided to use its own system for the non-financial reporting process for the years 2017 and 2018, having as the main reference the standards for sustainability reporting of the Global Reporting Initiative (GRI). The United Nations Sustainable Development Goals (UN SDGs) were used as a secondary reference in the process of identifying the areas relevant to this document.

The Global Reporting Initiative (GRI) recommends that companies which produce sustainability (non-financial) reports comply with ten principles in the reporting process: four principles that concern the process itself (stakeholder inclusion, sustainability context, materiality and conclusiveness) and six principles that refer to the quality of the information to be included in the report (accuracy, balance, clarity, comparability, correctness and timeliness).

For the correct identification of the topics to be covered by this report, the relevant topics addressed by a number of companies in the pharmaceutical industry operating on the Romanian market were studied and they were found either in the annual non-financial reports or in the strategies of the respective companies.

Thus, the following topics have proved to be important for the Romanian pharmaceutical industry:

- › **The efficient use of resources (water, energy) + Waste** (environment);
- › **Employees + Safety and security at work** (social);
- › **The transparency, including through non-financial reporting** (economic);
- › **Anti-corruption measures** (economic);
- › **The relationship between management and employees** (social);
- › **The marketing policy + Safety of participants in clinical studies** (social);
- › **The access to medicines - those on the WHO pre-qualified list of medicines intended for the public health** (social);
- › **The pricing policy** (economic);



- Drug safety and adverse effects (social);
- The professional training (social);
- Supporting the development of the local community (social);
- The procurement practices (economic).

### Secondary themes

A number of secondary topics were identified, which in turn were brought to the attention of the interested parties consulted by Antibiotice SA, during a consultative meeting organized at the company's headquarters:

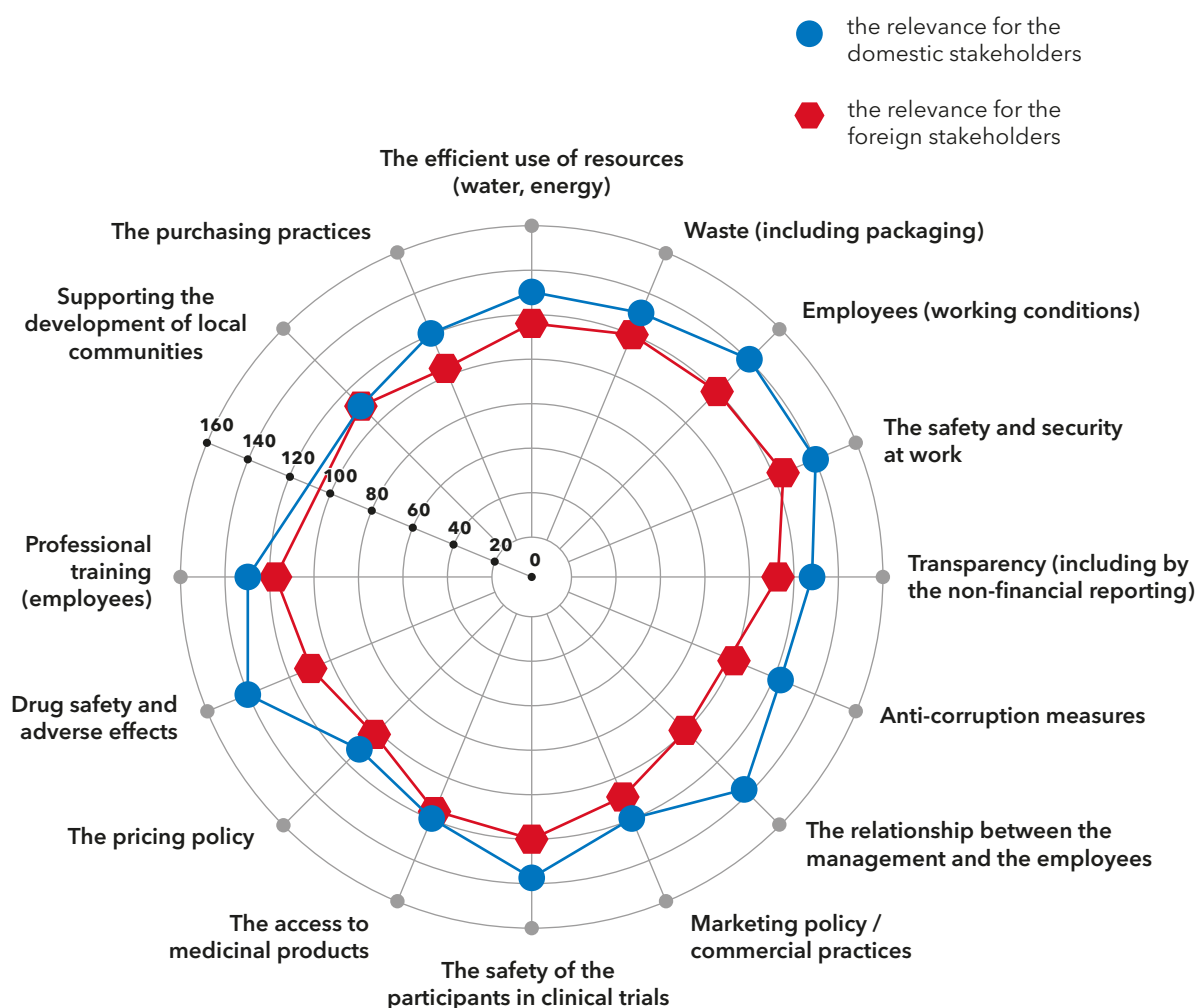
- The reduction of CO<sub>2</sub> emissions (environment);
- Research and development (economic);
- Public-private partnerships to improve access to health services (social);
- The promotion of a healthy lifestyle (social);
- The struggle against counterfeit drugs (social)

### Materiality matrix

The preliminary themes were evaluated by the stakeholders, who appreciated the relevance of each theme for Antibiotice SA in the context of the legislation on the non-financial reporting. The result is shown in the materiality matrix, in which the blue line represents the scale of relevance for the domestic stakeholders, and the red line represents the scale of relevance for the foreign stakeholders.

Based upon the results from the materiality matrix, the management team decided to respond to the expectations of the stakeholders and to include in this report information from topics relevant to the pharmaceutical industry in Romania.

Regarding the secondary list of topics, this will be taken into account for both the risk monitoring activity and the subsequent policy development and the publication of information, as the impact of these themes becomes significant.





# 03

## Economic matters

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# Transparency

Antibiotice SA makes a solid commitment to investors, shareholders and other categories of stakeholders, facilitating their access to relevant information through a sustained and transparent dialogue, through regular reports to various institutions and authorities as well as by publishing these reports on its company website. Through this mode of communication Antibiotice SA ensures a fair treatment of all stakeholders.

## Transparency in the capital market

Antibiotice SA has been present in the capital market since 1997, being listed in the Premium category of the Bucharest Stock Exchange. This made its economic activity more transparent, our company becoming increasingly attractive for shareholders. A good information of the players in the capital market leads to increasing the knowledge and confidence in our company and the share market value as well.

In the reporting period, 1.7 million of shares with a total value of 1.8 million EUR were traded.

Since 2012 Antibiotice SA adopted the principles of the Corporate Governance Code of the Bucharest Stock Exchange which have a significant role in protecting the stakeholders' interests and ensuring a fair treatment for our shareholders. The Corporate Governance Code is at the base of developing and maintaining strong relationships with the company's shareholders and stakeholders, by making our activities and processes transparent and efficient, investors having access to accurate, quality and timely information.

According to the regulations imposed by the Law no. 297/2004 amended and supplemented by the provisions of the Law no. 10/2015, GEO 90/2014 and the CNVM regulations issued for its application as well as according to the Regulation of the Financial Supervisory Authority no. 5/2018 on issuers of financial instruments and market operations, in 2018, Antibiotice SA submitted to the Bucharest Stock Exchange (BVB) and Financial Supervisory Authority the following documents:



**21 years**  
in the capital  
market

Date	Documents submitted	The documents were submitted to/posted on
15.01.2018	Financial Calendar 2018	BVB, ASF, our website
01.02.2018	Notice to attend the OGMS and EGMS of 05/06.03.2018	BVB, ASF, our website, Official Gazette, Evenimentul Newspaper
14.02.2018	2017 Preliminary Financial Results	BVB, ASF, our website
05.03.2018	OGMS and EGMS Decisions - 05.03.2018 approved in OGMS of 05.03.2018	BVB, ASF, our website, Evenimentul Newspaper
06.03.2018	Current Report - an explanation regarding the IEB	BVB, ASF, our website
16.03.2018	Notice to attend the OGMS and EGMS of 26/27.04.2018	BVB, ASF, our website, Official Gazette, Evenimentul Newspaper
16.03.2018	Dividend proposal for the financial year 2017	BVB, ASF, our website
26.04.2018	OGMS and EGMS Decisions - 26.04.2018	BVB, ASF, our website, RoCoApp - Central Depository Evenimentul Newspaper
26.04.2018	2017 Annual Report	BVB, ASF, our website
14.05.2018	Q1 2018 Financial Results	BVB, ASF, our website, Bursa Newspaper
07.06.2018	Notification - Transactions made by initiated persons - purchase	BVB, our website

Date	Documents submitted	The documents were submitted to/posted on
14.08.2018	Notice to attend the OGMS and EGMS of 24/25.09.2018	BVB, ASF, our website, Official Gazette, Evenimentul Newspaper
14.08.2018	H I 2018 Financial Results	BVB, ASF, our website, Bursa Newspaper
03.09.2018	Press release for payment of 2017 dividends	BVB, ASF, RoCoApp - Central Depository, our website
03.09.2018	Change of the 208 financial calendar	BVB, ASF, our website
03.09.2018	Meeting with investors and analysts - Presentation of the HI 2018 Report	BVB, ASF, our website
24.09.2018	Not meeting quorum in OGMS and EGMS of 24.09.2018	BVB, ASF, our website
25.09.2018	OGMS and EGMS Decisions - 25.09.2018	BVB, ASF, our website
09.10.2018	Press release on the payment of dividends 2014	BVB, ASF, our website
14.11.2018	Q III 2018 Financial Results	BVB, ASF, our website, Bursa Newspaper
23.11.2018	Notification regarding the share threshold / number of votes greater than 15%	BVB, ASF, our website

Toate documentele au versiuni în limba română și engleză

General meetings of shareholders are mandatorily held twice a year (annually and semi-annually), according to the Financial Calendar or whenever necessary.

### Transparency on the activity of sponsoring health professionals

Antibiotice SA is a reliable partner for the health professionals, being actively involved in the process of continuing medical education.

According to the provisions of art. 814 of Law no. 95/2006 on the healthcare reform, Antibiotice submitted for 2018 the original forms for declaring the sponsorship activities, as well as the other expenses, other than the sponsorship, at the Registrar's Office of the National Agency for Medicines and Medical Devices in Romania (NAMMDR).

## Anti-corruption measures



**Zero incidents**  
of corruption

Antibiotice SA gives maximum priority to meeting ethical and moral standards and is permanently committed to implementing the measures necessary to prevent abuse in its relationships with all the categories of collaborators, as well as to manage its assets and funds.

Our company elaborated and implemented reference documents that include, among others, anti-corruption policies and procedures: Corporate Governance Code, Code of Ethics, Good Practice Code in the relationship with health professionals, Sponsorship and Patronage Policy, Internal Rules as well as the Integrity Plan drawn up

in accordance with the provisions of the 2016-2020 National Anticorruption Strategy.

All the above-mentioned documents were brought to the notice of the employees, at the same time being published on the company website, thus being accessible without restriction to any party concerned.

The purpose of these documents is to highlight the elements on which the company policy is based in terms of anti-corruption measures, ethics and business morality. Assuming these values is essential and consequently all the decisions of the company management are in accordance

with the provisions and recommendations of the listed documents. Our company has a coordinator for implementing the Integrity Plan who is a member of the company management as well as contact persons, who have execution positions in the company, and their duties are also established.

In order to prevent the occurrence of corruption incidents, both with internal and external partners, Antibiotice SA introduced in the procedures related to the negotiation and elaboration of contracts, specific clauses by which the contractual parties firmly undertake not to commit, authorize or allow any action that would cause them to violate any of the national, European or international anti-corruption laws or regulations in force, at the same time obliging themselves to notify the competent judicial authorities, specialized in the prevention and combating the corruption facts if they become aware of any corruption act related to the negotiation, conclusion or execution of the contracts.

In 2018 for the objective "Reducing the risks of corruption within the company by establishing measures aimed at ensuring the compliance with ethics and integrity programs" one risk regarding "involvement of our employees in activities affecting the legal and efficient running of the company" was identified. After implementing the control measures, the risk is in the "tolerance" area.

All the activities carried out by Antibiotice SA are based on the following fundamental values:

➤ **Integrity** - the obligation to declare any personal interests that may conflict with the objective exercise of the duties of the position held within the public company, as well as the refusal to accept any financial or other benefit from persons or organizations that could influence the performance of the job duties. Also, the institution's obligation to take all necessary measures to avoid conflicts of interests and incompatibilities;

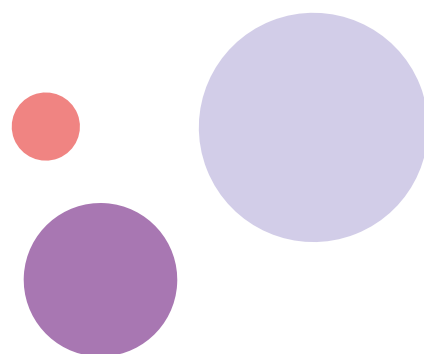
➤ **Transparency** - adopting an open and transparent attitude in all the decisions and actions made by the company's staff. Ensuring the unrestricted access to information of public interest and transparency of the decision-making process;

➤ **Objectivity** - performing the job duties, assigning the contracts, approving or rejecting the draft decisions debated in the Management Board, by adopting an objective attitude, which will lead to the correct decisions meant to protect the company's interest;

➤ **Professionalism** - promoting the fundamental values and principles in the public enterprise's activities, through a responsible attitude in the company's and its shareholders' interest.

There were no incidents of corruption and no acts that violate the measures provided for in the Integrity Plan in the reporting period within our company.

□ The anti-corruption measures adopted by Antibiotice SA can be found in the Declaration of Accession to the National Anticorruption Strategy (<https://bit.ly/2oaoFYJ>), Integrity Plan (<https://bit.ly/2o82g LJ>) adopted in accordance with SNA, Code of Ethics (<https://bit.ly/2oOfRHT>), Ethics Form (<https://bit.ly/2olsSTF>) and the Good Practice Code (<https://bit.ly/2py8r Ji>).



## Tariff Policy

The need to provide adequate stocks of medicines at a reasonable cost to maintain public health, support efficiency in the production of medicines and encourage the research and development of new medicines has imposed regulating the prices of medicines for human use at the European level.

In Romania, the price of medicines for human use is regulated by the Order of the Ministry of Health no. 368/2017, for the approval of the Norms regarding the calculation method and the procedure for approving the maximum prices of medicinal products for human use, which transposes art.1-4 of the Council Directive no. 89/105/EEC of December 21, 1988, on the transparency of the measures governing the pricing of medicinal products for human use and their inclusion in the scope of the national health insurance system, published in the Official Journal of the European Communities, series L, no. 40 of February 11, 1989.

This normative act provides for the calculation method and procedure for approving the manufacturer price, the wholesale and retail price for the prescription medicines.

In substantiating its prices, Antibiotice, manufacturer of generic medicinal products (product therapeutically equivalent with the original pharmaceutical product whose patent expired and which contain the same active substance as the original product, being equivalent in terms of dose, concentration, route of administration, safety, efficacy and therapeutic indications), comply with the legislative requirements.

Thus, a first step in establishing the manufacturer price is the comparison of the proposed price with the price of the same medicine, authorized in the Czech Republic, Republic of Bulgaria, Republic of Hungary, Republic of Poland, Slovak Republic, Republic of Austria, Kingdom of Belgium, Italian Republic, Lithuania, Spain, Greece, Germany. If there is a price authorized in the mentioned countries, the proposed manufacturer price must be lower or at most equal to the lowest price.

If, as a result of the checks, it is found that the medicinal product has no price registered in the countries included in the referen-

ce list, the price is compared with the price in the country of origin, having to be lower or at most equal to the lowest price.

In case the medicinal product has no price registered in the reference countries nor in the country of origin, the proposed price is approved, which in the case of generic medicines cannot exceed the generic reference price.

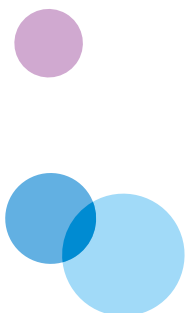
The price of non-prescription medicines (OTCs), food supplements and cosmetics is freely set and changed, taking into account market demands and trends.

Participation through distributors in public tenders for medicines ensures the access of all medical institutions to the Antibiotice medicines under conditions of competitiveness and transparency, our company proving its flexibility by reducing the price within profitability limits.

The market policy of Antibiotice SA is made in the ethical spirit of competitive practices and behaviors, in compliance with the legislation in force (Law no. 21/1996, republished), as well as with the Code of Ethics (<https://bit.ly/2oOfRHT>) and Good Practice Code of Antibiotice (<https://bit.ly/2py8rJi>) for the promotion of prescription medicines and for interactions with medical professionals.

In 2018 our company recorded increases and penalties related mainly to the clawback tax, additionally established by the fiscal inspection report concluded in 2015. The amounts were calculated as a result of the decisions regarding the accessory fiscal obligations issued in 2018 by the National Agency for Fiscal Administration Bucharest. The clawback tax is the amount owed by the pharmaceutical companies for the medicines supported by the Unique National Health Insurance Fund and by the Budget of the Ministry of Health.

In the reporting period, Antibiotice SA was not involved in legal or judicial proceedings having as object accusations of anti-competitive behavior or violations of the Antitrust and Monopoly Legislation, and in this context there are no court decisions pronounced in this respect.





# Sustainable procurement

Procurement is an important link in the value chain that generates favorable conditions for the sustainable development of Antibiotice SA Iași. This activity is organized to meet the needs of our company, developing business relationships with suppliers from the Romanian market, as well as from the intra- and extra-community areas.

## Domestic procurement

**The main rules that are strictly followed in the domestic procurement activity:**

- compliance with the regulations and legislation in force;
- a fair treatment in the selection process, offering all potential suppliers equal contracting opportunities;
- implementing a fair, ethical and transparent system of supplier evaluation, able to promote long-term, stable partnerships, based on technological and manufacturing capabilities, quality, price, delivery capacity and corporate stability;
- a fair cost-volume ratio, which allows our company to obtain substantial savings in all the manufacturing stages;
- a continuous communication with our suppliers, so that any risks related to the production and procurement be known, evaluated and solved in due time.

The share of purchases made through the local suppliers is 36% of the total purchases.

## Foreign procurement

Given the company's internationalization policy, in order to anticipate and prevent any risks, the external procurement process is based on risk analyses.

When making external purchases, a special emphasis is placed on optimizing the costs, identifying the eligible sources of raw materials, equipment, technologies and work installations, in order to ensure compliance with the quality and manufacturing standards imposed by both the legislation in force and good practices in our domain of activity.

**Our strategic objectives on the external procurement:**

- strengthening the medium- and long-term partnerships through making the business relationships with our suppliers more and more transparent and predictable;
- mitigating the risks throughout the procurement chain, in order to secure the company's operations;
- encouraging innovation in relationships with our partners to create added value throughout the procurement chain, starting from the selection of sources in research & development projects up to the launch of the product in manufacturing;
- generating competitive advantages by identifying and optimizing the capabilities of suppliers (technology, production capabilities, know-how, staff excellence).

The long-term relationships of Antibiotice SA with its suppliers, demonstrate our company's ability to build and maintain stable, ethical and trustworthy business partnerships for the benefit of the company, its employees, partners and last but not least in the benefit of the national economy.



**36%**

the share of purchases made through the suppliers from Romania

**The selection of offers are based on:**

- **economic criteria:**  
quantity, price, place and time
- **quality criteria:**  
the compliance with national and international standards

# 04

## Social matters

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## Our company's people

Antibiotice SA wishes all of its 1,415 employees to embrace the company's mission **of doing more and better for people's health**.

This mission will be fulfilled also in the next years, by focusing our organizational culture towards innovation and performance, an increased satisfaction level and attachment to the organization.

For this reason, Antibiotice SA seeks to provide its employees with conditions for professional and personal growth, a stimulating and challenging working environment, respecting the principles of diversity, non-discrimination and equal opportunities.

### Equality and diversity

In order to achieve the business objectives, a variety of specialists work within our company. These are professionals in research, manufacture of medicines and active substances: pharmacists, biologists, chemists, chemical engineers, assistant chemists, chemical operators, as well as highly qualified specialists in quality assurance and control, engineering and

service, economy, marketing, sales, procurement and logistics.

The average number of employees (1,415) in the reporting period is only slightly smaller than the figure recorded in 2017 (1420). Our employees' distribution is well-balanced within the company's departments as regards the gender, age and education level.

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Age and gender breakdown - 2018 versus 2017

	Age group	< 30	30 - 50	> 50	Total (%)
2018	Women (%)	4.27	32.99	17.80	55.06
	Men (%)	2.99	26.71	15.24	44.94
	Total	7.26	59.70	33.04	100
2017	Women (%)	17.28	22.95	14.52	54.75
	Men (%)	13.03	18.06	14.16	45.25
	Total	30.31	41.01	28.68	100

55,06%

Women



44,94%

Men



From the total of **1,415** employees, **44%** graduated higher studies (of which **5.4%** completed their doctoral studies), and **56%** graduated secondary studies.

Regarding the career development, 20 employees were promoted to management positions in 2018, 13 of them being women (65%). Thus, the structure of the management positions by gender, at the end of 2018, was the following:

2018	Management positions	No. of empl.	%
	Women	104	61.54
	Men	65	38.46
	Total	169	100

Women represent  
**61.5%**  
of the total management staff

Ensuring a positive climate conducive to innovation and performance is a priority for the human resources management. For this reason, in 2018, two studies were carried out in the company, one for the analysis of the organizational climate and one for identifying the employees' perception on the employer brand of Antibiotice.

The conclusions of both studies will be the basis of the plans of measures to be implemented starting with 2019 so that the organizational climate be a high one, built on solid foundations and healthy relationships.

From the confessional point of view, 96% of our employees are persons of Orthodox confession while 4% of them are of Catholic confession, proportion that respects the confessional structure at national level. This characteristic, as well as those related to gender, age, nationality or presence of disabilities are not limiting criteria for employment.

11 employees are persons with disabilities, they benefit from fair and non-discriminatory treatment at the workplace.

### Employee retention

In Antibiotice SA three generations of people work together harmoniously, the oldest having about 40 years of activity. Our recruitment and internal mentoring programs are based both on our senior specialists eager to hand the torch to the young, capable and passionate employees and on attracting new talents.

102 persons were employed in 2018:

- **46 of employees with higher education**, of which 23 for developing the research, portfolio management, production, engineering teams and 23 for replacing the employees for whom the labor relations ceased;
- **56 employees with secondary education**, of which 5 for developing the production and engineering teams and 51 for replacing the employees for whom the labor relations ceased.

### Employees newly hired in 2018, by gender and age

	< 30	30 - 50	> 50	Total (%)
Women (%)	20	34	4	58
Men (%)	12	28	4	44
Total	32	62	8	102

In the context of expanding our business in the international market and opening new representative offices in Vietnam, Republic of Moldova and Ukraine, our company hired seven people for running our activities in these regions.

Representative office	No. of employees
Vietnam	1 (100% of men)
Moldova	4 (75% are women and 25% are men)
Ucraina	2 (50% are women and 50% are men)

In 2018, 111 employees ceased their activity within our organization, as follows:

	< 30	30 - 50	> 50	Total (%)
Women (%)	5	25	27	57
Men (%)	9	26	19	54
Total	14	51	46	111

The staff fluctuation rate in 2018 was 4.37%, lower than in 2017 (8.45%). In order to keep this indicator as low as possible, a plan of measures will be implemented to attract the most suitable candidates, compatible with the values of the organizational culture and professional level required by the available positions.

## Employee benefits

Our management created a unitary and modern wage system, which are to be implemented in the period 2019-2022 in order to attract new employees able to support the company's vision and to counterbalance the shortage of certain specialists in the labor market. The new system aims to align the package of financial and non-financial benefits to the level of performance and individual contribution of each employee to the company's objectives.

Launched in 2018, this system is structured on predictable pay levels, corresponding to each job appropriately positioned in an internal hierarchy.

In addition to the financial benefits resulting from this reward system, the company grants to all employees, regardless of the type of contract, a complex package of benefits (some of them being negotiated and established by the Collective Labor Agreement at the organizational level).

These benefits include:

- annual bonuses on the occasion of Easter and Christmas holidays;
- bonuses on the occasion of March 8;
- performance bonuses for the employees included in the Management by Objectives (MBO), depending on the fulfillment of the indicators;
- share of our company's net profit (up to a maximum of 10%) based on the established performance criteria;
- meal tickets;
- a 10% subsidy for the lunch served by the company buffet;
- free transportation to and from the workplace;

- possibility of accessing the financial facilities provided by the Employees' Mutual Aid House of Antibiotice SA.;
- sports ground (located at the company's headquarters), as well as the necessary equipment;
- profits from banking operations (customized agreements with the partner banks of Antibiotice at which the employees have the payroll cards);
- financial support in special situations (events in private life: birth of an employee's child, health recovery, death of a 1<sup>st</sup> degree relative);
- providing flu vaccination for employees;
- solving the dental emergencies within the company's dental office;
- access to the non-prescription medicines from our company's portfolio at a manufacturer price.

Starting with 2018, our company initiated a pilot program for the provision of private health insurance. 136 employees benefited of this program, according to the established granting policy.

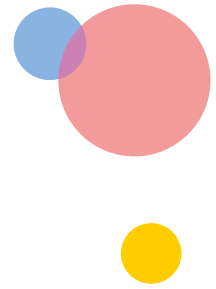
Antibiotice SA additionally grants paid days off for:

- special events in the family or other situations (an employee's marriage, marriage of a child or other family members, birth of a child);
- additional rest leave, depending on the age at work and working conditions at the workplace (between 4 and 5 days);
- an additional 3 days leave is granted per year for the employees with disabilities.



In 2018, the child-raising leave was requested and approved for **19** employees. Another 21 employees resumed their activity after completing the same type of leave.

**55** funeral grants in 2018



## Safety and security in the workplace



In 2018, the absenteeism rate due to work-related injuries was **zero** and no deaths were recorded.

Antibiotice SA pays a special attention to the safety and security of employees and persons visiting the company. Internal Prevention & Protection Department, directly subordinate to the General Director, ensures the compliance with the regulations contained in the Occupational Safety and Health Law no. 319/2006. We have also employees responsible in this field who are periodically trained so as to have the necessary skills to identify hazards and assess risks whenever changes occur (in equipment, work environment or tasks).

Since 2007, the Integrated Management System (quality, environment, occupational health and security) of Antibiotice SA has been certified in accordance with the ISO 9001/14001/18001 international standards.

In the Collective Labor Agreement, concluded between the Employer and the Trade Union, a separate chapter (Chapter III) is dedicated to the provisions regarding the working conditions, occupational health and safety.

According to this chapter, Antibiotice SA constituted a Committee on Occupational Safety and Health (CSSM) composed of five representatives of the employer, five representatives of the employees (the company's union leader as well as other

union leaders of various departments) and the occupational health physician. This committee establishes and monitors the implementation of the Prevention & Protection Plan aimed at continuously improving the working conditions, keeping under control the risks of work-related injuries and occupational diseases, as well as assimilating the technical progress and the new regulations in the field.


In 2018 CSSM organized 4 sessions, implementing, until the end of 2018, **all the measures included in the Prevention & Protection Plan for 2017-2019.**

Antibiotice has also a medical office and a team of occupational health physicians and nurses. The medical office works permanently (24 hours a day) and has the medical equipment necessary for:

- providing medical checks on employment;
- providing the first aid in case of medical emergencies;
- providing medical checks for the permanent assessment of the employees' health status, according to the occupational medicine legislation, but also to the requirements on quality and safety of the manufacture of medicines.

During the reference year, a work accident of an employee with a 27-day temporary work incapacity was recorded in Antibiotice SA. The work accident was not due to the organizational issues in the field of occupational safety in our company.



	No. of work accidents	Absenteeism due to work-related injuries
2018	1	27 days
2017	2	93 days

Following the investigations carried out, the measure of revising and completing the instructions regarding the used equipment, as well as the training of the personnel involved in similar activities were established..

**Our employees benefit from the facilities provided for working under extreme temperatures (starting with temperatures of -10 degrees (compared to the legal limit of -20 degrees) and above +32 degrees Celsius (compared to the legal limit of +37 degrees Celsius).**

### Internal emergency alarm exercises

Being a company with an industrial profile active in the field of chemical industry, Antibiotice SA established its own Emergency Situation Department. This Department has, according to the law, the following main attributions:

- to inform and train all the employees as regards the compliance with fire protection rules;
- to carry out activities for preventing the occurrence of incidents on the company's site;
- to extinguish the fire, give first aid and save the people and goods.

Based on the Emergency Preparedness Plan approved by the Inspectorate for Emergency Situations of Iași County, 8 alarm exercises were carried out in 2018 to verify the capacity of responding to different emergency situations - fire, earthquake, emissions of dangerous substances.

## Professional training

### Programs implemented and assistance offered to improve the skills of our employees

In order to support its employees in obtaining professional performances, Antibiotice SA developed programs adapted to the specific of each activity, according to the internal needs and in close correlation with the legislative changes in the pharmaceutical field.

Unlike other fields of activity, the manufacture of medicinal products is an extremely regulated sector which constantly undergoes changes that need to be understood and implemented.

Professional development programs for extending the competence of our employees in key areas are supported either by highly competent persons inside the company or by external trainers.

In order to harmonize the knowledge and operational processes, Antibiotice organizes courses with in-house trainers with a high expertise in their field for its employees in the production of medicines, national and international sales, procurement, medical research, logistics and quality assurance. In turn, our internal trainers have access to national and international training courses, in line with the level of specialization required by the industry and competitiveness.

### Professional training programs for our employees

- **retention programs for employees in key positions** (subsidizing the expenses for individual training courses, according to the approved annual training plans);
- **career plans**, which aim to advise and support our employees in the process of accumulating new knowledge and discovering and practicing skills,

both for improving the performances in the current positions, but also for a hierarchical evolution;



- **"Summer school a+"** - annual programs of continuous professional training and personal development, with internal and external trainers in management, leadership, communication, product management.

Given the complexity of the pharmaceutical production, especially the synthesis of the active substance Nystatin, a manufacturing process unique in Romania, we develop mentor teams that facilitate the professional training and skills development of our new employees.

Year	Number of participants in trainings	Number of training hours per employee
<b>2018</b>	<b>665</b>	<b>35,2</b>
<b>2017</b>	<b>580</b>	<b>36,3</b>

In 2018, a number of 665 employees attended the training sessions scheduled in specific areas, resulting in an average number of 35,2 training hours/employee.

Distribution of the number of employees în funcție de gen who benefited from professional training in 2018:

<b>2018</b>		Nr. pers	%
	<b>Women</b>	<b>366</b>	<b>55.06</b>
	<b>Men</b>	<b>299</b>	<b>44.94</b>

Repartizarea numărului de angajați în funcție de vârstă, care au beneficiat de formare profesională în 2018:

<b>2018</b>	< 30	30 - 50	> 50
<b>Women</b>	<b>8.5%</b>	<b>75%</b>	<b>16.5%</b>
<b>Men</b>	<b>10%</b>	<b>76%</b>	<b>14%</b>
<b>Total</b>	<b>9.1%</b>	<b>74%</b>	<b>16.9%</b>



From the training sessions conducted in 2018, a part of them was carried out within the "Summer School a+" program, a traditional project in our company, that reached its 9<sup>th</sup> edition. Its purpose is to increase the level of professional training and personal development of the employees holding management positions (top managers, middle managers, line managers), but also of the execution staff with higher and secondary education in the key areas for developing our business.

### Evaluation of our employees' individual performances

Every year, our employees go through a process of evaluating their individual performances. Employees from all hierarchical levels are included in this process, the process being differentiated as follows:

- **evaluation of managers by hierarchically superior managers;**
- **evaluation of the execution staff by hierarchically superior managers;**
- **evaluation of managers by subordinates**

The results of these evaluations are subsequently communicated to the employees, discussed, in order to optimize their activities and improve their performances.



## Management & Employee Relationship

Each of our employees is eligible to join the Independent Trade Union of Antibiotice, an employee representation body established on the basis of the law on freedom of association.

The Independent Trade Union of Antibiotice is a permanent social dialogue partner of our company's management, participating every two years in the negotiation and conclusion of the clauses contained in the Collective Labor Agreement. Under this contract the following types of clauses are established, with extended validity for all the employees:

- **Conditions regarding the conclusion/ modification of the individual labour contract;**
- **Provisions regarding the working conditions, occupational health protection and safety, environmental protection and emergency situations;**
- **The general framework regarding the payroll and other benefits;**
- **Continuous professional training;**
- **Work and rest time;**
- **Other protection measures and facilities granted to employees.**

The union leaders have frequent meetings with the management in which they are informed about the company's financial evolution, objective achievement level, immediate perspectives of the activity. All decisions affecting the employees are discussed and analyzed in advance with the employees' representatives.

Percentage of employees who are union members

2018	77%
2017	83.4%

## Marketing policy

Marketing policies of Antibiotice SA, both internal and international ones, are based exclusively on ethical practices of marketing, promotion and sale for prescription, non-prescription medicinal products and food supplements.

These practices are assumed by the entire company by a Good Practice Code for the promotion of prescription medicines and for the interactions with medical and pharmaceutical professionals. (<https://bit.ly/2py8rJi>). This Code aims at preventing the possible incidents while the internal Committee on Ethics and Integrity solves the warnings, fines or penalties for non-compliances.

This Code, together with the Code of Ethics and the Company's Internal Regulations, is a support for ensuring a legal, transparent and ethical framework for promotion activities, for creating a fair competitive environment for non-prescription medicinal products.

The current Good Practice Code reflects also the requirements of the EFPIA Code of Practice (European Federation of Pharmaceutical Industries and Associations), ARPIM Code (Romanian Association of International Medicine Manufacturers), APMGR Code (Association of Generic Medicine Producers from Romania) as well as the Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

The Code defines and implements the ethical standards specific to the promotion of medicines which ensure the correct transmission of the information regarding the generic medicines to the healthcare professionals. This way the Committee on Ethics and Integrity can prevent or solve the possible deviations.

The provisions of this Code are fully compliant with and complement the applicable laws.

As regards the practical application of the provisions of the legal and voluntary norms in promotion, Antibiotice SA received no fines or warnings for the non-compliance with the legislation on labeling, promotion and marketing communications..

**Zero fines and zero warnings** for the non-complying with the legislation on medicine advertising

## Access to medicines

Antibiotice has been developing a complex portfolio of medicinal products of 12 therapeutic classes, being the number 1 world-wide manufacturer of the active substance Nystatin, a vertically-integrated product in the production of finished medicinal products (pessaries, creams and tablets).

By its very mission, our company makes the valuable generic medicines more accessible for patients, physicians and pharmacists.

The medicines from the Antibiotice portfolio are delivered locally and internationally in Europe, Asia, North America and Africa.

Both in the domestic and international market, the Antibiotice medicines reach the hospitals and pharmacies through our distribution partners with which the company concludes ethical and transparent commercial relations for a continuous, active and extensive presence of our products in the pharmaceutical system.

**The ten partners with whom we collaborate in the Romanian market have supply contracts with all those 576 hospitals in the country (367 public and 209 private ones) and with the 7,850 pharmacies (of which 2,000 belong to national chains and the other ones are community and regional pharmacies).**

(source: INS report on the activity of the health units in 2017)

When concluding the distribution agreements, Antibiotice SA makes sure that the distribution partner has the ability to continuously market the products, without discontinuities in delivery, according to the Good Distribution Practice (GDP) standards and to respond to the needs of providing medicines at affordable prices. Our company also makes sure that the partner can develop long-term development strategies, leading to a growing and sustainable evolution of our business in the respective territories.



Constant orientation towards facilitating the access of as many patients as possible to the Antibiotice products has determined the company to expand its commercial representation network (Republic of Moldova, Vietnam, Serbia and Ukraine). Through this representative offices, Antibiotice is closer to the consumer and local health system, it knows and understands the consumption and therapeutic habits, adapting its strategy to the local consumers' needs.

Our territorial expansion strategy considers also approaching other territories with developed economies in Europe, America but also emerging countries in Asia.

With its medicines at affordable prices, Antibiotice reaches also disadvantaged territories. Our company's mission includes supporting the communities and health systems from these countries by providing them with therapeutically effective medicines, at prices adapted to the local economic context. In countries from Africa or the Middle East, our company supports the international organizations for combating tuberculosis (Tunisia) and for treating the cardiovascular diseases (Ethiopia, Irak).

From the WHO Model List of Essential Medicines published by the World Health Organization, Antibiotice portfolio provides a number of 46 medicines that meet the needs of healthcare for the majority of the population, used in the treatment of the most widespread diseases).

- **Zero** products withdrawn from the market
- **46 Antibiotice medicinal products** are considered essential medicines, according to the WHO classification
- **39 Marketing Authorizations (MAs)** for medicinal products and Notifications for food supplements in 8 countries from Asia, Africa, CIS area and Europe
- the Romanian, WHO prequalified manufacturer of the entire range of **essential antituberculous medicines**.

## Safety of participants in clinical trials

Clinical trials conducted by Antibiotice specialists are in accordance with the Declaration of Helsinki on ethical principles for medical research involving human subjects. The trial protocol includes the objective and the way in which the trial is conducted, describes how the ethical principles are addressed, being analyzed and approved by the National Bioethics Committee for Medicines and Medical Devices.

The rights, safety and well-being of the subjects in a clinical trial are the most important consideration and should prevail over any scientific interest of the company. The inclusion of human subjects in a trial is made only after their informed and documented consent. Participation of subjects is voluntary, they may choose to withdraw from the trial at any time.

The clinical bioequivalence trials certify that the generic medicines developed by Antibiotice SA are therapeutically equivalent to the innovative reference medicines, according to European and national regulations on Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) for medicinal products for human use.

The robust procedures to ensure the safety of volunteers participating in bioequivalence clinical trials are paramount in the development of the Antibiotice medicines.



In 2018, **there were no bioequivalence clinical trials prematurely concluded** for reasons related to the safety of volunteers.

# Safety of medicines and their adverse effects

Safety of the patients treated with Antibiotice medicines is our company's top priority. Product labeling is the first way of properly informing the patients and consumers about the medicines' action and their safe mode of administration.

The safety in use, storage and administration of the Antibiotice products are ensured by warnings clearly mentioned on the product label and on its package leaflet, along with other specific information, provided in an appropriate language so as to facilitate the understanding of the terms by the patient and consumer.

The labeling and package leaflet of each medicinal product is subject to the approval of the regulatory authority, National Agency for Medicines and Medical Devices of Romania (NAMMDR), prior to the marketing of medicines and the information is periodically reviewed and aligned with the requirements of the relevant legislation.

**During 2018, no incidents were recorded regarding:**

- **failure to comply with the legal regulations which may result in the imposition of fines or penalties;**
- **failure to comply with the legal regulations which may result in the imposition of warnings;**
- **non-compliance with the voluntarily assumed codes in the field.**

Monitoring the effectiveness and safety in the administration of medicines for which Antibiotice SA has Marketing Authorizations (MAs) is part of an ongoing process, carried out through our internal pharmacovigilance activity. The rigorous analysis of the benefit-risk ratio ensures that the benefit of administering a medicine in a patient overcomes the risks for the patient.

All spontaneous reports of suspected adverse reactions are collected, evaluated and reported in accordance with the legislation in force. By connecting itself, in 2007, to the European database on

pharmacovigilance, Eudravigilance, our company contributes permanently to maintaining safety in the use of its medicines and allows also the detection of possible global safety signals and the initiation of appropriate measures for the protection of public health, if such be the case.

Safety of a medicinal product is monitored throughout the life cycle, from its development, launch and marketing, until the expiry of the marketing authorization.

The patients can report a suspected adverse event to any of the Antibiotice medicines with marketing authorization at the email address: [sigmedumane@antibiotice.ro](mailto:sigmedumane@antibiotice.ro) and the number phones: 0232.209.249 and 0232.209.256.

In 2018, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) evaluated the systemic (oral or injected) medicines as well as inhalation medicines containing fluoroquinolones and quinolones, following a review of disabling and potentially long-lasting side effects reported with these medicines. In order to maintain the benefit /risk ratio, the Committee recommended the restriction in use of fluorquinolones in some mild or moderate infections and also in prophylaxis.

In addition to the restriction indications, the evaluation led to recommendations for avoiding fluoroquinolone administration in patients with a history of serious adverse reactions associated with the use of quinolones or fluoroquinolones and recommendations for use with extreme caution in the elderly, patients with kidney disease, patients with organ transplants, due to the increased risk of tendon injury in these patients.

The PRAC recommendations were transmitted to the Committee for Medicinal Products for Human Use (CHMP) which is the European Medicines Agency's

committee responsible for human medicines. This authority has reached a final conclusion which will be subsequently forwarded to the European Commission for adopting a decision with mandatory applicability in all EU countries.

The medicines from the Antibiotice portfolio belonging to the fluoroquinolone class are: Ciproquin® 500 mg coated tablets (ciprofloxacin) and Norfloxacină Atb® 400 mg tablets (norfloxacin).

**No products were withdrawn from the market during 2018 for safety reasons and no unexpected adverse reactions of the Antibiotice products were recorded.**

In 2018, Antibiotice took also important steps in implementing the system for verifying the medicines to combat counterfeiting and, starting from February 2019, our company will be in line with the provisions of European Directive 2011/62 / EU on counterfeit medicines that prevents the

infiltration of falsified medicines in the pharmaceutical chain. In order to comply with the new rules and having export interests, Antibiotice SA invested important resources in serialization equipment and software for the finished product warehouse and for all the manufacturing flows.

Serialization equipment ensures the application of the safety elements and individualization of each medicine box, so that it can be identified anywhere in the distribution chain, from the manufacturer to pharmacies and hospitals.





# Supporting the development of our community

Antibiotice takes responsibility for contributing as a “good citizen” to the community life, being directly involved in developing a better society and a cleaner environment.

Antibiotice SA emphasizes its commitment of acting sustainably and creating long-term value for the business itself and stakeholders, while respecting the environment, supporting the communities in which it operates.

We are involved in the community's life through social responsibility programs based on four strategic pillars: health, education, social matters and environmental protection.

## Health

Antibiotice has been developing social responsibility programs to improve the health of its employees, but also the health of the people in the community it operates.

These programs include campaigns for educating and informing the population about health prevention.

### Antibiotics of the 3<sup>rd</sup> Millennium

Antibiotice launched on November 9, 2018 the social responsibility program Antibiotics of the 3<sup>rd</sup> Millennium by bringing together international and local experts as well as professionals who consistently advocate the judicious use of antibiotics in human and veterinary medicine. The event took place in the week ahead of the World Health Organization's World Antibiotic Awareness Week. The debate brought together different perspectives on antibiotic use and resistance, a theme with a wide social addressability.

Antimicrobial resistance is a priority for many European countries, but also worldwide. Antibiotice's involvement in limiting the antibiotic resistance phenomenon is a responsible approach, natural to a pharmaceutical manufacturer in a continuous international expansion, because this is a global crisis that can not be ignored.

The Antibiotics of the 3<sup>rd</sup> Millennium program aims at drawing attention to the antibiotic resistance phenomenon, supporting the development and dissemination of good practices in the use of antibiotics, addressing a community of patients and general public, doctors, nurses, pharmacists, manufacturers, environmental experts, academic and entrepreneurial representatives.

### Donate blood! Put your soul to life!

The acute blood crisis in the Romanian hospitals determined our company's employees to involve, starting with 2010, in the blood donation campaigns initiated by the “Antibiotice – Science and Soul” Foundation, in partnership with the Regional Blood Transfusion Center (CRTS) Iași.

On April 7, 2018, on the occasion of the World Health Day, 60 Antibiotice employees donated 30 liters of blood thus saving more than 150 lives. The second round of the campaign took place on October 11, 2018, when 50 Antibiotice employees donated 25 liters of blood, saving 130 lives.





## Education

Antibiotice SA invests, with science and soul, in the education of young people who, like its employees, can be highly performing in their career and become responsible behavior models. We recognize and support the role of the local community in forming and developing the company's main source of value – the well trained people.

### "Science and Soul" Scholarships

For 18 years, Antibiotice has been sustaining the "Pro Ruralis" Association and the scholarship program for rural pupils with a higher intelligence quotient from disadvantaged families. Since November 2010, the project has been taken over and run through the "Antibiotice – Science and Soul" Foundation.

Initiated in 2001, this project provides the chance for intelligent children without material opportunities living in the countryside to complete their education according to their potential at the elite high-schools in Iași.

In 2018, this social responsibility project won the third place at the "Romanian CSR Awards 2018" Gala, in the Inter-sectoral Partnership category.

The generations of pupils who benefited in the past years from financial support of Antibiotice SA have been currently attending the courses of various university education institutions.

### Each of us can save a life!

Constantly concerned about its employees' safety, Antibiotice SA organized for them first aid courses, on the occasion of the World Heart Day which promotes the awareness for prevention measures to reduce the risk of heart attack.

On October 16-17, 2018, a number of 100 Antibiotice employees participated in first aid courses organized by our company in partnership with the Emergency Department – (UPU) SMURD Iași and professors from the University of Medicine and Pharmacy Iași (Emergency Medicine). The project entitled "Each of us can save a life!" aimed at promoting basic first aid measures among Antibiotice

employees but also at placing more responsibility on them in emergencies in order to help their fellow human beings.

The course was supported by doctors from SMURD (Mobile Emergency Service for Resuscitation and Extrication) of Iași and consisted of the theoretical and practical presentation of the first aid concepts. Within the project, leaflets with important information related to first aid measures were distributed to all our company's employees.

### At home in the community. After school at the Valea Lupului School

For the second year in a row, our company's employees supported the programme "At home in the community – after school at Valea Lupului School".

The After School Program includes orphaned children, children in grandparents' care or children with sick parents but talented and intelligent who benefit from personal development programs with the support of a psychologist and volunteer teachers.

On May 30, 2018, our employees saw a charity theatre show "Poem in clay" put into the stage by the Cantalup theatre troupe of the Valea Lupului School. The amount collected from the employees' donations was doubled by the "Antibiotice – Science and Soul" Foundation for supporting 70 pupils included in this program intended to prevent school dropouts.

After a year of running this program, the learning results of the children included in the project improved significantly, and that's why we decided to extend this project.



### The "Science and Soul Scholarships"

Project won the third place at the "Romanian CSR Awards 2018", in the Inter-sectoral Partnership category.



**100**

**Antibiotice employees were trained to provide first aid**

47



**Antibiotice employees support**

**70 pupils**

**at risk of dropping out**



## Environment

Antibiotice SA develops a sustainable partnership with the community by carrying out activities meant to protect the environment, being permanently concerned with improving its environmental performance.

### Orchard at school

The second edition of the "Orchard at school" project took roots in three schools from the Iași County. Thus 120 Antibiotice volunteers together with their families planted in two stages, 300 fruit trees at schools in the neighboring localities of Iași (Lețcani, Rediu and Cogeasca).

Through the "Orchard at school" project, developed by the "Science and Soul" Foundation Antibiotice, employees voluntarily engage and try to inspire the younger generation for protecting the environment, maintaining a healthy lifestyle and cultivating the civic spirit in the community.

Through the power of the example offered by Antibiotice employees, this project flourished. 710 trees got roots in eight schools in Iași County, contributing to a healthier and better life of the community.

### Earth Hour

Our company participated in the Earth Hour action, the largest environmental event of all times, which draws attention to the effects of global warming. On March 24, 2018, between 20:30 and 21:30, our company symbolically switched off the

lights (in areas where this was possible) in the tenth consecutive participation of the company in this action.

Such actions are meant to demonstrate the importance of rational consumption of natural resources and our commitment to protect the environment both for our employees and the communities in which we operate.

### Doors Open Day

Antibiotice uses responsibly the resources, meets the highest quality standards for manufacturing medicines and for protecting the environment.

Responsibility for the environment is a constant concern of our company and, in this respect, it opened its doors to facilitate a dialogue on environmental issues with the communities in its neighborhood.

On July 17, 2018, in collaboration with the Valea Lupului City Hall, Antibiotice organized the Doors Open Day for the inhabitants of this community. The company's specialists presented to all the participants how Antibiotice protects the environment. They had the opportunity to learn about the investments exceeding 5 million EUR made in the latest years in modern manufacturing technologies to protect the environment:

- > **Wastewater Treatment Plant** that transforms technologically wastewater from production areas into pre-cleaned, odorless, environmentally friendly water that is then transported to the city's wastewater treatment plant;
- > **Waste Incineration Plant** which stores, recycles and incinerate the waste resulting from the company's activity with minimal impact on the environment.

Through such actions, Antibiotice aims to convey to the community, through the power of example, responsibility for the environment.

## Social matters

Antibiotice, through the "Science and Soul" Foundation engages itself in the community life by supporting disadvantaged groups through social programs, some of which have become traditional.

### "Be generous, Be Santa Claus!"

For the sixth consecutive year, the "Science and Soul" Foundation organized „Be generous, Be Santa Claus!" campaign in partnership with Pro Vita Department of the Mission Sector of the Archdiocese of Iași.

In the centennial year, the campaign was organized for a number of 100 children from families with reduced material opportunities living in rural areas from Iași and Botoșani Counties. The Antibiotice employees became true Santa's elves for these children, giving them the desired gifts, during a festivity organized within our company.





# 05

## Environment

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Through all its activities, our company seeks to protect the environment and its resources and promote responsible behavior towards them.

The development of the community in the vicinity of Antibiotice, the effects of some phenomena such as global warming and our concern for reducing the consumption of energy resources are just as many reasons why protecting the environment is among the priority concerns of our company, beyond the legal obligations.

This chapter includes information about the two areas identified by our stakeholders as relevant for assessing the impact of our company on the environment, as well as for understanding the approach and the way of tracking in time:

- 1 Effective use of resources (water, energy)**
- 2 Waste management**

Because the environmental issues continuously concern us, for a better understanding of the activities to be optimized in order to reduce the impact level, we decided to include emission information in this chapter as well.

Antibiotice has the following environmental regulatory documents:

- **Integrated Environmental Authorization no.1/10.01.2011 (valid until 2021)** for our main activity "manufacture of basic pharmaceutical products", as well as other secondary activities, issued by the Environmental Protection Agency (APM) Bacău, revised in March 2018 by APM Iași;
- **Water management authorization no. 303/20.12.2010 (valid until 2020)**, issued by ANAR ABA Prut Bârlad.

We obtained also the certificate attesting the compliance of the Environment Management System with the requirements of ISO 14001:2015 standard (recertification) as part of the Integrated Management System implemented, maintained and continuously improved since 2007.



# Energy

**26**  
newly  
purchased  
Euro 6  
cars



**46,7%**  
from the  
electricity  
consumed  
comes from  
renewable  
sources

52



**9%**  
reducerea  
consumului  
de  
combustibili

In 2018, the total amount of energy consumed, consisting of electricity, natural gas and fuel, was **259 Tj**.

The amount of energy from conventional (non-renewable) sources consumed by Antibiotice SA in 2018 was **234 Tj**, divided as follows:

- **28 Tj** conventional power (suppliers of utilities)
- **187 Tj** natural gases (suppliers of utilities)
- **19 Tj** fuels

Compared to 2017, there were no significant deviations of the consumption of electricity and natural gas (28 Tj and 183 Tj respectively). Our company reduced the fuel consumption by about 9% (from 21 Tj in 2017).

This reduction is mainly due to the acquisition of 5 new cars through the 2017-2019 Car Park Renewal Program, funded by the Environment Fund. The new vehicles are equipped with Euro 6 system.

Energy from renewable sources, used in 2018, totaled 25 Tj, higher by 1 Tj compared to the value recorded in 2017, which shows the tendency to reduce the impact on environment due to the resource consumption.

In 2018, the percentage of energy consumed from renewable sources increased, related to the total value of energy used by the company - 10.68% in 2018 compared to 10.34% in 2017.

## Total electricity consumption (Tj) from conventional (non-renewable) and renewable sources, 2017 versus 2018

	2017	2018
Total electricity consumption (Tj), of which:	52	53
➤ from renewable sources	24	25
➤ from non-renewable sources	28	28
➤ electricity from renewable sources (%)	45.19	46.67

## Fuel consumption (Tj), from conventional (non-renewable) sources, 2017 versus 2018

Energy, by types of fuel (Tj)	2017	2018
Diesel fuel	19.258	18.024
Gaz fuel	0.915	0.565
Total	21	19

## Natural gas consumption (Tj), from conventional (non-renewable) sources, 2017 versus 2018

Natural gas consumption	2017		2018	
	Nmc	Energy, Tj	Nmc	Energy, Tj
Total per year	4,696,000	183	4,864,000	187

As regards the volume of electricity, heat and steam consumed, produced and / or recovered in 2018, it consisted of:

- consumed electricity = 53 Tj
- produced/consumed steam = 28,100 Gcal

The quantities of energy were calculated based on the records and information received from the utility and fuel providers, using the calorific power, but also the agreed conversion factors for energy units, according to the specialized literature.

The values used for the calculation of energy consumption can be found for checking, as follows:

- PCS (higher calorific value of natural gas), with the average value calculated for the 2018 - 38.53 GJ/Nmc, according to the information specified in the invoices received from the utility provider;
- PCN (calorific power of fuels), i.e. 42.63 GJ/ton for diesel fuel and 43.51 GJ/ton for gas fuel, according to: [http://www.mmediu.ro/app/webroot/uploads/files/2014-03-18\\_Lista\\_valorilor\\_nationale\\_FE\\_PCN-2014.pdf](http://www.mmediu.ro/app/webroot/uploads/files/2014-03-18_Lista_valorilor_nationale_FE_PCN-2014.pdf)

### Energy consumption, 2017 versus 2018 (electricity, fuels, natural gas)

	2017	2018	Comments
<b>Total energy consumed (Tj), of which:</b>	256	259	a 1% increase in 2018, correlated with an increased production
<b>Total electricity (Tj), of which:</b>	52	53	the same value with the value recorded in 2017
> from renewable sources, (Tj)	24	25	slight growth, by 2%
> electricity from renewable sources, (%)	45.19	46.67	a 3% increase as a result of increasing the percentage out of total energy, according to the energy label
<b>fuel (Tj)</b>	21	19	a 9% decrease in consumption as a result of renewing of the car park and applying the measures for a more efficient transport
<b>natural gas (Tj)</b>	183	187	a 2% increase as a result of increased production

- the energy label for 2018, made available by the electricity supplier, <https://www.enel.ro/content/dam/enel-ro/informatii-utile/reglementari/Ethicheta/ethichetaeem/Report/2018/Eticheta%20CPC%20Enel%20Energie%20Muntania%202018.pdf>

**Energy intensity**, expressed in Tj/thousand lei commodity production, decreased in 2018 by approximately 7% compared to 2017. This decrease is the result of monitoring the energy consumption, using efficiently of energy, as well as adopting lower energy technical solutions (new manufacturing equipment).

### Intelligent Energy Monitoring System

In order to make use energy more efficiently and reduce the CO<sub>2</sub> footprint, in 2018, our company implemented the project Monitoring energy consumption in industrial consumers, co-financed from European funds through the Large Infrastructure Operational Program 2014–2020.

Initiated in 2017, the project involved the implementation of a smart metering system to reduce the energy used (electricity and natural gas), corresponding to the reduction of the energy intensity (kgep/1000 euros), by 1% on average, in the next five years after implementation. This will also result in a 662.45 ton reduction of CO<sub>2</sub> emissions in the within this 5-year period.

### Total energy consumption (Tj), 2017 versus 2018 (electricity + natural gas + fuel)

	2017	2018
<b>Total per year (Tj)</b>	256	259
<b>Production value (thd LEI)</b>	337,000	365,000
<b>Energy intensity (depending on the value of the production), Tj/thousand lei commodity production</b>	76	0,71

Specifically, the project consisted of installing 160 meters, linked by fiber optics to a central computer, for measuring and monitoring the consumption of electricity, natural gas and compressed air.

The detailed monitoring of the existing consumption and the strategies for streamlining the energy consumption, natural gas and compressed air will lead to the expected reduction.

The project had a total value of 238,000 EUR, of which 84% were European non-reimbursable funds.



Within a 5-year period, the intelligent monitoring system will result in a **reduction of 662.45 tonnes** of CO<sub>2</sub> emissions.

# Water

The total volume of water captured or consumed in 2018, registered by measuring equipment, was 141,900 cm, down by 11% compared to 2017 (158,200 mc).

The decrease in water consumption was due to the efficient use of the resources, permanent monitoring of the consumption, correlated with the reduction of the losses.

The entire quantity was supplied by the municipal network through the operator Apa Vital SA Iași.

Total volume of effluents recorded in 2018 was 208,400 cm (up from the previous year, when the total volume recorded was 121,150 mc), as a result of increasing the precipitation quantities, as follows:

- 123,000 cm in the sewerage network from our own wastewater pre-treatment plant
- 85,400 cm in the emissary

The flows were measured by the measuring equipment, and the registrations are based on the minutes concluded with the authorized operator.

The quality of waste water (pre-treated in our own wastewater treatment plant, in operation since 2006) and discharged into the sewerage network, as well as the quality the rainwater discharged into the emissary falls within the parameters established by the environmental legislation.

Antibiotice SA determines the quality indicators for water discharged through its own laboratory, as well as through third-party laboratories, accredited by RENAR.

The quantities of pollutants from the pre-treated wastewater are determined by the mass flow method (calculation based on the values determined through laboratory analyses).

The condensate resulting from the steam production and distribution facilities is recovered and re-introduced into the water circuit for supplying the steam boilers. In 2018, the quantities measured with specialized equipment and verified in the internal metrology laboratory were 1,102 cm condensate from the steam for heating and 4,476 cm from the steam for preheating.



## Water

	2017	2018	Comparison
Water consumption (cm)	158,200	141,900	about 11% decrease
Specific water consumption (cm/thousand commodity production)	0.47	0.39	a 17% decrease



# Waste



Total weight of (hazardous and non-hazardous) waste recorded in 2018 by Antibiotice Iași was 738.46 tons. Of this quantity, hazardous waste weighing 16.86 tons (2.28%), was disposed of by incineration. As regards the non-hazardous waste, weighing 721.6 tons, a part of this quantity (96 tons, representing 13.3 %, was sold (including the related energy). Another part (26.2 tons) was incinerated in our own incineration plant while 220.8 tons were transferred to the municipal waste landfill and 499 tons were stored on our site.

Waste	2017	2018	Comparison
Amount of generated waste (tons), of which:	1900	738.46	60% decrease
> hazardous (tons)	18	16.86	6% decrease
> non-hazardous (tons)	1882	721.6	62% decrease

The amounts of waste recovered/eliminated by different methods in 2018 versus 2017, are presented in the table below:

Waste categories and methods of recovery/elimination	2017		2018	
	Amount of hazardous waste (tons)	Amount of non-hazardous waste (tons)	Amount of hazardous waste (tons)	Amount of non-hazardous waste (tons)
Sold (including the energy recovery)	-	1156	-	96
Incineration	18	30	16.6	26.2
Storage at the municipal landfill	-	192	-	220.8
Storage on the company's site	-	514	-	499

55

With regard to packaging waste, of the total quantity of packaging placed in the market (998 tons), 56.9 % of them were recycled and 3.1 % were sold. This way, Antibiotice met the legal 60% recycling/recovery target of the total packaging placed in the market (according to Law 249/2015 on management of packaging and packaging generated waste).

In 2018 also, Antibiotice S.A. concluded a service contract with an Authorized Responsibility Transfer Organization to take over the responsibility of achieving the annual objectives regarding the recycling/recovery of packaging waste.

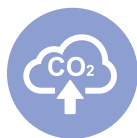
Our company did not record outstanding payments to the Environmental Fund Administration in the reporting year.

Packaging	2017	2018	Comparație
Packaging placed in the market (tons), of which:	950	998	slight growth, by 5%, due to an increased production
> recycled/sold, (tons)	570	597	slight growth, by 5%
> recycled/sold, %	60%	60%	the percentage was maintained - the legal objective was 100% achieved



**60%** of the total packaging placed in the market were **recycled**

## Emissions



The total amount of greenhouse gas emissions calculated for the entire company for 2018 was 14,376 tons of CO<sub>2</sub> equivalents, from the following sources: energy 3,608 tons of CO<sub>2</sub> equivalents), natural gases (9,397 tons of CO<sub>2</sub> equivalents) and fuels (1390 tons of CO<sub>2</sub> equivalents).

The amount was by 8%, higher than the previous year compared to 2017 (13,322 tons of CO<sub>2</sub> equivalents from the following sources: energy (4,060 tons of CO<sub>2</sub> equivalents), natural gases (9,054 tons of CO<sub>2</sub> equivalents) and fuels (208 tons of CO<sub>2</sub> equivalents).

The intensity of greenhouse gas emissions in 2018, in the amount of 0.0394 tons equivalent CO<sub>2</sub>/thousand LEI commodity production was maintained at about the same level compared to 2017, when the value was 0.0395 tons equivalent CO<sub>2</sub>/thousand LEI commodity production, even in the conditions of an increased production.

CO<sub>2</sub> emission values for 2018, compared to 2017, are presented in the following table:

CO <sub>2</sub> emission	2017	2018
Purpose 1 (direct emissions from combustion of fuels and natural gas), (t CO <sub>2</sub> )	9,262	10,768
Purpose 2 (indirect emissions from using electricity from suppliers), (t CO <sub>2</sub> )	4,060	3,608
Total per year (t CO <sub>2</sub> )	13,322	14,376
Production value ( thousand LEI)	337,000	365,000
Intensity of CO <sub>2</sub> emission (depending on the value of production), t CO <sub>2</sub> /thousand LEI commodity production	0.0395	0.0394

The values used for calculating the emissions, according to the standard methodology provided by Regulation EC 601/2012 on monitoring and reporting the greenhouse gas emissions, in accordance with Directive 2003/87 / EC (calculation made by multiplying the activity data, corresponding to the fuel category used, based on the net calorific value, with the corresponding emission factors, according to the IPPC Guidelines, 2006), can be found for checking, as follows:

- > PCS (higher calorific power of natural gas), with the average value calculated for 2018 - 38.53 GJ/Nmc, according to the information specified in the invoices received from the utility supplier;
- > The value of the emission factor for natural gas is in accordance with the energy label for 2018, issued by the utility supplier:  
<https://www.enel.ro/content/dam/enel-ro/informatii-utile/reglementari/Ethicheta/ethichetaeem/Report/2018/Eticheta%20CPC%20Enel%20Energie%20Muntenia%202018.pdf>
- > PCN (putere calorică a combustibililor), respectiv 42,63 GJ/tonă pentru motorină, precum și 43,51 GJ/tonă pentru benzină, precum și factorii de emisie pentru calculul cantităților emise de CO<sub>2</sub> sunt corespunzător Anexei VI, din Regulamentul EC nr. 601/2012 privind monitorizarea și raportarea emisiilor de gaze cu efect de seră, în conformitate cu Directiva 2003/87/CE: [http://mmediu.ro/new/wp-content/uploads/2014/04/2014-04-30\\_Regulament601-2012monitorizare\\_raportare.pdf](http://mmediu.ro/new/wp-content/uploads/2014/04/2014-04-30_Regulament601-2012monitorizare_raportare.pdf)

Antibiotice SA urmărește cu atenție calitatea aerului în perimetrul companiei atât prin determinări efectuate în cadrul laboratorului propriu, dar și colaborând în acest sens cu un laborator terț acreditat RENAR.



Sursele de emisii în aer sunt următoarele:

- evacuări dirijate din secțiile de producție (ventilație, echipamente de reținere noxe),
- ardere combustibil gaze natural în centrala termică proprie,
- incinerare deșeuri nepericuloase și periculoase proprii în instalația de incinerare,
- activitate de transport (flotă auto).

Buletinele de analize au relevat în mod constant respectarea condițiilor stabilite prin actele de reglementare deținute, precum și a cerințelor legale aplicabile activității desfășurate, în vigoare. Din acest punct de vedere, se constată cu satisfacție că în anul 2018 nu au fost înregistrate incidente privind emisii necontrolate de poluanți în aer.

Antibiotice SA a manifestat constant o preocupare privind respectarea cerințelor legale referitoare la protecția mediului, concomitent cu implementarea, menținerea și îmbunătățirea unui sistem de management de mediu eficace.

Aspectele de mediu, precum și riscurile asociate sunt identificate și evaluate periodic, fiind monitorizate permanent măsurile stabilite pentru menținerea sub control sau reducerea impactului negativ asupra mediului, rezultat din activitatea noastră.

Rezultatele adoptării voluntare a unui Sistem de Management de Mediu, parte a Sistemului de Management integrat, corelate cu acțiunile desfășurate în domeniul protecției mediului, se concretizează în absența de sancțiuni pentru nerespectarea legislației de mediu. Acest fapt reconfirmă grija și eforturile companiei pentru diminuarea impactului asupra mediului înconjurător.

**0 sancțiuni**  
pentru  
nerespectarea  
legislației  
de mediu.



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