



NON-FINANCIAL REPORT



2017

Together for
a better life



Antibiotice **at**
Science and soul

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About this report

This is the first non-financial report prepared by the Antibiotice's management team.

As per the legislation in force we will publish such a document each year, hoping that at some point, we will be able to put together the financial and non-financial data in one single document.

The current report includes information about our activity to the headquarter-

ters, located in Iași but also data revealing our economic, social and environment performance as well as our activity's impact in the domestic and international markets where we operate.

Although, the legislation stipulates the publication of the non-financial data for 2017, we considered that our stakeholders's interest is to have access to 2016 comparative data, to keep track of evolution on the levels of interest.

Purpose

The purpose of this report is to meet the provisions of the OMPF no. 1938/2016 according to which " entities of a public interest that exceed the criterion of an average number of 500 employees during the financial exercise, as of the balance sheet date, shall include a non-financial statement in their administrators' report, that

contains, provided that it is required to understand the development, performance and position of the entity and the impact of its activity, information regarding at least the environmental, social and staff-related issues, respect for human rights, fight against corruption and bribery."

Reporting period

This document contains information for the financial year 2017 (January 1 – December 31, 2017). Where we deemed necessary, we also included information about the financial year 2016 (January 1 – December 31, 2016).

Acknowledgement

The Antibiotice's management team wants to thank all the people inside and outside the company who contributed to this approach. Our effort would not have been as successful without their substantial contribution. We also thank all our employees involved with science and soul in the production of medicinal products.

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

Foreword



Ioan Nani
Antibiotice's Chief Executive Officer

We are honoured to submit you the first non-financial report of Antibiotice S.A., the most important Romanian manufacturer of generic medicines.

As many of you know, our company is a trustworthy partner of the health system in Romania. We have been operating for six decades and we continue to develop our business, permanently focused towards accesible, therapeutically valuable medicines. Meeting the highest GMP and FDA standards, our products cover a wide range of therapeutic areas and our infective medicines that made us well-known are available in all the hospitals in Romania.

Thanks to our team's professionalism and passion, the Antibiotice brand has been experiencing a steady international expansion in recent years. We proved that, meeting rigorously the international quality standards, a Romanian brand can reach the worldwide performance. We are proud that the medicines manufactured in the city of Iași - Romania reach many countries of the world and, more than that, we are proud that a product manufactured on our site is the worlwide leader.

By our own mission, we make our

valuable medicines more accessible to patients, physicians and pharmacists. The 150 medicines from our portfolio are delivered both in the domestic market and in 75 markets worldwide.

Worthy to emphasize is also that our portfolio ensures a number of medicines considered essential according to the World Health Organization Model List of Essential Medicines, medicines deemed essential for addressing the most important public health needs globally.

Our success is due to the dedicated team of specialists which are loyal to our mission and values, permanently open to knowledge and quality-focused performance. This is, in fact, the most important ingredient of our success - the quality of people and processes - all of these leading to our high-quality products.

A variety of highly qualified specialists work within our company from physicians, pharmacists, engineers, biologists to chemist operators and technicians. They are distributed in all our departments in a balanced manner by age, gender and education level.

On the other hand it is worth noting that, we have not been exempted from

the challenges all the pharmaceutical companies face in the complex context of the nowadays world.

Like our partners, health professionals and last but not least our end-beneficiaries - the patients, we have been going through a period of profound changes.

In this general ever-changing climate, we consider that our responsibility is even greater. For this reason, we are decided to respond promptly and professionally to the our stakeholders' requirements and expectations.

Sustainability is an important pillar in our strategy and operating mode, so we are constantly preoccupied as the impact of our activity on our employees, patients, community, enviroment to be an extremely positive one.

To us, sustainability in business also means ethics and transparency in the relationship with all our company's stakeholders. We want to continuously develop our business, keep in line with the latest trends, be a highly profitable company. We aim to improve performance and offer sustainable solutions, starting with the diversity of the offered therapeutic options.

By preparing this first non-financial report we highlighted another key dimension of the performance - the social one, the value created for our people and community which blends harmoniously with the financial one.

We hope each of you will find in the pages below clear evidence that the principles guiding us are fundamentally focused on the well being of those affected by our activities.

The willpower of Antibiotice team to give people a healthier and better life remains just as strong as always.

We therefore invite you to discover in this report the most significant actions and measures adopted and implemented by Antibiotice SA in 2017 with a direct economic, social and environmental impact. We are convinced that you will find known and less known aspects, reflecting the importance we give to the beneficiaries' satisfaction, our employees' health and safety, care for our community, concern for our environment in which we have been operating since 1955.

On behalf of the whole Antibiotice team, I strongly affirm that my conviction that, through everything we do now, our organization will continue creating value, an investment for a better future. Like always we will go ahead with our partners whom I thank them once again for their trust.

2017 results

Economic matters

337.6 million lei net turnover

35.3 million lei gross profit

74.4 million lei contributions to the consolidated state budget and local budget

1,420 average number of employees Zero incidents of corruption

Social matters 45% acquisitions from suppliers in Romania

83.4% of our employees are union members

54.8% of our employees are women

Half of our company's management team is made up of women

36.3 – the average number of training hours per employee

Zero products on the FDA's and EMA's alert list

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

Environmental matters

60% - recycling / recovery rate for packaging waste

Zero environmental incidents

About Antibiotice

Antibiotice
at



Brief presentation

Antibiotice SA, the most important Romanian producer of generic medicines was established in 1955. With its eight distinct manufacturing sites, our company has the most complex manufacturing structure among the pharmaceutical companies in Romania. 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.

With a tradition of over 60 years and a portfolio that currently exceeds 150 products, our company has gained its reputation by relying on performance through quality. Firstly substantiated through the therapeutic value of the medicines offered, quality is an attribute embedded in our organization's DNA, being also reflected in its processes and people. All of these highlight the company's orientation towards sustainable development.

With science and soul, Antibiotice team has managed to make valuable medicines accessible not only in the Romanian market, but also in other 75 countries worldwide. Moreover, the active substance Nystatin manufactured in Iași – the only pharmaceutical product obtained by biosynthesis - has turned the company into the world leader in this

segment. Nystatin manufactured by Antibiotice has become the international reference standard, meeting the highest quality standards. Beyond the global recognition, the Antibiotice brand remains firmly committed to its mission of providing a better health and life to the people.

As a manufacturer of generic anti-infectives used in the hospitals from all over Romania, as well as other valuable products from 12 therapeutic classes, Antibiotice is a Romanian reference brand in the pharmaceutical industry and an important contributor for the health-care system in Romania.

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. All of them, specialists experienced in specific areas such as medicine research, quality assurance and control, production and marketing contribute together to the total value created by our company.

Our history is widely presented on the company's website and can be accessed [here](#).



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. Moreover, our company has been 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.



Corporate governance

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

Corporate governance represents the premise of transparency on the company's activities, aiming to protect our social partners' interests while the guarantee of achieving the objectives is ensured through the control system efficiently

implemented within our company.

In 2017 we proved consistency as regards the followed strategic directions, accompanied by appropriate investment programs. This was done by applying the principles of good corporate governance, which enabled the mobilization of the full potential of our employees to implement and maintain high standards in all the company's activities.

Our company's governance system is based on:

- Management Board
- Advisory Committees
- Executive Management
- Code of Ethics
- Corporate Governance Code
- Internal Audit, Managerial Control

Management Board

The Management Board's duties are described in the company's Articles of Association and in the relevant internal regulations available on the company's website, under the Corporate Governance section.

In 2017, the Management Board met in 11 sessions and adopted decisions that

allowed it to perform its duties in an effective and efficient manner.

The five members of the Management Board represent a guarantee for the effective ability to supervise, analyze and evaluate the activity of the directors as well as for the fair treatment of the shareholders.

Management Board of Antibiotice S.A. on December 31, 2017

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

Economist, Ioan Nani,
Vice President of the Management Board and Antibiotice's CEO

Physician, Adela-Petria Neagoe,
Member of the Management Board and representative of the Ministry of Health

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

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

Advisory Committees

The Advisory Committees conducted investigations, analyses and made recommendations for the Management Board in specific areas, submitting periodic reports on their activities.

In 2017, the specialized advisory committees had the following membership structure:
Audit Committee: Mr. Ionut Sebastian Iavor, Mr. Nicolae Stoian and Ms. Elena Calitoiu;
Nomination and Remuneration Committee: Ms. Elena Calitoiu and Ms. Adela-Petria Neagoe;
Trade Policy Committee: Mr. Ionut Sebastian Iavor and Mr. Nicolae Stoian.

Executive management

Antibiotice S.A. is represented by the Chief Executive Officer, according to the powers provided by law and company's Articles of Association. The Management Board represents the company in relation with the appointed directors.

The Antibiotice's executive management is ensured by ten directors, one of whom is the Chief Executive Officer who is also the Vice President of the Board and nine specialty executives.

Antibiotice's Executive Management on December 31, 2017

Economist, Ioan Nani
Chief Executive Officer and Vice President of the Management Board

Engineer, Cornelia Moraru
Technical & Production Director

Economist, Paula Luminița Coman
Financial Director

Economist, Vasile Chebac
Commercial & Logistics Director

Engineer, Eugen Florin Osadeț
Engineering & Investment Director

Engineer, Cristina Lavinia Dimitriu
Quality Director

Economist, Gica Rusu
Human Resource Director

Economist Ovidiu Bățaș,
Marketing & Domestic Sales Director

Physician, Mihaela Moșneagu
Medical Director

Economist, Mihai Stoian
International Business Director

*Half of our company's management team
is made up of women*

Code of Ethics

Antibiotice's Code of Ethics sets out principles and rules designed to establish a honest professional conduct and create an organizational culture based on integrity standards, in line with the current legislation and corporate values.

The Code of Ethics also regulates the responsibilities and business obligations of the company's members and the company's operating procedures.

The fundamental ethical values assumed within the entire organization are:

Integrity
Professionalism
Responsibility
Transparency

The Code of Ethics is extensively presented on our company's website to the following [link](#).

Corporate Governance Code

The Corporate Governance Code of our company is divided into four chapters:

- Chapter I - Management Board's responsibilities
- Chapter II - Risk management & internal control system
- Chapter III - Fair reward and motivation
- Chapter IV - Investors relations

It also has two annexes:

- Annex I - Management Board's Rules of Procedure
- Annex II - Rules for evaluating the Antibiotice's administrators

Antibiotice's Corporate Governance Code and its annexes outline the general framework under which the Management Board operates, in accordance with the rules and principles of corporate governance established by the Bucharest Stock Exchange, based on best practices and principles of transparency and trust.

General Meeting of Shareholders

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



Economic performance

Our company's economic performance is the result of consistently applying the strategies included in the business plan. The main diagnostic indicators highlight the upward trend our company had in the period 2015-2017 as well as our management's concern for constantly streamlining our business and maintaining the financial balance. ([Financial results 2017](#))

Economic indicators	2015	2016	2017
Net turnover	331,740,206	334,990,734	337,629,448
Gross profit	32,047,535	34,881,646	35,361,430
Average number of employees	1,458	1,449	1420
Taxes and duties			
Taxes on income from wages (income tax, social security contribution, health insurance contribution, unemployment fund contribution)	29,681,315	29,965,651	34,169,838
Other taxes to the state budget (profit tax, value added tax, dividend tax)	12,293,372	15,448,356	9,241,601
Clawback tax	26,278,102	22,398,133	29,923,031
Local taxes and duties	1,062,156	1,072,087	1,106,741
Total	69,314,945	68,884,227	74,441,211

Lei

A quarter of our sales value (74.44 million LEI) is paid to the state budget as taxes and duties



Our products

For more than 6 decades we are the most important Romanian manufacturer of generic medicines which contributes to maintaining health and wellbeing of Romanians and people all over the world.

Investing in excellence, technology and human resources, we have met high internal and international standards certifying the safety, quality and efficiency of the 150 products from our portfolio.

Our constant preoccupation to meet the patients' needs has led to developing a complex and updated portfolio, fully adapted to the current global therapeutic trends. The portfolio consists of generic medicines for acute and chronic diseases, veterinary medicines, self-care products and products obtained by biosynthesis, Antibiotice being the world's number one manufacturer in the production of the active substance Nystatin.

Therapeutic classes in our portfolio:

antiinfectives of systemic use, including medicines intended for the treatment of tuberculosis;

cardiovascular medicines;

dermatological medicines;

medicines for *central nervous system* disorders;

products for *self-care products* (prophylaxis, adjuvants in certain diseases with increased incidence and for maintaining health) - in the category of dietary supplements, dermatocosmetics, medical devices and medicines without prescription (OTCs).

The anti-infectives portfolio, a reliable ally of doctors and patients for treating infections, from mild to the severe ones, is permanently supplemented with medicines for anti-infective therapies. These are community infections (respiratory, ENT, urogenital, digestive, skin and soft tissue infections), current infections and as well as resistant germ infections in the hospitalized patients.

The significant anti-infective medicines, some of which are nationally unique, are: Ampicilina Atb[®], Amoxicilina

Atb[®], Penicilina Atb[®], Amoxiplus[®] (amoxicillin/ clavulanic acid), Ampiplus[®] (ampicillin/sulbactam), Eficef[®] (cefixime), Cefort[®] (ceftriaxone), Colistina Atb[®], Meropenem Atb[®], Imipenem/Cilastatin Atb[®].

Our company supports the National Tuberculosis Control Programme by providing the necessary first and second-line anti-tuberculosis drugs.

The world's number one manufacturer in the production of the active substance Nystatin

According to the TB Situation Analysis - 2017 prepared by the National Institute of Public Health, tuberculosis in Romania is one of the priority public health issues. The major objective of the National Tuberculosis Control Strategy is to quickly stop the spread of infection among the population by diagnosing tuberculosis as promptly as possible to the symptomatic person until healing is complete.

In our portfolio, topical products cover an important segment, being represented by a varied range of pharmaceutical dosage forms: ointments, creams, gels, suppositories and pessaries. They address the treatment or prophylaxis of many diseases, the products belonging to the following therapeutic classes: anti-inflammatories, antifungals, vasoprotectives, corticosteroids for dermatological use, antibiotics, products for genitourinary disorders and, last but not least, cosmetics. We plan to expand this product segment whose value has been confirmed and maintain our leading position from quantitative viewpoint in the market of ointments and suppositories, all the more so as topical products treat at home diseases with major social impact (such as psoriasis), the patients being rapidly reintegrated into society.

Along with the traditional topical medicines - Nidoflor[®] cream (triamcinolone acetonide, neomycin, nystatin), Fluocinolon[®] N ointment (fluocinolone acetonide, neomycin sulphate), Clafen[®] gel, cream (diclofenac sodium), Hemorzon[®] suppositories, ointment (tetracycline, hydrocortisone acetate, benzocaine), glycerin suppositories (for adults and children), we have pessaries in the 2017 product range - Zifex[®] complex (nystatin, neomycin, metronidazole, hydrocortisone acetate), Zifex[®] duo (metronidazole, clotrimazole) and Nistatina Atb[®].

Antibiotice SA has also developed a complex portfolio of medicines which can provide the complete therapeutic regimen for the treatment of cardiovascular diseases. This portfolio addresses chronic cardiovascular disorders such as hypertension, angina pectoris, heart failure. Our cardiovascular portfolio provides the access of our patients to the main subclasses of medicines used in the cardiovascular therapy: beta - blockers (Bisotens[®] - bisoprolol, Nolet[®] - nebivolol), converting enzyme inhibitors (Lisinopril Atb[®], Ramipril Atb[®]), calcium channel blockers (Almacor[®] - amlodipine), statins (Rosuvastatina Atb[®]) and sartans Candesartan Atb[®].

150 products from 12 therapeutic areas

Complex anti-infective portfolio

Complete therapeutic regimen for cardiovascular diseases

Varied portfolio for topical treatment of dermatological and rheumatic diseases

Top 20 most recognized Antibiotic brands

The top 20 brands (by value of sales) marketed by Antibiotice in 2017 recorded sales amounting to RON 195.1 million.

Brand name	International common name	Therapeutic class + Method of administration	Main competitors
Amoxicilină® 250 mg and 500 mg	amoxicillinum	Anti-infective drugs for systemic use beta-lactam antibacterials, penicillin-capsules and injectables	Amoxicilină® (Novartis) Ospamox® (Novartis) Duomox® (Astellas Pharma)
Amoxiplus® 1.2 g and 875 / 125 mg	amoxicillinum + acidum clavulanicum	Anti-infective drugs for systemic use beta-lactam antibacterials, injectable penicillins and tablets	Augumentin® (GlaxoSmithKline) Amoksiklav® (Novartis)
Ampicilină® 250 mg, 500 mg and 1 g	ampicillinum	Anti-infective drugs for systemic use beta-lactam antibacterials, penicillin-capsules and injectables	Ampicilină® (Novartis) Pamecil® (Medochemie) Ampicilină® (Farmex Company)
Ampiplus® 1000 mg + 500 mg	ampicillinum + inhibitor de enzimă	Anti-infective drugs for systemic use beta-lactam antibacterials, injectable penicillins	Unique product
Cefort® 250 mg, 1 g and 2 g	ceftriaxonum	Anti-infective drugs for systemic use - other beta-lactam antibacterial injectables	Oframax® (Sun Pharma) Rocephin® (Hoffmann La Roche) Medaxone® (Medochemie)
Cefuroximă Antibiotice® 750 mg and 1.5 g	cefuroximum	Anti-infective drugs for systemic use Other antibacterial beta-lactam antibiotics for injection	Zinnat® (GlaxoSmithKline) Axetine® (Medochemie)
Gama Clafen® 10 mg/g, 50 mg/g, 100 mg	diclofenacum	Musculoskeletal system anti-inflammatory/non-steroidal antirheumatic ointment and suppositories	Diclac®/Voltaren® (Novartis) Diclofenac MK®/Diflex® (Fiterman)
Colistină Atb® 1.000.000 U.I.	colistini sulfas	Anti-infective drugs for systemic use -other antibacterial drugs - for injection	Unique product
Eficef® 100 mg and 200 mg	cefiximum	Anti-infective drugs for systemic use Other antibacterial beta-lactam antibiotics - capsules	Xifia® (Alkaloid AD)
Fluocinolon N® 18 g	fluocinoloni acetonidum + neomycinum	Dermatological preparations -corticosteroids in combination with antibiotics - ointment	Fluocinolon Acetonid® (Laropharm) Fluocinolon G MK® (Fiterman)
Fluxiv®	supliment alimentar	Cardiovascular system - Varicose therapy - tablets	Detralex® (Servier) Devaricid® (Biofarm) Endolex® (Sun Wave Pharma)
Hemorzon®	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system - topical antihemorrhoids - ointment and suppositories	Procto Glyvenol® (Recordati) Ultraproct® (Bayer) Proctolog® (Pfizer)
Meropenem Atb® 500 mg and 1 g	meropenemum	Anti-infective drugs for systemic use other antibacterial beta-lactam antibiotics - for injection	Meropenem Kabi (Fresenius) Loditer® (Sun Pharma) Meropenem Hospira (Hospira)
Nidoflor® 15 g	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatological preparations - corticosteroids in combination with antibiotics - ointments	Triderm® (Merck & Co)
Nolet® 5 mg	nebolololum	Cardiovascular system - beta blockers - tablets	Nebile® (Menarini) Nebivolol Actavis(Teva) Nebivolol Torrent (Torrent Pharma)
Oxacilină® 250 mg, 500 mg and 1 g	oxacillinum	Anti-infective drugs for systemic use beta-lactam antibacterials, penicillin - capsules and injectables	Oxacilină® (Novartis) Oxacilină® (Farmex Company)
Penicilina GK 1.000.000 U.I. Penicilina GNa 400.000 U.I. and 1.000.000 U.I.	benzylpenicillinum	Anti-infective drugs for systemic use beta-lactam antibacterials, penicillin - for injection	Produs unic
Ranitidină Atb® 150 mg	ranitidinum	Digestive tract and metabolism - anti-ulcerous drugs - tablets	Ranitidină (Laropharm) Ranitidină (Lab. Magistra) Ranitidina LPH (Alvogen)
Silithor®	supliment alimentar	Digestive tract and metabolism - hepatoprotective - capsules	Ranitidină (Laropharm) Ranitidină (Lab. Magistra) Ranitidina LPH (Alvogen)
Supozitoare Glicerină adulți Supozitoare Glicerină copii	glycerolum	Digestive tract and metabolism - laxative - suppository	4Lax® (Solacium Pharma) Supozitoare Glicerină® (Solacium Pharma)

Data source: CegeDim România 2017

The top of products for which Antibiotice is the only manufacturer

The products for which Antibiotice is the only producer on the market recorded sales of RON 103.6 million, up 9.8% compared to the previous year.

Brand name	International common name	Therapeutic class + Method of administration
Aceclofen® 500 mg/50 mg	diclofenacum + paracetamololum	Musculoskeletal system suppositories
Amoxiplus® 1000 mg/200 mg	amoxicillinum + acidum clavulanicum	Anti-infective drugs for systemic use Powder for injection
Ampiplus® 1000 mg/500 mg	ampicillinum + sulbactamum	Anti-infective drugs for systemic use Powder for injection
Clo-Ekarzin®	bethametasonum + clotrimazolum	Dermatological preparations Cream
Colistină Atb® 1.000.000 UI	sodium colistimethate	Anti-infective drugs for systemic use Powder for injection
Cutaden Bebe®	zinc oxide + titanium dioxide + ichthammol + Vital ET®	Dermatological preparations Emollient and protective cream
Cutaden®	ichthammol+hamamelis virginiana extract + sodium borate + zinc oxide + titanium dioxide	Dermatological preparations Emollient and protective cream
Fluocinolon N®	fluocinoloni acetonidum + neomycini sulfas	Dermatological preparations Ointment
Fluxiv®	diosminum + hesperidinum + troxerutin + acidum ascorbicum	Cardiovascular system - Food supplement playing a role in the normal functioning of blood vessels - Tablets
Hemorzon® unguent	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system - antihemorrhoidal for topical use - Ointment
Hemorzon® supozitoare	tetracyclinum + hydrocortisonum+ benzocainum	Cardiovascular system - antihemorrhoidal for topical use - suppositories
Hidrocortizon Atb® 10 mg/g	hydrocortisonum	Dermatological preparations Ointment
Lisinopril Atb® 40 mg	lisinoprilum	Cardiovascular system Tablets
Nidoflor®	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatological preparations Cream
Nistatină Atb® 500.000 UI	nystatinum	Intestinal anti-infective drugs Film-coated tablets
Nistatină Atb® ovule 100.000 UI	nystatinum	Gynecological anti-infective drugs pessaries
Oxacilină Atb® 500 mg și 1 g	oxacillinum	Anti-infective drugs for systemic use Powder for injection
Penicilină G potasică 1.000.000 UI și Penicilină G sodică 400.000 UI și 1.000.000 UI	benzylpenicillinum	Anti - infective drugs for systemic use Powder for injection
Piafen®	metamizolum natricum + pitofenonum + fempipramidum	Digestive tract and metabolism Tablets
Saliform Forte®	methylis salicylas + levomentholum	Musculoskeletal system Cream
Silithor®	silimarinum + L-methioninum + L-cisteinum	Digestive tract and metabolism - Hepatoprotective Food Supplement - capsules
Soriso®	rhodiola rosea + ocimum basilicum	Central Nervous System - adaptive food supplement - Film-coated tablets
Tetracilină Atb® 30 mg/g	tetracyclinum	Dermatological preparations ointments
Triamcinolon S Atb® 1 mg/30 mg/g	triamcinolonum + chlorquinaldolum	Dermatological preparations Cream
Zifex Complex® ovule	metronidazololum + nystatinum + neomycini sulfas + hydrocortisonum	Gynecological anti-infective drugs pessaries
Antituberculous drugs (Izoniazidă Atb® 100 mg and 300 mg, Pirazinamidă Atb® 500 mg, Cicloserină Atb® 250 mg, Sinerdol® (rifampicinum) 300 mg, Sinerdol® ISO (rifampicinum+izoniazidum))		

Data source: CegeDim România 2017



Domestic market

We are a Romanian company dedicated to our mission to produce quality, safe and effective medicines. Therefore, for 62 years, we have been a reliable partner for physicians and pharmacists.

We are very proud that, in over six decades of existence, generations of patients got cured using our medicines.

Antibiotice enriches the Romanian market with a 150-product portfolio, generic medicines with medical prescription and OTCs from 12 therapeutic areas. As per 2017 Cegedim Report, it ranks on top positions, in the following segments:

the main Romanian manufacturer of generic medicines

ranks fourth among the manufacturers of generic medicines with medical prescription in the national market

leader in terms of quantity in the ointment & suppository segment

leader in terms of value in the segment of anti-infective generics,

present in all the hospitals in Romania

One of our responsibilities, as an important manufacturer of anti-infectives, is to maintain the efficacy of antibiotics as high-valuable therapeutic options for infections but also as a prophylactic support in multiple modern treatment techniques.

For the trust that our patients and partners, physicians and pharmacists have given us, in the future we have the responsibility to offer new health alternatives, through a valuable portfolio.

In response to the new therapeutic trends, our company has been developing new generic medicines for treating diseases of the cardiovascular system, central nervous system, dermatological diseases, but also prophylactic and self-care products.

Antibiotice products reach the medical units and pharmacies via our reliable partners, national distributors.

to export our finished products through partnerships with our local distributors for a steadily increasing and sustainable evolution;

to develop new business models and partnerships in sound and highly regulated markets (out-licensing, co-development, contract manufacturing and co-marketing) designed to accelerate our international expansion;

to adapt our export portfolio to the specificities and needs of foreign markets;

to open representative offices in external markets with a high potential, evolving in an economically and socially stable environment, but also according to the compatibility with our product portfolio.

During the reporting period, our company adjusted its foreign expansion policies to the new health regulations, taking into account both the trends in health consumption but also the specificities of each market.

The US market is still the biggest and most valuable market for trading the FDA certified anti-infective products and the active substance Nystatin. As regards Nystatin, our product is the international reference standard, Antibiotice being the world leading manufacturer of this substance.

In the South-East Asia, Vietnam is the main market which is going to record annual increases in the next period. We also carefully analyze the potential for the development of our commercial relations with Philippines, Hong Kong and Taiwan.

At European level, the main markets are Germany, the Netherlands, Denmark and Serbia.

Our exports in Russia and CIS area have increased mainly due to cardiovasculars, suppositories as well as to the injectable anti-infectives (Ukraine).

The value of our exported products has steadily increased, accounting for one third of the company's turnover at the end of 2017.



External markets

In addition to the Romanian market, which is extremely significant for our company, the steady expansion of our brand and products in the international market represents one of the strategic medium and long-term development pillars.

From this perspective, we focus on the following directions:

to strengthen our position as a world leading manufacturer of the active substance Nystatin also by increasing the exports on regulated markets such as the United States of America;



Value chain

Our company's value reflected in products and economic performance is the result of the synergy between our human, technological and financial resources. We always seek to develop this knowledge capital and, with the passion that inspires us, we put it in the service of people to make their health and life better.

We have been constantly researching and developing new quality pharmaceutical products patients need, taking into consideration in which medical professionals the patients can trust. We use quality raw materials and materials purchased from prestigious manufacturers in Romania and abroad. Last but not least, we constantly pursue to streamline the packaging, storage and transport processes as a guarantee that the medicines we produce reach the end-users in the best possible conditions.

We are honoured to have strong partners and, together with them, we focus on developing sustainable partnerships, making our valuable medicines accessible to as many patients as possible. We are also preoccupied with identifying the elements that could slow processes on the value chain and acting in a timely manner so not only to reduce the risks but to visibly increase our business from year to year.

Procurement

Distribution





Licenses and certifications

We have as a benchmark an internal quality culture expressing our assumed responsibility for our employees' and consumers' health as well as for the environment.

In this respect, our company's processes are conducted according to the Integrated Management System (quality, environment, occupational health and safety). This framework governs all processes, from research & development, supply, production and control to the distribution of medicines to the end-user.

The Integrated Management System was certified in 2007 by Lloyd's Register Quality Assurance, the last recertification audit being conducted in 2017.

Our quality, environmental, occupational health and safety standards are strictly met through rigorous policies and procedures. These procedures are periodically revised and improved, in accordance with the specific EU-GMP and ISO requirements.



Pyramid structure of the Antibiotice's Quality Management System

Our quality, environmental, occupational health and safety policy can be accessed [here](#).

Antibiotice S.A. holds the following operating licenses and certifications for the products it manufactures and markets:

- **Manufacturing Authorization** No. 30F of 04.08.2017;
- **GMP certificate** No. 040/2017/RO of 11.08.2017 for medicines for human use (tablets, capsules, ointments, suppositories);
- **GMP certificate** No. 041/2017/RO of 11.08.2017 for human use investigational medicinal products (tablets, capsules, ointments, suppositories);
- **GMP certificate** No. 046/2016/RO of 16.12.2016 for medicines for human use - sterile products, powders for solutions/suspensions for injection;
- **GMP certificate** No. 043/2016/RO of 29.11.2016 for Nystatin - active substance;
- **US FDA Acceptance** of 02.06.2017;
- **GMP certificate** No. 44/2016/RO of 11.02.2016 for veterinary medicinal products;
- **GMP certificate** No. 49 of 05.07.2017 for the Bioanalytical Laboratory;
- **Authorization** to conduct clinical trials in the field of medicines No. 450/2016 of 15.07.2016;
- **Authorization** No. 8Fsp / 2017 of 03.02.2017 for the manufacture of preparations containing narcotic and psychotropic substances.
- **ISO 9001:2015 Certificate** No. 10049922 of 03.12.2017 (Quality Management System)
- **ISO 14001:2015 Certificate** No. 10049926 of 08.12.2017 (Environmental Management System)
- **OHSAS 18001:2007 Certificate** No. BUC0170534 of 03.12.2016 (Occupational Health and Safety Management System)

- **Certificate of conformity** No. 387 of 10.11.2017 for aluminium tubes for the packaging of ointments, creams and gels;

- **Certificate of conformity** No. 388 of 10.11.2017 for threaded caps and membrane penetration device used to close aluminum tubes for ointments, creams, gels;

- **Certificate of conformity** No. 389 of 10.11.2017 for the metal cap for closing the vials filled with antibiotic products.

The compliance with the Quality Management System norms - implemented according to EU GMP requirements - is internally monitored by the specialists within the responsible departments and externally, by our business partners (through periodic audits), National Agency for Medicines and Medical Devices (which also verifies and certifies the system), National Sanitary Veterinary and Food Safety Authority and other equivalent authorities in the countries where we have authorized the company's products.

The Quality Management System within Antibiotice S.A. complies also with the GMP requirements of US FDA (CFR 210&211 requirements), as certified by the letter of acceptance in 2017.

This recognition has increased the confidence of our international partners in the robustness and performance of our quality system, making possible a communication in a common language and our openness to the whole world.





Affiliations

Antibiotice SA is a WHO pre-qualified company, a reliable partner of the Ministry of Health in the National Tuberculosis Control Program for the range of essential antituberculosis drugs.

Our company is also an active member of the following organizations:

Industrial Medicine Producers' Employer Association of Romania (PRIMER)

Romanian Association of the Self-Care Industry (RASCI)

Romanian Organization for Serializing Medicines (OSMR)

Iași Chamber of Commerce and Industry

Chamber of Commerce and Industry of Romania

International Chamber of Commerce

National Association of Romanian Exporters and Importers (ANEIR)



Risk management

We are preoccupied with continually assessing the risks to which the company's activity may be exposed, affecting the achievement of its strategic and financial objectives.

Our risk management strategy aims to secure the medium- and long-term sustainability and achieve the indicators predicted under controlled risk conditions that ensure both continuity in the conduct of business as well as protection of the shareholders' and customers' interests.

The main risk categories identified by our specialists are:

Liquidity risk arises from the company's failure to honor, at any time, the short-term payment obligations.

Foreign exchange risk a component of the financial risk, occurs frequently in the current market economy where monetary rates fluctuate under the supply and demand rule.

Commercial (default) risk is the risk of incurring losses or not-reaching the estimated profits due to lack of financial liquidity of the debtor and the failure to pay upon maturity.

In addition, our specialists identified:

Legislative risk (generated by the legislative changes regarding the pharmaceutical market in Romania),

Image risk (potential negative impact on profit and capital as a result of the unfavorable perception over the company),

Out-of-control risks (natural disasters, economic instability, labour conflicts or conflicts outside our company).

The impacts of these risks have been assessed and, as far as possible, prevented. We detailed all the risks and related measures in the 2017 Management Report, which can be accessed [here](#).



Dialogue and consultation

Our company has initiated a dialogue and consultation process of the stakeholders, primarily for identifying the risks, opportunities and aspects that require increased attention from our company's management team and employees.

The above-mentioned process took place in the first part of 2018 through a comprehensive methodological approach (one-to-one interviews in Iași and Bucharest, an extended meeting organized at the company headquarters in Iași and an online questionnaire), with the following objectives:

identifying the stakeholders' needs and expectations about the economic, social and environmental impacts generated by the Antibiotice's activity;

identifying potential risks and opportunities.

Previously, more precisely during 2017 and in the first months of 2018, such meetings were held at our company headquarters in Iași, both with the management team and with the project team. The aim was to ensure that all data providers and those who have the legal responsibility for their fair reporting have a common understanding of the role and importance of non-financial reporting.

The consultation process referred to the AccountAbility AA1000 SES standard and GRI 101 standard of Global Reporting Initiative.

Thus, for identifying the stakeholder groups to be consulted, the characteristics recommended in the AA1000 SES standard were taken into account, namely:

*legal, commercial, operational or **ethical role and responsibility** of our company in relation to that stakeholder group;*

***influence** of Antibiotice's business on the stakeholder group (or one single stakeholder) or of the stakeholder group's activity on the Antibiotice's business respectively;*

***representativeness** of the stakeholder group/ a particular stakeholder;*

***diversity of opinions**, that provide a broader and balanced image and a better understanding of the context in which our company conducts its business.*

The proposals regarding the stakeholders prior to initiating the consultative process included the following

***internal:** managers (quality, marketing, human resources, economic, medical, CSR, the Antibiotice Union and Foudation "Antibiotice - Science and soul");*

***external:** local authorities, academic environment, regulation bodies (The Environmental Agency, Environmental Guard, Ministry of Health, Territorial Labour Inspectorate), business partners, NNOs*

Finally, we filled out a list containing 37 people representative for all the initial proposals.

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 Antibiotice's business, there were analyzed the topics included by the operators representative in the pharmaceutical industry in Romania, a series of international standards and European and local legislation on non-financial reporting.

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

The stakeholders evaluated the preliminary topics, appraising the relevance of each of them for Antibiotice SA in the context of the non-financial reporting legislation, potential risks and opportunities.



Methodology used in the reporting process

Antibiotice S.A. decided to use its own system for the 2017 non-financial reporting process, having as main reference the Global Reporting Initiative (GRI) Standards for Sustainability Reporting.

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 Organization(GRI) recommends companies which prepare sustainability (or non-financial) reports to observe a set of ten principles in the reporting process: four of them addressing the process

itself (stakeholder inclusion, sustainability context, materiality and conclusiveness) and six referring to the quality of the information to be included in the report (accuracy, balance, clarity, comparability, fairness 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 in the Romanian market were studied, these being found either in the annual non-financial reports or in the strategies of the companies in question.

Thus, the following topics for the pharmaceutical industry in Romania emerged as important:

- Effective use of resources (water, energy) + Waste (environment)*
- Employees + Occupational safety and security (social)*
- Transparency (including through the non-financial reporting) (economic)*
- Anti-corruption measures (economic)*
- Relationship between management and employees (social)*
- Marketing policy + Safety of clinical trial participants (social)*
- Access to medicines (those on the list of pre-qualified WHO medicines aiming at the public health) (social)*
- Tariff policy (economic)*
- Safety of medicines and adverse effects (social)*
- Professional training (social)*
- Supporting local community development (social)*
- Procurement practices (economic)*

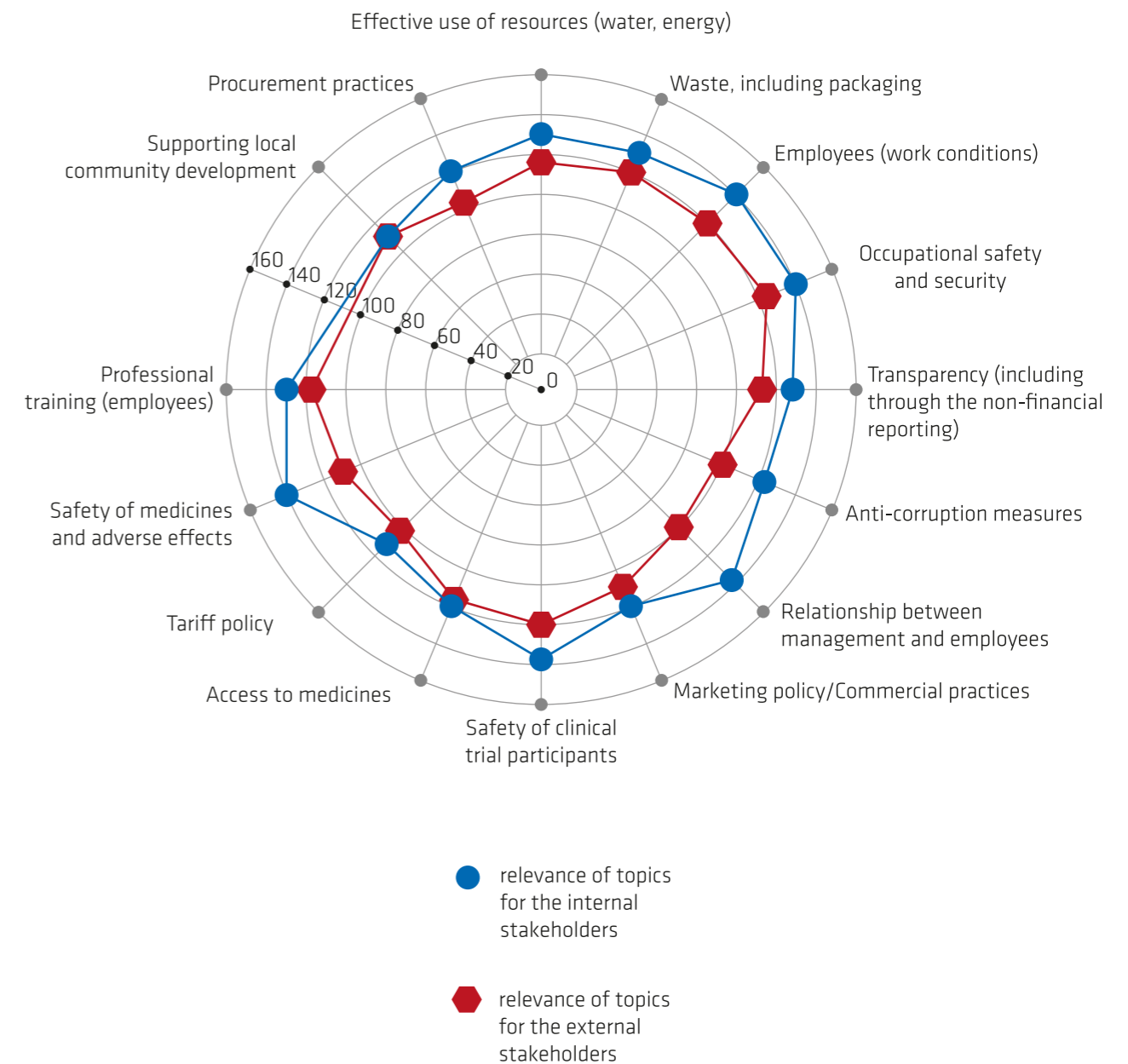
Secondary topics

Secondarily, a number of topics were identified that were subject to the attention of the stakeholders consulted by Antibiotice Iași in a consultative meeting organized at our headquarters, this being also part of the 2017 non-financial reporting process:

- Reduction of CO2 emissions (environment)*
- Research & Development (economic)*
- Private-public partnerships for improving the access to health services (social)*
- Promoting a healthy lifestyle (social)*
- Combating counterfeit medicines (social)*

Materiality matrix

The preliminary topics were evaluated by stakeholders, who appraised the relevance of each of them for Antibiotice Iași in the context of the non-financial reporting legislation. The result is presented in the materiality matrix (the figure below) in which the blue line represents the relevance scale for the internal stakeholders and the red line represents the relevance scale for the external stakeholders.



Based on the above results, the management team decided to respond to stakeholders' expectations and to include in this report relevant information from relevant topics for the pharmaceutical industry in Romania.

As to the secondary list of topics, this will be considered for both risk monitoring activity and for further policy development and information disclosure to the extent that the impact of these themes becomes significant.

This chapter includes information about the four areas identified by the stakeholders as relevant to understanding both policies and procedures in the market and within Antibiotice SA and how we approach and follow them over time.

Transparency (including through the non-financial reporting)

Anti-corruption measures

Tariff policy

Procurement practices



Transparency

Practice in the field of transparency is strongly imprinted in our activity, the first steps towards this direction being made since 1997, when our company started to be listed on the Stock Exchange Bucharest, which meant that our economic activity has become transparent, increasing our business attractiveness for investors.

By preparing our first non-financial report, we take another step towards assuming the transparency principles.

The legal support for the principles on the transparency of the company's activity is represented by:

- Law no. 297/2004 amended and completed by the provisions of the Law no. 10/2015 and GEO 90/2014, CNVM regulations for applying it;

- Regulation of the Financial Supervisory Authority no. 6/2014 for amending and completing the Regulation of the National Commission of Securities no. 1/2006 concerning issuers and securities transactions as well as for completing the Regulation of the National Commission of Securities no. 6/2009 on exercising certain rights of shareholders in general meetings of the trading companies.

In accordance with the regulations in force, in 2017 Antibiotice SA sent to the Bucharest Stock Exchange (BVB) and Financial Supervisory Authority (ASF) the following documents in Romanian and English:

Date	Document (In Romanian and English)	Institutions to which the documents were sent
30.01.2017	2017 Financial Calendar	BVB, ASF, Antibiotice website
15.02.2017	2016 Preliminary financial results	BVB, ASF, Antibiotice website
03.03.2017	Convening of Ordinary and Extraordinary GMS - 06/07.04.2017	BVB, ASF, Atb website Official Gazette, Evenimentul Newspaper
06.03.2017	Dividend proposals for the financial year 2016	BVB, ASF, Antibiotice website
06.04.2017	Decisions Ordinary and Extraordinary GMS - 06.04.2014	BVB, ASF, Antibiotice website, RoCoApp Central Depository, Evenimentul Newspaper
06.04.2017	2016 Annual Report (annual financial results)	BVB, ASF, Antibiotice website
15.05.2017	Q1 2017 Financial results	BVB, ASF, Antibiotice website Bursa Newspaper
25.05.2017	Current report on provisions of GEO 29/2017	BVB, ASF, Antibiotice website
25.05.2017	OGMS convener - 28/29.06.2017	BVB, ASF, Atb website, Official Gazette, Evenimentul Newspaper
28.06.2017	Ordinary and Extraordinary GMS Decisions - 28.06.2017	BVB, ASF, Antibiotice website, Evenimentul Newspaper
14.08.2017	OGMS convener 20/21.09.2017	BVB, ASF, Antibiotice website, RoCoApp Central Depository, Evenimentul Newspaper
14.08.2017	Current report- conclusion of the Auditor's Report, application of GEO - 29/2017	BVB, ASF, Antibiotice website
16.08.2017	H1 2017 Financial results	BVB, ASF, Antibiotice website, Bursa Newspaper
12.09.2017	Payment of dividends for 2016	BVB, ASF, RoCoApp Central Depository, Antibiotice website
20.09.2017	OGMS Decisions - 20.09.2017	BVB, ASF, Antibiotice website, Evenimentul Newspaper
22.09.2017	Current report -Antibiotice Iași imposes the quality standard for Nystatin	BVB, ASF, Antibiotice website
16.10.2017	Stopping the payment of dividends 2013	BVB, ASF, Antibiotice website
15.11.2017	3Q 2018 Financial results	BVB, ASF, Antibiotice website, Bursa Newspaper

General Meetings are mandatory to be convened twice a year (half-yearly and annually), according to the Financial Calendar or whenever necessary.

In addition, on 23.02.2017, in accordance with the Law 227/2015 on the Fiscal Code and Fiscal Procedure Code, the 205 Form, an informative statement for 2016 regarding the income tax withheld and earnings/losses realised by each beneficiary was sent to the Ministry of Public Finances.



Anti-corruption measures

The National Anticorruption Strategy (SNA) 2016-2020, adopted by the Romanian Government by Decision no. 583/2016, proposes a change of vision on corruption, focusing on prevention measures and education in order to prevent the corruption acts.

According to the SNA 2016-2020, each manager of a public enterprise must assume his/her responsibility for applying certain internal standards designed to prevent corruption.

In this context, taking into consideration that Antibiotice S.A. – according to the provisions of article 2 from GEO 109/2011 on corporate governance of public enterprises – makes part of this category, in correlation with the fact that the provisions of the Government Decision no. 583/2016 are also applicable, our company's management team implemented the provisions of the normative act, observing the terms contained herein.

A Declaration was thus adopted on adhering to the fundamental SNA values, principles, objectives and moni-

toring system, which was communicated to the responsible department of the Ministry of Justice and published on [our website](#).

Antibiotice elaborated also the company's Integrity Plan that includes the implemented anti-corruption measures approved by the executive management and forwarded to the Ministry of Justice. This plan is available on [our website](#).

By the same decision, a coordinator for implementing the Integrity Plan was appointed. This coordinator is a member of the company's management. Persons of contact with execution positions in the company were also appointed, their attributions being established.

For the reporting period (the financial year 2017), we mention that, in our company, no corruption incident and no act that violates the measures provided in the Integrity Plan was recorded.

Zero incidents of corruption

To know all the anti-corruption measures adopted by Antibiotice S.A., you can read the Declaration on adhering to the National Anti-Corruption Strategy, Integrity Plan adopted in accordance with the SNA, Code of Ethics, Form of Ethics, Code of Good Practice at the next [link](#). The main anti-corruption measures are presented in the table below.

Anti-corruption measures adopted by Antibiotice S.A.:

Anti-corruption measures	Description
Standardizing and turning the procurement process into a more transparent one, through the development and application of internal procedural procurement norms, publishing them in an open data format.	Antibiotice S.A. uses internal procedural procurement norms approved by the company's Management Board. These norms are elaborated for regulating the procurement procedures of the trading companies and have, cumulatively, the following purposes: compliance with the opportunity, efficiency and effectiveness criteria as well as compliance of our company's activities with the specific laws of the domestic and external market.
Facilitating the access to the public interest information, by publishing some relevant data on the management of the company in an open data format.	To ensure the transparency of its activities, Antibiotice S.A. publishes on its website the decisions of public interest adopted by the General Meeting of Shareholders and Management Board as well as other public interest information on our trading company's activities.
Establishing some ethical procedures and methods containing anti-corruption measures for a proper relationship between our medical representatives and the doctors and pharmacists involved in marketing/promotion/use of products sold by our company. The sponsorship contracts, hospitality events and the gifts offered and other similar actions are conducted in a standardized and transparent way.	Antibiotice prepared the Code of Good Practices for promoting the medicines with medical prescription and for the interaction with the health professionals. Our medical representatives have the obligation to give proper respect to the health professionals in all their specific activities conducted in the interest of our company.
Establishing principles and rules for an honest professional conduct and an organizational culture based on integrity standards. Establishing some rules and procedures for solving the conflicts of interest.	Antibiotice elaborated a Code of Ethics applicable to its employees and administrators for the purpose of highlighting the legal and moral aspects on which our company's policy is based from ethical viewpoint. Assuming these values is essential for ensuring the prosperity of our company and therefore all the decisions made by our management comply with the provisions of the Code of Ethics.
Adding some clauses in the contracts concluded with our partners to discourage and sanction the attempt of involving our company and/or its employees in corruption facts and acts.	In the contracts concluded by our company are included anti-corruption clauses whose purpose is to prevent and discourage any deed of this kind.
Creating an internal structure responsible for identifying and sanctioning violation of the good practice and ethics norms (incidents of ethics). Developing operational working procedures and a set of specific documents for recording, solving and reporting the incidents of integrity.	Our company set up the Council of Ethics and Integrity responsible for identifying and sanctioning violation of the good practice and ethics norms.
Encouraging the whistleblowers and protecting their integrity. Elaborating a reference book for the integrity of whistleblowers containing aspects related to their notifications, ways of transmission and the potential recipients as well as the system for protecting them.	Antibiotic S.A. created and maintains on its website a Form of Ethics by which, the possible violations of the ethics and good practice rules, including any act of corruption involving our company can be confidentially brought to the knowledge of our company's management.



Tariff Policy

We believe that a valuable medicine is not necessarily an expensive one but one that people can afford to buy and gives us a reasonable benefit allowing us to target performance, investing continuously in people, high technology and exigently selected partnerships.

Given the specificity of our business, the price of the products we produce are established in accordance with the legal regulations in force.

In Romania, the tariff policy is subject to the provisions of the Order of the Minister of Health no. 368/2017 approving the norms regarding the method of calculation and the procedure for approving the maximum prices of medicinal products for human use with medical prescription, with the subsequent amendments and completions.

Our participation through distributors in public auctions provides the access of all the medical institutions to our medicines, under conditions of competitiveness and transparency, while proving our flexibility by reducing our prices within the limits of profitability.

We apply this market policy in the ethical spirit of the fair competitive practices and behaviours, in compliance with the legislation in force (Law no.

21/1996 republished) and with the [Code of Good Practices of Antibiotice](#) for promoting the medicines with medical prescriptions and for the interactions with the health professionals.

In the year of this non-financial report, Antibiotice S.A. was not involved in legal or other kind of actions having as object the unfair competitive behaviour or violation of antitrust or anti-monopoly legislation.

In 2017, our company registered increases and penalties for the non-payment of an additional amount to the clawback tax, notified initially for the period 2009-2011. This amount additionally fixed by the National Agency for Fiscal Administration for the period 2009-2011 was mentioned in a tax inspection report completed in 2015. Subsequently, it was the object of a litigation, being suspended as an obligation tax until 2017 when it was paid. The clawback tax is the amount owed by the pharmaceutical companies for the medicines supported by the National Unique Health Insurance Fund and by the budget of the Ministry of Health.



Procurement policy

Purchasing process is an important link in the value chain ensuring the context favourable for a sustainable development of Antibiotice S.A.

Harmonization of commercial conditions imposed by the specifics of the pharmaceutical industry with the current trends in the domestic and external market is

the main direction of our company's commercial policy.

Antibiotice S.A. develops partnerships for purchases with suppliers both from Romania and from the intra- and extra-community areas. The share of the purchases from the local suppliers is 45% of the total acquisitions.

We strictly apply the following principles in the acquisition activity:

compliance with the regulations and legislation in force;

impartial treatment in the selection process, offering all suppliers equal contracting opportunities;

a fair, ethical and transparent assessment system of suppliers for promoting a long-term partnerships based on technological and manufacturing capabilities, quality, price, delivery and corporate stability;

a fair cost-volume ratio, enabling our company to obtain substantial savings related to the manufacturing stages;

a continuous communication with the suppliers, so that any risks associated with production and acquisition are known, assessed and solved in due time.

45% - the share of purchases from suppliers in Romania

Social





Our company's people

It is in the spirit of our brand to expand our knowledge, cherish cooperation and acknowledge each other's meaning and value. All of these bring us together and give us the necessary resources to accomplish our mission of ensuring a better life and health for the people. Together, as a team, we materialize our company's vision into an ambitious performance target.

Equality and diversity

Highly qualified professionals, from doctors, pharmacists, engineers, biologists to chemist operators and technicians are found in all the departments of the company, in a balanced distribution by age, gender and level of education.

In 2017, Antibiotice team had a total average number of 1,420 employees. Age and gender breakdown:

Age group	< 30	30 – 50	> 50	Total (%)
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

As regards our employees' level of education, 42.32% graduated from higher education (5 % of them have a PhD degree) while 57.68% have a secondary education.

Level of education	Number of employees	Share (%)
Higher education	601	42.3
PhD degree	32	5
Secondary education	819	57.7

Three generations of people harmoniously collaborate in our company, the eldest having about 40 years of activity.

Our continuous preoccupation to ensure the proper conditions as the

senior specialists to pass on the torch to the younger colleagues passionate of the pharmaceutical field as well as to attract new talents underpin the recruitment and mentoring programs.

In 2017 our company employed 122 persons, from which 53 were women and 69 were men. With reference to the above-mentioned new employees:

49 of them are higher education graduates (25 employees joined the research, portfolio management, production and engineering teams and 24 occupied the available positions of those who left the company)

73 are secondary education graduates, of which 11 are in the production and engineering areas in newly created positions and 62 occupied the released positions.

The table below presents the breakdown of the employees who left the company by age and gender groups:

Age group	< 30	30 – 50	> 50	Total
Women	8	24	19	51
Men	15	23	31	69
Total	23	47	50	120

In 2017, the staff turnover rate was 8.45%. In order to reduce this indicator and increase our company's attractiveness, the management intends to implement in 2018 an employment branding program both for the current employees and potential applicants for the jobs available in our company.

Employee benefits

Employees, regardless of the type of contract, are offered a standard benefit package, some of which are negotiated and established at the organization level. These benefits include:

- annual bonuses on the occasion of March 8, Easter and Christmas holidays
- days of additional paid leave
- free transportation of employees to/from work with the company's fleet of buses
- meal tickets
- a 34% subsidy for the meal offered by the company's buffet
- financial support to employees for the birth of a child or in case of death (in 2017, our company granted 63 bereavement allowances and 21 childbirth allowances)
- free paid days for certain events (marriage, childbirth, death, move to another home, completion of studies)
- partial payment of the tickets for treating certain diseases (2 employees benefited from social aids for occupational diseases)
- the possibility of purchasing medicines produced by our company on the basis of a prescription released by a physician, our employees paying the social contributions and

the tax on the values of the medicines at the producer's price

- financial support for other special cases (disasters, serious health problems – 27 employees received this type of financial support in 2017)
- a share from the annual profit distributed to our employees in accordance with the legislation in force.

The parental leave was requested by and approved for 18 employees (100% women) and 11 employees (100% women) returned from the same type of leave in 2017.



Occupational safety and security

We pay special attention to the security and safety of our employees and those who visit our company. Thus, we have an Internal Prevention and Protection Service directly subordinated to our CEO. The activity of this department complies with the provisions of the Law no. 319/2006 and its employees have the necessary skills and evaluate the professional risks whenever changes occur in their work (equipment, work environment, work tasks).

In Antibiotice S.A. there is a permanent clinic, with a highly qualified team of occupational physicians and nurses. The clinic is properly equipped for providing pre-employment medical checks, giving the first aid in case of medical emergencies and permanently monitoring the health status of our employees.

We also have in our company a Committee on Health and Safety at Work (CSSM) composed of five representatives of the employer, five representatives of the employees (the union leader and leaders of other structures), including the

coordinating occupational physician and the employer is the Chairman of the Committee on Health and Safety at Work.

Since 2007, Antibiotice's Integrated Management System (quality, environment, occupational health and safety) has been certified by Lloyd's Register Quality Assurance Limited in accordance with the international ISO 9001, ISO 14001 and OHSAS 18001 standards.

During the reference year, Antibiotice S.A. recorded two work injuries (one woman and one man) with a total temporary work incapacity of 93 days. The two work accidents were not caused by a poor organization within our company. The results of these investigations identified as causes of the accidents the non-compliance with the occupational health and safety instructions and with the requirements on the protective equipment.

These events led to new training sessions so our employees be aware of

these dangers. Rate of absenteeism due to work accidents was zero and no death was recorded.

Permanent clinic

First aid in case of emergency

Occupational medical checks



Professional training

In the context of the complex changes in the labour market, an easier access to the information and increased job opportunities, instilling loyalty in our employees and retaining them have become more challenging.

At the same time, demographic decline and labor mobility make the human capital deficit in Romania a major risk for organizations.

Taking into account the competitiveness in the pharmaceutical industry, the professional and individual development of our employees and other ways of motivating them are top priorities for our company.

In order to ensure the continuity of our business, every year we analyze our staff by departments, periodically establishing the necessary staff reserve according to the organizational structure. The employees who are to be retired continue their activity until the communication of the retirement decision.

We are permanently looking for timely solutions to ensure the highly-specialized staff, we increase our employees' awareness and involvement in the decision-making process and in the life of our community.

In 2017, the average number of training hours per employee was 36.26, the distribution of employees receiving training by age and gender groups being the following:

Age group		< 30	30 – 50	> 50
Total	100%	8,2%	73%	18,8%
Women	54.5%	7,5%	73%	19,5%
Men	45.5%	9%	74%	17%

The degree of competitiveness and our products' quality can not grow without investment in professional development. In this respect, each department identifies its training needs, depending on legislative changes, technological developments or trends.

Our company provides its employees with training programs with internal lecturers, as well as courses lectured by external trainers, the training plan and related resources being regularly agreed.

At its eighth edition, the Summer School a+ is an important component of the employees' professional training. The objective of this project is to raise the level of professional training and personal development of the employees concerned with enriching and refining their knowledge.

In 2017, 580 persons participated in the training sessions with external lecturers, the topics aiming to increase the professional skills and integrate the new regulations in production, quality assurance, engineering and equipment qualification or validation of analytical and bioanalytical methods.

Thus, the employees involved in research, pharmaceutical formulation and portfolio management updated their knowledge about the trends on the food supplements, pharmacovigilance, medi-

cal ethics and bioequivalence studies while the staff from the bioanalytical laboratories received training on the use of the latest generation laboratory equipment.

Marketing, promotion and sales teams were specialized in using modern market analysis tools, in communication and sales techniques, in efficient time management and presentation skills.

Through the periodic (annual) evaluation process of performance, each employee knows the value of his/her contribution and how they can improve the individual performance.

All our employees on all the hierarchical levels are included in the evaluation process, this being differentiated as follows:

*our managers are evaluated by the hierarchical superior
our execution staff is evaluated by the hierarchical superiors
our managers are evaluated by their subordinates*

36.3 - the average number of training hours per employee



Relation between management and employees

Our organizational culture encourages ideas and solutions sharing, innovation and team spirit in order to overachieve ourselves individually and collectively. Antibiotice's management sustains the transparent communication and feedback with all the employees, regardless of the hierarchical structure.

The Independent Union is formed within the company and has 1,184 members, representing 83.38% of all our employees. The Union is the permanent partner of social dialogue with the Antibiotice management, participating in the negotiation and conclusion of the Collective Labor Agreement.

The Independent Union within Antibiotice grants to its members social benefits in the event of: the death of a trade union member, family members (wife, children, parents-in-law) benefits for special medical conditions and financial aids for special social cases.

*83.38% of all our employees are members
of The Independent Union*



Marketing policies

Antibiotice's internal and international marketing policies are exclusively based on ethical practices of marketing, promotion and sale, whether it's about medicines with or without prescription or dietary supplements.

These practices are assumed by the entire company in a Code of Good Practices for promoting the medicines with prescription and which refers to the interactions with the health and pharmaceutical professionals. The Code can be accessed [here](#).

The Code of Good Practices together with the Code of Ethics and Internal Rules of our company represent a support for ensuring a legal, transparent and ethical framework for performing the promotional activities and for creating a fair competitive environment for the over-the-counter medicines.

The current Code reflects also the requirements of the EFPIA Code (European Federation of Industries and Pharmaceutical Associations), ARPIM Code (Romanian Association of International Medicines Manufacturers), APMGR Code (Association of Generic Medicines

Producers from Romania) and of the Council Directive 2001/83/EC.

The Code defines and implements the ethical standards specific for promoting our medicines, ensuring a fair communication with the medical and pharmaceutical professionals regarding the generic medicines, making prevention possible.

In addition to the provisions of this Code, our employees meet the legislation in force.

Since 2017 Antibiotice have become a member of the Romanian Association of the Self-Care Industry (RASCI).

Regarding the enforcement of the legal and voluntary provisions in the field of promotion, our company did not receive any fines or warnings for the non-compliance with the legislation on product labelling, promotion and marketing communications.

Since 2017 Antibiotice have become a member of the Romanian Association of the Self-Care Industry (RASCI)

Zero fines and zero warnings for the non-compliance with the legislation on the advertising of medicines



Access to medicines

By our mission, we make our valuable generic medicines more accessible as a means of healthcare for patients, physicians and pharmacists. 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.

The 150 medicines from our portfolio are delivered both in the domestic market and in 75 countries worldwide.

In the national market, the Antibiotice products are delivered in hospitals and pharmacies through 10 local partners.

In the external market, Antibiotice ranks first in the production of the active substance, Nystatin delivered worldwide through our partners. The US remains the largest and most valuable market for trading our active substance, Nystatin and anti-infective drugs.

Access to medicines – domestic market

The Romanian patient, regardless the region of the country or purchasing power, has unlimited access to the Antibiotice's medicines.

Our 10 partners in the Romanian market concluded supply contracts with all the 576 hospitals in the country (367 public hospitals and 209 private hospitals) and with the 7,850 pharmacies (from which 2,000 belong to the national chains and the other ones are community and regional pharmacies). Data source: [the report on the activity of sanitary units in 2017](#), prepared by National Institute of Statistics.

The main purpose of our business relations with the distributors is to

ensure a continuous and active presence of our products in the entire healthcare system, applying ethical and transparent commercial and competitive practices.

Our portfolio provides, according to [World Health Organization Model List of Essential Medicines](#), a total of 37 drugs considered essential, according to the World Health Organization classification, namely medicines that meet the health needs of the majority of the population, used to treat the most widespread diseases.

37 Antibiotice medicines are considered essential, according to the World Health Organization classification

Access to medicines – external market

Our business internationalization is based on sustainable trade policies developed in the external markets. Our presence in these markets is possible through the compliance with the international quality standards and competences in research and regulatory affairs. This way, we guarantee the quality, safety and efficiency of our products, attributes that give our partners confidence in a fair and sustainable partnership.

Ethical promotion in the international market has become very important in our strategy of increasing the presence and access of our products in these

markets. We will intensify this activity, both through our own representative offices in Vietnam, Ukraine and Republic of Moldova and through our attendance in well-known international fairs, exhibitions and events (such as the Cphl Worldwide, the most important annual global event in the pharmaceutical industry).

In the reporting period, our company adapted its international development policies to the new health regulations, taking into consideration both the consumption trends and specificities of each market.

Our medicines have become more accessible internationally through our representative offices in Vietnam, Ukraine and Republic of Moldova



Safety of participants in clinical trials

Clinical trials are conducted in accordance with the Helsinki Declaration on ethical principles of research that involve human subjects. The protocol of the trial includes the goal of the trial, the way in which it is conducted and describes how the ethical principles are approached. The protocol is analyzed and approved by the Commission of Ethics. The rights, safety and wellbeing of a human subject in a clinical trial are put before any scientific or company's interest. The human subjects are included in the trial

only after their informed and documented consent. Human subjects participate voluntarily in the clinical trials, having the right to withdraw at any time.

The bioequivalence studies certify that the generic medicines developed and produced by Antibiotice are therapeutically equivalent with the innovative reference medicines, in accordance with the European regulations on Good Clinical Practice and Good Laboratory Practice.

The robust procedures of assuring the safety of volunteers in the clinical bioequivalence trials are of a highest importance.

In 2017, there were no bioequivalence trials prematurely terminated for safety reasons.



Drug safety and adverse effects

Safety of patients treated with Antibiotice medicines is a priority of our company. Monitoring the efficacy and safety in administering the medicines for which we hold marketing authorization is part of a continuous process conducted through the internal activity of pharmacovigilance. Through a rigorous analysis of the benefit-risk ratio, we make sure that the benefit of a medicine exceeds the risks to the patient.

All the spontaneous reports of the suspected adverse reactions are collected, evaluated and reported according to the legislation in force. By linking to the European Pharmacovigilance database, Eudravigilance, our company constantly contributes to maintaining the safety in uses of its medicinal products and, at the same time, enables the detection of possible global safety signals and the initiation of appropriate measures to protect public health, if necessary.

The safety of the medicines is monitored throughout the life cycle of the products from development, launch and until the expiry of the marketing authorization. To report an adverse event to any of the Antibiotice medicines with a marketing authorization, the patients can use the e-mail address: sigmedu-mane@antibiotice.ro and two phone

numbers: 0232 209 249 and 0232 209 256 together with other information on the leaflet of the product.

As regards, the permanent monitoring of the adverse effects, no Antibiotice product was on the FDA alert list (Food and Drug Administration) or EMA alert list (European Medicines Agency), no product was withdrawn from the market for safety reasons and there was no serious or unexpected adverse reaction to the Antibiotice products.

Product labeling is the first way to properly inform patients and consumers on the actions and use of medicines in order to maintain safety of patients.

Safety of use, storage and disposal of Antibiotic products are provided by warnings clearly stated on the product label and in its leaflet, together with other specific information provided in an appropriate language so as the patient and consumer to easily understand the terms.

The labeling and leaflet of each product are subject to the approval of the National Agency for Medicines and Medical Devices before placing it in the market and the information is periodically reviewed and aligned with the requirements of the relevant legislation.

In 2017, zero incidents regarding labeling were recorded:

no failure to comply with legal regulations resulting in fines or penalties

no failure to comply with legal regulations resulting in warnings

no failure to comply with the voluntarily assumed codes in the field

Zero incidents regarding the failure to comply with the legal regulations on the information related to and labeling of medicines

Zero Antibiotic products on the FDA alert list (Food and Drug Administration) or EMA alert list (European Medicines Agency)



Support for the local community development

We are constantly concerned, through all our activities, to improve people's health and life, create a climate of trust in the relationships with our stakeholders and protect the environment.

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

We involve in our community through social responsibility programs based on four strategic pillars: health, education, social matters and environment.

Health

We develop social responsibility programs to improve the health of our employees and people within the communities in which we operate. Under these programs there are campaigns to educate and inform the population about health prevention.

Awareness campaign on the responsible use of antibiotics

Our company's ethical involvement in various actions to prevent the bacterial resistance is part of its mission to responsibly manufacture medicinal products.

Judiciously used, these life-saving medicines remain effective for the future generations as well.

The Caravan „Antibiotics save lives! Use them responsibly”

Between November 18 and 25, 2017, on the occasion of the European Antibiotic Awareness Day, our company offered its support to the „Antibiotics save lives! Use them responsibly” Caravan, a project initiated by the students' associations from ”Gr. T. Popa” University of Medicine and Pharmacy, for the third year in a row. The caravan moved to three rural localities in the County of Iași and aimed at informing and educating rural residents about the judicious use of antibiotics.

The contest „Antibiotics – use them with care! Everyone is responsible”

In 2017, our company organized the ceremony for awarding the winning projects of the contest „Antibiotics – use them with care! Everyone is responsible” dedicated to the students from ”Gr. T. Popa” University of Medicine and Pharmacy - Iași. The participants in this contest initiated a year before used their creativity by delivering integrated communication campaigns, whose core message was the rational use of antibiotics.

”We live healthy in a healthy company”

We sustain our business also through a constant concern for our employees by initiating the project ”We live healthy in a healthy company” whose purpose is educational. Antibiotic's employees received valuable information about the correct and balanced nutrition, about a healthy lifestyle.

Within this project, two conferences were held at our company's headquarters in collaboration with a nutritionist to raise awareness about eating habits and the importance of healthy eating.

Education

We invest with science and soul in the education of youths that, like our employees, can do career performance 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.

Summer School a+

Antibiotice's traditional program, **Summer School a+** aims to attract future specialists in the fields of research, quality control and production of medicinal products. Between June–August 2017, our specialists with a vast experience in specific areas were lecturers at the free

courses in the 8th edition of Summer School a+ for the 30 students, graduates and master's students of the Chemistry, Biology and Chemical Engineering faculties of the Iasi universities, selected in this program.

330 students in the fields of Pharmacy, Biology, Medicine, Chemistry, Chemical Engineering participated in the 8th edition courses of the "Summer School a+" program

38 participants in the 8 editions of "Summer School a+" were later employed by our company in the following areas: research, quality assurance and control, regulatory affairs, bioequivalence studies and production

Perform a+ project

Initiated in 2016, this project aims to cultivate among young specialists the passion for the pharmaceutical industry and offer information about the specifics of a career in this field. The approach addresses to students in the terminal year and graduates (residents, PhD students) of the Pharmacy Faculty. This project also offers the possibility of

completing the knowledge acquired during the academic years with a theoretical and practical program coached by mentors appointed from the company's specialists.

In 2017, the courses attended by 10 admitted students were completed with the submission of some specialty projects, in which they demonstrated their

knowledge gained in formulating a pharmaceutical product.

The evaluation's results will be the basis for selecting well-trained people for completing the teams of specialists within Antibiotice SA.

6 graduates from the two editions of Perform a+ were hired by Antibiotice S.A. in 2017

"Perform a+" project was awarded within the EduManager.ro Gala 2017 and received Diploma of excellence

Educational partnerships

We invest with science and soul in the education of young people in our community,

making available our technological and human capabilities.

In order to increase the performance of the education system and support the university and pre-university practice programs specific to the pharmaceutical field, Antibiotice has concluded annual education partnerships with:

- County School Inspectorate of Iași (we support the best students from our community within the "Gala of Excellence in Education" as well as their participation in olympiads and international competitions);
- Local educational units and those for the Moldova region In 2017. Within the "A different school" project, Antibiotice opened its gates for 480 pupils from the pre-university education institutions in Iași;
- "Petru Poni" Technological High-School, Iași and Technical High School of Mechatronics and Automation, Iași, for supporting the practice programs. 60 pupils benefited from this partnership in the school year 2016-2017.

Antibiotice supports the Former Employees Association

Antibiotice supports our company's Former Employees Association by providing them with the necessary medicines, visits to the home of the sufferers, legal assistance in litigation with local or national authorities. This Association represents a connection bridge between our management and the former employees of Antibiotice S.A.

The Former Employees Association was founded in 2005 and aims to monitor and solve the various problems faced by pensioners, our former employees.

All these actions show our concern for those who contributed over the years to developing and consolidating our business in the pharmaceutical market.

Environmental protection

Antibiotice wants to develop a durable partnership company-community by running activities for protecting the environment, being constantly concerned with improving its performance in this field.

"The Orchard at School"

Antibiotice launched in 2017 the project "The Orchard at School" in which 120 employees involved voluntarily, planting 410 fruit trees in two stages, at the schools in the neighboring localities: Miroslava, Proselnici, Vorovești, Valea Lupului and Uricani (apple trees, plum trees, cherry trees and sour cherry trees).

The project turned the unused spaces around the schools into a green area.

"The Orchard at School" is also a project by which Antibiotice's employers try to inspire the young generation's respect for protecting the environment, maintaining a healthy lifestyle, and cultivating the civic spirit in the community.

5 orchards planted at the schools in rural areas

Earth Hour

Our company participated in the Earth Hour campaign, the world's largest lights-out movement that draws attention to the effects of global warming. On March 25, 2017, Antibiotice symbolically turned off the non-essential electric lights for one hour. This is the company's ninth participation in this project.

ment. Our company involved all the children from the "Valea Lupului" Secondary School in a creative contest entitled "**Be pro-nature! Put your soul!**". Their work were auctioned and bought by our employees at a charity exhibition entitled "**We support the education in the community**". The amount of 4,000 LEI was donated for supporting those 52 children from the "Valea Lupului" Secondary School in difficulty and at risk of dropping out of school included in the program „**Home in the community – after-school**” at the "Valea Lupului" Secondary School.

Be pro-nature! Put your soul!

Antibiotice marked the World Environment Day, opening its gates on May 29, 2017 for 60 pupils from the "Valea Lupului" Secondary School. The children were presented with the Waste Water Treatment Plant, Waste Incinerator as well as with the entire procedure by which Antibiotice protects the environ-

Social matters

Antibiotice, through its "Antibiotice – Science and Soul" Foundation has been permanently involved in the community's life, supporting disadvantaged groups by developing social programs, some of which have become traditional.

Donate blood! Put your soul to life!

The acute blood crisis in Romanian hospitals determined our company's

employees to get involved since 2010 in the blood donation campaign initiated by the "Antibiotice-Science and Soul"

Foundation in partnership with the Regional Blood Transfusion Center Iași.

Our campaign entitled **Donate blood! Put your soul to life!** runs twice a year at Antibiotice's headquarters and aims at completing the blood deficit in the healthcare units, but also at sensitizing the civil society to engage more actively in voluntary blood donation.

In 2017, 111 employees donated 52 liters of blood, in two editions of this campaign thus helping to save over 270 lives. Antibiotice collected blood 13 times until 2017, 700 blood donations being recorded from the initiation of the program, which is equivalent to a voluntary contribution of our employees to the saving of 2,000 human lives.

111 employees donated blood in 2017

"Science and Soul" Scholarships

For 16 years, Antibiotice has been supporting the "ProRuralis Association", annually granting five "Science and Soul" scholarships to the education of rural children – children with great skills but without material possibilities, supporting them to continue their studies at the

secondary school and high school. The first generation of scholars graduated in 2008. The second generation of scholars supported by the "Antibiotice -Science and Soul" Foundation, starting with the fifth grade, graduated in 2017 and are currently students at different faculties in Iași.

We have been supporting for 16 years the "Science and Soul" Scholarships project

The power of deed!

Near the Easter holidays, on April 12, 2017 the "**Antibiotice – Science and Soul**" **Foudation** helped 25 disadvantaged families in the Petrești Village, Golăiești township, County of Iași, giving them strictly necessary food in order to properly prepare themselves for the traditional Christian feast.

receive from Santa and the letters arrived to more employees who enthusiastically assumed the role of Santa's elves, fulfilling the children's desires.

"Be generous, be Santa Claus"

Antibiotice's employees were the Santa Claus's elves for 80 children from large families with seven, eight or nine brothers and sisters from the rural localities of the County of Iași.

Children aged between 1 and 14 put on paper everything they wanted to

International Children's Day

It has already become a tradition for our company to offer a gift to all its employees' children on the International Children's Day. Thus, 120 children of our employees were invited to the event "**Garden of the Game and the Round Dance of Sun Rays**" where they enjoyed outdoor educational workshops, theater, dance, games and sweet surprises in the Casa Pogor Garden. Twenty children from the "Bogdana" Placement Center from Bogdănești also attended the event.



We are continuously concerned to minimize our activities' impact on the environment, monitoring the responsible resource consumption so that we can take action to reduce the environmental footprint of our business.

This chapter includes information about the two areas identified by our stakeholders as relevant to understanding both environment policies and procedures and how we approach and monitor them over time.

Effective use of resources (water, energy) Waste

In addition, because environmental issues concern us and equally help us better understand which of our activities can be optimized so as to reduce our negative impact, 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 National Environmental Protection Agency Bacău, revised in March 2018;
- Water management authorization no. 303/20.12.2010 (valid until 2021), issued by National Administration "Romanian Waters", Water Administration - Prut-Bârlad River Basin.

At the same time, we obtained the Certificate of Management System Compliance with the requirements of ISO 14001:2015 standard (recertification) as part of the Integrated Management System implemented, maintained and continuously improved since 2005. The certificate was issued by Lloyd's Register Quality Assurance, following regular surveillance and certification audits.



Energy

In 2017, the total amount of energy from non - renewable sources consumed by Antibiotice SA was 232 Tj, divided as follows:

28 Tj conventional power (suppliers of utilities)

183 Tj natural gases (suppliers of utilities)

21 Tj fuels

Compared to 2016, there were no significant deviations in conventional electricity and natural gas consumption. Our company reduced by about 10% the fuel consumption (from 23 Tj in 2016 to 21 Tj in 2017).

Electricity from renewable sources and additionally used by our company was 24 Tj (10.34% as compared to energy from non-renewable sources) while the figure in 2016 was 21 Tj, showing the tendency to reduce the negative impact on the environment.

Electricity, heat and consumed, produced and / or recovered steam were composed of:

consumed electricity = 52 Tj
produced/ consumed steam = 27,000 Gcal

Quantities were calculated based on our own records and information received from our utility suppliers (in correlation with the invoiced and paid amounts) using the heating power but also the agreed conversion factors for energy units, according to the specialty literature.

The correlation was also made with the values indicated in the 2016 and 2017 energy labels made available to us by the energy suppliers.

In 2017, Antibiotice initiated a European funded project (POIM 6.2, entitled "[Intelligent Energy Monitoring System within Antibiotice S.A.](#)") which will be completed by the end of 2018. The overall objective of the project is the reduction by 1%, of the specific energy consumption (kgep / 1,000 euro) in the company, i.e. 2047GJ /year, in a 5-year period after the project implementation. The specific objective of the project is the implementation of a smart metering system to monitor the consumption of electricity, natural gases and compressed air.



Water

The total counted volume of captured or consumed water in 2017 was 158,200 cm, higher than the figure recorded in 2016 (when the recorded consumption was 155,000 cm). Supplementing water consumption occurred

amid an increase in production activity.

The amount of water was fully provided by the municipal network, through the operator APA VITAL SA Iași.

In 2017, the total volume of effluents was 121,150 cm (higher than the figure

recorded in 2016, i.e. 115,233 cm), divided as follows: 111,000 cm in the sewage system from our own wastewater pre-treatment plant and 10,150 cm in the emissary. The flows were measured by measuring equipment and the records are based on the reports concluded with the authorized operator.

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

Antibiotice performs determinations on the quality indicators of discharged waters, through its own laboratories as well as through third-party laboratories authorized by RENAR.

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

With regard to the water recovery / recycling, this process takes place within the steam production and distribution system. Steam condensate comes from the steam for preheating the water in boilers and from the steam used to produce the thermal agent. These quantities of water are recovered by reintroducing the steam boilers into the water supply circuit.

In 2017, the quantities measured with specialized equipment and checked by our metrology laboratory were: 2,147 cm of condensate from steam for heating and 5,768 cm from the preheating steam.



Waste

Total weight of (hazardous and non-hazardous) waste recorded in 2017 by Antibiotice Iași was 1.900 tons. Of this quantity, hazardous waste weighing 18 tons ((0.95% of total waste) was disposed of by incineration. As regards the non-hazardous waste, weighing 1,882 tons, a part of this quantity (1,146 tons, representing 61.42%) (including the related energy) was sold. Another part (30 tons) was incinerated in our own incineration plant while 192 tons were transferred to the municipal waste landfill and 514 tons were stored on our site.

With regard to packaging waste, of

the total quantity of packaging placed on the market (950 tons), 57,58% of them were recycled, 2.42% were sold. This way, Antibiotice met the legal 60% recycling / recovery target of the total packaging placed on the market (according to Law 249/2015 on management of packaging and packaging generated waste).

In 2017, Antibiotice S.A. concluded a service contract with an Authorized Responsibility Transfer Organization on taking over responsibility for recycling / recovery of packaging waste.

In the mentioned year, our company did not record outstanding payments to the Environmental Fund Administration.

60 % of the total packaging placed on the market were recycled/sold

61 % of waste were sold (including the related energy)



Emissions

Total quantity of emissions calculated for the entire company in 2017 was 13,322 tons of CO2 equivalents, from the following sources: energy (4,060 tons of CO2 equivalents), natural gases (9,054 tons of CO2 equivalents) and fuels (208 tons of CO2 equivalents).

Total quantity of emissions was reduced by 4 % as compared to 2016, recording 13,804 tons of CO2 equivalents, divided as follows: energy (4,703 tons of CO2 equivalents), natural gases (8,844 tons of CO2 equivalents) and fuels (257 tons of CO2 equivalents).

We carefully monitor the air quality on our company's site, both by performing determinations carried out by our laboratory, but also by collaborating with an RENAR accredited third-party laboratory. The air emission sources are as follows:

direct discharges from production sites (ventilation, noxious retention equipment)

burning of natural gas in our own heating station

incineration of non-hazardous and hazardous waste in the incineration plant

transportation (car fleet).

The volumes were calculated according to the standard methodology specified in the EC Regulation 601/2013 on monitoring and reporting the greenhouse gas emissions in accordance with Directive 2003/87 /EC. The calculation was done by multiplying the activity data (corresponding to the used fuel category based on net heating value) with the corresponding emission factors (according to the IPPC Guidelines, 2006), as well as based on the energy label information received from the electricity supplier.

The certificates of analysis constantly revealed the observance of the conditions established by the regulatory documents, as well as the observance of the legal requirements in force applicable to the performed activity. Antibiotice did not record in 2017 any incidents on uncontrolled pollutant emissions in the air.

Antibiotice has been constantly concerned to comply with the legal requirements relating to environmental protection, while implementing, maintaining and improving an effective environmental management system.

Environmental issues, as well as associated risks, are identified and evaluated on a regular basis, our compa-

ny permanently monitoring the measures established for keeping under control or reducing the negative impacts on the environment resulting from our activity.

The results for voluntarily embracing an Environmental Management System, part of the Integrated Management System, correlated with the actions undertaken in the field of environmental protection, materialized in the fact that no sanctions were imposed regarding the non-observance of the applicable environmental legislation. This reconfirms our concern and our efforts to mitigate the impact on the environment.

In 2017 total emissions were by 4% lower than in 2016

Zero emission incidents

Zero sanctions for the non-compliance with applicable environmental legislation

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102-10	Significant changes within the organization or in the value chain	Because this is our first non-financial report, the reference system for reporting potential changes will be available in the future.
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102-46	Determining the content of the report	29
102-47	List of material domains	29
102-48	Updates to the information in the previous reports	Our company did not issue another non-financial report.

102-49	Changes in the reporting practices	Our company did not issue another non-financial report.
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102-51	Date of latest report	Our company did not issue another non-financial report.
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