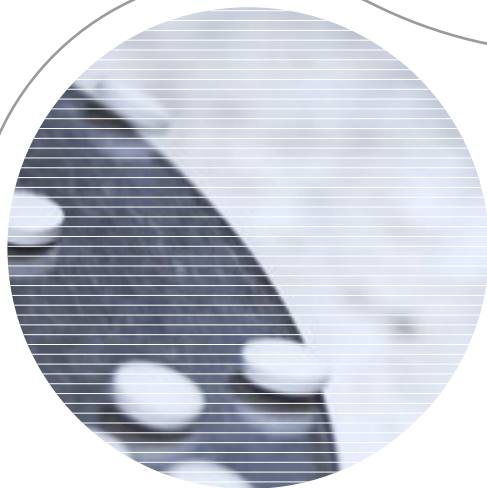




# ANNUAL REPORT 2017


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# The CEO's Message

In 2017, Antibiotice, the most important Romanian producer of generic drugs in the domestic market continued its mission to manufacture high-quality medicines in order to give people hope for a healthy life.

For 62 years Antibiotice has proved to be a modern and competitive company which demonstrated that the performances of the world pharmaceutical industry can be achieved in Romania as well. Antibiotice has become a company adapted to the contemporary pharmaceutical market, which puts a genuine Romanian brand on the global market.



Contemplating the present and the future, one can say that Antibiotice operates in a very turbulent national and international economy. Our company's development strategies and medium and long-term plans are influenced by a variety of aspects of the national and international market. This is why maturity, competence, performance and prestige are some of the attributes that guide our actions. In terms of evolution, we have shown we can adapt to what happens at economic level and to the changes in the pharmaceutical industry. Recently, we were ranked on the 363rd position in the top 1000 companies in Romania (top put together by Ziarul Financiar).

Following the market trend in Romania in 2017, Antibiotice consolidated sales of non-prescription drugs (OTC), recording a steady growth of 17.5% and an increase in physical sales on the domestic market by 11.5% compared to 2016. We also maintained leadership position on the Hospital segment of the domestic market in terms of therapeutic units sold (injectable powders) with a market share of 79.15%. Competition is fierce and we must fight so that each of the 520 million pharmaceutical units we produce reaches pharmacies, hospitals and patients, by adapting to market conditions where all distributors have been bought by multinational companies and sophisticated systems are adopted more and more frequently.

2017 is the third consecutive year when Nystatin maintains world leadership position. At the same time, this biosynthesis product obtained the ultimate international recognition, namely the Trophy USP Reference Standard for Nystatin.

By extending our business worldwide, in recent years we have managed to reach major markets in Europe, the United States and Asia with export sales of about 29 million dollars. This effort, based on in-depth market studies, on the continuous development of partnerships and specialized human resources and the adaptation of registration files to international regulatory requirements was made step by step. In 2020-2022 we intend our export sales to reach 50% of turnover. It is an important goal that we can achieve.

We have been consistent to the portfolio renewal policies so that in 2017 we obtained seven new marketing authorizations and notified two dietary supplements. Given that 9,000 pharmaceutical products are sold in Romania, the permanent renewal of the product portfolio is one of the main challenges we have to address.

In order to increase the safety of administration for consumers and patients worldwide, we have continued to invest in serializing products in line with the international regulatory requirements. Also, the investment in the new production facility for topical products, suppositories and pessaries that started last year, continued in 2017 alongside an updating of production systems in all plants. The modernization of research laboratories, quality control laboratories, of the storage, transport and utility production infrastructure are real concerns of the management team.

We are fully aware that skilled, well-trained staff represent the future of our company. This is why we pay great attention to the employee selection process, we promote diversity, equal opportunities, integration and ongoing professional development. A permanently trained workforce, as well as the adaptation of human resources to national, international and organizational changes and to everything new is a necessary prerequisite for performance.

Antibiotice believes in the necessity of supporting social responsibility projects and is constantly concerned to contribute to the protection of the environment, improving the health and life of people. Our responsible behavior, environmental care, concern for human health and employee development, transparency and ethics translate into sustainability. Our goal is to maintain business profitability and increase the satisfaction of our customers, shareholders and employees.

For the next five years we intend to further develop the Antibiotice platform. We are in a continuous movement that means life, health and the desire to move forward.

**Ec. Ioan Nani**  
**CEO**  
**Vicepresident of the Management Board**



# Company Profile

## Antibiotice today

The main manufacturer of anti-infective generics in Romania;

Portfolio consisting of **157 products** in 12 therapeutic classes;

A leading manufacturer of anti-inflammatory drugs, dermatologicals and medicinal products for the digestive tract, cardiovascular and central nervous system;

8 manufacture lines for: sterile powders for injection, penicillin capsules, non-penicillin capsules, cephalosporin capsules, tablets, ointments, creams and gels, suppositories, pessaries and active substances obtained by biosynthesis;

Sales revenues amounting to **336,9 million lei** in 2017 higher by **1.3%** than 2016;

Internationally recognized certifications and authorizations: US Food and Drug Administration authorization for Nystatin and injectable products, USP international standard reference for Nystatin, Certificate of Suitability for Nystatin (CoS), the GMP Certificate for all manufacturing lines, integrated management system;

Antibiotice has a modern Research and Development Center;

It is the first company in Europe prequalified by the World Health Organization for the range of essential anti-TB drugs;

**1420 employees.**

# Brief History

## 1955

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The Chemical Factory no. 2 was built in Iași between 1953 and 1955, being the first manufacturer of penicillin active ingredient in the South-East Europe. The first batch of penicillin was obtained on December 11, 1955.

## 1959

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This year marks the start of the Streptomycin (API) production and of the first finished dosage forms: ointments, creams, suppositories. The Chemical Factory no. 2 changes its name into the Factory of Antibiotics.

## 1977

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The Food and Drug Administration from the United States (FDA) authorizes the manufacturing line for Streptomycin active ingredient.

## 1990

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Antibiotice becomes a joint-stock company by taking over the assets of the former plant Antibiotice Enterprise Iași, according to GD no. 1200/12.11.1990.

# 1992

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Antibiotice manufactures the first medicinal products formulated as tablets.

# 1993

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Ampicillin 250 mg and Oxacillin 250 mg are the first capsules manufactured by Antibiotice on the penicillin manufacturing line.

# 1997

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Starting with April 14, 1997 Antibiotice shares (ATB symbol) have been listed on the first tier of the Bucharest Stock Exchange.

The company implements an efficient, state-of-the art quality assurance system that implies a strict control of the manufacturing processes.

# 1999

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Antibiotice becomes the first Romanian producer to obtain the GMP certification for the line manufacturing injectable powders.

# 2010

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Antibiotice delivers the first finished products on the US market; up to 2010 the company exported to the US active pharmaceutical ingredients only.

# 2011

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The line manufacturing penicillins formulated as sterile powders for injection obtains the FDA's approval which allows Antibiotice to launch these products on the US market.

Antibiotice launches the first CNS medicines.

# 2012

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Antibiotice enters the market of oncological medicines and becomes the first WHO prequalified company in Europe for its range of anti-tuberculosis drugs.

# 2013

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Antibiotice is FDA, GMP and NAMMD reauthorized for the lines producing sterile powders for injection and Nystatin.

Antibiotice becomes the leading worldwide producer of Nystatin.

The first export of Nafcillin is made on the North American market.

Antibiotice opens an international area office in Chişinău, the Republic of Moldova.

# 2002

The company's plant producing Nystatin obtains the FDA approval, which allows exports to the United States. As a result, Nystatin becomes the most important product exported, securing Antibiotice's position as a top worldwide producer of Nystatin.

# 2005

On the occasion of its fiftieth anniversary on December 11, 2005, Antibiotice launches a new brand identity: the Antibiotice a+ logo and the slogan "Science and Soul".

# 2006

Antibiotice establishes its own Center for Drug Evaluation that conducts phase I clinical studies and bioequivalence studies. The Center for Drug Evaluation is GLP certified and authorized by the Romanian Ministry of Health.

The quality management system implemented by Antibiotice is ISO 9001:2000 certified by Lloyd's Register Quality Assurance (LRQA).

# 2007

Antibiotice earned recognition for implementing the Integrated Management System on quality, environment, occupational health and safety as per standards EN ISO 9001:2008, EN ISO 14001:2004 and OHSAS 18001:2007.

By launching four new products Antibiotice completes its cardiovascular portfolio with medicines covering the treatment of the main cardiovascular diseases.

# 2014

Antibiotice extends its business in the Republic of Serbia through its partner, Pharma which represents the company in commercial relations.

Antibiotice starts investing in a new Ointment & Suppository Plant.

# 2015

Antibiotice gets the US FDA reapproval for the sterile injectable finished products and Nystatin (API).

Antibiotice celebrates 60 years of Romanian continuity and performance.

Our company is granted gold medals and an Award at EUROINVENT 2015, the largest exhibition of inventions, projects and research in South East Europe.

Antibiotice joins the awareness campaign on antibiotics "Antibiotics - use them with care!"

# 2016

Record sale of injectable Products for the US Market (Nafcillin 1g and 2g and Ampicillin 500mg, 1g and 2g).

Antibiotice opens a commercial office in Hanoi, Vietnam.

Antibiotice obtains the "Strongest in Romania" certification 2016: a financially responsible, credible and credit worthy company with partners in the country and abroad.

The company launches "Perform a +", a project for attracting specialized personnel and new collaborators in the research and development field. The project is dedicated to young students and interns of the Faculty of Pharmacy of the University of Medicine and Pharmacy Iasi.

# 2017

Antibiotice Iasi imposes the quality standard for Nystatin at world level. The United States Pharmacopeia gives our company the title of international reference for Nystatin active ingredient.

Antibiotice participates for the 15th time at the most important worldwide event of the pharmaceutical industry, CPhI Worldwide.





# Corporate Governance

To build a strong relationship with our shareholders and potential investors, our company has adopted the principles and recommendations of the Corporate Governance Code of the Bucharest Stock Exchange (CGC-BVB), principles that underpin the fulfillment of the company's good corporate governance standards.

The term governance means management and involves all the activities within an entity falling into the sphere of management. As a result, it can be said that this concept – corporate governance – means thoroughly managing the entire organization by accepting all internal components that work together but which will eventually be integrated with the management and implementation of risk management within the organization as well as with the financial management and internal control system including the internal audit.

Corporate governance provides a greater degree of assurance that an effective control system is in place at the entity level, thus ensuring that the business is managed in the interest of investors (shareholders) and stakeholders. Therefore, if the Corporate Governance is the premise of transparency of the company's activities, in order to protect the interests of the social partners, the guarantee of achieving the objectives is the audit.

The governance system is in accordance with the provisions of Law 24/2017 on issuers of financial instruments and market operations, Law no. 31/1990 republished, with all subsequent amendments, CNMV Regulation no. 6/2009, Law no. 111/2016 for approving the Government Emergency Ordinance no. 109/2011 on corporate governance of public enterprises, BVB Code, the Corporate Governance Code of the BVB and those of the Articles of Association of the Company.

Solidity of the Antibiotice team is demonstrated through the strategic guidance of the company and promptness with which it is capable to react, developing responsible and transparent business practices. This is true for the management team, operational teams and for the entire staff of the company that succeed in achieving a balance between compliance and performance.

In 2017, our company proved consistency in its strategic directions accompanied by appropriate investment programs. This was done by applying the good corporate governance principles, what enabled the mobilization of the entire potential of our employees for implementing and maintaining high standards in all the company's activities.

The governance  
system of the  
company is based  
on:

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

# Management Board

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

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

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

Thus, on the monthly meetings, the Management Board analyzed in detail the financial results obtained in the reporting period and cumulatively since the beginning of the year as well as the economic performance relative to the budget and to the same period last year. Depending on the situation, the Board requested, detailed explanations from the executive management in connection with the plans for increasing the production efficiency, investment plans, provisions made, liquidity management, operational and general profitability and of activity as well as the commercial policies. After analyzing in detail the results of the period, the Management Board decided their approval for publishing and sending them to the Bucharest Stock Exchange and Financial Supervision Authority, falling each time within the Financial Communication Calendar.

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 adviser, Ionuț-Sebastian IAVOR, 42 years old  
President of the Management Board and representative  
of the Ministry of Health**

At the Ordinary General Meeting of Shareholders held on April 30, 2015 Mr. Iavor was elected as a member of the Management Board and then appointed by the Board's members as a President.

Mr. Ionuț Sebastian Iavor is currently General Manager of the General Directorate for Human Resources, Legal Issues and Litigation of the Ministry of Health.

**Number of Antibiotice SA shares held - 0\***

**Economist, Ioan NANI, 58 years old  
Vice President of the Management Board and General  
Manager**

At the Ordinary General Meeting of Shareholders held on April 19, 2016, Mr. Nani was reconfirmed as a member of Management Board, for a 4-year period, the members of the Management Board electing him as the Board's Vice President. Mr. Nani is an economist specialized in management and accountant expert, member of the Management Board since 2009 and General Manager (1998 - 2008 and 2009 - present).

**Number of Antibiotice SA shares held – 1,513\***

**Physician, Adela-Petrinia NEAGOE, 59 years old**  
**Member of the Management Board and representative of the Ministry of Health**

At the Ordinary General Meeting of Shareholders held on March 20, 2014, Ms. Neagoe was elected as a member of the Management Board for a 4-year period.

PhD in Medical Sciences, Primary Care Physician in Pediatrics, Primary Care Physician in Public Health and Sanitary Management, member of the Management Board since March 20, 2014 and Government Inspector within the General Secretariat of the Government of Romania.

**Number of Antibiotice SA shares held - 0\***

**Economist Nicolae STOIAN, 61 years old**  
**Member of the Management Board and representative of the shareholder SIF Oltenia and other shareholders - legal entities**

At the Ordinary General Meeting of Shareholders held on April 19, 2016, Mr. Stoian was elected as a member of the Management Board for a 4-year period.

Tax consultant and Accounting expert.  
ment of Romania.

**Number of Antibiotice SA shares held - 0\***

**Engineer, Elena CALITOIU, 55 years old**  
**Member of the Management Board and representative of the shareholder SIF Oltenia and other shareholders - legal entities**

Confirmed as a member in the OGMS held on April 19, 2016, for a 4-year period.

Mechanic engineer and Director of Placements & Risk Management Department, S.I.F. Oltenia, member of the Management Board since 2016.

**Number of Antibiotice SA shares held - 0\***

\* Number of Antibiotice shares (ATB) held on September 11, 2017, according to the latest database owned by Antibiotice for 2017.

## Advisory Committees

**In 2017, the specialized advisory committees had the following composition:**

**Audit Committee:** Mr. Ionut Sebastian Iavor, Mr. Nicolae Stoian and Mrs. Elena Calitoiu;

**Nomination and Remuneration Committee:** Mrs. Elena Calitoiu and Mrs. Adela-Petrinia Neagoe;

**Trade Policy Committee:** Mr. Ionut Sebastian Iavor and Mr. Nicolae Stoian.

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

**The Audit Committee had 5 meetings with the following objectives:**

- to examine and verify the fairness of the annual and interim consolidated financial statements of the trading company and any other financial reporting before their submission to the Board for approval;
- to analyze and recommend to the Management Board the appointment, reappointment or revocation of external auditors;
- to periodically evaluate the efficiency, independence and objectivity of the external auditor and to monitor the relationship with this auditor;
- to propose additional verifications in specific areas which may be required from the external auditor;
- to analyze and approve the tasks of the Internal Audit Office and to monitor its activity to ensure that it acts objectively and independently.

**The Trade Policy Committee** met in two sessions aiming at assessing the commercial activity in the domestic and foreign market.

**The Nomination and Remuneration Committee** met in three sessions having as objectives the observance of the principles and criteria of remuneration, evaluation of objectives and performance criteria for 2017.

## Executive management

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

The executive management of Antibiotice is ensured by ten directors, one of whom is the General Manager who is also the Vice President of the Board and nine specialty executives.

## Antibiotice's Executive Management on December 31, 2017

### **Ec. Ioan Nani, 58 years old General Manager and VicePresident of the Management Board**

Graduated from the Faculty of Economic Sciences of Alexandru Ioan Cuza University of Iași, Mr. Nani is an economist specialized in management and an expert accountant.

Between 1991 and 1993 he worked as a financial inspector with the General Directorate of Public Finance Iași and then with the Court of Auditors of Romania. In 1994, Mr. Nani returned to Antibiotice as a Financial Executive Director and became General Manager in 1998. In February 2009, he was appointed Vice President of the Authority for State Assets Recovery (AVAS), and in June, same year, he was appointed General Manager of Antibiotice.

Mr. Nani has been General Manager since 2009

**Number of Antibiotice SA shares held – 1,513\***

### **Engineer, Cornelia Moraru, 52 years old Technical & Production Director**

Mrs. Moraru graduated from the Faculty of Chemical Technology of Gheorghe Asachi Technical University Iași. After graduation, she worked as a chemical engineer at the Fălticeni Chemical Factory. Mrs. Moraru has been working with Antibiotice since 1990, firstly in the Penicillin Plant II until 1998 and then in the Biosynthesis Department for a year. Starting July 1999 she worked as a biosynthesis technologist in the Penicillin Plant II. In January 2001 she was appointed as the Head of the Tablet Plant. In May 2003 she was appointed Director of the Pharmaceutical Division.

Mrs. Moraru has been Technical & Production Director since 2005.

**Number of Antibiotice SA shares held – 1,513\***

### **Economist Paula Luminita Coman, 50 years old Financial Director**

Graduated from the Faculty of Economics and Business Administration of Alexandru Ioan Cuza University of Iași, Mrs. Coman has been an expert accountant since 2006 and tax consultant since 2007.

After graduation, Mrs. Coman worked as an economist at the County Iași Tourism Office. Mrs. Coman has been working with Antibiotice SA since 1991. Firstly she was an economist in the Pricing Efficiency Office. In 1998 Mrs. Coman became the Head of Economic Analysis Department and then Head of Financial-Accounting Department in 2003.

Mrs. Coman has been the Financial Director since 2011.

**Number of Antibiotice SA shares held - 0\***

### **Economist, Vasile Chebac, 63 years old Commercial & Logistics Director**

Graduated from the Faculty of Economic Sciences of Alexandru Ioan Cuza University of Iași, Mr. Chebac has been an active member of the Body of Expert and Licensed Accountants of Romania, Iași Branch since 1993 and a financial auditor, member of the Chamber of Auditors of Romania since 2008.

Starting with February 1991 he worked as a financial inspector at the General Directorate of Public Finance Iasi and, from July 1993, he worked as a financial inspector at the Chamber of Auditors Iași. In January 1998 Mr. Chebac was appointed Chief Commissioner at the Financial Guard Iași. In September 2001, he returned to Antibiotice SA as a Commercial & General Services Director.

Mr. Chebac has been Commercial & Logistics Director since 2005.

**Number of Antibiotice SA shares held - 0\***

### **Engineer, Eugen Florin Osadeț, 62 years old Engineering & Investment Director**

Graduated from the Faculty of Mechanics of Gheorghe Asachi Technical University of Iași, In 2000, Mr. Osadeț obtained the Master's Degree in Management and Business Administration at the same university.

He has been working with Antibiotice SA since 1980, initially as a mechanic engineer in the team for obtaining the industrial cold and then as a thermal energy dispatcher. In 1997 he became the Head of the Thermo-Energetic Workshop.

Mr. Eugen Osadeț has been Engineering & Investment Director since 2000.

**Number of Antibiotice SA shares held – 1,511\***

### **Engineer, Cristina Lavinia Dimitriu, 60 years old Quality Director**

Graduated from the Faculty of Chemical Technology of Gheorghe Asachi Technical University of Iași, Mrs. Dimitriu obtained in 2000 the Master's Degree in Management and Business Administration at the same university. In 2007, she obtained the degree of Master in Management and Marketing granted by the Faculty of Pharmacy of the Grigore T. Popa University of Medicine and Pharmacy Iasi. Starting with the same year, he has become a PhD student of the Pharmacy Faculty Iasi .

After graduating from the faculty, she worked as a chemist engineer at the Fagaras Chemical Plant. She has been working with Antibiotice SA since 1987, initially in the Biosynthesis-Lysine Plant. In 1990, she became the production manager of the Parenteral Product Plant and, in 2000, she became Quality Control Manager for physico-chemical and microbiological

analyzes. In 2007 she has become the qualified person in the manufacturing/import units of the medicines for human use and the representative of the management team for the integrated management system.

Ms. Lavinia Dimitriu has been Quality Director since 2003.

**Number of Antibiotice SA shares held – 0\***

**Economist, Gica Rusu, 54 years old**  
**Human Resource Director**

Graduated from the Faculty of Economic Sciences of Alexandru Ioan Cuza University of Iasi, Mrs. Rusu obtained in 2003 the Master's Degree in Management and Business Administration at the same university.

She has been working with Antibiotice since 1981, initially as an economist in the Penicillin Plant and then, starting with 1996, in the Financial Department. In 1999, she became the Head of Human Resources Department.

Mrs. Rusu has been Human Resources Director since 2004.

**Number of Antibiotice SA shares held – 1,510\***

**Economist, Ovidiu Bătagă, 40 years old**  
**Marketing & Domestic Sales Director**

Graduated from the Faculty of Economics and Business Administration (FEAA) of Alexandru Ioan Cuza University of Iasi, Mr. Bătagă holds three master's degrees in financial Management (granted by the same university in 2001), pharmaceutical marketing (granted by the Grigore T. Popa University of Medicine and Pharmacy Iasi in 2003) and project management (granted by the Gheorghe Asachi Technical University in 2007).

After graduating from the faculty, he was a junior teaching assistant at the Currency and Credit Department, Finance specialty within FEAA. He has been working with Antibiotice SA since February 2001, initially as an economist in the Economic Analysis Department then in the Accountancy Department and Marketing Department. In January 2006 he was appointed as the Head of Market Analysis & Strategic Planning Department.

Mr. Bătagă has been Marketing & Domestic Sales Director since 2010.

**Number of Antibiotice SA shares held – 0\***

**Physician, Mihaela Moşneguţu, 48 years old**  
**Medical Director**

Graduated from the Faculty of General Medicine of Grigore T. Popa University of Medicine and Pharmacy Iasi, Mrs. Moşneguţu is a specialist in family medicine.

She started her professional activity as a physician in the Iaşi County. She has been working with Antibiotice since 2000, initially in the Promotion Office, becoming the Head of this office in 2001. In 2005, she became the Head of Pharmacovigilance and Medical Consultancy Department and then, in 2009, she was appointed as the Medical & Retail Promotion Manager.

Mrs. Moşneguţu has been Medical Director since 2011.

**Number of Antibiotice SA shares held – 0\***

**Economist, Mihai STOIAN, 42 years old**  
**International Business Director**

Graduated from the Faculty of Economic Sciences of Alexandru Ioan Cuza University Iasi, in the International Economic Relations section.

He has been working with Antibiotice SA since May 2005, initially as an Area Sales Export Manager – Active Ingredients. In July 2008, Mr. Stoian was

appointed as the Head of the Intra-Community Deliveries & Export Department.

In August 2009, he became Export Manager and then, in June 2011, Business Development Manager.

Mr. Stoian has been International Business Director since 2012.

**Number of Antibiotice SA shares held - 0\***

**\*No of shares held on 11th September 2017 as per the latest 2017 database.**



# Code of Ethics

The Code of Ethics of Antibiotice SA presents the ethical standards of conduct that establish and regulate the corporate values, the company's business responsibilities and obligations and how it works.

The Code of Ethics provides rules in key areas relating to employees, human rights, environmental management, social responsibility and corporate governance and contains the guidelines that help the company pursue its values.

The Code is a set of rules based on which the company has developed, rules of ethical behavior in business and how to prevent illegal actions that might arise during the course of affairs within the

company. The Code is binding and applies to all structures and activities of the company.

The Code of Ethics is a fundamental commitment of our company to do its best in order to comply with the high ethical standards and applicable legal requirements wherever it operates.

The Code of Ethics is presented in detail on the website of the company ([www.antibiotice.ro/Investors/CorporateGovernance/Reference documents /Code of Ethics](http://www.antibiotice.ro/Investors/CorporateGovernance/Reference%20documents/Code%20of%20Ethics))

# Code of Corporate Governance

The Code of Corporate Governance of Antibiotice SA embraced the principles and recommendations of the Bucharest Stock Exchange and represents the tool through which Antibiotice implements these principles and recommendations by observing the rules of corporate governance.

The aim of the Corporate Governance Code is to create the framework for establishing strong relationships with the shareholders and other holders of interests, as well as for an effective and transparent, trust-based communication.

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

Chapter I – Responsibilities of the Management Board

Chapter II - Risk Management and Internal Control System

Chapter III - Fair reward and motivation

Chapter IV - Investor relations

It also has two annexes:

Annex I - Management Board's Rules of Procedure

Annex II - Rules for evaluating the Antibiotice's administrators

**Chapter I - Responsibilities of the Management Board**, defines the role of this body while setting the guidelines in terms of competence, experience, knowledge and independence of its members, enabling them to effectively perform their specific duties and responsibilities.

**Chapter II - Risk Management and Internal Control System** demonstrates that the company's activity is supervised by certain risk management and internal control systems set up for this purpose. Also, internal audits are conducted in order to assess independently and periodically the safety and effectiveness of the risk management and internal control systems.

**Chapter III - Fair reward and motivation**, establishes the general principles and conditions that are the foundation of the method for

setting the level of remuneration for the members of the Board and for the company's management team.

**Chapter IV- Investor relations** states the fact that Antibiotice must make constant efforts to provide the shareholders with updated information on events of interest to them (e.g. general meetings of shareholders, payment of dividends, etc.).

In conclusion, the Corporate Governance Code of Antibiotice SA and its annexes draws the general framework under which the Management Board develops its activity in accordance with the rules and principles of corporate governance established by the Bucharest Stock Exchange, in order to create an attractive capital market, based on the best practices, transparency and trust.

# Rights of holders of financial instruments

## The adopted and applied corporate governance framework:

**protects** the shareholders' rights;  
**ensures** the fair treatment of all shareholders,  
**recognizes** the role of third parties with interests in the company,  
**guarantees** the information and transparency,  
**assures** the Management Board's responsibility towards the company and the shareholders.

On the website address [www.antibiotice.ro/investors/information for shareholders](http://www.antibiotice.ro/investors/information-for-shareholders), there is a section dedicated to shareholders for accessing and downloading documents related to the General Meetings of Shareholders: procedures relating to the access to and participation in the meetings, convening notice, additions to the agenda, informative materials, special proxies, correspondence voting forms, draft decisions, resolutions, results of votes etc.

The company provides all interested parties with periodic and annual financial statements drafted in accordance with the legislation in force. The company meets also all the publishing requirements in

accordance with the legislation on the trading companies and capital market.

The company has a specialized department called Investor Relations responsible for developing a good communication with the company's current and potential shareholders. The persons responsible for maintaining the connection with the investors treats with maximum efficiency the shareholders' requests and facilitates the dialogue with the company's management team. The company creates and develops an adequate policy to promote the effective communication with the shareholders and investors.

# General Meeting of Shareholders

The 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.

In 2017, the Management Board convoked three Ordinary General Meetings on **April 6, 2017, June 28, 2017 and September 20, 2017** and an Extraordinary General Meeting of Shareholders on April 6, 2017.

All the documents necessary for the proper conduct of the General Meetings were published in due time and according to the legislation in force.

The Ordinary General Meeting of Shareholders held on **April 6, 2017** approved the company's financial results for 2016 drafted in accordance with the Order of Minister of Public Finance no. 881/25.06.2012, Order of Minister of Public Finance no. 1286/2012 for the approval of the accounting regulations compliant with the international financial reporting standards, applicable to the trading companies whose securities are admitted to trading on a regulated market, Order of Minister of Public Finance no. 1690/2012 regarding the modification and completion of some accounting regulations, Order of Minister of Public Finance no. 123/2016 on the main aspects of preparing and submitting the annual financial statements and accounting reports of economic operators to the territorial units of the Ministry of Public Finance.

Within the same meetings, the following decisions were taken:

- Approval to distribute the net profit for 2016 amounting to 30,370,811 lei, setting the gross dividend at 0.03835158 LEI per share and the beginning of the payment of dividends with the date of 15.09.2017;
- Approval for registering the unsolicited and unclaimed dividends for the fiscal year 2012 as revenues;
- Approving the discharge of administration for the activity conducted in the fiscal year 2016, base on the submitted reports;
- Approval of the Income & Expenditure Budget for 2017;
- Approval of the degree of achieving the objectives and performance criteria for 2016 for the members of the Management Board;
- Approving the objectives set in the management plan for the members of the Management Board for 2017.

The Extraordinary General Meeting of Shareholders approved:

- to extend for 12 months the validity period of the multicurrency multiproduct credit amounting to 30 million LEI borrowed by Antibiotice SA from the Export-Import Bank of Romania - Exim-Bank SA;
- to maintain the guarantees relative to the multicurrency multiproduct credit amounting to 30 million LEI throughout the entire validity period resulting from the extension above mentioned in the para 1 in the Agenda;
- to issue a decision-commitment of Antibiotice SA not to divide itself, not to merge or decide the anticipated dissolution throughout the entire validity period of the multicurrency multiproduct credit without the prior consent of Eximbank SA;
- to empower Mr. Ioan Nani, General Manager and Mrs. Paula Coman, Financial Director to sign on behalf of the company all the documents related to the credit facility extension, in accordance with the paragraphs 1 and 2 in the Agenda, as well as the documents related to the obligations assumed by the company in accordance with the paragraph 3 in the Agenda;
- to change, update and renumber some articles from the Articles of Association;
- to establish the company's representative office in Vietnam in the Sannam building located on Duy Tan St. 78, Dich Vong Hau Ward, sector Cau Giay, Hanoi.

The Ordinary General Meeting of Shareholders held on **June 28, 2017** approved:

- the financial audit contract concluded with the Accountancy, Expertise and Accounting Consultancy Company - SOCECC Ltd. Bucharest, for a three-year period;
- remunerations for the members of Management Board according to the provisions of the Government Emergency Ordinance no. 109/2011 on corporate governance of public enterprises;
- to approve the Antibiotice's membership to the Romanian Association of the Self-Care Industry - RASCI;
- to approve the participation of Antibiotice SA Iasi as a founding member in the establishment of the Patronage of Industrial Medicines Producers in Romania – PRIMER.

The Ordinary General Meeting of Shareholders held on **September 20, 2017** approved the company's financial statements for the first semester of 2017, based on the Management Report and Financial Auditor's Report.

# Internal Control

The specialized internal control activities specified by the legislation in force are made by the Internal Audit Office. These are the followings: internal audit, financial management control, management control; these activities are carried out in a methodological and procedural framework regulated by laws, norms and codes of professional conduct specific to each activity.

The procedure of setting and achieving the objectives of the Internal Audit Office, findings and recommendations resulted from all internal control actions were quarterly submitted to the Audit Committee of the Management Board for evaluating the activity and internal control within the company.

The internal audit activity is organized and developed in accordance with the provisions of:

- Law no. 672/2002, on internal public audit;
- Its own methodological norms, issued on the basis of G.D. no. 1086/2013, for approving the General Norms on the exercise of public internal audit;
- O.M.F.P. no. 252/2004, Code of Ethics of the Internal Auditor, with subsequent amendments and additions;
- Corporate Governance Code of Antibiotice S.A.

9 internal audit missions were undertaken in 2017. They were planned in the Annual Internal Audit Plan, approved by the Audit Committee, extracted from the Multi - Annual Audit Plan for 2015-2019. The objectives of the internal audit missions aimed at:

- examining if the principles, specific procedural and methodological rules are met;
- examining the way of organizing the activity;
- evaluating the management and control system of the activity;
- other objectives specific to the audited structure's domain of activity.

Internal audit missions assessed the activity of audited structures and found that their management and control systems were transparent, in accordance with the rules of legality, regularity, efficiency and effectiveness.

Internal audit activities are carried out systematically and methodically, objectively ensuring and counseling the management on the functionality level of the control systems applied to its activities in order to eliminate / mitigate the potential risks that may affect the achievement of the company's objectives.

The activity of financial management control is organized by internal decision, according to art. 3, para 5, letter a), e) of the Emergency Government Ordinance no. 94/2011, regarding the organizing and functioning the economic-financial inspection and to the

Methodological Norms of the Decision no. 1151/2012, regarding the organizing and exercising the financial management control.

The financial management control was carried out under the Control Plan for 2017 approved the company's manager. Six control actions were carried out with the following objectives:

- to verify the compliance with the legal provisions on the registration in the accounting records of the economic and financial operations;
- to verify the compliance with the legal provisions regarding the execution of the revenue & expenditure budget;
- to verify the compliance with the legal provisions in substantiating the draft income and expenditure budget for 2017;
- to verify the legal provisions and internal regulations on how to perform the annual inventory of assets, debts and equity at 31.12.2017;
- to verify the compliance with the legal provisions and internal regulations in respect of receipts and payments in LEI and foreign currency of any kind, in cash or by transfer;
- to verify the compliance with the legal provisions and internal regulations regarding the preparation, circulation, keeping and archiving of primary, accounting and technical-operative documents.

As a result of the financial control actions, control reports were drawn up, according to the established objectives, containing the findings and measures proposed for improving the verified activities. The issued control reports were submitted to the General Manager, who decided the implementation of the proposed measures.

The management control activity is organized according to the legal and procedural framework established by:

- Accounting law no. 82/1991, republished and updated;
- Law no. 22/1969 on the employment of managers, setting up of guarantees and the responsibilities involved in the management of goods;
- O.M.P. F. no. 2861/09.10.2009 for approving the rules on the organization and conduct of the inventory of assets, liabilities and equity;
- Operating procedures, Internal Notes, Internal Decisions of the company's management.

In 2017, a total of 15 inventory actions were undertaken for: the central warehouses for raw materials, materials and finished products and inventories of raw materials and materials within the manufacturing plants.

The objectives pursued in the inventory control activities were: confronting the scripted stocks with the factual stocks in order to establish the possible differences; determining the causes of the differences found; correlating scripted stocks with factual stocks.

As a result of the verifications carried out, it was found that the legal regulations and internal decisions regarding the stock management were observed and there is a correlation between the scripted and factual stocks resulting from their good management.

The minutes drawn up during the stock inventory were sent to the Accounting Office so that the results to be used by the central committee designated for the annual inventory of the patrimony as a preparatory stage for drafting the financial reporting.

The internal control structure within Antibiotice, through the missions carried out, assured itself that, in the financial statements of 2017, the balance sheet items related to the fixed assets, stocks, receivables and debts are presented in accordance with the reality.



# Risk management

Risk management continuously evaluates the risks to which the company's activity is or may be exposed, affecting the achievement of the objectives. It aims to achieve the predicted indicators under the controlled risk conditions, ensuring the continuity of the activity and protecting the shareholders' and clients' interests.

The main purpose of risk management is to help understand and identify the risks to which the organization is exposed, so that they can be anticipated and managed without adversely affecting the organization's goals.

Running the risk management processes ensures the identification, analysis, assessment and management of risks to keep them at acceptable levels, depending on the company's risk tolerance and its ability to cover (absorb) these risks.

The main categories of risks which may occur in the company's activity are: financial, economical, technological, marketing, image, legislative.

The Company is exposed through its operations to the following financial risks:

Liquidity risk  
Foreign Exchange Risk  
Commercial risk/default risk  
Legislative Risk  
Image Risk

## Foreign exchange risk

**The 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.

Exchange rate fluctuations are reflected both in the costs of imported raw materials, as well as in the prices of finished goods for export.

During 2017, there were periods with a higher volatility, with depreciation time ranges of the Romanian LEU amid the domestic

and international events.

Since the beginning of the year, the national currency depreciated by 2.56% against EUR and appreciated by 9.9% against USD which fell below 4 LEI since August.

So, in 2017, foreign exchange earnings amounted to 4,786,767 LEI while the expenses were 8,047,855 LEI. The general impact of exchange rate differences generates a loss of 3,261,088 LEI

## Liquidity risk

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

Liquidity risk may occur in the following circumstances: collection of receivables at maturities exceeding 300 days; unpredictability and lack of transparency for the clawback tax calculation; insolvency of some customers; increasing the price of raw materials, utilities, and services.

The company's liquidity management policy is to maintain, to the

extent possible, sufficient liquidity to meet its obligations as they mature.

For controlling the risk, the company supervises the followings: level of expected cash inflows from the collection of trade receivables as well as the level of expected cash outflows for the payment of commercial debts and other debts, cover of the gap between receipts and payments from credits; negotiations with the suppliers for extending the payment terms.

## Commercial (default) risk

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

Default risk can arise in a number of circumstances: large exposures to the major distributors, long payment deadlines; insolvency of some pharmacies and distributors. In order to mitigate the commercial (default) risk and bring it into the tolerable area, the company took

the following steps: assessment of the trading partners' creditworthiness by checking them, before the conclusion of the contract; development of a relationship of loyalty with the customers by organizing periodical meetings for constructive approaches; request for guarantees (securities collateral agreements, letters of banking guarantee); cease of deliveries until the outstanding amounts are paid; expenditure provisions for covering the risk of default.

## Legislative risk

Legislative changes regarding the pharmaceutical market lead to the emergence of **legislative risk**, which must be continuously managed.

Pharmaceutical market is a regulated market, with clear legislative requirements elaborated for controlling the quality and therapeutic efficiency of the medicines present in the market and for avoiding counterfeiting.

Conformation to these requirements is reflected both in additional costs related to updating the documentation of compliance with the latest quality standards, in terms of the impact on the maximum

sales prices as well as in the delays in the marketing of the products.

The company's strategy of managing these risks involves a permanent concern for obtaining international certifications for the manufacturing flows, updating the authorization documentation for the products in the portfolio, conducting bioequivalence and stability studies, continuously pursuing legislative changes at international level.

Reducing the risk of legislative instability will be achieved by continuously adapting the policies, rules and procedures to the occurred changes.

## Image risk

Image risk is defined as the current of future risk which negatively affects the profits and capital because of the unfavorable perception of the company's image.

In order to effectively manage the events that could lead to the risk of image, the following measures are envisaged: monitoring of the company's image in the mass media in order to identify any rumors which could generate image risks; periodical press releases with positive information; a good and transparent relation with the mass media; control of risks which could affect the company's image.

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

In the process of evaluating the risks, the company identified a series of risks that can not be controlled, namely:

- risk of natural disasters (earthquake, flood, fire, etc.);
- risk of wars or ethnic conflicts;
- risk of economic instability;
- risk of social instability (strikes, labor disputes, etc.);
- risk of legislative instability;
- risk of classified information leakage.

The company will apply all the measures at its disposal to mitigate the effects of these risks by developing specific plans:

- emergency** evacuation plan;
- plan of intervention** in case of natural disasters (earthquake, flood);
- fire intervention** plan;
- accident prevention** policy involving dangerous substances (acetone, methanol);
- program for preventing** the classified information leakage.

All these plans are for protecting the employees, assets and environment.



# Company Performance

## Strategic evolution

### New products in the portfolio

In 2017 we obtained:

Marketing Authorizations for seven medicinal products:

**Betahistină Atb®**

8 mg and 24 mg, tablets, cardiovascular system;

**Ertapenem Atb®**

1 g, powder for solution for infusion, anti-infectives for systemic use;

**Caspofungină Atb®**

50 mg and 70 mg, powder for concentrate for solution for infusion, anti-infectives for systemic use;

**Tigeciclină Atb®**

50 mg, powder for solution for infusion, anti-infectives for systemic use;

**Clobetazol Atb®**

0,5 mg/g cream, dermatological preparations.

**Notification** for 2 new dietary supplements: **Sprinten®** film-coated tablets and **Fezivit® C** capsules.

**9 new marketing authorizations** for Antibiotic products in countries in Europe, Asia and Africa, and the completion of 21 re-authorization procedures for existing products. Continuing the two European decentralized procedures (DCP) for simultaneous authorization in EU countries for Perasin® (piperacillin / tazobactam) of 2.25 g and 4.5 g of powder for solution for infusion and Nebivolol Atb® 5 mg and 10 mg tablets, procedures to be finalized in the first part of 2018.

## Performance on the domestic market

- Leader in prescription generics for hospitals;
- Occupies the 4th place among the 123 producers of prescription medicines on the Romanian market (8.8% market share);
- The Romanian manufacturer of the full range of essential anti-tuberculosis drugs;
- Strengthening the leading position in the market of generics and non-prescription medicines sold in Romanian hospitals with a market share of 17.4%;
- 14th place in the top of companies operating on the OTC market in Romania (out of a total of 213 companies), climbing one position compared to 2016;
- Strengthening the 4th position among manufacturers of generic prescription drugs and non-prescription medicines (OTC) in Romania.
- Higher and balanced use of the drug portfolio, with significant increases in non-prescription medicines (+ 26% over 2016);
- Strengthening leadership position in Hospital Antiinfectives (injectables) by registering a market share of 43% in 2017;
- Strengthening the leading position in the injectable powders market, the Hospital segment, both in terms of consumption (market share of 79.1%) and in terms of value, with a market share of 26.6 %;
- Maintaining the leadership position in the suppository market both in terms of volume (40.3% market share) and value (23% market share) and maintaining the leading position on the ointment market in quantitative terms (27% market share).

## Active presence on the foreign market

- Exports turnover amounting to 28.75 million dollars;
- No.1 worldwide producer of Nystatin;
- Drugs exported to 75 countries;
- Share of exports in total turnover is 35%.



## Top 20 most recognized Antibiotic brands

The top 20 brands (by value of sales) marketed by Antibiotic 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®	food supplement	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	nebivololum	Cardiovascular system - beta blockers - tablets	Nebile® (Menarini) Nebivolol Actavis(Teva) Nebivolol Torrent (Torrent Pharma)

Brand name	International common name	Therapeutic class + Method of administration	Main competitors
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	Unique product
Ranitidină Atb® 150 mg	ranitidinum	Digestive tract and metabolism - anti-ulcerous drugs - tablets	Ranitidină (Laropharm) Ranitidină (Lab. Magistra) Ranitidina LPH (Alvogen)
Silithor®	food supplement	Digestive tract and metabolism - hepatoprotective - capsules	Ranitidină (Laropharm) Ranitidină (Lab. Magistra) Ranitidina LPH (Alvogen)
Glycerin Suppositories for Adults Glycerin Suppositories for Children	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 + Form of administration
Aceclofen® 500 mg/50 mg	diclofenacum + paracetamolum	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

Brand name	International common name	Therapeutic class + Form of administration
Hemorzon® ointment	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system - antihemorrhoidal for topical use - Ointment
Hemorzon® pessaries	tetracyclinum + hydrocortisonum+ benzocainum	Cardiovascular system - antihemorrhoidal for topical use - suppositories
Hydrocortizon Atb® 10 mg/g	hydrocortisonum	Dermatological preparations Ointment
Lisinopril Atb® 40 mg	lisinoprilum	Cardiovascular system Tablets
Nidoflor®	nystatinum + neomycini sulfas + triamcinoloni acetamidum	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 and 1 g	oxacillinum	Anti-infective drugs for systemic use Powder for injection
Penicilină G potasică 1.000.000 UI and Penicilină G sodică 400.000 UI and 1.000.000 UI	benzylpenicillinum	Anti - infective drugs for systemic use Powder for injection
Piafen®	metamizolum natrium + pitofenonum + fencipramidum	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® pessarie	metronidazolum + 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

# Financial evolution

Sales revenues in 2017 registered the value of 336.9 million RON, up by **1.3%** compared to 2016 when 332.4 million RON was registered, as a result of the company's sustained effort to consolidate business.

The **profit before tax** for the current year is **35.36 million RON**, higher than that registered in 2016 by 1% and 1% higher compared to the estimated profit in the Antibiotice Revenue and Expenditure Budget.

The profit after tax is RON 33.56 million, higher than the profit of 2016 by 11% and higher than the budgeted profit by 17%.

The net profit of 2017 in the amount of **33.558 thousand RON** is the result of the deductibility of the reinvested profit in technological equipment and of the doubtful debts highlighted.

## The evolution of the main economic and financial indicators

	31.12.2016	31.12.2017	2017/2016
Sales income	332,435,059	336,904,666	101.3%
Operating profit	39,529,669	37,325,063	94.4%
Gross profit	34,881,646	35,361,430	101.4%
Net profit	30,370,811	33,558,354	110.5%
Fixed assets	216,841,805	236,350,512	109.0%
Current assets, of which:	316,553,852	336,585,032	106.3%
- receivables	242,456,065	264,212,743	109.0%
- stock	60,195,101	67,264,546	111.7%
Total liabilities, of which:	124,329,298	156,057,704	125.5%
- commercial debt	49,045,370	55,535,974	113.2%
- bank credits	40,705,967	69,731,310	171.3%
Total assets	533,395,657	572,935,544	107.4%
TOTAL EQUITY	409,066,359	416,877,840	101.9%
Staff average number	1449	1420	98.0%
Work productivity	229.424	237.257	103.4%

Lei

		31.12.2016	31.12.2017
ROE (return on capital employed)	=Profit before interest and taxes / Equity	7.4%	8%
ROA (return on assets)	=Net Profit/Total Assets	5.7%	5.9%
EPS (RON/Share)	=Net profit/Share	0.045	0.050
NET PROFIT RATE	=Profit/Sales income	9%	10%
GENERAL LIQUIDITY	=Current Assets/Current liabilities	3.1	2.5
FAST LIQUIDITY RATE	=(Current Assets-Stocks)/Current liabilities	2.5	2.0
Level of indebtedness	=Debts/Total Assets	23%	27%
No. of shares		671,338,040	671,338,040

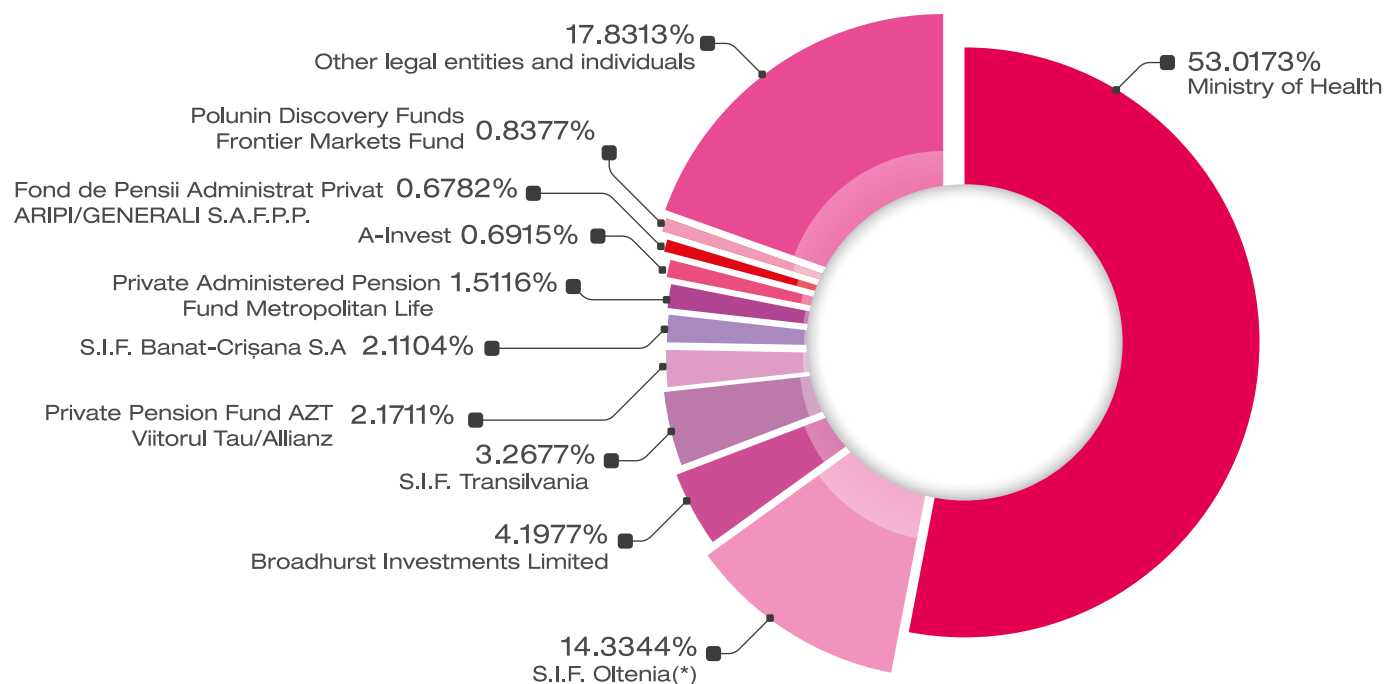
The company's main diagnostic indicators highlight the financial equilibrium and the perpetual concern for the business efficiency and adaptation to the business climate change, so that the liquidity indicators were slightly higher than in 2016, with indebtedness rising from 23% to 27%.

# Stock exchange evolution

I. Investors (according to the Shareholders' Registry on 11.09.2017)

- Ministry of Health(\*) - 53.0173%
- S.I.F. Oltenia(\*) - 14.3344%
- Broadhurst Investments Limited - 4.1977%
- S.I.F. Transilvania – 3.2677%
- Private Pension Fund AZT Viitorul Tau/Allianz – 2.1711%
- S.I.F. Banat-Crișana S.A – 2.1104%
- Private Administered Pension Fund Metropolitan Life – 1.5116%
- Polunin Discovery Funds – Frontier Markets Fund – 0.8377%
- A-Invest – 0.6915%
- Private Administered Pension Fund ARIPI/GENERALI S.A.F.P.P. – 0.6782%
- Other legal entities and individuals – 17.1824%.

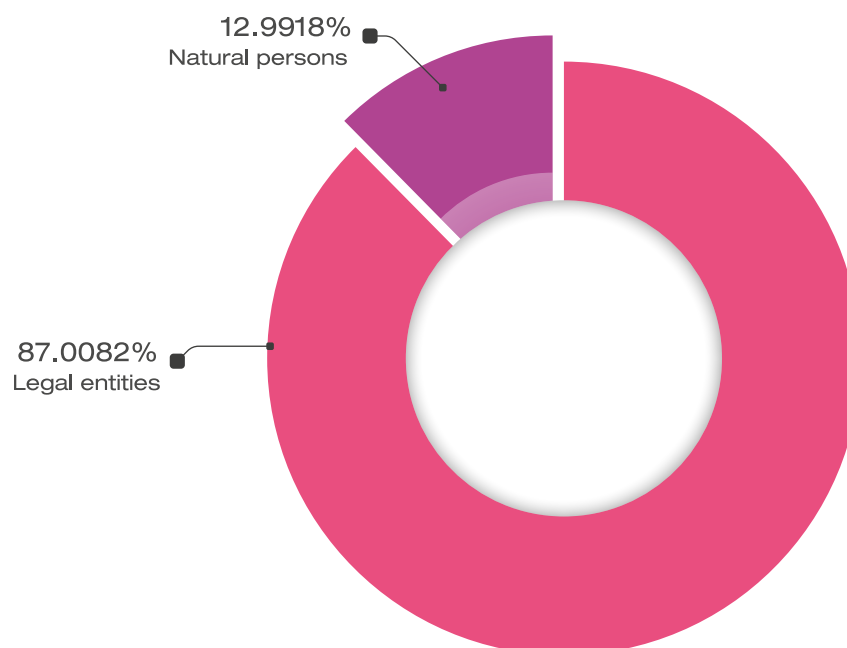
NOTE: (\*) - Significant shareholders, according to the Law no. 24/2017 on issuers of financial instruments and market operations , article 2, paragraph 1.



The ownership structure of investors



## II. Ownership structure



The ownership structure per classes of shareholders

In 2017, the company paid dividends for the fiscal years 2013, 2014, 2015 and 2016 amounting to 23,330,344.89 LEI, as follows:

### Dividend history (2013 – 2016)

Dividend history (2013 - 2016)

Period	Net dividends							Dividend payment suspending date
	Due	Paid				Not collected on 31.12.2016		
		lei			% (totally paid)	lei	%	
		Until 31.12.2016	01.01÷31.12 2017	Total				
2013	14,753,415	13,485,221.64	8,462	13,493,683.64	91.46	1,259,731.36	8.54	01.11.2017
2014	15,061,293	13,906,537.65	27,731.10	13,934,268.75	92.52	1,127,024.25	7.48	payment in progress
2015	13,753,343	12,579,067.01	36,611.78	12,615,678.79	91.73	1,137,664.21	8.27	payment in progress
2016	25,401,595	-	23,257,540.01	23,257,540.01	91.56	2,144,054.99	8.44	payment in progress

Dividends for 2013 were distributed directly from the company's headquarters, by bank transfer and postal order and those for 2014, 2015 and 2016, through the Central Depository Bucharest and, implicitly, through the CEC Bank.

# Antibiotice in the securities market

Since 1997, shares issued by Antibiotice are listed in the PREMIUM category of the Bucharest Stock Exchange under the symbol ATB.

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

Both the business plans and financial results recorded by our company represent a solid guarantee that Antibiotice has consolidated its position in the national pharmaceutical market.

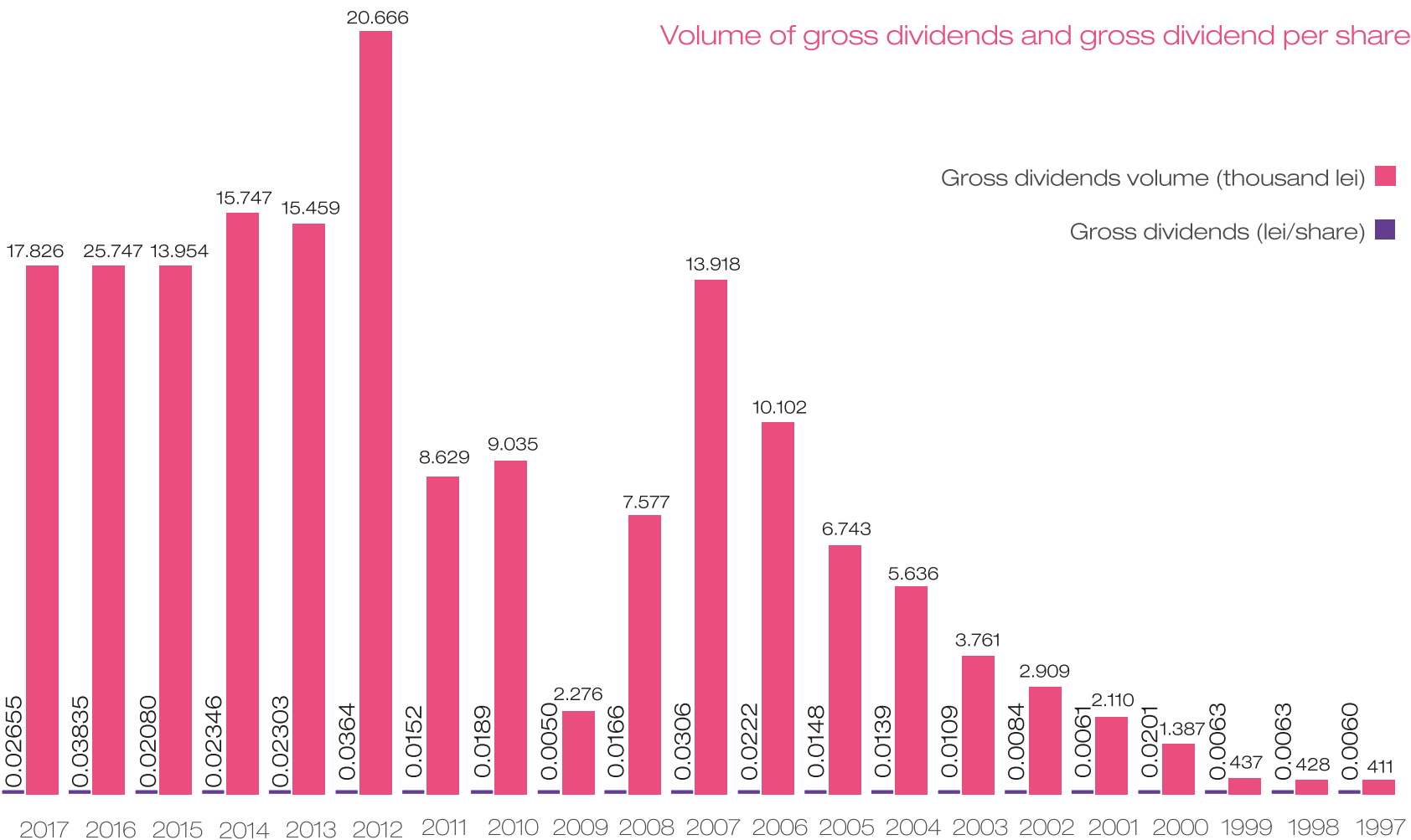
Antibiotice shares (ATB) traded on the Bucharest Stock Exchange:

- Are included in the BET-Plus index, which includes the Romanian companies listed on the BSE market that meet the minimum selection criteria except for financial investment companies.
- Are included in the BET-BK index, an index reflecting the evolution of share prices issued by local and foreign companies admitted to trading on the regulated market administered by the BSE.

This reflects the fact that Antibiotice is a solid company developed on a strong economic foundation.

In 2017, the minimum price of the ATB shares was 0.5200 LEI. The share price increased up to the maximum value of 0.5920 LEI/share.

The stock market capitalization of Antibiotice on December 31, 2017 (the last trading day of the year) was 361,180 thousand LEI.



### Antibiotice shares – ATB / Regular Market

Total traded value (million lei)	2013	2014	2015	2016	2017
Number of shares	671,338,040	671,338,040	671,338,040	671,338,040	671,338,040
Stock market capitalization (thousand LEI)*	374,607	390,719	357,152	349,096	361,180
Stock market capitalization (thousand EUR)*	83,919	87,173	78,868	76,875	77,511
Stock market capitalization (thousand USD)*	115,413	105,978	86,167	81,123	92,813
Total transaction value (million LEI)	23	16	11	6	12
No. of traded shares	48,439,486	27,467,454	18,844,935	12,555,866	21,113,565
Opening price (LEI/share)	0.3774	0.5520	0.5850	0.5320	0.5200
Maximum price (LEI/share)	0.5680	0.6170	0.6170	0.5420	0.5920
Minimum price (LEI/share)	0.3700	0.5410	0.5240	0.4200	0.5200
Price at the end of the year (LEI/share)	0.5580	0.5850	0.5320	0.5200	0.5380
Average price (LEI/share)	0.4692	0.5845	0.5836	0.5032	0.5585
Earnings/share (LEI/share)***	0.0467	0.0467	0.0405	0.0452	0.0500
Gross dividend/share (LEI/share)**	0.0230	0.0235	0.0197	0.0235	0.026552598
Dividend yield****	4.12%	4.03%	3.69%	4.05%	4.59%
Dividend Distribution Rate *****	49%	51%	49%	52%	53%

\* Calculated based on the share price on the last trading day of that year

\*\* Proposed dividend,

\*\*\* Calculation of earnings per share is based on the net profit of each year,

\*\*\*\* Dividend per share/ price of the share on the first trading day of each year,

\*\*\*\*\* Dividend distribution rate = (total number of shares x gross dividend per share)/ total net profit.

In 2017, a number of 21,113,565 shares were traded amounting to 11.8 million LEI (2.5 million EUR, 2.9 million USD), with an average price of 0.5585 LEI/share.

According to the Chapter VI , Section 2, Art. 92 – BSE Code, the Financial Communication Calendar for 2017 is presented below:

Events	Date
Presentation of the annual preliminary financial results - 2016	15.02.2017
General Meeting of Shareholders for approving the annual financial results - 2016	06/07.04.2017
Presentation of the Annual Report - 2016	07.04.2017
Presentation of Quarterly Reports:	First quarter 2017 15.05.2017 Third quarter 2017 15.11.2017
Meeting with the investors and analysts	18.05.2017
Presentation of the Half-Yearly Report 2017: Art. 65 (1) of the Law no. 24/2017	20/21.09.2017
Meeting with the investors and analysts	19.10.2017

# Actions and Results in 2017

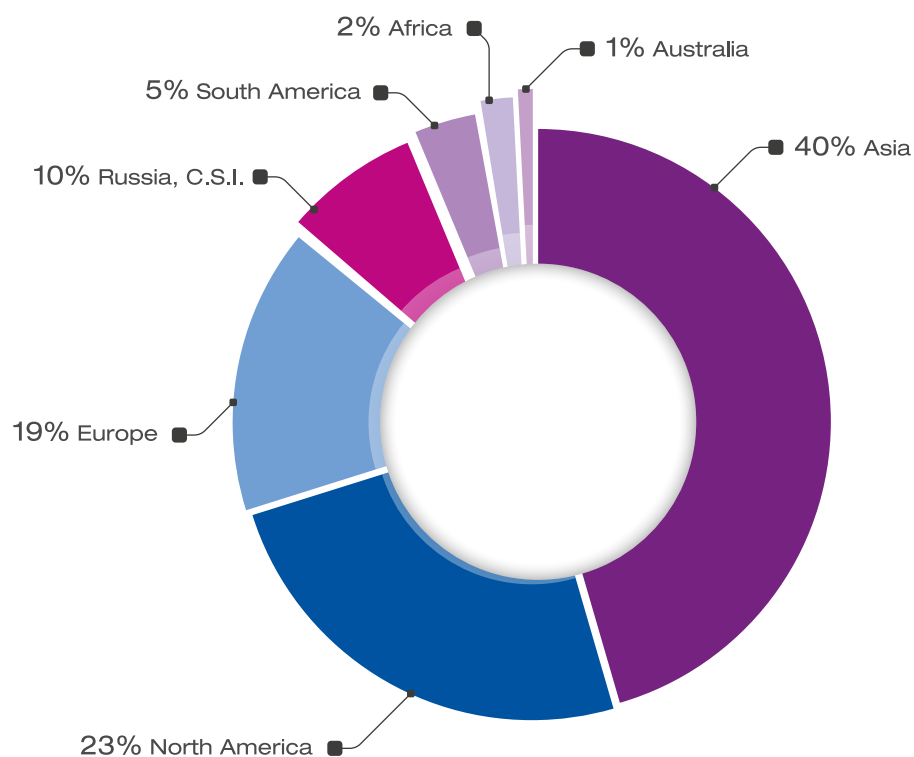
## Developing the company's international business

Antibiotice's exports amounted to 28.75 million USD in 2017, higher by 12.80% as compared to 2016.

The increase in export sales was generated both by the development of exports of finished pharmaceutical forms (+18.05%) and Nystatin API (+10.10%) as compared to the previous year.

Asia has been representing the main destination of the Antibiotice's sales in the international markets mainly due to rising the exports of finished products in the Vietnamese market. Nystatin API recorded the highest rhythm of growth in the US market with a significant impact on both the volume of exports but especially on the profitability of the product.

Europe is the third geographic area for the company's exports, being followed by Russia and CIS, South America and Africa.



Geographic breakdown of exports in 2017 (USD)

## Nystatin API – maintaining the world leadership

Nystatin API holds the largest share in sales in the foreign markets, being a strategic product of Antibiotice. Compliance with the requirements of international pharmacopoeias in force, quality certifications obtained and solid business partnerships built over time have allowed our company to become a world leader for this product. The most significant increase regarding Nystatin was recorded in the US market where the volume exported in 2017 was 50% higher than in the previous year. Increasing the market share in the US has represented a strategic objective of our company and the authorizations

granted by end-users create the premises for Antibiotice to become the main supplier of Nystatin in the US market.

In 2017, the main markets for Nystatin, active ingredient were: Asia (China, India, Vietnam), the Middle East (Iran, Irak, the United Arab Emirates) and Europe (Germany, The Netherlands). The geographic distribution of Nystatin exports made by Antibiotice overlaps with the world's largest consumer areas.

Antibiotice's strategy as regards Nystatin has two main objectives:

**Maintain** the world leadership position for this product;

**Increase** the market share in the regulated markets, especially in the US market.

This strategy is supported by the international certifications: FDA authorization for the Biosynthesis Plant and the Certificate of Suitability (CoS) issued by the European Directorate for the Quality of Medicines (EDQM) which allow access to the regulated markets.

## Exports of finished products

In 2017, the main destinations for exporting the finished products were: Asia (Vietnam), Europe (The Netherlands, the Baltic countries, Denmark, Serbia), North America (the US, Canada), Russia and the CIS (Republic of Moldova, the Russian Federation, Ukraine) and the Middle East (Irak, Yemen). The class of antiinfectives had the highest share in the export of finished products, followed by the medicines for the digestive tract and metabolism, cardiovasculars, dermatologicals and the medicines for the musculoskeletal system.

In the medium and long-term, Antibiotice intends to increase its presence in the international markets selling its top product

antiinfectives and dermatologicals) without neglecting the products with a high potential from other therapeutic areas (cardiovasculars, food supplements, etc.)

Developing the export of dermatologicals represents a strategic priority, taking into consideration the company's tradition in this area. Antibiotice intends to develop business partnerships with companies involved in this area in the international market for elaborating the registration documentations and marketing of these products.

## Development strategies tailored to the international pharmaceutical market

Pharmaceutical market has experienced major changes in recent years, being influenced by the social, demographic and economic context. Even though developed markets continue to remain the largest markets in terms of value, it is estimated that the emerging markets will have higher growth rates due to increased purchasing power and population access to health systems.

The medium and long-term Antibiotice's strategy is to tackle both developed and highly regulated markets as well as the emerging markets with a high growth potential. This strategy is supported by the EuGMP and U.S. FDA certifications of the manufacturing flows in the context in which the degree of regulation of international markets is steadily increasing.

The main directions for increasing the exports are:

- Develop/consolidate** our company's presence in the current markets and identify new markets with a high potential for Antibiotice;
- Focus** our efforts for increasing the exports in the strategic markets;
- Develop** new business models and partnerships in the external markets for speeding up our company's international development;
- Adapt** the product portfolio traded in the external markets to the specifics of local consumption.

Given the need to promote its products on foreign markets, Antibiotice started the procedures for setting up its own representative offices, the first of which being in Vietnam, a market on which our company recorded significant increases of the sales in the recent years. In the next period, the company's local offices will be opened in Ukraine and Republic of Moldova in order to boost our sales in these markets.

## International promotion

In 2017 Antibiotice participated for the sixteenth time at the CphI Worldwide Fair held in Frankfurt. The fair brought together 2,500 exhibitors from 150 countries and was visited by 36,000 professional visitors from the pharmaceutical field. Participation in the event was aimed both at negotiating and developing the current partnerships as well as developing the new business projects for export of finished pharmaceutical dosage forms and Nystatin API.



# Ensuring a sustainable and marketable portfolio by increasing the degree of product innovation

## The evolution of the pharmaceutical market in Romania

In 2017, the pharmaceutical market in Romania registered a 9.1% growth in the value of RON 14.12 billion compared to RON 12.95 billion in 2016. The positive trend was also registered at the physical consumption level of pharmaceutical products increasing it by 959 million physical units, from 11.7 billion units in 2016 to 12.6 billion in 2017.

With a share of 88% of the total sales and 98% of the total drug consumption, the retail channel (open-circuit pharmacies) is the main selling segment upon the pharmaceutical market in Romania. The hospital channel (hospitals) accounts for only 12% of the total value sales and 2% of quantitative sales.

On the Romanian pharmaceutical market, the original medicines have the supremacy in terms of value (57.2% of the total sales) but in terms of volume, most of the drugs consumed are generic drugs and OTCs (72.5%).

In terms of the prescription mode, the pharmaceutical market is dominated by prescription drugs (Rx) that account for 78% of the total value sales and 70.9% of the total drug use in Romania.

The increase of the population's interest in prevention, health and quality of life has led to an increase in the consumption of the OTC drugs and dietary supplements over the last few years, reaching 22% in 2017 of the pharmaceutical market in Romania, with an average annual growth rate of 17.5% (2014-2017).

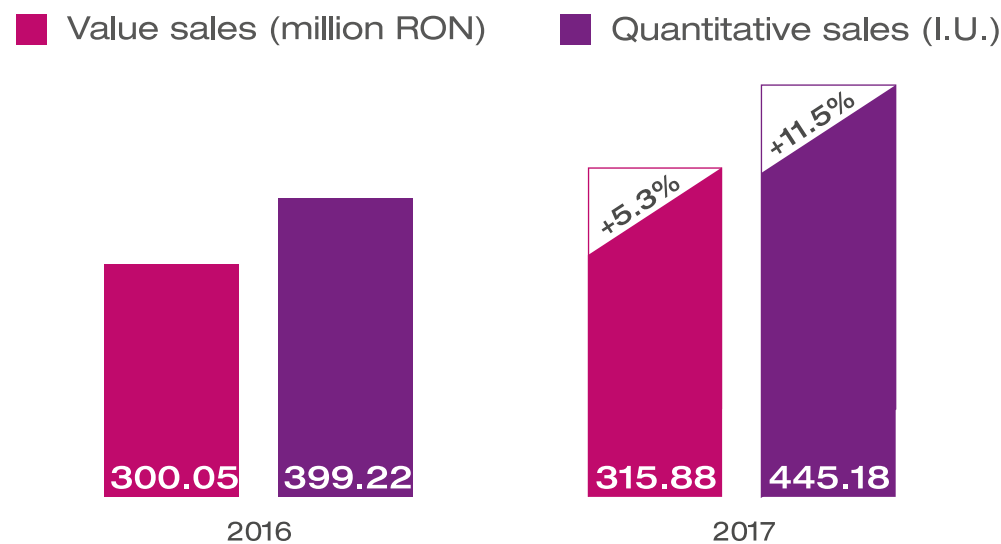
The first 5 therapeutic classes on the pharmaceutical market in Romania, according to the share in the value sales are:

- Digestive tract (18.3%)
- Cardiovascular system (14.3%)
- Anti-infective drugs (14.2%)
- Oncology (14.0%)
- Central Nervous System (11.2%)

Accumulated, the first 5 classes account for 71.9% of total value sales in Romania.

## Antibiotice in the context of the pharmaceutical market in Romania

In the context of the pharmaceutical market in Romania, Antibiotice experiences an increase in sales from pharmacies and hospitals of 5.3% compared to 2016, with a portfolio sale value of RON 315.9 million.



Evolution of Antibiotice sales in pharmacies and hospitals

The retail pharmacy segment is up by 5.7% compared to 2016, from RON 223.6 million to RON 236.3 million, while the Hospitals segment is growing by 4% from RON 76.5 million in 2016 to RON 79.5 million in 2017.

Also, the physical sales grew by 11.5%, amidst an increase of only 8.2% in the total drug consumption at the total market level.

The main therapeutic classes with significant increases in value compared to 2016 are: Digestive tract (+ RON 4.3 million), Cardiovascular system (+RON 14.4 million) and Central Nervous System (+RON 2.2 million) generated both the contribution of new products and the positive evolution of the Company's top products.

Among these there are products with a contribution of more than RON 1 million: Indapamidă Atb® tablets (+5 RON million), Silithor®

(+RON 4.9 million), Fluxiv® (+RON 4 million), Rosuvastatină Atb® tablets (+RON 2.8 million), Meropenem® range, product for injection (+RON 1.7 million), Equilibra® (+RON 1.6 million), Nolet® tablets (+RON 1.4 million), Memantină Atb® range (+RON 1.4 million), Imipenem/Cilastatin Atb® (+RON 1.3 million) and Bisotens® range tablets (+RON 1.2 million).

In 2017, Antibiotice maintained its leading position on the generic and OTC market in hospitals, with a market share of 17.4%.

On the generic and OTC segment, the Company ranks the 4th, with a market share of 5.2%, while at the level of the total pharmaceutical market it ranks 17th with a market share of 2.24%.

In 2017, through its capitalized portfolio, Antibiotice maintains its leading position in terms of ointment units with a market share of 27%, suppositories with a market share of 40.3% and powders for

injection, with a market share of 74.7%.

The OTC drugs have experienced a steady increase in sales in recent years, reaching in 2017: 22% of the total market, with an average annual growth rate of 17.5% (2014-2017).

Through the non-prescription medicinal products and food supplements portfolio, Antibiotice is ranked 14th among the top OTC companies in Romania (out of a total of 213 companies), climbing 4 positions compared to the year 2015 (18th place). The average annual growth rate recorded for the period 2014-2017 is 25.2%, above the overall market rate (17.5%).

The share of OTC drugs in the Company's turnover increased in 1917 to 19.1% (16% in 2016, 13% in 2015); the products which performed were the food supplements Fluxiv®, Silithor®, Equilibra®,

Soriso®, Cutaden Bebe® as well as Clafen® OTC topical range, Saliform® Forte and Cicatrol®.

Through promotional and commercial policies conducted during the first part of this year, the food supplements held in the portfolio have been able to perform on relevant markets: Fluxiv® is the third most consumed medicinal product, out of 25 products with a market share of 7.12%; Equilibra® - occupies 4th place in consumption, on a relevant market where 38 products are present, with a share market of 10.9%; Silithor® - ranked no. 7 in consumption, out of more than 55 products, with a market share of 4.3%; Soriso® - ranks first in consumption, with a market share of 36.3%, on a market where 20 competing products are active

## Top products

*Among the Antibiotice brand medicines, Eficel® is the most widely known<sup>[1]</sup>*

The most valuable product marketed by Antibiotice is Cefort® 1g powder for injection (ceftriaxonum) with a share in the total turnover of 7.0%.

The second place in the sales recorded by Antibiotice in 2017 is Eficel® 200 mg capsules (share in sales of 5.67%), followed by Amoxicillin 500 mg capsules (3.65%), AmpiPlus® 1.5 g product for injection (3.56%) and Colistina Atb® product for injection (3.32%).

From the non-prescription drug portfolio, the brands which have

been highlighted in 2017 are: Silithor®, a hepatoprotective supplement launched in 2014, with a value input of RON 4.9 million; Fluxiv®, a food supplement launched in 2016, with a value input of RON 3.95 million; Equilibra® capsules, with a value input of RON 1.6 million; Soriso®, an adaptogen food supplement launched in 2016 with an input value of RON 0.9 million; Cutaden Bebe® with a value input of RON 0.9 million and Clafen® gel 5%, with an input value of RON 0.53 million.

## New products launched on the market in 2017

The portfolio dedicated to human use comprising 136 drugs (finished products marketed at the exit of Antibiotice in 2017) covering 12 therapeutic classes attests the fact that the Antibiotice strategy is a perpetual orientation towards the renewal of the product portfolio and the manufacture of generic medicinal products therapeutically bioequivalent with the original products under the conditions of maintaining high quality standards.

37 drugs in the Antibiotice portfolio are essential medicinal products according to the World Health Organization classification, i.e. medicines that meet the health needs of the majority of the population and are used to treat the most widespread diseases.

[1] Company Brand fame Research – Product Brand Research Report, ISRA Center, February 2016

The activity of Antibiotice - ranging from research, production and sales - is structured upon a portfolio of medicines varied in terms of pharmaceutical forms and therapeutic classes:

**Antiinfectives** for systemic use

**Cardiovascular** drugs

**Dermatologicals**

**Central Nervous System** drugs

**Self-care products** (prophylaxis, supplements in certain diseases with higher incidence, preserving health, dietary supplements, derma cosmetics, medical devices and OTCs)

In the year 2017, the Antibiotice's product portfolio was completed with:

- Zifex® Complex Ovules - a new product intended for gynecological diseases, complemented by the Zifex® range. This drug is unique on the pharmaceutical market in Romania containing Nystatin, the active substance for whose production Antibiotice is the world leader. Zifex® Complex adds value to the Antibiotice portfolio and will contribute alongside Nistatina Atb® tablets, Nidoflor® and Nystatin Atb® ovules to the Nystatin Vertical Integration Project.

Following the general tendency of the population to focus more upon preventive therapies at the expense of treatments, thus consuming food supplements, in 2017, two food supplements were assimilated into the Company's portfolio:

- Sprinten® tablets - a food supplement that maintains the health of the bone system, reduces the stiffness and joint fatigue, thus improving the movement.

- Fezivit® a combination for the normal body functioning, through the skin collagen formation, the red blood cell formation and hemo

globin to reduce fatigue.

Also, in 2017, a number of products have been awarded the Marketing Authorization and will be marketed starting 2018:

- Clobetazol® cream - corticosteroid for topical use, indicated in the short-term treatment of resistant dermatoses (psoriasis, treatment-resistant eczema for flat lichen, chronic lupus erythematosus).

- Betahistină Atb® tablets - a medicine belonging to the anti-vertiginous therapeutic subclass, prescribed for the treatment of vertigo caused by disturbances of the blood flow in the inner ear.

- Caspofungină Atb® powder for concentrate for solution for infusion – a systemic antifungal drug for the treatment of invasive candidiasis and invasive aspergillosis.

The development of new products, especially in a dynamic and specialized industry such as the pharmaceutical industry, has as main objective the gradual replacement of products in the medical therapy, while maintaining or increasing the volume of future sales.

## Antibiotice was present in 2017 at the main national scientific events

The distribution and sale activity is complemented by the medical promotion of the products in the portfolio, structured on the main therapeutic areas: anti-infective, cardiovascular, dermatology, digestive tract and metabolism, central nervous system and musculoskeletal system products.

Starting with 2016, Antibiotice provides to healthcare professionals new therapies to address pathologies in obstetrics and gynecology (Nistatină Atb® range of ovules, Zifex® Duo, Zifex® Complex).

The Promotional and Commercial Divisions have supported the medical promotion to health professionals by organizing and partici

pating in the most important national scientific events that took place during 2017.

The themes approached during these conferences referred to the scientific experience with the molecules present in the Antibiotice portfolio, but also to the newly assimilated products in the portfolio.

Other topics addressed were the people's access to medication and the economic impact of the generic drug use, the adherence to treatments, the use and recommendation of food supplements in the context of preventing and maintaining a healthy lifestyle.

A category of promotional tools approached in 2017 was the

communication plan to health professionals by participating in scientific events with the objective of increasing the brand awareness of the company brand and product brands, loyalty to the target audience and increasing the market share: 360° National Prevention Conference in Bucharest, the National Conference of Family Medicine in Bucharest, the National Congress of Internal Medicine in Căciulata, the Sinaia National Congress of Psychiatry, the National Conference of Sibiu Cardiology Working Groups, the National Congress of the Romanian Society of Anesthesia and Intensive Care, The „Dermatological Spring from Iași”, the „Gh. Năstase Days in Iași” Conference, the National Congress of Dermatology, the National Congress of the Romanian Urology Society, the National Otolaryngology Congressional Congress, the National Congress of Cardiology in Sinaia, the National Congress of Urogynology in Bucharest, the National Dobrovici Medical Days Conference in Iași.

Also, a series of promotional programs and actions were carried out:

- Organizing working meetings with independent pharmacies and mini-chain pharmacies;
- Promoting the Company brand and product brands through the campaign intended for the public to monitor the state of health:

*“The specialist doctor in rural areas”* carried out in family doctor's offices in order to determine and monitor the cardiovascular risk in the rural patients, a project developed with the support of cardiologists;

- The „Romanian Products from Sea to Summit” Campaign dedicated to the general public intended to promote the Fluxiv®, Equilibra®, Silithor® and Soriso® food supplements and the Cutaden® Bebe cosmetic product in the context of an increasing interest in maintaining the quality of life;

- Social media campaigns for the products Cutaden Bebe®, Silithor® and Equilibra® intended for the general public;

- Nationwide radio campaigns for the products Cutaden Bebe® and Equilibra® intended to increase the brand awareness and to promote the Fluxiv® and Soriso® brands in specific radio shows;

- Shelf products marketing campaigns in open-circuit pharmacies;

- The joining of Antibiotice in the campaign for the European Antibiotic Awareness Day. During the campaign, information leaflets and information were provided to the general public about what the bacterial resistance is and how to properly use antibiotics so that the future generations may benefit from the effectiveness of this valuable therapeutic resource.

## The development of the R&D structures for the adaptation and sustainable consolidation of the company's portfolio

In 2017, Antibiotice continued to invest in the research and development of products from classes considered strategic by the Company for their impact upon the public health: Anti-Infective drugs, Cardiovascular, Neurodegenerative diseases and Central Nervous System, as well as dermatological products and self-care products (OTC drugs without prescription, food supplements and cosmetic products).

The Antibiotice pipeline currently includes 33 products in different stages of development, from the therapeutic classes that define the Company's directions of development. These are: anti-infective drugs (7 products), cardiovascular drugs (5 products), dermatological drugs (4 products), genitourinary drugs (1 product), central nervous system drugs (1 product), anti-inflammatory drugs (1 product), digestive tract drugs (2 products) and respiratory tract drugs (1 product). Another direction of research has been directed towards products for the disease prevention and quality of life. These include food supplements and OTC medicines (11 products).

A permanent concern was also the training of young Research & Development employees to develop new research knowledge and techniques in line with the latest European and international guidelines.

**9 new marketing authorizations at international level and 7 new products on the Romanian market**

The favorable results from the research and development stages have allowed for new marketing authorizations and the re-authorization of the medicines already known on the domestic and international market.

In Romania, 7 new Marketing Authorizations for medicines from the following classes were obtained using the national procedure: cardiovascular (Betahistină Atb® 8 mg and 24 mg tablets), anti-infective drugs (Ertapenem Atb® 1g powder for solution for infusion, Caspofungină Atb® 50 mg powder for concentrate for solution for infusion, Tigeciclină Atb® 50 mg powder for solution for infusion) and dermatology (Clobetazol Atb® 0.5 mg/g cream); 2 new food supplements have been notified: Sprinten® film-coated tablets and Fezivit® C capsules.

The development on international markets has been supported by the obtainment of nine new marketing authorizations for Antibiotice products in countries in Europe, Asia and Africa. The presence on the international markets of interest was also consolidated through the completion of 21 re-authorization procedures for the existing products.

In 2017, the two decentralized European (DCP) procedures for simultaneous authorization in EU countries for Perasin® (piperacilin/tazobactam) of 2.25 g and 4.5 g of powder for solution for infusion and Nebivolol Atb® 5 mg and 10 mg tablets continued; the procedures are expected to be completed in the first part of 2018.



# The Center for Drug Evaluation

## Clinical studies

In the course of 2017 three bioequivalence clinical trials were conducted, one for a product in the Antibiotice portfolio and two clinical studies for an external sponsor. Also, the documentation and preparation stage of clinical trial protocols for two other new products was completed.

## Inspections/Certifications

During the first semester of 2017, the NMMDA inspection for GCP/GLP recertification of the Center for Drug Evaluation and Bioanalytical Laboratory took place. Following this inspection, the GLP (Good Laboratory Practice) certificate and GCP (Good Clinical Practice) authorization were obtained with a validity of 2 years. At the same time, during the first half of 2017, the recertification of GMP (Good Manufacturing Practice) of the secondary packaging line for the “Investigational Medicinal Product” of the Center for Drug Evaluation took place. This certification allows the secondary packaging of oral medicines (tablets and capsules) as well as of solid topical forms (pessaries and suppositories) for administration in clinical trials.

## Pharmacovigilance and health policies

The monitoring of the efficacy and safety of Antibiotice medicines is a continuous process through the pharmacovigilance activity, as Antibiotice is linked to the European data processing network for medicines safety, EudraVigilance. In 2017, the access to the European drug safety monitoring system was expanded by developing the EVDAS (“EudraVigilance data warehouse and analysis system”) module which allows the analysis of data stored in the European database and a faster detection of possible safety alerts by the marketing authorization holders and the initiation of appropriate measures to protect public health.

In 2017, Antibiotice became a member of the Romanian Association of OTC Drugs, Food Supplements and Medical Devices Manufacturers (RASCI), thus actively engaging in the dialogue with regulatory entities in this field to create an appropriate framework for promoting ethics and sustaining a fair competitive environment, as well as in conducting educational campaigns on the informed and responsible consumption of self-medication products.

## Modernizing and streamlining manufacturing flows

Antibiotice's development strategy for 2017 estimated the upgrading and development of product portfolio and manufacturing line as a priority.

Antibiotice manufactures for domestic and external partners the following five pharmaceutical forms:

- Sterile injectable powders
- Capsules
- Tablets
- Products for topical use (ointments, creams, gels)
- Suppositories, pessaries.



The quality of the products is ensured by processes that meet the latest requirements in the field of good manufacturing practice, as all the eight manufacturing lines of the company are EU-GMP certified. The manufacturing lines of sterile injectable products and Nystatin active substance are also certified by the US Food and Drug Administration.

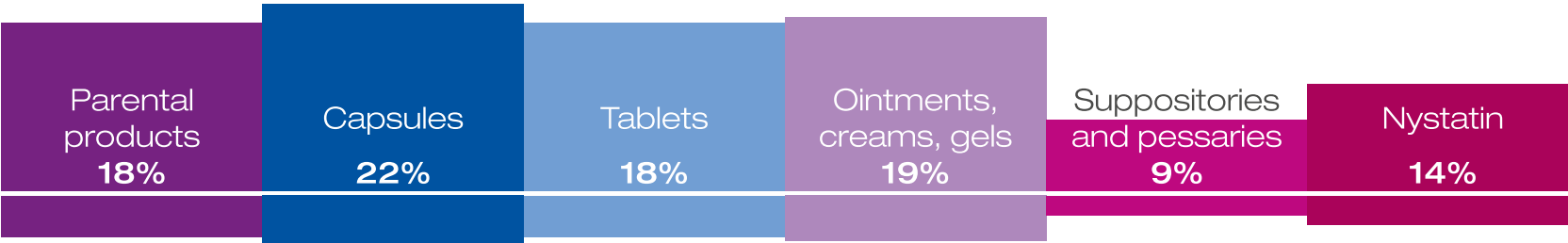
The implementation of the all regulatory requirements and the assessment of the quality management system by regulatory authorities and customers across the globe result in maintaining the level of quality, efficacy and safety of Antibiotice drugs.

Antibiotice manufactured in 2017:

522 million pharmaceutical units in the form of tablets, capsules, parenteral products, ointments, creams, gels, suppositories and pessaries;

bulk active substance (Nystatin) in a quantity comparable to that of the previous year.

The production of the year 2017 on pharmaceutical forms



The objectives achieved by Antibiotice in 2017 in the field of pharmaceutical manufacturing:

**The manufacturing** of parenteral products for foreign companies based upon manufacturing and control contracts. The production for export of parenteral products accounted for 31.11% of the total value of products intended for foreign markets;

**The reducing** of raw material costs by optimizing the manufacturing formulations and identifying new sources for the excipients utilized in finished products technology;

**Reducing** the utility consumption through the careful management across all the production sites;

**To continue** the efforts to implement the environmental protection program on volatile organic emissions during the Nystatin extraction phase.

# The investment policy - medium and long-term development by investing in new facilities

The investment objectives included in the 2017 program were as follows:

- the achievement of a new, high performance facility, equipped with modern production installations for the manufacture of ointments and suppositories, subject to GMP and FDA approval;
- the upgrading and refurbishing of the existing production lines to increase the production capacities, product quality and to reduce production costs;
- the upgrading of the facilities that provide utilities for the entire platform;
- the achieving of targets to respond to the pollution reduction and the environmental protection strategy;
- to strengthen the integrated management system, to create new production facilities in order to reduce utility costs and consumption, to increase the labor productivity, the continuous compliance with the GMP rules and to the work and environmental protection regulations.
- the increasing of the storage capacity for raw materials corresponding to the increased production capacity.

## The achievement of a new Ointments and Suppositories production capacity

The aim of the project is to create a new production facility for the manufacturing of semi-solid pharmaceutical products divided into tubes and suppositories in order to increase the turnover and the capacity of Antibiotice to register, manufacture and market Romanian quality medicines by investing in a new plant.

### Justification of the investment

The achievement of this modern plant for the manufacture of semi-solid products divided into tubes (ointments, creams, gels) and suppositories represents for Antibiotice the guarantee of a long-term business development and is part of the Company's development strategy focused upon maintaining and expanding the portfolio of semi-solid products divided into tubes and suppositories.

The future portfolio will be intended for the domestic market, but the diversification and penetration into major new external markets in Europe, North America, Asia and Africa are also underway.

In order to ensure the main characteristics of the medicines (quality, efficiency and safety), their manufacture must be carried out in facilities equipped with high-performance equipment which meet the GMP (Good Manufacturing Practice) requirements.

## Investments in manufacturing lines

In 2017, equipment, installations, various equipment and laboratory equipment were purchased for the purpose of refurbishing the manufacturing lines. They are state-of-the-art, with high productivity, low energy consumption and high operational safety.

The new manufacturing equipment is designed to replace the old equipment with significant physical wear, which generates high maintenance costs and low productivity. The purchase of equipment and facilities to ensure environmental protection measures was also required in order to reduce the energy consumption and to ensure safety at work.

## The procurement of new product licenses and research projects

The new product development program has the following objectives:

- the upgrading of the Company's product portfolio in order to provide last generation generic drugs to the domestic market, that are therapeutically effective and safe in administration;
- the provision of competitive pharmaceutical products on the foreign market and ensuring, in the long term, the growth of Antibiotice's turnover and competitiveness.

## Investments in research

Research is one of the most dynamic activities in society, which records permanent changes and an upward trend, acting as a dynamic element of the entire system, generating new products, which leads to an increase in production. With a specific consumption of intelligence and creativity, research contributes to the development of the product portfolio.

Also, within the Center for Drug Evaluation, the investment program included equipment, endowments and software programs to support and improve the research activities in order to obtain new, quality, valuable, competitive products on the market.

## Investments in quality

Given the ongoing review of the pharmacopœial monographs and the increasing accuracy of analytical methods in the pharmaceutical laboratories, it has become imperative to acquire state-of-the-art equipment to enable verifying the quality of products manufactured by Antibiotice to be maintained at international standards. The demonstration of the quality and compliance of the manufactured products is achieved in the Quality Control Laboratories, equipped with the most modern and performing equipment.

## Investments to ensure logistics

The investments were mainly directed towards the refurbishment of the car fleet. Thus, modern means of transportation have been procured to ensure a safe operation; they are equipped according to the current transport legislation, for the transportation of raw materials and finished products and for the partial replacement of the outworn car fleet.

## Investments for the production and transport of utilities

The investments were mainly focused upon the modernization and upgrading of utility systems (steam, compressed air, water, demineralized water, methane gas, electricity, drinking water, sewage, etc.), from the entire platform of our Company in order to sizing and adapting utility routes to the current consumption of manufacturing lines so as to achieve energy savings by reducing consumption and eliminating losses.

The benefits of these investments are such as:

- safety in operation;
- increasing labor productivity
- reducing the intervention times by implementing a diagnosis system that reduces the maintenance and repair work;
- savings of energy and resources and, implicitly, a better environmental protection;
- ease in operation of the equipment by the human operator.

# Economic & Financial Activity

## Net profit for the period increased by 10% compared to 2016

Antibiotice developed its activity in 2017 in the spirit of achieving its objectives and indicators set in the Revenue and Expenditure Budget.

Starting with the fiscal year 2012, our company applied for the first time the International Financial Reporting Standards (IFRS) which required the restatement of accounting information in accordance

with the Order of the Minister of Public Finance no. 881/2012, Order of the Minister of Public Finance no. 1286/2012 and Order of the Minister of Public Finance no. 2844/2016, 2013 being the first fiscal year in which the accounting was recorded under the provisions of IFRS.

## Statement of the global result

In 2017, the sales income amounted to 336.9 million LEI, higher by 1.3% compared to 2016 when the recorded value was 332.4 million LEI, a result of the sustained effort of the whole company to consolidate its business.

Statement of the Global Result (Lei)	31.12.2016	31.12.2017	2017/ 2016
<b>Sales income</b>	<b>332,435,059</b>	<b>336,904,666</b>	<b>1.013</b>
Other operating revenues	20,262,937	37,796,667	1.87
Income related to product stock costs	-900,215	4,235,363	-4.70
Income generated by the entity and capitalized	2,177,574	1,850,831	0.85
Raw materials and consumables expenses	126,867,849	127,072,000	1.00
Personnel expenses, of which:	76,846,812	85,897,194	1.12
- current personnel expenses	71,800,968	81,310,923	1.01
- provisions for personnel	5,045,844	4,586,271	2.29
Depreciation and impairment expenses	18,948,912	17,098,098	1.25
Other operating expenses	91,782,114	113,395,172	0.84
<b>Operating profit</b>	<b>39,529,669</b>	<b>37,325,063</b>	<b>1.07</b>
Financial income	8,134	4,287	0.53
Financial expenses	4,656,157	1,967,920	0.42
<b>Pre-tax profit</b>	<b>34,881,646</b>	<b>35,361,430</b>	<b>1.01</b>
Income tax expenses	4,510,835	1,803,076	0.40
<b>Profit</b>	<b>30,370,811</b>	<b>33,558,354</b>	<b>1.10</b>

Structurally, the main items of expenditure evolved this way:

**raw materials** and consumables expenses diminished as a result of changing the manufacturing structure and reducing the production;

**personnel expenses** grew by 12% as compared to 2016 and by 3% compared to the forecasted values due to the wage increases granted in May 2017 according to the Income and Expense Budget approved by the General Meeting of Shareholders;

**other operating expenses** amounted to 113.4 million LEI, higher by 24% compared to the same period last year and by 37 % compared to the budgeted values. These increases were offset by higher operating income. The increase in these expenses is mainly due to recording of the doubtful receivables amounting to 7.8 million LEI as expenses, increasing the clawback tax up to 29.2 million LEI, unfavorable exchange rate differences amounting to 8 million LEI and stopped research projects in value of 1.1 million LEI.

Financial income and expenses are the income and expenses on interestv .

In the fiscal year 2017, **the pre-tax profit** was **35.36 million LEI**, higher by 1% compared to the figure recorded in 2016, and by 1% compared to the profit estimated in Income and Expense Budget.

**After-tax profit** was **33.56 million LEI**, higher by 11% compared to the figure recorded in 2016, and by 17 % compared to the budgeted profit.

**Net profit** in 2017, amounting to **33,558 thousand LEI** is the result of the deductibility of the earnings reinvested in technological equipment and of the doubtful receivables removed from the accounts.

## Statement of financial position

On December 31, 2017, the company's fixed assets grew by 9 % as compared to the beginning of the year. Accounting depreciation is calculated using the straight line method according to IFRS.

ASSETS	31.12.2016	31.12.2017	2017/ 2016
<b>FIXED ASSETS</b>			
Tangible fixed assets	206,702,347	223,242,890	1.08
Intangible fixed assets	10,139,458	13,107,622	1.29
<b>TOTAL FIXED ASSETS</b>	<b>216,841,805</b>	<b>236,350,512</b>	<b>1.09</b>
<b>CURRENT ASSETS</b>			
Stocks	60,195,101	67,264,546	1.12
Commercial and similar receivables	242,456,065	264,212,743	1.09
Financial assets held for sale	0	0	-
Cash and cash equivalents	13,902,686	5,107,743	0.37
<b>TOTAL CURRENT ASSETS</b>	<b>316,553,852</b>	<b>336,585,032</b>	<b>1.06</b>
<b>TOTAL ASSETS</b>	<b>533,395,657</b>	<b>572,935,544</b>	<b>1.07</b>
<b>LIABILITIES</b>			
<b>CURRENT LIABILITIES</b>			
Trade and other payables	49,045,370	55,535,974	1.13
Amounts owed to credit institutions	40,705,967	69,731,310	1.71
Tax and current tax liabilities	11,486,302	9,792,887	1.28
Short-term provisions	1,418,895	-	0.00
Subsidies for investments	275,047	326,246	1.19
<b>TOTAL CURRENT LIABILITIES</b>	<b>102,656,534</b>	<b>135,386,417</b>	<b>1.32</b>
<b>LONG -TERM DEBTS</b>			
Subsidies for investments	2,639,349	2,498,889	0.95
Deferred tax	18,758,368	18,172,398	0.97
Long-term provisions	0	0	-
<b>TOTAL LONG-TERM DEBT</b>	<b>21,672,764</b>	<b>20,671,287</b>	<b>0.97</b>
<b>TOTAL DEBT</b>	<b>124,329,298</b>	<b>156,057,704</b>	<b>1.26</b>
<b>SHARE CAPITAL AND RESERVES</b>			
<b>SHARE CAPITAL</b>	<b>264,835,156</b>	<b>264,835,156</b>	<b>1.00</b>
Revaluation reserves	16,925,870	14,556,141	0.86
Legal reserves	13,426,761	13,426,761	1.00
Other reserves	146,528,189	162,134,513	1.11
Reported result	-63,020,428	-71,633,085	1.14
Current result	30,370,811	33,558,354	1.10
<b>TOTAL EQUITY</b>	<b>409,066,359</b>	<b>416,877,840</b>	<b>1.02</b>
<b>TOTAL EQUITY AND DEBT</b>	<b>533,395,657</b>	<b>572,935,544</b>	<b>1.07</b>

Lei



## Current assets:

**stocks** grew by 12% compared to 2016;

**total receivables** grew by 9 % due to delays in the health care system.

The average time for collecting the receivables on the foreign market was 79 days in 2017, compared with 353 days in the domestic market, resulting in an average collection time of 257 days.

Cash and cash equivalents at the end of 2017 recorded a value of 5.1 million LEI.

The company's main diagnostic indicators highlight the financial balance and continuous concern for streamlining the business and adapting it to the business climate changes. So the liquidity ratios were slightly higher than in 2016, with the indebtedness level rising from 23% to 27%.

		31.12.2016	31.12.2017
<b>ROE (return on equity)</b>	= Net profit/Equity	7.4%	8.0%
<b>ROA (return on assets)</b>	= Net profit /Total assets	5.7%	5.9%
<b>EPS (LEI/share)</b>	= Net profit /share	0.045	0.050
<b>Net Profit Rate</b>	= Profit/Sales income	9%	10%
<b>General Liquidity</b>	= Current assets/Current liabilities	3.1	2.5
<b>Quick Liquidity Rate</b>	= (Current assets - Stocks)/ Current liabilities	2.5	2.0
<b>Level of indebtedness</b>	= Debts/Total assets	23%	27%
<b>Number of shares</b>		671,338,040	671,338,040

## Balance sheet liabilities

On December 31, 2017, our company recorded current debts amounting to 135.4 million LEI, higher by 32% compared to 2016, the need for cash being higher for the clawback tax, leading to greater use of credit lines.

## Amounts owed to credit institutions at 31.12.2017

Short-term contract no. IAS3-42-2016/ 17.08.2016 with Unicredit Bank S.A.	
Objective	Credit line - circulating capital
Amount	30,000,000 Lei
Maturity	16.08.2018
Balance at December 31, 2017	28,769,000 Lei
Warranties	Mortgage contract for buildings, land/ Contract for assignment of receivables

Short-term contract no. 12/01.07.2013 with Romanian Export Import Bank  
EXIMBANK S.A.

Objective	Credit line - circulating capital
Amount	30,000,000 Lei
Maturity	26.06.2018
Balance at December 31, 2017	25,905,001.42 Lei
Warranties	Mortgage contract for buildings, land / Contract for assignment of receivables

Short-term contract no. 12239/22.05.2012 with ING BANK N.V. AMSTERDAM  
Romanian Branch

Objective	Credit line - circulating capital
Amount	9,500,000 EUR
Maturity	22.05.2018
Balance at December 31, 2017	8,739,544.83 Lei 1,355,830.54 EUR ( 6,317,763.57 Lei )
Warranties	Contract ipotecă clădiri, teren/ Contract de cesiune de creanțe

## Amounts owed to credit institutions at 31.12.2016

Short-term contract no. IAS3-42-2016/ 17.08.2016 with Unicredit Bank S.A.

Objective	Credit line - circulating capital
Amount	30,000,000 Lei
Maturity	16.08.2017
Balance at December 31, 2017	22,919,001 Lei
Warranties	Mortgage contract for buildings, land / Contract for assignment of receivables

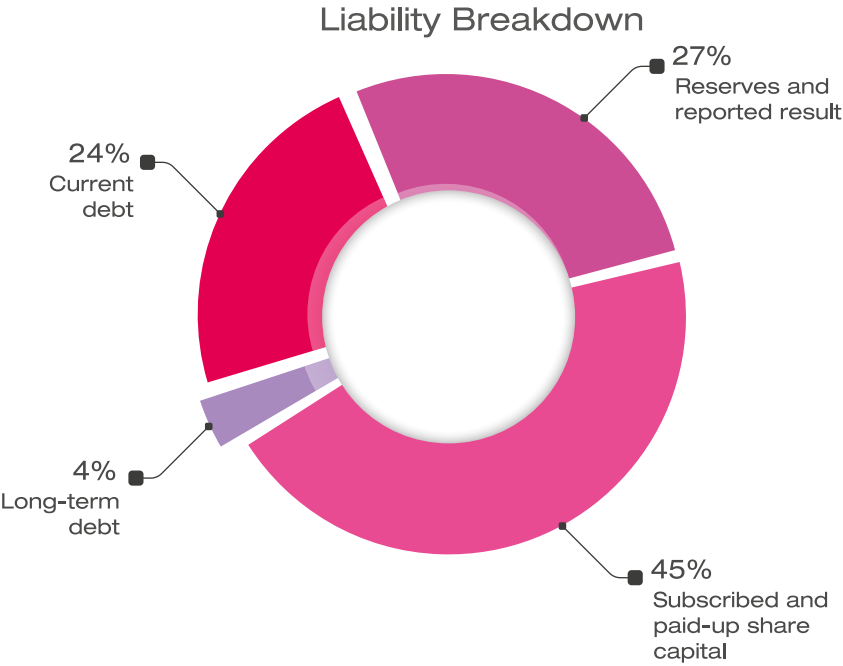
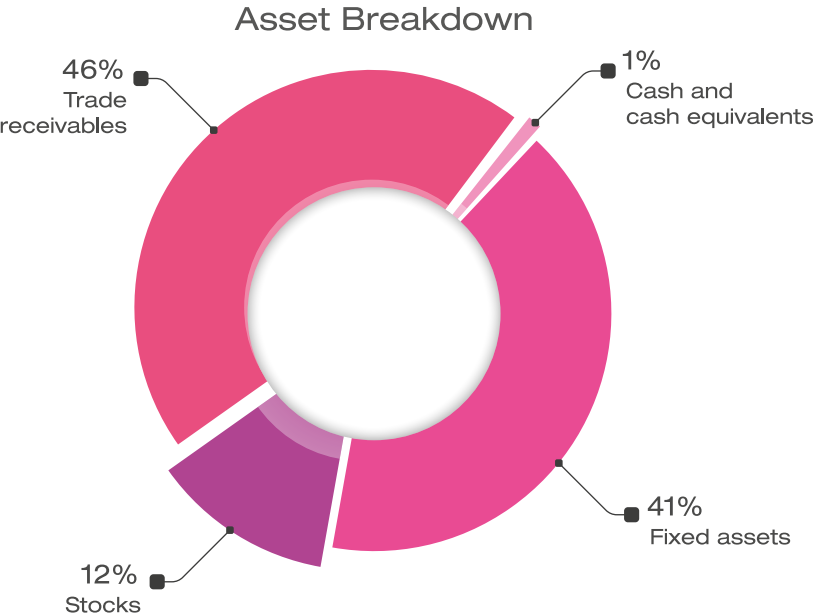
Short-term contract no. 12/01.07.2013 with Romanian Export Import Bank  
EXIMBANK S.A.

Objective	Credit line - circulating capital
Amount	60,000,000 Lei
Maturity	27.06.2017
Balance at December 31, 2017	0 Lei
Warranties	Contract ipotecă clădiri, teren, creanțe

Short-term contract no. 12239/22.05.2012 with ING BANK N.V. AMSTERDAM  
Romanian Branch

Objective	Credit line - circulating capital
Amount	9,500,000 EUR
Maturity	22.05.2017
Balance at December 31, 2017	3.916.884,93 EUR (17.786.966,16 Lei )
Warranties	Contract for assignment of receivables / Mortgage contract for buildings, land

The trading company Antibiotice SA did not lodge any warranties and did not pledge or mortgaged its own assets to guarantee obligations in favor of a third party.



## Cash flow

At the beginning of the period, cash and cash equivalents were -26.8 million LEI, representing credit lines amounting to 40.7 million LEI from which 13.9 million LEI remained unused in the bank accounts from the same credit lines. Cash receipts from operating activities were 313.46 million LEI. Cash payments to suppliers of goods and services were 179.35 million LEI and those to and on behalf of employees were 77.4 million LEI.

There were also made payments of 8.88 million LEI representing income tax, VAT, local taxes and bank interests, and payments were made for the acquisition of fixed assets amounting to 43.31 million LEI. Our company paid the contributions to the Ministry of Health (the clawback tax) worth 28.43 million LEI.

As regards the financing activity, dividends worth 13.66 million LEI were paid.

At the end of the period, cash and cash equivalents were -64.62 million LEI, representing credit lines for the current activity (69.73 million LEI) from which 5.11 million LEI remained available in banks from the same credit lines.

Our company paid in full its obligations to the state and local budget in value of 76 million LEI.

<b>I. Cash flows from operating activities</b>	<b>31.12.2016</b>	<b>31.12.2017</b>
Cash receipts from sale of goods and services	295,903,157	313,461,633
Cash receipts from royalties, fees, commissions and other income	(3,985,726)	(9,827,652)
Cash payments to suppliers of goods and services	(189,347,963)	(169,526,601)
Cash payments to and on behalf of employees, payments made by the employer relative to staff	(68,264,144)	(77,395,419)
Value Added Tax Paid	(1,937,385)	(2,667,613)
Contributions to the Ministry of Health and Ministry of Environment	(20,192,307)	(28,427,073)
Other paid taxes, fees and assimilated payments	(2,366,757)	(1,635,017)
<b>Operating cash flow</b>	<b>9,808,875</b>	<b>23,982,258</b>
Collected interests	8,134	4,287
Paid interests	(1,014,156)	(1,252,021)
Paid profit tax	(5,982,931)	(3,328,251)
<b>Net cash flows from operating activities</b>	<b>2,819,922</b>	<b>19,406,273</b>

<b>II. Cash flows from investment activities</b>	<b>31.12.2016</b>	<b>31.12.2017</b>
Cash payments for the acquisition of land and fixed assets, intangible assets and other long-term assets	(17,681,181)	(43,312,921)
<b>Net cash from investment activities</b>	<b>(17,681,181)</b>	<b>(43,312,921)</b>

<b>III. Cash flows from financing activities</b>	<b>31.12.2016</b>	<b>31.12.2017</b>
Acquisition of shares	220	-
Paid dividends	(7,433,677)	(13,660,457)
<b>Net cash flows from financing activities</b>	<b>(7,433,457)</b>	<b>(13,660,457)</b>
Gains/losses from foreign exchange differences	(112,030)	(253,181)
<b>Net increase/(decrease) in cash</b>	<b>(22,406,746)</b>	<b>(37,820,285)</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>(4,396,535)</b>	<b>(26,803,281)</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>(26,803,281)</b>	<b>(64,623,567)</b>
<b>Cash and cash equivalents at the end of the period include:</b>		
Bank accounts and cash	13,902,686	5,107,743
Credit lines	(40,705,967)	(69,731,310)
	<b>(26,803,281)</b>	<b>(64,623,567)</b>

# Commercial policy

## Raw materials import

In the context of the internationalization of the Company's business, the procurement of raw materials, packaging and finished products for production becomes relevant throughout the value chain and an important link in generating added value for the company.

The main challenge of 2017 was the correlation of the procurement program for raw materials or sub-contract manufacturing products with the sales structure generated by the Romanian strategy as well as the new markets addressed through the internationalization of the business: Vietnam, Ukraine and Serbia. The entire process has been carried out by observing three fundamental principles: certified quality, the lowest price for the order volume and the guarantee of a „just-in-time” delivery.

Beyond the necessity of the continuous cost optimization, the

import activity is a costly process of knowledge and adaptation to various external markets, so that the management of this activity gains international and multi-disciplinary valences: technical knowledge, quality assurance, sustainable and principled relationship, negotiation and trading.

Their goal is to anticipate the emergence of risks in the procurement process by assessing the potential suppliers in the (pre) selection phase, budgeting by reference to a fair cost-volume parameter, the monitoring from the moment the order is launched until the receipt of the goods.

Procurement is an important link on the value chain that generates downstream favorable conditions for the sustainable development of Antibiotice.

## Domestic market acquisitions

The procurement process on the domestic market is the result of interdepartmental efforts from production planning to ensuring the transport of raw materials and consumables necessary to carry out the manufacturing process.

Harmonization of the commercial conditions imposed by the specificity of the activity in the pharmaceutical industry with the trends in the domestic market is the commercial policy of Antibiotice.

In 2017, the trade policy on the domestic market took into account the following aspects:

- Ensuring the offers (*a minimum of three*) for the raw materials and consumables necessary for production, in order to obtain the most competitive price on the market;
- The increase of the payment terms (supplier credit) included in contract up to 90 days;
- Obtaining prompt deliveries from suppliers;
- The renegotiation of contracts with the suppliers of raw materials, printing materials, consumables, solvents, reagents, spare parts and auxiliary materials (*in the sense of lowering prices*), with direct implications for the manufacturing costs;

- The elimination of complaints about the quality of raw materials and consumables that can cause malfunctions in the production process;
- The development and maintaining of favorable relationships with the company's suppliers, as well as seeking and developing new ones.

A continuous concern was to reduce the operating costs to increase the yield of the exploitation activity.

In this sense, a plan for reorganizing and resizing the activities and their profitability was launched, aiming especially at the most competitive price, the highest possible supplier credit with the financing capacity and the recovery of the market requirements without any compromise from quality standards.

Issues related to the transport of raw materials, printing materials, solvents, reagents, spare parts, as well as staggered delivery times were considered to avoid the overloading of deposits and the creation of stocks.

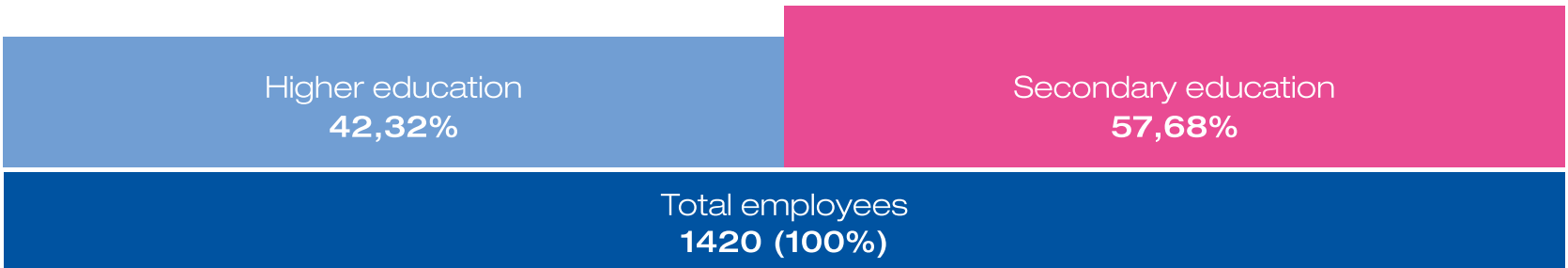


# Motivating the human resources and providing the skills needed to achieve strategic directions

The Human Resources Policy in 2017 aimed to ensure that the most important resource of the company, people, is represented by the best specialists, well-trained and integrated into the teams in all fields of activity.

## Structure of staff

Due to the nature of the specific activities carried out in Antibiotice, the structure by levels of education and professional training of the personnel is the following:



## Running ongoing professional training programs

In order to achieve professional performance - a prerequisite for increasing the competitiveness and quality of our business, our concerns are reflected in human resource development projects, with training programs in each direction, according to the needs identified for each organizational structure and in close correlation with the community legislative changes applicable and the domestic law.

## Training with external lecturers

In addition to the training programs with internal lecturers, Antibiotice organizes for employees continuous training programs with external lecturers from the country and abroad according to the annual training plan approved and budgeted for the current year.

In 2017, the topics addressed were meant to improve professional skills and integrate regulatory changes into production, quality assurance, engineering and equipment qualification, laboratory

analytical and bioanalytical validation.

Antibiotice employees in the field of pharmaceutical research and formulation and portfolio management have updated their information in the areas of nutritional supplements, pharmacovigilance, medical ethics and bioequivalence studies, and researchers from analytical laboratories have been trained to use some state-of-the-art laboratory equipment.

The marketing, promotion and sales team has specialized in the use of modern market analysis tools, advanced communication and sales techniques. Managers in these activities have improved their coaching and presentation skills to support team work in the territory. Time management and conflict resolution were topics addressed to managers in various fields of activity.

**In 2017 a number of 580 employees followed the scheduled training sessions, by field of specialization.**

## Summer Summer School a+, 8th edition

Between June and August 2017, the Summer School a+ program was developed, by now one of the company's traditions, which reached the 8th edition. Its goal was to provide learning experiences to increase the level of knowledge and permanent adaptation to change for both employees and graduates among whom the company will select future specialists.

Under this program, 244 employees received training from external or in-house lecturers.

**The program had two distinct components:**

**The in-house component** – to increase the level of professional training and personal development of senior management employees - top managers, middle managers, line managers, staff with higher education and secondary education staff structured on two modules:

- Organizational development – initial training in management, human resource management, conflict management, talent management, employer brand;
- Development of specialized skills in quality assurance, laboratory techniques, engineering, new requirements in the validation of manufacturing processes and equipment recalibration.

For the second year of the Summer School a+, a group of junior managers followed an extended module during 8 training sessions, the "Initial Training of Managers". Organized with the support of Iasi university, this module gave them the main notions about organizing and coordinating the team, obtaining results, behavior and communication in the team of young colleagues who did not receive management training in their academic training.

**External component** - for the purpose of training specialists in the fields of pharmacy, biology, chemistry, chemical engineering for vacancies in Pharmaceutical Development, Quality Assurance, Quality Control, Production, by familiarizing candidates with the working environment, concepts and regulations in the pharmaceutical industry, in order to attract them in future recruitment processes.

Through this project promoted in the Iasi academics, among the final year students from Iasi universities, a number of 30 participants benefited from specialized training during July - August. The topics addressed were related to quality assurance in a pharmaceutical company, pharmacovigilance, Regulatory Affairs, specific laboratory techniques in quality control, pharmaceutical research and formulation, technology and equipment in the pharmaceutical industry, and graduates were enrolled in the database for future staff selections.

**To date, 36 participants have been hired following the 8 editions of Summer School a+.**

## The Performa+ project, 2nd edition - a tool for communication and collaboration with academic institutions

The project aims at selecting, attracting and training pharmacists and physicians (interns and final year students), biologists and chemists for the specific activities of the Medical Unit and the Quality Unit, as well as creating a long-term communication and collaboration framework with Grigore T. Popa University of Medicine and Pharmacy, Alexandru Ioan University and Gh. Asachi Technical University in order to train and attract specialized personnel.

The Performa+ project continued in 2017 with a second edition within the Medical Unit in collaboration with the Faculty of Pharmacy

Iasi for the selection of graduates of the Pharmaceutical Development Department with a program of theoretical and practical activities carried out through mentors appointed from among the employees of the company.

The meetings scheduled with the 10 students took place between May and July 2017 and were completed with the support of specialized projects where students demonstrated how they acquired the knowledge of formulating a pharmaceutical product. The results obtained from the evaluation will be the basis for the selection of Antibiotice specialists' teams.

During 2017, another 6 of the graduates of this project were hired.

## Partnership with pre-university education institutions

Also, within the partnerships established with the Petru Poni Technological High School Iasi and the Technological High School of Mechatronics and Automation, in 2016 and 2017, 60 students from the 11th and 12th grades have done their internships within the company – for the specializations: lab chemist technician/ chemist operator in the medical and cosmetics industry and mechatronist / electro-mechanical technician.

Antibiotice opened the doors to 480 students from pre-academic institutions in Iasi to provide knowledge of the pharmaceutical production process, one of the oldest and most stable landmarks in the Iasi industry.

## Performance management

All employees in Antibiotice contribute their work to the success of the company. Through the regular performance appraisal process, employees are aware of the extent of this contribution and how they can strengthen leadership in drug production through continuous improvement and personal engagement.

The rewarding policy is established in interdependence with the level of these performances, with all employees benefiting from profit sharing as they contribute to their achievement.

At the end of the year, with the 62-year anniversary of the company's existence, a number of 62 highly-valued employees received the management's appreciation in a festive setting.

### *Management by objectives*

Based on indicators approved in the Income and Expense Budget for 2017 and starting from the company's Business Plan for the period 2017 - 2020, the annual general objectives were set out and the specific objectives for each activity for the employees included in the Management by objectives system .

These goals are identified and established in accordance with the company's overall mission and objectives and involve employee involvement and motivation to achieve them through a focused and well-coordinated effort.

In 2017, 321 employees were involved in this system.

## Occupational health and safety

At the end of 2017 LRQA reconfirmed and certified the compliance of the Occupational Health and Safety Management System, with the 18001 international standard, integrated with the quality and environmental management systems.

To reduce professional risks and in view of continuous improvement, we continued to implement measures to ensure:

**Reducing** the physical effort by completing the Biosynthesis plant with electrical transport equipment for lifting the raw materials and the finished product;

**Reducing** exposure to chemical agents by ensuring the storage of chemical reagents in Medical Unit laboratories in cabinets with vapor filtration system, and the purchase of a chemical test for granulometric measuring.

Knowledge and awareness of staff on current concerns in the field of health and safety at work:

- the aging of employees in healthy conditions;
- preventing health problems during their professional life.

Maintaining and developing an effective Occupational Health and Safety Management System is the guarantee for:

- Creating a unique and coherent framework to eliminate the dangers and risks associated with work;
- A more effective control over the risk factors for injury and / or professional illness;
- Improving the working environment and inter-human relations at the workplace;
- Getting better performance from employees;
- Awareness of the staff about the value the organization gives to its human capital.

# Quality management to comply with the legal, national and international requirements specific to the pharmaceutical industry.

## Certified quality

Increasing of the confidence in the quality, efficiency and safety of the Company's products is achieved daily by keeping under control and improving the Integrated Management System, attested by the results of the following inspections/audits during 2017.

## Inspections performed by authorities

- In the period 06-14.03.2017 the US FDA inspection was carried out to assess the cGMP compliance of the Quality Management System of Antibiotice SA and the manufacturing lines of penicillin parenteral products (vials with powder for injectable suspensions) and the line of Nystatin active substance. At the end of the inspection, a Form 483 was issued, and then the Company sent the Corrective and Preventive Measures (CAPA) Plan to the US FDA. Subsequently, after assessing the proposed remedies, the US FDA issued the Establishment Investigation Report (EIR), the final inspection report, which considered the inspection closed, with favorable results.

- During the period 24-27.04.2017 the National Agency for Medicines and Medical Devices (NAMMD) inspection unfolded to assess the compliance with the Good Manufacturing Practice (GMP, EU GMP) requirements of the Quality Management System of Antibiotice SA and the manufacturing lines of capsules, tablets, semi-solid products and suppositories, including IMPs (investigational medicinal product). Following the receipt of the list of deficiencies, the CAPA Plans were submitted, alongside the issuance of the Production and Import Authorization 30F of 04.08.2017 and the GMP Certificates no. 040/2017/RO and no.041/2017/RO of 11.08.2017.

- During the period 03-04.05.2017 the NAMMM inspection was carried out for the assessment of the compliance with the Good Laboratory Practice (GLP, EU GLP) requirements for the GLP recertification of the Bioanalytical Laboratory and Clinical Unit. Following the receipt of the Deficiency List, the CAPA Plans (for the clinical stage and for the bioanalytical stage) were submitted, and the GLP Certificate no. 49 was issued on 05.07.2017.

- During the period 05-06.12.2017, the Iraqi authority inspection unfolded for assessing the GMP compliance of the Quality Management System of Antibiotice SA and the manufacturing lines for penicillin, non-penicillin products, cephalosporins, tablets, semi-solid products and suppositories and parenteral products.

## Audits of certification bodies

The ISO 9001 recertification by SRAC for aluminum tubes, threaded polyethylene caps and metal seals manufactured at the Micro-production Plant following the recertification audit from 28-30.06.2017 was carried out.

During 13-17.11.2017 the ISO recertification audit was carried out by Lloyd's Register Quality Assurance, according to ISO 9001: 2015 and ISO 14001: 2015 (new standards), respectively according to OHSAS 18001: 2007 and the audit reports were subsequently issued with the favorable conclusion and the new ISO Certificates.

## Audits from customers

### Customer audits for the Nystatin active substance

During the year 2017 audits were carried out by specialized firms or external clients, beneficiaries or potential beneficiaries of the Nystatin active substance manufactured on the Antibiotice line. The audits were completed without identifying non-conformities; thus, Antibiotice was proposed to qualify as supplier of Nystatin.

### Customer audits for penicillin capsules

In order to assess the penicillin capsule manufacturing line and to re-qualify Antibiotice as a contract beneficiary, the audit of a contract supplier took place; the results were favorable and Antibiotice was further recommended as a contract beneficiary for the Amoxicillin 500 mg capsules.

### Audits to suppliers of active substances, primary packaging materials, finished products

The auditing of suppliers of active substances, primary packaging materials, finished products manufactured under contract is a mandatory requirement at European level for the marketing authorization holders of pharmaceutical products.

The current legislation forces the Marketing Authorization Holder to periodically verify the compliance with the EU GMP requirements of manufacturers/distributors of active substances over a period of time not exceeding 3 years.

During the year 2017, audits were carried out on the suppliers of active substances and primary packaging materials from Europe and on the suppliers or potential suppliers of active substances from China and contract manufacturing for finished products.





# Social Responsibility

## Antibiotice is a responsible company involved in sustainable development

Antibiotice believes in the need to support social responsibility projects and is constantly concerned that, through all its activities, it contributes to protecting the environment, improving people's lives and health, creating a trustworthy relationship with stakeholders.

Sustainability in business means transparency, ethics and care towards the environment in which the business operates. For this reason, Antibiotice's activities are the result of responsible behavior

such as environmental care, human health, employee development, education, community involvement through social and educational programs.

Antibiotice's goal is to become a model of sustainable development through social responsibility programs, with a strategy based on 4 pillars: health, education-spirituality, social-cultural-charitable activities and environmental protection.

### Health

Antibiotice contributes through social responsibility programs to improving the health of the population. One of the directions is the development of campaigns to educate and inform the population about health prevention.

#### Campaigns for the responsible use of antibiotics

Antibiotice continued in 2017 to inform people about the correct use of antibiotics. Thus, on 21 March 2017, Antibiotice organized the award ceremony of the competition for students of the University of Medicine and Pharmacy Iași "**Antibiotics - use them with care! Everyone is responsible**" initiated in the previous year. Students enrolled in the contest highlighted their creativity by implementing integrated communication campaigns, whose message was the rational use of antibiotics.

*The caravan „Antibiotics saves lives! Use them with care!”*

Between November 18-25, 2017 on the occasion of the European Antibiotic Awareness Day, Antibiotice supported for the third consecutive year the caravan "**Antibiotics saves lives! Use them with care!**" initiated by the Student Associations of the University of Medicine and Pharmacy Iasi.

The caravan has traveled to rural areas in Iasi, Victoria, Mironeasa and Voinesti, aiming to inform and educate rural residents about the judicious use of antibiotics, in areas where the population has less access to healthcare professionals. In the caravan, medical students along with Antibiotice employees have provided useful information about the role, benefits and risks of administering antibiotics, as well as the responsible use of this type of medicines, ways to prevent antibiotic resistance so that these life-saving drugs can maintain their effectiveness for the present as well as for future generations.

Antibiotice's ethical involvement in actions to prevent bacterial resistance is part of its mission to make medicines responsibly. As a manufacturer, Antibiotice is interested in keeping the value of these medicines, which, judiciously used, save lives. Involvement in such campaigns leads to an increase in the level of knowledge and accountability of the population in order to preserve the effectiveness of long-term antibiotics.

On this occasion, the Facebook "Science and Health" page was launched to support the educational message of the campaign "**Antibiotics save lives! Use them with care!**" and to create a community of health professionals, students, general public interested in the topic, who adhere to the educational message and receive correct and consistent information. The site contains information on abusive use of antibiotics, recommendations for rational use of antibiotics, video support, and various messages of interest to the general public, infographics and animations with essential information about what antibiotics are, how they help us, how they are administered and what their future is.

On 24th March 2017, Antibiotice held the awareness events organized on the occasion of the World Tuberculosis Day, by the TB Dispensary of the Iasi Clinical Pneumofiziologie Hospital, in collaboration with the Iasi Public Health Department and the Grigore T Popa University of Medicine and Pharmacy.

On this occasion a flash-mob was set-up on the esplanade from Faculty of Medicine and Pharmacy Iasi, pointing out that tuberculosis is one of the priority health problems and it is important that all the partners involved in the fight against tuberculosis join forces for this treatable disease to be eradicated.

## **“Donate blood! Save a life!”**

Under the urge “Donate blood! Save a life!” 51 employees of Antibiotice volunteered on 10 April 2017 for a blood donation campaign organized by the Antibiotice Science and Soul Foundation, in partnership with the Regional Blood Transfusion Center Iasi.

On World Health Day, the company's employees donated 25 liters of blood to help save over 130 lives. The second round of the campaign "Donate blood! Save a life!" took place on October 17, 2017, when 60 employees donated 27 liters of blood, giving life to 140 people.

## “Healthy living in a healthy company”

The health of the company's employees is important and for this reason, in 2017, the project "Healthy Living in a Healthy Company" was initiated, which aims at raising awareness among the employees on the fact that good health is maintained by adopting a correct and balanced diet.

Two conferences were organized in November 2017 in collaboration with a nutritionist, recommending the employees to adopt a healthy diet and establish the particularities of their diet and nutrition habits.

## Education and spirituality

Social responsibility programs for youth education, who, like our employees, can reach career performance and become responsible role models in society, were also carried out in 2017.

## “Science and Soul” Scholarships

For 16 years, Antibiotice has joined the "ProRuralis" Association and contributed with scholarships to the education of rural children, children with special skills but without material opportunities, supporting them through high school. The first generation of scholars graduated in 2008. A second generation of scholarship students taken over by the Antibiotice Science and Soul Foundation in the 5th grade have graduated in 2017 Garabet Ibraileanu Highschool and are currently students at various faculties in Iași.

## We invest in excellence

In 2017 we continued to invest in excellence by developing educational partnerships designed to support the young generation:

**Annual educational partnership** with Iasi School Inspectorate by supporting the "Gala of Excellence in Education", an event attended by both students and teachers for the real recognition of performance and educational partnerships with prestigious high schools in Iași for national and international school Olympiads .

**An educational partnership** with the St. Sava kindergarten in Iasi, in 2017 whose result was a mini Museum project dedicated to the promotion of authentic Romanian values for the 242 preschool children.

## Social programs

*Beyond its economic performance, Antibiotice, thanks to the Science and Soul Foundation, engages in community life by supporting disadvantaged groups such as children from underprivileged families, elderly people, people in difficulty by developing social programs, some of which have already become traditional.*

### Play, songs and joy on Children's Day

It has already become a tradition for Antibiotice to offer a gift to all employees' children on 1st June. Thus, on 6 June 2017, 120 children of Antibiotice employees were invited to the "Garden of Games and Sunshine" event, where they enjoyed educational workshops, theater, dancing, playing and surprises outdoors.

The children actively participated in the workshop *"Enescu and the rays of sunshine"* which combined elements of musical theory presented in a friendly way with visual elements of national identity:

illustrations with authentic folklore patterns on blouses, wipes and old carpets. The little ones stepped into the world of puppet theater watching the play "Memories from childhood" and popular dances.

Later, the children invited to the event engaged in team play. Ball trails, facepainting, balloon modeling, inflatable toboggans and hammocks have cheered children in the shade of the trees at Pogor Garden. The event was also attended by 20 children from the Bogdana Placement Center in Bogdanesti.

### The Power of Action

On April 12th, 2017 the Antibiotice Science and Soul Foundation supported 25 disadvantaged families and elderly people in Petresti village, Golaesti commune, Iasi county, offering them foods to prepare for the traditional Easter holidays. The village of Petresti is a remote place on the banks of the Prut river, this area being one of the most disadvantaged in the country, on the border with the Republic of Moldova.

### Antibiotice employees were Santa's elves for 80 underprivileged children

For the fifth consecutive year, Antibiotice's Science and Soul Foundation organized the *"Be generous! Be Santa Claus!"* campaign in partnership with the Pro Vita Department of the Archdiocese of Iasi. The campaign addressed children from very numerous families with 7, 8 or 9 siblings, from the rural localities of Iasi county: Cuza Voda, Vlădeni, Traian, Dobrovăț, Mogoșești Galata, Bivolari, Serbești, Fere-den - Deleni.

The 80 children aged 1 to 14 years old have put down on paper everything they want to receive from Santa. Their touching letters reached several of our employees, who enthusiastically assumed the role of Santa's "elves", fulfilling the children's wishes. Coming from

disadvantaged backgrounds, children wanted simple things: school-bags, clothes, boots, books, dolls or cars, fruits and sweets, but Santa and his goblins struggled to offer them more than that.

During the festivities that took place by Antibiotice's Christmas tree on December 18th, 2017, the children were glad to meet Santa and some of the elves who fulfilled their desires. As a sign of thanksgiving, the little ones shared bright smiles and sang Christmas carols

## Environmental protection

Care for protecting the environment is an important direction in the company's social responsibility strategy. Our actions aim to minimize any potential negative impact of our activity on the environment by investing in modern manufacturing technologies and in specific environmental protection actions.

### *“The School Orchard” Project has taken root in five schools in Iași*

Antibiotice has been involved in the community by developing alongside its employees a social responsibility project for environmental protection: the School Orchard Project. Within this project, the company's employees planted, in two stages, 410 fruit trees at schools in neighboring towns or villages: Miroslava, Proselnici, Vorovești, Valea Lupului și Uricani

In the first step of the project, 70 Antibiotice volunteers planted 300 fruit trees at schools in the villages of Vorovești and Proselnici and at the “Mihail Kogalniceanu” Technological Highschool in Miroslava.

The second stage of the School Orchard project took place on 21 October 2017, with the involvement of 50 Antibiotice volunteers who planted 110 fruit trees at the schools in Valea Lupului and Uricani.

*“The School Orchard”* is a project through which Antibiotice employees volunteer and try to inspire the young generation to respect and protect the environment, to maintain a healthy lifestyle and get involved in the life of their community.

### *Earth Hour*

Just as in previous years, Antibiotice participated in the Earth Hour, the largest environmental event of all time, which draws attention to the effects of global warming. On March 25, 2017, Antibiotice symbolically switched off the lights in the company's areas where this was possible.

### *“Be Pro Nature! Put soul!”*

Antibiotice marked the World Environment Day on May 29, 2017 by inviting 60 students from the Valea Lupului High School. The event was aimed at raising awareness on the environment to the young generation, enhancing their concern for protecting and preserving the environment.

As part of the action, children were presented with the wastewater treatment plant and industrial waste incinerator and the way Antibiotice protects the environment. Also, the students of Valea

Lupului highschool participated in a creative contest entitled ***“Be Pro Nature! Put your soul!”*** on the topic of protecting the environment. Their work was sold to the employees at a charity exhibition called ***“We support community education”***, and the amount of 4,000 RON was donated to support the 52 underprivileged children from Valea Lupului School who risk dropping out of school, included in the program ***“At Home, in the community - after school program”***.

## Promoting environmental promotion

Through the Environmental Management System, the environmental protection activity within Antibiotice manages the prevention of pollution and the continuous improvement of environmental performance, acting in order to comply with the requirements of environmental legislation.

By obtaining an Integrated Environmental Authorization in January 2011, valid for a period of 10 years, Antibiotice proves that it respects environmental requirements, emissions of pollutants to air, water and soil are below the limits stipulated by the applicable rules in the field.

## Responsibility for the environment

The activity of the company in the field of environmental protection is regulated by the Integrated Environmental Authorization no. 1/10.01.2011 issued by the Regional Environmental Protection Agency Bacau (valid until 10.01.2021) and by the Water Management Permit no. 303 / 20.12.2010 issued by the Romanian Waters Administration, the Prut-Barlad Water Basin Administration (valid until 31.12.2020).

In order to comply with the legislation in the field of environmental protection, Antibiotice provided the necessary endowments and

qualified personnel. The entire activity is regulated by specific procedures of the environmental management system, as well as by operating procedures and working instructions.

The monitoring of the environmental factors has been carried out according to the requirements of the Integrated Environmental Authorization, both through its own laboratories and through third party laboratories, authorized by the Romanian Accreditation Association (RENAR).

## Specific consumption and use of energy

The activity of the Biosynthesis Plant which produces Nystatin, active substance, enters under the European Integrated Pollution Prevention and Control (IPPC) Directive. In 2017, the Biosynthesis Plant observed the norms of consumption relative to the amount of solvents used.

## Air quality

In 2017, air quality monitoring was carried out in our own laboratory on emissions/ immissions of air pollutants with regard to the indicators: nitrogen oxides, ammonia, suspended particles and sedimentable powders. The maximum acceptable concentrations provided in the Integrated Environmental Authorization were not exceeded.

## Water quality

Water quality monitoring required analyses on the quality of the water entering our water treatment plant and discharged into the municipal sewage system, of conventionally clean water discharged into the natural emissary and underground water.

No exceedances of the maximum acceptable concentrations established by the Integrated Environmental Authorization, Water Management Permit, and by NTPA 001 and NTPA 002 - 2005 have been recorded.

## Soil and groundwater protection

Of the total area of the land owned by Antibiotice, about 40% is free, green spaces being set up.

The quality of groundwater was monitored by monthly sampling and analysis of samples obtained from perimeter observation drilling and drilling downstream of the landfill site. There was no accidental pollution or environmental incident that would lead to the degradation of soil quality in the area of influence of the company's activity.



## Waste management

Antibiotice has implemented a selective waste collection system, each production plant and auxiliary plant being equipped with appropriate collection containers. Recyclable waste was redeemed on the basis of contracts with authorized economic operators.

Unusable waste was incinerated within our facility or disposed of by landfilling at the municipal landfill.

The company respects the packaging waste management requirements (corresponding to the quantity of products that Antibiotice has put on the Romanian market). The overall objective, as well as the minimum recycling recovery targets, by type of material, set for 2017 (according to Law No. 249 of 2015, with subsequent amendments), have been achieved.

## Environmental plans and programs

For 2017, the environmental targets set at the company level were:

**Increasing** the number of EURO 6 equipped vehicles by purchasing a new vehicle, objective formulated in the Investment Plan 2017 and achieved.

**Reduction** by 1% of the specific electricity consumption (kw/Gcal) for the supply of thermal energy (hot water) compared to 2016.

## Prevention and management of emergency situations

At Antibiotice, the prevention of emergency situations and providing intervention in the event of accidents are ensured by these services: Emergency Situations, Environmental Protection, Prevention and Protection.

For this purpose, the accident prevention and control plan, the accident prevention policy for the use of hazardous substances (solvents), the fire protection plan (fire prevention and extinguishing), the fire safety scenario, emergency response procedures, emergency

preparedness and response capability procedures, authorizations / documents required for all equipment subject to the regulations of the State Inspectorate for Boiler Control, Pressure Vessels and Lifting Installations (ISCIR) were elaborated.

In 2017, six internal alarm drills were carried out. During the drills, the capacities of emergency response teams were tested and evaluated.

## External audits

In 2017 two external audits were carried out by the environmental protection institutions (National Environmental Guard and Romanian Waters Administration, Prut - Bârlad Water Basin Administration). The legal requirements in the field were observed, as well as the regulatory requirements.

Within the legal deadline imposed by the Order of the Minister of Public Finance 1938/2016, Antibiotice SA is committed to publishing a Non-Financial Report that will be made available to the public on the company's website.



# Independent Auditor's Report

On the individual financial statements drawn up for the fiscal year ended to December 31, 2017

## To the shareholders of Antibiotice

### Report on the audit of financial statements

#### Our opinion

We audit the attached financial statements of ANTIBIOTICE S.A. ("The Company") with its registered office in Iași, Valea Lupului St. , tax identification number RO1973096 comprising the financial position statement as of December 31, 2017, statement of comprehensive income, statement of changes in equity and cash flow statement for the financial year ended at the above-mentioned date and a summary of the significant accounting policies and other explanatory notes.

The individual financial statements as of December 31, 2017 are identified as such:

- Net assets/ total equity:  
416,877,840 LEI
- Net profit of the fiscal year:  
33,558,354 LEI

In our opinion, the attached individual financial statements give a true and fair view, in all significant aspects, of the financial position of Antibiotice company on December 31, 2017, as well as of the financial performance and cash flows for the fiscal year ended on the above-mentioned date in accordance with the Order of the Minister of Public Finance no. 2844/2016 for approving the accounting regulations compliant with the International Financial Reporting Standards adopted by the European Union ("IFRS-UE").

We conducted our audit in accordance with the International Standards on Auditing ("ISA"), " European Parliament and European Council Regulation no. 537 ("The Regulation") and Law no. 162/2017. Our responsibilities are described in detail in the section Auditor's responsibilities in an audit of financial statements in our

report. We are independent of the Company, in accordance with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants (IESBA code), according to the relevant ethical requirements for the audit of financial statements in Romania, including the Regulation and Law no. 162/2017 and we fulfilled our responsibilities according to these requirements and IESBA code. We believe that our audit evidence is sufficient and appropriate to provide a basis for our audit opinion.

#### Key issues

Key audit issues are those issues that, based on our professional reasoning/judgement had the greatest importance/significance for the audit of the financial statements of the current period. The following key issue was approached in the context of the audit of the financial statements as a whole and in forming our opinion on them and we do not offer a separate opinion on this key issue.

#### Key issue – Value of trade receivables

Presentation value of trade receivables according to IFRA depends significantly on the calculation and estimation process of the trade discounts as well as on the process of estimating their recoverability. The company presented in the financial statements in the explanatory note no. 4 – "Sales Income" the value of the granted trade discounts and, in the explanatory note no. 15 – "Trade and other receivables" it presented the trade receivables in net value of 256 million LEI, adjusted with the estimated depreciation.

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

- assessment of the compliance of the policies for

recognizing the income and trade receivables

- analytical review procedures and detailed tests for verifying the amount of reduction granted, including the expansion of the verifications of the granted discounts in the next fiscal year related to the sales from the audited exercise;
- procedures for direct confirmation of trade receivables balances;
- evaluation of internal procedures and methods used by the management team for estimating the probable amount to be cashed;
- verifying the consistency of applying the accounting policies related to the adjustment of trade receivables.

## Other information – Management Report

The administrators are responsible for drafting and submitting other information. Those other information include the Management Report but they do not include the financial statements and auditor's report on them. The Management is responsible for this information.

Our audit opinion on the financial statements do not cover other information and we do not express any conclusion with regard to these.

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

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

- in the Management Report we did not identify information that is not consistent in all material respects with the information presented in the financial statements on December 31, 2017;
- The Management Report identified above includes, in all the significant aspects, the information requested by OMFP no. 2844/2016 to the para 15-19 of the Annex no. 1;
- The Management Report does not include the non-financial declaration specified to the paragraphs 39 -42 from OMFP no. 2844/2016 which will be presented later in a separate report;
- Based on our knowledge and our understanding gained during the audit of the financial statements drafted on December 31, 2017 about the company and its environment, we did not identify significant erroneous information presented in the Management Report.

## Responsibility of the management and other persons responsible for governance on the financial statements

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

When drafting the financial statements, the management is responsible for assessing the company's ability to continue its activity, presenting, if needed, the aspects of the continuation of the activity and using the accounting based on the continuity of activity unless the company plans to either liquidate the company or or it has no realistic alternative outside of them.

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

## Auditor's responsibility

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

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

- We identify and evaluate the risks of significant misstatement of the financial statements caused either by fraud or by error, establish and perform audit procedures which to address to these risks and we get enough and appropriate audit evidence to form a basis for our opinion. The risk of not detecting significant distortion caused by fraud is higher, because fraud may include complicity, forgery, intentional omissions, false statements, or avoidance of internal control.
- We understand the internal audit relevant to the audit to establish the appropriate audit procedures in the given circumstances, but not to express an opinion on the effectiveness of internal control of the company.
- We assess the appropriateness of the accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.

- We formulate a conclusion on the appropriateness of the company's use of the continuity principle and determine, based on the audit evidence obtained, whether there is significant uncertainty about events or conditions that could raise significant doubts about the Company's ability to continue its activity. If we conclude that there is a significant uncertainty, we need to draw attention in the audit report to the accompanying financial statements or, if these presentations are inappropriate, we must change our opinion. Our conclusions are based on the audit evidence obtained by the date of our audit report. However, future events or conditions may cause the Company not to continue operating on a business continuity basis.
- We evaluate the presentation, structure and overall content of the financial statements, including disclosures and the extent to which the financial statements reflect the transactions and underlying events in a manner that performs the accurate presentation.

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

## Report on other legal and regulatory requests

We were appointed by the General Meeting of Shareholders held on June 28, 2017 to audit the financial statements of ANTIBIOTICE S.A. S.A. Iași for the fiscal year ended at December 31, 2017. The uninterrupted total duration of our commitment is 3 years, covering the financial exercises ended at 31.12.2017, 31.12.2018, 31.12.2019.

We confirm that:

- Our audit opinion in accordance with the additional report submitted to the Audit Committee of the Company which we issued on the same date to which we issued this report. Also, in conducting our audit, we have retained our independence from the audited entity.
- We have not provided non-audit services for the company that are banned according to the article 5, para. (1) from the UE Regulation no. 537/2014.

*In the name of,  
Accounting, Expertise & Accounting  
Consultancy Company SOCECC Ltd.  
headquartered in Buchares, registered at  
the Chamber of Financial Auditors of Romania  
with the no.227/2002 through Zegrea Laurențiu,  
CAFR certified no. 2666*

*Iași, March 14, 2018*