

## MANAGEMENT REPORT 2017

Annual report according to:	IFRS
For the fiscal year:	2017
Report date:	March, 14 2018
Name of the company:	Antibiotice SA
Registered office:	Iasi, 1 Valea Lupului St.
Phone number:	0232/209000, Fax 0232/209633
Tax registration code:	RO 1973096
Regulated market on which the issued shares are traded:	Bucharest Stock Exchange
Subscribed and paid-up share capital:	67,133,804 LEI
Main characteristics of the securities issued by the trading company:	Nominal shares, nominal value: 0.10 LEI

The Management Plan for 2016 - 2020 is assessed for 2017 in the current Management Report.

### CORPORATE GOVERNANCE

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

The governance term means management and involves all activities within an entity which fall into the sphere of management. As a result, it can be said that this concept - corporate governance - means 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 Incorporation of the Company.

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

In 2017, our company proved consistency as regards the 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 is administered by a Management Board responsible for fulfilling 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 Board of Directors and the Executive Management. There is a clear division of responsibilities between the Management Board and the Executive Management.

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

The duties of the Management Board 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 12 sessions and adopted decisions which have allowed to perform its duties in an effective and efficient manner.

Thus, on the monthly meetings, the Management Board analyzed in detail about the financial results in the reporting period and cumulatively since the beginning of the year as well as the economic performance relative to the budget and the same period last year. Depending on the situation, the Board requested, detailed explanations of the executive management in connection with the plans to increase production efficiency, the investment plans, provisions made, liquidity management, operational and general profitability and of activity as well as the commercial policies. After analyzing in detail

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the results of the period, the Management Board decided their approval for publishing and sending them to the Bucharest Stock Exchange and to the Financial Supervision Authority, falling each time within the Financial Communication Calendar.

Cei 5 membri ai Consiliului garanteaza eficienta capacitatii de a supraveghea, analiza si evalua activitatea directorilor, precum si tratamentul echitabil al actionarilor.

Those five members of the Management Board guarantees the efficiency of the ability to supervise, analyze and evaluate the activity of the directors as well as the fair treatment of the shareholders.

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

**Legal adviser, IAVOR Ionuț-Sebastian, 42 years old**

**Chairman 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 of the company and then appointed by the Board members as a Chairman.

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

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

**Economist, Ioan NANI, 58 years old**

**Vice President of 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 Vice President. Economist specialized in management and accountant expert, member of the Management Board since 2009 and General Manager (1998 - 2008 si 2009 - present).

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

**Physician, Adela-Petria 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 2014, Ms. Neagoe was elected as a member of the Management Board for a 4-year period.

Doctor of Medical Sciences, Primary Specialist in Pediatrics, Primary Specialist 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.

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Tax consultant and Accounting expert  
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 in the OGMS held on April 19, 2016, for a 4-year period.

Mechanic engineer and Director of the Placements and Risk Management Department , 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 Ms. Elena CALITOIU;

- *Nomination and Remuneration Committee:* Ms. Elena CALITOIU and Ms. Adela-Petria NEAGOE

- *Trade Policy Committee:* Mr. Ionut Sebastian IAVOR and Mr. Nicolae STOIAN.

The Advisory Committees conducted investigations, analyses and 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 specific areas in which additional verifications 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.

### INTERNAL CONTROL

The specialized internal control activities specified by the legislation in force are made by the Internal Audit Office. These are the following: internal audit, financial management control, management control; these activities are carried out in a

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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 from 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 for Plan, approved by the Audit Committee, extracted from the Multi - Annual Audit Plan for 2015-2019. The objectives of the internal audit missions were targeted:

- to examine if the principles, specific procedural and methodological rules are met;
- to examine the way of organizing the activity;
- to evaluate the management and control system of the activity;
- other objectives specific to the activity of the audited structure.

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, and recommendations were made to improve them.

Internal audit activities are carried out systematically and methodically, providing objective assurance and counseling of the management on the level of functionality 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 of 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 if 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;

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- 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 proposed measures for improving the verified activities. The issued control reports were submitted to the General Manager, who decided the implementation of the proposed measures.

The controlling 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, the 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 management 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 fixes 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.

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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

**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 has 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** 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 following: level of expected cash inflows from the collection of commercial 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** 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.

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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 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.

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.

*Image risk* is defined as the current or 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 these risks by developing the specific plans:

- Emergency evacuation plan;



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- 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.

The legislative instability risk will be mitigated by adapting continuously the policies, norms and procedures to the occurred changes.

The Trade Policy Committee met in two sessions aiming at assessing the commercial activity on 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:

**Remuneration** to the Management Board and Executive Management (General Manager) is presented in the following table:

Description	For the year ended at	
	31-12-17	31-12-16
Wages	1,014,017	817,142
Taxes and social contributions	227,308	183,909
<b>Total</b>	<b>1,241,325</b>	<b>1,001,051</b>

Administrators and directors with a mandate agreement (general manager) are entitled to receive a fixed monthly allowance and a variable allowance for their work.

The variable allowance is payable according to the fulfillment of the performance indicators and criteria established in the management agreements and mandate agreement.

The fixed monthly allowance is established in accordance with the provisions of the art. I.33. para. (3) of Law no. 111/2016 for approving the Government Emergency Ordinance no. 109/2011 on the corporate governance of the public enterprises. The fixed and variable allowance for the members of the Management Board is approved by the General Meeting of Shareholders. General limits for the remuneration of the directors with a mandate agreement are approved by the General Meeting of Shareholders; based on these general limits, the Management Board fixes the amount of the remuneration for the directors with a mandate agreement.

### 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 and also the Vice President of the Board and nine specialty executives.

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### 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 Economics, the "Alexandru Ioan Cuza" University of Iași, Mr. Nani is an economist specialized in management and an expert accountant.

He started his career as an economist within Antibiotice in 1987. Between 1991 and 1993 he worked as a financial control 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, the Technical University "Gheorghe Asachi" Iași. After graduation Mrs. Moraru worked as a chemical engineer at the Fălticeni Chemical Factory. Mrs. Moraru has been working at Antibiotice since 1990, 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 Tablets 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, the "Alexandru Ioan Cuza" University of Iași, 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 Price Effectiveness Office. In 1998 Mrs. Coman became the Head of the Economic Analysis Department and then the Head of the 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 and Logistics Director**

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Graduated from the Faculty of Economics, the "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.

Mr. Chebac started working with Antibiotice SA in 1972. In 1987 Mr. Chebac was an economist in the Planning & Development Office within the Investment Department. Starting with February 1991 Mr. Chebac worked as a financial inspector at the General Directorate of Public Finance Iasi and, starting July 1993, he worked as a financial controller at the Chamber of Auditors Iași. In January 1998 Mr. Chebac was appointed Chief Commissioner at the Financial Guard Iași. In September 2001, Mr. Chebac returned to Antibiotice SA as Commercial & General Services Director.

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

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

**Engineer, Eugen Florin OSADET, 62 years old**

**Engineering & Investment Director**

Graduated from the "Gheorghe Asachi" Technical University of Iași, the Faculty of Mechanics. 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, 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 Thermoenergetic 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 "Gheorghe Asachi" Technical University of Iași, Faculty of Chemical Technology, Ms. 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 of Science (MSc) 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, she 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**

**Huma Resource Director**

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Graduated from the Alexandru Ioan Cuza University of Iasi, Faculty of Economic Sciences, 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 BATAGA, 40 years old**

**Marketing & Domestic Sales Director**

Graduated from the Faculty of Economics and Business Administration (FEAA), 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 Chair, Finance specialty within FEAA. He has been working with Antibiotice SA since February 2001, initially as an economist in the Economic analysis Department and Accountancy & Marketing Department. In January 2006 he was appointed 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 MOSNEGUTU, 48 years old**

**Medical Director**

Graduated from the Faculty of General Medicine, Grigore T. Popa University of Medicine and Pharmacy Iasi, Mrs. Moşneţu 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. Starting with 2005, she became Head of Pharmacovigilance and Medical Consultancy Department and then, in 2009, she was appointed Medical & Retail Promotion Manager.

Mrs. Moşneţu 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 Alexandru Ioan Cuza University of Iasi, Faculty of Economic Sciences, at the International Economic Relations section.

He has been working with Antibiotice SA since 2005, initially as an Area Sales Export Manager - Active Ingredients.

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

Mr. Stoian has been International Business Director since 2012.

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

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

### Code of Ethics

The Code of Ethics of Antibiotice SA presents the ethical standards of conduct that establish and regulate the corporate values, business responsibilities and obligations of the organization 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 guidelines that help the company pursue its values.

The Code is a set of rules under 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 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/Corporate Governance/Reference documents /Code of Ethics](http://www.antibiotice.ro/Investors/Corporate_Governance/Reference_documents_/Code_of_Ethics)).

### Code of Corporate Governance

The Code of Corporate Governance of Antibiotice SA embraced the principles and recommendations of the BSE 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 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 - Guidelines for assessing the Antibiotice administrators

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**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 traces 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

To the website address [www.antibiotice.ro/investors/information\\_for\\_shareholders](http://www.antibiotice.ro/investors/information_for_shareholders), there is a section dedicated for 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, modifications of the agenda, informative materials, special proxies, correspondence voting forms, draft decisions, resolutions, results of votes etc.

The company provides all interested parties with regular 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 for the trading companies and capital market.

The company has a specialized department responsible for the relation with the current and potential shareholders called Investor Relations which has as main role, ensuring a good communication with the company's shareholders. The persons

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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 a proper 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. 2844/2016 for the approval of the accounting regulations compliant with the international financial reporting standards, Order of Minister of Public Finance no. 166/2017 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.

At the same meeting, 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, based 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:

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- 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 - EximBank S.A.;
- 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 S.A.;
- 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 OTCs, Food Supplements and Medical Devices Manufacturers - 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.

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

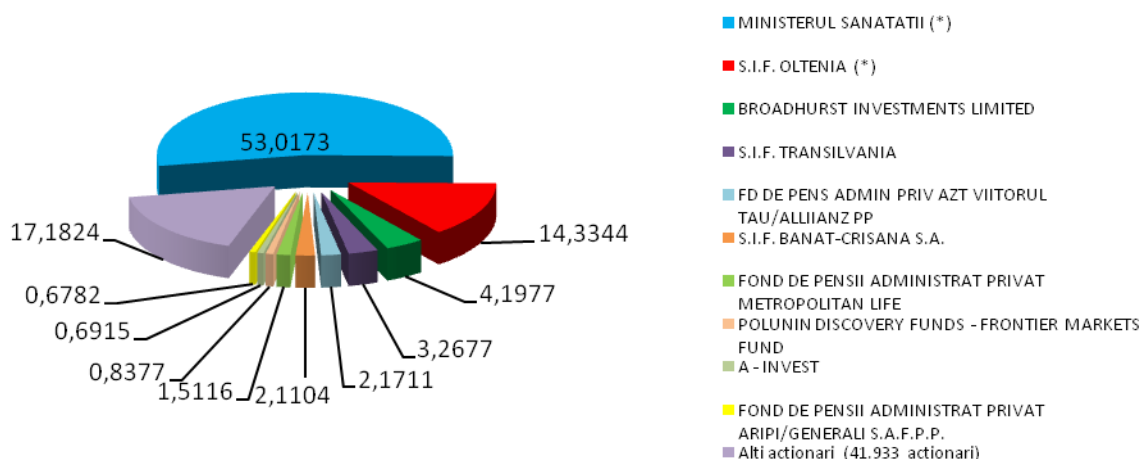
- Ministry of Health (\*) - 53.0173%,
- S.I.F. Oltenia (\*) - 14.3344%
- Broadhurst Investments Limited - 4.1977%
- S.I.F. Transilvania - 3.2677%
- Private Pension Fund AZT Viitorul Tau/Allianz - 2.1711%
- S.I.F. Banat-Crisana S.A - 2,1104%
- Private Administered Pension Fund Metropolitan Life - 1,5116%
- Polunin Discovery Funds - Frontier Markets Fund - 0.8377%
- A-Invest - 0.6915%



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- Private Administered Pension Fund ARIPI/GENERALI S.A.F.P.P. - 0.6782%
- Other legal entities and individuals- 17.1824%.

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



### II. The ownership structure per classes of shareholders

- Lgal entities- 87.0082%,
- Natural persons - 12.9918%.

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 - 2014 - 2015 - 2016)

Period	Net dividends							Dividend payment suspending date
	Due	Paid				Not collected on 31.12.2017		
		LEI			% (totally paid)	LEI	%	
		Until 31.12.2016	01.01÷31.12 2017	Total				
0	1	2	3	4	5	6	7	8
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 of Bucharest and, implicitly, through CEC Bank.

## MANAGEMENT REPORT 2017

### Antibiotice in the securities market

The securities issued by Antibiotice are listed in the PREMIUM category of the Bucharest Stock Exchange under the symbol ATB since 1997.

The first transaction was recorded in April 16, 1997, at a reference price of 0.3500 LEI/ share. The maximum was reached in July 10, 2007 with the price of 2.1700 LEI/share and the 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 medicines 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 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 share was 0.5200 LEI. The price of the share increased to the maximum value of 0.5920 LEI/share.

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

### Antibiotice shares - ATB / Regular Market

	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 euro)*	83,919	87,173	78,868	76,875	77,511
Stock market capitalization (thousand \$)*	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	0.0464	0.0405	0.0452	0.0500
Dividend brut/actiune (LEI/share)**	0.0230	0.0235	0.0197	0.0384	0.026552598
Dividend yeald****	4.12%	4.03%	3.69%	4.05%	4.59%
Dividend Distribution Rate *****	49%	51%	49%	52%	53%

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- \* 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 \$), with an average price of 0.5585 LEI/share.

According to the Chapter VI , Section 2, Art. 92 - BSE Code, *the timetable for financial communication 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 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: <i>Art. 65 (1) of the Law no. 24/2017</i>	20/21.09.2017
• Meeting with the investors and analysts	19.10.2017

## ANALYSIS OF ACTIVITY

In 2017, Antibiotice, the most important Romanian producer of generic medicines continued its mission of manufacturing high quality medicines at affordable prices to give people the hope for a healthy life.

In 62 years of activity, Antibiotice has proved to be a modern and competitive company that has demonstrated that it is possible to achieve in Romania the performances of the world pharmaceutical market. Our company has become a company adapted to the contemporary pharmaceutical market which makes globally known a genuine Romanian brand.

Antibiotice continues to strengthen its activity in Romania, being the main manufacturer of generic anti-infective medicines and leader in the production of topical medicines. Its portfolio comprises 157 generic medicines from 12 therapeutic areas. At the same time, it develops new generic and accessible alternatives for treating cardiovascular, dermatological, central nervous system disorders and for the prophylaxis and quality of life.

2017 is the third consecutive year in which Nystatin, a biosynthesis product (an antifungal used in both the pharmaceutical and cosmetic industries) maintains its position as a world leader. This product obtained also the the world's supreme

## MANAGEMENT REPORT 2017

recognition, receiving the Diploma and the USP Trophy for Nystatin - Reference Standard.

The company's finished products manufactured on the 8 manufacturing flows are sold in 75 countries worldwide.

Following continued investment in manufacturing technologies and workforce training, Antibiotice has continued to have a positive evolution. The national and international top positions are evidence of these sustained efforts. These investments are also reflected in the recognition of quality of the Antibiotice brands as a result of obtaining internationally recognized quality certificates: FDA authorization (granted by the U.S. Food and Drug Administration), Certificate of Suitability with the European Pharmacopoeia (CoS) for Nystatin and GMP authorization for all 8 manufacturing flows. Antibiotice is also pre-qualified by the World Health Organization for its essential antituberculous range.

Antibiotice continues to be a support of the Romanian health system through involvement in national health programs, along with the Ministry of Health.

The Pharmacovigilance & Medical Consulting Department, connected to the European Medicines Data Processing Network - EudraVigilance - is constantly monitoring the efficacy and safety of our medicines. Antibiotice was the first Romanian company which has aligned itself with the European Pharmacovigilance Standards.

In 2007, Antibiotice has become the first certified company in Romania to gain recognition of implementing the Integrated Management System continuously maintained and updated. This was made possible by manufacturing high-quality products, obtained safely and securely to the employees without harming the environment.

The Antibiotice's management team attaches great importance to the introduction of new products into production. Thus, the modern Research & Development Center (finalized in 2011) reduced the necessary times for testing and launching the generics for innovative medicines whose patents expire.

Antibiotice's performances have been recognized at national level in 2017 when it obtained the *Diploma of Excellence* for positioning for 10 consecutive years on the podium of the companies from Iasi and the seventh consecutive year on the 1st place in the category "Industry - very large enterprises - manufacture of basic pharmaceutical products " in a top launched by the Romanian Chambers of Commerce.

A company's success is not only measured by financial indicators and profits but also by giving back to the community. Antibiotice carries out its own charitable actions (Be Santa Claus), humanitarian programs (blood donation) and education programs (ProRuralis Scholarships). Thus, underprivileged families, elderly people and young people without material opportunities or patients receive support when needed.

In order to meet the expectations of its shareholders - to increase the confidence in the company and in its stock market capitalization - the priority actions of the management team were grouped into the following strategic directions:

- I. **Developing the international business component;**
- II. **Providing a sustainable and marketable portfolio by increasing the degree of innovation;;**
- III. **Optimizing the operating costs and increasing the operating efficiency**

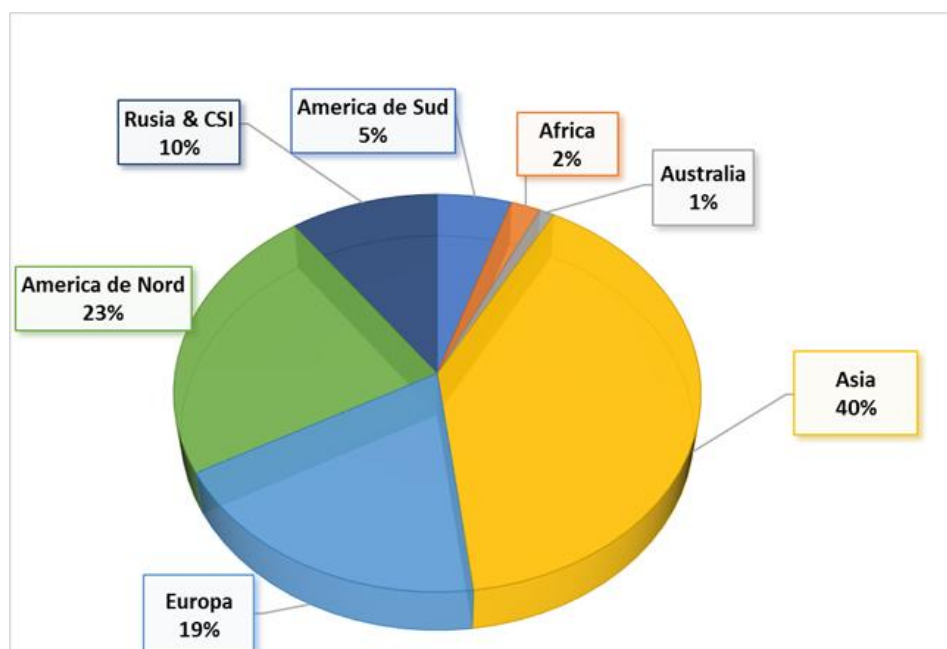
- IV. Adapting the human resource and providing the necessary skills to achieve strategic directions;
- V. Quality management for compliance with the legal, national and international requirements, specific to the pharmaceutical industry.

### I. Developing the international business component

Antibiotic 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 increase of finished pharmaceutical forms by 18.05%, as well as the increase by 10,10% of the export of Nystatin, active ingredient.

Geographic breakdown of exports in 2017 (USD)



Asia represented the main destination of the Antibiotic exports, mainly due to rising the exports of finished products in the Vietnamese market. Nystatin API recorded the most significant growth pace in the US market, with significant impact both on the volume of exports and especially on the profitability of the product.

Europe represented the third geographic area of the company's exports, followed by Russia & CIS, South America and Africa.

**Maintaining the world leadership position for Nystatin API**

## MANAGEMENT REPORT 2017

Nystatin API has the largest share in the sales on the external markets, being one of the Antibiotice's strategic products. The compliance with the current international pharmacopoeias, international certifications on quality and solid partnerships developed over time allowed our company to become the world leading manufacturer of this product. In 2017, by continuously improving the quality of Nystatin, by obtaining the international certifications for accessing the regulated markets and by our flexibility in dealing with the external partners, Antibiotice became a world leader in the market of this product. The most significant increase for Nystatin was recorded in the US market where the volume exported in 2017 was by 50 % higher as compared to the previous year. Increase of the market share in the USA has been a strategic objective of our company and the authorizations obtained in the recent years by end users create the premises as Antibiotice to become the main supplier of this product.

In 2017, the main markets for Nystatin API were: Asia (China, India, Vietnam), North America (the US), Middle East (Iran, Irak, the United Arab Emirates) and Europe (Germany, the Netherlands). The geographic breakdown in the Antibiotice exports of Nystatin API overlaps with the world's largest consumer areas.

The Antibiotice's strategy for Nystatin API has two main objectives:

- to maintaining its worldwide leading position for this product;
- to increase the share in the regulated markets, especially in the US market

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

### **Export of finished products**

In 2017, the main destinations for the export of finished products were: Asia (Vietnam), Europe (the Netherlands, the Baltic countries, Denmark, Serbia), North America (the US, Canada), Russia & C.S.I. (Republic of Moldova, the Russian Federation, Ukraine) and Middle East (Irak, Yemen). Anti-infective products had the highest share in the export of finished products, followed by the medicines for 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 for the well-known products of the company (anti-infectives and dermatologicals) without neglecting the products with a high potential from other therapeutic areas (cardiovasculars, food supplements, etc)

Developing the export of dermatological products represents a strategic priority, taking into account our company's tradition in this field. Antibiotice intends to develop partnerships with dermatological companies in the international market for drafting the registration documentation and marketing of these products

## MANAGEMENT REPORT 2017

### Development strategies adapted to the international pharmaceutical market

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

Antibiotice's strategy in the medium and long term is to address both developed and strongly regulated markets as well as emerging markets with a high growth potential. This strategy is based on 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 of export development are:

- to increase/ consolidate our presence in the current markets and identify new markets with a high potential for Antibiotice;
- to focus our efforts for increasing the Antibiotice's exports in the strategic markets;
- to develop new business models and partnerships in the external markets for speeding the company's development at the international level;
- to adapt the product portfolio traded in the external markets depending on the local consumption.

Considering the need to promote the products on foreign markets, Antibiotice has started the procedures for establishing its own representative offices, the first being in Vietnam, the market in which our company recorded significant increases in the sales in the recent years. In the next period, our company will open representative offices in Ukraine and Republic of Moldova, in order to boost the sales in these markets.

### International promotion

In 2017, Antibiotice participated for the sixteenth time at the Cphl Worldwide Fair held in Frankfurt. The Fair reunited 2, 500 exhibitors from 150 countries and was visited by 36,000 visitors, specialists in the pharmaceutical industry. Attendance at the event aimed at negotiating and developing the current partnerships and developing new business projects, both for export of finished pharmaceutical forms, as well as for Nystatin API.

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

In 2017, Romanian pharmaceutical market recorded an increase in value of 9.1%, reaching 14.12 billion LEI as compared to the value of 12.95 billion LEI recorded in 2016. Physical consumption of medicines recorded also a positive evolution, increasing by 959 million physical units, from 11.7 billion in 2016 to 12.6 billion in 2017.

The following risks can be detected in the pharmaceutical market in Romania:

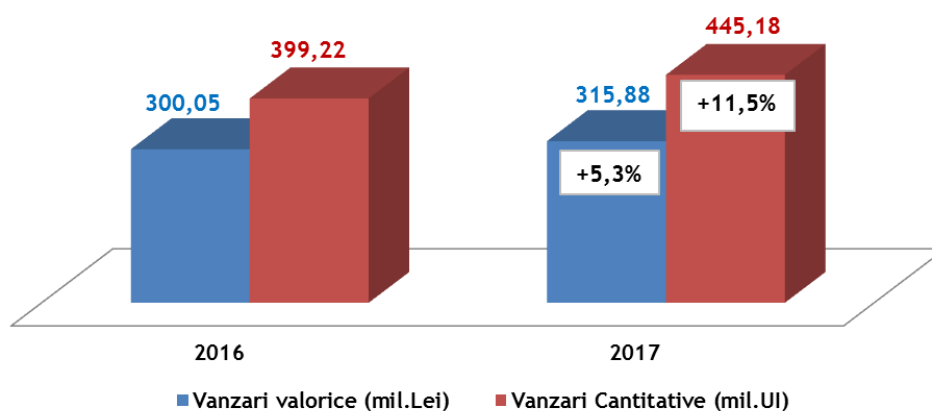
## MANAGEMENT REPORT 2017

- the progressive increase of the clawback tax representing 23.45%, in the fourth quarter 2017 from 18.89% in the similar period of 2016 ( 12.65% in the fourth quarter of 2015);
- increased manufacturing costs due to increase in the prices of raw materials;
- disappearance of family pharmacies and increase of the pharmacy chains and mini-chains has attracted the allocation of more important budgets for pharmacy chains and mini-chains by adjusting the policy of selling of the mini-chain pharmacies and independent pharmacies to the policies implemented by pharmacy chains (negotiation of molecules, negotiation of portfolios, promotion of products by types of diseases, providing a zero co-payment level for the patient);
- lists of compensated medicines have been updated by introducing new molecules so that patients in Romania have access to the latest generation therapies;
- centralized tenders for purchasing drugs, antibiotics and oncologicals, which will lead in 2018 to rationalizing the consumption of resources from the health budget;
- the premise of lowering prices for original medicines under the patent protection that affects drug manufacturers on the one hand. On the other hand, patients will face the disappearance of products on the market, thus the access to medicines will be limited.

In this context, Antibiotice, with a sale value of the portfolio amounting to 315.9 million LEI records a sale increase of 5.3% in the sales in pharmacies and hospitals as compared to the percent recorded in 2016.

### Evolution of Antibiotice sales in pharmacies and hospitals (sell-out)

#### Evolutia vanzarilor companiei Antibiotice din farmacii si spitale (iesiri sell-out)



The retail pharmacy segment is up 5.7% compared to 2016, from 223.6 million lei to 236.3 million lei, while the Hospitals segment records a 4% increase from 76.5 million lei in 2016 to 79.5 million in 2017.

Also, physical sales increased by 11.5%, amid an increase of only 8.2% in total drug consumption.



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The main therapeutic classes which recorded significant increases as compared to 2016: Tract digestive tract (+4.3 million lei), cardiovascular system(+14.4 million lei) and central nervous system (+2.2 million lei) generated by both new products and the positive evolution of the company's top products.

Among these are the products with a contribution of over 1 million lei: Indapamida Atb® tb (+5 million lei), Silithor® (+4.9 million lei), Fluxiv® (+4 million lei), Rosuvastatina Atb® tb. (+2,8 million lei), Meropenem® the range for injection (+1.7 million lei), Equilibra® (+1.6 million lei), Nolet® tb. (+1.4 million lei), Memantina Atb® range (+1.4 million lei), Imipenem/Cilastatin Atb® (+1.3 million lei) and Bisotens® range, tb. (+1.2 million lei).

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

On the generic and OTC segment, the company ranks fourth, with a market share of 5.2%, while the total pharmaceutical market is ranked 17th, with a market share of 2.24%.

Through the sold portfolio in 2017, Antibiotice maintains its leading position from the point of view of units sold on the ointment segment with a market share of 27%, suppositories with a market share of 40.3% and injectable powders with a market share of 74.7%.

The sales of OTCs recorded a steady growth in the recent years, recording in 2017: 22% of total market, with an average annual growth rate of 17.5% (2014-2017).

Ritmul mediu anual de crestere inregistrat in perioada 2014-2017 este de 25,2%, superior ritmului inregistrat de piata totala de profil (17,5%). Through the portfolio of medicines without prescription and dietary supplements, Antibiotice ranks 14th among the companies activating in the Romanian OTC market (out of a total of 213 companies), higher by four positions as compared to 2015 (ranked 18th. The average annual growth rate recorded in 2014-2017 is 25.2%, above the overall market share rate (17.5%).

The share of OTC drugs in sales increased in 2017 to 19.1% (16% in 2016, 13% in 2015), the performing products they being the food supplements Fluxiv®, Silithor®, Equilibra®, Soriso®, Cutaden Bebe® as well as the OTCs Clafen® topical range, Saliform® Forte% and Cicatrol®.

Prin politicile de promovare si comerciale derulate in prima parte a acestui an, suplimentele alimentare detinute in portofoliu au reusit sa performeze in pietele relevante: Through the promotional and commercial policies in the first part of this year, food supplements in the company's portfolio were able to perform in relevant markets: Fluxiv® - ranks third in consumption, out of a total of 25 products, with a 6.9% market share in the second year of sale; Equilibra® - ranks third in consumption, in a relevant market with 40 products, recording a market share of 11.7%; Silithor® - ranks the sixth in the consumption, out of over 65 products, with a market share of 4.7%; Soriso® - ranks first in consumption, with a market share of 37.3%, in the second year of sale, on a market wit 21 competing products.

## MANAGEMENT REPORT 2017

### PRODUCT STRATEGY

The portfolio of 136 medicines for human use (finished products marketed at the exit of Antibiotice in 2017) covering 12 therapeutic classes attests to the fact that Antibiotice's strategy is the permanent orientation towards the renewal of the product portfolio and the manufacture of generic medicinal products which are bioequivalent to the original products while maintaining high quality standards.

Antibiotice's activity - ranging from research, production and sales - is structured on a portfolio of varied medicines in terms of pharmaceutical forms and therapeutic classes.

The new products that are found in the company portfolio in 2017 are:

- Zifex® Complex ovules - a new product for gynecological disorders, completing the Zifex® range. This drug is unique in the pharmaceutical market in Romania containing Nystatin, the active substance whose leading producer is Antibiotice. Zifex® Complex adds value to the Antibiotice portfolio and will contribute together with Nystatin Atb® tablets, Nidoflor® and Nistatina Atb® pessaries to the vertical integration of Nystatin.

- Clobetazol® cream - corticosteroid for topical use, indicated for the short-term treatment of resistant dermatoses (psoriasis, treatment-resistant eczema for flat lichen, chronic lupus erythematosus); the Marketing Authorization was obtained in the first part of the year 2017;

- Betahistin 24 mg ATB® tablets - a medicine belonging to the antivertigo therapeutic subclass, prescribed for the treatment of vertigo caused by blood flow disruptions in the inner ear; the Marketing Authorization was obtained in the first part of 2017;

- Caspofungin ATB@ powder for concentrate for solution for infusion - a systemic antifungal drug for the treatment of invasive candidiasis and invasive aspergillosis; the Marketing Authorization was obtained in the first part of 2017.

Following the general tendency of the population to focus more on preventive therapies at the expense of treatments by consuming food supplements, the company's portfolio was enriched with two food supplements in 2017: Sprinten @ tablets - a dietary supplement that maintains the health of the skeletal system, reduces stiffness and joint fatigue, improving movement; the product has been marketed since November 2017; Fezivit® capsules, a combination for normal body functioning, through the formation of skin collagen, formation of red blood cell and hemoglobin, reduction of fatigue; the product has been marketed since December 2017.

The development of new products, especially in a dynamic and specialized industry as the pharmaceutical one, has as main objective the gradual replacement of products in the medical therapeutics.

### PRICE STRATEGY

Drug legislation limits pharmaceutical companies' ability to use the price as a strategic tool for differentiating between manufacturers.

Price strategies in 2017 have consistently pursued the correlation between the maximum level required by law, increasing the profitability of the portfolio and ensuring

## MANAGEMENT REPORT 2017

a competitive level compared to other players in the market (positioning as the first generic, positioning as reference medicine, best price / quality ratio).

In 2017, the food supplements and non-prescription medicine portfolio (15 OTC products) experienced three price increases (January, July and October), following both competitive market positioning and profit margins optimization.

### DISTRIBUTION STRATEGY

The main objective of 2017 was to strengthen partnerships with major national distributors where significant sales growth was planned.

The product portfolio was supported throughout the year through distribution (monthly offer, periodic campaigns, promotion and merchandising on OTC products) as well as through its own business team and Call Center team with specific actions.

A supply calendar was created on a monthly basis in which profitable products were promoted, with significant weightings in the planned figures, as well as those that represent a significant share in the distributors' stock.

Actions carried out in 2017:

- establishment of monthly / quarterly sales shares with each partner, so as to generate a sales increase in the market compared to 2016;
- taking action to reduce stocks- monthly stock analysis on each partner in terms of products representing 80% of the value stock, products with high storage times (over 2.5 months) and the validity terms;
- keeping offers with constant business conditions for specified periods.

In order to secure the indicators, the company's strategy focused mainly on the increase of the presence in pharmacies chains and minichains segment, which have significant share in the total value of the retail pharmaceutical market.

### PROMOTIONAL STRATEGY

Promotional activities sustained during the analyzed period:

- implementing a pharmaceutical continuing education program addressed to pharmacists;
- Open Door Policy - Visiting the company by physicians and pharmacists;
- participation in events organized by student organisations to promote the company brand among future specialists;
- shelf products marketing campaigns in open-circuit pharmacies;
- organizing interdisciplinary Events in University Centers - Interdisciplinary Symposium "**We've known each other for a lifetime**".

Among the major national events attended by Antibiotice SA in 2017 we mention: National Congress of Internal Medicine, INSPIR, National Congress of Urogynecology, National Congress of Cardiology Sinaia, National Congress of Dermatology Brasov, National Congress of Flebology Timisoara, National Congress of Toxicology Bucharest , The National Congress of Psychiatry in Sinaia, as well as in the main national conferences and scientific symposia held at a national level.

In parallel with the company's participation in the main national events dedicated to health professionals, there were also promotional activities to the general public: Facebook and YouTube communication campaigns, CATP lasi branding project,

## MANAGEMENT REPORT 2017

foiling partner car fleet project (Iasi), promotion of food supplements in events for the general public - Magic of Balloons (Iasi), Rocanotherword (Iasi), Afterhills (Iasi), Neversea (Constanta), Seaside Campaign 2017.

Between November and December, a broad public awareness campaign on antibiotic use was carried out: "Antibiotics save lives. Use them with care". There were presentations for the general public by family doctors in 3 rural locations with 200 participants.

The objectives pursued by the implementation of these promotional activities were: increasing the reputation of the company and the promoted products, training the health specialists to identify the patient profile, therapeutic options and identification of associated recommendations.

The continued implementation of these strategies will enable Antibiotice SA to strengthen its current position - leader of anti-infective medication in the generic manufacturer sector, leader of the hospital sector - generic drugs, a quantitative leader for the following pharmaceutical formulations: ointments, suppositories and injectable powders.

In a market that is so competitive, dynamic and regulated as the pharmaceutical market, Antibiotice's portfolio shows the sustained efforts to promote the company brands and notoriety.

Data source: Sales Cegecim 2016-2017

### **Development of research and development structures for the sustainable adaptation and consolidation of the company portfolio**

In 2017, Antibiotice continued to invest in the research and development of products from classes considered strategic by the company for their impact on public health: Anti-infectives, Cardiovascular, neurodegenerative and Central Nervous System as well as dermatological products and self-medication products (OTC drugs, food supplements and cosmetics).

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

A permanent concern was also the training of young R & D employees for the development of new knowledge and research techniques in line with the latest European and international guidelines.

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

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

In Romania, 7 new Marketing Authorizations for medicines from the following classes were obtained using national procedure: cardiovascular (Betahistina Atb® 8 mg tablets, Betahistina Atb® 24 mg tablets), anti-infectives (Ertapenem Atb® 1g powder for solution for infusion, Caspofungina Atb® 50 mg powder for concentrate for solution for infusion, Caspofungina Atb® 70 mg powder for concentrate for solution for infusion, Tigecycline Atb® 50 mg powder for solution for infusion) and dermatology (Clobetasol Atb® 0,5 mg / g cream) and 2 new food supplements have been notified: Sprinten® film-coated tablets and Fezivit® C capsules.

Development in international markets have been supported by the obtainment of nine new marketing authorizations for Antibiotice products in countries of 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® (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 continued; the procedures are expected to be completed in the first part of 2018.

### **The Medicines Evaluation Center**

#### **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**

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

#### **Pharmacovigilance and health policies**

The monitoring of efficacy and safety of Antibiotice medicines throughout their use is a continuous process, Antibiotice being linked to the European data processing network for medicines safety, EudraVigilance through Pharmacovigilance system. In 2017, access to the European drug safety monitoring system was expanded by developing the EVDAS (EudraVigilance data warehouse and analysis system) module which allows the

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analysis of data stored in the European database and a faster detection of a 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 informed and responsible consumption of self-medication products.

### **Manufacturing activity - Modernizing and streamlining manufacturing flows**

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

Antibiotice produces for the internal 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, all eight manufacturing flows of the company being certified EU-GMP. The manufacturing flows of sterile injectable products and the active substance Nystatin are also certified by the US Food and Drug Administration.

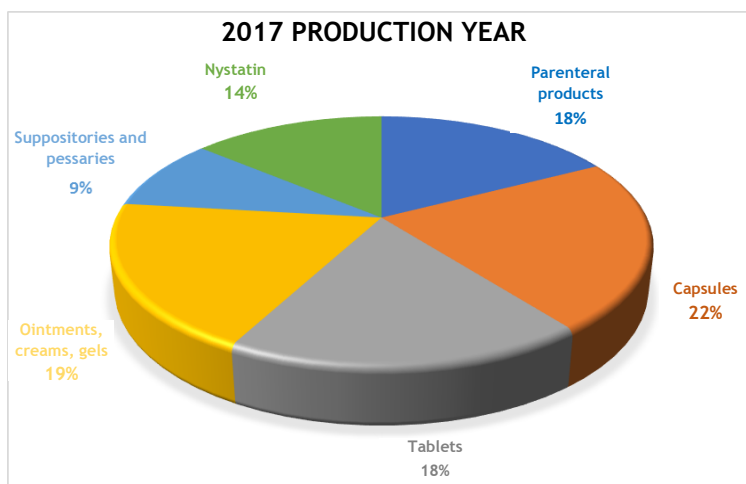
Implementing all regulatory requirements and assessing the quality management system by regulatory authorities and customers across the globe result in maintaining the level of quality, efficacy and safety of Antibiotice drugs.

#### **Antibiotice produced 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 2017 production year related to pharmaceutical forms is presented in the chart below:

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**The objectives of Antibiotice in 2017 in the field of pharmaceutical manufacturing:**

- Manufacturing of parenteral products for foreign companies based on manufacturing and control contracts. Production for export of parenteral products accounted for 31.11% of the total value of products destined for foreign markets;
- Reducing raw material costs by optimizing manufacturing formulations and identifying new sources for the excipients used in finished products technology;
- Reducing utility consumption through careful management across all production sites;
- To continue the efforts to implement the environmental protection program on volatile organic emissions during the Nystatin extraction phase.

**Investment policy - Medium and long term development through investment in new facilities**

The total approved value of the investment program for the year 2017 is 72,094 lei. The achieved value at 31.12.2017 is of 41,017 lei or 56.9%.

ANTIBIOTICE S.A. makes valuable medicines, accessible as a health care tool for patients, doctors and pharmacists.

A permanent concern is the modernization of activity and products.

A valuable medicinal product is not necessarily an expensive one, but one that people can afford and that brings a reasonable gain that can sustain the production and performance by investing continuously in people, technology and successful partnerships to strengthen the position of the company on the market and to enter new potential markets.

In order to achieve this goal, it is always necessary to have well-planned investment that will contribute effectively to a balanced development of all the company structures: production, research, quality control, utilities, logistics.

The investment objectives included in the program are being pursued to achieve:

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- a new, high performance capacity equipped with modern production facilities for the manufacture of ointments and suppositories that is suitable for being authorized by GMP and FDA;
- Modernization and refurbishment of existing production flows to increase production capacities, product quality and reduce production costs;
- modernization of installations that provide utilities for the entire platform;
- achieving objectives that are in line with the strategy to reduce pollution and protect the environment;
- a constant compliance with the rules of Good Manufacturing Practice (GMP) as well as regulations for labor protection and environment protection to consolidate the integrated management system, create new production facilities to reduce costs, utility consumption and increase work productivity;
- increasing the storage capacity for raw materials corresponding to the increase of the production capacity.

### I. ONGOING INVESTMENTS

#### 1. Equipment for production, quality and research plants

Laboratory equipment and apparatus were contracted in 2016 for the purpose of refurbishing production flows and quality control laboratories and research laboratories for which payments were made in 2017. Both manufacturing and laboratory equipment are the latest generation, with high productivity, low energy consumption and high operational safety. The manufacturing equipment is designed to replace older generation equipment with significant physical wear that generates high maintenance costs and low productivity. The acquisition of modern laboratory equipment is required by the ongoing revision of pharmacopoeial monographs and increasing of the precision of analytical methods in laboratories in the farm industry.

#### 2. Rehabilitation of the system for supporting and distribution of utility transport networks

It continues the actions taken to upgrade the system of transportation and distribution of utilities (steam, compressed air, hot water, demineralized water, methane gas, electricity) from the entire platform of the company, started in the previous years. The main goal of this investment is to configure and adapt the utility routes to the current consumption of the production flows in order to achieve energy savings by reducing consumption and eliminating losses.

#### 3. Storage for biosynthetic raw materials

Based on analysis, it was proposed to set up a biosynthetic raw material storage room near the manufacturing department, the main advantage being the location in close proximity to the production flow, thus reducing the fuel consumption of the goods from the warehouse to the production plant, increasing labor productivity.

### II. NEW INVESTMENTS

#### 1. Creating a production capacity for Ointments and Suppositories

The aim of the project is to establish a new production facility to manufacture semi-solid pharmaceutical products divided into tubes and suppositories in order to increase the turnover and capacity of Antibiotice S.A. to register, produce and market



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quality Romanian medicines by investing in a new plant suitable to receive GMP certification in all regulated pharmaceutical markets (Europe, USA and Canada).

Objectives of the investment:

- construction and proper equipping of an Ointment and Suppository Plant suitable to receive Authorized EU-GMP and FDA certification.

- GMP Certification of the newly constructed Ointment and Suppositories plant by the national regulatory authority in the field (National Agency for Medicines and Medical Devices).

- ensuring the conditions for the manufacture of medicinal products in compliance with legislative and pharmacopoeial requirements to be registered and marketed on all regulated markets, especially in Europe, the USA and Canada.

Justifying the investment

The construction of a modern plant for the manufacture of semisolid drugs divided into tubes (ointments, creams, gels) and suppositories is for Antibiotice S.A. the guarantee of long-term business development.

The company's development strategy focuses on maintaining and expanding the portfolio of semisolid products divided into tubes and suppositories.

The strategy is based on developing the portfolio for the domestic market, but also on the diversification and access into new major foreign markets in Europe, North America, Asia and Africa.

In order to ensure the main characteristics of the medicines (quality, efficacy, safety), their manufacture must be carried out in facilities equipped with efficient equipment and critical utilities that meet the requirements of Good Practice of Manufacturing (GMP).

### **2. Investments in manufacturing flows - Production Unit**

In 2017 it was proposed to acquire equipment, installations, various appliances and laboratory equipment in order to refurbish the production flows. The manufacturing equipment and the purchased installations are the latest generation, with high productivity, low energy consumption and high operational safety. The manufacturing equipment is designed to replace equipment with significant physical wear, which generates high maintenance costs and low productivity. Purchase of equipment and various appliances was also necessary in order to implement environmental protection measures, to reduce energy consumption and to ensure work safety.

### **3. Licensing for new products and research projects - Medical Unit**

The new product development program has the following objectives:

- Modernization of the company's product portfolio in order to ensure and supply the internal market with generic drugs of the latest generation, therapeutically effective and safe in administration;

- Providing competitive pharmaceutical products on the foreign market and ensuring, in the long term, the growth of Antibiotice's turnover and competitiveness.

### **4. Research investments - Medical Division**

Research is one of the most dynamic company's activities, which undergoes permanent changes and an ascending evolution. For the entire company, research acts as a dynamic element of the whole system, generating new products that lead to a

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production increase. Using intelligence and creativity, the research area contributes to product portfolio development.

Considering the importance of the information obtained in the Medicines Evaluation Center, the investment program included a range of equipment, appliances and software to support and improve research in order to obtain new, quality, valuable, competitive products.

### **5. Quality Investments - Quality Unit**

In view of the ongoing revision of pharmacopoeial monographs and the increased precision of analytical methods in the pharmaceutical industry laboratories, it has become imperative to acquire the latest generation equipment that will make it possible to maintain the quality control of the products manufactured by Antibiotice at international standards. Quality Control Laboratories have a decisive role in demonstrating the quality and compliance of the products manufactured in our company, which is why they need to be permanently equipped with the most modern and efficient laboratory equipment.

### **6. Investments to ensure logistics - Commercial Unit**

Investments are mainly directed towards the refurbishment of the auto park fleet. Thus, modern means of transport equipped according to the current transport legislation have been acquired to ensure safety in handling for the transportation of raw materials and finished products and for the partial replacement of the used auto fleet.

### **7. Investments for the production and transportation of utilities - Engineering and Investments Division**

The investments were mainly focused on the modernization and upgrading of the systems, equipment and installations for the production of utilities (steam, compressed air, hot water, demineralized water, methane gas, electricity, drinking water, sewerage, etc.). In order to adjust and adapt utility routes to the current consumption of manufacturing flows, so as to save energy by reducing consumption and eliminating losses.

These investments generate many benefits:

- safety in operation;
- increasing labor productivity;
- reducing intervention times by implementing a powerful diagnosis system based on error messages, which leads to a decrease in maintenance and repair work;
- economy of energy and resources and implicitly better environmental protection;
- ease of use in handling the equipment by the human operator.

For objective reasons, a number of scheduled investments were made only partially, such as:

-Creating an Ointment and Suppository production capacity.

In 2017, for this objective, an amount of 23,433,000 lei was estimated, of which part represents the value of construction works and installations for the first stage (construction of the perimeter for manufacturing area and the technical-administrative building) and the rest representing the estimates for the advances to be paid to the technology equipment supplier and the clean room provider. From the total estimated value, an amount of 9,304,000 lei was invested, representing the value of construction and repair works for stage I.

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Since a proper analysis of the equipment provider's proposals and a good correlation between the equipment and the installations related to the construction elements of the building and the cleanrooms as well as the related installations were necessary, the time was insufficient to make all the corrections and, thus, to conclude the contract and payment of the advance in 2017. The selection procedure of the supplier of clean rooms and related installations was started in September 2017, when the URS was finalized by the designer Sinprest SA (completion of the URS was conditioned by the provision of technical data by the technology equipment supplier).

Initially, three companies from Europe (Cleantek Switzerland, M + W Group Germany and Cleangrad Slovenia) were selected, with experience to design cleanrooms for the pharmaceutical industry; these companies were asked to submit offers for the completion of four-turnkey manufacturing flows. The first two companies could not support our project. Thus, the procedure was resumed by selecting two other companies: Klimaoprema Croatia and Nicomac Italy. The Nicomac company informed us that they are only manufacturers of cleanroom supplies and could not make a turnkey project as requested but can recommend a company that can support a turnkey project - the Soimar company in Italy. Following the recommendation, the offer was also requested from this company. All these steps led to the prolongation of the selection procedure, so signing the contract and paying the advance were not possible in 2017.

- Aquisition and installation of a ventilation system at the Parenteral Products Plant. An amount of 1,000,000 lei was estimated for this objective and an amount of 543,711 lei was invested because only the climate control center and the related installations were set up; the indoor ventilation system, related to the clean areas, will be built in 2018 because it requires a rigorous design by a specialized firm and it takes a longer time.

- Storage space for finished products - Medical Unit - scheduled value of 682,500 lei. This goal was not achieved in 2017, as no suitable space for such a storage space with all the necessary facilities was identified.

- Relocation of acids and bases storage - the Storage service - estimated value 614,250 lei, invested 10,500 lei

Being a new warehouse for dangerous substances, it is necessary to do it after a rigorous project, prepared by a specialized designer. Construction must also be authorized. Both designing and authorisation are activities that take a long time (about 6 months or more). It was also not possible to provide all design data to the designer. The current hydrochloric acid storage containers have high physical wear and need to be replaced. The process of identifying a manufacturer for these type of equipments (with a special design to withstand the corrosive action of acid) was difficult. By the end of 2017, a manufacturer that has the technical possibilities to make such equipment has been identified. The dimensions and geometry of these containers are essential design data for sizing the retention tank and installations. For these reasons, the design project was not finished and the authorization process of the construction could not start.

### III. The optimization of operational costs and the increase of exploitation yield

#### THE NET INCOME OF THE PERIOD GROWS BY 10% IN COMPARISON WITH 2016

Antibiotice carried out its activity during 2017 in the spirit of achieving the objectives and indicators established through the Budget of Income and Expenses.

Starting with the 2012's financial exercise there have been adopted for the first time the International Financial Reporting Standards (IFRS) which required the the **restatement of the accounting information** in compliance with the Order of the Public Finances Minister no.1286/2012 and with the Order of the Public Finances Minister no.2844/2016, 2013 being the first financial exercise in which the accounting is registered in accordance with the IFRS provision.

#### The statement of the global result

The sales income in 2017 have registered a value of 336.9 million RON, increasing by 1.3% compared to 2016 when 332.4 million RON were registered, as a result of the collective effort by the company to consolidate business.

STATEMENT OF THE GLOBAL RESULT (RON)	31.12.2016	31.12.2017	2017/ 2016
<b>Sales income</b>	332,435,059	336,904,666	1.013
Other operating revenues	20,262,937	37,796,667	1.87
Revenue associated with product stock costs	-900,215	4,235,363	-4.70
Revenue from the capitalization of the activity	2,177,574	1,850,831	0.85
Expenses with raw materials and consumables	126,867,849	127,072,000	1.00
Expenses with staff, of which:	76,846,812	85,897,194	1.12
- current expenses with staff	71,800,968	81,310,923	1.13
- staff provisions	5,045,844	4,586,271	0.91
Expenses with amortization and depreciation	18,948,912	17,098,098	0.90
Other operating expenses	91,782,114	113,395,172	1.24
<b>Operating profit</b>	<b>39,529,669</b>	<b>37,325,063</b>	<b>0.94</b>
Financial incomes	8,134	4,287	0.53
Financial expenses	4,656,157	1,967,920	0.42
<b>Profit before tax</b>	<b>34,881,646</b>	<b>35,361,430</b>	<b>1.01</b>
Expenses with profit tax	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 expenses progressed by:

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- the diminuation of the expenses with raw materials and consumables is determined by the fabrication structure as well as by the production diminuation;
- the expenses with staff have increasing by 12% compared to 2016 and increasing by 3% compared with the planned values due to the salary increase granted in May in compliance with IEB approved in the General Meeting of Shareholders;
- other expenses registered a value of 113,4 million RON, increasing by 24% in comparison with the same period of last year and by 37% compared to the budget values. These increases were counterbalanced by the superior operating revenues values. Mainly, the increase of these expenses is caused by the listing of uncertain expenses receivables amounting to 7.8 million RON, the increase of the clawback tax to 29.2 million RON, disadvantageous exchange rates of 8 million RON, halted research projects of 1.1 million RON.

The financial income and expenses represent income and expenses with interest.

The profit before tax for the current financial exercise amounts to **35.36 million RON**, higher than that of 2016 by 1%, and by 1% up than the profit estimated in Antibiotice's IEB.

The profit after taxing amounts to **33.56 million RON**, higher than that of 2016 by 11% and the one budgeted by 17%.

The net profit in 2017 amounting to 33.558 million RON is the result of este rezultatul the deductibility of the profit reinvested in technological equipment and the uncertain receivables taken out of evidence.

### Statement of the financial position

On 31.12.2017, the fixed assets of the company recorded an increase by 9% compared to the beginning of the year. The accounting damping is calculated using the linear method according to the IFRS standards.

	01.01.2017	31.12.2017	
<b>ASSETS</b>			
<b>FIXED ASSETS</b>			
Tangible assets	206,702,347	223,242,890	1.08
Intangible 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>CIRCULATING 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 CIRCULATING 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>DEBT</b>			

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### CURRENT DEBT

Commercial debts and similar	49,045,370	55,535,974	1.13
Amounts owed to credit institutions	40,705,967	69,731,310	1.71
Debts from current taxes	11,486,302	9,792,887	0.85
Short-term provisions	1,418,895		0.00
Investment subsidies	275,047	326,246	1.19
<b>TOTAL CURRENT DEBT</b>	<b>102,931,581</b>	<b>135,386,417</b>	<b>1.32</b>

### LONG-TERM DEBT

Investment grants	2,639,349	2,498,889	0.95
Postponed taxes	18,758,368	18,172,398	0.97
Long-term provisions	0	0	
<b>TOTAL LONG-TERM DEBT</b>	<b>21,397,717</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>

### Share capital and reserves

Share capital	264,835,156	264,835,156	1.00
Re-evaluation 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	-60,650,699	0.96
Profit allocation	-	-10,982,386	
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 CAPITAL AND DEBT</b>	<b>533,395,657</b>	<b>572,935,544</b>	<b>1.07</b>

#### Current assets:

- stocks see an increase of 12% compared to 2016;
- total receivables see an increase in value of 9% due to late payments in the sanitary system.

The average time for collecting receivables from the external market in 2017 was 79 days while from the domestic market was 353 days, resulting in an average time for collection of 257 days.

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

The main diagnostic indicators of the company highlight the financial equilibrium and the continuing concern for business efficiency and adjustment to changes in the business climate so that liquidity indicators were slightly higher than in 2016, with the level of indebtedness increasing from 23% to 27%.

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		31.12.2016	31.12.2017
<b>ROE (return on capital employed)</b>	=Net profit/Equity capital	7.4%	8.0%
<b>ROA (return on assets)</b>	=Net profit/Total assets	5.7%	5.9%
<b>EPS (RON/Share)</b>	=Net profit/Share	0.045	0.050
<b>NET PROFIT RATIO</b>	=Profit/Sales income	9%	10%
<b>GENERAL LIQUIDITY</b>	=Current assets/Current bonds	3.1	2.5
<b>QUICK LIQUIDITY RATIO</b>	=(Current assets-Stocks)/Current bonds	2.5	2.0
<b>Level of indebtedness</b>	=Debt/Total assets	23%	27%
<b>No shares</b>		671,338,040	671,338,040

### Elements of liabilities

The company has on 31 December 2017 current debts amounting to 135.4 million RON increasing by 32% compared to 2016, the company's need of cash in 2017 being superior to 2016, for payment of the claw back tax, leading to a greater use of the credit lines.

### Amounts owed to banks 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 RON
Deadline	16.08.2018
<b>Balance at 31 Decembrie 2017</b>	28,769,000 RON
Guarantees	Mortgage on 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 RON
Deadline	26.06.2018
<b>Balance at 31 Decembrie 2017</b>	25,905,001,42 RON
Guarantees	Mortgage contract for buildings, land / Contract for assignment of receivables

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

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- Romanian Subsidiary

Objective	Credit line - circulating capital
Amount	9,500,000 EUR
Deadline	22.05.2018
<b>Balance at 31 Decembrie 2017</b>	8,739,544.83 RON 1,355,830.54 EUR ( 6,317,763.57 RON )
Guarantees	Mortgage contract for buildings, land / Contract for assignment of receivables

### 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 RON
Deadline	16.08.2017
<b>Balance at 31 Decembrie 2016</b>	22,919,001 RON
Guarantees	Mortgage 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 RON
Deadline	27.06.2017
<b>Balance at 31 Decembrie 2016</b>	0 RON
Guarantees	Mortgage contract for buildings, land, receivables

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

- Romanian Subsidiary

Objective	Credit line - circulating capital
Amount	9,500,000 EUR
Deadline	22.05.2017
<b>Balance at 31 Decembrie 2015</b>	3,916,884.93 EUR (17,786,966.16 RON )
Guarantees	Contract for assignment of receivables / Mortgage contract for buildings, land

SC Antibiotice SA has not submitted guarantees and has not pledged or mortgaged its own assets to guarantee obligations in favor of a third party.



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### Cash flow

The amount of cash and cash equivalents at the beginning of the period was of - 26,8 million RON, representing loans/credit amounting to 40.7 million RON of which 13.9 million RON remained unused, available in accounts with banks from the same credit lines. Cash revenues from the operations were 313.46 million RON. Cash payments to goods and services suppliers were 179.35 million RON and those to and on behalf of employees were 77.4 million RON.

Also, payments of 8.88 million RON representing income tax, VAT, local taxes and bank interests and payments of 43.31 million RON for the acquisition of fixed assets were made. Contributions were paid to the Ministry of Health (claw back tax) of 28.43 million RON.

Regarding the financing activity, dividends were paid amounting to 13.66 million RON.

At the end of the period, cash and cash equivalents amounted to 64.62 million RON, which represents credit lines for the current activity (RON 69.73 million) of which 5.11 million RON remained available in banks of the same credit lines.

The company has fully paid its obligations to the state and local budget amounting to 76 million RON.

## COMMERCIAL POLICY

### Raw materials imports

In the context of internationalization of the company's business, the mission of the procurement team extends from the cost-optimization area to identifying eligible sources that provide safety in meeting the quality and manufacturing standards required by current legislation.

In this way, it is attempted to anticipate the occurrence of risks in the acquisition process through the interdepartmental evaluation of the potential suppliers in the (pre) selection phase, to encourage strategic partnerships with representative international suppliers, direct and transparent communication, to follow the procurement process from the moment the order is launched until the receipt of the goods in the warehouses of Antibiotice.

In the continuous research and development of the portfolio of products from various therapeutic areas or involving complex pharmaceutical forms and production steps, the acquisition activity has the role of identifying and contracting the most optimal alternative through the quality of the raw material, the costs and the security of the acquisition source.

Antibiotice uses an exhaustive process of identifying suppliers, applying gradual selection criteria, so at the end it has at least 2 viable and safe sources for each raw material.

#### ***Top 5 rules to be respected in the acquisition activity:***

- Compliance with the current regulations and legislation
- Impartial handling in the selection process, offering all potential suppliers equal opportunities to a contract

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- Implementing a fair, ethical and transparent supplier rating system that promotes stable long-term partnerships through technology and manufacturing capacities, quality, price, delivery capacity, corporate stability, etc.
- A fair cost to volume ratio, allowing the company to achieve economies of scale related to manufacturing campaigns
- Continuous communication with the supplier so that any risks associated with production and acquisition are known, evaluated and resolved in the best possible time.

### Internal market acquisitions

The procurement process on the internal market is the result of interdepartmental efforts ranging from production planning to ensuring the transport of raw materials and materials needed to carry out the manufacturing process. The harmonization of the commercial conditions imposed by the specificity of the activity in the pharmaceutical industry with the trends on the internal market is the commercial policy of Antibiotice.

In 2017, the internal trade policy considered the following:

- Ensuring the offers (minimum three) for the raw materials and materials necessary for the production, in order to obtain the most competitive price on the market;
- Increase of payment terms (supplier credit) included in contracts up to 90 days;
- Obtaining prompt deliveries from suppliers;
- The renegotiation of contracts with suppliers of raw materials, printing materials, consumables, solvents, reagents, spare parts and auxiliary materials (in the sense of discounts), with direct implications for manufacturing costs;
- Elimination of complaints about the quality of raw materials and materials that can cause malfunctions in the production process;
- Developing and maintaining favorable relationships with the company's suppliers, as well as seeking and developing new ones.

A continuing concern was reducing operating costs to increase operating efficiency. In this sense, a plan for reorganizing and resizing the activities and their profitability was launched, focusing on the most competitive price, the largest supplier credit in terms of financing capacity and market requirements recovery without compromising on quality standards. Issues related to the transport of raw materials, printing materials, solvents, reagents, spare parts, as well as timed delivery times to avoid overloading and stockpiling were taken into account.

## IV. Adapting of human resources and the assurance of the necessary competencies to achieve strategic directions

The human resources policy promotes the diversity and equal opportunities in recruiting, selecting and integrating employees. We provide employees with all the rights deriving from the law, offering fair and equitable working and professional development conditions.

**On 31.12.2017 the average number of staff is 1420.**

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By the nature of the specific activities carried out at Antibiotice, the structure upon the levels of education and professional training of the staff is the following:

Higher education - 601 employees, of which:	42.32%
- 32 employees with completed doctoral studies (5%)	
Secondary education - 819 employees	57.68%
<b>Total 1420</b>	<b>100%</b>

In order to achieve the strategic objectives of the Business Plan for the period 2017-2020, the activity of the Human Resources Management Department in 2017 aimed at fulfilling the specific objectives, structured within the strategies and action measures.

The strategy „Providing with staff, training of the skills necessary to achieve the objectives and increasing the degree of involvement”

The concrete actions taken in implementing this strategy were aimed at:

### ***1. Identifying of the staffing needs of each structure to achieve the objectives***

In order to put into practice an integrated vision of all the Company's directions in terms of staffing to the needs of the proposed strategic objectives, there is an **Employment Commission** within Antibiotice, which has the role of establishing the necessary staffing to ensure an optimal structure of functioning, but also to maintain the balance of indicators assumed and approved through the Income and Expense Budget.

During the meetings of the commission in the year 2017, the results of the analyzes regarding the staff needs upon the organizational structures of the Company were presented taking into account the following:

- the need to fill vacancies;
- developing teams in priority areas:
  - o research & development
  - o portfolio management;
  - o production;
  - o automation and investment.

### ***2. Providing specialized staff and training of the necessary skills***

#### **Ensuring the staffing needs**

During the year 2017, 120 persons were employed, namely:

- 47 employees with higher education, 21 of which for the development of research teams, portfolio management, production, engineering and 26 for completing vacancies;

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- 73 with secondary education of which 8 for the development of production and engineering teams and 65 for filling vacancies.

The staffing has been accomplished both through the specific recruitment and selection stages, as well as through specific projects of attraction and selection.

### **“Perform a+”, 2nd Edition**

The project aims to select, attract and develop pharmacists (residents and final year students), physicians (residents and final year students), biologists (final year students), chemists (final year students) for specific activities within the Medical Unit, a the creation of a long-term communication and collaboration platform with the “Gr.T.Popa” University of Medicine and Pharmacy of Iasi, the „Al.I.Cuza” University of Iasi and „Gh. Asachi” Technical University of Iasi in order to train and attract specialized staff.

The „Perform a+” project continued this year also in the Medical Unit through the collaboration with the Faculty of Pharmacy in Iasi for the selection of graduates for Pharmaceutical Development, with a program of theoretical and practical activities carried out through mentors appointed amongst the employees of the Company; 6 of the graduates were attracted during the year 2017 through this project.

### **„Summer School a+” 8th Edition**

The external component of this project is aimed at training specialists in the fields of pharmacy, biology, chemistry, chemical engineering for selection in order to fill vacant positions in Pharmaceutical Development, Quality Assurance, Quality Control and Production structures by familiarizing candidates with the work environment, the concepts and regulations in the pharmaceutical industry.

Through this well-known project in the academic environment of the city of Iasi and among the final years students of the Iasi universities, a number of 30 participants benefited from the training of our Company’s specialists during the period July - August. The themes approached during the „Summer School a+” classes dealt with 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 the program was completed with the testing the acquired knowledge and enrolling graduates in the database for future selections.

*To date, a total of 36 participants have been hired during the past 8 „Summer School a+” editions.*

### **Partnerships with pre-university education institutions**

Also, within the partnerships established with the „Petru Poni” Technological High School of Iasi and the Technological High School of Mechatronics and Automatizations for the school year 2016 - 2017, 60 pupils from the 11th grade 12th, specialized as laboratory chemist/chemist operator in the medicine and cosmetics industry and mechatronist/electromechanical technician have undergone internships in our Company.

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The program aims at building practical skills and enhancing the students' knowledge in order to attract staff to replace the employees facing retirement opportunities.

Under the „A different school” program, Antibiotice received more than 450 students from the pre-university education institutions in Iasi to make them familiar with the history and the way of working of one of the most famous landmarks of the industry in the Iasi area.

### ***3. Carrying out of professional skills training programs***

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

In addition to the internal lecture programs set for each structure according to the specifics of the activity, Antibiotice organizes for its employees continuous training programs with external lecturers according to the Annual Training Plan approved and budgeted for the current year.

During 2017 a number of 580 employees followed scheduled training sessions, by specialization fields.

In 2017, the number of training hours per employee was 36.26 compared to 35 hours per employee as previously planned.

#### **The training was structured as follows:**

- 4 themes for the sales staff in the domestic market;
- 6 themes for the quality and research specialists;
- 3 themes for the automation specialists;
- 2 themes for the production specialists;
- 3 themes for the legal advisers.

The internal component of the “Summer school a+” program provided for the employees this year offered also at its eighth edition, the possibility for 244 employees to benefit from training aiming at developing specialized skills in the fields of quality assurance, laboratory techniques, engineering, new requirements in validating manufacturing processes and equipment re-qualification, as well as organizational development through human resource management, conflict management, talent management and employer branding.

A new group of junior managers attended an extended module during 8 training sessions called „Initial Training of Managers” which provided them with the main notions about the team organization and coordination, achievement of results, behavior and team communication with young colleagues who have not undergone management training during their academic education.

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### 4. Increasing the degree of awareness of employees as well as their involvement in all organizational structures

Setting the 2017 targets for MBO staff

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

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

Once established and assumed, the objectives were transposed into addenda to individual labor contracts for a number of 321 employees involved in this system.

#### ***Annual Performance of Individual Performance***

According to the internal procedure, the process of evaluating the performance of employees in the activity carried out in 2016 was done on the basis of the evaluation forms. Employees on all hierarchical levels are included in the evaluation process, the assessment being differentiated as follows:

- ***The assessment of management personnel (managers)*** - takes into account both the assessment made by the hierarchical superiors according to the way of planning and administration of the subordinate personnel, the decision making and implementation of these decisions, the assumption of the responsibility of these decisions, the identification and prioritization of activities, balanced assignment of tasks, training and evaluation of subordinate staff, creating a favorable working climate, efficient use of assigned resources and budgeting, activity control, identification and correction of deficiencies, compliance with procedures and regulations, preoccupation to improve the activity and performances of the managed structure as well as the evaluation made by the subordinates.

- ***The execution staff*** was assessed according to the quantitative and qualitative criteria related to: the degree of achievement and the level of the quality of the assigned works, the compliance with the consumption and budget norms, the compliance with the established execution deadlines, the results obtained at the evaluation of the professional trainings, compliance with discipline and internal regulations, team spirit, improvement of activity proposals and involvement in the implementation of improvement solutions.

The report and analysis of the evaluation results were presented to the company's

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management for validation and underpinned the application of the motivational principles in the salary negotiation process.

### The staff motivation strategy

A Program to increase the attractiveness of the company was initiated, in view of the attraction and retention of staff that will actually take place in the year 2018 by establishing specific objectives in the human resources activity:

- Establishment of a salary study that is based on the foundation of the salary system for the positions in the organizational structure of the society based on analyzes of the current salary system compared to the levels of similar positions on the labor market and the hierarchy of posts on the basis of their complexity.

- Dynamization and diversification of collaborative projects with university and pre-university education institutions for the attraction and training of graduates with the necessary qualifications established by the Human Resources Plan.

### ASPECTS ON DIVERSITY

#### Ensuring a favorable work environment and an organizational culture geared towards innovation and performance

The employees' representatives together with the management of the company identify the best solutions in order to maintain a beneficial climate for the professional activities.

Antibiotice applies ethical standards based on principles of honesty, integrity, fairness and transparency and focuses equally on all stakeholders, employees, business partners, authorities, society and the community in general.

Antibiotice increased the number of women employed each year, providing equal opportunities for personal development, so that 54.75% of all employees are women.

In our company there is a balanced distribution of employees according to gender and age:

Age interval	20 y.o.	20-30	30-40	40-50	50-55	over 55	Total (%)
Women (%)	0.07	4.25	12.96	22.95	7.44	7.08	54.75
Men (%)	0.14	3.82	9.07	18.06	5.74	8.43	45.25
<b>Total (%)</b>	<b>0.21</b>	<b>8.07</b>	<b>22.03</b>	<b>41.01</b>	<b>13.18</b>	<b>15.51</b>	<b>100</b>

From the confessional point of view, our employees are 96% of Orthodox and 4% Catholic, a proportion that respects the confessional structure at national level. This feature, as well as those related to gender, age, nationality or the presence of disabilities, are not limiting hiring criteria. 9 of our employees are people with disabilities and benefit from legal provisions but also from fair and non-discriminatory treatment at the workplace.

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Dialogue with the co-interested groups is important for everything that our social responsibility policy means. Therefore, we are always looking for opportunities for dialogue with our employees, shareholders, our business partners, local communities and pharmaceutical industry organizations to see how we can work together and how we can improve our performance.

Through collective negotiation within the company, the clauses of the Collective Labor Agreement are set at the company level, thus guaranteeing employees protection of work, social protection, as well as providing additional facilities for training and professional development.

### 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. In order to reduce occupational risks and continuous improvement, the implementation of measures to ensure:

- Reducing the physical effort by completing the endowments of the Biosynthesis Plant with electrical transport/lifting equipment
- Reducing exposure to chemical agents by ensuring the storage of chemical reagents in the Medical Unit's laboratories in reagent cabinets with vapor filtration system and the purchase of a chemical niche for granulometric determinations.

Staff awareness and awareness of our current concerns in the field of health and safety at work:

- promoting sustainable work and healthy aging from the very beginning of professional life;
- prevention of health problems during professional life.

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

- Creating a unique and coherent framework for the elimination of hazards and risks related to work
- Making a more effective control over the risk factors of injury and/or occupational disease;
- Improving the working environment and interpersonal relationships at the workplace
- Getting better performance from employees;
- Awareness of the staff about the value the organization gives to its human capital



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### V. Quality management for compliance with legal, national and international requirements, specific to pharma industry.

#### Certified Quality

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

#### 1. Inspections conducted by the authorities

*1.1. During 06-14.03.2017, the US FDA inspection was carried out to assess the compliance of cGMP with the Quality Management System of Antibiotice SA and the production of penicillin parenteral products (powder for injection) and the production flow of Nystatin. At the end of the inspection, Form 483 with 5 comments was issued and the CAPA Plan was sent. Subsequently, after evaluating the proposed corrective measures, the US FDA issued the EIR mentioning that it considered the inspection closed, and the result was favorable.*

*1.2. On 24-27.04.2017 an ANMDM inspection was carried out to assess the GMP compliance of the Quality Management System of Antibiotice and the manufacturing lines of capsules, tablets, semisolids and suppositories, including MIC. Following the receipt of the Deficiency List, the CAPA Plans were submitted, the Production and Import Authorization 30F of 04.08.2017, GMP Certificates no. 040/2017 / RO, respectively no. 041/2017 / RO of 11.08.2017 were issued.*

*1.3. On 03-04.05.2017 the NAMMD inspection for GLP compliance assessment was carried out in order to recertify the GLP of the Bioanalytical Laboratory and the Clinical Unit. Following the receipt of the Deficiency List, the CAPA Plans (for the clinical phase, respectively for the bioanalytical stage) were submitted, the GLP Certificate no. 49 in 05.07.2017 was issued.*

*1.4. On 05-06.12.2017, the Iraqi Authority's inspection for GMP compliance assessment of the Quality Management System of Antibiotice SA and the manufacturing lines of penicillin, non-penicillin, cephalosporin capsules, tablets, semisolids and suppositories, parenteral products were carried out.*

#### 2. Audits of Certification Bodies

The recertification of ISO 9001 by SRAC for aluminum tubes, polyethylene screw caps and metal caps manufactured in the Microproduction Unit was carried out after the recertification audit from 28-30.06.2017.

Between 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 Report will be sent.

**3. Audits from clients (5 audits for Nystatin active substance, 1 final product audit)**

**4. Audits to 20 suppliers of raw materials / primary packaging materials / finished products**

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### ENVIRONMENTAL PROTECTION

#### **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. At the level of 2017, the Biosynthesis section was included in the planned specific consumption, regarding the quantities of solvents used.

#### **Air quality**

In 2017, air quality monitoring was carried out in our own laboratory on emissions / immissions of air pollutants for the indicators: nitrogen oxides, ammonia, suspended particulates and sedimentable powders. There have been no exceedances of the maximum acceptance concentrations provided in the Integrated Environmental Authorization.

#### **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 admissible concentrations established by the Integrated Environmental Authorization, Water Management Permit, and by NTPA 001 and NTPA 002 - 2005 have been recorded.

#### **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.

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The company respects the packaging waste management requirements (corresponding to the quantity of products that Antibiotice has introduced 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 and completions), have been achieved.

### **Environmental plans and programs**

For the year 2017, the environmental objectives set at the company level were:

- Reduction by 1% of the specific electricity consumption (kw/ Gcal) for the supply of thermal energy (in the form of hot water) from the heating circuit compared
- Increasing the number of EURO 6 equipped vehicles by purchasing a new vehicle, objective proposed in the Investment Plan 2017 and objective achieved..

### **Prevention and management of emergency situations**

At Antibiotice, the prevention of emergency situations and the providing intervention capacity in the event of accidents are ensured through the activity of the 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).

In 2017, six internal alarm drill were performed. During the drill, the response capacities of emergency response teams were tested and evaluated.

### **Promoting environmental promotion**

Through the Environmental Management System, the environmental protection activity of 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 getting in January 2011 an Integrated Environmental Authorization, 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.

Under the Corporate Responsibility Program "**Be Pro Nature. Put Soul!** ", In 2017, **Earth Hour 2017** took place. Antibiotice participated for the tenth consecutive year at what became the largest environmental campaign of all times. " Earth Hour" was marked by the fact that between 20:30 and 21:30, on March 25, 2017, the external lighting system was switched off on company premises in the areas where it was possible, as a symbolic gesture which calls for responsible resource management.

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Also, through the same program "Be Pro Nature. Put soul! runs the "School Orchard Project", in which in 2017 were planted five fruit orchards in the surroundings of the company, showing the younger generation respect for environmental protection, and maintaining a healthy lifestyle

### External audits

In the year 2017 two external audits were carried out by the environmental protection institutions (National Environmental Guard and Romanian Waters Administration, Prut - Barlad Water Basin Administration), with the observance of the legal requirements in the field, as well as the requirements of regulatory documents held by the company.

## 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 the life and health of people, creating a climate of trust in the relationships with the stakeholders. Sustainability in business means transparency, ethics, and care for the environment in which the business operates. For this reason, Antibiotice's activities are the result of responsible behavior such as environmental concern, human health, employee development, education, community involvement through social and educational programs.

The objective of Antibiotice is that through social responsibility programs, we become a model of sustainable development, building on the four pillars: health, spirituality, social-cultural - charitable and environmental protection.

### Health

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

### Campaigns on the responsible use of antibiotics

Antibiotice continued in 2017 the events of raising awareness in the population about the correct use of antibiotics. Thus, on 21 March 2017, Antibiotice organized the award ceremony of the project contest for the students of the University of Medicine and Pharmacy Gr. T. Popa Iasi, **Antibiotics - use them with care!** Students enrolled in the contest have made their creativity valuable by implementing integrated communication campaigns, whose message has been on the front line of rational use of antibiotics.

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### **The "Antibiotics save lives! Use them with care!" Caravan**

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 went to the villages of Victoria, Mironeasa and Voinesti and aimed to inform and educate the inhabitants of the countryside about the correct use of antibiotics.

Antibiotice's ethical involvement in bacterial resistance prevention is part of our mission to manufacture 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 responsibility of the population in order to preserve the long-term effectiveness of 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 24<sup>th</sup> March 2017, Antibiotice held the awareness events organized on the occasion of the World Tuberculosis Day by the TB Dispensary of the Iasi Clinical Pneumoftiziologie Hospital, in collaboration with the Iasi Public Health Department and the Grigore T Popa University of Medicine and Pharmacy.

### **Donate blood! Save a life!**

Under the slogan "Donate blood! Save a life!", 51 employees responded on April 10, 2017 to the blood donation campaign organized by the Antibiotice - Science and Soul Foundation, in partnership with Regional Blood Transfusion Center (CRTS) 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

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place on October 17, 2017, when 60 employees donated 27 liters of blood, giving life to 140 people.

### **"We Live Healthily in a Healthy Company"**

The health of the company's employees is important and for this reason, in 2017, the project "We Live Healthily in a Healthy Company" was initiated, which aims at raising the awareness among the employees of Antibiotice 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 at the company's headquarters, recommending the employees to adopt a healthy diet and establish the particularities of their food 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 by contributing with Science and Soul scholarships to the education of rural children, children with special skills but without material opportunities, supporting them to continue their studies in 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 5th grade have graduated in 2017 Garabet Ibraileanu Highschool and are currently students at various faculties in Iasi.

### **We invest in excellence**

In 2017 we continued to invest in excellence by developing educational partnerships designed to support 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 for the national and international school Olympiads with prestigious high schools in Iasi.
- ✓ 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".

### **Protecting the environment**

*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*

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*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 Iasi**

Antibiotice has been involved in the community by developing alongside its employees a social responsibility project for environmental protection. Within this project, the company's employees planted, in two stages, 410 fruit trees at schools in neighboring towns or villages.

### **Earth Hour**

This year as well Antibiotice participated in the Earth Hour action, 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, receiving 60 students from the Valea Lupului High School. The event was aimed at raising awareness for the environment to the young generation, enhancing their concern for protecting and preserving the environment for sustainable development.

### **Social programs**

*Beyond its economic performance, Antibiotice, thanks to the "Antibiotice - 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 become traditional.*

### **Play, song and joy on Children's Day**

It has already become a tradition for Antibiotice to offer a gift to all employees' children on 1<sup>st</sup> 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 sweet surprises outdoors. Twenty children from the Bogdanesti Placement Center also participated in the event.

### **The Power of Deed!**

On April 12<sup>th</sup>, the Antibiotice "Science and Soul" Foundation supported 25 disadvantaged families and elderly people in the Petresti village, Golaiesti commune, Iasi county, offering them foods to prepare for the traditional Easter holidays. The village of

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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 elevés for 80 children with an underprivileged background.

S.O.C.E.C.C. Bucharest audited the financial statements for 2017 and issued a qualified opinion. The financial statements were submitted in due course to the Management Board for analysis.

The annual financial statements were approved by the Board on March 15, 2018 and will be subsequently submitted for discussion at the General Meeting of Shareholders, which will take place on 26.04.2018. Relationships between management and employees are normal, without the collective actions of contesting the management, there is a permanent dialogue between them and the representatives of the trade union.

In the legal deadline imposed by the Order of the Minister of Public Finance 1938/2016, Antibiotice undertakes to publish a Non-Financial Report which will be made available to the public on the company's website.

### Conclusions:

- Net profit amounting of 33.56 million LEI, 10% higher than 2016;
- 12.8% increase in sales on the foreign market;
- the 17.5% increase in sales of non-prescription medicines on the Romanian market;
- 11.5% increase of physical sales compared 2016.

Vicepresident of the Management Board,  
Ec. Ioan Nani

Financial Director,  
Ec. Paula - Luminita Coman