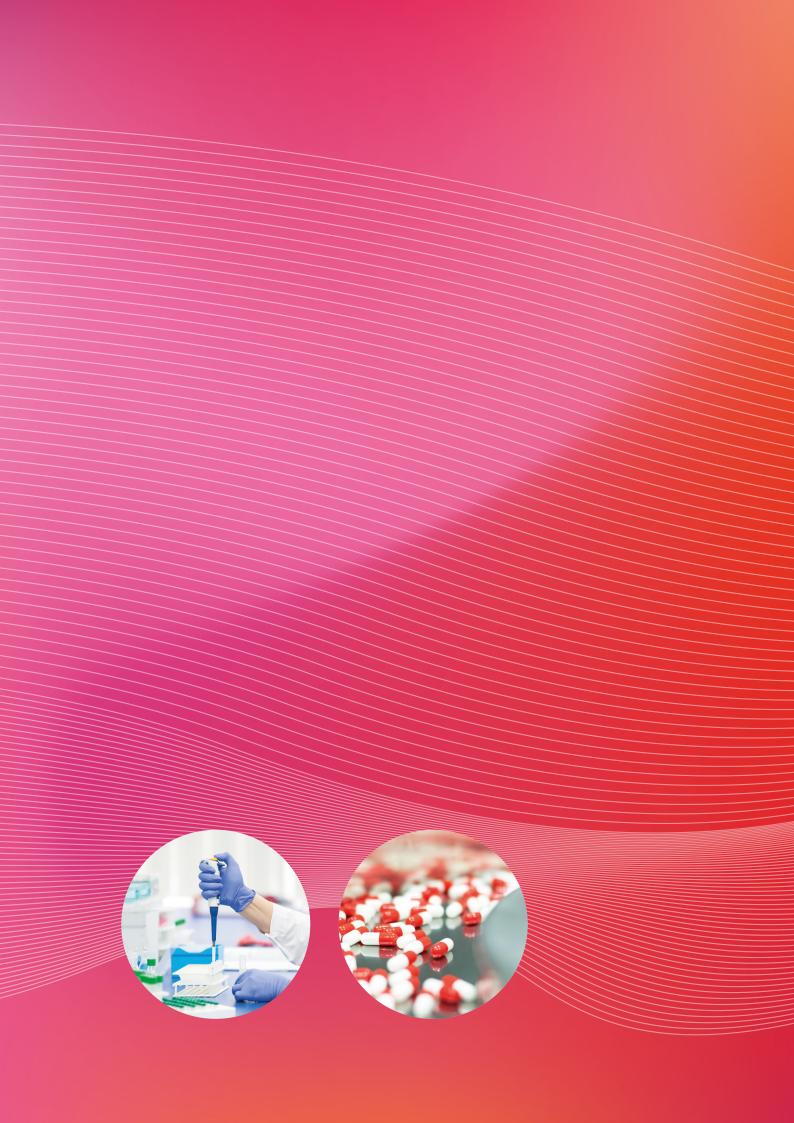


# ANNUAL REPORT 2019





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# A message from our General Director

#### Dear Esteemed Stakeholders.

Our world and implicitly the business world will no longer be the same after the SARS-CoV-2 virus pandemic which has been rapidly expanding worldwide since the first months of 2020. Certainly, there will be many lessons to be learned by governments, medical authorities, pharmaceutical manufacturers and consumers alike, because we have never experienced a public health crisis of this magnitude in the modern era.

The Romanian medical system has often had to deal with critical situations in the last 20 years. In my opinion, now it is the time to think strategically, at national level, of the medical security concept, placing it in the center of public health policies so that we can domestically manufacture sanitary materials and medicines of strict necessity, in a critical situation. We have been continuously supporting the health system in Romania. We produce generic medicines used in many therapies and we are able to produce on our own manufacturing facilities other medicinal products that, at times such as the coronavirus epidemic, may be helpful to physicians in treating diseases that make patients vulnerable.

As regards this report and the course of our company, I can say that we evolved in 2019 according to our shareholders' wishes and expectations. We are a Romanian business, we believe in our tradition and continuity and we have the ability and desire to do sustainable things for the future.

The actions taken in the previous years for expanding our business internationally bore fruits. The best proof is the significant increase of the Antibiotice's foreign business affairs which accounted for 40% of the turnover in 2019. Our exports sales amounted to 152 million LEI, by about 25% higher than in 2018, this growth being the highest recorded in the last 5 years.

In 2019, the exports of finished products (95 medicinal products) significantly outpaced the sales of Nystatin, the active substance that has been ranking us as the world leader in the last 5 years.

In the territories where Antibiotice opened its own representative offices (Vietnam, Republic of Moldova, Ukraine and Serbia), our exports of medicines increased by 65% compared to 2018. Starting from the principle that our company must apply in these territories similar strategies with those applied in the Romanian market in terms of product porfolios, business models, promotion actions, we developed a multiannual strategy by 2025 meant to ensure a rhythmic growth in these areas, generically called ATB territories.

We have been continuously strengthening the leading position of the active substance Nystatin in the international market, a direct result of the indisputable quality of this product recognized by the USFDA as a USP reference standard. The upward sales trend in the last 5 years are a strong proof in this regard. As a natural consequence, the number of new partners from Europe, South America, North America increased.

Certainly, we support our expansion in the international markets also through strategic investments. In 2019, we completed 80% of our investment in a new manufacturing plant for topical products which is to be the most modern in Eastern Europe. With a production capacity of 500 tons/year, our new facility will be authorized by the end of 2020 so as to support our international representatives offices ready to market new products, as they are registered in those markets.

Meanwhile, in the Romanian market, we have been continuing to distribute all over 150 pharmaceutical products from our portfolio, repositioning them under three communication concepts: Hospital&Partners includes all the medicines for hospitals; Quality of Life includes both medicines intended for prevention and treatment for various conditions (cardiovascular, genito-urinary, dermatological, digestive tract) and dietary supplements from the Nutriensa® range; Women's Health, a complex concept that brings together medicines for different conditions in the women's life. With these new concepts, we will develop communication with our partners in the ATB territories so that the good reputation of our top products in Romania (sterile injectable powders, ointments, creams and suppositories) be known by health professionals and consumers in the new territories.

In our approach to internationally develop our business, in 2019 we structurally reorganized the company's activity to be in line with the business plans for the next 10 years. Thus, we established three production divisions, the equivalent of three distinct factories: Topical Products Division, Oral Solid Dosage Forms Division and the Sterile Products Division. At the same time, we harmonized the new form of organization to the existing human resources on the site and attracted new valuable employees into the organization, completing the human resources and marketing management teams. We are now a young community of specialists: pharmacists, doctors, engineers, biologists, physicists, biochemists, IT specialists, economists, chemical operators, mechanics, automatists.

In conclusion, we can say that, at the end of 2019, we recorded total revenues of 389.71 million LEI, higher by 7% compared to 2018. Given that our medicines are sold at prices that do not exceed the prices of similar products from 12 European countries and that we paid to the State Budget - a clawback tax by 15 % higher than in the previous year, we made a pre-tax profit of 35.2 million LEI, a value comparable to that recorded in 2018. These figures show our constant concern for maintaining the profitability of the business, through careful and continuous improvement of the process management, as you will notice by reading the pages of this report.

I end this message by telling our investors and over 50,000 shareholders that Antibiotice is a company that, in the year of celebrating its 65<sup>th</sup> anniversary, has all the resources to successfully evolve in the global market. I send my thanks to our employees, suppliers and customers for joining us in 2019 with their constructive energy, devotion and confidence in a better future.

Ioan Nani,

Vice President of Management Board General Director of Antibiotice

# Company Profile

Brief history
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Antibiotice today

8





# **Brief history**



#### 1955

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

#### 1959

A new active substance, streptomycin starts to be produced and the first finished dosage forms: ointments, creams and suppositories are obtained. The Chemical Factory no. 2 changes its name to Antibiotice Factory.



#### 1977

The Food and Drug Administration from the United States (USFDA) certifies the manufacturing flow of the active substance streptomycin.

#### 1990

Antibiotice becomes a joint-stock company by taking over the patrimony of the former Antibiotice Enterprise Iaşi, according to GD no. 1200 of November 12, 1990.

#### 1992

Antibiotice manufacturers the first medicinal products formulated as tablets.

#### 1993

Ampicillin 250 mg and Oxacillin 250 mg are the first medicinal products formulated as capsules manufactured by Antibiotice, on the flow of penicillin products.



#### 1997

Starting with April 14, Antibiotice shares (ATB symbol) have been traded on the Bucharest Stock Exchange, to the first category; Antibiotice becomes the joint-stock company Antibiotice SA.
Our company implements a quality assurance system that involves the strict control of manufacturing processes.



Antibiotice SA becomes the first GMP certified Romanian pharmaceutical manufacturer for the injectable powder flow.



#### 2002

The manufacturing flow of Nystatin obtains the FDA approval, which allows the export of this active susbtance to the United States. Antibiotice is ranked as the world's leading manufacturer of Nystatin, its most important product for export.



On the occasion of its fiftieth anniversary on December 11, 2015, Antibiotice launches a new brand identity: the "Antibiotice a+" logo and "Science and Soul" slogan.

#### 2006

Antibiotice establishes its own Center for Drug Evaluation (CDE) that conducts phase I clinical studies and bioequivalence studies. CEM is Good Laboratory Practice (GLP) certified and authorized by the Romanian Ministry of Health.



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

# **Brief history**

#### 2007

Antibiotice earns recognition for implementing the Integrated Quality, Environment, Health and Safety Management System in accordance with the requirements of EN ISO 9001: 2008, EN ISO 14001: 2004 and OHSAS 18001: 2007.

By launching four new products, Antibiotice enriches its cardiovascular portfolio with medicinal products covering the treatment of major cardiovascular diseases.

#### 2010

Antibiotice deliveries the first finished products in the US market; up to 2010 our company exported to the U.S. only active substances.

#### 2011

The manufacturing flow of penicillins formulated as sterile powders for injection gets the FDA approval, which allows expanding the export of these products in the US market.

Antibiotice launches its first central nervous system (CNS) medicines.

#### 2012

Antibiotice enters the market of oncologicals and becomes the first WHO prequalified company in Europe for its range of antituberculosis medicines.

# 2013

Antibiotice is FDA recertified, being also GMP reauthorized by NAMMD for the manufacturing flows of sterile powders for injection and for the manufacturing flow of Nystatin.

Antibiotice becomes the leading worldwide producer of the active substance Nystatin.

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

Antibiotice opens an international representative office in Chișinău, Republic of Moldova.

Antibiotice is awarded the "Industrial and Commercial Merit" Order in the rank of Commander by the Presidency of Romania.

#### 2014

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

Antibiotice starts investing in a new Ointment & Suppository Plant.

#### 2015

Antibiotice gets the USFDA reapproval for the sterile injectable finished products and for the active substance Nystatin.

Antibiotice celebrates 60 years of Romanian continuity and performance.

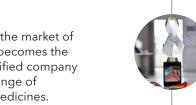
Antibiotice wins two gold medals and the First Prize of the Medicine Section at EUROINVENT 2015, the largest exhibition of inventions, projects and researches in South East Europe.

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











#### 2016

A record delivery of injectable products in the US market (Nafcillin 1 g and 2 g, Ampicillin 500 mg, 1 g and 2 g).

Antibiotice opens am international representative office in Hanoi, Vietnam.

Antibiotice gets the "Strongest in Romania" certification: a financially responsible, credible and solvent company with partners in the country and abroad.



Antibiotice launches the "Perform a+", a project for attracting specialized staff and new collaborators in the research-development area. The project is dedicated to the young students and residents of the Faculty of Pharmacy of the Grigore T. Popa University of Medicine and Pharmacy laşi.



Antibiotice imposes worlwide the quality standard for Nystatin by obtaining the title of international reference standard for the active substance Nystatin granted by the United States Pharmacopeia (USP).



Antibiotice participates for the 15<sup>th</sup> time at the world's largest pharmaceutical exhibition, CPhI Worldwide.

#### 2018

Antibiotice wins the third place at the "Romanian CSR Awards 2018" Gala, in the Intersectoral Partnership category, for the project "Science and Soul" scholarships.

Antibiotice publishes its first non-financial report 2017.

Our company opens its third international representative office in Kiev, Ukraine.

Antibiotice launches the "Antibiotics of the 3<sup>rd</sup> Millennium", a social responsibility program which supports the judicious use of antibiotics in the human and veterinary medicine.

#### 2019



Antibiotice Antibiotice implements the medicine verification system to combat counterfeiting, in accordance with the norms of European Directive 2011/62/EU and Regulation 161/2016.

Our company resumes the manufacture of Moldamin®, an injectable product in a new formulation of benzathine benzylpenicillin.

Antibiotice joins the Romanian Investors Relations Association (ARIR).



Antibiotice receives two awards at the "Romanian CSR Awards 2019" Gala: the 1<sup>st</sup> place and the trophy in the category "Internal CSR campaigns" for the project "Donate Blood! Put your soul to life!" and a mention in the category "Supporting our employees" for the project "Each of us can save a life" - First aid course for the Antibiotice employees.

The "Antibiotice - Science and Soul" Foundation receives the distinction "Savior Hero" 2019 granted by the National Institute of Transfusion Hematology Bucharest.



# **Antibiotice today**

# The main manufacturer

of anti-infective generics in Romania, with a rich tradition of 64 years

# Leader in the Romanian market

in the production of anti-infectives, ointments, gels and suppositories



# World leader

in the production of the active substance Nystatin which is the USP Reference Standard - an international quality standard

# Commercial representative

offices in Vietnam, Republic of Moldova, Ukraine, Serbia

# 8 manufacturing flows

for: sterile injectable powders, penicillin capsules, non-penicillin capsules, cephalosporin capsules, tablets, ointments, creams and gels, suppositories, pessaries, active substances obtained by biosynthesis

# 37 medicines

from our company's portfolio are essential according to the World Health Organization

# Internationally recognized

certifications and authorizations:

- Food and Drug Administration (FDA), the US regulatory body responsible for protecting public health, authorized the active subtance Nystatin and injectable medicines produced by our company;
- International quality recognition of the active substance Nystatin that has become the USP Reference Standard;
- Certificate of Compliance with the European Pharmacopoeia (CoS) for Nystatin;
- Good Manufacturing Practice (GMP) certificate for all the manufacturing flows;
- Integrated Management System

# 150 products

from 12 therapeutic classes, containing 100 active substances

Has its own
ResearchDevelopment
Center

# Social responsibility programs

supported by the "Antibiotice - Science and Soul" Foundation

Significant employer - 1,415 employees



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# Corporate governance

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# Corporate governance - the company's management and control principles

Antibiotice has been continuing the process of implementing the good corporate governance practices, strictly meeting the principles and recommendations of the Corporate Governance Code of the Bucharest Stock Exchange (CGC-BVB) adopted in 2012.

By applying these principles, our company makes its activities and processes more transparent and effective, offering this way in the long run the proper context for maximizing the value of its shares and for increasing its attractiveness towards the investors.

Our company's management considers the Corporate Governance Code an important tool for achieving sustainable performance, ensuring the accuracy and transparency of the decision-making process through the equal access of all the shareholders to relevant information about our company.

The Antibiotice corporate governance system is based on the following pillars:

- Corporate Governance Code
- Code of Ethics
- General Meeting of Shareholders
- Management Board

- Advisory Committees
- Executive Management
- Internal audit, Inventory Financial Control and Risk Management

# **Corporate Governance Code**

The Corporate Governance Code of Antibiotice SA adopted the principles and recommendations of the Bucharest Stock Exchange and represents the tool through which our company implements these principles and recommendations.

The Corporate Governance Code creates the necessary framework for establishing strong relationships with the shareholders and stakeholders, as well as for an effective and transparent, trust-based communication.

The Corporate Governance Code of Antibiotice SA is divided into four chapters (https://bit.ly/2zJydPQ):

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

**Chapter II** - Risk Management System and Internal Control

Chapter III - Fair reward and motivation

Chapter IV - Investor relations

It also has two annexes:

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

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

Chapter I - Responsibilities of the Management Board - defines the role of this body and sets the requirements on competence, experience, knowledge and independence of its members, which enable them to effectively perform their specific duties and responsibilities.

Chapter II - Risk Management System and Internal Control - 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 Board members and company's management.

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, shareholder-related rights, etc)

In conclusion, The Corporate Governance Code of Antibiotice SA and its annexes draw the general framework based on 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.

The stage of compliance with the provisions of the new Corporate Governance Code of the BVB1 at December 31, 2019 is presented in Annex no.1 to this report.

# Code of Fthics

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

The Code of Ethics provides rules in the key areas relating to employees, human rights, environmental management, social responsibility and corporate governance.

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

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



The Code of Ethics is fully presented on our company website: https://bit.ly/2ybDEa9

# **General Meeting of Shareholders**

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

During 2019, our Management Board convoked two Ordinary and two Extraordinary General Meetings of Shareholders on April 18, 2019 and September 10, 2019.

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

# The Ordinary General Meeting of Shareholders of April 18, 2019 approved:

- **1.** the company's financial statements for the fiscal year 2018, based on the Management Report and Financial Auditor Report;
- **2.** distribution of the 2018 net profit, setting the gross dividend per share in value of 0.009991506 LEI/share and setting the payment date on 20.09.2019;
- **3.** registration of the unclaimed and unpaid dividends for the financial year 2014 as revenues;
- **4.** the 2019 Income & Expenditure Budget;
- **5.** the degree of achieving the objectives and performance criteria for 2018 by the members of the Management Board;
- **6.** the discharge of administration for the activity conducted in the fiscal year 2018, based on reports submitted;

- **7.** the objectives of the Management Board's members set in the 2019 Administration Plan;
- **8.** setting the remuneration of the Management Board's members, according to the provisions of GEO no. 109/2011 on the corporate governance of public enterprises and GD no. 722/2016 for the approval of the Methodological Norms for the application of certain provisions of the Government Emergency Ordinance no.109/2011 on the corporate governance of public enterprises;
- **9.** modifying the composition of the Management Board by appointing Mr. Cristian Vasile Grasu as interim administrator in accordance with the provisions of art. 641 of GEO no. 109/2011 on the corporate governance of public enterprises;
- 10. starting the process for selecting a new member of the Management Board, according to the provisions of the art. 644 of GEO no. 109/2011 on the corporate governance of public enterprises and art. 4, para. 3 of GD no. 722/2016 for the approval of the Methodological Norms for the application of certain provisions of the GEO no.109 / 2011 on the corporate governance of public enterprises as well as the empowering the Mangement Board to select the new administrator in accordance with the provisions of art. 29, para 2 of GEO no. 109/2011 on the corporate governance of public enterprises and art. 4, para. 5 of GD no. 722/2016 for the approval of the Methodological Norms for the application of certain provisions of the GEO no.109 / 2011 on the corporate governance of public enterprises;

# The Extraordinary General Meeting of Shareholders of April 18, 2019 approved:

- **1.** a 12-month extension of 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 SA;
- **2.** to maintain the guaranties related to the multi-product multi-currency credit amounting to 30 million LEI throughout the validity period (one calendar year starting with 26.06.2019) resulting from the extension under point 1 of the Agenda;
- **3.** to issue a decision-commitment of Antibiotice not to divide itself, not to merge and decide the anticipated dissolution throughout the entire validity period of the multi-product multicurrency credit without the prior consent of the Export-Import Bank of Romania EximBank SA;
- **4.** to empower the General Director Mr. Ioan Nani and Financial Director Ms. Paula Coman to sign on behalf of the company all documents related to the credit facility extension under paragraphs 1 and 2 of the Agenda, as well as documents related to the obligations assumed by our company in accordance with paragraph 3 of the Agenda.

## The Ordinary General Meeting of Shareholders of September 10, 2019 approved:

- **1.** the company's financial statements for the first semester of 2019, based on the Management Report and Financial Auditor Report;
- **2.** the appointment of Mr. Cristian Vasile Grasu as a non-executive administrator for a 4-year term, in accordance with the procedures established in the art. 29 of GEO no. 109/2011 on the corporate governance of public enterprises;

# The Extraordinary General Meeting of Shareholders of September 10, 2019 approved:

- **1.** to extend the grace period and the period of use of the investment loan related to the IAS3-20-2018/03.05.2018 contract, concluded with Unicredit Bank until 30.06.2020;
- **2.** to empower Mr. Ioan Nani as General Director and Mrs. Paula Luminita Coman as Financial Director to sign on behalf of the company any additional document related to the present credit contract as well as any additional documents related to the credit contracts concluded with UniCredit Bank:
- **3.** to empower Mr. Ioan Nani as General Director signature I and Mrs. Paula Luminita Coman as Financial Director signature II to sign on behalf of the company the additional documents related to the facility contracts, guarantee contracts and the related additional documents, guaranteed promissory notes, requests for use/reimbursement, requests for issuing letters of guarantee and opening letters of credit, in relation to ING Bank;
- **4.** to establish the headquarters of the Antibiotice representative office in the Republic of Moldova at the following address: Office 705, 7<sup>th</sup> floor, with a total area of 62.20 sqm., in the building located on 5/4 Dimitrie Cantemir Blvd., Chişinău, Republic of Moldova;
- **5.** to establish the headquarters of the Antibiotice representative office in Vietnam, at the following address: Room 807, 8<sup>th</sup> floor, Building 3A, 3 Lane 82 Day Tan, Can Giay District, City of Hanoi, Vietnam.

# Rights of the financial instruments' holders

The corporate governance framework adopted and applied:

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

On the company's website at https://bit.ly/2z5WMGE, there is a section dedicated to our shareholders, where they can access and download documents related to the General Meetings of Shareholders: procedures regarding the access and participation in the meetings, the notice to attend, additions to the agenda, informative materials, special representation proxies, correspondence voting forms, decision drafts, decisions, voting results, etc.

Antibiotice makes available to all interested the periodical and annual financial statements prepared according to the legislation in force. The company also complies with all the publication requirements under the laws of trading companies and capital market.

Our company has a department specialized in the relations with the existing and potential investors, called Investor Relations, whose main roles are to implement and monitor the corporate governance standards within our company, to inform the shareholders and investors in accordance with the legal provisions,

to proactively communicate with our investors focused on their information needs.

The persons appointed to keep in touch with the investors deal the shareholders' requests with maximum efficiency and facilitate the dialogue with our company's management. Our company creates and develops an appropriate policy to promote an effective communication with our investors and shareholders.

Being permanently focused on developing its transparency towards shareholders, in completing its strategy of improving the relations with investors and from the desire to create value for shareholders, on July 31, 2019 Antibiotice joined the Romanian Investor Relations Association (A.R.I.R.), a lively new community in the Romanian capital market.

The Romanian Investor Relations Association (A.R.I.R.) is a non-governmental and non-profit organization that was set-up to provide current and potential issuers with a platform for the development of Investor Relations (IR) professionals and contribute to the implementation of best practices on corporate governance and in the communication with our investors.

For its Investor Relations activity and for the degree of transparency, accuracy and completeness of the information and accessibility of its website, Antibiotice got the 10 score granted by the Romanian Investor Relations Association that evaluated 78 issuers in the Romanian capital market.

Antibiotice has achieved this performance by approaching new and efficient communication tools. This way, the investors, analysts, brokers, journalists have the opportunity to learn about the Antibiotice business.

# **Management Board**

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

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

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

In 2019, the Management Board met in 11 sessions, registering a 100% presence each time, and adopted decisions that enabled it to carry out its tasks in an effective and efficient manner.

Thus, at the monthly meetings, the Board analyzed in detail the financial results obtained during the reporting period and cumulative period from the beginning of the year as well as the economic performance in relation to the budget and compared to the similar period of the previous year.

Depending on the situation, the Board requested detailed explanations from the executive management related to the plans for increasing the production efficiency, investment plans, constituted provisions, liquidity management, operational and overall profitability. Following the detailed analysis of the results, the Board decided to approve them for publishing and sending them to the Bucharest Stock Exchange and the Financial Supervisory Authority, each time meeting the deadline included in the Financial Communication Calendar.

The 5 members of the Management Board guarantee the efficiency of their capacity to supervise, analyze and evaluate the activity of directors, as well as the fair treatment of the shareholders.

# Management Board of Antibiotice SA on December 31, 2019

Dan Octavian Alexandrescu, Physician, 44 years old

# President of the Management Board and representative of the Ministry of Health

At the Ordinary General Meeting of Shareholders held on September 29, 2018, Mr. Alexandrescu was elected as a member of the Management Board, for a 4-year period.

Mr. Dan-Octavian Alexandrescu is a primary physician with competence in laparoscopic surgery and the Coordinator of the Policy Directorate for Medicines and Medical Devices of the Ministry of Health since March 2017.

Number of Antibiotice SA shares held - 0\*

## Ioan Nani, Economist, 60 years old Executive member of the Management Board and General Director

At the Ordinary General Meeting of Shareholders held on April 19, 2016, Mr. Nani was reconfirmed as a member of the Management Board, for a 4-year period, the Board electing him as its Vice President.

Mr. Nani is an economist specialized in management and chartered accountant, member of the Management Board since 2009 and General Director (1998-2008 and 2009 - present).

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

# Cristian Vasile Grasu, Physiscian, 59 years old

# Member of the Management Board and representative of the Ministry of Health

At the Ordinary General Meeting of Shareholders held on September 10, 2019 Mr. Grasu was elected as a member of the Management Board, for a 4-year period. Physician, Coordinator of the General Directorate of Public Healthcare of the Department for Monitoring and Coordination of Regional Hospitals, as well as of the priority actions of the Ministry of Health. Number of Antibiotice SA shares held – 0\*

Nicolae Stoian, Economist, 63 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 reelected as a member of the Management Board for a 4-year period. Mr. Stoian is a chartered accountant, tax consultant and financial auditor, representative of the Internal Control Department at

Number of Antibiotice SA shares held - 0\*

Elena Caliţoiu, Engineer, 56 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, Ms. Calitoiu was confirmed as a member of the Management Board, for a 4-year period.

Ms. Calitoiu is a mechanical engineer and Director of Placements & Risk Management Department, SIF Oltenia Number of Antibiotice SA shares held - 0\*

# **Advisory committees**

SIF Oltenia.

The Advisory Committees carried out investigations, analyzes and elaborated recommendations for the Management Board in the specific fields and submitted periodically reports on their activity to the Management Board.

The specialized advisory committees in 2019:

- > Audit Committee: Mr. Cristian-Vasile Grasu, Mr. Nicolae Stoian and Ms. Elena Caliţoiu;
- Nomination and Remuneration
   Committee: Mr. Dan-Octavian
   Alexandrescu and Ms. Elena Caliţoiu;
- > Trade Policy Committee: Mr. Dan Octavian Alexandrescu and Mr. Nicolae Stoian.

In 2019, the Audit Committee met in three sessions in order to fulfill its responsibilities on financial reporting, external and internal audit, risk management and internal control.

In the reporting period, the Nomination and Remuneration Committee met in four sessions to evaluate the administrators' activity and followed the procedure for selecting a Management Board member.

The remuneration granted to the Management Board and Executive Management (General Director) in 2019 amounted to 4,233,682 LEI. This value represents the monthly fixed allowance and the variable allowance, according to the legislation in force:

- > the monthly fixed allowance is established in accordance with the legal provisions, i.e. the provisions of art. 37 paragraph (2) of GEO 109/2011;
- > the variable allowance is granted if the performance indicators and criteria included in the administration contracts and mandate contract are properly fulfilled.

The fixed and variable allowance for the Management Board members is approved by the General Meeting of Shareholders. The General Meeting of Shareholders also approves the general limits within which the directors with a mandate contract are remunerated. Based on these general limits, the Management Board sets the remuneration of the directors with a mandate contract.

<sup>\*</sup> Number of Antibiotice (ATB) shares held on December 31, 2019 according to the latest database owned by Antibiotice for 2019.

# **Executive management**

Antibiotice SA is represented by the General Director, according to the powers provided by law and by the company's Articles of Association. The Management Board represents the company in relationship with the appointed directors. The Executive Management of Antibiotice is ensured by the General Director who is also the Vice-President of the Management Board and nine specialty executives.

#### **Antibiotice's Executive Management** on December 31, 2019

## Ioan Nani, Economist, 60 years old General Director and Vice President of the Management Board

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

He started his career as an economist at Antibiotice in 1987. Between 1991 and 1993 he worked as a financial inspector with the General Directorate of Public Finance Iași and then with the Court of Auditors of Romania. In 1994, Mr. Nani returned to Antibiotice as a Financial Executive Director and became General Director 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 Director of Antibiotice.

Mr. Nani has been General Director since 2009.

Number of Antibiotice SA shares held -1.513\*

## Cornelia Moraru, Engineer, 54 years old Specialty Director - Engineering, Investments & Strategic Projects Unit

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

Mrs. Moraru held the position of Technical & Production Director between 2005-2019. Number of Antibiotice SA shares held -1.513\*

#### Paula Luminița Coman, Economist, 52 years old

#### Specialty Director - Financial Unit

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

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

Mrs. Coman has been Financial Director since 2011.

Number of Antibiotice SA shares held - 0

## Vasile Chebac, Economist, 65 years old Specialty Director - Procurement and Logistics Unit

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

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

Logistics Director since 2005.

Number of Antibiotice SA shares held - 0\*

# Mihaela Murariu, Psychologist, 41 years old Specialty Director - Human Resources Unit

Graduated from the Faculty of Psychology and Educational Sciences of Alexandru Ioan Cuza University of Iaşi, Mrs. Murariu obtained in 2003 the title of Master in Psychological Assessment, Training and Counseling of the personnel.

Mrs. Murariu has been working with Antibiotice since 2019. In the period 2012-2019 she held the position of Human Resources Manager Business Unit within Delphi Diesel Systems, ZF Group and Tester Grup.

Mrs. Murariu has been Human Resources Director since May 2019.

Number of Antibiotice SA shares held - 0\*

## Cristina Diaconescu, Engineer, 52 years old Specialty Director -Research & Development Unit

A graduate of the Faculty of Industrial Chemistry of the Gheorghe Asachi Technical University of Iași, Mrs Diaconescu holds two master's degrees, one of them in business management granted by the Faculty of Economics and Business Administration of Gheorghe Asachi University of Iași and the other one in Pharmaceutical Management and Marketing granted by Grigore T. Popa University of Medicine and Pharmacy of Iași - the Faculty of Pharmacy.

Mrs Diaconescu has been working with Antibiotice since 1994. In 2005 she was appointed Domestic Marketing Deputy Director. In January 2008 Mrs. Diaconescu became Promotion & Retail Sales Manager and as of February 2015 she was appointed Quality Control Manager.

Mrs Diaconescu currently holds the position of Research & Development Director.

Number of Antibiotice SA shares owned - 1514\*

#### Dana Elena Săcărescu, Economist, 47 years old

# Specialty Director - Strategic Planning and Performance Management

Mrs. Săcărescu graduated from the Mihail Kogălniceanu University Iași, specialization in International Economic Relations. Starting with 1999, she worked as economist within the Economic Analysis & Financial Forecast Office and in 2008 she was appointed Head of the Economic Analysis & Financial Forecasts Department.

Mrs. Săcărescu has been Strategic Planning & Performance Management Director since September 2019.

Number of Antibiotice SA shares owned - 222\*

# **losif-Oliver Ababei**, pharmacist, 44 years old

#### Specialty Director - Quality Assurance Unit

Graduated from the Grigore T. Popa University of Medicine and Pharmacy of Iași - the Faculty of Pharmacy, Mr. Ababei holds the title of Master in Pharmaceutical Management and Marketing.

Starting with September 1998, he worked within Antibiotice as a pharmacist, Quality Assurance Officer, Quality Assurance Manager.

Between 2000-2002 he held the position of University Preparator within the Faculty of Pharmacy, Grigore T. Popa University of Medicine and Pharmacy Iași - the discipline "Pharmaceutical Biotechnologies (Medicines Industry)".

Mr. Ababei has been Quality Assurance Director since November 2019.

Number of Antibiotice SA shares owned - 0\*

# Liviu Vătavu, Legal Adviser, 48 years old Specialty Director - Legal Unit

Graduated from the Petre Andrei University laşi, Mr. Vătavu has a Bachelor's Degree from the Alexandru Ioan Cuza University laşi. Starting with 2000, Mr. Vătavu has been working within Antibiotice, holding the following positions: Legal Adviser, Head of Intellectual Property Office, Head of Legal Office, Legal Counseling Coordinator.

Mr. Vătavu is currently Legal Director. Number of Antibiotice SA shares owned - 0\*

<sup>\*</sup> Number of Antibiotice (ATB) shares held on December 31, 2019, according to the latest database owned by Antibiotice for 2019.

# Internal audit, Inventory Financial Control and Risk Management

The specialized internal control provided by the legislation in force is carried out by our own internal audit activity complemented by the financial inventory control and the inventory control.

The way of setting and achieving the objectives of the internal audit activity, findings and recommendations resulting from all the internal control actions are presented quarterly to the Audit Committee within the Management Board, for assessing the activity and internal control exercised in the company.

So, in 2019, our specialized department conducted 10 audit missions having the following general objectives specific for each area:

- to examine the compliance of the audited activity with all the principles, specific procedural and methodological rules, internal notes and decisions;
- to examine the way in which the audited activity is organized;
- > to evaluate the management and control system of the audited activity;
- > other specific objectives.

The audit missions were carried out in compliance with the audit procedures, and internal audit reports were submitted to the General Director to be approved. The conclusions and recommendations of the audit reports were acknowledged by the audited structures.

The Internal Control Department monitored the implementation of the recommendations made during the internal audit missions. 50 recommendations were made in 2019. Out of 35 recommendations having as deadline 31.12.2019, 18 of them were implemented while for the remaining 17 an extension of the implementation deadline was requested.

As part of the inventory control activity, 21 inventory actions were carried out in 2019, involving the following structures:

- > central warehouses for raw materials and consumables:
- places of consumption of raw materials and consumables with stock management in place;
- > departments where the inventory administrators were changed.

The inventory activity aimed at observing the legal framework established by the following normative acts:

- Accounting Law no. 82/1991, republished and updated;
- Law no. 22/1969 on the employment of warehouse operatives, provision of guarantees and liability for the management of goods;
- O.M.F. 2861/09.10.2009 for the approval of the Norms on organizing and performing the inventory of assets, debts and equity;
- Operating procedures, notes and internal decisions issued by the company's management.

The control actions found the compliance with the legal regulations and internal decisions regarding the stock management as well as the correspondence between the factual and scriptic stocks as a result of the periodical checking during the year between the quantitative and the quantitative-value evidence.

The Financial inventory control actions conducted in compliance with the provisions of G.D. 1151/2012, had the following objectives:

to verify the compliance of the accounting registration of the economic-financial operations with the legal provisions;

- > to verify if the Income & Expenditure Budget for 2018 was executed in compliance with the legal provisions;
- to verify if, in substantiating the draft of the Income & Expenditure Budget for 2019 the legal requirements were met;
- > to verify if the annual inventory of assets, liabilities and equity for 2018 was made in compliance with the legal provisions and internal regulations;
- to verify if the receipts and payments in LEI and foreign currency, of any kind, in cash or by transfer were made in compliance with the legal provisions and internal regulations;
- to verify if the elaboration, circulation, keeping and archiving of primary, accounting and technical-operative documents were made in compliance with the legal provisions and internal regulations;

The financial inventory controls were completed by drawing up control reports in which findings and improvement measures were presented.

# **Risk Management**

Our company complies with the applicable legal and regulatory requirements for identifying, assessing, managing and reporting the risks:

- Government Secretary General Order (OSGG) no. 400/2015 modified and completed by OSGG no. 200/2016 and OSGG no. 600/2018;
- Requirements of the Corporate Governance Code of the Bucharest Stock Exchange.

The main purpose of risk management is to help people understand and identify the risks to which the organization is exposed so that they can anticipate and manage these risks without compromising the organization's effectiveness.

Antibiotice's objectives on risk management:

- > to understand the risks to which our company is exposed as well as their general and specific causes;
- > to improve the risk profile of our company by effectively managing the process of identifying, evaluating and managing risks and by implementing the control measures needed to maintain the risk exposure at acceptable levels.

The Antibiotice's Risk Management Department together with our risk managers and employees are responsible for the risk management. Our Risk Management Department annually analyzes and prioritises the significant risks that may affect the achievement of the company's overall goals, by establishing the risk profile and tolerance limit approved by the management of the company. They also draw up the "Plan for implementing the control measures for significant risks related to our company's business" and submit it for approval to the General Director.

In 2019, the General Risk Register aimed at minimizing the significant risks to which Antibiotice is exposed was prepared and approved. The specific risks identified for each organizational structure of Antibiotice SA were submitted to the Audit Committee.



#### The main risks identified:

#### 1. Financial risks

In terms of financial risk management, the risks to which our company is exposed are: currency risk, liquidity risk and commercial (non-payment) risk.

1.1. Currency risk, a component of the financial risk which 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 and in the prices of finished goods for export.

2019 had periods with higher volatility, with depreciation of our currency, LEU.

In order to reduce the exposure to the currency risk, our company took a series of measures such as: synchronization of import and export by correlating payment and collection terms, as well as correlating the weight of currencies so that the payment for the imported goods be made as close to or even simultaneous with the collection of money for the exported products.

**1.2. 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: lack of cash-flow generated by the gap between receipts and payments determined by the collection of receivables at maturities exceeding 300 days, fluctuations in interest rates and currency rates, volume of investments, level of taxation (clawback tax), price of raw materials.

Our company's policy on liquidity risk is to maintain, as far as possible, sufficient liquid resources to meet the payment obligations as they reach maturity and to obtain necessary financing through credit lines. **1.3. Commercial risk** is the risk of incurring losses or not-reaching the estimated profits due to lack of financial liquidity of the borrowers and their failure to pay upon maturity.

Circumstances of non-payment risk: the large exposures of the company to the major national distributors, long payment periods caused mainly by the delays with which the invoices for health services are settled by the National Health Insurance House.

The measures taken by our company to control and reduce the commercial risk include: monitoring the customer credit-worthiness, diversifying the customer portfolio and requesting guaranties.

#### 2. Legislative risk

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

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

Our effort for complying with these provisions is reflected in additional costs related to updating the documentation and processes for meeting the latest quality standards.

Our 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, continuous monitoring the legislative changes at international level, constantly adapting our policies, rules and procedures to changes.

#### 3. Human resource risk

The main human resource risk is the lack on the labor market of candidates properly trained in fields specific for the pharmaceutical industry. The measures taken to control and reduce this risk: "Summer School + a" attended by the best students, promotion of our company in faculties, study visits for students in our company and partnerships concluded with the university institutions. We mention here the project "Perform a+" developed together with the Grigore T. Popa University of Medicine and Pharmacy (UMF) laşi.

4. Reputational risk is defined as the current or future risk of negatively affecting the company's profits and equity determined by the unfavorable perception on the company's image.

In order to effectively manage the events that could lead to a reputational risk, the following measures are envisaged: monitoring the image of the company in the media in order to identify any rumors that could generate image risks, periodical press releases with positive information, control of risks that may affect the image of the company, continuous training of personnel, rapid adaptation to the legislative requirements in the field, compliance with procedures.

**5. Operational risk** is the risk of loss that results either from the use of some inadequate processes, persons or internal systems that did not perform their function properly, or from external events.

Operational risks can materialize in equipment failures, human errors, faulty operational processes which can lead to unplanned shutdowns.

Antibiotice constantly monitors the operational risks in order to take measures to maintain them at an acceptable level that does not threaten its financial stability, interests of creditors, shareholders, employees, partners.





# Company Performance in 2019

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# Strategic evolution

# Renewal of our product portfolio

Development of new products for completing the portfolio and authorization of the product dossiers in new territories for increasing our sales in international markets resulted in:

- **5 new Marketing Authorizations** (MAs) for our medicinal products to be traded in the teritorries from Asia and Europe
- **15 products** are in different research stages to be subsequently authorized in Romania
  - 11 products are in different stages of authorization in the
- foreign markets

In the research stage	In the stage of authorization	Already authorized
15	11	5
products	products	products

39.21%

market share in the hospital segment anti-infectives

4

Ranks 4<sup>th</sup> among 129 manufacturers of prescription generic medicines

16

Ranks 16<sup>th</sup> among 230 manufacturers of OTCs and food supplements



# Antibiotice's domestic performance

- leader in the hospital segment injectable anti-infectives with a 39.21% market share;
- leader in the segment of generics and OTCs sold in hospitals, with a 15.6% market share;
- leader in terms of quantity for the following pharmaceutical dosage forms: ointments (23.9% market share), suppositories (42.5% market share) and injectable powders (72.9% market share);
- ranks 4<sup>th</sup> among 129 companies in the Romanian market, in the top manufacturers of prescription generic medicines (8.07% market share);
- ranks 6<sup>th</sup> in the segment of generics and OTCs (4.53% market share) and the 20<sup>th</sup> in the total pharmaceutical market (1.89% market share);
- ranks 16<sup>th</sup> among 230 companies in the Romanian market as a manufacturer of non-prescription medicines (OTCs) and food supplements;
- is the Romanian manufacturer of the complete range of essential anti-tuberculosis medicines.

# Antibiotice's international performance

- its export grew by about 25% (152.1 million LEI) compared to 2018;
- 40% of its turnover was generated by exports;
- our company has been constantly consolidating its position of world leading manufacturer of Nystatin;
- the sales of sterile injectable penicillins in the US market increased by more than 50%;
- the sales of finished medicinal products significantly surpassed the sales of the active substance Nystatin in the international market, up 65% compared to 2018;
- the main exporter in the Vietnamese market, with a value traded of about 10 million USD in 2019;
- 95 finished products sold in the foreign markets.

# Top 20 Antibiotice best-selling brands

Top 20 Antibiotice best-selling brands recorded 204.7 million LEI in 2019.

Rank	Brand	International Non- Proprietary Name	Therapeutic class and form of administration	Main competitors
1	<b>Cefort®</b> 250 mg, 1 g and 2 g	ceftriaxonum	Anti-infectives for systemic use Other beta-lactam antibacterials Injectables	Medaxone® (Medochemie)
2	<b>Eficef</b> ® 100 mg and 200 mg	cefiximum	Anti-infectives for systemic use Other beta-lactam antibacterials Capsules	Xifia® (Alkaloid AD) Forexo (Alkaloid AD)
3	<b>Ampiplus®</b> 1000 mg + 500 mg	ampicillinum + enzyme inhibitor	Anti-infectives for systemic use Beta-lactam antibacterials, penicillins Injectables	Unique product
4	Colistină Atb® 1.000.000 U.I.	colistini sulfas	Anti-infectives for systemic use Other antibacterials. Injectables	Unique product
5	<b>Amoxicilină Atb®</b> 250 mg and 500 mg	amoxicillinum	Anti-infectives for systemic use Beta-lactam antibacterials, penicillins Capsules	Amoxicilină® (Novartis), Ospamox® (Novartis), Amoxicilină® (Arena Group)
6	Nidoflor® 15 g	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatological preparations Corticosteroids in combination with antibiotics Ointments	Triderm® (Merck & Co)
7	Amoxiplus® 1.2 g	amoxicillinum + acidum clavulanicum	Anti-infectives for systemic use Beta-lactam antibacterials, penicillins Capsules	Unique product
8	Meropenem Atb® 500 mg and 1 g	meropenemum	Anti-infectives for systemic use Beta-lactam antibacterials, penicillins Injectables	Meropenem Kabi (Fresenius)
9	Glycerin Suppositories adults and Glycerin Suppositories children	glycerolum	Digestive tract and metabolism Laxatives Suppositories	Dulcolax® (Sanofi), 4Lax® (Solacium Pharma), Glycerin suppositories (Zentiva)
10	Nolet® 5 mg	nebivololum	Cardiovascular system Beta blockers Tablets	Nebilet® (Menarini) Nevivolol Actavis (Teva) Nebinorm (Genmark Pharma)
11	<b>Indapamidă®</b> 1.5 mg	indapamidum	Cardiovascular system Diuretics Tablets	Indapamid LPH® (Alvogen), Tertensif® (Servier), Indapamida Terapia (Sun Pharma)
12	<b>Ranitidină Atb®</b> 150 mg	ranitidinum	Digestive tract and metabolism Antiulcer medicines Tablets	Ranitidină (Laropharm), Ranitidină LPH (Alvogen), Ranitidina (Magistra C&C)
13	Silithor®	food supplement	Digestive tract and metabolism Hepatoprotectors Capsules	Essentiale Forte® (Sanofi), Fortifikat® (Sun Pharma), Esentin Forte (Sun Wave Pharma)
14	<b>Fluocinolon N Atb</b> ® 18 g	fluocinoloni cetonidum + aneomycinum	Dermatological preparations Corticosteroids in combination with antibiotics. Ointments	Fluocinolon Acetonid (Laropharm), Fluocinolon G MK (Fiterman)
15	Fluxiv®	food supplement	Cardiovascular system Capillary tonics Tablets	Detralex® (Servier), Devaricid® (Biofarm), Endolex® (Sun Wave Pharma)
	Fluxiv® tonic cream	cosmetic	Cardiovascular system Varicose veins therapy Ointments	Troxevasin (Teva), Endolex® (Sun Wave Pharma), Ruscoven (Aboca)
16	<b>Oxacilină®</b> 250 mg and 500 mg	oxacillinum	Anti-infectives for systemic use Beta-lactam antibacterials, penicillins Capsules and injectables	Oxacilină® (Novartis), Oxacilină® (Farmex Company), Oxacilină® (Arena Group)

Ran	k Brand	International Non- Proprietary Name	Therapeutic class and form of administration	Main competitors
17	<b>Ampicilină®</b> 250 mg, 500 mg and 1g	ampicillinum	Anti-infectives for systemic use Beta-lactam antibacterials, penicillins Capsules and injectables	Ampicilină® (Novartis), Ampicilină® (Farmex Company), Standacillin (Novartis)
18	<b>Ceftamil</b> ® 1 g	ceftazidimum	Anti-infectives for systemic use Beta-lactamics. Injectables	Fortum (GlaxoSmithKline)
19	<b>Memantină Atb</b> ® 10 mg and 20 mg	memantinum	Central nervous system Anti-Alzheimer's medicines Tablets	Memantina Terapia (Sun Pharma), Ebixa (Lundbeck) Nemdatine (Teva)
20	<b>Bisotens®</b> 5 mg and 10 mg	bisoprololum	Sistem Cardiovascular Beta blockers Tablets	Concor® (Merck Kgaa), Bisogamma® (Wörwag Pharma), Sobyc® (Krka)

Data sources: Cegedim Romania 2019

# Top products for which Antibiotice is the only manufacturer

The products for which Antibiotice is the only manufacturer in the market recorded sales of 121.13 million LEI in 2019.

No.	Brand	International Non-Proprietary Name	Therapeutic class and form of administration
1	Aceclofen®	diclofenacum + paracetamolum	Musculoskeletal system Suppositories
2	<b>Amoxiplus®</b> 1000 mg/200 mg	amoxicillinum + acidum clavulanicum	Anti-infectives for systemic use Powder for injection
3	<b>Ampiplus®</b> 1000 mg/500 mg	ampicillinum + sulbactamum	Anti-infectives for systemic use Powder for injection
4	<b>Cicloserină Atb®</b> 250 mg	cycloserinum	Anti-infectives for systemic use, treatment for tuberculosis. Capsules
5	<b>Clo-Ekarzin®</b> 15 g	bethametasonum + clotrimazolum	Dermatological preparations Cream
6	Colistină Atb® 1.000.000 UI	sodium colistimethate	Anti-infectives for systemic use Powder for injection
7	<b>Cutaben Bebe®</b> 40 g and 100 g	zinc oxide + titanium dioxide + ichthammol + Vital ET®	Dermatological preparations Emollient and protective cream
8	<b>Cutaden®</b> 40 g	ichthammol + hamamelis virginiana extract + sodium borate + zinc oxide + titanium dioxide	Dermatological preparations Wound healing ointment
9	Fezivit <sup>®</sup>	Vitamin C + iron + zinc	Dermatological preparations Other dermatological preparations Capsules
10	<b>Fluocinolon N Atb</b> ® 18 g	fluocinoloni acetonidum + neomycini sulfas	Dermatological preparations Topical corticosteroid in combination Ointments
11	Fluxiv®	diosminum + hesperidinum + troxerutin + acidum ascorbicum	Cardiovascular system Food supplement to improve blood circulation Coated tablets
12	Fluxiv® tonic cream 40 g and 100 g	troxerutin + D-pantenol	Cardiovascular system Topical treatment for varicose veins Cream
13	<b>Hemorzon®</b> Suppositories	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Hemorrhoidal suppository for topical use Suppositories
14	<b>Hemorzon®</b> Ointment 18 g	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Hemorrhoidal suppository for topical use Ointments

No.	Brand	International Non-Proprietary Name	Therapeutic class and form of administration
15	<b>Izoniazidă Atb®</b> 100 mg and 300 mg	isoniazidum	Anti-infectives for systemic use, treatment for tuberculosis. Tablets
16	Lejer®	senna + rubarba + ghimbir + hibiscus	Digestive tract and metabolism, laxatives Capsules
17	<b>Lisinopril Atb®</b> 10 mg, 20 mg and 40 mg	lisinoprilum	Cardiovascular system Angiotensin converting enzyme inhibitors Tablets
18	<b>Moldamin®</b> 1,200,000 UI	benzathini benzylpenicillinum	Anti-infectives for systemic use, peniciline cu spectru larg. Powder for injection
19	<b>Nidoflor®</b> 15 g	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatological preparations Cream
20	Nistatină Atb® 500,000 UI	nystatinum	Intestinal anti-infectives Coated tablets
21	Nistatină Atb® Ovule 100,000 Ul	nystatinum	Gynecological anti-infectives Pessaries
22	Oxacilină Atb® 250 mg and 500 mg	oxacillinum	Anti-infectives for systemic use, peniciline Capsules
23	<b>Oxacilină Atb®</b> 500 mg and 1 g	oxacillinum	Anti-infectives for systemic use, peniciline Powder for injection
24	Penicillin G Atb® potassium 1,000,000 UI and Penicillin G Atb® sodium 400,000 UI and 1,000,000 UI	benzylpenicillinum	Anti-infectives for systemic use, broad spectrum penicillins Powder for injection
25	<b>Piafen®</b> 500 mg	metamizolum natricum + pitofenonum + fenpipramidum	Digestive tract and metabolism, antispastics in combination with analgesics. Tablets
26	<b>Pirazinamidă Atb®</b> 500 mg	pyrazinamidum	Anti-infectives for systemic use, treatment for tuberculosis. Tablets
27	Saliform Forte®	methylis salicylas + levomentholum	Musculoskeletal system Cream
28	Silithor®	silimarinum + L-methioninum + L-cisteinum	Digestive tract and metabolism Hepatoprotective food supplement Capsules
29	Sinerdol® 150 mg and 300 mg	rifampicinum	Anti-infectives for systemic use, treatment for tuberculosis. Capsules
30	Sinerdol® ISO	rifampicinum + isoniazidum	Anti-infectives for systemic use, treatment for tuberculosis. Capsules
31	Soriso®	rhodiola rosea + ocimum basilicum	Central nervous system Adaptogen food supplement Coated tablets
32	<b>Tetraciclină Atb® HCL</b> 250 mg	tetracyclinum	Anti-infectives for systemic use, tetracyclines Capsules
33	<b>Tetraciclină Atb® HCL</b> 12 g	tetracyclinum	Dermatological preparations Ointments
34	Tinero® Gel 40 g	nicotinamidum	Dermatological, anti-acne preparations Ointments
35	<b>Triamcinolon S Atb</b> ® 15 g	triamcinolonum + chlorquinaldolum	Dermatological preparations Cream
36	Zifex® Complex	metronidazolum + nystatinum + neomycini sulfas + hydrocortisonum	Gynecological anti-infectives Pessaries
37	<b>Zifex® Duo</b> 500 mg/200 mg	metronidazolum + clotrimazolum	Gynecological anti-infectives and antiseptics Pessaries

Data sources: Cegedim Romania 2019

# **Evolution of the main economic-financial indicators**

In 2019, the value of sales revenue was 389,710,740 LEI, by 7% higher than the value recorded in 2018.

Operating profit amounted to 40,007,906 LEI, up 2% compared to the value recorded in 2018.

Pre-tax profit recorded the same level as in 2018, being the result of the sustained expense management effort, given that the claw-back tax\* paid in 2019 amounted to 42,210,924 LEI, higher by 5,726,085 LEI (15%) than the value recorded in the previous year.

#### Evolution of the main economic-financial indicators

			1
	31.12.2018	31.12.2019	2019/2018
Sales revenues (LEI)	364,576,466	389,710,740	1.07
Operating profit (LEI)	39,312,791	40,007,906	1.02
Gross profit (LEI)	35,088,611	35,179,893	1.00
Net profit (LEI)	34,303,788	30,823,278	0.90
Fixed assets (LEI)	325,669,381	380,002,320	1.17
Current assets (LEI), of which:	380,435,802	414,013,171	1.09
receivables (LEI)	313,094,458	338,159,774	1.08
stocks (LEI)	64,964,661	73,975,988	1.14
Total liabilities (LEI), of which:	233,377,868	297,172,576	1.27
commercial liabilities (LEI)	67,171,084	72,337,840	1.08
short-term bank loans (LEI)	100,729,229	125,875,879	1.25
long-term bank loans (LEI)	26,662,433	57,080,354	2.14
Total assets (LEI)	706,105,183	794,015,491	1.12
Total equity (LEI)	472,727,315	496,842,915	1.05
Average number of employees	1,415	1,415	1.00
Average collection period of receivab	oles (days) 329	302	0.92
Stock turnover (days)	65	69	1.06
Labor productivity (days)	257,651	275,414	1.07
Degree of indebtedness (%)	33	37	1.12
EPS (LEI/shares)	0.051	0.046	0.90
Number of shares	671,338,040	671,338,040	1.00

<sup>\*</sup> The claw-back tax represents the contribution due to the State Budget by the marketing authorization holders of medicines or by their legal representatives, for the medicines included in national health programs under GEO no. 77/2011 with subsequent amendments.

# Stock market evolution

# **Investitors**

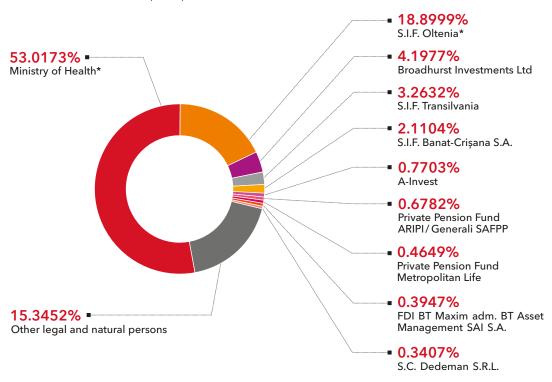
Antibiotice SA is a trading company in which the majority shareholder is the Ministry of Health with 53.0173% of the subscribed and paid-up capital. Bucharest Stock Exchange (BVB) is the regulated market in which the securities issued by Antibiotice SA are traded in the PREMIUM category.

#### The main Antibiotice shareholders on 31.12.2019

(extracted from the Shareholders' Registry):

- > Ministry of Health (\*) 53.0173%,
- > S.I.F. Oltenia (\*) 18.8999%
- > Broadhurst Investments Limited 4.1977%
- > S.I.F. Transilvania 3.2632%
- > S.I.F. Banat-Crișana S.A 2.1104%
- A-Invest 0.7703%
- Private Pension Fund ARIPI/Generali SAFPP 0.6782%
- > Private Pension Fund Metropolitan Life 0.4649%
- > FDI BT Maxim adm. BT Asset Management SAI S.A. 0.3947%
- > S.C. Dedeman S.R.L. 0.3407%
- > Other legal and natural persons 15.3452%.

NOTE: (\*) - Significant shareholders, according to Law no. 297 of 28.06.2004, Art. 2, Para. 1





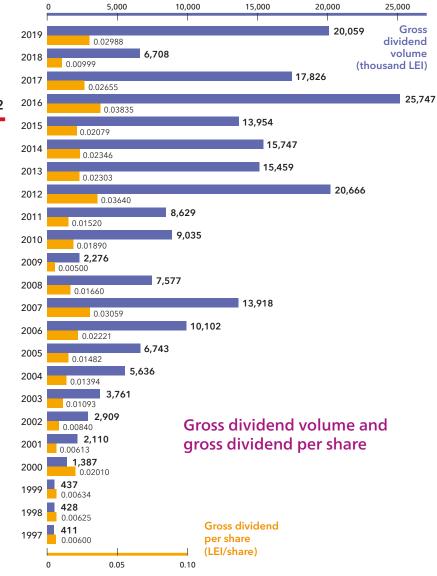
#### Net dividends

þo			Paid (LEI)			Unclaimed dividends whic		Date on which the payment of
Period	Due	Until 31.12.2018	01.01÷31.12 2019	Total	Total, %	LEI	%	dividends ceases
2015	13,753,343	12,653,207.76	11,948.01	12,665,155.77	92.09	1,088,187.23	7.91	15.09.2019
2016	25,401,595	23,325,012.26	53,762.17	23,378,774.43	92.04	2,022,820.57	7.96	in progress
2017	17,588,679.97	16,093,548.70	44,614.60	16,138,163.30	91.75	1,450,516.67	8.25	in progress
2018	6,612,624.05	_	6,055,864.22	6,055,864.22	91.58	556,759.83	8.42	in progress

In 2019, our company paid dividends for the financial years 2015, 2016 2017 and 2018 amounting to 6,166,189 LEI.

The dividends for the fiscal years 2015, 2016, 2017 and 2018 were paid through the Central Depository Bucharest and, implicitly, through the CEC Bank - the Paying Agent.

# Antibiotice in the securities market



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

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

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

The Antibiotice (ATB) shares traded on the Bucharest Stock Exchange are included in the BET-Plus index which comprises the Romanian companies listed on the BVB market that meet the minimum selection criteria, except for financial investment companies.

In 2019, the minimum price of the ATB share had the value of 0.4500 LEI. The share price increased to maximum value of 0.5260 LEI/share.

Stock market capitalization of Antibiotice on December 31, 2019 (the last trading day of the year) was 341,040 thousand LEI.

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# Antibiotice shares – ATB/Regular market

	2015	2016	2017	2018	2019
Number of shares	671,338,040	671,338,040	671,338,040	671,338,040	671,338,040
Stock market capitalization (thousand LEI)*	357,152	349,096	361,180	326,942	341,040
Stock market capitalization (thousand EUR)*	78,868	76,875	77,511	70,100	71,370
Stock market capitalization (thousand \$)*	86,167	81,123	92,813	80,259	79,873
Total traded value (million LEI)	11	6	12	9	15
No. of traded shares	18,844,935	12,555,866	21,113,565	17,109,263	30,364,292
Opening price (LEI/share)	0.5850	0.5320	0.5200	0.5780	0.4800
Maximum price (LEI/share)	0.6170	0.5420	0.5920	0.5780	0.5260
Minimum price (LEI/share)	0.5240	0.4200	0.5200	0.4550	0.4500
Price at the end of the period (LEI/share)	0.5320	0.5270	0.5380	0.4870	0.5080
Average price (LEI/share)	0.5836	0.5032	0.5585	0.5028	0.4851
Earnings/share (LEI/share)***	0.0405	0.0452	0.0500	0.0511	0.0459
Gros dividend/share (LEI/share)**	0.0197	0.0384	0.026552598	0.009991506	0.029879738
Dividend yield****	3.69%	4.05%	4.59%	2.05%	6.20%
Dividend distribution rate****	49%	52%	53%	20%	65%

<sup>\*</sup> Calculation based on the share price in the last trading day of that year

In 2019, a number of 30,364,292 shares were traded, amounting to 14.73 million LEI (3.2 million EUR, 3.6 million USD), with an average price of 0.4851 LEI/share.

According to Chapter VI, Section 2, Art. 92 - Code B.V.B., the financial communication calendar of the company Antibiotice included the following events:

Events		Date
> Presentation of 2018 preliminary annual financial results		28.02.2019
> General Meeting of Shareholders approved the annual financial results for 2018		18/19.04.2019
> Presentation of 2018 Annual Report		19.04.2019
> Presentation of Quarterly Reports:	Q I, 2019	15.05.2019
	Q III, 2019	15.11.2019
> Meeting with investors and analysts for presenting the Q1 2019 Report		17.05.2019
> Presentation of the H1 2019 Report		08.08.2019
> Meeting (teleconference) with investors and analysts for presenting the Q1 2019 Report		12.08.2019

<sup>\*\*</sup> Proposed dividend

 $<sup>\</sup>ensuremath{^{***}}$  Calculation of the earnings per share is based on the net profit of each year

<sup>\*\*\*\*</sup> Dividend per share/price of the share in the first trading day of each year

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

# 05

# Actions and Results in 2019

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# Developing our business internationally

Antibiotice runs its business in all the continents of the world, with a portfolio comprising 95 finished products from various therapeutic classes and Nystatin, the active substance which ranks us as the world market leader.

In the reporting period, the exports accounted for 40 % of our company's turnover, reaching 152,1 million LEI, by about 25% higher than the value recorded in 2018. This growth had the fastest rate in the last five years.

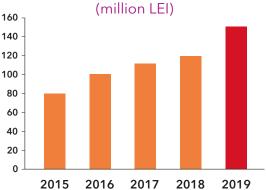
2019 was the first year in which the sales of finished products in the international markets significantly outpaced the sales of the active substance Nystatin. So, the main growth engine was the export of finished products in the territories where Antibiotice opened its own representative offices, the value of these exports recording an increase of over 65% compared to 2018, reaching a value of 44.4 million LEI.

In order to reach this sales level our company followed the main development directions in international markets, assumed through the 2019 management program:

# Consolidating and maintaining our world leading position for the active substance Nystatin

Strengthening our leading position for the active substance Nystatin in the international market, a direct result of the indisputable quality of this product, recognized by the USFDA as a USP reference standard is proved by the upward sales trend in the last 5 years. As a result, the number of new partners from Europe, South America, North America increased.





The 2019 selling target for Nystatin was fully achieved through a continuous management of costs, quantities manufactured and strategic partnerships with the main customers.

So, in 2019, our strategy for the product Nystatin sold in the international markets aimed at:

- consolidating our partnerships in the North and South America, leading to a 16% increase in the sales of Nystatin compared to the planned level;
- managing the markets in the Asia-Pacific area and Middle East;
- > starting new projects in Europe, a long-term growth source.

### In 2019

Antibiotice recorded the highest growth rate of export sales in the last 5 years

# World leader in the production

65%

of Nystatin

Increased sales by about 65% in the territories where Antibiotice opened its own representative offices

25%

The value of exports grew by about 25% compared to 2018

### >50%

The sales of sterile injectable penicillins increased by over 50% in the US market

### Developing our presence in the North American finished product market

Antibiotice recorded good sales of FDA certified finished products in the US market.

So, in 2019, Antibiotice recorded a 50% increase in the export sales of sterile injectable powders and laid the groundwork for launching a new product in 2020, thus creating the premises for a solid and long-term development of our business in this market.

# Increased sales by 65% in the territories where Antibiotice opened its own representative offices

In the territories where Antibiotice opened its own representative offices in the last 3 years (Vietnam, Republic of Moldova, Ukraine and Serbia) the sales of finished products increased by about 65% compared to 2018.

Starting from the principle that our company must apply in these territories similar strategies with those applied in the Romanian market in terms of product portfolios, business models, promotion actions, our specialists developed a multiannual strategy for the period 2020-2025 based on four strategic development pillars:

- > to registrate a portfolio of antiinfectives for hospitals, a segment in which our company is the leader in the Romanian market;
- > a market oriented pricing policy;
- solid partnerships with the local distribuitors;
- > to increase the high profile of the corporate brand and products.

In **Vietnam**, Antibiotice is the main Romanian exporter of pharmaceutical products, with a traded value of about 10 million USD in 2019. In this market our company registered 17 products, mainly antiinfectives, 4 of which were launched in 2019.

Because 80% of the medicines are sold in hospitals, this destination is compatible with the Antibiotice business which has a traditional portfolio of sterile injectables. Moreover, over 90% of the requests from Vietnam are for products that participate in tenders for hospitals, where the purchases are made according to the manufacturer's price and quality certifications. Antibiotice is among the top pharmaceutical manufacturers selling in the Vietnamese market because of its EU GMP certifications.

Until 2019, our company registered and traded 55 products from all the approached therapeutic classes in the **Republic of Moldova**. Of these, 5 antiinfectives for hospitals were launched in 2019.

In **Serbia**, Antibiotice sells 13 products (antiinfectives, sterile injectable powders, cardiovasculars and food supplements), one of them being launched in 2019.

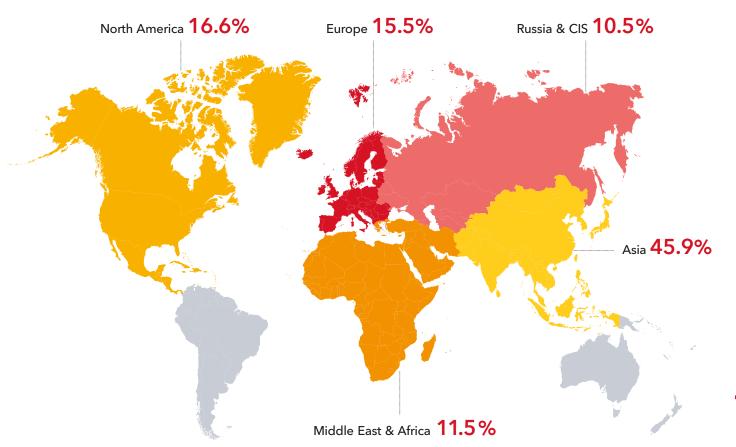
The Serbian market is of interest for Antibiotice because it shows similarities in consumption and therapeutic behaviors with the Romanian market.

Through its representative office from **Ukraine**, in the fourth quarter of 2019 Antibiotice started the registration procedures for 8 antiinfectives, 12 cardiovascular products and 4 food supplements.

In 2019, we launched in the foreign markets 10 new products and we concluded new local partnerships for extending the finished product portfolio - antiinfectives



### Sales of finished products in the international market



for the outpatient therapy and topical products (dermatological creams and ointments, anti-imflammatory medicines) and suppositories.

### Initiating new projects of territorial expansion, as the main pillar of growth in the medium and long term

International expansion of the Antibiotice business has two many directions:

- to develop the product portfolio in the current territories;
- > to access new markets with a recognized potential as regards

the consumption of anti-infective, dermatological and cardiovascular medicinal products.

So, in 2019, our company concluded representation contracts in the Scandinavian markets for a 14-product portfolio and started the negotiations for accessing the markets of Saudi Arabia and Philippines.

In 2019, Antibiotice SA adapted its external expansion policies to the new legal healthcare regulations, taking into account both the consumption trends and the specific habits of each market.

### 10 mill. USD

Antibiotice is the main Romanian exporter of pharmaceuticals in the Vietnamese market, with a traded value of about 10 million USD in 2019

# Ensuring a sustainable and marketable portfolio through increasing its degree of renewal

### 16

In terms of value Antibiotice ranks 16<sup>th</sup> among 230 companies which manufacture non-prescription medicines (OTCs) and food supplements.

### Evolution of the pharmaceutical market in Romania\*

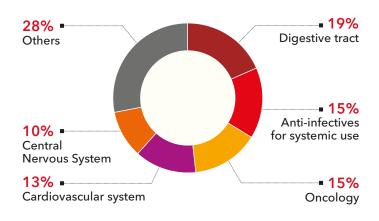
In 2019 the value of medicinal products released to the patients was 17.82 billion LEI (distribution price), up 10.9% compared to 2018. In terms of quantity (number of boxes) the market increased by 2.1% compared to the previous year.

Pharmaceutical market is dominated by the prescription medicines (RX). These represent 77% of the total value sales and 65% of the total consumption of medicines (number of boxes) in Romania. The prescription medicines recorded in the analyzed period an increase in terms of value of 10% from 12.5 billion LEI in 2018 to 13.8 billion LEI in 2019.

The non-prescription medicines (non-RX: OTCs, food, supplements, medical devices) recorded also an increase of 14% in terms of value, from 3.55 billion LEI in 2018 to 4.05 billion LEI at the end of 2019.

The main sales in the Romanian pharmaceutical market are made by the open-circuit pharmacies which represent 87% of the total sales and grew by 9.4% compared to 2018. The closed-circuit pharmacy segment increased by 22.1% compared to the previous year.

# Share of sales in Romania by pharmaceutical classes



In the Romanian market, the original medicines have a significant share in terms of value (58.4 of total sales). However, in terms of volume, the most consumed are the generic and non-prescription medicines (OTCs, dietary supplements, medical devices: 75%).

As regards the share of sales in terms of value, these are the first five therapeutic classes in the Romanian market: digestive tract, oncology, anti-infectives for systemic use, cardiovascular system and central nervous system. Cumulatively, the first five classes make 72% of the total value sales in Romania.

# Evolution of the relevant pharmaceutical market for Antibiotice SA\*\*

The market relevant for our company recorded in 2019 a value of 2.15 billion LEI, up 6.7% compared to 2018.

The quantitative consumption rose by 2.5%, a number of 141.5 million boxes being released by pharmacies. This segment also was dominated by the prescription medicines (RX) which represented 57.6% from the total value sales and 66.3% from the total consumption of medicines (reported as number of boxes).

The prescription medicinal products recorded in the analyzed period an increase of 2% in terms of value, from 1.21 billion LEI at the end of 2018 to 1.24 billion LEI in 2019. The non-prescription medicinal products (OTCs) recorded an increase of 13.9% in terms of value, from 799 million LEI in 2018 la 909.8 million LEI in 2019.

<sup>\*</sup> According to CEGEDIM Romania 2019

<sup>\*\*</sup>The relevant market is represented by the market to which the Antibiotice portfolio relates with regard to the therapeutic indication of the product (molecule, dosage form, concentration).

# Antibiotice in the Romanian pharmaceutical market

In the domestic market, Antibiotice recorded sales comparable to the sales recorded in 2018, both in pharmacies and hospitals, amounting to 335.9 million LEI.

The main therapeutic classes that recorded in 2019 significant increases in terms of value compared to 2018 were: dermatological preparations (+2.5 million LEI), medicinal products for the central nervous system (+1.6 million LEI), genitourinary system (+1.0 million LEI), respiratory system (+0.2 million LEI) and preparations for hospital (+0.06 million LEI). These increases were generated both by the contribu-tion of new products and by the positive evolution of our company's top products.

The medicinal products in our company's portfolio that had a contribution of over 1 million LEI in 2019 were: Ampiplus® 1000 mg/500 mg for injection (+1.4 million LEI), Amoxiplus® 1000 mg/200 mg for injection (+1.01 million LEI), Indapamidă Atb® 1.5 mg tablets (+1.4 million LEI), Memantină Atb® range (+1.7 million LEI), Saliform® Forte 50 g cream (+1.5 million LEI)

and Saliform® Forte 100 g cream (+1,3 million LEI).

In 2019, Antibiotice maintained its leading position in the segment of generics and OTCs sold in hospitals, with a 15.59% market share.

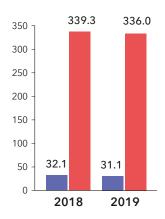
Our company ranked sixth in the segment of generics and OTCs with a 4.53% market share and ranked 20<sup>th</sup> in the total pharmaceutical market, with a 1.89% market share.

As regards the indivisible units sold in 2019, our company maintained also its leading position in the following segments: ointments (23.89%), suppositories (42.46%) and injectable powders (72.89%).

In 2019, the Antibiotice's portfolio was enriched with the following new products:

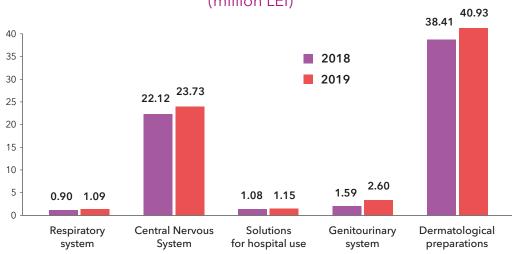
- Moldamin® 1,200,000 IU for injection
- Levofloxacină Atb® 500 mg tablets
- Nolet® 5 mg tablets
- Lejer® capsules.

### Evolution of the Antibiotice's sales in the period 2018-2019



- Sales in terms of quantity (millions of boxes)
- Sales in terms of value (million LEI)

Sales by therapeutic classes (million LEI)



15.59%

Antibiotice is the leader in the segment of generics and OTCs sold in hospitals, with a 15.59% market share In the reporting period, the Antibiotice portfolio was promoted to scientific events organized in partnership with the main medical professional bodies. Promotional actions were also carried out for health professionals, doctors and pharmacists, which aimed to increase the good reputation of our company brand as well as the product brands from the following classes: anti-infectives for systemic use, dermatological preparations, medicines for genitourinary system, musculoskeletal system and the Nutriensa® range of food supplements.

These events promoted our products belonging to the following portfolios: Hospital & Partners, dermatologicals as well as the Quality of Life, the latter including the Women's Health and Nutriensa® concepts.

Hospital&Partners is the portfolio for hospitals, the promotion focusing on the development of good practices in the use of antibiotics, supported by the "Antibiotics of the Third Millennium" campaign.

"Quality of Life" is the concept defined in medicine as being the physical, mental and social well-being as well as the ability of individuals to perform their usual tasks. Quality of life = prevention + treatment to maintain a normal biological condition.

Our company's portfolio comprise, under the "Quality of Life" concept, therapeutic solutions for different conditions in the following therapeutic areas: cardiovascular, genito-urinary, musculoskeletal, dermatology, digestive tract as well as remedies designed to maintain the body's homeostasis such as food supplements.

"Women's Health" - by this concept, Antibiotice aims to strengthen the identity of the portfolio intended for the prevention and treatment of diseases in obstetrics gynecology.

As a communication platform for the "Women's Health" concept, regional scientific events were held at which gynecologists and family doctors were invited.

**Nutriensa**® is an umbrella brand for the food supplements manufactured by Antibiotice from highest quality ingredients, in unique combinations, to maintain the health of each system of the human organism: central nervous system, digestive tract, peripheral vascular system, musculoskeletal system: Equilibra®, Fezivit C®, Fluxiv® tablets, Fluxiv® cream, Lejer®, Silithor®, Soriso®, Sprinten®.

All the Antibiotice food supplements are formulated by our experienced researchers being manufactured to the quality standards met for the medicinal products.

# Nutriensa® food supplements manufactured by Antibiotice



# Research-Development for adapting and durably consolidating our company portfolio

The main objective of the Research-Development Unit is to develop new medicines (topicals, tablets, capsules, sterile products and other new pharmaceutical dosage forms) in line with the company's development strategic directions until 2025.

The products under research will complete the following classes of the Antibiotice portfolio: antiinfectives (sterile oral and injectable powders), dermatological, cardiovascular, non-steroidal anti-inflammatory products, medicines for the digestive system and for women's health.

The products under research in 2019 included a number of 15 projects that, during the past year, went through different stages of research:

- > a project for a sterile injectable powder;
- > four projects for topical products;
- > ten projects for oral solid products.

### Moldamin - injectable product, the first recommendation in the prevention of acute joint rheumatism and rheumatic carditis

2019 meant the completion of the research project, obtaining of the Marketing Authorization and resumption of the manufacture of Moldamin®, a recognized brand present in our company's portfolio for almost 60 years.

Moldamin® returns in the medical practice, in a new formula, made according to modern formulation principles, containing the same active substance, benzatin benzyl penicillin, but other excipients. Moldamin® is a prolonged-action penicillin and is the first-line medicine in infections where it is necessary to provide prolonged antibiotic concentrations, such as in respiratory infections (streptococcal angina – red in the neck, otitis, sinusitis), venereal diseases (syphilis), skin infections (erysipelas).

It is also the first recommendation in the prevention of acute joint rheumatism and rheumatic carditis.

The research projects for topicals focus on products for dermatological use, local anti-inflammatory/anti-infective/anesthetic products and medicines for women's health. Of the ten research projects for oral solid products, four are food supplements that will enrich the portfolio of products aimed at improving and maintaining the well-being and health of the population.

## Increasing our international sales by authorizing new products

In order to extend its presence in the international market, our company obtained in 2019 five new Marketing Authorizations (MAs) for medicinal products which are to be traded in the territories from Asia and Europe.

Several products have been also optimized in accordance with the requirements in the territories where our company has commercial representative offices. We refer to 5 products in the form of sterile injectable powder, two topical products and four oral solid medicines which will receive the MA within the next 4 years.

# Pharmacovigilance - monitoring the safety of medicines

Monitoring the effectiveness and safety in the administration of medicines for which Antibiotice holds marketing authorizations (MAs), is part of a continuous process, carried out through our internal Pharmacovigilance Department. Our pharamcovigilance system is connected to EudraVigilance (the European network for processing data on medicine safety) and is permanently updated, in accordance with the European Community legislation.



The injectable product

Moldamin®

returns in the medical practice, in a new formula

In 2019, Antibiotice monitored the safety of the medicinal products for which it holds marketing authorizations through the following actions:

- maintained and updated the database with information related to the products authorized in Europe;
- collected and evaluated the reports on the medicinal products suspected by adverse reactions;
- > elaborated risk management plans;
- > reported periodically the updated data on the medicine safety.

Two bioequivalence studies were completed in 2019. One of them was conducted for an external partner, the second one (carried out in four stages), was conducted for an Antibiotice product.

A first clinical study for an Antibiotice topical product was also initiated in 2019 in partnership with several clinical centers in the country. This product has a valuable potential of development in the Antibiotice territories (where the company opened its own commercial representative offices) and in the assimilated areas.

### **Center for Clinical Studies**

Pe In 2019, our Center for Clinical Studies (a reseach unit authorized by the Ministry of Health) conducted bioequivalence studies but also efficiency studies, instrumental tests and several projects for developing and validating analytical methods, necessary to support the research plan.

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





#1

The first

tological

product

multicenter

clinical trial

for a derma-

# Complex manufacturing structure adapted to international GMP and FDA quality standards

The Antibiotice's portfolio (over 150 medicinal products) is manufactured on the most complex manufacturing structure in Romania which comprises 8 distinct manufacturing sites for sterile injectable powders, capsules, tablets, topical products (ointments, creams, gels), suppositories, pessaries and the active substance Nystatin.

The quality of our products is ensured by processes that comply with the latest requirements in the field of good manufacturing practice, all our eight manufacturing flow being EU-GMP certified. The manufacturing flows of the sterile injectable products and active substance Nystatin are approved by the Food and Drug Administration (FDA), the American agency responsible for protecting and promoting public health.

Implementation of all the regulatory requirements and evaluation of the quality management system conducted by the regulatory authorities and by our customers from all areas of the world, resulted in maintaining a high level of quality, efficiency and safety of our medicinal products.

Our 2019 production materialized in 546 million indivisible pharmaceutical units, by 21 million more than in 2018 (525 million pharmaceutical units) under the form of tablets, capsules, sterile injectable powders, suppositories, pessaries and topicals - ointments, creams, gels.

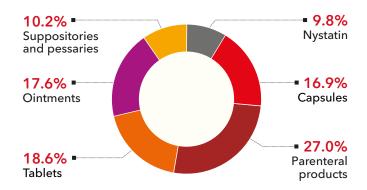
The total value of the production made in 2019 was 394.4 million LEI, up 9.5% compared to the previous year.

The value of the production manufactured for the other territories excluding Romania represented 28.7% of the total production made in 2019, by 11.5% higher than in the previous year.

In 2019, Antibiotice recorded savings of raw materials representing 1.6% of the total raw materials consumed as a result of the high yields obtained during the manufacturing process stages.

Utility consumptions fell within the estimated limits as a result of a careful manage-

## 2019 Production breakdown in terms of value (% of the total value of the production)



ment of utilities in all the manufacturing plants. Thus, the consumptions remained below the estimated levels, our company achieving a 5% saving. Efforts were continued to implement the environmental protection program on the reduction of volatile organic substances emissions in the extraction phase of Nystatin and reduction of the specific solvent consumption in the technological process.

Starting with February 2019, the manufacturing processes have been harmonized with the serialization process of the prescription medicines, in accordance with the EU Directive 62/2011, a mandatory condition for the marketing of medicinal products.

### New products manufactured in 2019

In 2019, our company launched in the production four new products from the following therapeutic classes:

- Antiinfectives for systemic use:
  Moldamin® 1,200,000 IU, for injection,
  Levofloxacin Atb® 500 mg tablets;
- Cardiovasculars: Nolet® 5 mg tablets;
- Food supplements (for digestive tract): Lejer® capsules.

### 546M

Antibiotice produced 546 million indivisible pharmaceutical units in 2019

new products launched in the production

# Medium and long-term development through investments

As a partner of the Romanian health system, Antibiotice is recognized as a leading manufacturer in the segment of anti-infective and dermatological products. In order to maintain and enhance its position, our company heavily invests in new production facilities, new laboratory equipment and in streamlining the manufacturing processes.

The investments made in 2019 amounted to 65,539,962 LEI.

#### Main investments in 2019

Investments in new manufacturing sites our company continued to build a new production capacity for topical products (ointmens, creams, gels) and suppositories

This investment totaling about 20 million EUR started in 2017 and consists of the construction of a fully equipped production capacity according to the EU-GMP (Good Manufacturing Practice) and FDA (Food and Drug Administration) requirements. This investment is performed according to the established schedule, so that in the latter part of 2020 it will enter the authorization process.

The new manufacturing plant will provide modern conditions for manufacturing medicinal products in compliance with the legislative and pharmacopoeia requirements necessary for their registration and marketing in all the regulated markets. Capacity of the plant will be 540 tons/year, from which 388 tons/year ointment mass (10 million tubes with an average mass of 40 g/tube) and 152 tons/year suppository mass (76 million suppositories with an average mass of 2 g/suppository).

#### Research & Development investments

From the total amounts invested in 2019 by our company, 8.18% was oriented towards the research-development activity.

The research represents one of the most dynamic activities within our company, experiencing permanent changes and an upward evolution. The research-development investment program includes equipment and software for supporting and improving the research activities, in order to obtain new quality, safe and efficient products, highly competitive in the market.

Investments for modernizing the existent manufacturing sites consisted in the purchase of production and laboratory equipment, installations for revamping the manufacturing flows and represented 10.60% of the total amount invested in 2019.

We purchased last generation manufacturing equipment, with a higher productivity, low energy consumption and high degree of safety in operation.

Investments in the Integrated Management System (1.99% of the total amount invested in 2019): Product Quality Control (through the acquisition of state-of-the-art equipment for ensuring the control of products manufactured in compliance to the international quality standards); Environmental Protection (in order to comply with the legal requirements regarding the protection of the environment); Occupational Safety and Health (aiming to continuously improve the employees' working conditions and their health and safety).

Investments for rehabilitating the industrial site (24.26% of the total amount invested in 2019): reintegration into the industrial circuit of land released after the demolition of the old plants; rehabilitation of the buildings (both manufacturing plants and auxiliary buildings); modernization of the transport and storage infrastructure (investments in the car fleet and in the storage areas); upgrading and streamlining the maintenance infrastructure, utilities production and distribution (so that savings to be achieved by reducing consumption and eliminating losses).

# Procurement - an important link in the value chain

Procurement represents an important link in the value chain that generates favorable conditions for the long term development of our business, bringing its contribution to the profitability of the company. The activity is organized to meet the needs of the company, developing business relationships both with the suppliers from Romania and from the intra- and extra-community areas.

In the context of an increased complexity and competitiveness in the world pharmaceutical market, Antibiotice has demonstrated its ability to build and maintain stable, ethical and trustworthy business partnerships with its suppliers for its own benefit and for the benefit of its employees, partners and not least of the Romanian economy in general.

# The staff involved in the procurement activity has:

- to comply with the regulations and legislation in force;
- to treat impartially the suppliers in the selection process, offering them equal contracting opportunities;
- to implement a fair, ethical and transparent evaluation system of the suppliers, able to promote long-term stable partnerships, taking into account the technological and manufacturing capabilities, quality, price, delivery capacity and corporate stability;
- to ensure a fair cost-volume ratio, which allows the company to obtain substantial savings, related to the manufacturing stages;
- to ensure a continuous communication with the suppliers, so that any risks associated with production and procurement can be known, evaluated and resolved in due time.

# Strategic objectives of the procurement activity in the international markets:

- to secure the purchasing sources, by making the medium and long-term partnerships transparent and predictable;
- to diminish the risks throughout the acquisition chain, in order to ensure the continuity of the company's operations;
- to encourage innovation in relationships with partners to create added value throughout the procurement chain, starting from the selection of sources in research and development projects;
- to generate competitive advantages, by identifying and optimaly using the suppliers' capabilities (technology, production facilities, know-how, staff experience and professionalism).

## Strategic measures on the foreign procurement in 2019:

- to correlate the procurement program of raw materials, packaging, reference substances / medicines, finished products with the sales structure generated by both the domestic and international markets, for achieving the proposed objectives;
- to create backup stocks to ensure the continuity of production and avoid syncopes in this process, as well as to secure the supply sources;
- to maintain the current partnerships and develop new strategic partnerships.

In the current economical and technological context, the efficient management of the purchasing chain is a permanent preoccupation of our company.

Professionalism, ethics, flexibility, interdisciplinarity and price sovereignty are essential attributes of the Procurement Department for ensuring a sustainable future for our company.

# Optimizing the operating costs and increasing the operating efficiency

## Economic-financial analysis of our company's activity

Antibiotice SA is the most important Romanian manufacturer of generic medicines, a national and international reference brand which has been continuing its mission of producing quality, safe and efficient medicines to give people the hope of a healthy life.

Organized in three divisions (Sterile Products & Active Substances Division, Oral Solid Dosage Forms Division and Topical Products Division), comprising the eight manufacturing flows, our company obtained sales revenue of 389,710,740 LEI in 2019, by 7% higher compared to the value recorded in 2018. The continuous effort to achieve higher revenues, as well as the expenditure management measures had

as objective to maintain the profitability of our business under the current legislative conditions which led to a significant increase of the claw-back tax.

Other operating income amounted to 33,008,685 LEI, by 27.30% lower than the value recorded in 2018.

Income generated by the entity and capitalized was 4,660,869 LEI, by 33% higher than the value recorded in 2018.

These results made it possible to promote a new payroll system, which sought to correlate the benefits with each employee's performance level. This increased the staff costs to 102,852,132 LEI, by 13% higher than the value recorded in 2018 (90.864.735 LEI). This measure highlighted once again how important the human resources are for our bussiness.

+2%

+7%

Sales revenues

were by 7%

higher than

previous year

the value

recorded

in the

Operating profit amounted to 40,007,906 LEI, by 2% higher than the value recorded in 2018

(LEI)

Indicators	31.12.2018	31.12.2019	2019/ 2018	
Sales income	364,576,466	389,710,740	1.07	
Other operating revenues	45,405,000	33,008,685	0.73	
Income related to the cost of product stocks	-1,259,715	4,564,960	4.62	
Income generated by the entity and capitalized	3,489,144	4,660,869	1.34	
Expenditure on raw materials and consumables	138,844,375	146,016,104	1.05	
Staff costs	90,864,735	102,852,132	1.13	
Amortization and depreciation expenses	20,237,870	21,416,603	1.06	
Other operating expenses	122,951,124	121,652,509	0.99	
Operating profit	39,312,791	40,007,906	1.02	
Financial income	4,991	8,313	1.67	
Financial expenses	4,229,171	4,836,326	1.14	
Pre-tax profit	35,088,611	35,179,893	1.00	
Income tax and other taxes	784,823	4,356,615	5.55	
Profit	34,303,788	30,823,278	0.90	

In 2019, the value of production achieved was by 9% higher than the value recorded in the previous year, which led to a 5% increase in the value of expenditures on raw materials and consumables.

Amortization and depreciation expenses amounted to 21,416,603 LEI, by 5.82% higher than the value recorded in 2018. In 2019, our company highly invested in the new Ointment & Suppository Plant, but being an ongoing investment, the impact on depreciation expense will be reflected after the investment is put into service.

In the structure of other operating expenses, the value of energy and water expenses increased by 19%, from 9,316,468 LEI to 11,124,204 LEI, an increase due to the increase in electricity tariffs. Our contribution to the finance of some health expenses (claw-back tax) increased by 15% as well.

#### **Assets**

In 2019, the current assets were higher than the short-term liabilities, and the permanent capital (equity and long-term debt) exceeded the fixed assets, which shows that the company complies with the principle of aligning the maturity of the assets and liabilities.

The total assets regcorded on 31.12.2019 amounted to 794,015,491 LEI, up 12% compared to the value recorded on 31.12.2018. In their structure, a significant increase of 17% was recorded in the tangible assets, as a result of the intense investment process (the new manufacturing plant for topical products).

The value of stocks recorded on 31.12.2019 was higher by 14% as compared to the previous year as a result of the purchase of raw materials necessary for additional production made by the existent Ointment & Suppository Plant to ensure the continuity of sales during the period when the transition from the current flow to



the new manufacturing flow will be done. Related to the increase of the stock value, the stock turnover indicator recorded a 6% increase.

The average collection period of receivables decreased as a result of the measures continuously taken by our company to optimize the commercial relations and due to a 7% increase in the sales revenues. Commercial and other receivables recorded on 31.12.2019 were by 8% higher compared to the value recorded in 2018.

#### **Liabilities and equity**

Consistent with the value of total assets, the value of equity and debt increased by 12%, compared to the value recorded on 31.12.2018.

In their structure, the value of current liabilities was by 18% higher than the value recorded in the previous year. A significant increase of 114%, recorded the value of the long-term bank loan, necessary to provide the financial resources for the investments in building the new manufacturing plant of topical products and purchasing equipment to comply with the serialization requirements.

Overall the amount of debt increased by 27%, which led to a 12% increase in the degree of indebtness (the ratio between total debts and total assets). The value of equity on 31.12.2019 increased by 5% compared to the value recorded at the same date of the previous year.

48

(LEI)

			2019/ 2018	
Indicatori	31.12.2018	31.12.2019		
ASSETS				
FIXED ASSETS				
Tangible assets	310,640,665	363,616,611	1.17	
Intangible assets	15,028,716	16,385,709	1.09	
TOTAL FIXED ASSETS	325,669,381	380,002,320	1.17	
CURRENT ASSETS				
Stocks	64,964,662	73,975,988	1.14	
Trade and similar receivables	313,094,458	338,159,774	1.08	
Cash and cash equivalents	2,376,682	1,877,409	0.79	
TOTAL CURRENT ASSETS	380,435,802	414,013,171	1.08	
TOTAL ASSETS	706,105,183	794,015,491	1.12	
LIABILITIES				
CURRENT LIABILITIES				
Commercial and similar debts	67,171,084	72,337,840	1.08	
Amounts owed to credit institutions	100,729,229	125,875,879	1.25	
Debts from current taxes	10,421,393	13,267,396	1.27	
Subventions for investments	637,008	0		
TOTAL CURRENT LIABILITIES	178,958,714	211,481,115	1.18	
LONG-TERM LIABILITIES				
Subventions for investments	2,489,791	3,079,169	1.24	
Deferred tax	25,266,930	25,531,938	1.01	
Amounts owed to credit institutions	26,662,433	57,080,354	2.14	
TOTAL LONG-TERM LIABILITIES	54,419,154	85,691,461	1.57	
TOTAL LIABILITIES	233,377,868	297,172,576	1.27	
SHARE CAPITAL AND RESERVES				
SHARE CAPITAL	264,835,156	264,835,156	1.00	
Revaluation reserves	53,459,596	50,804,319	0.95	
Legal reserves	13,426,761	13,426,761 1		
Other reserves	190,422,002	200,655,367	1.05	
Retained earnings	-60,182,699	-56,432,683	0.90	
Distribution of profit	-23,537,290	-7,269,283	0.27	
Current result	34,303,788	30,823,278	0.89	
TOTAL EQUITY	472,727,315	496,842,915	1.05	
TOTAL CAPITALS AND LIABILITIES	706,105,183	794,015,491	1.12	

### The amounts owed to credit institutions

on 31.12.2019 amounted to 182,956,233 LEI, of which:

amounts due in the short term: 125,875,879 LEI;

operation amounts due in the long term (interest included) 57,080,354 LEI

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

Objective	Credit line - working capital
Amount	55,000,000 LEI
Maturity	16.08.2020
iviacarrey	10.00.2020
Balance at December 31, 2019	54,330,807.68 LEI
Guaranties	Mortgage contract for buildings, land / Contract for assignment of receivables

### Contract no. IAS3-20-2018/03.05.2018 concluded with Unicredit Bank S.A.

Objective	Investment loan
Amount	15,406,300 EUR
Maturity	02.05.2028
Balance at December 31, 2019	11,943,245.63 EUR (57,080,353.84 LEI)
Guaranties	Mortgage contract for buildings, land / Contract for assignment of receivables

### Short-term contract no. 12/01.07.2013 concluded with Export-Import Bank of Romania - EXIMBANK S.A.

Objective	Credit line - working capital
Amount	30,000,000 LEI
Maturity	24.06.2020
Balance at December 31, 2019	29,592,915.74 LEI
Guaranties	Mortgage contract for buildings, land / Contract for assignment of receivables

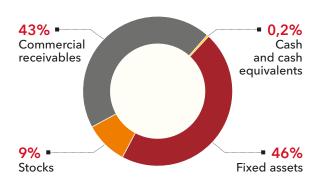
### Short-term contract no. 12239/22.05.2012 concluded with ING BANK N.V. Amsterdam - Romania Branch

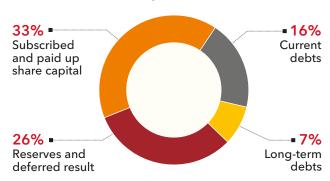
Objective	Credit line - working capital
Amount	9,500,000 EUR
Maturity	22.05.2020
Balance at December 31, 2019	24,021,730.10 LEI 3,251,946.88 EUR (15,542,029.72 LEI) 560,551.01 USD (2,388,395.74 LEI)
Guaranties	Mortgage contract for buildings, land / Contract for assignment of receivables

Antibiotice SA did not lodge guarantees and did not pledge or mortgage its own assets in order to guarantee certain obligations in favor of a third party.

### Asset breakdown

### Liability breakdown





 Cash flow
 (LEI)

 31.12.2018
 31.12.2019

 I. Cash flows from operating activities

I. Cash flows from operating activities		
Cash receipts from the sale of goods and the provision of services	342,163,055	363,059,643
Cash receipts from royalties, fees, commissions and other income	507,166	425,296
Cash payments to suppliers of goods and services	(196,684,926)	(203,130,502)
Cash payments to and on behalf of employees, payments made by the employer in connection with the staff	(82,487,294)	(89,954,560)
Value added tax paid	-	-
Contributions to the Ministry of Health and the Ministry of the Environment	(35,898,778)	(41,908,808)
Other taxes, fees and similar payments	(865,883)	(666,289)
Cash generated by the operation	26,733,341	27,824,781
Interest collected	4,991	8,313
Interest paid	(3,474,486)	(4,538,522)
Income tax/dividends paid	(2,400,279)	(2,669,237)
Net cash flows from operating activities	20,863,568	20,625,335
II. Cash flows from investment activities		
Cash payments for the purchase of land and fixed assets, intangible assets and other long-term assets	(64,596,506)	(69,180,345)
Net cash from investment activities	(64,596,506)	(69,180,345)
III. Cash flows from financing activities		
Receipts from long-term loans/reimbursements	26,627,446	29,595,638
Dividends paid	(16,235,156)	(6,150,225)
Net cash flows from financing activities	10,392,291	23,445,413
Gains/losses from exchange rate differences	(388,333)	(536,326)
Net cash increase/(decrease)	(33,728,980)	(25,645,923)
Cash and cash equivalents at the beginning of the period	(64,623,567)	(98,352,547)
Cash and cash equivalents at the end of the period	(98,352,547)	(123,998,470)
Cash and cash equivalents at the end of the period include:		
Bank accounts and cash	2,376,682	1,877,409
Credit lines	(100,729,229)	(125,875,879)
	(98,352,547)	(123,998,470)

At the beginning of 2019, cash and cash equivalents were -98,352,547 LEI, representing credit lines in value of 100,729,229 LEI, from which 2,376,682 LEI remained available in bank accounts from the amounts drawn from the credit lines. The cash receipts from the operating activity were 363,059,643 LEI. Cash payments to suppliers of goods and services were 203,130,502 LEI, and those to and on behalf of employees amounted to 89,954,560 LEI.

Our company paid also the amount of 7,874,048 LEI representing income tax, local taxes, bank interest and 69,180,345 LEI for purchasing fixed assets. The amounts paid to the state budget representing the contribution to finance some health expenses (clawback tax) amounted to 41,908,808 LEI.

As regards the financing activity, our company paid dividends amounting to 6,150,225 LEI.

At the end of the period, the level of cash and cash equivalents was -123,998,470 LEI, representing credit lines for the current activity (125,875,879 LEI), from which 1,877,409 LEI remained available in banks from the amounts drawn from the credit lines.

As of 31.12.2019, Antibiotice did not record obligations with a exceeded maturity to the state and local budget.

# Motivating the human resources and providing them with the necessary skills to achieve the strategic directions

Promotion of an attractive employer brand and harmonization of our human resources to the company's development strategy are the main directions of the actions carried out in 2019 in the human resources area.

In order to achieve the objectives set in the multiannual strategic plan, the human resources management aimed at achieving the following specific objectives:

# To identify and attract qualified staff for ensuring the optimal professional structure

This objective was supported by continuing the projects for promoting the employer brand towards the target audience:

> Perform a+, the 4<sup>th</sup> edition, a project for practical training and personnel selection, through partnership with the Grigore T. Popa University of Medicine and Pharmacy lasi. The edition held in 2019 attracted 10 participants. By the end of the year, of the 42 students who followed Perform a+, 12 have been employed in the company, in research, production and quality assurance.

> Summer school a+, the 10<sup>th</sup> edition, organized in partnership with the university centers of lasi to identify future specialists to be selected for the recruitment sessions on the vacant positions. The program, which has become a tradition, offers participants the opportunity to become familiar with the working environment, concepts and regulations of the pharmaceutical industry. About 400 students and graduates participated in the ten editions, of which 46 have been employed on the vacant positions in our company.





37.5
hours the average
number
of training
hours per
employee

4.6%
Employee turnover (due to the employees who left voluntarily our company)

> Partnerships established with preuniversity educational institutions, Petru Poni Technological High School and Technological High School of Mechatronics and Automation Iaşi, for internships in our company. In 2019, within these partnerships, the Iasi County School Inspectorate approved the organization of a dual education project that will ensure the preparation of 15 students for the profession of chemical operator for medicines and cosmetics and 10 students for the profession of electrician in the 2020-2021 school year.

# Development of professional skill training programs

The training programs focused on the continuous professional training of our staff but also on developing the necessary professional skills of our new employees. In 2019, the training courses for our employees were grouped in three main directions, as follows:

- Training courses for developing the professional competences;
- Training courses for developing the management skills;
- Trainings for obtaining professional certificates.

500 employees were included in 2019 in training programs with external lecturers. These programs followed the above-mentioned three directions, totaling 8,566 hours.

The average number of training hours with both external and internal lecturers per employee was 37.5 compared to the planned 35 hours.

Complementary, in 2019, a pilot training project with internal lecturers was carried out, having as a target audience specialists from the Marketing & International Sales Unit. After identifying the training needs, internal courses on legislation and medicine authorization procedures were conducted. The program will continue in 2020 with new themes and other audience categories.

# Strategies and measures to increase our employees' motivation

Actions were initiated in 2019 to improve the employee motivation system. Thus, the motivation system will be adapted so as to include a fixed and a variable component, in direct correlation with our employees' performances.

The reward system was redesigned after an ample analysis which involved the hierarchy of positions, depending on their complexity and the current payroll system, compared to the levels of similar positions in the labor market. Our company also established through an Addendum to the Collective Labor Agreement, a program for aligning the wage levels which will run between 2019-2022.

Along with the actions for attracting new staff and training our employees, the staff retention and motivation is very important for Antibiotice. Adapting the reward system and creating a consistent financial and non-financial motivation policy for employees aim at increasing our employees' satisfaction and improving the staff retention. Employee turnover (only the employees leaving voluntarily our company) was 4.6% in 2019, lower than the estimated percentage (5%).

### Ensuring a favorable working environment and an organizational culture oriented to innovation and performance

For achieving this objective, our company elaborated the 2019-2020 Action Plan for improving the organizational climate, following the results of the study conducted in 2018 for measuring our employees's degree of satisfaction related to the positions held.

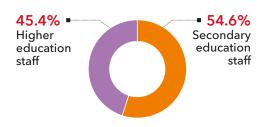
The Action Plan aimed at developing new communication channels, organizing internal events to ease and develop the interpersonal communication, improving the conditions in the common social areas of the production plants.

In order to monitor the evolution of the organizational climate and employees' satisfaction indicators, the diagnostic study will be resumed annually, the employee job satisfaction being a strategic indicator for our management.

# Diversity, equal opportunities, health and safety at work

The human resources policy applied in Antibiotice promotes the diversity and equal opportunities in recruiting, selecting and integrating the employees. Our staff benefits from all the rights deriving from the law, our company offering fair and equitable conditions of work and professional development.

Distribution of our 1,415 employees by education level at the end of 2019:



Distribution of employees by gender and age is balanced in the Antibiotice company.

Antibiotice SA ensures a fair and non-discriminatory treatment at the workplace. Proper conditions have been created for a number of 11 employees with disabilities to carry out their activity, benefiting from facilities in accordance with the applicable legal provisions.

# Occupational health and safety

By maintaining and developing an effective occupational health and safety management system within the company we create an optimal framework for managing and eliminating work-related risks, as well as for improving the relationships between employees.

### A balanced distribution of employees by gender and age

Age range	20-30	30-40	40-50	50-55	> 55	Total
Women (%)	4.37	12.46	19.70	12.61	6.09	55.23
Men (%)	3.15	8.88	16.76	8.45	7.53	44.77
Total (%)	7.52	21.34	36.46	21.06	13.62	100

The principles and measures of the occupational safety system are established and followed, through the Prevention & Protection Plan, by the Occupational Safety and Health Committee (CSSM), organized in our company.

In 2019, the Prevention & Protection Plan included several measures aimed at permanently improving the working conditions and preventing the work accidents and occupational diseases.

Thus, 3 meetings of the Occupational Safety and Health Committee were organized and the representatives of the Work Safety Committee were consulted for identifying new professional risks as well as for granting/replacing the work and protection equipment. All the measures included in the Prevention & Protection Plan were implemented, as follows:

- in order to reduce the physical effort, the Parenteral Product Plant and the Storage Department were equipped with electrical equipment for transporting and lifting the raw materials and the finished product;
- > in order to reduce the exposure to chemical agents, the chemical reagents from the laboratories of the Research & Development Unit were transferred in exhaust reagent cabinets (which ensure a constant aeration) and are fire-resistant.

Our company took also actions to inform and raise awareness of its employees on topics regarding the aging in health conditions and prevention of the health problems during their professional life. 55.23% Women



>45% of the 1,415 employees have a higher education

# Total quality management compliant with the legal national and international requirements specific for the pharmaceutical industry

The quality of our products is ensured by processes that comply with the latest good manufacturing practice requirements, all of our eight manufacturing flows being EU GMP certified. The manufacturing flows for sterile injectables and the active substance Nystatin are also certified by the Food and Drug Administration (FDA), the American authority in the field of medicine and food safety.

Implementation of all the regulatory requirements and evaluation of the quality management system made by the regulatory authorities and partners from all the areas of the world, have led to maintaining the level of quality, efficiency and safety of the medicines produced by Antibiotice.

### **Quality management**

EU-GMP for all the 8 manufacturing flows



 US FDA for sterile injectable powders and the active substance Nystatin



Nystatin - USP Reference Standard



Certificate of Suitability (CoS) for micronized Nystatin issued by EDQM



Integrated Quality Management System (quality, environment, occupational health and safety)



WHO prequalification for antituberculosis medicines



The trust capital in the Antibiotice products' quality increases by meeting the Good Manufacturing Practice (GMP) requirements and by permanently monitoring and improving the Integrated Management System implemented in our company that was recertified by TUV Rheinland Romania between December 2-5, 2019.

- Quality, ISO 9001:2015,
- Environment, ISO 14001:2015,
- Occupational health and safety, OHSAS 18001:2017.

### **Certified quality**

Quality of the Antibiotice products has been proved also by the results of the inspections and audits conducted in 2019:

#### Inspections conducted by authorities:

- Inspection conducted by the Russian regulatory agency (State Institute of Drugs and Good Practices - Ministry of Industry and Trade of the Russian Federation) for certifying the manufacturing flow of suppositories, in order to support the re-authorization of the medicines manufactured on this flow in Russia (January 29-31, 2019);
- > Inspection conducted by the National Sanitary Veterinary and Food Safety Authority, for assessing the compliance of the Quality Management System implemented in Antibiotice and of the manufacturing flows of veterinary medicines (parenterals and ointments) with the Good Manufacturing Practice requirements. The regulatory body issued the GMP certificate for the above-mentioned manufacturing flows (01-03.04.2019);
- > NAMMD inspection for evaluating the compliance of the Quality Management System implemented by Antibiotice and of the manufacturing flows of the parenteral products and the active substance Nystatin with the Good Manufacturing Practice requirements. (October 07-11, 2019)

#### Audits conducted by our customers:

- > Three audits were conducted on the manufacturing and control flow of Nystatin for requalifying Antibiotice as an API supplier. All the three audits were completed without finding nonconformities, the requalification of our company as an API supplier being recommended.
- > The parenteral manufacturing and control flow was audited for requalifying Antibiotice as a supplier of finished products. The audit was completed without finding critical non-conformities, the requalification of our company as a supplier of parenteral products being recommended.

### Audits conducted by our specialists to the premises of our suppliers of raw materials/ primary packaging materials and finished products

- According to the 2019 Audit Plan, an audit was conducted at a manufacturer of active substances, in order to re-qualify it as a supplier of non-sterile active substances.
- Our specialists audited a micronization company for the active substance Nystatin. No critical non-compliances were identified, so the company was qualified as a contract beneficiary for micronization of Nystatin.





# Social Responsibility







# Antibiotice - a responsible company involved in the sustainable development of the community

Development of a sustainable business, ethics and transparency, economic, social and environmental impact of the Antibiotice company represent strategic directions followed also in 2019. Acting sustainably, Antibiotice creates long-term value for both itself and stakeholders while respecting the environment, being concerned about the health and safety of its employees, supporting the community in which it operates.

"Responsible for a better life" is the concept through which Antibiotice elaborated in 2019 its second non-financial report (https://bit.ly/2WnKl0C). The document, which reflects the construction of a performing company responsible towards all the categories of stakeholders, represents a transparent approach, including relevant data that contribute to the understanding of the company's environmental, economic and social footprint. In this way, another dimension of the company's performance is presented, that of the value and impact it creates by assuming good practices in all its areas of activity.

In terms of community involvement, this approach is achieved through social responsibility programs based on four strategic pillars: health, education, environment and social matters.

#### Health

We develop social responsibility programs to improve the health of our employees, but also the health of the community in which we operate. These programs have been developed to educate and inform the population about health prevention.

### "Donate blood! Put your soul to life!" - a voluntary blood donation campaign

Under this urge, the Antibiotice employees have participated since 2010, in the blood donation campaigns, organized internally, by the "Science and Soul" Foundation in partnership with the Regional Blood Transfusion Center (CRTS) Iași. Performed biannually, this action responds both to the need to increase the blood reserves needed in hospitals and to the employees' desire to do a good deed for their fellow citizens, donating blood to solve the urgent medical cases. Our company organized two "Donate blood! Put your soul to life!" campaigns on April 7, 2019, on the occasion of the World Health Day and on October 2019. A number of 120 Antibiotice employees donated 60 liters of blood, saving this way 300 lives.

The "Science and Soul" Foundation was awarded three times in 2019 for its efforts to continuously organize (9 years in a row) blood donation campaigns in which the Antibiotice employees were the donors. Our Foundation received the first prize for this program within the Romanian CSR Adwards Gala organized by CSR Media and within the Blood Donor Gala organized by the Voluntary Emergency Service laşi. The Foundation was also given the "Rescue Hero" distinction granted by the National Institute of Transfusion Hematology Bucharest.



100 employees ready to provide

first aid

350 trees planted in the community

### "Each of us can save a life!" - first aid courses for the Antibiotice employees

First aid can make the difference between life and death and health education increases a person's chances of survival if those around him/her know how to intervene until the ambulance arrives. To this end, for the second year in a row, our company organized on the occasion of the Restart a Heart Day (October 16, 2019), a first aid course attended by 100 employees willing to learn the basic first aid measures. This action was carried out in partnership with the Emergency Receiving Unit of SMURD lasi and Emergency Medicine Department within Gr. T. Popa University of Medicine and Pharmacy. The campaign entitled "Each of us can save a life!" was awarded at the Romanian CSR Award 2019 Gala in the "Support for our employees" category and promotes the responsible behavior among the Antibiotice employees.

### **Education**

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

### "Science and Soul" Scholarships an annual scholarship program for supporting 5 pupils from the rural area

For 18 years running, through its "Science and Soul" Foundation, Antibiotice has been supporting together with the Pro Ruralis Association 5 pupils from the rural area by giving them annual scholarships. This way, our company contributes to the education of some children with special abilities and a higher intelligence coefficient but without material possibilities, supporting them to continue their studies at the secondary and high school, thus giving them the chance for professional achievement and personal development.

### **Environment**

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

### Be Pro-Nature! Put your Soul!

This is an environmental protection project encompassing more programs developed by our company in 2019:

"Orchard at school" is a program through which, year by year, the volunteer employees from Antibiotice plant a fruit orchard around the rural schools. Thus, in the month of April, 70 volunteers from Antibiotice planted fruit trees at the Day Care Center for children at risk in the Cornești Village, Miroslava commune as well as at the "Constantin Păunescu" Special Gymnasium School lasi for pupils with different mental disabilities. In 2019, in addition to its mission of instilling respect for environment in the young generation and maintaining a healthy lifestyle, the "Orchard at school" project also aimed at offering therapy activities for children with special needs such as planting and caring the young orchard.

"We plant oxygen in the community" is a tree planting program for our employees that involved the greening of an area near the company. Thus, in November 2019, 60 volunteer employees from Antibiotice planted 200 saplings in the immediate vicinity of our company.

**Earth Hour** - our company's participation in the Earth Hour campaign is part of the "Be Pro-Nature! Put your soul!" program and involves the symbolic turning off the



non-essential electric lights in our company for one hour. 2019 was the 11<sup>th</sup> consecutive year in which Antibiotice symbolically turned off the lights inside its facilities, joining this way the Earth Hour campaign, the largest environmental manifestation of all times, which draws attention to the effects of global warming and to the measures to be taken, at any level, to stop the phenomenon.

#### Social matters

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

### "Power of deed" -Charity in the Easter holidays

Around Easter, the "Science and Soul" Foundation made a humanitarian gesture for 23 needy families, which together have 121 children, from remote localities of the Iași County (Zmău Village, Lungani Commune, Dumești and Cosițeni villages from the Dumești Commune). Each family received a package containing basic foods, traditional products, cleaning products and stationery for children.

# We prepare the Future - Celebration of the International Children's Day at the Antibiotice headquarters

It has already become a tradition for Antibiotice to offer gifts every year to the employees' children on the occasion of the International Children's Day. In 2019, the company offered the children the opportunity to enter the traditional Moldavian world full of life and humor created by the greatest Romanian storyteller, Ion Creangă. The children were invited to the "Amintiri din copilărie" show held at the National Athenaeum in Iași.

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

In 2019, for the seventh year in a row the "Science and Soul" Foundation organized the "Be generous, Be Santa Claus!" campaign in partnership with Pro Vita Department of the Iasi Archdiocese Mission Sector. The campaign was organized for a number of 100 children from families with reduced material opportunities, from 12 rural localities of Iasi County. The children aged between 1 and 13 expressed their wishes in letters addressed to Santa Claus. Their moving words animated our colleagues who became the Santa Claus's elves, fulfilling the children's wishes. On December 18, 2019, Santa Claus rushed to appear at a festivity organized in our company. The kids enjoyed meeting him, many of them for the first time. As a sign of thanks, the little ones staged short artistic moments, singing Christmas carols.

100 letters for Santa and as many dreams came true





# 07

Independent Auditor's
Report on the Individual
Financial Statements
drawn up by Antibiotice SA
for the fiscal year ended
on December 31, 2019

### To the Antibiotice shareholders

### Report on the Audit of Financial Statements

### Our opinion

We audited the attached individual financial statements of ANTIBIOTICE S.A. ("The Company") with its registered office in laşi, Valea Lupului St., tax identification number RO1973096, comprising the financial position statement as of December 31, 2019, statement of comprehensive income, statement of changes in equity and cash flow statement for the financial year ended on the above-mentioned date as well as a summary of the significant accounting policies and other explanatory notes.

The individual financial statements as of December 31, 2019 are identified as such:

- Net assets/ total equity: 496,842,915 LEI
- Net profit of the fiscal year: 30,823,278 LEI

In our opinion, the attached individual financial statements give a true and fair view, in all significant aspects, on the financial position of Antibiotice company on December 31, 2019, as well as on the financial performance and cash flows for the fiscal year ended on the above-mentioned date in accordance with the Order of the Minister of Public Finance (OMPF) no. 2844/2016 for approving the accounting regulations compliant with the International Financial Reporting Standards adopted by the European Union ("IFRS-UE").

We conducted our audit in accordance with the International Standards on Auditing ("ISAs"), Regulation (EU) no. 537 of the European Parliament and of the European Council ("The Regulation") and Law no. 162/2017.

Our responsibilities are described in detail in the section Auditor's responsibilities in an audit of financial statements in our report.

We are independent of the Company, in accordance with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants (IESBA code), according to the relevant ethical requirements for the audit of financial statements in Romania, including the Regulation and Law no. 162/2017 and we fulfilled our ethical responsibilities according to the IESBA code requirements.

We believe that our audit evidence is sufficient and appropriate to provide a basis for our audit opinion.

#### Key issues

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

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

# Key issue - Value of trade receivables

Presentation value of trade receivables according to IFRS depends significantly on the calculation and estimation process of the trade discounts as well as on the process of estimating their recoverability.

The company presented in the financial statements in the explanatory note no. 4 – "Sales Income" the value of the granted trade discounts and, in the explanatory note no. 15 – "Trade and other receivables" the company presented the trade receivables in net value of 328 million LEI, adjusted with the estimated depreciation.

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

- We assessed the compliance of the policies for recognizing the income and trade receivables;
- > We conducted analytical review procedures and detail tests for verifying the amount of granted discounts, including through extending the verifications on the discounts granted in the next fiscal year related to the sales in the audited fiscal year;
- We conducted procedures for direct confirmation of trade receivable balances;
- We evaluated the internal procedures and methods used by the management team for estimating the probable amount to be collected;
- > We verified the consistency of applying the accounting policies related to the adjustment of trade receivables.

## Other information - Management Report

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

Our audit opinion on the financial statements does not cover other information and we do not express any conclusion with regard to these. In connection with our audit on the financial statements, our responsibility is to read this other information and, in this approach, to evaluate whether this information is significantly inconsistent with the financial statements or with the knowledge we gained from the audit or if it appears to include significant errors.

If, based on the performed activity, we come to the conclusion that there are significant errors in this information, we must report this. We have nothing to report on this matter.

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

- In the Management Report we did not identify information that is not consistent in all significant aspects with the information presented in the financial statements on December 31, 2019.
- The above-identified Management Report includes, in all the significant aspects, the information requested by OMPF no. 2844/2016 to the paragraphs 15-19 of the Annex no. 1;
- > The Management Report does not include the non-financial declaration specified to the paragraphs 39-42 from OMPF no. 2844/2016 which will be presented later in a separate report.
- > Based on our knowledge and our understanding gained during the audit of the financial statements drafted on December 31, 2019 about the Company and its environment, we did not identify significant erroneous information presented in the Management Report.

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

The Management team is responsible for drafting and fair presentation of these financial statements in accordance with OMPF no. 2844/2016 and for the internal

control which is considered relevant by the management for elaborating the financial statements without significant misstatements due to fraud or error.

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

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

### **Auditor's responsibility**

Our objectives are to obtain reasonable assurance that the financial statements as a whole do not include material misstatements, whether due to fraud or error, and to issue an auditor's report that includes our opinion. The reasonable assurance represents a high level of assurance but it is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement, if it exists.

Misstatements can arise from either fraud or error and are considered material if, they reasonably can be expected, individually or cumulatively, to influence the users' economic decisions based on these financial statements.

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

> We identify and evaluate the risks of material misstatements in the financial statements caused either by fraud of by error, establish and perform audit procedures to respond to these risks and we get enough and appropriate audit evidence to form a basis for our

- opinion. The risk of not detecting a material misstatement caused by fraud is greater than the risk of not detecting a material misstatement caused by error, as fraud may include complicity, forgery, intentional omissions, false statements, or avoidance of internal control.
- > We consider the internal control as relevant to the audit to establish the audit procedures appropriate in the given circumstances, but not to express an opinion on the effectiveness of the Company's internal control.
- > We assess the appropriateness of the used accounting policies and reasonableness of accounting estimates and of the related information presented by the management team.
- > We formulate a conclusion on the appropriateness of using the goingconcern principle by the company and determine, based on the obtained audit evidence whether there is a significant uncertainty related to events or conditions that could raise significant doubts about the Company's ability to continue its activity. If we conclude that there is a significant uncertainty, we need to draw attention in the audit report on the related presentations from the financial statements or, if these presentations are inappropriate, we must change our opinion. Our conclusions are based on the audit evidence obtained by the date of our audit report. However, future events or conditions may cause the Company not to continue operating on the going-concern principle.
- > We evaluate the presentation, structure and overall content of the financial statements, including the information presentations and the extent to which the financial statements reflect the transactions and basic events in a manner that lead to the accurate presentation.

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

# Report on other legal and regulatory requirements

We were appointed by the General Meeting of Shareholders held on June 28, 2017 to audit the financial statements of ANTIBIOTICE S.A. laşi for the fiscal year ended at December 31, 2019. The uninterrupted total duration of our commitment is 3 years, covering the financial exercises ended at 31.12.2017, 31.12.2018 and 31.12.2019.

#### We confirm that:

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

In the name of,

### Accounting, Expertise & Accounting Consultancy Company - SOCECC Ltd.

headquartered in Bucharest, registered in the Electronic Public Register with the no. FA227

through Zegrea Laurențiu, registered in the Electronic Public Register with the no. AF2666

Iași, March 4, 2020



# ANNUAL REPORT **2019**

### **Antibiotice SA**

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