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# CEO's message

In 2015 Antibiotice celebrated the completion of a stage, a beautiful history that crowns *60 years of continuity and performance in the Romanian pharmaceutical industry*. Following its destiny, Antibiotice was gradually transformed from a manufacturer with tradition in the production of active ingredients into a modern and competitive company, which provides a genuine Romanian product.

The 60 years anniversary provided the opportunity to four generations of people whose fates have been intertwined with the destiny of our company to suspend time for a second, to look to the past while raising their wings towards the future. Younger generations felt their roots have spread here, and we, the more mature ones, felt we were facing a **NEW BEGINNING**. The contemplation, even for a moment of an exemplary history, reminded us that on the path that we have chosen to go we have valuable partners and collaborators who share what it means to manufacture health, with devotion, passion and faith in people.

In 2015 our company ranked fourth among the manufacturers of generic drugs in Romania and ranked first worldwide in the manufacture of Nystatin active substance. There are two dimensions of this organization which, we believe, speak for themselves about the decades of evolution and continuous transformation that a Romanian-owned company has undergone based upon valuable human resources, capable of vision and boldly looking to the future.

In economic terms, Antibiotice ended the year 2015 with total sales of 330 million lei, up by 3% compared to 2014, while maintaining profitability indicators and expenditures within realistic values. Given that the generic prices in Romania were reduced by 20% and the claw back tax in the case of Antibiotice accounted for 11% of the revenues on the domestic market, we managed to reach the predicted indicators that we assumed towards our shareholders.

The Romanian pharmaceutical market facing the claw back tax constraints and the insolvency of certain players of the supply chain experienced for the first time in many years a decrease both in value (0.87%) and in quantity (4.74 %). On such a market, Antibiotice managed to achieve sales growth of 11.6% compared to 2014 and maintain its leading positions in the sales of sterile injectable products and topical products, reaching a market share of 5.5% in terms of sales volume.

These encouraging outcomes were achieved through a team effort of our colleagues from the Department of Marketing and Domestic Market Sales who have found the best strategy for capitalizing our company's diverse portfolio, covering more effectively the treatment needs that were identified in the market.

Externally, sales development has met the long-term projected targets. As one of the strategic development pillars, the internationalization of the business has brought us in 2015 the acquisition of new assets, including the strengthening of the Nystatin active substance sales on the US market, where sales have tripled compared to 2014 as a result of attracting new end-users.



On the other hand, the increased industry regulations in emerging markets provides us with a competitive advantage worth mentioning. Our presence in such markets - as it is the case of Moldova, where sales increased by 50% in 2015 over the previous year with the introduction of the mandatory GMP norms for producers - is a new challenge that we are ready to cope logistically. Antibiotice holds a EuGMP authorization for all its manufacture lines; it also holds the FDA approval to manufacture sterile injectable products and plans for the FDA authorization for new production capabilities.

Times are constantly changing not just for us, who are contemplating a moment of assessment, but also for the pharmaceutical industry globally. Therefore, the steps, the actions we conceive today must be the pieces of a puzzle that together compose the vision that our organization has designed for the five or ten years to come.

From this perspective, the steps taken towards the development of our portfolio aim that in the years 2016-2020 Antibiotice be a complex producer adapted to the therapeutic trends which manufactures alongside the products that define our core business (anti-infective products and dermatological preparations), essential generic drugs as alternatives to innovative products for the treatment of cardiovascular diseases, neurodegenerative diseases and diseases of the digestive tract.

The year 2015 has seen the introduction on the market of 8 new medicinal products that complement our company's strategic therapeutic classes; in 2015 our company has also obtained the necessary authorizations for the manufacture of 7 other products and 16 new research projects were initiated addressing different pharmaceutical formulations and manufacturing technologies.

To meet new challenges and increase the performance at the research level in 2015 an action plan was initiated intended to streamline the business, to reduce working time and to improve of the working conditions of our employees and their level of performance. Such a plan was also conceived for the Quality Unit where, due to the complexity increase of requirements and the number of products to be tested, a new way of systematizing the business was imposed.

Looking ahead, we cannot have a vision of Antibiotice in 2020 without knowing what, at the technological level, our company manufacturing sites will look like. In this respect feasibility studies were initiated to create the sustainable framework for the reconfiguration of the site coupled with the manufacturing development trends of Antibiotice. Moreover, in 2015 the construction of a new manufacturing capability for topical products and suppositories has already started, having the year 2018 as deadline. This new capability is designed to allow for further manufacture of the products for which we hold significant market shares as well as to manufacture new products to be exported on regulated markets in the US and Canada.

We also have future projects among our strategic plans. I personally believe in the destiny of this company and in our resources so that our 60th year of existence represents a NEW BEGINNING. By combining the achievements that define our history with what we know about the present and what we do for the future, we can state that these 60 years are young and vigorous and the decades to come will add new dimensions to the "Antibiotice - Science and Soul" brand which enjoys international recognition.

Ec. Ioan Nani,  
CEO and Vicepresident of the Management Board



# Company's



## Antibiotice today

- The Main Romanian manufacturer of generic **anti-infectives**;
- Portfolio consisting of **148 products in 12 therapeutic classes**;
- A major manufacturer of antiinflammatory, dermatological, digestive tract, oncological, cardiovascular and central nervous system medicines;
- **8 manufacturing lines** for: sterile powders for injection, penicillins capsules, non-penicillins capsules, cephalosporins capsules, tablets, ointments;
- Sales revenues in the amount of **RON 330 million in 2015, higher by 3%** as compared to 2014;

# profile



- Internationally recognized certifications and authorizations: U.S. Food and Drug Administration authorization **(FDA) for Nystatin and products for injection**, Certificate of Suitability with the European Pharmacopoeia **(CoS) for Nystatin**, Good Manufacturing Practice **(GMP) certificate for all the manufacturing lines**, **Integrated Management System**;
- It has a modern Research & Development Center;
- The first company in Europe pre-qualified by the World Health Organization for the range of essential antituberculosis drugs;
- Significant employer - **1458 employees**.

**1955**

Built in Iasi between 1953 and 1955, Fabrica Chimică nr. 2 (Chemical Factory No. 2) is the first factory in Southeastern Europe that manufactured Penicillin - active pharmaceutical ingredient. The first batch of Romanian penicillin is obtained on December 11, 1955.

**1959**

Antibiotice manufactures Streptomycin API and the first finished drug products, such as ointments, creams, and suppositories. Fabrica Chimică nr. 2 (Chemical Factory No. 2) changes its name into Fabrica de Antibiotice.

**1977**

The US Food and Drug Agency (FDA) authorizes the production line of the Streptomycin API.

**2006**

Antibiotice establishes its own Center for Drug Evaluation (rom. CEM), which conducts Phase I clinical trials and bioequivalence studies. CEM is GLP certified (Good Laboratory Practice) and authorized by the Ministry of Health.

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

**2005**

Upon celebrating 50 years of activity on December 11, 2005, Antibiotice launches its new brand identity: the logo "Antibiotice a+" and slogan "Science and Soul".

## History

**2007**

Antibiotice SA company gains recognition for the implementation of the Integrated Quality, Environment, Health and Safety Management System, according to the requirements of EN ISO 9001: 2008, EN ISO 14001: 2004 and OHSAS 18001: 2007.

With the introduction of four new products, Antibiotice supplements its cardio portfolio with drugs covering the treatment of the main cardiovascular diseases.

**2010-2011**

Antibiotice makes its first deliveries of finished products to the US, a market on which the company was present until 2010 only with active ingredients.

The production line for penicillins in the form of sterile injectable powders, obtains the FDA approval, which allows the expansion of the export of these products in the US market. Antibiotice launches the first products for the CNS therapy.

**1990**

Antibiotice becomes a joint-stock company and takes over the assets of the former Antibiotice Iași (according to the Government Decision no.1200 of November 12, 1990).

**1993**

Ampicilina 250 mg and Oxacilina 250 mg are first capsules obtained in Antibiotice, on the penicillin products line.

**1992**

Antibiotice manufactures the first drugs in the form of tablets.

**1997**

Starting April 14, Antibiotice shares (ATB symbol) are traded in the first category of the Bucharest Stock Exchange; Antibiotice becomes the joint-stock company Antibiotice SA. The company imposes an efficient Quality Assurance System involving a strict control of the manufacturing processes.

**2002**

FDA approves the production line for Nystatin, which opens the way to the export of the active ingredient to the United States. Antibiotice secures its position as a top international manufacturer of Nystatin and Nystatin becomes the most important product sold abroad.

**1999**

Antibiotice SA becomes the first Romanian producer to be granted the Good Manufacturing Practice (GMP) certificate for its production line dedicated to powders for injection.

**2013**

Antibiotice is re-approved by the FDA and is granted the GMP and ANMDM re-certifications for the manufacturing lines for sterile injectable powders and Nystatin production line. Antibiotice takes first place in the world production of Nystatin API. The first export of Nafcilin to the US market takes place. Antibiotice opens an international office in Chișinău, Republic of Moldova.

**2012**

Antibiotice enters the oncology drugs market and becomes the first company in Europe prequalified by the World Health Organization for the anti-TB range of drugs.

**2014**

Antibiotice expands its business in Serbia through the partner ATB Pharma, which represents it in commercial relations. Start of the investment works for a new manufacturing plant dedicated to ointments and suppositories.

# Company's strategic orientation

The pharmaceutical market forecasts at international and national levels indicate that the generics drugs will account for a growing percentage of the health expense in the coming years.

Consistent with the mission to increase patients access to health Antibiotice continuously adapts its pharmaceutical portfolio to encompass those generics essential for the treatment of chronic non-communicable diseases with high incidence in Romania (cardiovascular diseases, neurodegenerative diseases of the digestive tract), along with the anti-infective and dermatological medication, basic company portfolios. Also, Antibiotice develops further the portfolio for the prophylaxis and combating of risk factors associated with chronic diseases through the range of food supplements and dermatocosmetics intended to increase the quality of life.

## Development prospects at Antibiotice

In 2015 the company focused on growth in various international markets and strengthening the domestic market share by continuing the portfolio development policies through medicines research and non-prescription products covering an extensive array of dosage forms: tablets, capsules, sterile powders for injection, ointments, creams, ovules.

The strategic adaptation of the portfolio as a driver of business sustainable growth is based, from the perspective of years 2015-2020, on the following elements:

- Private research to supplement yearly portfolios that define the company, with generics that identify us as a viable alternative for patients:
  - with various chronic (cardiovascular, central nervous system) diseases,
  - with infectious diseases,
  - with various dermatological or musculoskeletal disorders,
  - with disorders of the digestive tract.

In 2014 a line of products designed to increase the quality of life was initiated as well as products for child care and women's health (medicines, food supplements and dermatocosmetics) which was developed and



1st place for  
powder  
for injection

1st place for  
suppositories

1st place for  
creams and  
gels





enriched with new products in 2015.

- The development of clinical research (Phase I clinical trials, bioequivalence and therapeutic efficacy trials) and pharmacovigilance which gives worldwide patients trust in the Antibiotice medicines;

- A Regulatory Affairs strategy suitable, predictable and adapted to pharmaceutical markets to which the company is orientated with the carrying out, on a case by case basis either of national authorization procedures or of European procedures (DCP) or FDA for generic drugs with various types of application;

- An effective marketing of the products newly introduced to the portfolio with the achievement of significant market shares from the earliest years.

### Novelty and consolidation

The integration on the Antibiotice platform of the stages of pharmaceutical development, analytical testing, adaptation of technologies specific to the researched products to the company manufacturing lines, bioequivalence and then the conduct of national or European authorization proceedings of medicinal prescription drugs or of non-prescription products, dietary supplements and dermatocosmetics was achieved through the multidisciplinary team of specialists in various fields (pharmacists, chemists, biologists, physicians).

The creativity, perseverance and the continuous improvement of the staff performing research activities support the development objectives and strategic adjustment of the portfolio and we can state that a new generation of researchers grows at Antibiotice alongside with the revamping efforts.

The year 2015 is also the year when special attention was given to the capabilities that can support research in the biotechnology field, supporting a traditional area of the company as a development opportunity in the coming years.

### The capitalization of the portfolio

On the anniversary of 60 years of Romanian continuity and performance, Antibiotice managed to capitalize the notoriety gained over time.

The products that make up the core of the business have maintained their leadership position:

- 1st place for the powders for injection (3 out of 4 patients are treated with Antibiotice products);

- 1st place for suppositories (1 out of 2 patients utilizes Antibiotice products);

- 1st place for the ointments, creams and gels (1 out of 3 patients utilize Antibiotice products).

The recognition of this is confirmed by the leadership position on the market of generics utilized in hospitals; Antibiotice is the most stable provider of medication for this segment.

Partnerships started long ago were also strengthened and maturity and stability were the guiding principles of all marketing activities to promote sales. The end of 2015 brought to our company a market share of 2.45% in Romania as Antibiotice remains the only Romanian company among the top 20 companies on the pharmaceutical market.

## Quality management

To achieve the strategic objectives up to 2020 an important role is to provide the legal framework for maintaining the Manufacturing and import Authorization that allows the company to operate, the continuous up-dating and the permanent control of the quality management system in accordance with the legal requirements specific to the pharmaceutical industry.

**Obtaining and maintaining the manufacturing and import authorization by obtaining the EU GMP re-certifications for all of the company manufacturing lines**

The contribution of this strategy to achieving the objectives in 2020 is to achieve and maintain the Manufacturing Authorization conferring the right to manufacture and sale pharmaceutical products by:

- Identifying the specific legislative trends and implementing them before the time of their formal entry into force;
- Implementing new legislative requirements specific to the pharmaceutical industry;
- Continuously train the staff on the requirements of the existing legislation or specific legislative trends;
- Developing and updating specific documentation of the Quality Management System at all levels;
- Conducting self inspections;
- Making all types of continuous monitoring specified and the improvement of the Quality Management System documentation, establishing preventive action to prevent the occurrence of nonconformities, investigate the cause of the reported nonconformities and setting corrective actions to prevent their recurrence.



## Supporting business partnerships

The implementation of this strategy will be achieved through:

- Providing the legislative framework for the manufacture and sale of Antibiotice products on the regulated foreign markets;
- Providing conditions for the conduct of the production under contract for the business growth;
- Conducting EU GMP compliance assessment audits for the providers of pharmaceutical active substances and primary packaging materials.

## Continued compliance of the integrated management system

Ensuring the compliance with the applicable standards and legislation is achieved by:

- Implementing the up-to-date requirements of international standards: ISO 9001:2008; ISO 14001:2004 and OHSAS 18001:2007;
- The development and updating of the documentation specific to the Integrated Management System in all Antibiotice processes;
- Conducting self inspections;
- Conducting all types of monitoring specified in the Integrated Management System documentation for a continuous improvement, investigating the causes of the reported nonconformities and establish corrective actions;
- The assessment of the internal and external customer satisfaction on the quality of Antibiotice products.

## Strengthening strategic partnerships on international markets

Developing the company presence on international markets is a strategic objective of Antibiotice on medium and long term.

The business internationalization strategy is characterized by a high degree of complexity requiring the adaptation of approaches to the specifics of each market. The development strategies can be translated from one market to another

only to a limited extent because of the heterogeneity of legal regulations, customs and consumer trends. These features require the adjustment of trade policies and product portfolio depending on the target markets in order to maximize the benefits and opportunities offered by foreign markets.

The main directions of export promotion are:

- Strengthening the company presence on current markets through existing partnerships and developing new partnerships;
- Identifying new markets both on the developed markets and the emerging markets;
- Initiating development partnerships for products in cooperation, co-marketing and promotion;
- Adapt the product portfolio to the requirements of international markets.

The product Nystatin active substance is marketed on virtually all markets where there is significant consumption. Antibiotice's strategy is to maintain its global leadership position and increase its market share on the regulated markets that offer great potential in terms of commercial profitability. The access to the regulated markets is possible due to the U.S. FDA approval and the CoS certificate (Certificate of Suitability issued by the EDQM - the European Regulatory Authority for Pharmaceuticals).

The global market for generic pharmaceutical products is characterized by an increase in the national regulatory authorities and by a high competitiveness. The company's strategy aims at both increasing the presence on developed markets (US, Europe) and the emerging markets (South East Asia, the former C.I.S. countries, Latin America). The EuGMP authorizations of manufacturing lines for finished products as well as the U.S. FDA authorization for injectable products are significant advantages.

Due to the importance of promoting products in the pharmaceutical industry Antibiotice decided to open offices in territories that offer growth potential. Opening the office in the Republic of Moldova generated a significant increase in turnover. In the next period the approvals and launch of the first products in Serbia are expected through the representative of our company in this country. Also, the opportunities of opening new

offices in territories such as South East Asia countries and of the former C. I. S. countries are assessed.

## **The management of operating costs and the increase of efficiency in operating, financial and investment activities**

The strategic pillar which considers the economic and financial activity involved the management activities based on income and expenditure budgets (cost centers and profit centers) applying corrective action programs in activities where there were variations from the planned figures.

Our company also aimed at ensuring the financial balance by a continuous assessment and prioritization of needs, the creation and tracking of cash flow so that all the activities are carried out smoothly.

## **Adapting human resources to the strategic orientation of the company**

The provision of the optimal number and structure of staff for the company's strategic objectives in compliance with the Business plan has involved in 2015 the reorganizing and adapting of this structure on some key organizational components of the company.

The priority was to increase the awareness and involvement for all the employees at all levels of the organizational structure either by involvement of the approximately 200 employees in the management by objectives, or by their inclusion in teams that manage the company's strategic projects.

## **Orienting the organizational culture towards innovation and performance**

To improve processes and orientation of the organizational culture towards innovation and performance, in 2015 projects of analysis and improvement for two of the company's strategic structures were initiated, where research and pharmaceutical formulation, quality assurance and management activities are carried out.

## **The management of ideas**

The year 2015 brought as a novelty the establishment of the "*Club of Ideas*" where debate meetings were held concerning proposals to improve the innovation activity in a framework that brought together employees from various organizational structures of the company through voluntary participation. Following these meetings over 80 ideas were recorded; these ideas are analyzed to determine the appropriateness and how they can be applied.

# Company

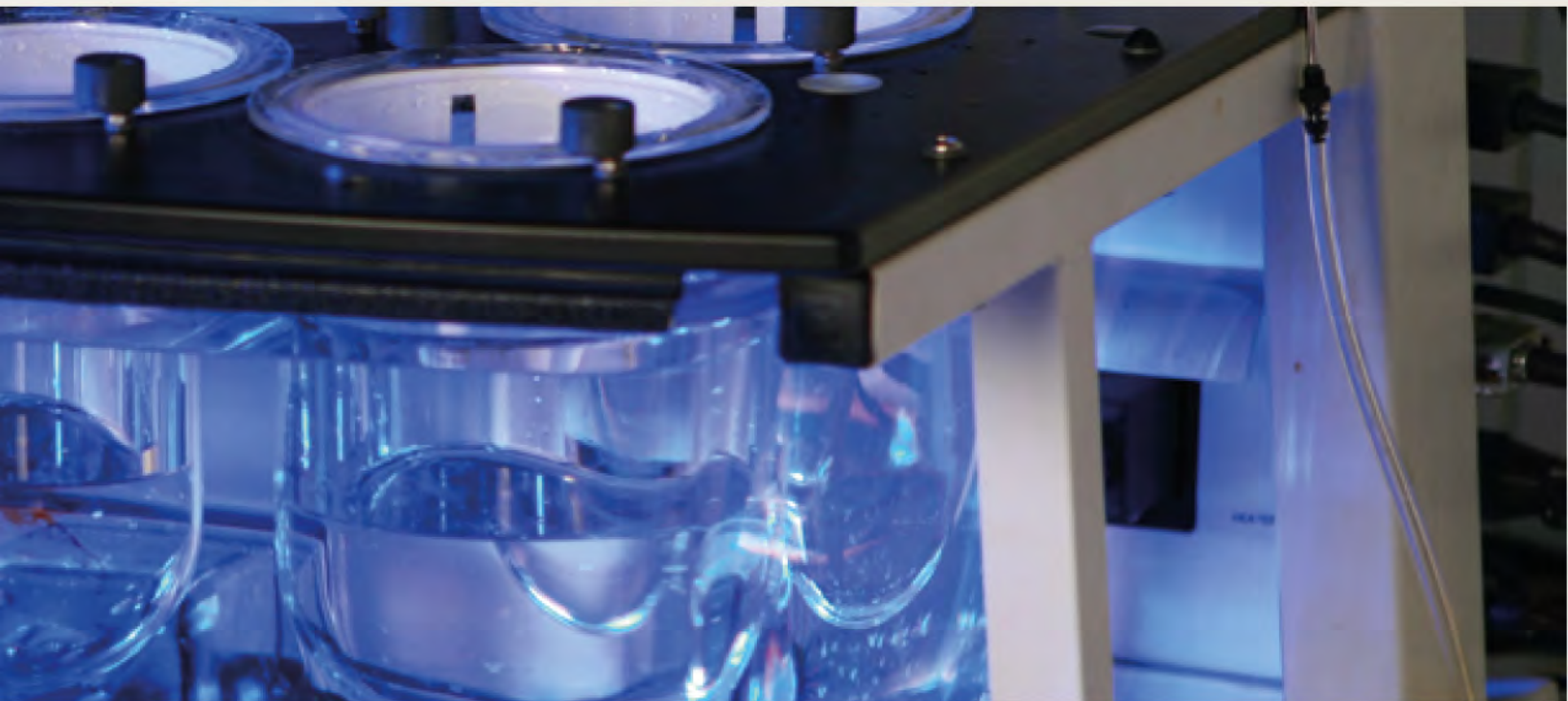
## Strategic evolution

The renewal of the portfolio by 8 new products

In 2015 the portfolio was supplemented by 8 new products in the therapeutic classes that Antibiotice wants to strengthen in the coming years:

<b>Rosuvastatină Atb® 5, 10 and 20 mg</b>	<b>Tablets, Cardiovascular System class</b>
<b>Clobetazol Atb® 0.5 mg/g</b>	<b>Ointment Dermatological class</b>
<b>Nistatină Atb® 100,000 UI</b>	<b>Ovules, Genitourinary Apparatus class</b>
<b>Zifex Duo® (metronidazol+clotrimazol) 500 mg/200 mg</b>	<b>Ovules, Genitourinary Apparatus class</b>
<b>Imipenem/Cilastatin Atb® 500 mg/500 mg</b>	<b>Powder for solution for infusion, Anti-infectives for systemic use class, Carbapenems subclass</b>
<b>Memantină Atb® 20 mg</b>	<b>Tablets, Central Nervous System class</b>

# Performance



## The assimilation of new products in the portfolio

In the year 2015 the following were obtained:

Marketing Authorizations (MA) for four drugs:

- **Indapamidă Atb® 1.5 mg extended-release tablets,** Cardiovascular System Class;
- **Clobetazol Atb® 0.5 mg/g, ointment,** Dermatologicals;
- **Nistatină Atb® 100.000 UI, ovules and Zifex Duo® 500 mg/200 mg, ovules.** Genitourinary Apparatus;

The European decentralized procedure (DCP) of simultaneous licensing in two EU countries (Romania and Germany) for **Zatinex® 30 mg and 60 mg capsules (duloxetine);**

Notification of two new supplements: **Fluxiv® tablets and Soriso® capsules;**

Twelve new Marketing Authorisations under the Antibiotice brandname in five countries in Europe, Asia and Africa;

The completion of the authorization procedure for the US market for **Ampicillin with sulbactam of 1.5 g and 3 g powder for solution for injection / infusion,** which joins the two finished products approved for the US market, namely **Ampicillin (4 doses) and Nafcillin (2 doses).**

## Performance on the domestic market

### 4th place

among the 126 producers of generic drugs by prescription

- Antibiotice is the leader in generic prescription medicines intended for hospitals;

- Antibiotice ranks 4th among the 126 producers of generic drugs by prescription on the Romanian market (9.1% market share);

- Antibiotice is the Romanian manufacturer of the full range of essential anti-tuberculosis drugs;

- Strengthening the position of leader on the generics and OTC drugs market sold to hospitals in Romania with a market share of 18.7% (+ 1.7% compared to the market share in 2014);

### Increase by 10,8%

of the retail (pharmacy) sales

- The increase by 10.8% of the retail (pharmacy) sales while the retail market experienced an overall decrease by 5.7%;

- The increase by 14.1% of sales in hospitals while the hospital market experienced an overall increase by 2.7%;

- The superior and balanced capitalization of the medicines portfolio with a significant increase both of the prescription drugs (11.7% compared to 2014) and for those without a prescription (11.3% compared to 2014);

### Leader in generic

medicines intended for hospitals

- The strengthening of the leadership position on the Hospital Anti-infectives segment (solutions for injection) - the increase of the value market share from 52.7% in 2014 to 53.2% in 2015;

- The strengthening of the market leader position on the powder for injection market, the Hospital seg



ment, both in terms of consumption (market share of 77.6%, up by 1.7% compared to 2014) and in terms of value achieved market share of 28.1% (+ 4.1% compared to the market share in 2014);

- Maintaining the market leader position on the suppositories market both in terms of quantity (market share of 42.4%) and value (market share of 26.7%, up by 0.5% compared to 2014) and the maintaining of the leadership position on the ointments market in terms of quantity (27.7% market share).



## Active presence on the foreign market

- Export turnover of **23 million USD**;
- **Leader** in world production of **Nystatin** (active substance);
- **The percentage of the exports** in the total turnover was **28%**;
- The increase by 3 times of the Nystatin active substance exports to the US market.

## Top 20 most popular Antibiotic brands in Romania

The first 20 brands (in terms of sales value) traded by Antibiotice in 2015 recorded sales amounting to RON 192.7 million, higher by 16.3%

Brand	International Nonproprietary Name	Therapeutic class + Form of administration	Main competitors
<b>Amoxicilină*</b> 250 mg and 500 mg	amoxicillinum	Systemic use antiinfectives - beta-lactam antibacterials, penicillins capsule	Amoxidlină* (Novartis) Ospamox* (Novartis) Duomox* (Astellas Pharma)
<b>Amoxipius*</b> 1.2 g, 500/125 mg și 875/125 mg	amoxicillinum + acidum clavulanicum	Systemic use antiinfectives - beta-lactam antibacterials, penicillins for Injection and tablets	Augumentin* (GlaxoSmithKline) Amoksiklav* (Novartis)
<b>Ampicilină*</b> 250 mg, 500mg și 1 g	ampicillinum	Systemic use antiinfectives - beta-lactam antibacterials, penicillins capsules and for Injection	Ampicilină* (Novartis) Pamecil* (Medochemie) Ampicilină* (Farmex Company)
<b>Amplius*</b> 1000 mg + 500 mg	ampicillinum + inhibitor de enzimă	Systemic use antiinfectives - beta-lactam antibacterials, penicillins for injection and tablets	Unique product*
<b>Cefort*</b> 250 mg, 1 g și 2 g	ceftriaxonum	Systemic use antiinfectives - other beta-lactam antibacterials - for injection	Oframax* (Sun Pharma) Rocephin* (Hoffmann La Roche) Medaxone* (Medochemie)
<b>Cefuroximă Antibiotice*</b> 250 mg, 500mg, 750mg and 1,5g	cefuroximum	Systemic use antiinfectives - other beta-lactam antibacterials for injection and tablets	Zinnat* (GlaxoSmithKline) Axetine* (Medochemie)
<b>Clafen Range*</b> 10 mg/g, 50 mg/g, 100 mg	diclofenacum	Musculoskeletal System nonsteroidal anti-inflammatories/ antirheumatics - ointments and suppositories	Diclac*/Voltaren* (Novartis) Diclofenac MK*/Diflex* (Fiterman) Diclofenac Terapie* (Sun Pharma)
<b>Collistină Atb*</b> 1,000,000 U.I.	collistini sulfas	Systemic use antiinfectives - other antibacterials for Injection	Unique product*
<b>Efcef*</b> 100 mg and 200 mg	cefiximum	Systemic use antiinfectives - other beta-lactam antibacterials, capsules	Xifia* (Alkaloid AD)
<b>Fluocinolon N*</b> 18 g	fluocinolon acetonidum + neomycinum	Dermatological preparations -corticosteroids in combination with antibiotics-ointment	Fluocinolon Acetonid* (Laropharm) Fluocinolon MK* (Fiterman)
<b>Hemorzon*</b>	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system -anti-hemorrhoid drugs - ointment and suppositories	Procto Glyvenol* (Recordati) Ultraproct* (Bayer) Proctolog* (Pfizer)
<b>Meropenem Atb*</b> 500 mg and 1 g	meropenemum	Systemic use antiinfectives - other beta-lactam antibacterials - for Injection	Meropenem Kabl (Fresenius) Loditer* (Sun Pharma) Meropenem Hospira (Hospira)
<b>Nidoflor*</b> 15 g	nystatinum + neomycini sulfas + triamcinolon acetonidum	Dermatological preparations -corticosteroids in combination with antibiotics-ointment	Triderm* (Merck & Co)
<b>Nolet*</b> 5 mg	nebulololum	Cardiovascular system -beta blockers - tablets	Nebilet* (Menarini) Nebivolol Actavis (Actavis) Nebinorm* (Glenmark)
<b>Novocalmin*</b> 300 mg and 500 mg	metamizolum natriicum	Central nervous system -analgesics and antipyretics- tablets and suppositories	Algocalmin* (Sanofi) Algozone* (Labormed)
<b>Oxacilină*</b> 250 mg, 500 mg and 1 g	oxacillinum	Systemic use antiinfectives - beta-lactam antibacterials, penicillins for injection and capsules	Oxacilină* (Novartis) Oxacilină* (Farmex Company)
<b>Plafen*</b> 500 mg	metamizolum natriicum + clorhidrat de pitofenonă + bromometilat de fenipramidă	Digestive tract and metabolism- antispasmodics in combination with analgesics - tablets	Quarelln* (Sanofi) Algifen* (Sanofi)
<b>Penicilina G*</b> 400,000 U.I. and 1,000,000 U.I.	benzylpenicillinum	Systemic use antiinfectives - beta-lactam antibacterials, penicillins for Injection	Unique product*
<b>Ranitidină Atb*</b> 150 mg	ranitidinum	Digestive tract and metabolism -antiulcer drugs - tablets	Ranitidină (Laropharm) Ranitidină LPH* (Alvogon) Zantac* (GlaxoSmithKline)
<b>Supozitoare Glicerină*</b> 1,39 g and 2,13 g	glycerolum	Digestive tract and metabolism -laxatives- suppositories	4Lax* (Solacium Pharma) Supozitoare Glicerină* (Solacium Pharma)

\* Unique product in the Romanian market.(Data source: Cegedim Romania 2015)

## Top medicines for which Antibiotice is the sole producer in Romania

The products for which Antibiotice is the sole producer in the market recorded sales amounting to RON 65.3 million, higher by 6.3 % as compared to the previous year.

Brand	International Nonproprietary Name	Therapeutic class + Form of administration
<b>Aceclofen®</b>	diclofenacum+paracetamolum	Musculoskeletal System Suppositorles
<b>Amoxplus®</b> 1000mg/200mg	amoxicillinum + acidum clavulanicum	Systemic use antiinfectives Powder for injection
<b>Ampicilină®</b> 250 mg	ampicillinum	Systemic use antiinfectives Powder for Injection
<b>Ampiplus®</b> 1000 mg / 500 mg	ampicillinum + sulbactamum	Systemic use antiinfectives Powder for injection
<b>Cefort®</b> 250 mg	ceftriaxonum	Systemic use antiinfectives Powder for injection
<b>Cicloserină Atb®</b> 250 mg	cycloserinum	Systemic use antiinfectives Capsules
<b>Colistină Atb®</b> 1,000,000 U.I.	colistini sulfas	Systemic use antiinfectives Powder for Injection
<b>Efcef®</b> 100 mg	cefiximum	Systemic use antiinfectives Capsules
<b>Izoniazidă Atb®</b> 100 mg and 300 mg	isoniazidum	Systemic use antiinfectives Tablets
<b>Lisinopril Atb®</b> 40 mg	lisinoprilum	Cardiovascular system Tablets
<b>Moldamin</b> 1,200,000 U.I.	benzathini benzylpenicillinum	Systemic use antiinfectives Powder for Injection
<b>Nidoflor®</b> 15 g	nystatinum + neomycini sulfas + triamicinoloni acetonidum	Dermatological preparations Cream
<b>Nistatină</b> 500,000 U.I.	nystatinum	Systemic use antiinfectives Tablets
<b>Oxacilină Atb®</b> 500 mg and 1 g	oxacillinum	Systemic use antiinfectives Powder for injection
<b>Penicilină G potasică</b> 1,000,000 U.I. and <b>Penicilină G sodică</b> 400,000 U.I. and 1,000,000 U.I.	benzylpenicillinum	Systemic use antiinfectives Powder for Injection
<b>Pirazinamidă</b> 500 mg	pyrazinamidum	Systemic use antiinfectives Tablets
<b>Sinerdol®</b> 300 mg	rifampicinum	Systemic use antiinfectives Tablets
<b>Sinerdol® ISO</b>	rifampicinum+isoniazidum	Systemic use antiinfectives Capsules
<b>Streptomycin Sulphate®</b> 1g	streptomycinum	Systemic use antiinfectives Powder for Injection
<b>Tetraciclină Atb® HCL</b> 12 g	tetracyclinum	Dermatological preparations Ointments
<b>Kanamicină S®</b> 5 g	kanamycinum	Sensory organs Ointments

Date source: Cegedim România 2015



# Financial evolution

Sales income recorded in 2015 was RON 330 million, higher by 3% compared to 2014 when the value was RON 318.9 million. This figure represents the result of the sustained actions to strengthen the company's business.

Taking into account that, in the pharmaceutical market:

- the prices of generics decreased on average by 20 % since July 01, 2015;
- the clawback tax for Antibiotice accounted for 11.1% of the income generated by the sales of products in the domestic market, Antibiotice **fulfilled the budgeted indicators** succeeding in:
  - increasing the sales income by 1% as compared to the budgeted figures;
  - applying a prudential policy with regard to the adjustments for the retail market customers (Antibiotice selling its products through about 5,000 pharmacies). Not making these adjustments would had resulted in a RON 42 million gross profit.

Net financial income was mainly influenced by the following expenses:

- Bank interest expenses of RON 1.5 million, lower by 30%;
- Expenses on granted discounts amounting to RON 3.4 million, lower by 68 %.

**Profit before tax for 2015 was RON 32 million, lower by 14 % than the figure recorded in 2014, but 23 % higher compared to the profit estimated in the Income and Expenditure Budget.**

**Profit after tax was RON 27.2 million.**

## Evolution of main economic-financial indicators

	31.12.2014	31.12.2015	2015/2014
<b>Sales income</b>	318,945,093	330,087,508	1.03
<b>Operating income</b>	50,277,530	36,936,839	0.73
<b>Gross profit</b>	37,363,132	32,047,535	0.86
<b>Net profit</b>	31,138,739	27,178,823	0.87
<b>Fixed assets</b>	196,493,836	215,675,376	1.10
<b>Current assets, of which:</b>	307,152,860	328,987,215	1.07
- receivables	232,062,022	231,314,744	1.00
- stocks	57,284,464	60,290,277	1.05
<b>Total debts, of which:</b>	139,315,696	152,012,707	1.09
- trade debts	46,916,170	71,391,757	1.52
- bank credits	54,783,341	41,778,509	0.76
<b>Total assets</b>	503,646,697	544,662,591	1.08
<b>TOTAL EQUITY</b>	364,331,001	392,649,884	1.08
<b>Average staff number</b>	1465	1458	0.995
<b>Work productivity</b>	217,710	226,397	1.04

		31.12.2014	31.12.2015
<b>ROE (return on Equity)</b>	=Profit before interest and tax / Shareholder equity	4.7%	3.8%
<b>ROA (return on assets)</b>	=Net profit / Total assets	1.2%	0.89%
<b>EPS (RON/share)</b>	=Net profit / share	0.046	0.040
<b>Net profit ratio</b>	=Profit / Sales income	10%	8%
<b>Overall liquidity</b>	=Current assets / Current liabilities	2.6	2.5
<b>Fast liquidity ratio</b>	=Current assets – Stocks / Current liabilities	2.1	2.1
<b>Degree of indebtedness</b>	= Debts / Total assets	28%	28%
<b>No. of shares</b>		671,338,040	



The subscribed and paid-up share capital on 2015 was 67,133,804 lei and accounted for 671,338,040 shares with a nominal value of 0.1000 lei.

Antibiotice has a strong shareholding structure, the Ministry of Health being its majority shareholder.

**The Antibiotice ownership structure** (*according to the Register of Shareholders on 15.09.2015*).

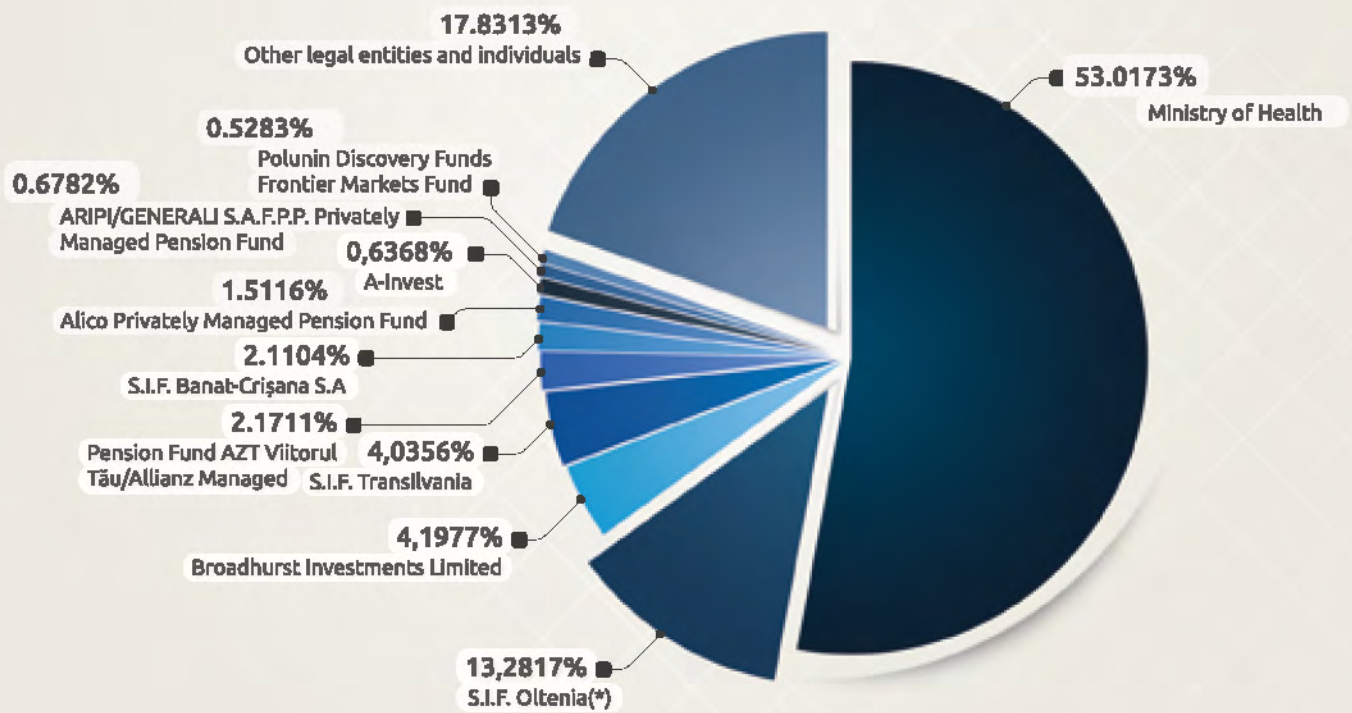


# The stock exchange evolution

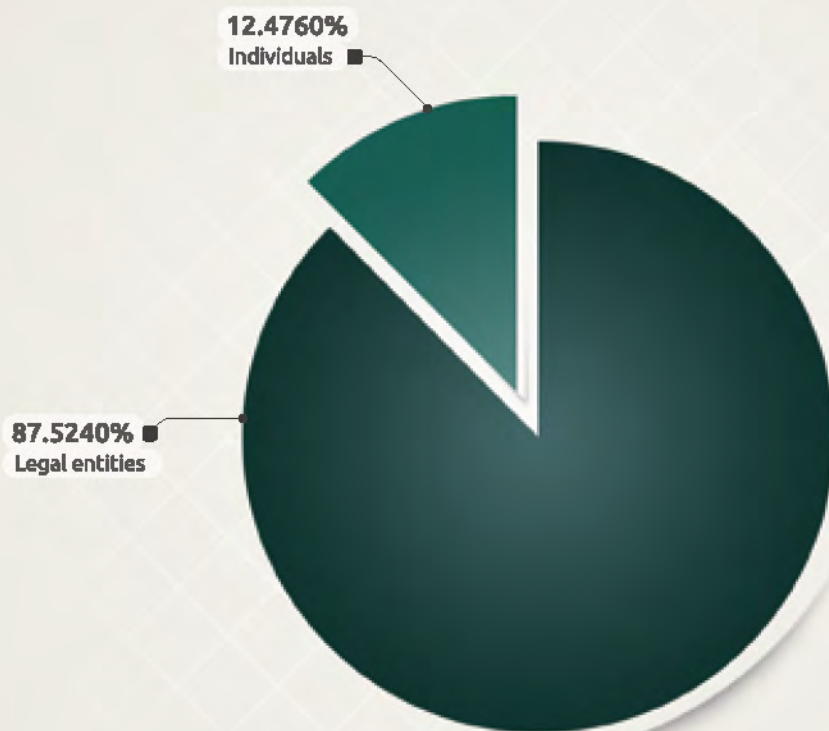
## Investors

- Ministry of Health(\*) - 53.0173%
- S.I.F. Oltenia(\*) - 13.2817%
- Broadhurst Investments Limited - 4.1977%
- S.I.F. Transilvania – 4.0356%
- Pension Fund AZT Viitorul Tău/Allianz Managed – 2.1711%
- S.I.F. Banat- Crişana S.A – 2.1104%
- Alico Privately Managed Pension Fund – 1.5116%
- ARIPI/GENERALI S.A.F.P.P. Privately Managed Pension Fund – 0.6782%
- A-Invest – 0.6368%
- Polunin Discovery Funds – Frontier Markets Fund – 0.5283%
- Other legal entities and individuals – 17.8313%

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



Shareholders breakdown by investors



Breakdown by class of shareholders



Throughout the year 2015, we paid dividends for the financial years 2011, 2012, 2013 and 2014, as follows:

### Dividend history (2011 – 2014)

Period	Net dividends							Suspending date - dividend payment
	Due	Paid				Unclaimed on 31.12.2014		
		Until 31.12.2014	01.01÷31.12 2015	Total	% (total paid)	lei	%	
2011	8,204,647	7,475,185	16,361	7,491,546	91.31	713,101	8.69	31.09.2015
2012	9,834,108	8,955,607	31,219	8,986,826	91.38	847,282	8.62	Payment in progress
2013	14,753,415	13,317,412.2	139,335	13,456,747.2	91.21	1,296,667.8	8.79	Payment in progress
2014	15,061,293	-	13,870,071.68	13,870,071.68	92.09	1,191,221.32	7.91	Payment in progress

For 2012 and 2013 dividends are distributed directly from the company's headquarters, by wire transfer and postal order and the dividends on 2014 through the Bucharest Central Depository and implicitly, through CEC Bank.

### Antibiotice on the securities market

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

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 was 0.0650 lei/share and was recorded on June 8 2000.

Both business plans and financial results of the company represented a solid guarantee that Antibiotice has consolidated its position on the drugs national market.

From the listing until the end of 2015, ATB shares have multiplied the investors' money 2.6 times.

18 years after the first transaction, more than 42,000 shareholders are following with interest the evolution of Antibiotice sales on the Bucharest Stock Exchange.

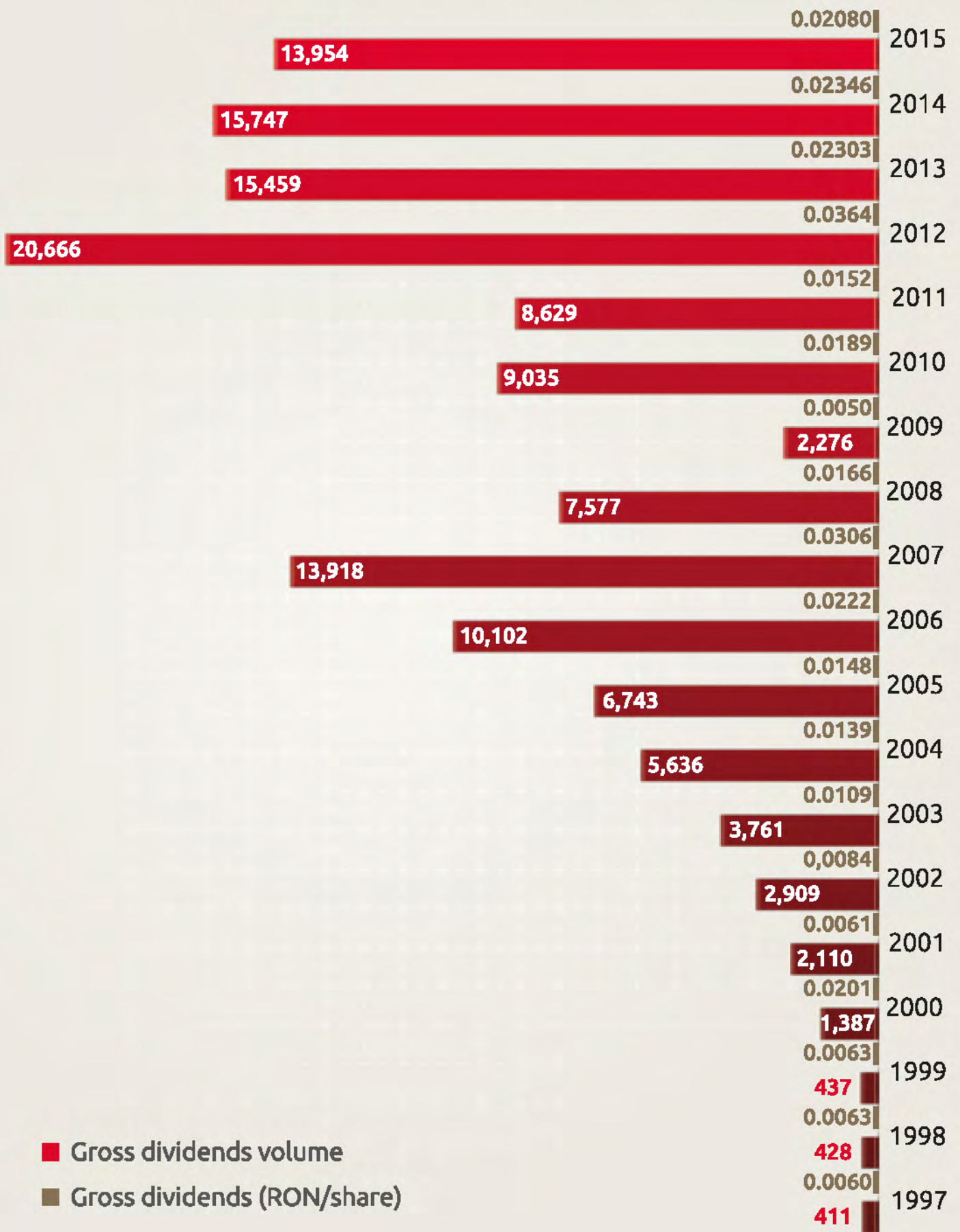
The Antibiotice company shares (ATB), traded on the Bucharest Stock Exchange:

- Are included in the BET-XT index, reflecting the price evolution of the 25 most liquid companies.
- Are included in the BET-XT-TR index reflecting the price performance of the 25 most liquid companies as well as the gross dividends and other cash distributions to shareholders.
- Are included in the BET- Plus index which includes the Romanian companies listed in the BSE market which meet the minimum selection criteria excluding the financial investment companies.
- Are included in the BET-BK index reflecting the evolution of the prices of shares issued by domestic and foreign companies admitted to trading on the regulated market administered by BSE.

In 2015 the minimum price of the ATB share was worth 0.5240 lei. The share price rose to a maximum value of 0.6170 lei/share.

The Antibiotice market capitalization on December 31st 2015 (The last trading day of the year) was 357,152 thousand lei.

## Gross dividends volume and gross dividends per share



Antibiotice



*ATB shares/ Regular Market*

	2012	2013	2014	2015
<b>Number of shares</b>	568,007,100	671,338,040	671,338,040	671,338,040
<b>Market capitalization (thousand RON)*</b>	213,798	374,607	390,719	357,152
<b>Market capitalization (thousand Euro)*</b>	48,276	83,919	87,173	78,868
<b>Market capitalization (thousand \$)*</b>	63,678	115,413	105,978	86,167
<b>Total value traded (million RON)</b>	10	23	16	11
<b>No. of shares traded</b>	24,002,033	48,439,486	27,467,454	18,844,935
<b>Opening price (RON/share)</b>	0.3974	0.3774	0.5520	0.5850
<b>Maximum price (RON/share)</b>	0.4400	0.5680	0.6170	0.6170
<b>Minimum price (RON/share)</b>	0.3300	0.3700	0.5410	0.5240
<b>Price at the end of the year (RON/share)</b>	0.3764	0.5580	0.5850	0.5320
<b>Average price (RON/share)</b>	0.3985	0.4692	0.5845	0.5836
<b>Earnings/share (RON/share)***</b>	0.0477	0.0467	0.0466	0.0405
<b>Gross dividend/share (RON/share)**</b>	0.0182	0.0230	0.0235	**0.0208
<b>Dividend yield****</b>	4.83%	4.12%	4.03%	3.91%
<b>Dividend distribution rate*****</b>	38%	49%	51%	51%

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

\*\* Dividend proposed,

\*\*\* The calculation of earnings per share is based on net profits of each year,

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

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

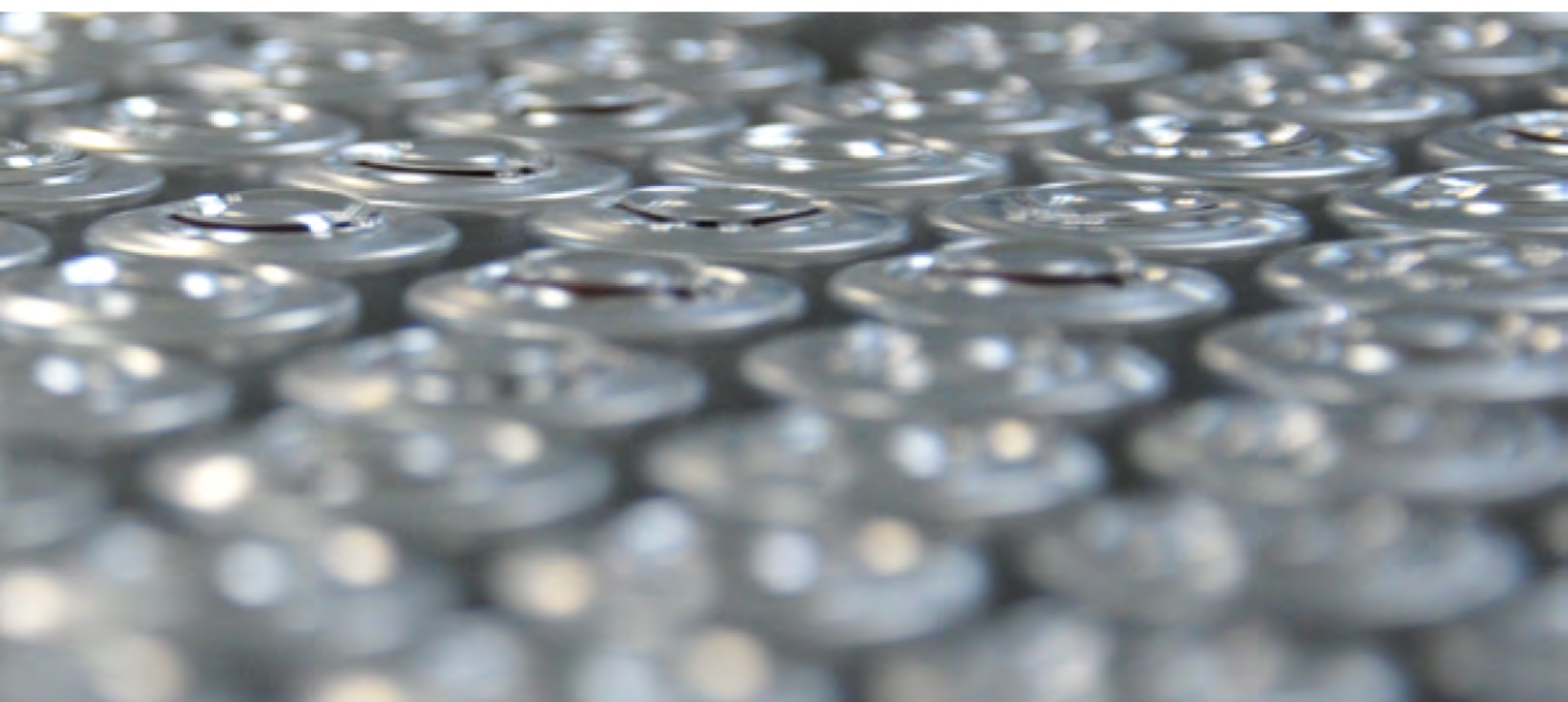


During the year 2015, 18,844,935 shares were traded, worth 11 million lei (2.4 million euros, \$ 2.6 million), with an average price of 0.5836 lei / share.

Constantly present in business charts, Antibiotice is included on average in the first 12 companies in the BET-PLUS, among the first 17 companies in the composition of the BET-XT index and among the top 20 companies in the BET-BK index.

In accordance with Chapter IV, Section 2, Art. 92 – Bucharest Stock Exchange Code, *the financial communication calendar for the year 2015* was as follows:

Events	Date
Presentation of preliminary annual financial results - 2014	13.02.2015
General Meeting of Shareholders to approve the annual financial results - 2014	29.04.2015
Presentation of the Annual Report - 2014	29.04.2015
Presentation of Quarterly Reports: I <sup>st</sup> quarter 2015 III <sup>rd</sup> quarter 2015	15.05.2015 13.11.2015
Meeting with investors and analysts	20.05.2015
Presentation of the half-yearly report 2015	14.08.2015
Meeting with investors and analysts	21.10.2015



# Actions and results



Investments in product research & development continued in order to strengthen the business and assert our company's ability as a producer of generic medicines, offering alternative for health maintenance through a valuable portfolio, in accordance with the therapeutic trends.

In 2015, three distinct pharmaceutical development groups were created to focus the research & development efforts in order to increase speed of launching new products in the market, while maintaining the flexibility. These groups are oriented towards:

- oral solid dosage forms;
- topical dosage forms;
- non-prescription products.

Thus, in 2015, the research departments developed concurrently more than 20 projects in intermediate and advanced development stages belonging to therapeutic classes which define the company's medium and long-term development directions: anti-infectives, topical, cardiovascular and CNS medicines.

Another direction of our research was oriented towards products for prophylaxis of some



# Research and Development

diseases and for increasing the life quality (food supplements, dermocosmetics and over the counter drugs), given the growing concern of the population for prevention and a healthy lifestyle.

During the development of medicines, our research specialists adapted the technologies specific for the researched products to the manufacturing flows existent in our company which involved implementing innovative technical solutions, both for technologies and for analytical control of the new products.

## More than 20 research projects conducted in 2015

The existent facilities enriched each year within the research departments allowed the progress of more than 20 projects for new products, of which 16 were conducted in 2015, belonging to following therapeutic classes: cardiovascular medicines (5), dermatological products (4), CNS medicines (2), OTCs and dietary supplements (5).



Research conducted in 2015 focused on various pharmaceutical dosage forms such as immediate-release tablets, gastroresistant extended-release tablets/capsules, ovules, topical medicines.

## Center of Drug Evaluation was reauthorized

Certification of efficacy and safety in administering the developed generics was carried out by our team of researchers from the Center for Drug Evaluation (CDE) through clinical bioequivalence studies and in vivo studies (dissolution profiles and biowaiver studies).

In 2015 CDE was re-authorized by the National Agency of Medicines and Medical Devices for implementing and meeting the Good Clinical Practice and Good Laboratory Practice norms. With a site dedicated for the packaging of medicinal products of clinical investigation, solid dosage forms, CDE received also the attestation of compliance with the Good Manufacturing Practice for this manufacturing stage.

A first in the CDE's activity was the participation in an international phase 1 multicenter study having as a sponsor a French company.

At the same time, in order to support developing our business on the regulated markets, our specialists developed the methodology for conducting two types of studies for the topical products according to the harmonised legislation developed by European Medicine Agency (EMA) and Food and Drug Administration (FDA):

- phase I, pharmacodynamic studies for the dermatological corticosteroid products;
- phase III extended clinical studies for dermatological antifungal products.

## 14 new international marketing authorizations and 7 new products in the Romanian market

Results of the research & development stages led to new marketing authorizations and new reauthorizations for the products already traded in the international markets.

Therefore, the European Decentralized Procedure (DCP) for authorizing simultaneously the product **Zatinex®** 30 mg and 60 mg, capsules (duloxetine) in the two EU countries (Romania and Germany) was completed in 2015.



Our company obtained through the national procedure 4 new Marketing Authorizations (MAs) in Romania for medicines belonging to the following classes: cardiovascular medicines (**Indapamida Atb®** 1.5 mg extended-release tablets), dermatological preparations (**Clobetazol Atb®** 0.5 mg/g, ointment) and genitourinary apparatus (**Nystatin Atb®** 100.000 UI, ovules, **Zifex Duo®** – metronidazole and clotrimazole 500 mg/200 mg, ovules).

Nine procedures for reauthorizing the existing products in the market were also completed.

Antibiotice's presence increased in the food supplement market by authorizing two food supplements: **Fluxiv®** tablets, a unique and complex antioxidant combination with a role in the normal functioning of blood vessels and **Soriso®** tablets, double innovative combination with adaptogenic role.

International development of Antibiotice's business was supported in 2015 by obtaining 12 new marketing authorizations for products under Antibiotice brand in 5 countries of Europe, Asia and Africa.

Development of the company's international market was also supported through completing the authorization procedure conducted by FDA for certifying Ampicillin with sulbactam – powder for solution for injection/infusion 1.5 g and 3 g in the US market. This product joins the other products already traded in this market, i.e. Ampicillin (4 concentrations) and Nafcillin (2 concentrations).

## Continuous preoccupation for training of our research specialists

Addressing the new formulations are challenging projects for our specialists.

In order to support the innovation but also the research strategy, our research & development staff updated and enriched their knowledge on good manufacturing practice, pharmaceutical design, quality assurance, according to the latest international regulatory guides (EMA and FDA).

Their participation at workshops, conferences and congresses facilitated the exchange of views and consultation with experts in the field, with a direct influence on developing new research projects and on the evolution of their research career.





# Activities conducted in the Quality Unit

Maintenance and continuous improvement of compliance with the specific requirements of the pharmaceutical industry in order to ensure the quality, safety and efficacy of the products manufactured by Antibiotice was assessed during 2015 through the self-inspection and external audit program.

## Audits conducted by regulatory authorities

1. GLP and GCP recertification inspection of the Center for Drug Evaluation conducted by NAMMD;
2. NAMMD Inspection for the GMP recertification of the secondary packaging line of clinical investigation medicines used in clinical trials;
3. US FDA re-approval Inspection of finished products for injection and Nystatin active ingredient, for the US market;
4. Inspection from Saudi Arabia regulatory agency for GMP recertification of the lines manufacturing finished products for injection and medicinal products for oral use (tablets and capsules).

All authorizations/approvals necessary to continue the manufacture or sale of products on the US and Middle East markets were renewed based on inspection results.

## Audits conducted by certification bodies

1. Supervisory audit of the Integrated Management System conducted by Lloyd's Register Quality Assurance on all three systems, quality (ISO 9001), environment (ISO 14001) and occupational health and safety (OHSAS 18001);
2. Recertification audit of product compliance (primary packaging) conducted by the SRAC CERT-SERV.

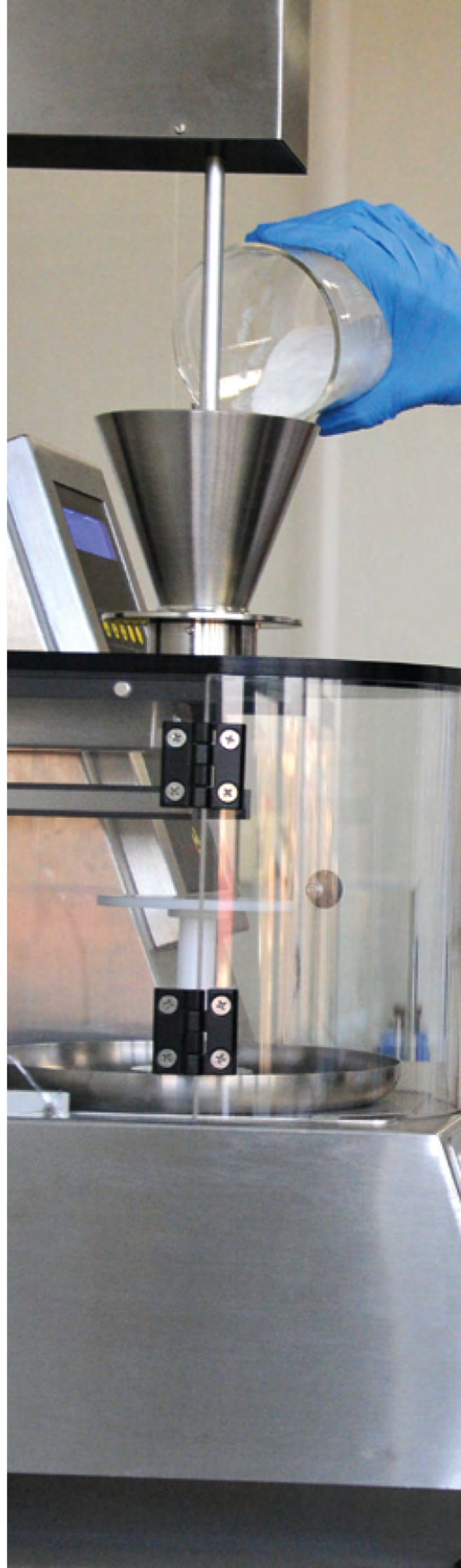
## Audits by active ingredients suppliers / contract manufacturing partners

1. In accordance with regulatory requirements, current clients and potential clients have conducted audits inspecting GMP requirements for Nystatin manufacture, audits completed by maintaining current customers and preliminary steps in view of signing contracts with new customers;

2. As a contract manufacturing producer, Antibiotice's production lines were audited by contract suppliers in order to assess compliance with GMP requirements and the outcome materialized in continuing production for these business partners.

## Audits by raw materials suppliers

In order to evaluate compliance with EU GMP requirements for manufacturers of active ingredients and intermediates in accordance with the external audits program for qualification / periodic assessment, the manufacturing flows of 27 such materials were audited.





# Modernizing and streamlining the manufacturing lines

**Antibiotice's development strategy for 2015 aims, as a priority direction, at modernizing and developing the product portfolio and the manufacturing lines.**

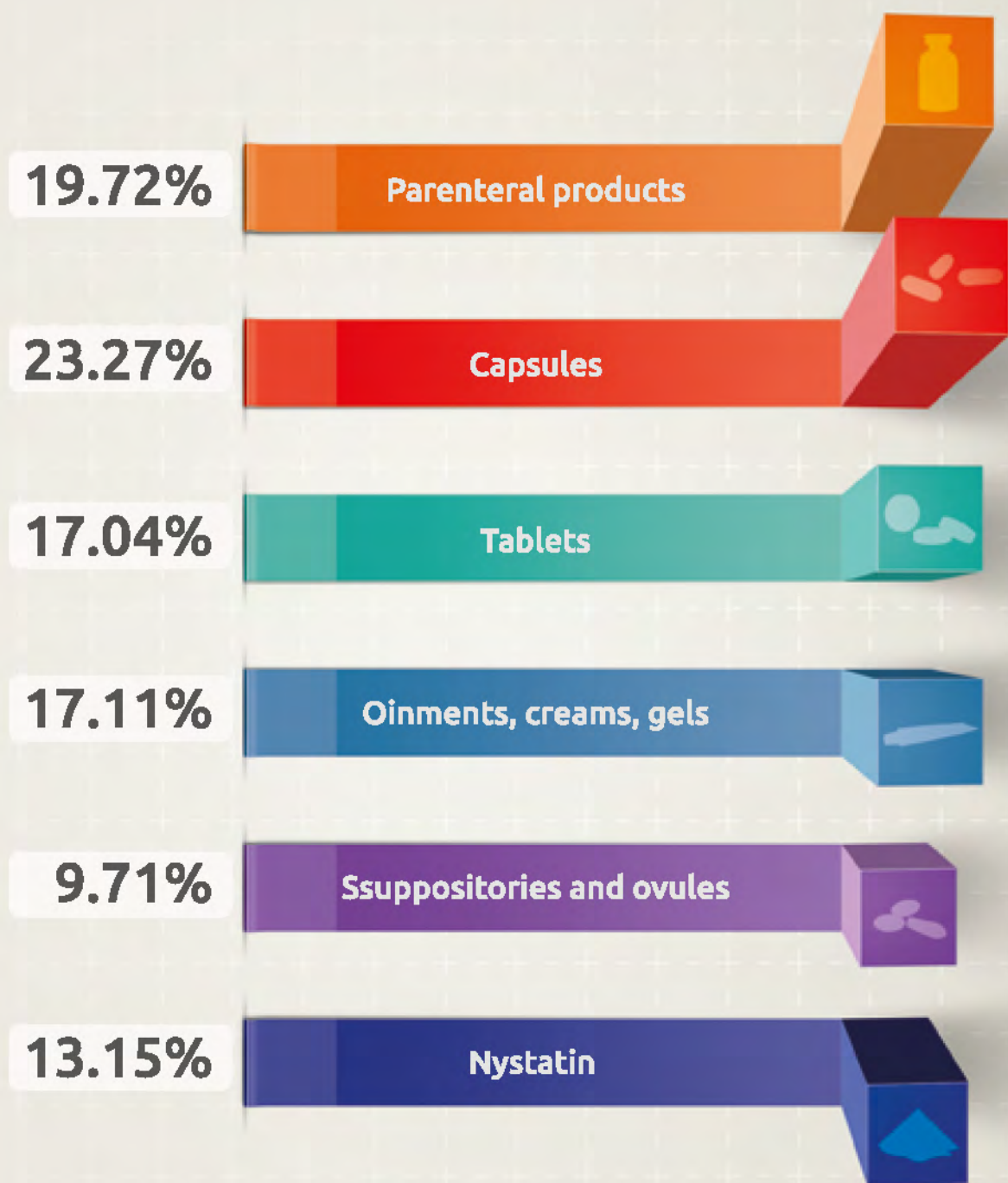
Our company produces 148 medicines in six pharmaceutical forms, for internal and external partners:

- Sterile powders for injection
- Capsules
- Tablets
- Topical products (ointments, gels, creams)
- Suppositories
- Ovules

The quality and safety of our products is ensured by processes complying with the latest GMP requirements, all the eight manufacturing lines being EU GMP-certified. The manufacturing lines for sterile injectable products and for the active ingredient Nystatin are certified also by Food and Drug Administration.

Implementing all the regulatory requirements and evaluating the quality management system by the regulatory authorities and by the customers from all over the world result in maintaining the quality, effectiveness and safety of medicines produced by Antibiotice.

The value of products for export (Nystatin and dosage forms) represents 20 % of the total production value in 2015.



Production in 2015

## Objectives achieved by Antibiotice in 2015:

- Manufacture of parenteral products for foreign companies under manufacturing and control contracts. The production of parenteral preparations for export accounted for 19.7% of the total production value intended for foreign markets;
- Reduction of costs with the raw materials by optimizing the manufacturing formulae and by identifying new sources for the excipients used in the dosage form technology;
- Reduction in the utility consumption, through a careful management, in all the manufacturing plants;
- Increase of the Nystatin production, while reducing costs and increasing the Nystatin drying productivity;
- Continuation of efforts to implement the environmental protection program on the emissions of volatile organic substances in the extraction phase of Nystatin;
- Increase of the production capacity of the non-penicillin capsule line, by purchasing a high-performing equipment for filling into capsules;
- Launching into manufacturing new products from the following classes:
  - Corticosteroids for dermatological use :  
**Clobetazol Atb®**(clotrimazole) 0.5 mg/g, ointment
  - Genitourinary System:
    - **Zifex duo®** (metronidazole, clotrimazole)  
500 mg/200 mg, ovules
    - **Nistatină Atb®** ovules
  - Vein dietary supplement: **Fluxiv®** (diosmin + hesperidine + troxerutin + vitamin C), tablets.





# The investment activity

In accordance with the general objectives of the company, in 2015 major investments were implemented. Therefore modernizing and revamping activities were carried out in view of increasing work productivity, energetic loss reduction and enhancing the safety of operation as well as complying with the legal requirements in the pharmaceutical industry.

## The future new manufacture plant

In 2015 activities were initiated for preparing the area where a new production capacity will be built, for the manufacture of topicals and suppositories. Moreover, in 2015 was finalized the design phase of the new plant that will enable the manufacture of current products in the portfolio and the development of new ones.

Since the long-term development strategy foresees the export of topical products, including markets heavily regulated such as Canada and the United States where FDA regulations are applied,

providing the equipment, the planning and design will therefore be expected to allow subsequent authorizations for the foreign markets.

According to estimations, the term for finalizing this investment is 2018.

## Completing the investment for a lab testing beta-lactam penicillins

The investment started in 2014 for the design, construction and equipping a laboratory for testing beta-lactam penicillin products was completed in 2015, providing conditions to achieve both physicochemical and microbiological testing including the sterility test in a single modern laboratory.

## Revamping the manufacturing lines and providing new lab equipment

To modernize the non-penicillin capsules plant, new equipment was purchased and installed in 2015 with a double productivity as compared to the existing one. This new equipment will enable increased productivity and diversification of the capsule range in the portfolio (capsules with pellets). The Tablet Plant purchased a modern hood with vertical laminar airflow, which modernizes the space in which the weighing of raw materials is conducted.

However, due to the expansion of the product portfolio, the changes in the Pharmacopoeia and the compliance with regulatory bodies requirements it was necessary to purchase new laboratory technique to be used in research and quality control. Thus, dissolution testers were purchased, HPLC sites, a spectrophotometer, climatic chambers and others.

## Upgrading the system to ensure data integrity within the Quality Control Laboratories

Data integrity is fundamental to a quality system that ensures the manufacture and marketing of a drug market with consistent quality.

In order to ensure compliance with the principles of data integrity as required by applicable guidelines (MHRA and US FDA) in 2015 was implemented and validated a centralized computer

system in the Quality Control laboratories: Distributed Open Lab CDS.

The main improvements it brings:

- secure access to each user;
- securing data on a centralized server in real time;
- performing regular backups;
- limit the right of access to certain features of the program for users (delete and update of records / data);
- audit trail.





Antibiotice



# Development of marketing activities

In 2015 Romanian pharmaceutical market recorded a 4.7% fall in value terms, reaching RON 11.7 billion as compared to RON 12.3 billion in 2014<sup>1</sup>. The physical consumption of products had the same negative evolution, dropping by 98.5 million physical units, from 11.3 billion in 2014 to 11.2 billion in 2015. This downward evolution was influenced by the following factors: legislative changes on compensating the drugs, decrease in drug prices by applying the order no.75 / 2009 subsequently amended and supplemented, progressive increase in the clawback tax and the insolvency of some distributors and pharmacies.

The activity on the Romanian pharmaceutical market faced the following risks:

- increase in the claw-back tax compared with the previous year;
- increase in the manufacturing costs as a result of rising the prices of utilities and raw materials;
- decrease in prices of drugs by applying the order no. 75/2009 subsequently amended and supplemented;
- rearrangement by categories of pharmacies (chain, small-chain and independent pharmacies) leading to the allocation of more significant budgets for the pharmacy chains and small chains;
- fluctuating legislation for hospitals;
- settlement of amounts due by the National House of Health Insurance to terms exceeding the time limits agreed in the master contract.

<sup>1</sup> The values are calculated based on the entry price in pharmacies according to the market analysis company Cegedim



## Development of Romanian pharmaceutical market, in short

With a 87% share in the total sales in terms of value in the pharmaceutical market and 98% of the total drug consumption in Romania, the retail channel (pharmacies) was the market share that marked the evolution of the total market. The retail sales in terms of value dropped by 5.7% from RON 10.8 billion in 2014 to RON 10.2 billion in 2015 while from the quantitative viewpoint the decrease was much lower (1%) from 11 billion units in 2014 to 10.9 billion units in 2015. In contrast to the retail segment, the hospital channel increased compared to 2014, both in value (2.7%) and in quantity (4%).

With increasing the impact of clawback tax on the indicators reported by the companies, the over-the-counter drug segment (for which no tax is charged) recorded in 2015 an increase in value of 14.9%, higher than the total market growth while the prescription medicines dropped by 8.6%. The quantities recorded the same different evolution, the OTC consumption increasing by 2.3% while the consumption of the prescription drugs dropped by 2.1%.

In 2015 the Digestive System drugs managed to reach the first place in the top sales (RON 2,043 million, representing 17.5 % of the total sales) in comparison with the third place in 2014. The Cardiovascular System drugs fell on the second position (16.6%, i.e. RON 1,942 million), followed by Oncologicals (16.1 %, i.e. RON 1,881 million), CNS drugs (12 %, i.e. RON 1,406 million) and Antiinfectives (9.6%, i.e. RON 1,126 million).

Together, these top five therapeutic classes generated 71.8% of the total sales in value terms recorded in the Romanian market.

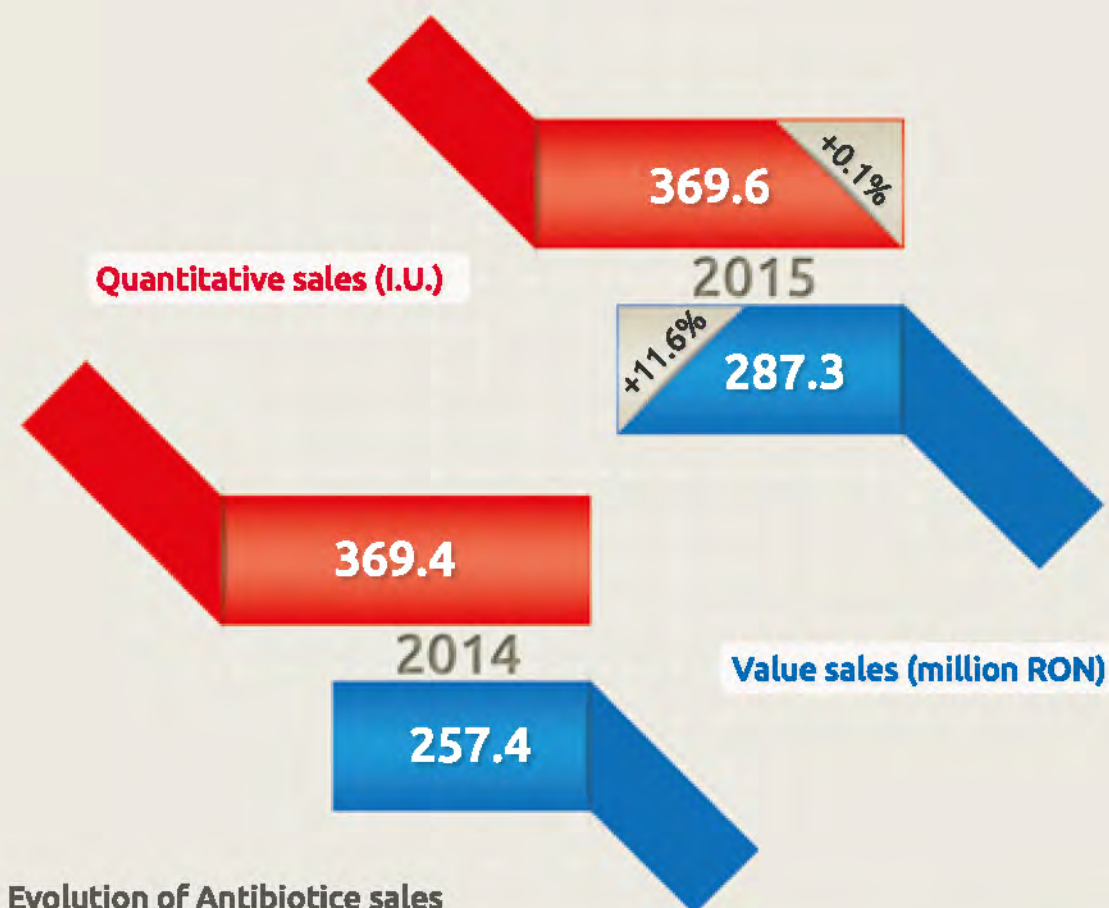
## Antibiotice in the market

In the context of negative developments in the domestic pharmaceutical market, Antibiotice managed in 2015 to increase its value sales up to RON 287.3 million, higher by 11.6% as compared to the previous year, according to the Cegedim data. The volume sales recorded also a very slight increase (0.1%) but amid a 1 % decline in the medicine consumption in the total market.

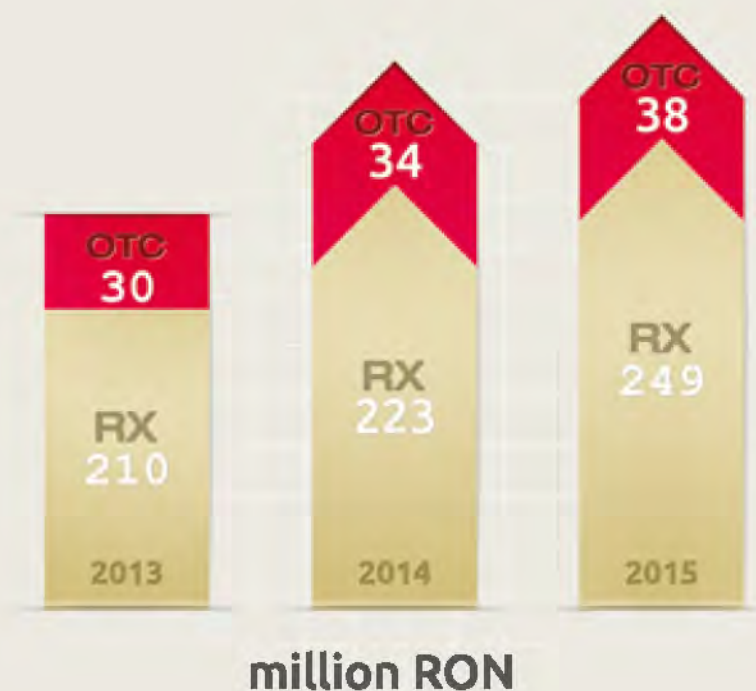
In the hierarchy of the 307 generic and innovative pharmaceutical companies in the Romanian market, Antibiotice ranked thirteenth at the end of 2015, climbing 2 positions as compared to 2014. According to the same sources, Antibiotice ranked fourth (climbing one position) among the producers of generics with medical prescription and drugs without medical prescription.

In the top five producers of generics with medical prescription and OTC drugs, Antibiotice recorded the highest value growth rate, i.e. 11.6% while the competitors recorded the following percents: Sun Pharma (-1.8%), Sanofi (+2.3%), Krka (-10%) and Novartis (- 2.1%).

The medical prescription drugs (RX) traded by Antibiotice recorded higher growth rates than the market rates, i.e. an increase of 11.7% versus a 8.6 % drop in the total market. The OTCs recorded also a similar increase (+11.3) but slightly below the growth of the total OTC market (+14.9%).



## Antibiotice, generic sales leader in hospitals



### Evolution of Rx and OTC sales

In 2015 Antibiotice maintained its leader position on the hospital segment exploiting in an optimum way the Antiinfectives portfolio.

With sales amounting to RON 71.8 million and a 18.7% market share, Antibiotice is the leader in the market of generics and OTCs sold in the Romanian hospitals, with an advance of RON 22 million in value terms compared to the second-ranked company.

Antibiotice has also the leading position as regards the sales of therapeutic units administered as powders for injection, with a 75.4% market share.

## Antibiotice, leader on the ointment & suppository segment

Antibiotice maintained its leading position in 2015 as regards the quantity sales of the entire range of ointments (27.7% market share) and suppositories (42.4 % market share).

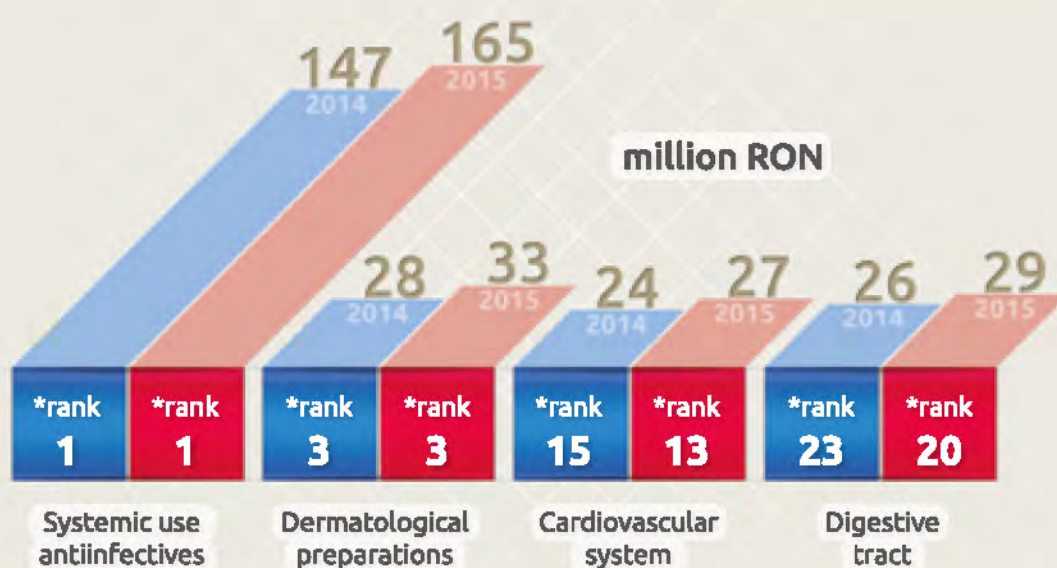
Increases recorded in 2015 were due to a continuous and sustained effort of our sales teams and of the team for promoting dermatological and anti-inflammatory products, whose actions worked synergistically and complementary for achieving the targets.

## Higher growth rates compared to the market rates for the following therapeutic classes: dermatological preparations, antiinfectives, digestive tract and cardiovascular system

Regarding the therapeutic areas, Antibiotice recorded in 2015 a higher growth rate compared to the market rate for the dermatological preparations, antiinfectives, digestive tract and cardiovascular system, as follows:

- **Dermatological preparations class** recorded an increase of 16.7%. The products with significant growth values in 2015 were: Nidoflor® ointment (nystatin+neomicin+triamcinolon) (+23.4%), Clotrimazol Atb®, (+18.6%), Neopreol®, (+ 41%);
- **Antiinfectives class** recorded a 12.6% increase while this class increased only by 0.4% in the market. The products with a significant share in the 2015 sales were: Cefort® for injection 1g (+ 22,8%), Eficef® range capsules, (+ 29,7%), Colistina Atb®, (+26%) and Meropenem Atb® range launched in 2013 which doubled its sales in 2015 compared to 2014;
- **Digestive Tract class** recorded a 12.6 % increase. The following products had a significant value contribution in achieving this class indicators: Ranitidina Atb® 150 mg, with an increase of 8.3% and Silithor® capsules, hepato-protective supplement launched in 2014, with sales of RON 1.6 million in 2015;
- **Cardiovascular System class** had a positive value trend, with a 10.6 % growth rate in 2015 as compared to 2014. The following products had a significant value contribution at increasing this class: Nolet® (nebivolol), + 82.3% and Hemorzon® range ointment and suppositories, + 12.4%.

### Evolution of the main therapeutic classes



\*Antibiotice's position in the top producers by each therapeutic class

## Cefort® - the best selling Antibiotic product

The best selling product traded by Antibiotice is Cefort® (*ceftriaxonum*), powder for injection 1g with a 7.3% share in the total turnover. This product recorded the most significant value share in the top 10 products, i.e. +3.9 million RON amid an increase in consumption of 820,000 vials. The upward trend of Cefort® 1g was recorded both on the hospital segment (+ 21.7%) and on the retail segment (+ 24.3%).

Compared to the direct competitors as regards the molecule *ceftriaxonum* of 1 g for injection, Cefort® managed to increase its market share both in value and quantity: from 95.5% in 2014 to almost 99% today.

Moreover, Cefort®, powder for injection 1g was the only product in the market of the molecule *ceftriaxonum* 1g which recorded increases while the other two competing companies declined in sales with more than 70% in value and over 65% from the quantitative viewpoint.

## Top products

*Eficef® capsules 200 mg* ranks secondly in Antibiotice sales (5.7%), followed by *Amoxicillin capsules 500 mg* (5.3%), *Nidoflor® ointment* (3.5%) and *Colistina Atb®* product for injection (3.5%).<sup>2</sup>

In 2015, the following brands from the over-the-counter drug portfolio, distinguished both in value and quantity: Silithor® hepatoprotective supplement (launched in 2014, with sales in 2015 amounting to RON 1.6 million and 2.8 million capsules), Clotrimazol range cream 15 g and 35 g (increase in value of 18.6% and in quantity of 5.4%), Neopreol® ointment (increase in value of 41% and in quantity of 10.6%) and Saliform® forte cream (increase in value of 31.4% and in quantity of 5.6%).

## 8 new products launched in the market in 2015

Our company's portfolio was enriched in 2015 with 8 new products from the following therapeutic

<sup>2</sup> Data source: Cegedim Romania, Pharma Market Report, 2015

classes: Cardiovascular system, Genitourinary Apparatus, Antiinfectives, Dermatology and Central Nervous System.

Antibiotice completed its Cardiovascular System portfolio creating its own range on the molecule rosuvastatine (cholesterol and triglyceride regulator): Rosuvastatină Atb®, tablets, 5, 10 and 20 mg.

Intending to develop the Genito-Urinary class, Antibiotice launched in 2015 2 new drugs belonging to the antiinfectives and gynecological antiseptics classes: Zifex Duo® (metronidazol + clotrimazol) and Nistatină Atb® ovules, while Zifex Complex® (nystatin + neomycin sulfate + metronidazole + hydrocortison acetate) will be launched at the beginning of 2016

As regards the Antiinfectives, the main traded therapeutic class, Antibiotice has consolidated its position on the beta-lactam antibacterials, by introducing, in addition to Meropenem Atb® range, the product for injection Imipenem/Cilastatin Atb®.

In the Dermatological Preparation portfolio, a new topical corticosteroid ointment, Clobetazol® 25 g was introduced.

While in 2014 Antibiotice focused its strategy on new products belonging to the central nervous system, introducing 3 anxiolytics (Alprazolam Atb®, tablets 0.25 mg, 0.5 mg and 1 mg), an Anti-Alzheimer product (Memantina Atb®, tablets 10 mg) and an antidepressant product, Nobixal® (tianeptine), in 2015 this portfolio was completed with Memantina Atb® 20 mg.

In the first launching year, the share of these 8 new medicines in turnover amounted to RON 4.5 million.

## Antibiotice promoted its portfolio in major national scientific events

Trading and distribution activity is completed by the marketing & promotion structure organized at territorial level according to the main therapeutic areas (Antiinfectives, Cardiovascular System, Central Nervous System, Dermatology, OTCs) for a ethical and professional promotion of the medicines among the medical specialists.

The activity of the Promotion Department and Commercial Department was also sustained in 2015 by organizing and attending local, regional and national scientific events, which approached themes about the access of the population to medicines and the economic impact of using generic medicines. Presentations on various diseases were made, with reference to Antibiotice drugs.

A series of programmes and promotion actions were also conducted:

- Implementation of a continuous pharmaceutical education program within the project "Partner for Antibiotice A+";
- Organizing workshops with independent and small-chain pharmacies;
- Promoting the company brand and product brands through the campaign for monitoring the general public health: "Health for my patients" addressed to family doctors which aims to monitor the risk of hypertension in patients from rural areas, a project developed with the support of the specialists in cardiology;
- A campaign dedicated to the large public for the cosmetic product Cutaden® Bebe, offered free of charge to the new mothers within the project "Discover my world" implemented in 100 public and 8 private maternities from all over the country;
- Marketing campaigns "Mysterious client" for promoting the product brands in the pharmacy chains;
- Marketing campaigns of the products on the shelves of the open-circuit pharmacies;
- Antibiotice entered the campaign on European Antibiotice Awareness Day ( November 18) developed in 2015 under the slogan (Anti

biotics - use them with care!". Within this campaign informative leaflets were distributed and information was provided to the public about bacterial resistance and how the antibiotics should be used correctly so that the future generations benefit by the effectiveness of this precious, therapeutic resource.

Of the major national events attended by Antibiotice in 2015, we can remember:

- National Alzheimer Conference, February 25-28, Bucharest
- National Congress of Internal Medicine, April 22-25, Căciulata
- National Conference of the Working Groups of the Romanian Society of Cardiology, May 7-9, Sibiu
- Conference of Dermatology " Gheorghe Năstase Days" May 7-9, Iași
- Spring Dermatology in Iași, May 28-30, Iași
- National Congress of Gastroenterology, June 11-13, Iași
- National Conference of Rhinology, July 1 -3, Sighișoara
- National Congress of Cardiology, September 17 -19, Sinaia
- National Congress of Dermatology, October, Bucharest
- Days of Cardiology "Prof. Dr. George Georgescu", October 29-31, Iași
- Days of the Romanian Association for Pediatric Education in Family Medicine, November, Sovata
- Pharma and Medical Forum conferences organized at national level
- Interdisciplinary Symposia „Antibiotice – 60 years of Romanian continuity and performance” Bucharest, Constanța, Iași, Craiova”



## Antibiotice – 60 years of Romanian continuity and performance in the Romanian pharmaceutical industry

In December 2015, the anniversary event "Antibiotice – 60 years of Romanian continuity and performance in the Romanian pharmaceutical industry" was held at our company's headquarters. This Conference brought together key players from the pharmaceutical industry: representatives of the College of Physicians, the College of Pharmacists, representatives of the academic community, physicians, pharmacists, health professionals, representatives from medical associations, scientific institutions, regulatory institutions in the field of medicine such as National Agency of Medicines and Medical Devices, Institute of Public Health, Institute for the Control of Biological Products and Veterinary Medicines, National Sanitary Veterinary Agency, distributors of medicines) and representatives of financial and banking institutions and of the Stock Exchange Bucharest. Invitations highlighted Antibiotice's important role in the health care system in Romania and in the business environment, considering our company as a prime representative of the Romanian pharmaceutical industry.



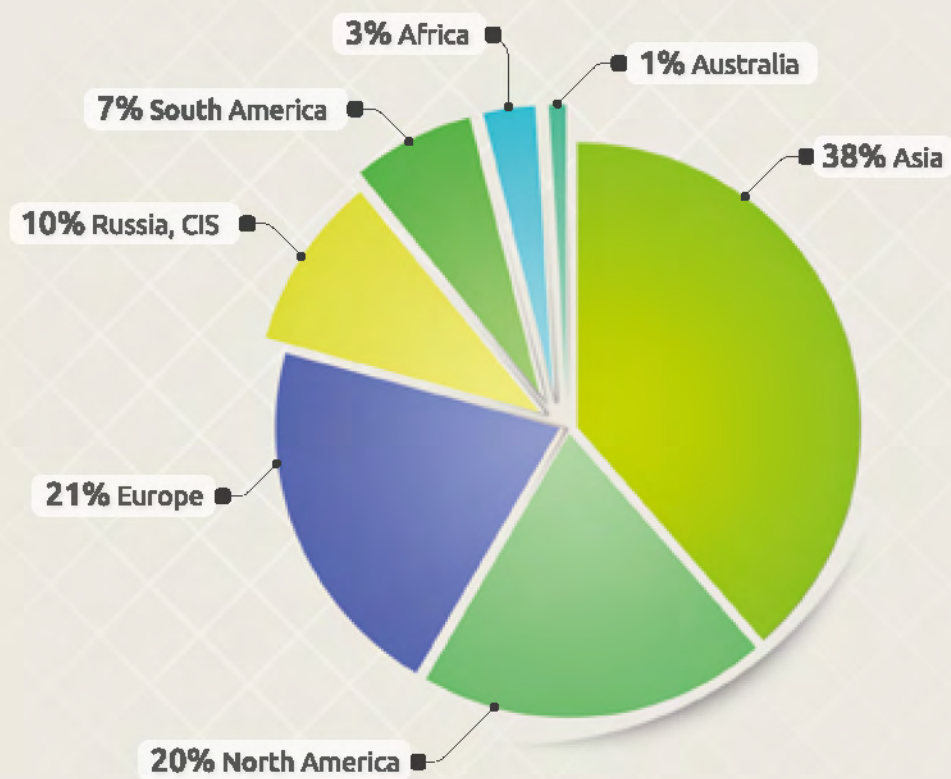
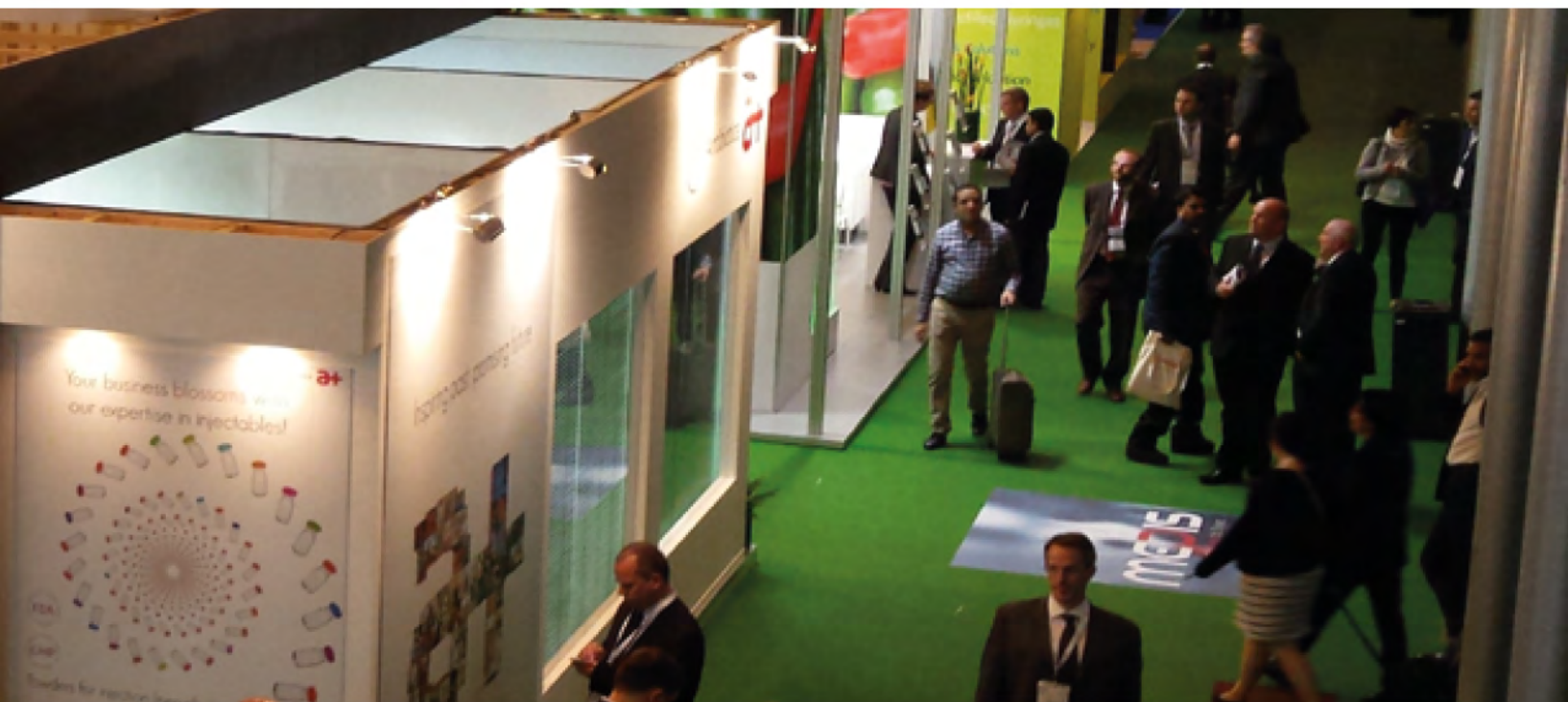


## Business development on foreign markets

Antibiotice's exports recorded USD 23 million in 2015, rising steadily in recent years from the value recorded in 2010 of USD 17,90 million.

The increase in export turnover was the result of an increase both in the sales of Nystatin and dosage forms. The export percentage in the 2015 total turnover was 28%.

Asia represents the main geographical area of the company's exports due to the large volume of deliveries of Nystatin. The following geographical areas are Europe and North America (especially the United States of America).



2015 Geographical export breakdown

## Sales of the active ingredient Nystatin, the export growth engine in 2015

2015 confirmed once again Antibiotice's leading position in the Nystatin global market. The US was the main market in which we recorded increases in the export of Nystatin. The delivered amounts tripled as compared to 2014. The US represents a strategic market for our company and the promotional efforts in 2015 resulted in attracting some important end-users in the Antibiotice portfolio. In the medium and long-term, our company's strategy for this region is to increase the market share by attracting new partners and to strengthen the traditional customer portfolio.

The main markets for Nystatin in 2015 were: Asia (China, India, Vietnam), Europe (Germany, Switzerland) and South America (Brazil, Colombia, Cuba).

Antibiotice's strategy for Nystatin aims at maintaining the world leader position and at increasing its presence on the regulated markets, especially the US and Europe. This desideratum is supported by the FDA authorization of the Biosynthesis Plant and by the Certificate of Suitability (CoS) issued by the European Directorate for the Quality of Medicines (EDQM) which allow the access to these markets. Our specialists assess also the possibility of a vertical integration through the manufacture of finished products based on Nystatin, taking into account the availability of this active ingredient and of the manufacturing capabilities for finished dosage forms.

## USA , the most important destination for the export of pharmaceutical dosage forms

The export of pharmaceutical dosage forms, another important direction of our strategy on the external plan, offers us the most significant potential for growing our presence on the external markets.

In 2015, the main destinations of the finished

product export were: North America (USA), Europe (Netherlands, Denmark), Middle East (Iraq, Vietnam) and Russia/CIS region (Moldova, Russia, Ukraine, Turkmenistan). The most significant share in the finished product export was recorded by: anti-infectives (delivered, especially, in the US market), followed by the cardiovascular, dermatological and musculoskeletal system products.

In perspective, our company has sufficient premises to sell the finished products on the regulated markets in Europe and the US, because the authorization procedure in the US market for a new finished product, Ampicillin with sulbactam 1 g and Ampicillin with sulbactam 3 g powder for solution for injection/infusion was completed in 2015.

## Quality certifications, a competitive advantage on the markets with a new, restrictive legislation

Antibiotice's strategy on the international markets consists in developing long-term partnerships, able to consolidate its position. The objectives for the finished pharmaceutical dosage forms are to increase the turnover and the volumes exported as well as their profitability in an increasingly competitive international market of generic products. Under these circumstances, the markets considered are both those regulated (USA, Europe, Australia, South Africa) and the emerging ones (Latin America, South East Asia, Middle East). Enhancing globally the regulatory framework confers a competitive advantage for Antibiotice which obtained EU GMP authorizations on all the manufacturing lines and FDA authorization for the injectable products, with the possibility to have another FDA certified manufacturing lines also.

In 2015, negotiations were initiated for developing new projects on the regulated markets (Europe, Canada) aiming especially the injectable and oral products. The commercial conditions were also negotiated for increasing the export of finished products on the US market, with the intention to increase the current market share.

New projects have been started in South East Asia, a region in which our products have favorable prospects for a long-term growth.

*The main directions of export development are:*

- *to evaluate the current partnerships and identify the possibilities of developing on the existing markets;*

- *to identify new markets and new partnerships on the current markets;*

- *to adapt the product portfolio to the requirements of the external markets and develop products with a potential success abroad;*

- *to develop strategic partnerships for developing, marketing and distributing our products.*

Because of the need for international promotion of the products, Antibiotice evaluated the opportunity to open representative offices abroad. After the offices opened in the Republic of Moldova and Serbia, our company intends to open new representative offices in the emerging markets in Latin America and South-East Asia, markets in which Antibiotice products have a significant potential for growth.

## International promotion

International promotion becomes more and more important, given the strategy for extending our presence on the external markets.

In 2015 Antibiotice participated for the fourteenth time at the Cphi Worldwide Fair held in Madrid. This fair reunited 2,500 exhibitors from 150 countries and was visited by 36,000 visitors, pharmaceutical industry professionals. Participation in the event offered our company the opportunity of meeting with the business partners for Nystatin in order to establish the future action strategies and contacting new partners to develop export, in licensing and out licensing projects.

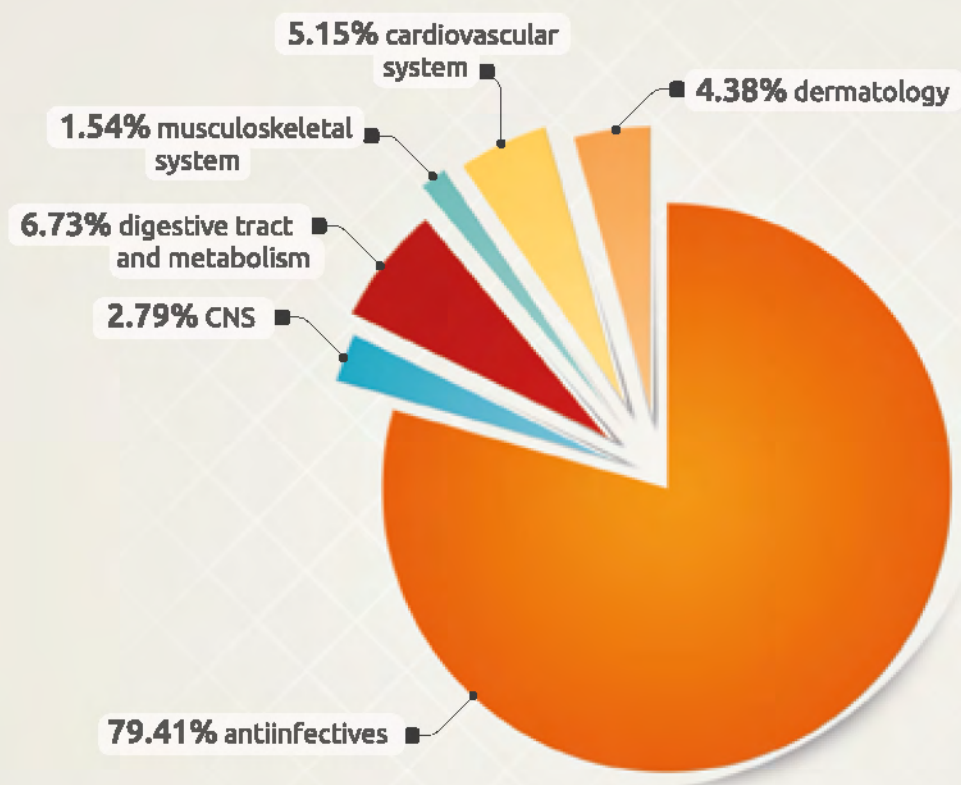
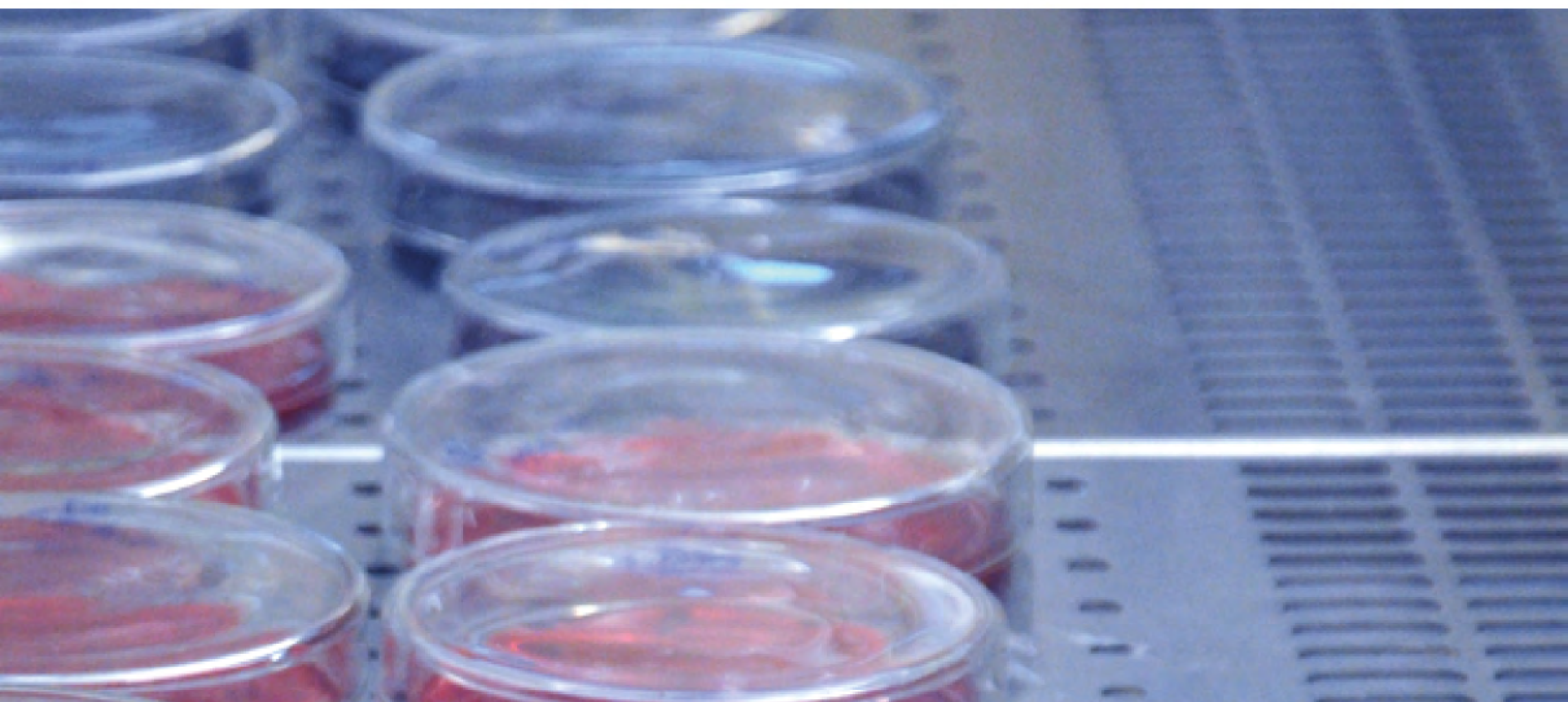
Antibiotice participated also to EuroPLX held in Athens in November 2015. EuroPLX is one of the most significant events in the field of pharmaceutical business development which offers prospects for business-to-business collaborations in the

most varied forms: in and out licensing, product development in partnership, co-marketing, etc.

A photograph showing a grid of petri dishes on a perforated metal tray. The dishes contain a red agar medium, with some showing faint bacterial growth. The lighting is bright, highlighting the texture of the agar and the metallic surface of the tray.

# Strengthening sustainable and effective partnerships

**Antibiotice has developed a complex portfolio of pharmaceutical dosage forms consisting of sterile powders for injections, capsules, tablets, topical preparations, suppositories and ovules. For supporting the manufacturing of all the pharmaceutical dosage forms, our company cooperates with other companies from various geographical areas, benefiting today by traditional partnerships which sustain Antibiotice's vision and strategy.**



Share of purchases of raw materials by therapeutic classes

A network of partners has been strengthened over time and today more than 70 % of them have been joining us for over 15 years.

A particular aspect of the pharmaceutical industry in the phase of designing the procurement chain is the need to find a balance between the suppliers' manufacturing capacity and anticipated market demand. Year after year, the importance of partnerships on the value chain increases as a result of the pharmaceutical market constraints, new regulations in the manufacture of medicinal products and as a consequence of the business internationalization which leads to the company's presence in more and more markets.

Ability to locate potential bottlenecks in the acquisitions channel, optimizing the purchase prices and ensuring manufacturing sources according to the GMP legislation are important steps in shaping an efficient and transparent acquisition activity. To accomplish this, the team responsible for the procurement activity and for value chain partnerships aims to:

- Manage the stocks, without creating undue financial fixed assets, but ensuring buffer stocks for emergency situations;
- Estimate correctly and inform the business partners;
- Manage the orders;
- Ensure the procurement visibility during transport;
- Communicate effectively with the business partners for sustaining the annual and multi-annual strategy of the company.

Through a direct communication based on transparency principles, Antibiotice aims to develop sustainable partnerships for consolidating our suppliers' trust, protecting their interests in parallel with their involvement in decisions on approaching the market and streamlining the operational process.

## Compliance with the regulations and legislation in the medicine manufacturing

Purchasing the raw materials for a medicine involves adopting measures by which Antibiotice ensures itself that the GMP as well as the distribution and transport requirements are met.

In recent years, the manufacture of raw materials have become more rigorous, aiming at complying to the GMP rules along the whole process. Meeting the transport and storage requirements, visibility over the conditions in which a raw material passes from the producer to the consumer have also become challenges for the pharmaceutical producers. In 2015, our procurement staff aimed at meeting the transport requirements and optimizing the costs in order to ensure a balance in the quality-cost ratio.

To minimize the influence of international changes but also to get a fair quality-price ratio, Antibiotice aims at a balanced geographical distribution of the partnerships in the value chain.





## Compliance with the company's strategy

Dynamics of the product portfolio's renewal and the opening of our company towards the international market involves permanently adapting the material base required for the manufacturing process, identifying stable raw material sources, securing purchases by authorizing at least two sources for each raw material.

Besides the traditional partnerships which confer stability, predictability and performance and help adapting fast to the changes in the market demand, Antibiotice has been continuously investing in prospecting the market and identifying new suppliers as sustainable alternatives for strategic raw materials or for new products.

All these efforts involve a good knowledge of the external partners' capabilities but also a continuous cooperation with the Quality Assurance, Quality Control and all the departments responsible for production, research and sales.

An important component of the acquisition process is represented, since 2006, by the in-licensing or contract manufacturing cooperations for the finished products. This type of business allowed Antibiotice to develop its product portfolio in therapeutic areas involving either a new specialization, different manufacturing lines or a fast exploitation of some favourable circumstances in the market such as expiry of patents, consumption niches or new government programmes.

## Procurement partnerships in the domestic market

The procurement process from the domestic market is the result of some interdepartmental efforts, starting from the production planning to the transport of raw materials and other materials necessary for the manufacturing process.

Harmonizing the commercial conditions imposed by the specifics of the pharmaceutical industry with the current trends in the domestic market is the main direction of Antibiotice's trade policy.

Reduction in the operating costs for increasing the return on operational activities has been a continuous preoccupation. In this regard, a reorganization and resizing plan was launched to make the activities more profitable, aiming especially at the most competitive price, greatest possible supplier credit correlated with the financing capacity and with the recovery of receivables from the market, without compromising the quality standards.

## Partnerships for distributing our products in the domestic market

The main objective in 2015 was to consolidate our partnerships with the main distributors with national coverage, resulting in significant sales increases.

Antibiotice's varied portfolio designed both for the medical units and for pharmacies (retail) requires powerful partnerships with distributors with national coverage. These distributors represent Antibiotice both in tenders or selection of offers organized by the health units with beds and in the open circuit pharmacies through the sales and tele-sales teams.

The main purpose of these distributors is to ensure, through commercial and competitive practices, a continuous and active presence of Antibiotice products both in the independent pharmacies (community ones) and in the national chain and small chain pharmacies.

The partnership between Antibiotice and distributors aims at fulfilling the common objective of being present in the domestic pharmaceutical market, the interest of both parts being to identify the best means of supporting the promotion and selling process as well as to optimize the delivery-/payment terms.

## Foreign market partnerships

Numerous partnerships between companies of diverse complexity are set up in the pharmaceutical market. In addition to acquisitions and merg

ers, the companies are active in the product licensing, research project /clinical study cooperations, acquisitions or additions to the portfolio. The goals of these partnerships are to increase the companies' revenues and profits by accessing new markets, develop their portfolio and access new technologies or therapeutical classes.

In this context, Antibiotice plans to expand its range of partnerships turning them into an instrument for speeding the internationalization of the business.

## Partnerships for exporting active ingredients

As regards the active ingredients (Nystatin), Antibiotice plans to consolidate its world leader position through some long-term partnerships with the end-users. Transparent partnerships allow an efficient and controlled distribution of the product for our company while the end-users have the guarantee that they receive from Antibiotice the technical & documentation support and the best trading conditions. Providing technical & documentation support and delivering the product under the required terms and conditions are essential in developing long-term business relations.

## Partnerships for exporting finished products

As concerns the finished product export, Antibiotice has developed both distribution partnerships and *out-licensing and contract manufacturing* partnerships. The complex partnerships aiming at developing products (research, formulation, clinical studies, bioequivalence studies, Marketing Authorizations in the targeted countries) and at selling them in the external markets are significantly important.

Export of Antibiotice products in various markets requires concluding distribution agreements by which our company should ensure that the local distributor has the ability to register and market its products, has the possibility to maxi-

mize all the selling channels and can elaborate long-term development strategies.

At the same time, for the highly complex external markets (especially the developed ones) Antibiotice takes into account out-licensing partnerships, through which Antibiotice products offered under license will be subsequently sold in other countries under the partners' brands. Licensing agreements allow the fast access to the external markets because our partners have a good reputation and the necessary experience in marketing and trading the products in the markets in question.

In the recent years, the complex product development and trading agreements with external partners have become more and more important. These projects aim the development of formulas, bioequivalence studies/clinical studies, compilation of files and their submission to the registration authorities and subsequently their launching in the market. We talk about complex, long-term partnerships involving both partners in the financial efforts for developing these projects and more advantages offered by each partner: the company's research and manufacturing capabilities and partners' capacity to efficiently launch the developed products in the international markets thanks to their experience and sales force.



# The Human Resources Policy

## Adapting the personnel's structure for reaching the goals

In the light of the objectives set in the 2014-2016 business plan at company level, the year 2015 meant for the human resources activity a focus on ensuring an optimal number and structure of personnel in all the activity fields and maintain stability and increase the engagement of employees.

Attracting and hiring a number of 32 specialized people had as a priority activity areas such as: promotion, sales on the domestic market and the international market, production, intellectual property, pharmaceutical development and internal audit. These fields are in close correlation with the development strategy of the company on the medium and long term.

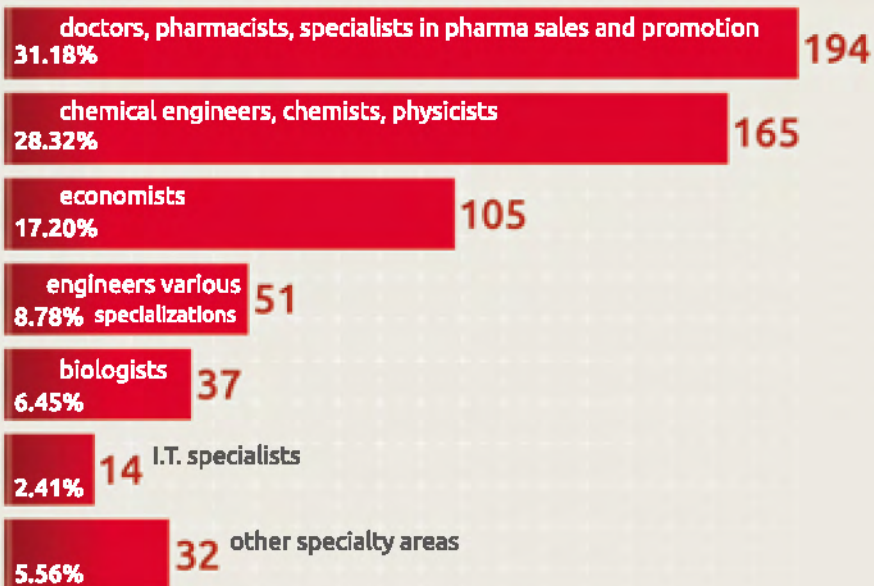
## The personnel structure on 31.12.2015:

The average number of employees is 1458, of which:

- higher education personnel = 598 employees representing 41% of the total staff;
- secondary education personnel = 860 employees representing 59% of the total staff.



**Higher  
education  
personnel**  
**598  
total**



**The structure of higher education personnel on 31.12.2015**

## Skills development programs for employees

### Continuous training programs

The trainings planned for 2015 for the Antibiotice employees covered topics in the fields of quality assurance and control, serialization and data integrity, pharmacovigilance and Regulatory Affairs, intellectual property, production planning and process improvement. Also, some employees have taken courses on contract conditions and payment management in international trade, coaching techniques, skills development on portfolio and territory management.

### Summer School a+, our company's recruitment pool

The "Summer School a+" project intended for attracting young professionals in the fields of pharmacy, biology, chemistry and chemical engineering reached its sixth edition in 2015.

Through this project - which became well known in academia and among university students in final years of Iași - a total of 45 participants received training from specialized trainers of our company.

The topics of the "Summer School a+" were: the quality assurance system in a pharmaceutical company, the pharmacovigilance, the Regulatory Affairs activity, specific laboratory techniques in Quality Control, research and pharmaceutical formulation, technology and equipment in the pharmaceutical industry, etc.

### Partnerships with the academia

During the year 2015 due to collaborative partnerships concluded with "Al. I. Cuza" University of Iași, the „Gr.T.Popa" Medicine and Pharmacy University of Iași and the "Gh. Asachi" Technical University conditions were ensured for the conduct of internships and study visits for 100 students majoring in pharmacy, chemical engineering and

biology.

Also, within the partnership "Internships and occupational guidance for a successful career" concluded with the "Petru Poni" Technology High-School a total of 22 9th grade and 12th grade students conducted their internships in the company, in the specialty of chemical laboratory technician / chemical operator in the pharmaceutical and cosmetics industry.

Through the project "A different type of school program" Antibiotice intended to open its doors to over 300 students from secondary education institutions from Iași to introduce them to the history and work of one of the most famous landmarks in the County Iași industry.

## Raising awareness and involvement at all levels of the organizational structure

### The system of management by objectives (MBO) in 2015

For the year 2015 in the MBO system a number of 185 employees of all company structures were included; they were in management and execution positions.

In formulating individual goals, they were intended to be consistent with the mission and vision of the company, to derive from the strategic orientation of Antibiotice for the period 2014 - 2016 and to boost the capitalization of opportunities while reducing the negative impact of the risks and limitations specific to the changing environment of the drug market.

## Improving the organizational climate and orienting the organizational culture towards innovation and performance

### The project "ideas are free of charge"

Started in 2013, the project "ideas are free of charge" has continued this year with the establishment of the "Club of ideas" in which meetings were held to debate proposals to improve the activity and innovation in a framework that brought together employees from different organizational structures of the company through voluntary participation.

## Recognition and appreciation

The celebration of 60 years of existence of the company has occasioned this year on December 11 the honoring of the most valuable of company employees.

On this occasion, homage medals were awarded to 60 employees for their involvement in the company's development over the years and 60 employees were awarded for the results of their activity in the year 2015.



# Risk



Risk management aims at securing sustainability in the medium and long term and at reducing uncertainty associated with Antibiotice's strategic and financial objectives.

The risk management process ensures the identification, analysis, assessment and management of all the risks in order to minimize their effects. Managing and reducing the identified and assessed risks take place at all the organizational levels of the company.

Risk management consists in implementing some proactive countermeasures to reduce the probability of occurrence of risks but also some reactive countermeasures for reducing the risk impact. Antibiotice has been continuously reassessing its existing risk portfolio, identifying new exposures and applying, when necessary, the most effective countermeasures for diminishing them.

The main categories of risks which may arise in our company's activity are:

financial  
economic  
technological  
marketing  
image  
legislative



# management



## Currency risk

Currency risk, a component of the financial risks, occurs frequently in the current conditions of the market economy in which monetary rates fluctuate under the rule of supply and demand.

Exchange rate fluctuations are reflected both in the costs of imported raw materials and in the selling prices of finished products for export. Suppliers from whom Antibiotice purchases raw materials for the production of medicines must have quality documents specified in the European medicine registration regulations. Our company cannot greatly restrict the purchases from third countries. The following measures are taken into account to limit the currency risk:

- synchronization between import and export, by correlating the payment and collection terms and by correlating the exchange shares;
- anticipation or delay in payment or in cashing by appropriately fixing the maturity date and by introducing some price margins correlated with the forecasts on the evolution of the paying currency;
- coverage of the gap between collections and payments from credits in the paying currency.

## Liquidity risk

Liquidity risk arises from the failure of the company to honour at any time the short-term payment obligations.

Circumstances of occurring the liquidity risk:

- Collection of receivables at maturities exceeding 300 days;
- Increase of taxation /lack of predictability (claw-back tax);
- Decrease in prices for certain generic drugs;
- Insolvency of some customers;

The following measures are taken into account to limit the liquidity risk:

- Business internationalization
- A more accurate estimation and correlation between payments and receipts;
- Monitoring the receivables and debts;
- Negotiations with our suppliers for extending the payment terms;
- Covering the gap between collections and payments from credits.

## Commercial risk (non-payment risk)

Commercial risk is defined as the risk which results in financial loss or in failures in expected profit due to lack of financial liquidities of the debtor and to failure to pay the obligations when they are due.

Circumstances of occurring the non-payment risk:

- Long-terms of payment;
- Insolvency of some pharmacies and distributors.

The following measures were taken to minimise the non-collecting risk:

- Assessing the creditworthiness of commercial partners through a full check, before concluding the contract;
- Monitoring the receivables through a permanent control and assessment of risks;
- Developing a relationship of loyalty with the clients through regular meetings for knowing them and for approaching a constructive attitude;
- Concluding some protocols for scheduling the payments;
- Concluding guarantee contracts;
- Establishing expense provisions for covering the non-payment risk

## Economic risk

Out of the economic risk category, our company faces the risk of increasing the price of raw materials due to reducing the number of manufacturers, implementing the GMP requirements, applying the environment policy and tightening inspections conducted by the authorities from Europe and the United States.

Our company reduces that risk by a permanent investment to authorize at least two sources for all the raw materials, by signing supply agreements with the limitation to a maximum price threshold during the contract, by introducing new products in the portfolio in order to reduce the impact of losing some old generation products due to the loss of raw material source.

This category includes also losing some markets (contracts) or reducing the future access

possibilities, affecting in this way the strategic forecasts related to the export of finished products.

Circumstances of occurring this risk are:

- Changing the legislative conditions in the local market;
- Price drop of the competing products on the market which lead to a non-competitive position;
- Decrease in the partners' interest for Antibiotic products following the entry of new products on the market;
- Protectionist legislation regarding the access of medicines on the market, conflict areas (Egypt, Syria, Afghanistan), the difficult situation in Ukraine and Russia.

To manage this risk the followings are taken into account:

- Continuous monitoring of trends in the international commercial policy;
- Adopting a diversified export strategy;
- Differentiated approach of developed and developing markets;
- Conclusion of strategic partnerships with leading companies in the international markets;
- Building a business relationship based on trust and loyalty with the local partners;
- Ensuring quality conditions and maintaining the international certifications in accordance with the latest standards;
- Anticipating the legislative conditions to focus the sales to other markets;
- Focus towards partnerships with local pharmaceutical companies which trade under their own brands the products manufactured by Antibiotic;
- Establishing new representative offices abroad.

## Legislative risk

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

Pharmaceutical market is a regulated market, with clear legislative provisions developed for

monitoring the quality and effectiveness of therapeutic products, as well as for avoiding counterfeiting.

Meeting these provisions is reflected both in additional costs for updating the documentation to the latest quality standards, in the influences on maximal selling prices and in delays in launching the products in the market.

Our company's strategy for managing these risks involves a continuous preoccupation for obtaining the international certifications of the manufacturing lines, updating the authorization documentation for the products, bioequivalence and stability studies and a continuous monitoring of the legislative changes at the international level.

Difficulties in attaining the turnover is another risk our company faces.

Among the causes which generate this risk, we can specify: reduction in the prices offered by the company's competitors in tenders, decreasing the hospital budgets, rationalisation in consumption of medicines, reduction in the sale of certain products in the pharmacy chains, emergence of some direct and indirect competitors on the market, delays in introducing the new drugs in the portfolio, setting the price for the generic products at 65% of the price of the original medicine, decreases in price for certain generics because of the harmonization of the pricing policy in the 12 reference states and insolvency of some partners. To manage this risk the following measures are taken into account:

- Adapting the commercial and promotion policy while maintaining profitability of products;
- Permanent monitoring of distributors;
- Refocusing towards other clients;
- Monitoring the commercial policy of the competitors;
- Directing the sales towards strategic and traditional products unaffected by the price declines;
- Partnerships with independent and small-chain pharmacies for promoting the entire product portfolio.

## Reputational risk

The image risk is defined as the current or future risk of negative impact on profit and capital caused by the unfavorable perception over the company's image.

The following measures are taken into account to efficiently manage the events which may generate the image risk:

- Monitoring the image of the company in mass-media for identifying any rumors which could generate image risks;
- Periodical press releases with positive information, transparency and a good relationship with the media.

A series of risks that can not be controlled were identified within the risk assessment process:

- Risk of natural disasters (earthquake, flood, fire, etc.)
- Risk of inter-ethnic conflicts or wars;
- Risk of economic, social and legislative instability.

Antibiotice will apply all the measures to reduce these risks, by specific plans:

- Evacuation plan in case of emergency situations;
- Intervention plan in case of natural disasters (earthquake, flood);
- Intervention plan in case of fire;
- Policy for preventing the accidents with dangerous substances (acetone, methanol).

All these plans aim at protecting our employees, property and environment.

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

# Corporate



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

Antibiotice SA believes that the corporate governance is an important tool for achieving performance in terms of sustainable development ensuring the accuracy and transparency in the company's decision making process with equal access for all shareholders to relevant information about the company. The system of governance is in accordance with Law no. 297/2004 amended supplemented by Law no. GEO 10/2015 and GEO 90/2014 and the CNVM regulations issued in its application of Law no. 31/1990, republished, with all subsequent amendments, the Regulation no. 6/2009, of the BSE Code, the BSE Corporate Governance Code and the company's Articles of Association.

The strength of the Antibiotice team is demonstrated by the company's strategic guidance and readiness with which it is

# governance



able to react by developing responsible and transparent business practices. This applies to both the management team and the operational teams and the entire staff of the company who manage to achieve a balance between compliance and performance.

In 2015 consistency was proved regarding the strategic directions, accompanied by adequate investment programs. This was achieved by applying the principles of good corporate governance, which has helped to harness the full potential of employees to implement and maintain high standards in all company activities.

Structures underlying the governance system at Antibiotice:

- Board of Directors
- Advisory Boards
- Executive Management
- Code of Ethics

## The Code of Corporate Governance

The Code of Corporate Governance of Antibiotice took over the principles and recommendations of the Bucharest Stock Exchange and it is the instrument by which Antibiotice implements these principles and recommendations observing the rules of corporate governance.

The purpose of the Corporate Governance Code is to create the framework necessary for establishing strong relationships with our company's shareholders and other interest holders, as well as an effective and transparent communication based upon trust.

The Code of Corporate Governance of Antibiotice SA is structured in four chapters:

**Chapter I - The Responsibilities of the Board of Directors**

**Chapter II - The Risk Management and Internal Control system**

**Chapter III - The fair reward and motivation**

**Chapter IV - The relationships with the investors**

It also has two annexes, namely:

**Annex I - Management Board Regulations**

**Annex II - Antibiotice Administrators Evaluation Regulation**

In **Chapter I - The responsibilities of the Board of Directors** the role of this body is defined alongside the establishment of the guidelines in terms of competence, experience, knowledge and the independence of its members, enabling them to effectively perform their specific duties and responsibilities.

**Chapter II - The Risk Management and Internal Control system** shows that the company's activity is subject to supervision exercised by certain risk management and internal control systems set up for this purpose. Also, internal audits are organized in order to independently and periodically assess the safety and efficiency of the risk management and internal control systems.

**Chapter III - The fair reward and motivation** establishes the general principles and conditions that are the basis of the method for establishing

the level of remuneration of the members of the Board of Directors and of the company management.

**Chapter IV - The relationships with the investors** stipulates that Antibiotice must make constant efforts to provide its shareholders with updated information on events of interest to them (e.g.: the General Meeting of Shareholders, the payment of dividends, etc.).

In conclusion, the Code of Corporate Governance of Antibiotice and its annexes outlines the general framework under which the Board of Directors operates, complying with the rules and principles of corporate governance set by the BSE in order to create an attractive capital market, based on the best practices, transparency and trust.

## The Board of Directors

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

The Board of Directors seeks to ensure that its own decisions, those of the company's management, the General Meeting of Shareholders as well as the internal regulations comply with the legal requirements and properly are implemented. The Board is responsible for monitoring the company's management on behalf of shareholders.

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

During 2015, the Board was met in 12 sessions, recording a turnout of 100% each time and adopted decisions which have allowed to perform their duties in an effective and efficient manner.

Thus on the monthly meetings the Board has discussed in detail the financial results in the reporting period and cumulatively since the beginning of the year as well as the economic performance relative to the budget and the same period last year. The Council requested, as appropriate, detailed explanations of the executive management in connection with the plans to increase production efficiency, the investment plans, the provisions made, the liquidity management, the operational profitability and of the overall activity. After the detailed analysis of the results for the period, the Council decided the approval thereof for publication and submission to the Bucharest Stock Exchange and the Financial Supervision Authority falling each time in the Financial Communication Calendar.

The 5 members of the Council shall ensure the effectiveness of the ability to monitor, analyze and evaluate the work of directors and the fair treatment of shareholders.



## The structure of the Board of Directors of Antibiotice SA on 31 December 2015

**avor Ionuț-Sebastian, 40 years old**  
**Chairman of the Board and representative of the Ministry of Health**

At the Ordinary General Meeting of Shareholders of April 30 2015 Mr. Iavor was elected to the Board of Directors of the company and then appointed by the Board members as Chairman.

Mr. Ionuț Sebastian Iavor is currently General Manager of the General Directorate of Human Resources and Legal Department within the Ministry of Health.

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

**Ec. Ioan Nani, 56 years old**  
**Vice Chairman of the Board and CEO**

At the Ordinary General Meeting of Shareholders of April 26, 2012, Mr. Nani was reconfirmed as a member of the Board of Directors, for a period of four years; Mr. Nani was appointed then by the members of the Board as Vice-President. Mr. Nani is an economist specialized in management, a chartered accountant and a member of the Board since 2009 as well as CEO (1998-2008 and 2009 - present day).

**Number of Antibiotice SA shares owned – 1.513\***

**Dr. Adela-Petrușia Neagoe, 57 years old**  
**Member of the Board and representative of the Ministry of Health**

At the Ordinary General Meeting of Shareholders of March 20, 2014 Mrs. Neagoe was appointed a member of the Board of Directors for a period of four years.

Mrs. Neagoe is a Doctor of medical sciences, a primary doctor in the specialty of pediatrics, a primary doctor in the specialty of Public Health and Health Management. Mrs. Neagoe is a member of the Board since March 20, 2014 and a Deputy Secretary General in the Ministry of Health.

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

**Ec. Nicolae Stoian, 59 years old**  
**Member of the Board and representative of the SIF Oltenia shareholding and other corporate shareholders**

At the Ordinary General Meeting of Shareholders of April 26 2012, Mr. Stoian was elected as a member of the Board of Directors for a period of four years.

Mr. Stoian is a chartered accountant, a tax consultant and financial auditor, as well as a representative of the Internal Control Department with SIF Oltenia.

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

**Eng. Gabriela Ilie, 66 years old**  
**Member of the Board of Directors and representative of SIF Oltenia shareholder and other corporate shareholders**

Mrs. Ilie was reconfirmed in 2005, 2008 and then at the Ordinary General Meeting of Shareholders of April 26 2012 for another four years.

Mrs. Ilie is a chemical engineer and former director of SIF Oltenia and is a member of the Board since 2004. Mrs. Ilie is currently retired.

**Number of Antibiotice SA shares owned – 14.894\***

*\*The number of Antibiotice shares (ATB) held on September 15 2015 according to the latest database held by Antibiotice for the year 2015.*

## The advisory committees

During the year 2015, the specialized advisory committees had the following membership:

- the Audit Committee: Mr. Ionuț Sebastian Iavor and Mr. Nicolae Stoian;
- the Nomination and Remuneration Committee: Mrs. Gabriela Ilie and Mrs. Adela-Petrușia Neagoe
- the Trade policies Committee: Mrs. Adela-Neagoe and Mr. Nicolae Stoian.

The advisory committees have conducted investigations, analyzes and developed recommendations for the Board of Directors in specific areas and submitted periodic reports on their activity.



## The executive leadership

Antibiotice is represented by the General Manager who signs employment documents to third parties and legal documents (according to Art. 17, Chap. V, the Statute company Antibiotice SA).

The Board of Directors retains the duty of representing the company in relationship with the directors whom they have appointed.

The executive management of the company is ensured by new directors, one of whom is the CEO who is also the Vice Chairman of the Board and eight specialty executives.

## Membership of the Executive Management of Antibiotice on December 31, 2015

**Ec. Ioan Nani, 56 years old**

**CEO and Vice Chairman of the Board**

Mr. Nani has graduated from the Faculty of Economics, the "Alexandru Ioan Cuza" University of Iași. Mr. Nani is an economist specializing in management and chartered accountant.

Mr. Nani began working as an economist at Antibiotice in 1987. Between 1991 and 1993 he was a financial control inspector with the General Directorate of Public Finance Iași and then with the Court of Auditors of Romania. In 1994 Mr. Nani returns to Antibiotice as a financial executive and in 1998 he becomes CEO. In February 2009 Mr. Nani is appointed Deputy Chairman of the Authority for State Assets Recovery (AVAS), and in

June the same year he becomes CEO of the Antibiotice Company.

He has been holding the position of CEO since 2009.

**Number of Antibiotice SA shares owned – 1.513\***

**Eng. Cornelia Moraru, 50 years old**

**Technical and Production Director**

Mrs. Moraru graduated from the Faculty of Chemical Technology, the Technical University "Gheorghe Asachi". After graduation Mrs. Moraru worked as a chemical engineer at the Fălticeni Chemical Factory. Mrs. Moraru has been working at Antibiotice since 1990. Until 1998 Mrs. Moraru has worked at the Penicillin II Plant and then at

Biosynthesis compartment for a year. From July 1999 until January 2001 Mrs. Moraru has worked as a biosynthesis technologist at the Penicillin II Plant. In January 2001 she becomes Head of the Tablets Plant and in May 2003 Mrs. Moraru was appointed Director of the Pharmaceutical Division.

Mrs. Moraru has been holding the position of Technical and Production Director since 2005.

**Number of Antibiotice SA shares owned – 1.513\***

**Ec. Paula Luminița Coman, 48 years old**

**Economic Director**

Mrs. Coman has graduated from the Faculty of Economics and Business Administration, the "Alexandru Ioan Cuza" University of Iași and has been a Chartered Accountant since 2006 and a tax consultant since 2007.

After graduation Mrs. Coman has worked as an economist at the County Iași Tourism Office. Mrs. Coman has been working at Antibiotice SA since 1991 as an economist in the Rates Efficiency Office. In 1998 Mrs. Coman has become Head of the Economic Analysis Compartment and in 2003 Head of the Financial-Accounting Department.

Mrs. Coman has been holding the position of Economic Manager since 2011.

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

**Ec. Vasile Chebac, 61 years old**

**Commercial and Logistics Director**

Mr. Chebac has graduated from the Faculty of Economics, the "Alexandru Ioan Cuza" University, has been an active member of the Body of Chartered Accountants, Iași Branch since 1993, a financial auditor and a member of the Chamber of Auditors of Romania since 2008. Mr. Chebac has started working at Antibiotice SA in 1972. In 1987 Mr. Chebac became an economist at the Planning and Development Department within the Investment Compartment. From February 1991 until July 1993 Mr. Chebac has worked as a financial controller at the General Directorate of Public Finance Iași, and in July 1993 Mr. Chebac became a financial auditor at the Court of Auditors Iași. In January 1998 Mr. Chebac was appointed Chief Commissioner at the Financial Guard Iași. In September 2001 Mr. Chebac returns to Antibiotice to the position of Chief Commercial Officer and General Services.

Mr. Chebac has been holding the position of Commercial and Logistics Director since 2005.

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

**Eng. Eugen Florin Osadeț, 60 years old**  
**Engineering and Investment Director**

Mr. Osadeț is a graduate of the "Gheorghe Asachi" Technical University of Iași, the Faculty of Mechanical Engineering. In 2000 Mr. Osadeț is granted the Master's Degree in Management and Business Administration at the same university.

Mr. Osadeț has been working at Antibiotice SA since 1980 working as a mechanical engineer in the industrial refrigeration team as a thermal power dispatcher. In 1997 Mr. Osadeț became the Head of the Thermal Power workshop.

Mr. Osadeț has been holding the position of Engineering and Investment Director since 2000.  
**Number of Antibiotice SA shares owned – 1.511\***

**Eng. Cristina Lavinia Dimitriu, 58 years old**  
**Quality Director**

Mrs. Dimitriu, a graduate of the "Gheorghe Asachi" Technical University of Iași, the Faculty of Chemical Technology, is granted in 2000 a Master's Degree in Management and Business Administration by the same university. Mrs. Dimitriu has been the holder of a Master's Degree Diploma in Management and Marketing granted by the Faculty of Pharmacy, the "Grigore T. Popa" University of Medicine and Pharmacy since 2007. During the same year, Mrs. Dimitriu becomes a PhD student of the Faculty of Pharmacy of Iași.

After graduation Mrs. Dimitriu worked as a chemical engineer at the Făgăraș Chemical Plant. Mrs. Dimitriu has been working at Antibiotice SA since 1987, at the Lysine -Biosynthesis Plant. In 1990 Mrs. Dimitriu has become a Production Manager at the Parenteral Plant and in 2000 she has held the position of Quality Control Manager for Physico-chemical and Microbiological Analysis. Since 2007 Mrs. Dimitriu has become a qualified person to the manufacture / import of medicinal products for human use and a Management Representative for the Integrated Management System.

Mrs. Dimitriu has been holding the position of Quality Manager since 2003.

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

**Ec. Gica Rusu, 52 years old**  
**Human Resources Director**

Mrs. Rusu, a graduate of the "Alexandru Ioan Cuza" University of Iași, the Faculty of Economics, was granted in 2003 a master's degree in manage-

ment and business administration by the same university.

Mrs. Rusu has been working at Antibiotice since 1981. In 1986 Mrs. Rusu was an economist at the Penicillin Plant and in 1996 was working in the Financial Department. In 1999 Mrs. Rusu has become the Head of the Human Resources Department.

Mrs. Rusu has been the Human Resources Director since 2004.

**Number of Antibiotice SA shares owned – 1.510\***

**Ec. Ovidiu Bățaga, 38 years old**  
**Domestic sales and marketing director**

Mr. Bățaga, a graduate of the Faculty of Economics and Business Administration (FEAA), the "Alexandru Ioan Cuza" University of Iași holds three titles of Masters in Financial Management (awarded by the same university in 2001), Pharmaceutical Marketing (from the "Grigore T. Popa" University of Medicine and Pharmacy in 2003) and Project Management (awarded by the "Gheorghe Asachi" Technical University in 2007).

After graduation Mr. Bățaga worked as a junior in the Currency and Credit Chair, Finance specialty, within the FEAA. Mr. Bățaga has been working at Antibiotice SA since February 2001 as an economist in the Economic Analysis, Accounting and Marketing Department. In January 2006 Mr. Bățaga was appointed Head of Market Analysis and Strategic Planning Department.

Mr. Bățaga has been the Domestic Sales and Marketing Director since 2010.

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

**Dr. Mihaela Moșneguțu, 46 years old**  
**Medical Director**

A graduate of the Faculty of Medicine, the "Grigore T. Popa" University of Medicine and Pharmacy, Dr. Moșneguțu is a specialist in family medicine.

Dr. Moșneguțu began work as a doctor in Iași. Dr. Moșneguțu has been working at Antibiotice since 2000. In 2000 she was working at the Promotion Office and in 2001 Dr. Moșneguțu becomes the Head thereof. Dr. Moșneguțu became the Head of the Pharmacovigilance and Medical Consultancy Department in 2005 and in 2009 she was appointed Medical and Retail Promotion Manager.

Dr. Moşneguţu has been Medical Director since 2011.

Number of Antibiotice SA shares owned – 0\*

*\*Number of Antibiotice shares (ATB) owned on September 15, 2015 according to the latest database held by Antibiotice in 2015.*

## The Code of Ethics

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

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

The Code is a set of rules under which the company was developed, rules of ethical behavior in business and how to prevent illegal actions that might arise during the course of affairs within the company. The Code is binding and applies to all structures and activities of the company.

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

The Code of Ethics is presented in detail on the website of the company ([www.antibiotice.ro/-Investitori/Guvernanta Corporativa/Documente de referinta /Cod de etica](http://www.antibiotice.ro/-Investitori/Guvernanta_Corporativa/Documente_de_referinta/Cod_de_etica)).

## The Code of Good Practice for the promotion of medicinal products on prescription and for the interactions with healthcare professionals

Within Antibiotice starting January 1, 2015 the Code of Good Practice for the promotion of medicinal products on prescription and for the interactions with healthcare professionals entered into force, developed by the specialists from the company and approved by the Board of Directors

of the company.

The new Code constitutes, together with the Code of Ethics and the Domestic Rules, a support for the legal and moral conduct of the promotional activities of the company representatives. Also, this code sets the principles and rules to be observed by Antibiotice medical and sales representatives in promotional activity and the interactions with physicians and pharmacists.

The Code of Practice reflects the requirements of the Codes of the European Federation of Pharmaceutical Industries and Associations, the Romanian Association of International Medicine Manufacturers, the Manufacturers Association of Generic Medicines in Romania as well as the European Directives on human medicines, which are consistent with the recent changes in laws regulating the advertising, the public information, the transparency and the reporting obligations.

## The rights of holders of financial instruments

The corporate governance framework partially adopted and applied:

- protects the rights of shareholders,
- ensure the fair treatment of all shareholders,
- recognizes the role of third parties with interests in the company,
- ensure information and transparency,
- ensures the Board's accountability to the company and the shareholders.

On the company's website at the address [www.antibiotice.ro/investitori/informatii actionari](http://www.antibiotice.ro/investitori/informatii_actionari), there is a section dedicated to shareholders, in which one can access and download documents related to the General Meetings of Shareholders: procedures for access to and participation in meetings, the convener, the additions to the agenda, information materials, special proxies for representation forms for voting by correspondence, draft decisions, resolutions, voting results, etc.

The company provides to all those interested the periodic and annual financial statements prepared in accordance with law. Also, the company complies with all the disclosure requirements under the companies' law and the capital market.

Within the company there is a specialized structure in the relation to existing and potential investors, called Investor Relations, whose main role is ensuring a good communication with the company's shareholders. The contact persons appointed to maintain the relationship with the investors treat with maximum efficiency the shareholders requests and facilitate the dialogue with the management of the company.

The company creates and develops an appropriate policy to promote an effective communication with investors and shareholders.

## The General Meeting of Shareholders

The General Meeting of Shareholders (GMS) is the highest decision-making body of the company, where shareholders participate directly and make decisions. Among other duties, the GMS decide on the distribution of profit, elect the Board of Directors, appoint auditors and establish the remuneration of the Board of Directors.

During 2015, the Board convened an Ordinary General Meeting of Shareholders and an Extraordinary General Meeting of Shareholders, on April 30, 2015, and an Ordinary General Meeting and an Extraordinary General Meeting on August 13, 2015. All necessary documents relating to the smooth conduct of the General Meetings were published on due time and as required by the law.

Within the Ordinary General Meeting of Shareholders on April 30, 2015 changing the composition of the Board was approved, by the dismissal of Mr. Valentin Radu as a result of his retirement and the election of Mr. Ionut Sebastian Iavor.

Also, the company's financial results for 2014 were approved; these results were drafted in accordance with the Order of the Minister of Public Finance no. 881/ 25.06.2012, the Order of the Minister of Public Finance No.1286 / 2012 for the approval of accounting regulations in accordance with the international financial reporting standards applicable to companies whose securities are admitted to trading on a regulated market,

the Order of the Minister of Public Finance no.1690 / 2012 on amending and supplementing certain accounting regulations, the Order of the Minister of Public Finance no. 65/2015 on the main aspects of preparing and submitting the annual financial statements and the annual accounting reports of economic operators to the local offices of the Ministry of Public Finance.

During the same meeting the following decisions were taken:

- The approval of the allocation of net profit for the year 2014 worth 31.138.739 lei, the setting of the gross dividend per share of 0.02345571 lei and the payment of dividends as of 01.10.2015;
- The approval of the discharge from administration for the activity during the financial year 2014, based upon the reports submitted;
- The approval of the Revenues and Expenditures Budget for 2015;
- The approval of the degree of achievement of the objectives and the performance criteria for the year 2014 for members of the Board of Directors;
- The approval of the extension of the audit contract with the "B.D.O. Audit" SRL company for a period of two years;
- The approval of the objectives set in the management plan for the Board members for the year 2015;
- The approval of the remuneration of the Board members in accordance with Government Emergency Ordinance no. 51/2013 on amending and supplementing the Government Emergency Ordinance no. 109/2011 regarding the corporate governance of public enterprises;
- The approval of lease to S.C. Apa Vital S.A. Iași a land area of 345 sqm., within the cadastral lot no. 133178, on which a decommissioned nitrogen plant is located for the development by SC Apa Vital S.A. Iași of an area project of water supply financed from European funds.

During the Extraordinary General Meeting of Shareholders the following were approved:

- The extension for a period of 12 months with of the multi-product credit validity (multi-currency, USD and Lei) in the amount of 60 million lei contracted by SC Antibiotice SA from the Export Import Bank of Romania - EximBank SA.
- The extension of a 12-month period of validity of the state guarantee worth 10 million lei corre

sponding to the multi-product credit (multi-currency, Lei and USD) in the amount of 60 million lei contracted by Antibiotice SA from the Export Import Bank of Romania - Eximbank SA.

- The maintaining of the multi-product credit related guarantees (multi-currency, USD and Lei) in the amount of 60 million lei for the entire period of validity resulting from the extension according to the points 1 and 2 on the Agenda.

- The making of a decision - a commitment of SC Antibiotice SA not to divide, not to merge and not to decide the anticipated dissolution throughout the life of the multi-product credit (multi-currency, Lei and USD) and the guarantee on behalf of the state issued by Eximbank without the prior consent of the Export Import Bank of Romania - EximBank SA.

- The empowering of Mr. Ioan Nani, CEO and Mrs. Paula Coman, Economic Director to sign on behalf of the Company all papers / documents related to the extension and conversion of the credit facility, according to the paragraphs 1 and 2 of the Agenda and the papers / documents related to the obligations assumed by the Company in accordance with the paragraphs 3 and 4 of the Agenda.

- The appropriate amendment of the Annex 1 - Administrators of SC Antibiotice SA - Iasi (Articles of Association) - according to the draft addendum in the annex of the convening notice.

- The amendment and update the Articles of Incorporation for the introduction at article 6, concerning the object of the company, in the main activity category of the building code in which it operates:

1. 2110 - The manufacture of basic pharmaceutical products / building code: P10-B and the introduction into the category of secondary activities of the following activities and of the appropriate CAEN codes together with the building code in which they operate;

2. 2120 - The manufacture of pharmaceutical products/ building codes: P1-US, P9-C, P11-PP, P13-CsP-Csc P14, P15-CsN;

3. Wholesale of pharmaceutical products/ building codes: P7-D;

4. 5210 - Storage / building code: P5-D, D-P28, P29-D, P33-D;

5. 5224 - Handlings;

6. 7120 - Research and development in biotechnology / building code: P21-MKP;

7. 7219 - Research and development in biotechnology / building code: P21-MKP;

8. 7211 - Research and development in biotechnology / building code: P21-MKP;

9. Packaging activities / buildings code: P1-US, P9-C, P11-PP, P13-CsP, P14-CsC, P15-CsN;

10. 8622 - Activities of specialized healthcare / building code: P16-CEM-RA.

During the Ordinary General Meeting dated August 13, 2015 the financial statements of the company for the first semester of 2015 were approved, based on the Directors' Report and the Financial Auditor's Report and within the Extraordinary General Assembly of Shareholders the supplement of the related multi-currency credit worth 60 million lei were approved, a credit contracted by the Antibiotice from the Export-Import Bank of Romania - EximBank SA with mortgage / transfer income / claims made based upon contracts signed with Farmexpert DCI (all present and future bills).

# Social Responsibility

A company's success is measured not only by achieving financial indicators and targets but also in terms of the contribution it brings to the community, how it protects our planet's resources and changes people's lives. Antibiotice is directly committed to the community through charitable actions, sponsorships, humanitarian, educational and cultural projects, acting for the development of a better society, but also to protect the environment.

## **"Antibiotice - Science and Soul" Foundation**

"Antibiotice - Science and Soul" Foundation conducts charitable activities, humanitarian, educational and cultural projects aiming to improve the health of the population and to solve certain social problems.

Moreover, the Foundation supports scientific activities intended for both doctors - by organizing training seminars and ongoing medical education - and the general public, by increasing awareness on the role of generic medicines or on various pathologies, by organizing events for educational and preventive purposes.

Throughout 2015, Antibiotice Science and Soul Foundation conducted humanitarian campaigns which helped numerous families, children in a serious health condition or in foster care, elderly, sick people in need. Actions under the campaigns "The Power of deed", "Be a volunteer! Donate blood!", "Give a toy, give a smile" or "With science and soul, close to people" and "Be Santa Claus!" brought joy and hope in the souls of those who needed humanitarian assistance.

## **Be a volunteer! Donate blood!**

In 2015, "Antibiotice - Science and Soul" Foundation organized two blood donation campaigns for the fifth consecutive year. The blood collect was responded to by 115 employees. The first one took place on April 21st and the second on 26th November, to show solidarity with the victims of the accident in Colectiv.

In 2015 we reached the 450th blood donation, which, according to statistics, means we've helped save more than 900 lives. As a result of the positive impact, the mobile blood collect will continue in upcoming years.

## **Deed power is in our power!**

On the occasion of Easter holidays, the Antibiotice Science and Soul Foundation helped 12 underprivileged families offering them essential and traditional foods, basic necessities and supplies.

Aids reached 70 people out of which 53 children who come from families with low income and 5 or 7 children, having health problems or living in precarious conditions in rural areas. Some children have disabilities or suffer from rare diseases.





## International Children's Day for the employees' children

On June 1st, the employees' children celebrated the International Children's Day at a children's fair with games, books and entertainment.

In the park of the Romanian Literature Museum, children have participated in theater plays, music, workshops and hopscotch competitions. The participants enjoyed taking part in arts and crafts workshops, competed at hopscotch, played volleyball, badminton and basketball. Others have drawn on asphalt with colored chalk and paint, created origami and played Japanese games, impersonated fairytale characters through face painting, danced and played various musical instruments. At the end, much to their delight, children received sweet gifts.

## Be Santa Claus!

For the third consecutive year, in a festive atmosphere, 34 children were visited by Santa's elves, at home, in Scânteia village. Antibiotice Foundation has managed to bring joy to children with limited material means or health problems from this rural area, for whom the arrival of Santa is the

happiest time of the year.

With the help of teachers or all by themselves, children aged 4 to 9 years old put down on paper everything they wanted to receive from Santa. Their letters have reached several of our company's employees who have enthusiastically taken the role of Santa's elves in order to fulfill the children's wishes.

Because they come from an underprivileged background, children wanted simple things: story books, slippers, dolls or toy cars, bananas, oranges and sweets, but Santa endeavored to offer more than that. During the ceremony held at Antibiotice, children gathered excitedly around Santa Claus, told him how patiently they waited for him and were glad to get to know some of the elves that helped fulfill their desires.

## Antibiotice supports the Association of Former Employees

Antibiotice supports the Former Employees Association by providing medicines and visits to the suffering, legal assistance in disputes with local or national authorities. The association is a bridge between the company management and former





employees. The Association of Former Employees was founded in 2005 and aims at monitoring and addressing the various issues retirees are facing.

All these actions show the concern Antibiotice has for those who have contributed over the years to developing and strengthening business in the pharmaceutical field.

attend various institutions of higher education. In addition, during the holidays and certain celebrations, the company offers students gifts consisting of school supplies, clothing and footwear and invitations to various shows.

## Education

### **"Science and soul" scholarships**

For over 15 years, Antibiotice joined the "Pro Ruralis" Association to support the scholarship program for rural students with good academic results, who come from underprivileged families. Since November 2010 the project was taken over and run by the "Antibiotice - Science and Soul" Foundation.

Initiated in 2001, this project offers intelligent children in rural areas the opportunity to complete their basic education according to their potential in elite high schools. In the academic year 2014 - 2015 Antibiotice has participated in this generous program offering five scholarships.

The first 5 young people who have recently benefited from our financial support graduated high school in the summer of 2009 and currently



# Promoting environmental protection

Through the Environmental Management System, the activity for protecting the environment aims at preventing pollution and improving continuously the environment performances, acting for complying with the requirements of environmental legislation.

By obtaining, in January 2011, the Integrated Environmental Authorization, valid for a 10-year period, Antibiotice proves to be a company meeting the environmental requirements, emissions of pollutants into air, water and soil being below the limits set by the rules applicable in the field.

Antibiotice started the environmental program **"Be pro nature! Get involved!"** in 2008. Our company participated for the sixth consecutive year in what has become the largest environmental campaign of all times, *Earth Hour 2015*.

Earth Hour was marked by turning off the outdoor lighting system on the premises of the company for one hour, from 8:30 to 9:30 p.m, in the areas where it was possible, as a symbolic gesture urging for the the responsible management responsibly the resources.

## Environmental responsibility

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

For the compliance with the environmental protection legislation, Antibiotice ensured the necessary specific equipment and qualified staff. Our entire activity is regulated by operating procedures of the environmental management system and by specific working instructions.

Monitoring of the environmental factors was



performed according to the requirements of the Integrated Environmental Authorization, both by our own laboratories and by a laboratory authorized by the Romanian Accreditation Association (RENAR).

### **Specific consumption and energy use**

The Biosynthesis Plant which produces the active ingredient Nystatin falls under the European Directive for Integrated Pollution Prevention and Control (IPPC). In 2015, the Biosynthesis Plant complied with the planned specific consumptions.

### **Air quality**

For monitoring the air quality, in 2015, the laboratory of the wastewater treatment plant carried out analyses on the emission of pollutants into the air, for the following indicators: nitrogen oxides, ammonia, powders in suspension and sedimentable powders.

There were no exceedances of the maximum

permitted levels set out in the Integrated Environmental Authorization.

### **Water quality**

Water quality monitoring involved testing the quality of water introduced in the wastewater treatment plant and evacuated in the municipal sewer system, on the conventional clean waters discharged into the natural emissary and on the groundwater.

No exceedances over the maximum admitted concentrations stipulated in the Integrated Environmental Authorization, Water Management Authorization and GD no. 352/2005 (NTPA 001 and NTPA 002) were recorded.

The waste water treatment operated with yields between 85% and 96%, which correspond to a performing operation.

### **Soil protection and groundwater**

Out of the land owned by Antibiotice, about 40% is free and arranged as green space.

Quality of groundwater was monitored by a monthly analysis of the samples collected from the nine observation perimeter drillings and from the drilling located downstream of the landfill location.

No accidental pollution or environmental incident was recorded which could lead to the degradation of the soil quality in the area of influence of the company's activity.

## Waste management

Antibiotice implemented a selective waste collection system, each manufacturing plant and ancillary activity being equipped with adequate collecting containers.

Recyclable waste were sold on the basis of contracts with authorized economic operators.

Non-recoverable waste were incinerated in the company's incinerator or stored in the municipal waste warehouse.

Our company complies with the requirements on managing the packaging waste (corresponding to the quantity of products that Antibiotice puts in the Romanian market). The overall objective, as well as the minimum goals set for 2015 of recovery through recycling by types of materials, (according to Law 249/ 2015) were met.

## Environmental plans and programs

For 2015, the established environmental objectives aimed at:

- Improving the aesthetic appearance and safety of installations/ buildings by rehabilitating 30% of the total length of the trestles system existent in 2013 – an objective maintained since 2014.
- Extending the protection vegetal curtain, on the perimeter of the company and improving the visual appearance by planting seedlings of trees.

## Prevention and management of emergency situations

In our company, preventing the emergency situations and providing the intervention capacity in case of accidents are ensured by the following departments: Emergency Situations, Environmental Protection, Prevention and Protection.

For this purpose, the following documents were elaborated: prevention and control plan for accidental pollution, policy for preventing the accidents when using dangerous solutions (solvents), the fire safety plan (prevention and firefighting), fire safety scenario, assumptions in case of fire, procedure for preparing the emergency situations and response capacity, authorizations/ documents required for all the types of equipment covered by the rules and regulations of the State Inspection for Control of Boilers, pressure vessels and lifting equipment (ISCIR).

In 2015 two internal alarm drills were performed. Within these drills, the speed of response of the intervention teams in case of emergencies were tested and evaluated.



# The economic and financial activity



In 2015 Antibiotice has performed its activity in line with the achievement of the objectives and indicators set out in the Income and Expenditure Budget (IEB). Since the year 2012 the International Financial Reporting Standards (IFRS) were first adopted that required the restatement of accounts information according to the Order of the Minister of Finance no. 881/2012 and of the Order of the Minister of Finance no.1286/2012 and the year 2013 was the first financial year in which the accounting was registered under the IFRS provisions.

## The statement of the comprehensive income

Given that in the pharmaceutical market:

- the prices of the generic medicinal products decreased on average by 20% from 01.07.2015;
- the claw back tax for Antibiotice represented 11.1% of the revenues from the sale of products on the domestic market, our company has fulfilled the budgeted indicators managing to:
  - increase the sales revenues by 1% compared to the budgeted figures;
  - apply a prudential policy regarding the adjustments to the retail market customers (Antibiotice SA is present through its products in approximately 5000 pharmacies). The failure to make these adjustments would have resulted in a gross profit of 42 million RON.

The sales revenues in 2015 were worth 330 million lei, up by 3% compared to 2014 when they were worth 318.9 million lei, the result of the sustained effort of the whole society to strengthen the business.

Statement of comprehensive income	31.12.2014	31.12.2015	BVC 2015	2015/ 2014	2015/ BVC
Sales revenues	318,945,093	330,087,508	326,148,000	1.03	1.01
Other operating revenues	15,314,945	14,631,018	11,325,000	0.96	1.29
Income related to costs of product stocks	9,297,266	6,546,669	-180,000	0.70	36.37
Income from the capitalized work performed by the entity	2,837,630	2,505,214	2,540,000	0.88	0.99
Expenses related to raw materials and consumables	108,174,189	118,818,573	111,476,000	1.10	1.07
Expenses related to staff	71,439,222	70,868,387	71,072,000	0.99	1.00
Expenses related to depreciation	17,057,809	15,099,989	17,144,000	0.89	0.88
Other operating expenses	99,446,184	112,046,621	103,783,000	1.13	1.08
<b>Operating profit</b>	<b>50,277,530</b>	<b>36,936,839</b>	<b>36,358,000</b>	<b>0.73</b>	<b>1.02</b>
Net financial income	-12,914,398	-4,889,304	-10,246,000	0.38	0.48
Profit before tax	37,363,132	32,047,535	26,112,000	0.86	1.23
Income tax expense	6,224,393	4,868,712	4,850,000	0.78	1.00
<b>Profit</b>	<b>31,138,739</b>	<b>27,178,823</b>	<b>21,262,000</b>	<b>0.87</b>	<b>1.28</b>

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The revenues from the sale of 78.42 million lei goods represent for the most part the value of the products of the Company's classification which were manufactured on other manufacturing lines (from abroad), on dedicated lines following the requirements of the good manufacturing practice rules in force.

These revenues were obtained with a commercial effort of 64.8 million lei representing the sale price differences on auctions in hospitals at least 25% and sales support through retail promotional campaigns.

Sales of finished products	31.12.2014	31.12.2015	2015/2014
Finished product sales	312,499,471	316,441,808	1.01
Merchandise sales	67,408,992	78,422,624	1.16
Commercial discount	(60,963,371)	(64,776,925)	1.06
<b>Total</b>	<b>318,945,093</b>	<b>330,087,508</b>	<b>1.03</b>

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The net financial income was mainly influenced by the following charges:

- The bank interest expenses of 1.5 million lei decreasing by 30%;
- The expenses concerning discounts granted worth 3.4 million lei down by 68%.

Description	31.12.2014	31.12.2015	2015/2014
Utilities	9,262,780	8,535,786	0.92
Repairs	2,038,820	2,146,827	1.05
Rent	135,489	154,412	1.14
Insurance	1,335,027	1,418,291	1.06
Banking fees	1,314,930	1,247,955	0.95
Advertising and promotional products	3,270,357	3,276,474	1.00
Travel and transport	3,863,649	2,904,673	0.75
Postal and telecommunication services	523,878	546,418	1.04
Other services provided by third parties	29,027,474	28,54,921	0.97
Other taxes	26,856,901	27,844,178	1.04
Environment protection	491,138	410,679	0.84
Expenses on disposal of assets	15,953	137,607	8.63
Losses and adjustments doubtful of debts	9,216,847	19,790,098	2.15
Other provisions	5,023,420	4,758,793	0.95
Exchange rate differences	5,484,841	8,592,541	1.57
Miscellaneous	1,584,680	2,126,968	1.34
<b>Total</b>	<b>99,446,184</b>	<b>112,046,621</b>	<b>1.13</b>

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The profit before tax for the current exercise is 32 million lei, 23% higher than the profit estimated in the IEB; Antibiotice applies a prudential policy regarding the adjustments to the market retail customers (Antibiotice SA is present with products in approximately 5000 pharmacies). The failure to make these adjustments would have resulted in a gross profit of 42 million lei.

The profit after tax is 27.2 million lei.

#### Distribution of profit for the year 2015

Intended use	Amount
Profit attributable to	27,178,823
Legal reserve	0
Own sources of financing and other distributions of profit prescribed by law:	13,224,488
▪ Own financing sources;	9,554,335
▪ Tax incentives for profits reinvested in technological equipment, work machinery and installations according to Art. 19 <sup>4</sup> of the Tax Code;	1,024,574
▪ Tax incentives for R&D activities according to Art. 191 of the Tax Code;	1,678,514
▪ Other allocations provided at Art. 1 of Government Ordinance no. 64/2001.	967,065
Dividends of which:	13,954,335
▪ Dividends due to the major shareholder	7,398,208
▪ Dividends due to other legal entities and individuals	6,556,127

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## Statement of the financial position

On 31.12.2015, the Company's fixed assets were worth 10% more compared to the beginning of the year. The accounting depreciation is calculated using the straight line method according to the IFRS standards.

The company worked to restructure the debt in order to reduce the banking exposure (making savings for the payment of interest worth 600.000 lei) and attract stable liabilities which do not confer risks or additional costs by reducing the total cost of financing of the core business and maintaining a constant indebtedness from 27.6 in 2014 to 27.9 in 2015.

Assets	31.12.2014	31.12.2015	2015/ 2014
<b>Fixed assets</b>	<b>196,493,836</b>	<b>215,675,376</b>	<b>1.10</b>
Tangible assets	188,576,994	205,945,190	1.09
Real estate investments	-	-	-
Intangible assets	7,916,842	9,730,186	1.23
Investments in equity instruments	-	-	-
<b>Current assets</b>	<b>307,152,860</b>	<b>328,987,215</b>	<b>1.07</b>
Stocks	57,284,464	60,290,277	1.05
Trade receivables	232,062,022	231,314,744	1.00
Financial assets intended for sale	140	220	1.57
Cash and cash equivalents	17,806,234	37,381,974	2.10
<b>TOTAL ASSETS</b>	<b>503,646,697</b>	<b>544,662,591</b>	<b>1.08</b>
<b>LIABILITIES AND EQUITIES</b>	<b>364,331,001</b>	<b>392,649,884</b>	<b>1.08</b>
<b>Equities</b>			
Paid-up share capital	264,835,156	264,835,156	1.00
Revaluation reserves	4,158,471	19,909,156	4.79
Legal reserves	13,189,007	13,426,762	1.02
Other reserves	118,149,425	133,303,701	1.13
Reported result	(67,139,797)	(66,003,714)	0.98
Current result	31,138,739	27,178,823	0.87
<b>Long-term liabilities</b>	<b>20,158,444</b>	<b>22,673,130</b>	<b>1.12</b>
Investment subsidies	3,521,762	3,193,972	0.91
Deferred tax	16,636,682	19,479,158	1.17
Long-term provisions	-	-	-
<b>Current Debts</b>	<b>119,157,252</b>	<b>129,339,577</b>	<b>1.09</b>
Commercial debts and similar	46,916,170	71,391,757	1.52
Amounts due to credit institutions	54,783,341	41,778,509	0.76
Debts due to current taxes and charges	12,436,407	8,989,373	0.72
Short-term provisions	5,021,334	7,179,938	1.43
<b>Total debts</b>	<b>139,315,696</b>	<b>152,012,707</b>	<b>1.09</b>
<b>Total equities and debts</b>	<b>503,646,697</b>	<b>544,662,591</b>	<b>1.08</b>

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### The current assets:

- The remaining stock at end of the year experienced an increase of 5% compared to the recorded value at the beginning of the year amidst the ensuring of the necessary raw materials for the production of the first quarter of 2016 and without exceeding the approved stock norms;

- The total claims experience constant values due to the policy of accelerating the revenue from distributors.

The average duration of debt collection from the foreign market was 98 days in 2015 while on the domestic market the debt collection duration was 363 days; thus the average collection period of 289 days.

At the end of 2015 the cash and cash equivalent increased by 110% compared to the year 2014.

The company's main indicators of diagnosis highlight the financial stability and the continuing concern for business efficiency.

### The evolution of the main economic and financial indicators

		31.12.2014	31.12.2015
ROE (return on equity)	=Profit before interest and tax/Equity	4.7%	3.8%
ROA (return on assets)	=Net Income/Total Assets	1.2%	0.89%
EPS (Lei/share)	=Net profit/share	0.046	0.040
Net profit rate	=Profit/Sales revenues	10%	8%
General liquidity	=Current Assets/Current Liabilities	2.6	2.5
The rapid liquidity ratio	=(Current assets - Stocks) /Current Liabilities	2.1	2.1
Level of indebtedness	=Debt/Total Assets	28%	28%
No. of shares		671,338,040	671,338,040

The reduction in the net profit rate was driven by pharmaceuticals market conditions:

- the prices of the generic medicinal products decreased on average by 20% from 01.07.2015;
- the claw back tax for Antibiotice accounted for 11% of the revenues from the sale of products on the domestic market;
- applying a prudential policy concerning the adjustments on the level of the retail market customers.

The failure to make these adjustments would have resulted in a gross profit of 42 million lei.

### Balance sheet liabilities

On December 31, 2015 the company records current liabilities amounting to 129.3 million RON increasing by 9% compared to the year 2014. Antibiotice worked to restructure debt in order to reduce its bank exposure (achieving savings to pay interest in the amount of 600.000 RON).

### Amounts owed to credit institutions on 31.12.2015

The short-term contract no. 28/18.04.2005 concluded with Alpha Bank-Iasi Branch

Objective	Credit line - working capital
Amount	8,000,000 RON 100,000 Eur
Maturity	28.05.2016
Balance at December 31, 2015	0 RON
Guarantees	Contract of assignment of receivables

The 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 Euro
Maturity	22.05.2016
Balance at December 31, 2015	5,476,518.79 EUR ( 24,778,509.27 RON )
Guarantees	Agreement of assignment of receivables / mortgage contract on buildings, land

The short-term contract no. 12/01.07.2013 concluded with the Export Import Bank of Romania EXIMBANK S.A.

Objective	Credit line – working capital
Amount	60.000.000 RON
Maturity	28.06.2016
Balance at December 31, 2015	16.999.999,75 RON
Guarantees	Mortgage contract on buildings, land, receivables

### Amounts owed to credit institutions on 31.12.2014

The short-term contract no. 28/18.04.2005 concluded with Alpha Bank-Iași Branch

Objective	Credit line – working capital
Amount	8,000,000 RON 100,000 Euro
Maturity	30.05.2015
Balance at December 31, 2014	3,694,740.11 RON
Guarantees	Contract of assignment of receivables

The short-term contract no. 12/01.07.2013 concluded with the Export Import Bank of Romania EXIMBANK S.A.

Objective	Credit line – working capital
Amount	60,000,000 RON
Maturity	30.06.2015
Balance at December 31, 2014	20,206,393.16 RON
Guarantees	Mortgage contract on buildings, land, receivables

The 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 Euro
Maturity	22.05.2015
Balance at December 31, 2014	6,890,120.15 EUR (30,882,207.53 RON )
Guarantees	Contract of assignment of receivables / mortgage contract on buildings, land

In the financial year 2015, Antibiotice has not filed any guarantees, pledged or mortgaged its own assets to guarantee obligations in favor of a third party.

<b>ASSETS</b>	
Fixed assets	215,675,376
Stocks	60,290,277
Trade receivables	231,314,964
Cash and cash equivalents	37,381,974
	544,662,591

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<b>LIABILITIES</b>	
Paid-up share capital	264,835,156
Reserves and retained earnings	127,814,728
Current liabilities	129,339,577
Long-term liabilities	22,673,130
	544,662,591

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## The cash flow

The level of the cash and cash equivalents at beginning of the period was 17.8 million RON. The cash receipts from the operating activities were worth 314.5 million RON. The cash payments to the suppliers for goods and services were 146.9 million RON, while those to and on behalf of the employees, payments made in connection with staff were worth 68.2 million.

Also, payments were made worth 14.5 million representing income tax, VAT, local taxes and bank interests and payments were made for the purchase of fixed assets of 12.2 million. Contributions were paid to the Ministry of Health (the claw back tax) worth 25.3 million RON (the remaining amount up to 26.3 million was paid in February 2016).

Regarding the financing activity payments were recorded of 13.6 million representing short-term loans and the payment of dividends of 14.3 million.

At the end of the year the level of the cash and cash equivalents was 37.4 million compared to 17.8 million on 01.01.2015.

<b>I. Cash flows from operating activities</b>	<b>31.12.2014</b>	<b>31.12.2015</b>
Cash receipts from the sale of goods and services	322,905,011	308,841,604
Cash receipts from royalties, fees, commissions and other incomes	(97,353)	5,661,481
Cash payments to suppliers of goods and services	(165,298,921)	(146,884,502)
Cash payments to and on behalf of employees, payments made by the employer in connection with staff	(69,137,056)	(68,237,135)
VAT paid	(1,059,262)	(5,472,945)
Contributions paid to the Ministry of Health and the Ministry of Environment	(18,254,337)	(25,274,718)
Other taxes, duties and similar expenses paid	(1,808,435)	(1,273,606)
<b>Cash generated by the operating activities</b>	<b>67,249,648</b>	<b>67,360,179</b>
Interest received	11,579	5,865
Interest paid	(2,111,806)	(1,519,772)
Tax dividends paid	(651,802)	(973,936)
Corporate tax paid	(7,002,580)	(5,286,209)
<b>Net cash flows from operating activities</b>	<b>58,146,841</b>	<b>59,586,127</b>

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<b>II. Cash flows from Investing activities</b>	<b>31.12.2014</b>	<b>31.12.2015</b>
Cash payments for the purchase of land and fixed assets, intangible assets and other assets on the long-term	(19,513,117)	(12,192,014)
<b>Net cash flows from Investing activities</b>	<b>(19,513,117)</b>	<b>(12,192,014)</b>

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<b>III. Cash flows from financing activities</b>	<b>31.12.2014</b>	<b>31.12.2015</b>
Receipts from short-term borrowings / reimbursements	(17,721,666)	(13,554,933)
Dividends paid	(13,593,559)	(14,263,440)
<b>Net cash flows from financing activities</b>	<b>(31,315,226)</b>	<b>(27,818,373)</b>
Effects of exchange rate variation on related cash and cash equivalents	0	
<b>Cash flows - Total</b>	<b>7,318,498</b>	<b>19,575,740</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>10,487,736</b>	<b>17,806,234</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>17,806,234</b>	<b>37,381,974</b>

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# Independent Auditor's Report

## To Antibiotice shareholders

1. We audited the enclosed financial statements of the trading company Antibiotice S.A. (hereby referred to as "the Company") comprising the financial position statement as of December 31st 2015, statement of comprehensive income, statement of changes in equity and cash flow statement for the financial year ended at the above-mentioned date and a summary of the significant accounting policies and other explanatory notes.

## Executive team's responsibility for the financial statements

2. The Company's executive team is responsible for the preparation and fair presentation of these financial statements in accordance with the International Financial Reporting Standards (IFRS) and for the internal control which the management considers it relevant for elaborating the financial statements without significant misstatements due to fraud or error.

## Auditor's responsibility

3. Our responsibility is to express an opinion on these financial statements, based on our audit. We conducted our audit in accordance with the International Standards on Auditing. These standards require us to comply with the ethical requirements, to plan and perform the audit in order to obtain reasonable assurance that the financial statements are free from significant misstatements.

4. An audit involves performing procedures

to obtain audit evidence on the amounts and information contained in the financial statements. The selection of procedures is based on the professional judgement of the auditor, including the evaluation of risks relative to significant misstatements in the financial statements due to error or fraud. In conducting these risk evaluations the auditor takes into account the internal control relevant for the drawing up and faithful presentation of these financial statements in order to set the relevant auditing procedures in the given circumstances, but not with the aim of expressing an opinion on the effectiveness of the internal control system of the company. Auditing the financial statements equally includes evaluating the appropriateness of the accounting policies used, reasonableness of the management's accounting estimates, as well as the assessment of the overall financial statement presentation.

5. We consider that the audit evidence obtained provide a reasonable basis for our qualified opinion.

## Basis for our qualified opinion

6. The financial statements reported on December 31, 2014 include costs amounting to RON 14.3 million, representing services purchased from distributors which might be considered trade discounts.

The mentioned aspect impairs the comparability of the financial statements reported on December 31, 2015 with those reported on December 31, 2014 without affecting the comprehensive income.

## Our qualified opinion

7. In our opinion, except for the possible adjustments resulting from those set out in paragraph [6], the financial statements give a true and fair view, in all significant aspects, of the financial position of Antibiotice on December 31st, 2015, as well as of the financial performance and cash flows for the financial year ended on the above-mentioned date in accordance with the International Financial Reporting Standards.

## Highlighting some issues

8. According to those mentioned in the Note 9 - Income tax expenses, the company was not the object of a tax audit for a period longer than 5 years. Given the frequent changes in tax legislation, in this period, any possible controls could lead to differences between the amounts presented in the financial statements and conclusions of the tax authorities

## Other issues

9. This report of the independent auditor is addressed solely to the company's shareholders. Our audit was conducted in order to be able to report to the shareholders of the company those aspects which are required to report in a financial audit, and not for other purposes. To the fullest extent permitted by law, we do not accept and we do not assume responsibility, except in relation to the company and its shareholders, for our audit, for our report on the financial statements and the report on the compliance or for the formed opinion.

## Report on the Management Report

10. The managers are responsible for the preparation and presentation of the Management Report in accordance with the requirements of OPFM no. 1286/2012 Accounting Regulations in accordance with International Financial Reporting Standards, applicable to the trading companies whose securities are admitted to trading on a regulated market, Annex 1, Section 3, paragraphs

10-14. The Management Report must not contain any significant misstatements and that internal control that the management considers it necessary to enable the preparation of the management report must not contain significant misstatements due to fraud or error.

The Management Report has 38 pages and is not part of the financial statements.

Our opinion on the individual financial statements does not cover the Management Report.

In connection with our audit of the individual financial statements, we read the Management Report attached to the financial statements and presented on the pages 1 to 38 and we report that:

a) we did not identify information in the Management Report that is not consistent in all significant aspects, with the information presented in the attached individual financial statements;

b) the above-mentioned Management Report includes, in all significant aspects, the information required by OPFM no. 1286/2012 Accounting regulations in accordance with the International Financial Reporting Standards, applicable to the trading companies whose securities are admitted to trading on a regulated market, Annex 1, Section 3, paragraphs 10-14;

c) based on our understanding and knowledge acquired during the audit of the individual financial statements for the financial year ended on December 31, 2015 with respect to the company and its environment, we did not identify the significantly flawed information included in the Management Report.

In the name of:  
BDO Conti Audit,  
Registered at the Chamber of Financial Auditors  
of Romania  
With the no. 18/02.08.2011

Signatory's name  
Silviu Manolescu  
Registered at the Chamber of Financial Auditors  
of Romania  
With the no. 1481/14.11.2002

March 14, 2016