#### MANAGEMENT REPORT H1 2017

Half-yearly report according to:	IFRS
For the financial year:	30.06.2017
Report date:	August 04, 2017
Name of trading company:	Antibiotice SA
Registered office:	Iasi, 1 Valea Lupului St.
Phone no.:	0232/209000; fax: 0232/209633
Fiscal registration code:	RO1973096
Order number in the Trade Register:	J22/285/1991
Regulated market on which	
the issued securities are traded:	Bucharest Stock Exchange
Subscribed and paid-up capital:	LEI 67,133,804
Main characteristics of the securities issue	ued
by the company:	nominative shares, nominal value: LEI 0.10

The Romanian pharmaceutical market recorded a stagnation in the first semester compared to the same period last year, reaching a value of LEI 6.5 billion, according to the market research company Cegedim Romania (HI 2017). The market is still supported by the value of national programs of hepatitis and by the products newly introduced in the cost-volume / cost-volume-result contracts.

The growing evolution of the hospital market is representative (+13% increase in value compared to the period January - June 2016) amid stagnation of the retail market. Growth of the hospital segment is supported by the positive evolution of the innovative medicines, the top 10 original brands achieving 65% of the increase in absolute value in this market and by the growth of the generic market of HIV antivirals. Except for this increase, the hospital market stagnated compared to the same period last year.

In the short term, pharmaceutical market is sensitive to the general economic framework, being influenced by:

- frequent legislative changes;

- the premise of lowering the prices of original medicines that have generics in the market;

- putting new molecules on the list of compensated and free of charge medicines ;

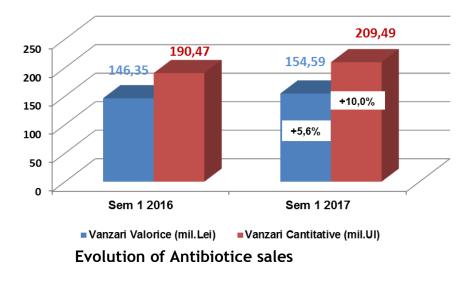
- organizing centralized tenders;

- the premise of increasing the clawback tax.

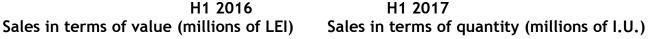
- the acute lack of some medicines for patients following the unprecedented development of parallel exports and disappearance of some cheap medicines, affected by the repeated reduction in price and by the clawback tax.

Since the beginning of this year, Antibiotice submitted to NAMMD 1,640 of discontinuity notifications on the products in the Romanian market, from which 176 renouncements to MAs/ permanent discontinuity notifications.

In the context of the Romanian pharmaceutical market (characterized by value stagnation and consumption regression), **Antibiotice** records a 5.6% growth in the sales in pharmacies and hospitals as compared to the first semester of 2016 (superior as compared to the pace recorded by the Romanian market) while the sales per therapeutic units recorded a 10% growth. At the same time, our market share is 2.38%, higher than the percent recorded in the first semester of 2016 (2.31%).



# **Evolutia vanzarilor Antibiotice**



With sales of LEI 154.6 million in terms of value, our company is still ranking 4t<sup>h</sup> among the manufacturers of prescription and non-prescription generic medicines.

The retail pharmacy segment is up +6.5% compared to the first half of 2016, from LEI 109.1 million to LEI 116.3 million, while the hospital segment records an increase of +2.9%, from LEI 37.2 million to LEI 38.3 million in 2017.

Indicator name	H I 2015	H I 2016	H I 2017	H I 2017/2016
Pharma market	6,098.05	6,330.41	6,500.16	+2.7%
Generics + OTC market	2,621.62	2,564.20	2,942.23	+14.7%
Share of Generics + OTC	43.0%	40.5%	45.3%	
Antibiotice marketshare	2.33%	2.31%	2.38%	
Antibiotice (value at the exit from pharmacy)	141.79	146.35	154.59	+5.6%
Share of OTCs in the Antibiotice portfolio (value at the exit from pharmacy)	13.0%	14.8%	18.5%	

Million LEI

Following the general market trend driven by the increased interest in prevention, maintenance of health and quality of life, the Antibiotice OTC portfolio recorded a 31.4% increase between January-June 2017, higher than the rate recorded by the total profile

market (+21.5%). This increase was obtained as a result of the marketing, promotion and commercial policies, conducted in the analyzed period.

Through the existing portfolio, Antibiotice ranks 14<sup>th</sup> in the top of the companies producing OTCs in Romania (out of a total of 213 companies) higher by one position as compared to the first half of 2016. The share of the OTC medicines in the company's sales increased in the H1 2017 to 18.5% (from 13% in the H1 2015 and 14.8% in the H1 2016). The successful products are food supplements: Fluxiv®, Silithor®, Equilibra®, Soriso®, as well as the OTCs: Rompirin®E, Saliform® Forte, Clafen® gel 5% and Cicatrol®.

Through promotional and commercial policies conducted in the first part of this year, the food supplements existing in our portfolio have vecome successful on the relevant markets: Fluxiv® - ranks third in consumption, with a 4.7% marketshare, in the second year of sale; Equilibra® - ranks fourth in consumption with a 8.9% marketshare; Silithor® - ranks sixth in consumption with a 5.2% marketshare, in the third year of sale; Soriso® - ranks first in consumption, with a 34.7% marketshare, in the second year of sale.

In the anlyzed period, Antibiotice achieved net sales on the domestic market (ATB outputs) of LEI 79.66 million while the distribution sales amounted to LEI 150 million and the sales in pharmacies and hospitals amounted to LEI 154.6 millioane (estimation, data source: Cegedim Romania).

Indicator name	H I 2016	H I 2017	ΔΗΙ 2017/2016
Distribuitors outputs*	142,42	142,6	+5.3%
Pharmacy & Hospital's outputs*	146,35	154,60	+5.6%

(million LEI)

\* Values reported to pharmacy entry price

For the first semester of 2017, all our efforts were focused towards destocking the sale chanels: distribution, hospital pharmacies, retail pharmacies.

#### All the three sales segments show value increases:

- **Pharmacy chains:** +15.8% compared to the similar period of 2016 (from LEI 33.6 million in the H I 2016 to LEI 39.0 million in the H I 2017);
- Independent pharmacies and Minichains: +2.3% (from LEI 71.2 million in the H I 2016 to LEI 72.9 million in the H I 2017);
- **Hospitals:** +1.5% from LEI 37.6 million in the H1 2016 to LEI 38.2 million in the H1 2017.

In order to achieve the objectives proposed for 2017, the following strategies were implemented in the first semester:

## PRODUCT STRATEGY

Product strategy aims to increase the presence of the Antibiotice medicines in pharmacies, by orienting both the sales structure and the promotion policy towards valuable therapeutic drugs.

The whole activity of the company - from research to production and sales - is structured on a portfolio of generic drugs as varied as possible concerning the pharmaceutical forms and therapeutic classes covered.

Our 136-product portfolio covering 12 therapeutic classes attests that the Antibiotice strategy is the permanent orientation towards the portfolio renewal and manufacture of some generic medicines terapeutically bioequivalent with the original products while maintaining high quality standards.

Development of new products, especially in a so dynamic and specialized industry, as the pharmaceutical one, aims mainly at the gradual replacement of products in the medical therapy, while maintaining or increasing the volume of future sales.

# Actions carried out in semester I 2017:

 $\rightarrow$  Assimilation of new products in the company's portfolio:

• Zifex® Complex, pessaries - a new product for gynecological diseases, for completing the Zifex® range. This medicine is unique in the Romanian pharmaceutical market, containing nystatin, the active ingredient for whose production Antibiotice is a world leader. Zifex® Complex adds value to the Antibiotice portfolio and will contribute alongside Nistatina Atb® tablets, Nidoflor® and Nistatina Atb® pessaries to the vertical integration project of nystatin.

• Clobetazol® cream - corticosteroid for topical use, indicated in the short-term treatment of resistant dermatoses; Marketing Authorization was obtained in the H I 2017;

• Betahistina Atb® tablets - a medicine belonging to the anti-vertigo therapeutic subclass, prescribed for the treatment of vertigo; Marketing Authorization was obtained in the first semester of 2017;

• **Caspofungina Atb**@ powder for concentrate solution for infusion - backup systemic antifungal drug; Marketing Authorization was obtained in the first semester of 2017;

• Sprinten@ tablets - food supplement that maintains the health of the bone system, reduces joint stiffness and fatigue, improving movement; Marketing Notification was obtained in the H I 2017;

## $\rightarrow$ Variations of packaging form for the current portfolio:

• Equilibra® - carton box with 10 cps and carton box with x 60 cps. The 10-capsule pack will support the product promotion policy, being offered as a sample; the 60-capsule pack will be introduced as a result of aligning the product to the other food supplements from our portfolio (Silithor®, Fluxiv® and Soriso®). At the same time, the 60-capsule pack ensures the one-month treatment with Equilibra®, two capsules a day. This variation was applied starting with January 2017.

Likewise, in H1 2017, our company obtained for **Equilibra@** the Notification issued by the Ministry of Health for the new composition of the vegetable capsule.

Share of new products in total portfolio at the end of the first semester 2017 was 15 % (data source: distributor sales).

## PRICING STRATEGY

On the Hospital segment, the average price of the products from the Antibiotice portfolio was 2.221 LEI/ therapeutic unit, representing 34% of the average market price (6.60 LEI/ therapeutic unit); Antibiotice continues its policy of supporting the portfolio for sales in hospitals, generating savings in this consumption segment.

On the Retail segment - medicines with medical prescription, Antibiotice recorded an average price of 0.569 LEI/ therapeutic unit, representing 57.5% of the average market price (0.991 LEI/ therapeutic unit), according to the reporting source Cegedim Romania, being in the same pace with current legislation that regulates the prices for products with medical prescription (mximum 65% of the innovator's price).

On the OTC segment - Antibiotice recorded an average price of 0.747 LEI/ therapeutic unit, representing 89.4% of the average market price (0.836 LEI/ therapeutic unit), according to Cegedim Romania, being permanently adapted to positioning strategies in the pharmaceutical market.

Pricing strategies both for the current and future portfolio will permanently aim to make the correlation among the maximum level imposed by law, increase of profitability and a competitiveness comparable with competition's quotation, (positioning as the first generic, as a reference medicine, best price / quality ratio).

## DISTRIBUTION STRATEGY

The main objective of 2017 was to strengthen our partnerships with national-coverage key distributors through which significant increases in sales were planned.

Product portfolio was supported in the first semester of 2017 both by distribution (monthly offer, periodical campaigns, project for promoting and merchandising OTC products), and by our own commercial team and Call Center team.

Monthly, an offer calendar was prepared that supported profitable products with significant shares in the planned figures, as well as those that represent a significant share in the stock of distributors.

Commercial budget was particularly focused on campaigns for highly competing products that must become supporting pillars for the company's long-term portfolio and are on the upward slope of the life cycle (with a marketshare lower than 30% and with more than two competitors). The most promoted products are in the categories:

Food supplements:

- Silithor (liver protector) : 74 competing products; 5.2% quantitative share and 6.6% value share (6<sup>th</sup> place);
- Equilibra (mineral supplement) : 49 products; 8.9% quantitative share and 4.6% value share (4<sup>th</sup> place);
- Fluxiv (varicose therapy) : 21 products, 4.7% quantitative share and 4.2% value share (3<sup>th</sup> place);
- Soriso (antidepressant) : 15 products, 34.7% quantitative share and 27,3% value share (1<sup>st</sup> place);

- Cardiovascular products :

Bisotens 5 mg (beta-blocker agent) : 8 products, 29.8% quantitative share and 18,2% value share (2<sup>nd</sup> place);

Indapamida 1,5 mg (diuretic product) : 11 products, 2.4% quantitative share and 2.1% value share (6<sup>th</sup> place);

The supporting level for these products is comparable to that of other manufacturers' products in this market.

Products in the Antibiotice portfolio have been continuously delivered to partners, pharmacies and hospitals, optimum stocks being ensured to meet the consumer demands.

# **PROMOTION STRATEGY**

Promoting activities conducted in the first semester of 2017:

• a continuous pharmaceutical education program addressed to pharmacists has been implemented;

• Open Door Policy has been initiated, involving visits made by our colaborators, physicians and pharmacists;

• participation in events organized by student associations to promote our company brand among future specialists;

• marketing campaigns of the products on the shelf of the open-circuit pharmacies;

• Interdisciplinary events between Antibiotice and university centers have been organized: Interdisciplinary symposium "We know each other for a lifetime"

# Among the major national events that Antibiotice attended, we mention:

- "Prevention 360 + 5" National Conference promoting food supplements, February 2017, Bucharest;
- National Conference of Family Physician Association, Bucharest, 30 March 30 April 2 2017;
- Internal Medicine National Congress, April 2017, at Călimănești Căciulata;
- SRUOG, April 2017, Targu Mures;
- Conference for Launching the Updated Edition of the Management Guideline of Infections Associated to Medical Assistance April 27-29, 2017, Targu Mures;
- Dermatological Spring in Iași, April 2017, Iasi;
- Dermatology Conference "Days Gheorghe Nastase", May 2017, Iași;
- SRATI, May 2017, Sinaia;
- National Otolaryngology Conference, May 2017, Sibiu;
- National Congress of Vascular Surgery,, Sibiu 2017;
- Mental Health Conference, May 2017, Galati;
- The 15<sup>th</sup> Romanian Congress of Flebology, May 2017, Timisoara;
- Participation of the product manager team at the Vitafoods Europe, Geneva May 9-11, 2017 the global nutraceutical event;
- ROMURO, June 2017, Bucharest;
- INSPIR, June 2017, Iași;
- Infertility Management, June 2017, lasi;
- Summer School and Conference on Community Psychiatry and Psychosocial Rehabilitation June July 2017, Campulung Moldovenesc;
- Interdisciplinary Symposia "We know each other for a lifetime" in the partnership with the College of Physicians and College of Pharmacists: Brasov March 24, 2017; lasi May 5, 2017; Bucharest May 24, 2017;

In addition to commercial actions, media projects with multi-channel communication for the OTCs and food supplement category were developed:

- participation to the "Prevention 360 + 5" National Conference promoting food supplements
- launching the product website Cutaden® bebe, www.cutadenbebe.ro, in parallel with promoting actions on the parenting blogs
- promoting the video spot Cutaden® bebe on YouTube and Facebook;
- a project to promote Cutaden<sup>®</sup> bebe and food supplements (Equilibra<sup>®</sup>, Silithor<sup>®</sup>, Fluxiv<sup>®</sup>, Soriso<sup>®</sup>) to the general public ;
- CATP station wrapping in lasi;
- promotion to the general public posters in Palas Iasi: Equilibra<sup>®</sup>, Silithor<sup>®</sup>, Fluxiv<sup>®</sup>, Soriso<sup>®</sup>;
- a Facebook campaign for Silithor<sup>®</sup>, Equilibra<sup>®</sup>;
- a Brand Ambasador Project for Cicatrol®
- a project for Spaverin "control the pain, treat the spasms";
- promotion of the food supplements: Equilibra<sup>®</sup>, Silithor<sup>®</sup>, Fluxiv<sup>®</sup>, Soriso<sup>®</sup> (140 wrapped cars in the distributors' fleet)
- promotion of the food supplements: Equilibra<sup>®</sup>, Silithor<sup>®</sup>, Fluxiv<sup>®</sup>, Soriso<sup>®</sup> in events intended for the general public Magic of balloons (Iasi), Rocanotherword (Iasi), Afterhills (Iasi), Neversea (Constanta).
- a scientific event, intended for mini-chain pharmacies, May 2017, Tulcea.
- promotion of the food supplements: Equilibra<sup>®</sup>, Silithor<sup>®</sup>, Fluxiv<sup>®</sup>, Soriso in the Food Supplements Directory

During the first semester of 2017, numerous promotion projects were developed with long-term impact on increasing the brand awareness.

The prescription products were promoted and brought to the attention of pharmacists, banners with promotional campaigns being displayed in pharmacies for products like Nidoflor®, Amoxiplus®, Indapamida, Cipro Quin®, Zifex® Duo, Clobetazol.

The over-the counter products were present on the pharmacies shelves, displayed by categories of diseases, being positioned in the minds of patients not just as brands but also as "good medication to". In such projects we took into consideration not only to increase the brand awareness but also the number of boxes on the shelves. The products involved in this project were: Equilibra®, Ibufen®, Spaverin® range, Paracetamol suppositories range, Silithor®, Fluxiv®, Clotrimazol range, Saliform® Forte, Cutaden® Bebe.

Also, through these projects, our portfolio benefited from the promotion with printed materials, promotion in the online environment (banners on specialized sites, discount products in the product presentation section). The products that benefited from such campaigns in the first part of this year were: Clafen® range, Spaverin® range, Silithor® and Soriso®.

The objectives pursued through the implementation of these promotion actions:

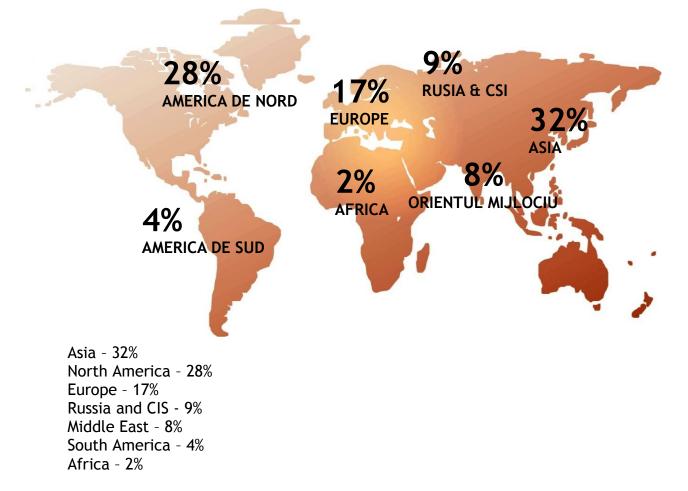
- to increase our company and product brand awarenes;

- to help our health professionals identify the patient's profile, therapeutical options and associated recommendations.

The continous implementation of these strategies will enable the company to strengthen its current position - leader in the antiinfective medication field in the segment of generic manufacturers, leader on the Hospital segment - generic medicines - leader in quantitative terms for the pharmaceutical forms: ointments, suppositories and powders for injection.

#### FOREIGN MARKET

Exports made in the first six months of 2017 were LEI 67.57 million, higher by 25% compared to the same period of 2016. The main destinations of the Antibiotice products (finished products and Nystatin) were Asia (31.59%), North America (27.76%) and Europe (16.76%), the sales in these areas representing about 75% of the total sales in the H1 2017.



These results were made possible by applying the following strategies on the international markets:

- strengthening the world leadership position for Nystatin, API by maintaining the traditional markets and increasing the exports in the regulated markets, especially the US;
- export of the company's finished products under the Antibiotice brand in the external markets by partnerships with local distributors, these partnerships allowing us a stable, long-term export development;

- development of out-licensing, co-development, contract manufacturing and co-marketing partnerships on certain strongly developed, regulated markets;
- opening offices in certain territories on the basis of the potential assessment in terms of: market potential, compatibility of the company's portfolio with consumption in the assessed markets, economic, political and social environment etc.

In the **US market**, the growth achieved in the first semester of 2017 was 27% compared to the same period of 2016. The main sources of growth in this market were the higher sales of Nafcillin for injection (+27% in quantity terms and +31% in value terms compared to 2016) and the export of Nystatin, active ingredient which doubled in value terms compared to the first half of 2016.

Increase in the export share of Nystatin in the US market, the most important selling market for this product, was a priority objective materialized this year in significantly higher deliveries by attracting in the company's portfolio some of the main end-users of this product in this market. This year's growth is not an opportunistic one, the contracts with the partners in this market being concluded in the long term.

In **South-East Asia**, Vietnam is the main market that will generate growth in the coming years. The sales of finished products in the first 6 months of 2017 tripled compared to the same period of the last year, especially through the input of products from the antiinfective class: Amoxicillin 500 mg, Ampiplus 1.5 g.

Most of these sales were made through bidding. The Antibiotice strategy for the future in this area is to increase the sales on the retail segment. In this respect, projects with distributors are under discussion to assess the potential of those 30 products chosen for registration by the end of 2020 in Vietnam. Other markets are also targeted in the South-East Asia such as Philippines, Hong Kong, Taiwan.

**Exports of Nystatin recorded a 21% growth.** Our representation office in Vietnam, functional starting with 2017, will offer new opportunities by registering new products, especially from the antiinfective class, the main therapeutic class in this country and, at the same time, a traditional therapeutic class for Antibiotice. Other markets are also targeted in the South-East Asia such as Philippines, Hong Kong, Taiwan.

In the **European market** we record increases in the sales of the finished products for injection by winning biddings in Holland, Denmark and Bosnia. Thus, sales on this pharmaceutical form increased by approximately 50% in quatitative terms and 57% in value terms respectively. Increase in sales is facilitated by the representation contract in **Serbia** where 12 products under the Antibiotice brand were registered, most from the cardiovascular class. 4 new products are currently being registered in Serbia and a new project addresses the dermatological segment.

Exports in **Russia & CIS** recorded an increase by 70%, especially due to the increases recorded by the exports of cardiovascular products (Bisotens 5 mg, Bisotens 10 mg) and suppositories in the Russian Federation (Glycerin for adults, Glycerin for children). The Business Plan for 2021 is focused on the retail segment, which offers stability and continuity, but requires also specific activities for increasing the Antibiotice brand.

Promotion activity at international level becomes very important in the strategy of growing the Antibiotice presence in the external markets. We will continue this activity with the help of our representations, our partners and by participating to the internationally recognized events (CPHI, EuroPLX) and by promoting actions specific for the countries in which we conduct projects with a high growth potential. The objectives of these actions are to increase the Antibiotice brand awareness and the awareness of our products registered in the external markets.

#### HUMAN RESOURCES STRATEGY

Our company leads its entire activity towards promoting diversity and equal opportunities in recruitment, selection and integration of employees. This way, the employees are guaranteed all rights under the law, the company providing the correct and equitable conditions of employment and professional development.

In order to reach the goals included in the Business Plan for 2017, 19 new higher education employees were recruited and integrated in the Antibiotice team, to fill the vacancies in the fields of research and pharmaceutical development, promotion and domestic market sales, quality assurance and control, production, engineering.

#### Staff structure on 30.06.2017

Average number of employees:1,420, of which:

- staff with higher education: 41.68%
- staff with secondary education: 58.32%.

## Employee training programs

Employee training programs, conducted both in the country and abroad, are a continuous effort that allows the company to maintain its position in a highly competitive environment.

In the first semester of 2017, 370 of employees participated in seminars regarding the regulatory requirements in the pharmaceutical industry, good laboratory proctice, legislation in various fields of activity.

Employees in promotion, marketing and sales teams have had developed their leading and negotiation skills, management skills of the performing teams by workshops and teambuilding programs.

The internal component of the Summer School a+ offered this year also, at its VIII edition, the possibility for a new group of junior managers to follow an extended module during 8 training sessions named "Initial Formation of Managers" which gave them the main notions about organizing and coordinating the team, getting results, behavior and communication skills. Except this training module, our employees benefited from workshops on talent management, role of the employer brand, new requirements in validating the manufacturing processes and requalifying the equipment as well as the conflict management.

#### Partnerships with the academia

We invest in the education of young people, as well as in the education of our employees in order to make them build a career and become models of responsible behavior. We recognize and support the role of local communities in the formation and development of the company's main source of value - well trained people. Antibiotice supports the increased performance of the education system through social, education and culture programs (Summer School a+, Perform a+, ProRuralis Scholarships).

## Perform a+ Project

The **Perform** a+ project started in 2016 through our collaboration with the Faculty of Pharmacy Iași and included a program of theoretical and practical activities offered to students through mentors appointed among the employees of the company.

Through this project we are looking to create a long-term communication and collaboration platform with the Grigore T. Popa University of Medicine and Pharmacy and Gh. Asachi Technical University from Iași in order to train and attract specialized personnel for the pharmaceutical industry.

In the first semester of 2017, 10 students in the last year at the Faculty of Pharmacy Iași carried out an internship completed by supporting projects by which they demonstrated how they learned the knowledge on the formulation of a pharmaceutical product.

120 students from the specialities: pharmacy, medical bioengineering, chemical engineering and biology held internships and study visits in the first part of 2017 within the collaboration with Al.I. Cuza Iași University, Gr. T. Popa University of Medicine and Pharmacy and Gh. Asachi Technical University Iași.

Also, within the partnerships established with the Petru Poni Technological High-School Iași and Technical High-School of Mechatronics and Automation Iași, 60 pupils from the 11th and 12th grades in the specialties chemist technician chemist/ chemist operator in the medicine and cosmetics industry and mechatronist/electromechanical technician have run their internships in our company.

Under the "Other School" program, Antibiotice received more than 450 pupils from the pre-university education institutions from Iași to make them familiar with the history and way of working of one the most famous landmarks in the Iasi industry.

#### Employee involvement in social responsibility projects

#### "Orchard at school " project

The Antibiotice employees participated voluntarily on April 1, 2017 in planting 300 fruit trees at the schools from the neighboring localities (Miroslava Village). This action was the first step of the project which will be continued in the second semester of 2017.

## Donate blood! Put soul for life!

51 Antibiotice employees donated voluntarily blood on April 10, 2017, the first stage of this project, giving hope to those 153 patients who benefited from this blood.

#### Employee involvement in achieving the strategic goals

#### Management by objective system (MBO) in 2017

Based on the indicators approved in the Income and Expense Budget for 2017 and starting from the Business Plan for the period 2017 -2010, the management established the general annual objectives out of which the specific objectives derives for each activity for a number of 317 employees included in the Management by Objective System.

In the formulation of individual objectives we aimed to be consistent with the mission and vision of the company, which are derived from strategic orientation of the company, to boost the

exploitation of opportunities, to control and mitigate the negative impact of risks and limitations of the dynamic environment of pharmaceutical market.

# **ISSUES ON DIVERSITY**

# Working climate favorable to an organizational culture geared towards innovation and performance

Employee representatives frequently attend meetings with the company's management in order to identify the best solutions for maintaining a beneficial climate for carrying out professional activities.

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

Antibiotice increased the number of women employed each year by ensuring equal opportunities for personal development. Thus, of the total number of employees, 54.75 % are women and, as regards the management and top management staff, 59% are women.

Higher education, of which:	42%
- 31 employees with doctoral studies completed	
(5%)	
Secondary education	<b>58</b> %
	100%

In our company, there is a balanced distribution of the employees, depending on gender and age:

	20	20-30	30-40	40-50	50-55	Over 55	
Age range	years	years	years	years	years	years	Total
Women - %	0.07	4.35	13.2	23.7	6.64	6.78	54.75
Men - %	0.14	3.43	9.64	18.42	5.07	8.57	45.25
Total - %	0.21	7.78	22.84	42.11	11.71	15.35	100

From a confessional viewpoint, 96% of the employees are of Orthodox rite and 4% are catholic, proportion that respects the confessional structure at national level. This characteristic, as well as those related to race, gender, age, nationality or the presence of disabilities do not limit the hiring criteria.

8 employees are people with disabilities and benefit from the legal provisions but also frpm a fair and nondiscriminatory treatment in the workplace.

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

Through collective negotiation, Antibiotice SA establishes the Collective Labor Agreement clauses guaranteeing in this way the labour protection, social protection but also providing additional training and professional development facilities for its employees.

#### **RESEARCH & DEVELOPMENT**

The research infrastructure developed in the recent years and focus on developing generic products to represent treatment standards in therapeutic guidelines led in the first semester of 2017 to obtaining the Marketing Authorization for 5 new products from the anti-infective, dermatology and CNS classes and Marketing Notifications for two food supplements.

At the same time, the antiinfectives portfolio, representative for our company both nationally and internationally, is to be completed with a new beta-lactam antibiotic in association with beta-lactamase inhibitors, a product for which the decentralized authorization procedure was initiated in 2016 (Romania and EU member countries) which passed through the most important evaluation stages conducted by the regulatory authorities in the first semester of 2017, with positive results.

International expansion was materialized in the H1, 2017 by obtaining 4 new marketing authorizations for medicinal products and notifications for food supplements under the Antibiotice brand in 3 countries in Asia and Europe.

Maintaining the current drug portfolio was achieved by updating the authorization documentation both in the domestic and external markets (2 national authorization procedures were completed and 11 international products were re-authorized).

The medicinal products made by our own research concern various pharmaceutical forms (injectables, tablets, capsules, pessaries, ointments, creams, gels).

The pipeline of products in research includes other 34 projects in in different stages of development, from the therapeutic classes which define the company: oral antiinfectives, injectable antiinfectives, dermatologicals, cardiovasculars, non-steroidal anti-inflammatory drugs, drugs for the digestive system and for women's health. At the same time, the portfolio of food supplements and products for prophylaxis is reinforced.

Two bioequivalence studies were conducted by the Center for Drug Evaluation, one of them for an external partner. The National Agency for Medicines and Medical Devices inspected our premises in May 2012 and reissued the Good Clinical Practice (GCP) certificate for the Clinical Unit - CDE for conducting clinical studies and the Good Laboratory Practice (GLP) certificate for the Bioanalytic Unit.

Permanent monitoring of efficacy and safety in administering the Antibiotice drugs is conducted by the Department of Pharmacovigilance and Medical Consulting, connected to the European data processing network on medicines safety - EudraVigilance. In 2017 the access to the drug safety monitoring system was extended by the development of the EVDAS module (EudraVigilance data warehouse and analysis system) which allows the analysis of the data stored in the European database and the marketing authorization holders can detect faster any possible safety signals.

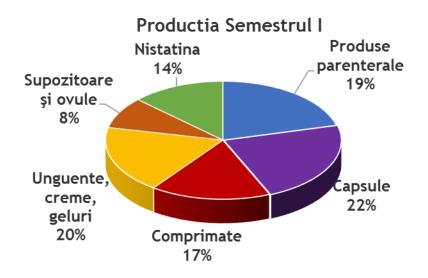
# THE PRODUCTION ACTIVITY

# In the first semester of 2017 Antibiotice manufactured the following products:

- 309 million pharmaceutical units in the form of tablets, capsules, parenteral products, ointments, creams, gels, suppositories and ovules;

- bulk active ingredient (Nystatin) in a quantity comparable to that of the previous year;

The value of manufactured goods for export (Nystatin and finished products) represents 33% of the total production value made in the first semester of 2017.



Production in the first semester

Nystatin 14% Suppositories and ovules 8% Ointments, creams and gels 20% Tablets 17% Parenteral products 19% Capsules 22%

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

- manufacture of parenteral products for foreign companies based upon manufacturing and control contracts. The export production of parenteral products accounted for 34.79% of the total value of products intended for the foreign markets;

- reduction of raw material costs by optimizing manufacturing formulations and identifying new sources for the excipients utilized in the finished product technology;

 reduction of utilities consumption, through careful management, in all the production areas;
efforts to enforce the environmental protection program on the volatile organic substance emissions during the Nystatin extraction stage and to reduce the specific solvent consumption within the technological process have continued.

# **INVESTMENT POLICY**

	INVESTMENT OBJECTIVES (thousand lei)	APPROVED 2017	Achieved until 30.06.2017
	EXPENDITURE ON INVESTMENTS, of which:	72.094	15.872
1	Investments in progress, out of which:	10.041	4.123
	Capsule Equipment, Parenteral Products	9.040	3.261
	Rehabilitation of supporting and distributing system for utility networks	591	472
	Storage of raw materials for nystatin	410	390
2	New investments, of which:	62.053	11.749
	Achieving a production capacity for ointments and suppositories	23.433	4.610
	Investments in the Tablet Plant	3.906	87
	Investments in the Biosynthesis Plant	1.101	619
	Investments in the Parenteral Products Plant	4.255	637
	Investments in the Operculated Capsule Plant	2.526	74
	Investments in the Ointment & Suppository Plant	1.080	476
	Medical Unit - License acquisition for new products and research projects	3.185	995
	Laboratory technique for the Medical Unit	3.542	989
	Laboratory technique for the Quality Unit	4.274	872
	Marketing Unit - Acquisition of cars and computer equipment	2.921	102
	Financial Unit - Acquisition of computer equipment	91	30
	Commercial Unit - Acquisitions of equipment and installations, refurbishment, rehabilitation	3.094	903
	Engineering & Investment Unit - Acquisition of equipment and installations, refurbishment, rehabilitation	8.645	1.355

ANTIBIOTICE S.A. manufactures valuable drugs, affordable as a health care tool for patients, doctors and pharmacists.

There is a permanent concern for the modernization of activity and products.

A valuable medicine is not necessarily an expensive one but one that people can afford to buy and gives us a reasonable benefit, allowing us to target performance, investing continuosly in people, high technology and exigently selected partnerships for strengthening our position in the current markets and for penetrating new markets with potential. In order to attain this goal, it is always necessary to have well-planned investments that will contribute effectively to the balanced development of all the structures of the society: production, research, quality control, utilities and logistics.

The investment objectives included in the program pursue:

- a new, high performing-manufacturing capacity equipped with modern production facilities for the manufacture of ointments and suppositories, authorized by GMP and FDA;

- modernization and refurbishment of the existing production lines to increase the production capacity, the product quality and reduce production costs;

- modernization of installations that provide utilities for the entire company;

- achievement of objectives that are in line with the strategy for pollution reduction and environmental protection;

- the consolidation of the integrated management system, the creation of new production facilities in order to reduce costs, utility consumption and increase work productivity, the continuous compliance with the increasing requirements of the Good Manufacturing Practice and the work and environment protection.

- increase of the storage capacity for raw materials corresponding to the increase of the production capacity.

## I. ONGOING INVESTMENTS

1. Equipment for the production, quality and research plants

Laboratory equipment and apparatus were purchased in 2016 for refurbishing the production lines, quality control laboratories and research laboratories, for which payments will be made in 2017. Both the manufacturing and laboratory equipment are of the latest generation with high productivity and low energy consumption and with high degree of operational safety. Manufacturing equipment is intended to replace the older generation equipment with significant physical wear that generates high maintenance costs and low productivity. The acquisition of modern laboratory equipment is required by the continuous review of pharmacopoeial monographs and increase of the precision of analytical methods in the laboratories from the pharmaceutical industry.

2. The rehabilitation of the support and distribution system of utility transport networks

It represents the continuation of the modernization actions of the transport and distribution system of utilities (steam, compressed air, thermal water, demineralized water, methane gas, electricity) on the entire platform of the company, started in the previous years. The main objective of this investment is to dimension and adapt the utility routes to the current consumption of the production lines so as to achieve energy savings by reducing consumption and eliminating losses.

3. Raw material warehouse for biosynthesis

Following the analysis, the establishement of a biosynthesis raw material storage facility near the manufacturing plant was proposed, with the main advantage of being positioned in close proximity to the production line, thus reducing the consumption of fuel for the transport of goods from the warehouse to the manufacturing plant, thus increasing the labor productivity.

# **II. NEW INVESTMENTS**

# 1. Building of an Ointment & Suppository manufacturing facility

The aim of the project is the building of a new manufacturing facility for the production of semi-solid pharmaceutical products filled into tubes and suppositories, in order to increase the turnover and capacity of Antibiotice to register, manufacture and market quality Romanian medicines by investing in a new, GMP authorized plant for all the regulated pharmaceutical markets (Europe, USA and Canada).

# Objectives of the investment

- The building and adequate equipping of an EU-GMP and FDA authorized Ointment and Suppository plant.

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

- The provision of the appropriate conditions for the manufacture of medicines in compliance with legislative and pharmacopoeial requirements, for their registration and marketing on all the regulated markets, especially in Europe, USA and Canada.

## Justification of the investment

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

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

The strategy is based upon the development of the portfolio intended for the domestic market, but also on the diversification and penetration of new foreign markets in Europe, North America, Asia and Africa.

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

# 2. Investments in manufacturing lines

In 2017 the acquisition of equipment, installations, various endowments and laboratory equipment in order to refurbish the production lines was proposed. The manufacturing equipment and the installations to be purchased are of the latest generation, with high productivity, low energy consumption, and high operational safety. The manufacturing equipment is intended to replace equipment with significant physical wear, which generates high maintenance costs and low productivity. It is also necessary to purchase equipment and endowments to ensure environmental protection measures, to reduce energy consumption and to increase work safety.

# 3. Licensing for new products and research projects

The new product development program has the following objectives:

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

- to provide pharmaceutical products competitive on the foreign market and which ensure, in the long run, the growth of Antibiotice's turnover and competitiveness;

- to reduce the NHIH (National Health Insurance House) expenditures for the purchase of imported expensive drugs or drugs involving a risk of discontinuity.

## 4. Investments in Research

Research is one of the most dynamic activities in the company, which experiences permanent changes and an ascending evolution. Throughout the whole of the company, the research acts as a dynamic element of the entire system, generating new products that drive growth in production. With a specific consumption of intelligence and creativity, the research contributes to the product portfolio development.

Given the importance of the information generated in the Center for Drug Evaluation, the investment program includes a range of equipment, endowments and software to support and improve the research activities in order to obtain new, quality, valuable and competitive products in the market.

# 5. Investments in Quality

Given the ongoing review of pharmacopoeial monographs and the increased accuracy of the analytical methods in the pharmaceutical industry laboratories, it has become imperative to acquire the latest generation equipment to make it possible to verify the quality of the products manufactured by Antibiotice at international standards. The Quality Control laboratories have a decisive role in demonstrating the quality and conformity of the products manufactured in our company, which is why they must be permanently equipped with the most modern and performing laboratory equipment.

## 6. Investments to provide logistics

The investments are mainly directed towards the refurbishment of the car fleet. There is a need to acquire modern means of transport to ensure safety in operation, equipped according to the current transport legislation, for the transportation of raw materials and finished products and for the partial replacement of the outworn car fleet.

# 7. Investments for the production and transport of utilities

Investments are mainly focused on modernizing and upgrading the systems, equipment and installations for producing utilities (steam, compressed air, water, demineralized water, methane gas, electricity, drinking water, sewage, etc.) on the entire territory of the company, in order to dimension and adapt the utility routes to the current consumption of the production lines, so as to save energy by reducing consumption and eliminating losses.

By making these investments there will be benefits such as:

- safety in operation;

- increasing labor productivity;

- reducing intervention times by implementing a powerful diagnosis system based upon error messages that reduce maintenance and repair work;

-economy of energy and resources and implicitly a better environmental protection;

- ease in the operation of the equipment by the human operator

The planned value for investments for the year 2017 is LEI 72.094 thousand. From this value, the value of LEI 15.872 thousand, representing 22% of the total programmed total was achieved until 30.06.2017.

For objective reasons, a series of scheduled investments will only be partially accomplished, such as:

- The purchase and installation of a ventilation system - at the Parental Product Plant. For this investment objective, the value of LEI 1,000,000 has been estimated and a value of about 500.000 lei will be realized, because only the central climate unit will be acquired, and the indoor ventilation system for the clean areas will be installed in 2018, as it requires a rigorous design by a specialized company and the projection takes a long time. This investment objective cannot be completed this year because the manufacture and delivery of components of such a ventilation system require long manufacturing times.

- Setting up a storage area for finished products - within the Medical Unit - an estimated value - LEI 682,500. This goal will not be achieved during the year 2017 because no suitable space was yet identified, an area providing all the necessary facilities for organizing such a warehouse.

- The relocation of the acids and bases warehouse - Storage Department - estimated value - LEI 614,250.

As it is a new warehouse for hazardous substances, it is necessary to be built upon the basis of a rigorous project, prepared by a specialized designer. The construction must also be authorized. Both the designing and licensing are activities that take a long time (about 6 months or more). At this time, the design stage is underway and is expected to be completed in October 2017. Thus, by the end of 2017, the design and authorization of the construction will be finalized and the construction works will be carried out during the year 2018.

- The access will be possible from DN 28 at gate no. 2 of the company (roundabout) - the Commercial Unit - estimated value - 637.000 lei.

This investment objective requires a design by the authorized designer for this type of work. Also, the authorization of the construction works, considering that they are located on a public road where there are many utilities networks (drinking water supply of the city of lasi, high voltage electrical networks, telephone networks, natural gas networks, special communications networks, etc.), the approval and authorization procedure will take a long time (over 6 months). At this point, the gyration project is in progress. We estimate that in 2017 the construction project will be carried out and the building permit will be completed, and during 2018 the construction works will be carried out.

# Estimates in relation to planned times for the progress of investment objectives

In the course of the investment objectives, frequent delays occur due to the following main reasons:

1. The laborious working processes of the public authorities for approval and authorization;

2. Long (variable) deadlines for the release of documents, documentation and approvals necessary for the approval and authorization of constructions;

2. Legislative changes, at national and local level, which modify and supplement the investment requirements (e.g. Prevention and Firefighting legislation from 2016). The specific pharmaceutical legislation always has significant up-grading implying a permanent adaptation and addition of manufacturing lines (e.g. serialization equipment), with implications in the concrete organization of production capacities (where possible - finding solutions for redevelopment in already built-up areas involve deadlines that cannot be accurately predicted);

4. The land owned by Antibiotice has numerous underground abandoned routes, due to the physical wear and tear caused by time (recirculated water, thermal water, industrial water, electric cables, etc.). These aspects involve special arrangements (depending on the situation), with redesign, re-evaluation and extensions of the execution periods;

5. The permanent completion of the product portfolio involves up-gradings of the manufacturing, requiring specific modifications that could not be anticipated initially (when the production capacity project was completed);

6. The internal procurement procedures involving meetings, discussions, analyzes, and finally with successive negotiations, with deadlines that cannot be initially anticipated, may lead to delays in achieving the planned investment objectives.

# CERTIFIED QUALITY

Increasing the confidence in the quality, effectiveness and safety of our products is done every day by maintaining the Integrated Management System under control and constantly improving it, which is certified by the results of the following inspections / audits during the first semester of 2017.

## 1. Inspections conducted by authorities

1.1. In the period 06-14.03.2017 **a US FDA inspection** was conducted for verifying the compliance of the Quality Management System with the specific GMP requirements for the manufacturing flows in the Parenteral Product Plant (aseptically prepared products for injection) and in the Biosynthesis Plant (nystatin, active ingredient). On 07.06.2017 our company received the final inspection report from US FDA (EIR, *Establisment Inspection*)

*Report*), the conclusion being that the inspection is "closed" which means that the CAPA plan was accepted and the manufacturing flows are compliant with the GMP requirements.

1.2. In the period 24-27.04.2017 the NAMMD ispection was conducted for recertifying the manuafacturing flows for capsules, tablets, semisolids and suppositories, including MIC. Following the receipt of the Deficiency List, we sent the CAPA plans and we expect the final inspection in the next period.

# 2. Audits conducted by clients

Two audits werre conducted for evaluating the manufacturing flow of Nystatin, active ingredient. No critical non-conformities were identified, Antibiotice being proposed for the requalification as a provider of Nystatin API.

## 3. <u>Audits conducted to the premises of suppliers of raw materials/primary packaging</u> <u>materials/finished products</u>

11 audits were conducted for verifying the compliance of the Quality Management System with the GMP requirements to the suppliers of active ingredients. No nonconformities were identified.

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A valuable medicine is not necessarily an expensive one but one that people can afford to buy and gives us a reasonable benefit, allowing us to target performance, investing continuosly in people, high technology and exigently selected partnerships for strengthening our position in the current markets and for penetrating new markets with potential.

To achieve this, we permanently need thoroughly planned investments that would contribute effectively to the balanced development of all the company's structures: production, research, quality control, utilities, logistics.

# ENVIRONMENTAL PROTECTION

## Responsibility to the environment

An important tool is the Environmental Management System, part of the Integrated Management System - Quality, Environment, Occupational Health and Safety, implemented in the company whose compliance with the requirements of the ISO 9001, 14001 and OHSAS 18001 was recertified in 2016, following the audit performed by LRQA.

By obtaining the Integrated Environmental Authorization no. 1/10.01.2011, issued by the Regional Environmental Protection Agency Bacău, valid for a 10-year period, Antibiotice proves that it is a company observing the environmental requirements, the emissions of air, water and soil pollutants, falling under the maximum acceptance limits set by the applicable rules in the field. Our company has also the Water Management Authorization no. 303/20.12.2010 issued by the National Administration of Romanian Waters, Water Basin Administration Prut-Barlad (valid until 31.12.2020).

In order to comply with legislation in the field of environmental protection, Antibiotice provided the necessary equipment and the qualified staff. The whole activity is regulated through operating procedures of the environmental management system and specific working

## instructions.

Environmental factors were monitored in accordance with the requirements of the Integrated Environmental Authorization, both by our own laboratories and by a laboratory authorized by the Accreditation Association in Romania (RENAR).

Within the environmental programs developed by our company in the first semester of 2017 a series of actions took place, as follows:

# Earth Hour 2017

Antibiotice participated for the ninth consecutive year in what has become the largest environmental campaign ever. *Earth Hour* was marked by the fact that, between 20:30 and 21:30 on March 25, 2017, the external lighting system was interrupted on the territory of the company, in the areas where it was possible, as a symbolic gesture that urges to the responsible management of resources.

# Open Gates Day at ANTIBIOTICE lasi

On May 29, 2017, 60 pupils from the Gymnasium School Valea Lupului were invited to Antibiotice to celebrate the World Environment Day. The event was aimed at raising the awareness of the young generation with regard to environmental responsibility. The pupils visited different manufacturing plants where they were able to follow specific activities, including the measures to prevent possible pollution, as well as the environmental protection equipment.

# Specific consumption and energy use

The activity of the Biosynthesis Plant where Nystatin, API is produced is governed by the European Integrated Pollution Prevention and Control Directive (IPPC). In the first semester of 2017 the Biosynthesis Plant met the planned specific consumption.

## Air quality

In the first semester of 2017, our own laboratory monitored the air quality, analyzing emissions of air pollutants for the indicators: nitrogen oxides, ammonia, suspension and sedimentable powders.

We also have a permanent concern for reducing the effects of emissions of technological odours, by supervising and monitoring, as well as through the use of different technical solutions to limit them (equipment fitted with filters, etc.).

No exceedances were recorded regarding the maximum admissible concentrations provided in the Integrated Environmental Authorization.

## Water quality

Water quality monitoring required analyzes regarding the quality of water entering its own sewage treatment plant and discharged into the municipal sewage system, the quality of the conventional clean water discharged into the natural emissary as well as the quality of the underground water.

No exceedances were recorded on the maximum admissible concentrations established under the Integrated Environmental Authorization, Water Management Authorization and GD no. 352/2005 (NTPA 001 and NTPA 002).

## Soil protection and groundwater

Out of the total land, which is owned by Antibiotice, about 40% is free, having green spaces. Quality of the groundwater was monitored by collecting and analyzing, on a monthly basis, the samples obtained from the perimeter drills. No accidental pollution or environmental incident was recorded which could lead to degradation of soil quality in the area of influence of the company.

## Waste management

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

Recyclable waste was recovered on the basis of contracts with authorized economic operators. Non-recyclable waste was incinerated in our own facility or removed by storage at the municipal waste disposal site.

Our company complies with the requirements for packaging waste management (corresponding to the quantity of products that our company introduced to the market) established by the specific legislation.

## Environmental plans and programs

For 2017, the environmental objectives are:

- purchasing vehicles with EURO 6 engines objective in progress traced back from 2016, being included in the Investment Plan 2017.
- reduction by 1% of the specific electricity consumption (kw/Gcal) for the supply of thermal energy (in the form of hot water) from the heating circuit, as compared to 2016 objective in progress with two low-energy pumps being purchased.

## Prevention and management of emergency situations

In our company, preventing emergencies and ensuring the intervention capacity in case of accidents are ensured through the activity of the following departments: Emergency Department, Environmental Protection Department and Prevention & Protection Department. For this purpose, we developed: the Plan for preventing and combating accidental pollution, accident prevention policy when using hazardous substances (solvents), Fire Protection Plan (Fire Prevention and Extinction - PFE), fire safety scenario, fire intervention assumptions, emergency preparedness and response capability procedure, authorizations / documents required for all equipment subject to the regulations of the State Inspection for Control of Boilers, Pressure Vessels and Lifting Installations (ISCIR).

#### **RISK MANAGEMENT**

In our company, the risk management is a process which implies the identification of the significant risks which could harm the company as a whole or one of its structures, evaluation, ranking and prioiritization of these risks, as well as the establishment of measures to mitigate exposure in accordance with the limits of risk tolerance in order to provide a reasonable assurance regarding the fulfillment of the established objectives and activities.

The main categories of risks that may arise in the company's activity are: financial, image and legislative.

Our company is exposed through its operations to the following financial risks:

- Foreign exchange risk
- Liquidity risk
- Commercial (default) risk)

**Foreign exchange risk**, a component of the financial risks, occurs frequently in the current market economy where monetary rates fluctuate under the supply and demand rule. Another factor also causing the occurence of currency risk is the national and international political context.

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

In order to minimise the risk, the following measures were considered:

The company's risk management strategy assumes: synchronizing the import with the export, by correlating the payment and collection terms as well as by correlating the share of foreign exchange, so that the moments in which the payments are to be done to be as close as possible, or even simultaneous with the export receipts; anticipating or delaying the payment or collection by fixing the appropriate maturity and introducing some protective price margins in conjunction with the forecasts on the evolution of the payment currency; bridging the gap between cash proceeds and payments from loans in the currency of the transaction

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

Liquidity risk may occur in the following circumstances: collection of receivables at maturities exceeding 300 days; increase in taxation/ lack of predictability (clawback tax); insolvency of some customers; increase in the price of raw materials, utilities, and services.

The following measures were taken in order to mitigate the risk: business internationalization; assessing the creditworthiness of commercial partners; monitoring receivables through permanent control and evaluation; estimating as accurately as possible and correlating payments with earnings; covering the gap between receipts and payments from credits; negotiations with suppliers on the extension of payment terms.

**Commercial (default) risk** is the risk of incurring losses or not-reaching the estimated profits due to lack of financial liquidity of the borrower and the failure to pay upon maturity. Commercial (default) risk may occur in the following circumstances: large exposures to major distributors, long payment periods, plus the rescheduling, insolvency of some pharmacies and distributors.

The following measures were taken for mitigating the commercial (default) risk: assessment of the trading partners' creditworthiness by checking them, in multiple ways, before the conclusion of the contract; monitoring of the receivables through a permanent control and evaluation of risks; development of a relationship of loyalty with the customers by organizing periodical meetings for constructive approaches; conclusion of protocols for reschedulling the payments; request of guarantees (insurance policies, collateral security agreements, checks, guaranteed promissory notes, bank guarantee letters); stopping deliveries until liquidation of outstanding amounts; diversifying client portfolios to reduce exposure to large clients; the provisioning of expenses to cover the risk of non-payment.

Legislative changes aiming the pharmaceutical market lead to the occurence of the *legislative risk*, which must be continuously monitored.

Pharmaceutical market is a regulated market, with clear legislative provisions developed in order to control the quality and therapeutic efficiency of drugs in the market and to avoid counterfeiting.

Conformation to these requirements is reflected both in extra costs for updating the documentation for meeting the quality standards, in the influences on maximum sale prices and and in the delays in launching the products in the market.

Our company's strategy to mitigate these risks involve a permanent concern for obtaining the international certifications for all the manufacturing flows, for updating the authorization documentation for its products and for conducting the bioequivalence and stability studies. It also involves a continuous monitoring of the international legislative changes.

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

In order to effectively manage the events that could lead to the risk of image, the following measures are envisaged: monitoring of the company's image in the mass media in order to identify any rumors which could generate image risks; periodical press releases with positive information; a continuous and open communication with stakeholders; control of risks which could affect the company's image, existence of a unique voice to avoid confusion.

# ECONOMIC & FINANCIAL RESULTS IN H1 2017

Net profit of LEI 19.2 million, higher by 21% as compared to the estimation planned in the IEB and by 17% higher than the figure recorded in the first semester of 2016.

## Economic & Financial Results in H1 2017

Development of our company in 2017 is based on the annual indicators from the Income and Expense Budget approved in the General Meeting of Shareholders of April 6, 2017. In the period January - June 2017, the financial balance was maintained through a correlation of receivables with debts, ensuring the stability for the achievement of the current activities.

## Statement of comprehensive income

In the first semester of 2017, all our efforts were focused on destocking the phaarmcies and distribution channels (distribution, hospitals, retails), on selling from distribution to pharmacies and hospitals, given that the pharmaceutical market has come to a standstill or even has regressed in consumption.

Sales revenues in the H1 2017 recorded a value of LEI 147.2 million, higher by 7% as compared to the values planned in the Income and Expense Budget and by 2% higher than the values recorded in 2016.

Statement of Comprehensive Income (LEI)	30.06.2016	BVC SEM I 2017	30.06.2017	2017/ 2016	2017/ BVC
1	2	3	4	5=4/2	6=4/3
Sales revenues	143.801.779	138.051.000	147.200.095	1,02	1,07
Other operating revenues	9.012.759	10.166.000	13.517.588	1,50	1,33
Income associated with product stock costs	25.882.519	26.949.000	19.038.444	0,74	0,71
Revenues from the capitalized activity of the entity	921.955	1.572.000	800.167	0,87	0,51
Expenditure on raw materials and consumables	71.711.431	69.186.000	65.349.770	0,91	0,94
Staff costs	34.711.035	39.030.000	38.235.362	1,10	0,98
Expenses with depreciation and amortization	8.859.850	9.532.000	8.574.285	0,97	0,90
Other operating expenses	43.279.318	38.439.000	47.749.054	1,10	1,24
Operating profit	21.057.378	20.551.000	20.647.822	0,98	1,00
Net financial income	-2.206.628	-1.695.000	-590.220	0,27	0,35
Pre-tax profit	18.850.750	18.856.000	20.057.602	1,06	1,06
Profit tax expenses	2.409.131	3.016.960	861.407	0,36	0,29
Profit	16.441.619	15.839.040	19.196.195	1,17	1,21

The main expenditures have evolved as follows:

 $\succ$  reduction in the expenditure on raw materials and materials is determined both by the manufacturing structure and by the reduction of production during this period;

> staff costs decreased by 2 % as compared to the values estimated in the IEB in and a 10% increaseas compared to 2016 due to the wage increases in the month of May according to the IEB approved in the General Meeting of Shereholders ;

> other operating expenses recorded a value of LEI **47.7** million, by 24% higher compared to budgeted values, due mainly to the increase in the claw back tax value by LEI 2.6 million, in spending LEI 1.7 million on audio and online media communication campaigns and due to the exchange rate differences higher by LEI 1.5 million.

**Gross profit** of the period records a value higher by LEI **20,06** million, 6% higher than the values estimated in the Income and Expense Budget.

Net profit of the period record a value of LEI 19.2 million, higher by 21% compared to the IEB and by 17% higher than in the first semester of 2016.

The positive results of the period are also reflected in the indicators below, as follows:

- labor productivity has a superior evolution with 7% compared to the values estimated for the IEB;

- ratio of total expenditures to 1000 lei total revenues decreased by 1%;

- share of personnel expenses in both value added and sales revenue was reduced, both compared to the semester I, 2016 and with the IEB estimations.

	6 months 2016	6 months REB	6 months 2017	2017/ 2016	2017/ REB
Average staff number	1465	1420	1420	0,97	1,00
Added value/Staff number	56	54	56	1,00	1,03
Satff costs /Added value (<60%)	43%	51%	<b>48</b> %	113%	<b>95</b> %
Staff costs/ Sales income	24%	28%	26%	108%	<b>92</b> %
Work productivity (LEI) = Sales income/staff number	98.158	97.219	103.662	1,06	1,07
Total expeditures on 1000 LEI total income	893	888	883	0,99	0,99
Gross margin rate (Gross profit/Sales income)	13,1%	13,7%	13,6%	104%	100%

# Statement of financial position

On 30.06.2017, our company's fixed as	ssets recorded a	1% increase con	npared tol 2016
- LEI -	31.12.2016	30.06.2017	2017/2016
ASSETS			
FIXED ASSETS			
Tangible assets	206.702.347	209.657.759	1,01
Intangible assets	10.139.458	10.334.115	1,02
TOTAL FIXED ASSETS	216.841.805	219.991.874	1,01
CURRENT ASSETS			
Stocks	60.195.101	84.772.630	1,41
Trade and similar receivables	242.456.065	259.294.824	1,07
Cash and cash equivalents	13.902.686	8.141.408	0,59
TOTAL CURRENT ASSETS	316.553.852	352.208.862	1,11
TOTAL ASSETS	533.395.657	572.200.736	1,07
LIABILITIES			
CURRENT LIABILITIES			
Trade and similar payables	49.045.370	69.811.870	1,42
Amounts owed to credit institutions	40.705.967	71.218.719	1,75
Liabilities from current taxes	11.486.302	7.382.227	0,64
Short-term provisions	1.418.895		0,00
Subsidies for investments	275.047	275.116	1,00
TOTAL CURRENT LIABILITIES	102.931.581	148.687.932	1,44
LONG TERM LIABILITIES			
Subsidies for investments	2.639.349	2.562.158	0,97
Deferred tax	18.758.368	18.434.965	0,98
TOTAL LONG-TERM LIABILITIES	21.397.717	20.997.123	0,98
TOTAL LIABILITIES	124.329.298	169.685.055	1,36

Share capital and reserves			
Share capital	264.835.156	264.835.156	1,00
Rezerve din reevaluare	16.925.870	15.581.312	0,92
Revaluation reserves	13.426.761	13.426.761	1,00
Legal reserves	146.528.189	151.152.127	1,03
Reported result	(63.020.428)	(61.675.870)	0.98
Current result	30.370.811	19.196.195	0.63
TOTAL EQUITY	409.066.359	402.515.681	0.98
TOTAL EQUITY AND LIABILITIES	533.395.657	572.200.736	1.07

#### Current assets:

- stocks at the end of the first semester record an increase of 41% compared to the end of the last year on the background of ensuring the need of finished products for the two-month general overhaul, being funded by increasing commercial debt and bank debt (financing lines) by LEI 24.6 million.

- total receivables record values higher by 7% from LEI 242.47 million at the end of 2016 to LEI 259.3 million at the end of the first semester 2017. This growth is driven by the development of new and existing partnerships in the rising pace of sales in pharmacies and hospitals.

#### **Balance sheet liabilities**

On June 30, 2017, our company record current debts worth LEI 148.69 million, higher by 44% compared with the end of 2016 on the background of ensuring the need of finished products for the two-month general overhaul, being funded by increasing commercial debt and bank debt (financing lines).

The company's main diagnostic indicators highlight the financial balance and continued concern for business efficiency, for continuing the current activity. Current liquidity diminished from 2.65 in the H1 2016 to 2.36 in the H1 2017 due to the use of 30% more credit lines compared to the previous year as well as the increase of receivables with 10% and the degree of indebtedness increased from 13.8% to 17.7% in the first semester of the current year, the growth remaining at the company's historical level.

Indicato name	Calculation method	30.06.2016	30.06.2017
Current liquidity	Current assets/current liabilities	2,65	2,36
Degree of indebtedness	Borrowed capital/ Equity x 100	13.8%	17.7%
Speed of customer flow rotation	Average customer balance / Sales income x Time	314 days	325 days
Speed of rotation of fixed assets	Sales income /Fixed assets	0,68	0,67

#### Cash flow

Cash and cash equivalents at the beginning of the period were LEI -26,8 million, representing credit lines amounting to LEI 40.7 from which LEI 13.9 million remained unused in

bank accounts from the same credit lines. Cash receipts from operating activities were LEI 136.64 million. Cash payments to suppliers of goods and services were LEI 86.37 million and those to and on behalf of employees were LEI 36.45 million.

At the same time our company paid LEI 21.65 million, representing corporate tax, VAT, local taxes and bank interest, and we also paid LEI 14.76 million for the purchase of fixed assets. We paid the contributions to the Ministry of Health (clawback tax) worth LEI 15.23 million.

As regards the financing activity, we paid dividends of LEI 13.65 million.

Cash and cash equivalents at the end of the period were LEI 63.08 million, representing credit lines for the current activity (LEI 71.22 million) from which LEI 8.14 million remained unused in bank accounts from the same credit lines.

Our company fully paid its obligations to the state and local budget until June 30, 2017 amounting to LEI 39.36 million.

Financial statements were approved by the Management Board and are to be approved in the GMS.

## MANAGEMENT OF THE TRADING COMPANY

Executive management coordinates the company's strategic development, in close cooperation with the Management Board. Periodically, the two bodies analyze the results obtained in implementing the strategy according to the business plan, performance criteria and revenue & expenditure budget. In this respect, the Management of the company informed the Management Board in seven sessions in the first semester 2017 on all significant aspects of the activity carried out and its evolution in relation to the previous forecast, submitting reports according to the agendas of the meetings. These reports were analyzed by the members of the Management Board and, based on them and other information, decisions were taken with effects in the conduct of the company's activities.

Management Board has the attribution of Company's representation in relation to the directors appointed.

The president coordinates the Management Board's activity and reports about it to the General Meeting of Shareholders. The President oversees the proper functioning of the company.

The President represents the Management Board in the relations with third parties. Other powers may be delegated to the President by the Management Board.

The executive management of Antibiotice lasi is assured by executive directors, one of whom is General Director and Vice-President of the Management Board.

The Vice-President replaces lawfully the President of the Management Board when the latter is missing. (according to the Article 37, Chapter V, Article of Association of the trading company Antibiotice Iași).

The General Meeting of Shareholders is the highest decision-making body where the shareholders directly participate and make decisions. Among other attributions, it decides on the distribution of profit, chooses the Management Board, appoints the auditors and determines the remuneration of the Management Board.

During the first semester of 2017, our Management Board convoked two Ordinary General Meetings and one Extraordinary General Meeting of Shareholders on *April 6, 2017* (Ordinary and Extraordinary Meeting) and on June 28, 2017 (Ordinary Meeting).

All necessary documents related to the smooth running of the General Meetings were published in due time and according to the legislation in force.

The Ordinary General Meeting dated April 6, 2017 approved the company's financial statements for 2016 base on the Management Report and Auditor's Report. The OGMS approved also the distribution of the net profit for 2016, setting the gross dividend in value of LEI 0.03835158 per share and establishing the payment of dividends beginning with 15.09.2017.

At the same meeting, the following decisions were made:

- Approval of the registration as revenues unsolicited and uncollected dividends for 2012;
- Approving the discharge of liability of the administrators, for the activity carried out during the financial year 2016 based on the reports submitted;
- Approval of the Income & Expenditure Budget for 2017;
- approval of the achievement of the Management Board members of the objectives and performance criteria for the year 2017;
- Approval of the objectives included in the management plan for the members of the Management Board;
- Approval of the registration date 01.09.2017, in order to identify the shareholders who are affected by the effects of the adopted decisions, according to the provisions of the article 238, para 1 of the Law 297/2004 regarding the capital market, modified and completed by the provisions of the Law L10/2015 and setting 31.08.2017 as the ex-date.

The Extraordinary General Meeting dated April 6, 2017, took the following decisions:

- to extend by 12 months the validity period of the multicurrency multiproduct ceiling amounting to LEI 30 million borrowed by Antibiotice from the Export-Import Bank of Romania Eximbank.
- to maintain the guarantees relative to the multicurrency multiproduct ceiling amounting to LEI 30 million throughout the entire term of validity resulted from extension;
- to issue a decision-commitment of Antibiotice not to divide itself, not to merge and not to decide the anticipated dissolution throughout the entire validity period of the multicurrency multi-product ceiling without prior consent of Eximbank SA.;
- to empower the General Director, Mr. Ioan NANI and Financial Director, Ms. Paula COMAN to sign on behalf of the company all documents related to the credit facility extension, under items 1 and 2 of the Agenda, as well as documents related to obligations assumed by the company in accordance with item 3 on the Agenda;
- to establish the Antibiotice area office in Vietnam, in the Sannam building located on Duy Tan St. 78, Dich Vong Hau Ward, sector Cau Giay, Hanoi;
- the registration date 01.09.2017, in order to identify the shareholders on which the effects of the adopted decisions are reflected, according to the provisions of art. 238,

paragraph 1 of the Law no. 297/2004 regarding the capital market, modified and completed by the provisions of Law 10 / 2015 and to set the ex-date for 31.08.2017;

• to amend and update the following clauses from the Articles of Incorporation.

## Article 29 of the Articles of Association of Antibiotice will be modified as follows:

"Art. 29 Members of the Management Board"

Our company is managed by a Management Board consisting of 5 members, natural or legal persons having experience in administrating/ managing profitable public enterprises and/or trading companies in the company's activity field.

At least two of the members of the Management Board must have a degree in economics or law and at least 5-year experience in the economic, legal, accounting, auditing or finance field.

Most members of the Management Board are non-executive and independent administrators. In order to have a legally valid appointment, person appointed as an administrator must expressly accept this appointment.

Members of the Management Board will conclude a professional liability insurance under the limits and conditions imposed by the General Meeting of Shareholders.

## Art. 46 of the Articles of Association of Antibiotice will be modified as follows:

Art. 46 Alienation/acquisition of company assets by the administrator

The administrators may, in their own name, dispose or acquire goods to or from the company, having a value of more than 10% of the value of the company's net assets, only after getting the approval of the Extraordinary General Meeting of Shareholders which was attended by shareholders who own at least 2/3 of the total number of voting rights. The provisons of the paragraph 1 also apply to the lease and rental operations.

## Article 47 of the Articles of Association of Antibiotice will be modified as follows: Article 47 - Company management

Members of the Management Board are appointed by the General Meeting of Shareholders, at the proposal of the current Management Board or at the proposal of shareholders.

Based on mandate contracts, Management Board delegates the management of the company to one or more directors, appointing one of them as a general director.

Director of a trading company can be only the person to whom powers have been delegated by the management company. Any other person, regardless of the technical name of the position held within the company, is excluded from the application of legal norms related to the directors of a joint stock company.

Directors may be appointed from outside the Management Board or from the administrators which become executive directors. In any case, the selection of directors will be made in compliance with the legal provisions and will take into account the specificity of the field and complexity of the company's activity.

If the directors are appointed by the company's employees, their individual employment contracts are suspended during the mandate.

The Ordinary General Meeting dated June 28, 2017, took the following decisions:

- to approve the financial audit contract with SOCECC S.R.L. Bucharest, an accounting, expertise and accounting consultancy firm for a 3-year period;
- to approve the remuneration of the members of the Management Board in accordance with the provisions of Government Emergency Ordinance no. 109/2011 on the corporate governance of public enterprises.
- to approve the Antibiotice's membership to the Romanian Association of OTCs, Food Supplements and Medical Devices Manufacturers RASCI;

• to approve the participation of Antibiotice as a founding member in the establishment of the PATRONAGE OF INDUSTRIAL MEDICINES PRODUCERS IN ROMANIA - PRIMER ;

• to approve the registration date 14.07.2017, in order to identify the shareholders who are affected by the decisions taken, according to the Law 24 / 2017 and to set the ex-date for 13.07.2017.

	2014	2015	2016	Sem. I 2017
Number of shares	671.338.040	671.338.040	671.338.040	671.338.040
Stock Market Capitalization (Thousand Lei) *	390.719	357.152	349.096	363.865
Stock Market Capitalization (Thousand Euros) *	87.173	78.868	76.875	79.902
Stock Market Capitalization (Thousand USD) *	105.978	86.167	81.123	91.160
Total amount traded (million Lei)	16	11	6	7
No. of traded shares	27.467.454	18.844.935	12.555.866	13.741.898
Opening price (Lei/share)	0.5520	0.5850	0.5320	0.5200
Maximum price (Lei/share)	0.6170	0.6170	0.5420	0.5820
Minimum price (Lei/share)	0.5410	0.5240	0.4200	0.5200
Price at the end of the period (Lei/share)	0.5850	0.5320	0.5200	0.5420
Average price (Lei/share)	0.5845	0.5836	0.5032	0.5598

## Antibiotice shares - ATB / REGULAR MARKET

 $^{\ast}$  Calculated based on the share price on the last trading day of that period

The Accounting, Expertise and Accounting Consultancy Company - SOCECC LLC Buckarest audited the financial statements for the first semester of 2017 and revised the compliance between the half-yearly report and the financial statements.

# **Conclusions:**

- Net profit amounting to LEI 19.2 million, higher by 21% as compared to IEB and higher by 17% compared to H1 2016.
- 25% increase in sales on the foreign market;

■ Increase in value sales in the domestic market on all three segments for sale (Pharmacies Chains, Independent Pharmacies and Mini-chains, Hospitals);

- 10% increase in quantitative sales in pharmacies and hospitals;
- Antibiotice invests in the continuous improvement of human capital.

Vice-President of Management Board

General Director Economist Ioan NANI

Financial Director Economist Paula COMAN