



60 years of experience  
and outstanding  
performance

Antibiotice **at**  
Science and soul

*We have a 60-year tradition. We have come a long way full of challenges but we are richer with experience and hope for the better...*

*At times, we had to set up the compass and change the route to follow, seek new landmarks to enlighten our route.*

*We have been consistently following our destiny: **to give the people hope in recovery, turning an authentic Romanian product into a recognizable brand in the entire world!***

## Our story


2015 marks 60 years since, in 1955, Antibiotice was founded. We also celebrate 10 years since we have adopted the symbol a+ and the slogan "science and soul" to communicate the continuous changes in our organization and our determination to do more for the health of people.

Thus, we contemplate the age we celebrate in multiple ways: the health brought to millions of people around the world, the assimilated international quality standards, and the performance of becoming **the leading Romanian producer of generics. Our company exports Romanian medicines to 73 countries worldwide.**

In recognition of the outstanding performance obtained, the Presidency of Romania granted us the highest official distinction that can be given to a company, the Order "Industrial and Commercial Merit" in the rank of Commander.







159 pharmaceutical products  
(prescription drugs, OTCs,  
food supplements, cosmetics)  
in various pharmaceutical  
dosage forms

97 molecules and  
combinations  
of molecules

39 products  
unique in the  
Romanian  
market

## Our portfolio

*What differentiates our company among the 280 companies activating in Romania is our name and tradition. Our reputation gained through the dozens of products that restored the health of millions of Romanians ever since 1955 allows us to launch in the market new medicines, under this slogan: "A product guaranteed by Antibiotice, manufactured with science and soul".*

It is estimated that penicillin has saved hundreds of millions of lives since its discovery. We are proud that a part of these lives have been saved by the penicillin manufactured for the first time in the South-East of Europe on December 11, 1955, by Antibiotice. We are also proud that this product still represents us after 60 years, being considered an antibiotic with a critical importance in certain diseases\*.

We have maintained a major role in the anti-infectives market because, in time, we have developed cephalosporins, macrolides, fluoroquinolones, carbapenems and polymyxins classes. This way we have accomplished our mission to bring modern and approachable therapeutic alternatives for both doctors and patients.

Today, our portfolio includes 159 generic medicines from multiple therapeutic areas, a significant share of 84% being represented by prescription drugs.

We are also a traditional manufacturer of ointments, creams, gels, suppositories and ovules for dermatology, musculoskeletal disorders and for women's health – imposed both in the Romanian and in the international market.

As regards the active ingredients manufactured by biosynthesis we continuously perfected the techno-

\* World Health Organization – Critically Important Antimicrobials for Human Medicine, 2011

logical characteristics of the microbial strains, we have developed in 60 years of industrial microbiology, an exceptional informational base (collections of microbial strains, technologies of microbial fermentation, working techniques).

**We respond to the therapeutic trends**

Today, a generic medicine represents a proved viable alternative to the reference medicinal product in terms of quality, effectiveness and safety in administration. These medicines will represent in the future an increasing percent of the budgetary allocations in healthcare worldwide, being focused towards the therapy of some priority pathologies.

To respond to these trends, Antibiotice has been permanently adapting its portfolio, developing in the last 10 years drugs for cardiovascular and central nervous system diseases (mainly depression and Alzheimer’s disease).

The way in which the patients have access to modern treatments through the generics we produce allows us to improve the health of “more and more...” people and ensure sustainability for the national health care system.

**Complex portfolio comprising medicines from 12 therapeutic areas**

|   |                                 |
|---|---------------------------------|
| Antibiotics of systemic use               | Cardiovascular system           |
| Central nervous system                    | Digestive tract and metabolism  |
| Musculoskeletal System                    | Dermatological preparations     |
| Antineoplastic and immunomodulating drugs | Sense organs                    |
| Blood and haematopoietic organs           | Varia (solutions for hospitals) |
| Respiratory system                        | Genito-urinary system           |

12 therapeutic areas

the only manufacturer of active ingredients obtained by biosynthesis

# We define our future through research & development

"Science and soul" are two simple words which, through their convergent power, manage to differentiate us from other pharmaceutical producers and make us look boldly toward the future.

The last decade has been full of unprecedented changes in the regulation and dynamics of the pharmaceutical market. The drug producers' strategies and policies have changed a lot under the pressure of keeping costs and competition under control in a market dominated by multinational pharmaceutical companies, with complex portfolios. At the same time, companies have had to raise the bar in research, quality and manufacturing technology to meet increasingly stringent standards introduced for the safety of patients by the authorities in the field of medicines.

We have kept our identity throughout this decade and we have the courage to look boldly towards the future! We are proud to say that we are the producer which many physicians and pharmacists from Romania have relied on in the past 60 years. We are proud that in the six decades of existence generations of patients were cured using our medicines.

*For the trust of doctors, pharmacists and patients in our work, we feel responsible to come up with new alternatives for health, through a valuable portfolio adapted to current and future needs.*

Following our tradition, we define our future. We will remain a reference producer in the field of anti-infectives, always adapted to the new trends in medicine and we will continue to develop topical products. We will also develop drugs for cardiovascular and CNS diseases. Because, in the coming years, we want to identify ourselves as a promoter for preventing diseases, we will develop products increasing people's life quality.

## **Modern Research & Development Center**

For a high flexibility in the strategy of renewing its portfolio, Antibiotice continues investing significant resources in new technologies for the Research-Development Center. A multidisciplinary team of highly-experienced specialists made up of pharmacists, physicians, chemists, chemists engineers, and biologists work in this center. In the recent years this team has been extended by attracting valuable young specialists.





Integrated  
R&D Center:  
from formula to end-product



The Research & Development Center is an integrated applied research unit structured into five departments for developing a medicine from formula to the marketing authorization:

- **Pharmaceutical Development and Physico-Chemical Analysis Laboratory** – elaborate and develop new pharmaceutical formulas;
- **Center for Drug Evaluation** – tests the effectiveness and safety of the researched medicines through *in vivo* studies (bioequivalence clinical trials) and *in vitro* studies (dissolution profiles and biowaiver studies); it has the capacity to conduct phase I clinical studies for its own products and for third parties;
- **Regulatory Affairs** – is the interface between the company and the national and international drug regulatory agencies, ensuring the obtaining/maintaining of the marketing authorisations in Romania and abroad;
- **Pharmacovigilance** – permanently monitors the adverse reactions suspected to the medicines from our portfolio, a mission assumed by each medical representative. This activity ensures the patients that the benefit/risk ratio is always favourable and all the medicines manufactured by Antibiotice have proved their efficacy when safely used;
- **Biotechnological research** – optimizes the existent technologies as well as performs in house works of isolation, identification, characterization, multiplication, development of new strains with potential commercial applications.







Knowledge, experience and devotion of our R&D specialists for developing new medicines are rewarded by the satisfaction of offering to millions of people the desired state of health thanks to doctors and pharmacists.

**70** specialists  
open to partnerships  
with professional  
organizations and  
academic institutions

**22** new products  
in the last  
two years

Research & development  
trends:

- Cardiovascular diseases
- Neurodegenerative and psychiatric diseases
- Treatment of pain
- Increasing life quality

## Traditional leader in the domestic market

*The natural gesture of a patient to enter a pharmacy to get the medicine (s)he needs involves a complex mechanism that one can discover after learning what is going on in the world of the drug producers. Only then, one can discover the complicated machinery that moves at the same tempo and connects what happens in the research and quality laboratories, with production and distribution, so that medicines reach the people who need them.*



### **Top positions in the Romanian market**

(Cegedim data, 2015):

- The most important producer of generic antiinfectives;
- Leader in generic prescription drugs traded in hospitals;
- Leader (from a quantity viewpoint) in the production of ointments and suppositories;
- Leader (from a quantity viewpoint) in the segment of sterile powders for injection;
- Producer of the entire range of essential antituberculous drugs.

It is our responsibility to preserve the effectiveness of antibiotics as valuable therapeutic resources for infections, as well as prophylactic support for multiple modern techniques of treatment. In order to develop the segments of antiinfective and dermatological products, in the context of an increasing global competition, we have defined strategies focused on our patients and on the specialists to whom our products are addressed.

Our medicines reach the medical units and pharmacies via our distribution partners, that make possible the permanent access of patients and health specialists to our products.

- In all Romanian hospitals, the patients benefit from treatments with Antibiotice brands;
- Our medicines lead to significant savings in the Romanian healthcare system.

We continue to affirm ourselves in Romania as a quality producer offering new and accessible alternatives for treating cardiovascular, CNS, dermatological, digestive tract and metabolism diseases.

# Leader

in the production of:  
sterile powders for injection,  
ointments, creams and  
suppositories

Today,  
Antibiotice  
ranks

the 4<sup>th</sup>  
in generic  
medicines

the 13<sup>th</sup>  
among the 280  
producers active  
in the Romanian  
market.



## Antibiotice, an internationally recognized brand

*Taking part, in recent years, in the changes of Antibiotice's international business is like evolving from playing a violin to interpreting the same music on five different instruments. The jump recorded in approaching international business is obvious.*

*If, in 2005, exports were represented mainly by the active ingredients, our company currently trades about 70 drugs in countries on five continents. And another remarkable thing: Antibiotice has consolidated its sales partnerships, **ranking first worldwide in the production of the active ingredient Nystatin.***

*Antibiotice is not only a well-known brand in Romania, it has become an internationally recognized brand.*

To be able to sell a product in countries with different cultures and pharmaceutical regulations we had to create multidisciplinary teams with specialists in Regulatory Affairs, research, quality and export. All of these specialists harmonized their activities and learned about the regional peculiarities of the industry, in each market. This way, Antibiotice has succeeded in proving to the regulating authorities that its products deserve to be present in the markets approached by us only in our strategy documents, a few years ago.

### Sustainable and healthy growth together with our partners

We look for partners that are not simple resellers of Antibiotice products but companies with which we can shape strategies and turn our products into real brands. We look for collaborators that consider us a sustainable partner, with quality products, having material and innovative resources for a long-term development.

We are prepared to build partnerships in strategic areas in the European Community, North America, Russia, Middle East, South-East Asia, South America, Africa, in fields such as:

- Research & development of new generics;
- Marketing and registration of products in foreign markets;
- In/Out-licensing, co-manufacturing projects.

In today's international market Antibiotice is equivalent to:



Exports to  
**73** countries

**30** %  
export share  
in total  
turnover

**First place**  
worldwide in the  
production of Nystatin

## Rise of our Nystatin towards the first place in the global production

When the idea of selling our active ingredient Nystatin in the US market emerged, we did not expect that Antibiotice will become a world leader in the manufacture of this product.

To be able to enter such a well regulated market as the North American one, Antibiotice started a complex process of harmonisation with the international quality standards, raised the training level of our professionals and invested significant resources for revamping the manufacturing lines.

2002 marks a milestone in the destiny of this product. That year, as a result of the audit conducted by FDA, the manufacturing line of Nystatin received the approval for exporting this product in the US market. Since then, this product has become the bright signal which, issued with constant frequencies in the international community, has been drawing attention to Antibiotice, as a producer meeting both the European and American regulatory requirements.

We are constantly preoccupied to make the process more profitable and increase the competitiveness of Nystatin. So, in 2005, we purchased a high-performing manufacturing technology of Nystatin and productivity doubled in a very short time.

### **Nystatin, the most important exported product starting with 2005**

The Certificate of Suitability with the European Pharmacopoeia obtained in 2005 represents a new recognition of the quality of Nystatin. The same year Nystatin became the most important exported product in our company's portfolio. Through our perseverance, manufacturers all over the world producing oral tablets, creams and gels based on Nystatin have become and remained our loyal customers. So, in 2013, Antibiotice ranked first in the world production of Nystatin.

We lucidly contemplate the place we hold in the market. We are going to keep this place defining well-adapted marketing policies and continuously investing in revamping the manufacturing line to meet the new manufacturing and quality standards.



First place  
worldwide in the  
production of Nystatin



Nystatin is exported in more  
than **50** countries  
on all continents

## Internationally certified quality

*The recent history of Antibiotice has a consistent chapter, written on many pages, with answers to questions that anyone might address: "How did Antibiotice, a Romanian company, manage to deliver medicines in the Unites States of America, one of most regulated markets in the world?", "How do we succeed in keeping our medicines among the top recommendations made by professionals in the pharmaceutical field since there are so many therapeutic alternatives?"*

The answers to all these questions can be predicted once our concern for quality is understood. From the moment new quality regulations emerged, we revamped both the manufacturing facilities and the way of thinking. So, in 1999, we received the first Good Manufacturing Practice (GMP) certificate granted in Romania.

In the next years, we obtained GMP certifications for all 8 manufacturing lines justified through significant investments in revamping the manufacturing lines, quality control laboratories and through staff training. At the same time, these GMP certifications proved our determination to harmonise our production with the national and international quality requirements in order to prove to the health authorities, specialists and patients that we manufacture quality, safe and effective medicines.


In 2007, our company succeeded in certifying all the three management systems (quality, environment, occupational health and safety), becoming the first pharmaceutical company in Romania which obtained the recognition for implementing the Integrated Management System.

### **Audits and inspections from everywhere in the world**

Expansion of our international Affairs involved, alongside commercial and marketing strategies, assimilation and integration of international quality standards into our system. This way our company has become a successful exporter on various international markets and a reliable partner for numerous external companies. Each inspection and audit is like an exam and we keep proving that Antibiotice has a robust quality assurance system which is continuously improved, implemented in all the activity fields (starting from research – development, acquisitions, production, control and ending with the distribution stage). This system has at its heart the concern for the health of patients.

Among the audits conducted by the regulating authorities, those conducted by the American regulating authority, Food and Drug Administration are the ones that we are most proud of. Each of the FDA inspections for certifying the manufacturing line of Nystatin and manufacturing line of sterile products for injection made our company very visible in the international community, recognized for the quality of its products, creating new development opportunities in perspective.





8 GMP certified manufacturing lines for:

- Sterile powders for injection
- Capsules
- Tablets
- Topical products (ointments, gels, creams)
- Suppositories and ovules
- Nystatin, active ingredient

**Moments certifying our commitment for quality:**

**2002**

The manufacturing line of Nystatin, active ingredient obtained the FDA authorization which allowed exports of this product in the US (FDA reinspected in 2007, 2013 and 2015)

**2005**

Antibiotice obtained the Certificate of Suitability with the European Pharmacopoeia for Nystatin

**2007**

Antibiotice obtained the recognition for implementing the Integrated Management System:

- ISO 9001:2000 Quality management
- ISO 14001:2004 Environmental management
- OHSAS 18001:2007 Management of occupational health and safety

**2010**

The manufacturing line of sterile penicillins for injection obtained the FDA certification (FDA reinspected in 2013 and 2015)



# Generations of people evolving together

*Over the last 60 years, four generations of people have evolved together, defining the culture and values of this organization. Generations of people shared their achievements, they adapted to the current times to write the history that brought our organization to the modern period. We see this change every time we look into the eyes of children.*

*The slogan **"Science and soul"** assumed by each of the 1500 employees 10 years ago remains as present today because it best reflects the essence of this culture and talks about how people are determined to do good things for other people.*

Our company's success is guaranteed also by the human resource strategies:

- by adapting the human resources to the strategic orientation of the company
- by focusing the organizational culture towards innovation and performance, by permanently assessing and improving the organizational climate.

## **Innovative and competitive spirit**

In our organizational culture, we appreciate the exchange of ideas and solutions, innovation and team spirit to overcome ourselves individually and collectively. For this purpose, in recent years, we have implemented the projects "Ideas are free of charge", a system which our employees are encouraged to share and implement ideas and solutions to improve their work while ensuring and monitoring the results obtained as a result of their application.

## **A team of experts focused on knowledge**

The focus on knowledge and development of the professional and personal skills have been supported through training programs for enabling our employees to adapt to dynamic market conditions, so as to cope with the technological challenges and increasing competition. One of these programmes, both for developing our employees as well as for attracting new valuable employees, in specialized fields, is the project "Summer school a+". For 6 years in a row, this program has provided both development of the professional skills of our employees, in line with the international trends of the industry, as well as the opportunity of hiring future specialists trained in the academic environment, who will take up the legacy "of continuity and performance."

1,465 employees

600 employees with higher education (doctors, pharmacists, chemists, engineers, economists, biologists, physicists and others)

Bringing in our daily activity, the principles and modern management methods, we aim at raising the awareness and involvement at all the levels of the organizational structure.

The Management by Objective System (MBO) implemented since 2005 enabled the employees to formulate their personal goals fully consistent with the mission and vision of the company, their achievement being rewarded through a specific incentive system.

## Results of the project **"Summer school a+"**

**500** employees attending personal development and professional courses

**275** graduates and students attended the "Summer school a+" courses

**25** graduates who attended the courses of "Summer school a+" have become our employees in the drug research, production and quality control









## With science and soul, alongside the community and those in need

A company's success is measured not only in the financial indicators and goals met, but also in its contribution to the community.

Through the Foundation "**Antibiotice – Science and soul**", our company does charity work, humanitarian projects. It also develops cultural and educational programs, designed to support children from disadvantaged families, old, suffering people, people in difficulty or valuable youngsters, without material possibilities.

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

Under this humanitarian urge, our employees have participated every year, since 2010, in the blood donation campaign, organized internally, in partnership with the Regional Centre for Blood Transfusion (CRTS) Iași. This action responds to both the increasing need of blood supply in hospitals and the employees' desire to save people's lives in medical emergencies.

### **"Science and Soul" Scholarships**

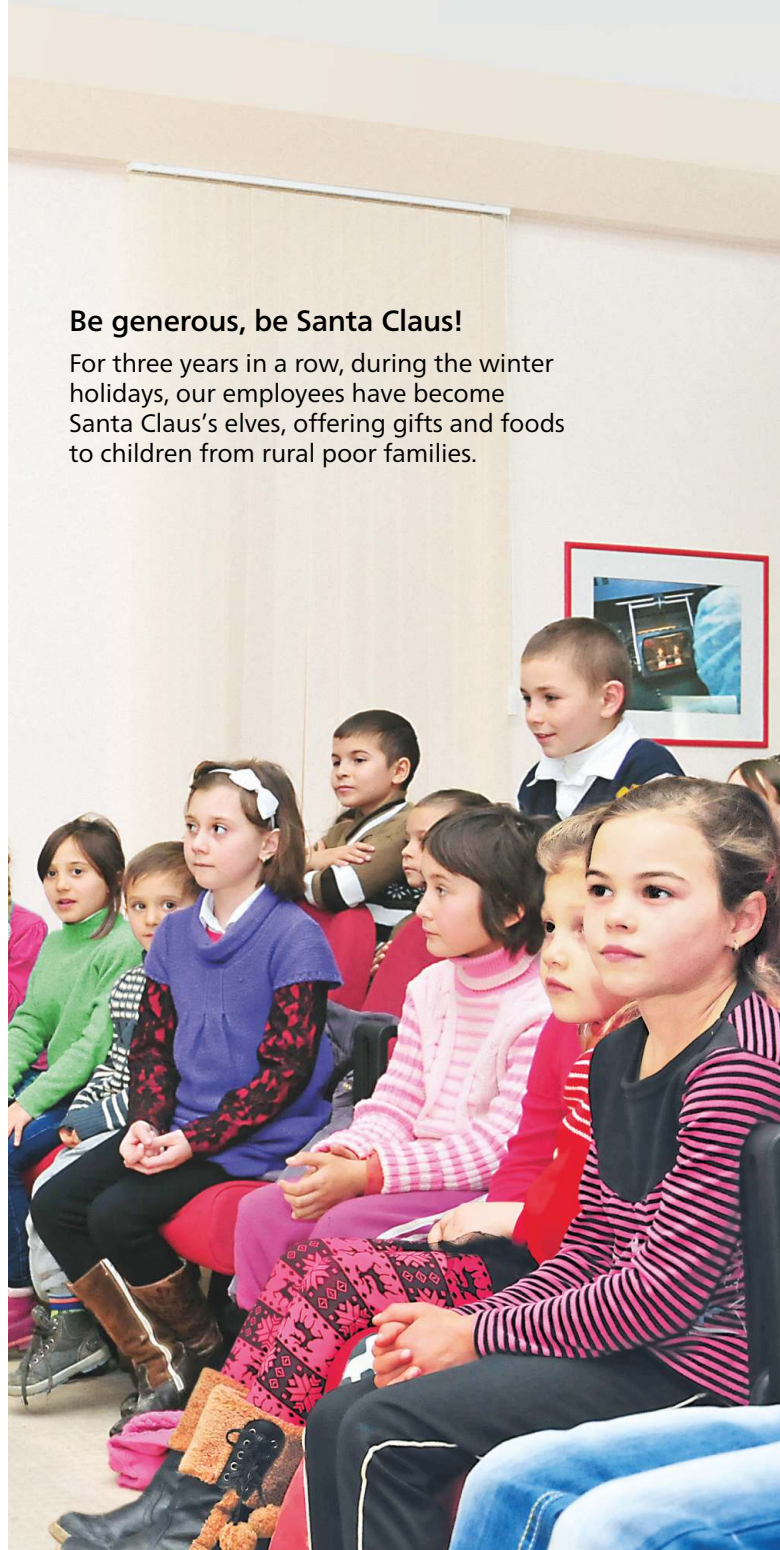
For 14 years, our company together with the "Pro Ruralis" Association have been contributing to the education of the high IQ children from rural areas coming from disadvantaged families. Thus, these children have the chance to continue their secondary and high school studies, which open new horizons in their professional and personal development.

### **Power of deed**

Starting with 2003, more than 8,000 people were supported through the program "Power of deed": children with special needs, disabled children or children with severe diseases such as AIDS, DOWN's syndrome etc., broken families facing a high risk of abandoning their children, sick or elderly people abandoned by the family.

### **Be generous, be Santa Claus!**

For three years in a row, during the winter holidays, our employees have become Santa Claus's elves, offering gifts and foods to children from rural poor families.



## Awards and honors

The results of our company have been recognized over the years by the main national and international authorities in the pharmaceutical industry. The important distinctions rewarded the economic and financial performance, quality standards and recognition of the community involvement:

- **“Order of Industrial and Commercial Merit”** in the degree of Commander, awarded by Romanian Presidency, the highest official distinction that can be given to a company (2013)
- **Honorary Trophy “The most dynamic manufacturer and exporter of medicines in Romania”** (6 years consecutively)
- **The “National Award” trophy**, 1st place in the category “Industry – large enterprises – manufacture of basic pharmaceutical products”, granted by the Chamber of Commerce and Industry of Romania (6 years in a row)
- **Medicine Award – Euroinvent** (2015)



328 million LEI,  
turnover  
in 2015,

30 %  
export share  
in total turnover

38.5 million EUR,  
invested,  
in recent years, for extending  
and revamping the manufac-  
turing capacities; a modern  
Research-Development Center,  
quality control laboratories,  
for protecting the environment  
and for training employees

300 specialists recently  
employed in the  
following fields:  
marketing and  
promotion, research,  
quality and  
production of drugs

More than  
10,000  
employees, over  
the last 60 years

**Antibiotice SA**

1 Valea Lupului Street

707410 Iași, Romania

T: +40 232 209 000

F: +40 232 065 633

[office@antibiotice.ro](mailto:office@antibiotice.ro)

[www.antibiotice.ro](http://www.antibiotice.ro)