

Antibiotice
Science and soul



Antibiotice, an international company





In service of life for a lifetime!

History



1955

Just only a decade later after the synthesis of penicillin, Antibiotice SA starts operating and becomes the first manufacturer of the active pharmaceutical ingredient in Romania and South East Europe.



1955-1990

Development of the manufacturing structure, especially for active pharmaceutical ingredients, sterile powders for injection, ointments and suppositories.



1990-2000

- Reconsideration of the manufacturing structure, investments in local and international marketing operations to adapt to the market economy
- Development of the manufacturing of finished dosage forms (i.e. capsules and tablets)
- Company's listing on the Bucharest Stock Exchange (April 1997)
- Optimization of the manufacturing technologies of Nystatin and Vitamin B12.



2000-2010

- EUR 60 million investment in updating manufacturing technologies, developing the product portfolio and environmental protection, to ensure compliance with the EU regulations
- US FDA approval for the manufacturing of Nystatin API and sterile powders for injection
- Certification of the quality systems to achieve compliance with the cGMP and US FDA requirements
- Opening of the in-house Center for Drug Evaluation



2010-2020

- First deliveries of finished products to the US as a result of the US FDA approval
- World's leading manufacturer of Nystatin API; Nystatin API made by Antibiotice becomes the USP reference standard for the substance
- Opening of business offices in the Republic of Moldova, Ukraine, Serbia and Vietnam
- Implementation of an integrated management system (quality, environment, occupational health and safety)

Antibiotice Today

Antibiotice is the largest pharmaceutical company with full Romanian capital, which has proved that is capable of manufacturing medicinal products to international industry standards. The company is recognized as:

- **The leading manufacturer** of generic anti-infective drugs in Romania
- **Leading manufacturer** of topical products in Romania, in terms of quantity
- **Worldwide leader** for the manufacturing of Nystatin API, which is the current United States Pharmacopoeia's (USP) reference standard for this substance
- Marketing and sales offices in Vietnam, Republic of Moldova, Ukraine and Serbia



Antibiotice has a complex portfolio of products and services, which includes:

- Finished products (medicinal products for human use, medicinal products for veterinary use)
- Active pharmaceutical ingredients
- Biocidal products
- Clinical trials and bioanalytical services

Antibiotice has its own Center for Research & Development as well as a Center for Clinical Trials, where R&D projects and clinical trials are performed for different pharmaceutical products to be manufactured by the three Manufacturing Divisions of the company, i.e.:

- the Sterile Products and APIs Division (penicillin injectable powders, biosynthesis APIs, biocidal solutions);
- the Solid Oral Forms Division (penicillin capsules, non-beta lactam capsules, cephalosporin capsules, and tablets);
- the Topical Products Division (ointments, creams, gels, suppositories and pessaries).

Antibiotic has the following internationally recognized certifications:

- Good Manufacturing Practice (EU-GMP)
- Certificate of Suitability (COS) issued by EDQM
- US Food and Drug Administration (FDA) approval
- Integrated Management System (since 2007) for quality (ISO 9001/2008), environment (ISO 14001/2004), occupational health and safety (OHSAS 18001/1999).

Quality management

- **WHO prequalification** for anti-tuberculosis medicines 
- **EU-GMP** for all the 8 manufacturing flows 
- **US FDA** for sterile injectable powders and the active substance Nystatin 
- **Certificate of Suitability (CoS)** for micronized Nystatin issued by EDQM 
- **Certificate TÜV Rheinland** for Integrated Quality Management System 



Strategic Development Plan for 2020-2030

The company's development objectives for 2020-2030 are described in the Strategic Organization and Development Plan, which reflects Antibiotice's long-term vision and commitment to a sustainable growth along with its business partners.

Antibiotice's aspirations and targets by 2030 are:

- > twofold increase of the business value and improvement of profitability;
- > business internationalization (international sales to account for 50% of the turnover) and increase in international business notoriety;
- > upholding the worldwide leading position as a manufacturer of Nystatin API;

- > sustainable development by improving the company's performance in relation to the Environmental, Social, Governance (ESG) criteria, which consider the impact of the company on the environment, employees, customers, and the communities where it operates

The fulfillment of these objectives relies mainly on the two types of future investments, i.e.:

- > Strategic investments in new manufacturing sites for sterile solutions and topical products, in the research of new products, license acquisition, and a new center for research in cooperation with academic entities
- > Investments for business consolidation, focused on the digitalization of processes, production of green energy and biofertilizers, site infrastructure upgrade



The Specialists of the Company

The long-term success of the company is possible owing to its valuable team of specialists, involved in all the manufacturing stages of a medicinal product, from molecule to market.

- **Complexity of activities:** acquisitions, manufacturing, quality control, research and regulatory affairs, clinical trials, local and international marketing and sales
- **Diversity of professions:** chemists, biochemists, pharmacists, physicians, biologists, economists, engineers, IT specialists, technicians, chemical operators, automation specialists
- **Three generations of professionals,** continuously trained

The development of professional, business and leadership competencies of the employees is carried out by the training programs offered by Academia a+.

Academia a+:

Business
School

Technical
College a+

Young people are attracted by the **Perform a+, Technical College a+** and dual education programs developed in cooperation with renowned pre-university and university institutions.

Portfolio of Finished Products and Active Ingredients

Antibiotice provides to patients and professionals, a valuable and complex portfolio of medicinal products, which includes:

- > 150 finished dosage forms from 11 therapeutic groups (generic medicines for human and veterinary use, medical devices, food supplements, cosmetics);
- > active pharmaceutical ingredients (three types of Nystatin),
- > biocidal products

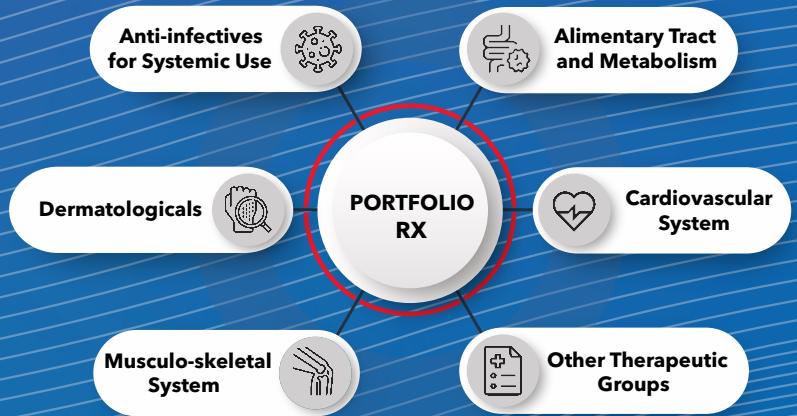
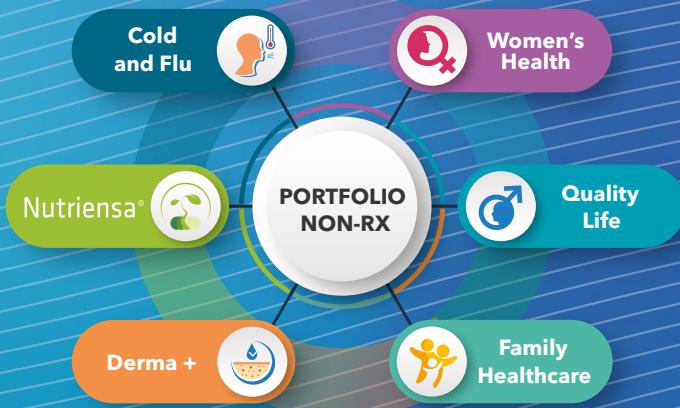
The generic medicines portfolio is intended particularly for patients with infectious, cardiovascular, dermatological, digestive, CNS diseases and disorders as well as for the prevention of different diseases and improvement of the quality of life.

- > **Antibiotice** - a renowned manufacturer of beta-lactam anti-infectives (penicillins, amino-penicillins, cephalosporins, carbapenems, polymyxin, tetracyclines), as well as macrolide anti-infectives and fluoroquinolones.
- > **The Nutriensa brand** - the collection of food supplements, with innovative formulas combining standardized extracts, vitamins and minerals

Antibiotice's portfolio of products includes also Nystatin, an active pharmaceutical ingredient (an antifungal antibiotic), which is manufactured by a process of biosynthesis, unique in Romania. The development of new finished medicinal products containing nystatin and of nanostructured medicines is part of the vertical integration and development strategy for this product.

Moreover, Antibiotice manufactures **TP1 (human hygiene)** and **TP2 (disinfection of surfaces)** biocidal products, whose microbiological efficacy is tested by certified laboratories.





Scientific Research in Line with the European Standards

The R&D team perform around 80% of the portfolio development operations in the in-house Research and Development Center.

The Center is appropriately equipped for the research and development of:

- value-added generics (tablets, capsules, topicals, products for injection)
- cosmetics and medical devices
- novel combinations of food supplements
- optimization of biosynthesis processes of the active ingredients
- development of products for ecological agriculture: biofertilizers, biostimulators and bioinsecticides
- disinfectants

The research activities are carried out by 100 specialists from different fields: intellectual property, pharmaceutical formulation, technological transfer, bioequivalence studies, Regulatory Affairs, pharmacovigilance, and portfolio management.

Antibiotice aims at enhancing its research capacity by establishing partnerships with universities and renowned scientific research entities (the **Inova a+** project), which would allow the implementation of valuable scientific results at industrial level.

Center for Clinical Trials

Antibiotice has its own Center for Clinical Trials since 2006, where clinical studies are conducted to demonstrate the efficacy of the products manufactured by the company or by third parties.

The Center is a scientific research unit authorized by the Romanian Ministry of Health to perform clinical trials (phase 1) and bioequivalence studies (with no therapeutic benefit).

The Center has a clinical unit, a bioanalytical one (with a cGLP-certified bioanalytical laboratory) and a secondary packaging line for the clinical investigational medicinal product.

Antibiotice provides to interested companies clinical and/or bioanalytical services specific to phase 1 clinical trials and bioequivalence studies.



More than
100
clinical trials
and bioequivalence
studies
conducted

Clients from
France,
Greece, Cyprus,
the Netherlands,
Norway and
Canada.

35%
of the specialists
involved in research
have a Ph.D

Antibiotice, an International Company

Antibiotice has business operations in Romania and internationally and has developed active partnerships with more than 70 partners for the marketing and sale of:

- > Nystatin - active pharmaceutical ingredient
- > finished dosage forms.

The territorial expansion plan to 2030 is focused on the internationalization of the portfolio of finished products (sterile anti-infectives, topicals), accessing new markets and strengthening the status of worldwide leader in the manufacturing of Nystatin API.

The company's main markets for the finished products are: USA, Canada, UK, the Netherlands, Denmark, Serbia, Republic of Moldova, Vietnam and Iraq.

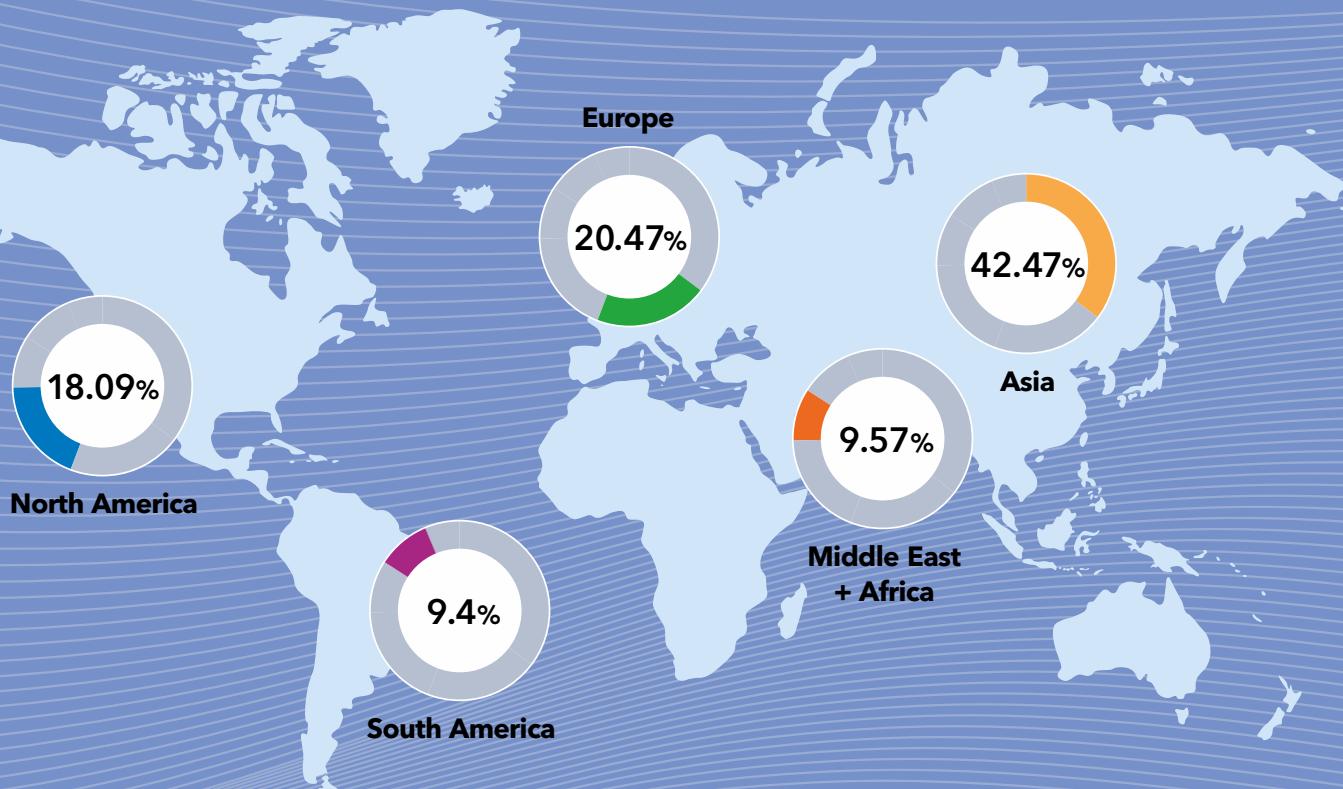


In the 45 years of Nystatin manufacturing, the quality of this active ingredient has been improved continuously, the following certifications attesting this progress:

- > **United States Pharmacopoeia's (USP)** reference standard for this substance since 2017.
- > **US Food and Drug Administration's approval** (which allows the sale of the product to the US)

Nystatin is delivered in countries from almost all continents, i.e. North America, Latin America, Europe, Asia and Africa, and is used in the production of tablets, oral suspensions, topical preparations (creams, ointments), and pessaries.

International Sales Breakdown



>158.2
million lei
revenue from
sales in the
foreign markets



Antibiotice, a Partner of Healthcare Systems

The valuable generic products manufactured by the company provide support for the national health systems in Romania and abroad, both in developed and emerging countries.

In Romania, Antibiotice:

- > Is present in all the 500 hospitals and over 8,000 pharmacies in Romania
- > Supports the health programs - main product supplier in the national tuberculosis control program
- > Provides access to treatment for most medical and surgical specialties: infectious diseases, intensive care, cardiovascular diseases, dermatological and rheumatic diseases, alimentary tract disorders, nervous system disorders

Acknowledgement from healthcare systems

Antibiotice's quality standards make possible the participation in different tenders held by the health authorities in other countries. Thus, the medicinal products manufactured by the company reach hospitals from:

- > UK
- > Denmark
- > USA
- > Vietnam

49
medicinal products
classified as essential
by the World Health
Organization





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