# In the service of life for a lifetime



Antibiotice



#### Tradition means continuity and recognition

1955	One decade only after penicillin synthesis, Antibiotice starts operating and becomes the first manufacturer of this active pharmaceutical ingredient in Romania and South East Europe
1955-1990	The manufacturing structure develops to include the production of other active ingredients, particularly sterile powders for injection, ointments and suppositories
1990 - 2000	<ul> <li>Antibiotice redefines its manufacturing structure and invests in internal and international marketing activities to adapt to the market economy;</li> <li>The company updates the manufacturing technologies and facilities;</li> <li>Antibiotice is listed on the Bucharest Stock Exchange - Premium Tier (April 1997)</li> <li>The company adopts the RICOP program coordinated by the World Bank</li> <li>Substantial investment (60 million EUR) in:         <ul> <li>updating technologies, acquisition of modern and competitive equipment</li> <li>utility production restructuring</li> <li>development of the product portfolio</li> </ul> </li> </ul>
2000 - 2005	<ul> <li>environmental protection to achieve compliance with the EU regulations</li> <li>certification of the quality systems to comply with the cGMP şi US FDA standards</li> <li>FDA approval for the manufacturing plants of Nystatin API and sterile powders for injection</li> <li>Launch of a fresh corporate brand identity (a new logo, a+ and a new slogan, "Science and Soul")</li> </ul>

Antibiotice

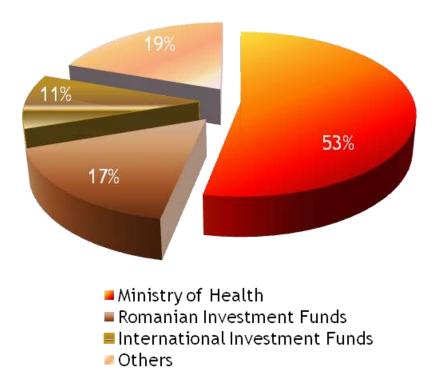
#### Tradition means continuity and recognition

2010 - 2015	<ul> <li>Antibiotice makes the first deliveries of finished products to the US following the FDA approval;</li> <li>Antibiotice becomes the world's leading manufacturer of Nystatin;</li> <li>Strong focus on business internationalization</li> <li>Business offices in the Republic of Moldavia and Serbia;</li> <li>Opening of the in-house Center for Drug Evaluation;</li> <li>The first WHO-prequalified European company for anti-tuberculosis drugs</li> </ul>
2015 - 2020	<ul> <li>Nystatin manufactured by Antibiotice becomes the USP reference standard for this substance</li> <li>Business offices in Vietnam and Ukraine;</li> <li>Product portfolio - 150 medicines from 12 therapeutic classes;</li> <li>Continual international business expansion following the obtaining of new marketing authorizations</li> </ul>
2020-2025	<ul> <li>Optimal staff structure and formation of competencies and skills for achieving the company's objectives;</li> <li>Achieving and maintaining all the certifications required for company operation and business partnerships development</li> <li>Strategies for portfolio expansion by increasing the number of generic products and stimulation of innovation;</li> <li>Sustainable development accelerated by efficient investments in new production facilities;</li> <li>Maximization of the company presence in the ATB territories;</li> </ul>



#### Antibiotice in the capital market

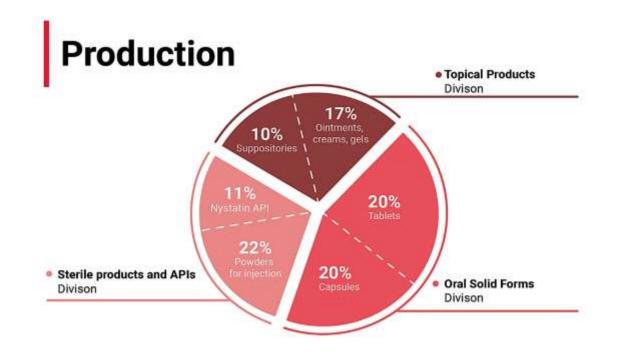
During the 23 years since the company was listed, more than **750 million shares** with a **total value exceeding 280 million EUR** have been traded.





#### Manufacturing

- **500 million pharmaceutical units** as tablets, capsules, products for injection, topicals (ointments, creams, gels), suppositories and pessaries;
- Active pharmaceutical ingredient, Nystatin





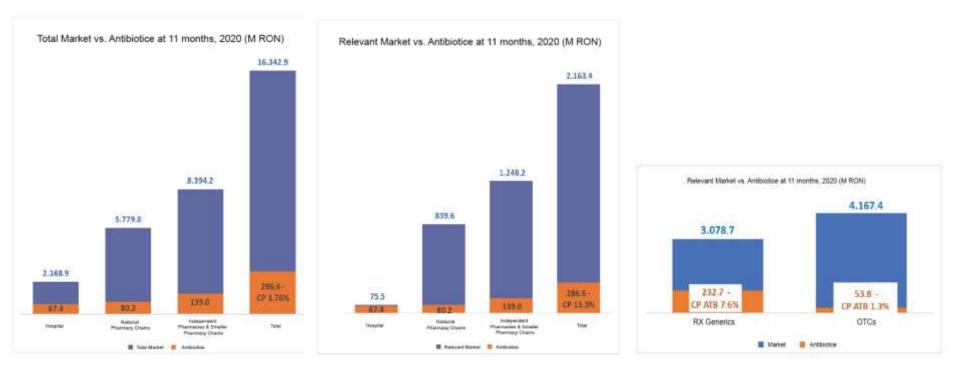
#### Antibiotice now

- > Portfolio of 150 de pharmaceutical products from 13 therapeutic groups
  - Anti-infectives for systemic use
  - Cardiovascular system
  - Dermatologicals
  - Alimentary tract and metabolism
  - Nervous system
  - Musculo-skeletal system
  - Sensory organs
  - Genito-urinary system
  - Respiratory system
  - Hospital solutions
  - Blood and blood forming organs
  - Dietary supplements
  - Sterile and biocidal solutions

#### Current place of Antibiotice in the market



- > No.21 spot in the total market (value market share: 1.76%)
- > No.2 spot on the list of top Romanian manufacturers of generics (market share: 13.07%)
- > No.1 spot in the relevant market (market share: 13.3%)
- > No.4 spot in the market of Rx generics (market share: 7.6%)
- > No.19 spot in the market of non-prescription medicines (market share: 1.3%)





#### **Business internationalization**

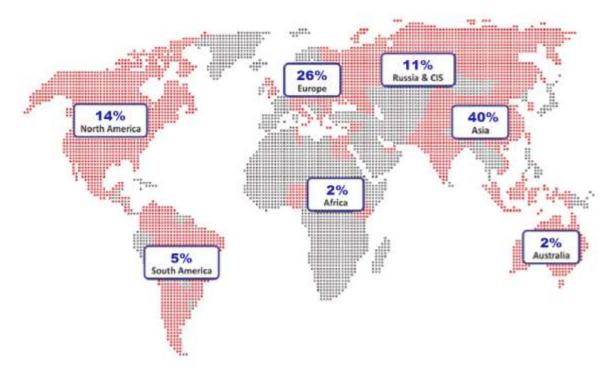
**158 million RON** export turnover in 2020

70 products registered in different countries

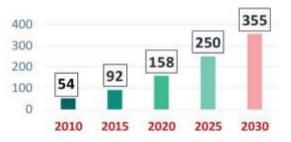
Nystatin API - worldwide leader

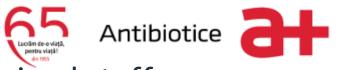
Ongoing international projects with a total value of 60 million RON in North America, EU, Southeast Asia, Russia, and CIS Representative offices in ATB territories: Socialist Republic of Vietnam, Republic of Moldova, Ukraine, Serbia

#### A Romanian brand with international recognition



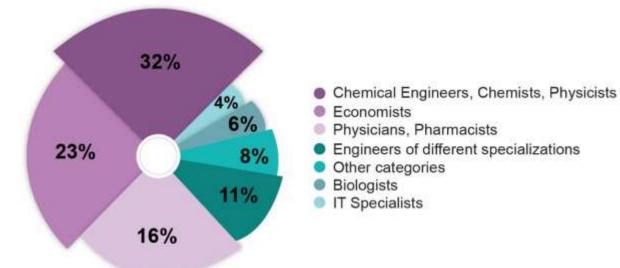






## Our most important resource: highly trained staff

- ✓ over 1400 employees
- $\checkmark$  three generations
- diversity of professions chemists, biochemists, pharmacists, physicians, biologists, economists, engineers, IT specialists, technicians, chemical operators, automation specialists
- Center for the formation and training of students from the Faculties of Biology, Medicine, Pharmacy, Chemistry, Chemical Engineering, Environmental Protection
- Provides to the future specialists the opportunity to develop their skills and acquire useful knowledge for a career in the pharmaceutical industry.



## Integrated quality management

Integrated quality management system

(quality, environment, occupational safety and health)

#### International quality certifications:

- EU-GMP for 8 manufacturing lines
- US FDA for sterile powders for injection and Nystatin API
- CoS (certificate of suitability) issued by EDQM in 2004 and renewed in 2018
- TÜV Rheinland certification for integrated management (quality, environment, occupational safety and health)
- Approvals for international partners (aprox. 20 annual audits)





European Directorate for the Quality of Medicines & HealthCare



Management System ISO 9001:2015 ISO 14001:2015 ISO 45001:2018

www.tuv.com ID 9000004194

**Objective:** Support of business partnerships

Antibiotice

## Research & Development - sustenability of the future

- A multidisciplinary team of more than 110 de specialists who perform, in an integrated manner, all the stages of research and development to the obtaining of the Marketing Authorization in Romania or abroad, in compliance with the current regulatory requirements of the European Medicines Agency, the US Food and Drug Administration or the national legislation:

- **Pre-formulation** (identification of authorized sources of raw materials, characterization of raw materials)
- Formulation (identification of the optimal formula, scale-up, quality and safety assessment by validated analytical and bioanalytical methods)
- Evaluation of efficacy and safety (phase 1 clinical trials, pharmacovigilance)
- Regulatory Affairs

- Development of partnerships with higher education institutions by projects and cooperation with the pharmaceutical industry;

- Retention of specialists (pharmacists, chemists, physicians) and the intellectual and research patrimony in Romania, by developing the competencies specific to the pharmaceutical industry, thus ensuring international competitiveness

Antibiotice



## Antibiotice, a responsible company

