

Company presentation

Tradition and experience

focus on sterile and non-sterile API production by semisynthesis and biosynthesis (penicillin and penicillin derivatives, nystatin, streptomycin, erythromycin, oxytetracyclin, tetracycline, griseofulvin, rifampicin, lysine, Vitamin B12)

began production of ointments, creams and suppositories

major investments for upgrading and acquisition of modern and competitive equipments

launch of the cardiovascular portfolio

launch of the oncology portfolio

11th of December 1955

1959

1974

Until '90

1990

1993-1997

1998

2005

2010

2012

2014

Antibiotice begins the production of Penicillin API by biosynthesis

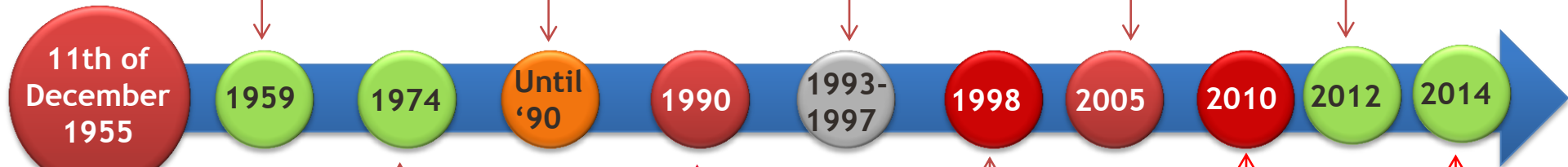
begins production of sterile powders for injection - penicillins

capsules and tablets workshops start up

launch of cephalosporin sterile powders for injection portfolio

launch of the CNS portfolio

launch of carba-penems



Who we are

We have proved, over the years, with professionalism and passion, that we deserve the reputation as the most important Romanian manufacturing company for anti-infective products.

60 years of continuity and tradition rank Antibiotice between the oldest and best known pharmaceutical brands in Romania and worldwide.

Values we believe in

We want to achieve growth, by creating valuable and accessible medicines for all the people in need.

We are always focused to produce and offer the best quality products, safe and efficient, to protect the environment and to insure the health and security of our employees.

We act according to this vision and to our mission, day by day, with science and soul, aiming to expand our horizon of knowledge, by searching new solutions and ideas.

How we see the future

We see ourselves as a company with a sustainable and healthy growth.

More than that, we know that in our organization, the added value is given by our focus on innovation, research and development of new generic medicines, new technologies and new pharmaceuticals forms and by our openness focus on international partnership.

The most complex manufacturing structure in Romania

Sterile powders for injection	PENICILLINS STERILE POWDERS FOR INJECTION	EuGMP U.S. FDA
Tablets	TABLETS	EuGMP
Capsules	CAPSULES Penicillins flow Cephalosporins flow Non β -lactams flow	EuGMP
Semisolids	OINTMENTS, CREAMS, GELS	EuGMP
Semisolids	SUPPOSITORIES	EuGMP
APIs	BIOSYNTHESIS: NYSTATIN	EuGMP U.S. FDA

- *Antibiotice* owns a **Research & Development Center**, (through an investments of above 10 million Eur), where qualified personnel selects and develops more than 13 - 15 new projects per year.
Our experience covers all the therapeutic areas and pharmaceutical forms.
- *Antibiotice* develops, by in-house research, its own generic product portfolio or new products for our partners, from the stage of developing a pharmaceutical formula to the confirmation of the product's efficacy and safety by bioequivalence studies, with all the required documentation.



Our mission is to make high quality products, safe and efficient

- *Antibiotice* owns one of the most modern Romanian Center for Clinical Studies.

It was founded in 2005, as the first Romanian **Drug Evaluation Center**, with an investment of 10 million Eur. Now, it is one of the largest centers of phase I clinical studies (including bioequivalence) in Romania and conducts 30 clinical trials/year.

All activities are carried out in conformity with the current EMA regulations on the good clinical practice (GCP) and good laboratory practice (GLP).

The trials are carried out both for *Antibiotice* and for other international pharmaceutical companies from the EU, USA or Canada.

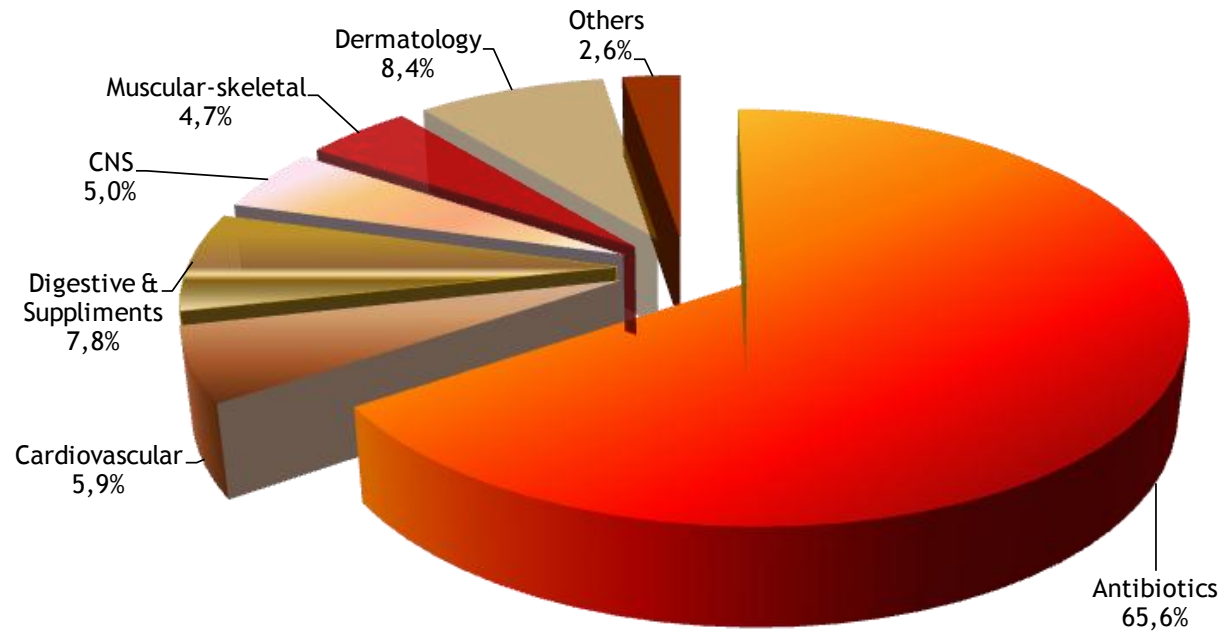
- *Antibiotice* is the first Romanian pharmaceutical company listed in the European network for the monitorization of the medicines' safety by connecting, in 2007, to **Eudravigilance**.



- EU-GMP approval for all manufacturing plants
- US FDA approval for sterile powders for injection and Nystatin API
- CoS for Nystatin issued by EDQM in 2004 and renewed in 2010
- Integrated management certification from Lloyd's Register Quality Assurance (quality, environment, occupational health and safety)
- We are also approved from various overseas Customers (about 20 audits each year)



140 human products, of which:



Key moments

- 1998: launch of Cephalosporin sterile powders for injection (2012 - leader, with 70% market share)
- 2005: launch of the Cardiovascular portfolio
- 2010: launch of the CNS portfolio
- 2012: launch of the Oncology portfolio

- Starting with 1998, Antibiotice has been a strategic partner of the Romanian Ministry of Health in the National Tuberculosis Control Program.
- Starting with 2013, Antibiotice becomes WHO prequalified for anti-tuberculosis products.

FIRST-LINE ANTI-TUBERCULOSIS DRUGS

- *Rifampicin* capsules 150 mg and 300 mg
- *Rifampicin + Isoniazid* capsules 300 mg + 150 mg
- *Isoniazid* tablets 100 mg and 300 mg
- *Ethambutol* coated tablets 250 mg and 400 mg
- *Pyrazinamid* tablets 500 mg
- *Streptomycin* powder for injection 1 g



World Health
Organization

SECOND-LINE ANTI-TUBERCULOSIS DRUGS

- *Cicloserin* capsules 250 mg (*cooperation*)
- *Ethionamid* film coated tablets 250 mg

Active presence on the Romanian market of generic drugs

Ist place on the Romanian market

- Sterile powders for injection - 73% of the market
- Ointments, creams, gels - 31% of the market
- Suppositories - 45% of the market
- Hospital segment - 21,4% of the market

IIIrd place on the Romanian market

- Dermatology - 13% of the market

IInd place on the Romanian market

- Anti-infectives - 16% of the markets
- Capsules - 10% of the market

IVth place on the Romanian market

- In top 10 generic companies

10th place from a total of more than 300 pharmaceutical companies present on the Romanian market

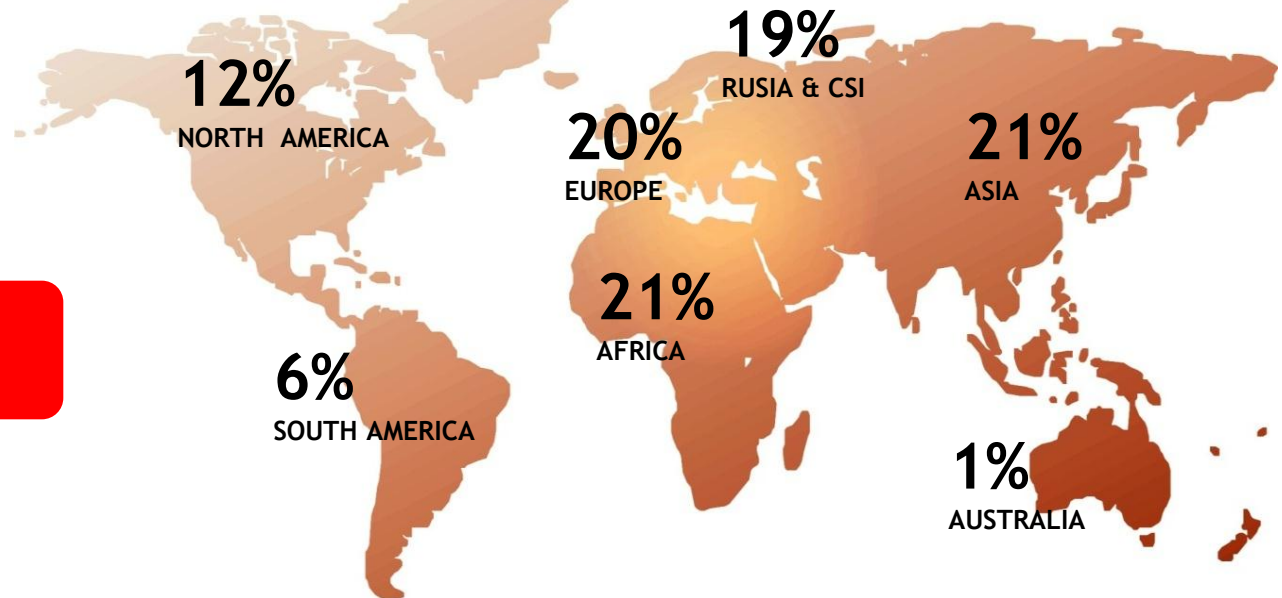
60 new products launched on the market in the period 2010 - 2014 from different therapeutic areas as: antibiotics, cardiovascular, CNS, digestive & supplements, dermatology, anti-inflammatory, oncology

Over 100 international partnerships worldwide

Leading worldwide manufacturer for Nystatin

70 products registered internationally

60 countries worldwide



- New projects of over 15 million USD developed with partners from North America, Canada European Union, Russia - C.I.S. countries, Australia, Middle East and North Africa.

- In 2010, Antibiotice set up the SUMMER SCHOOL a+ aimed at both increasing the professional training and development of its staff and attracting students.
- In 2008, we started the program “Be Pro Nature ! Get involved!”, to inform and make our employees aware about the environment.
- In 2005, we founded the Association of Former Antibiotice Employees, in order to monitor and solve the various problems encountered by the retired, former Antibiotice employees.
- During its history, over 5.000 people with disabilities, children and old people were helped through our social campaigns which spread joy and hope: “The power of action”, “Offer a book, offer a smile”, “With since and soul, close to people”



Thank you