Antibiotice
Science and soul

SUSTAINABILITY REPORT 2020

In service of life for a lifetime!

In service of life for a lifetime!

Contents

Message from the General Director of Antibiotice SA

Dear collaborators,

I am honored to present you the fourth Sustainability Report of Antibiotice SA, an approach by which we try to show that are honestly engaged in changing the paradigm about the use of natural resources and reducing the impact we have on the environment, we are open to dialogue with all the stakeholders so as to grow sustainably, together.

In 2020, our company celebrated 65 years of activity and I can only be proud of the fact that, in this turbulent year, our team proved empathy and solidarity with people in fulfilling our mission to manufacture affordable and valuable medicines that meet the needs of the healthcare system, health professionals and consumers, both nationally and internationally.

This year, in order to rapidly meet the immediate needs of the medical system and citizens, we have adapted the product portfolios, we brought into the market the medicines included in the treatment of SARS-CoV-2 associated infections, without raising their prices, despite the difficult conditions of import and production. We have also started producing biocides for surface disinfection, thus supporting a health system in need.

We have been permanently investing in our medicine portfolio by an innovative operational research in order to find therapeutic solutions adapted to the contemporary medical requirements.

So, at the end of 2020, Antibiotice had 24 research projects in progress, in various development stages.

We are glad that, for over seven years, we have maintained ourselves as a world leader in the production of the active substance Nystatin, but also because our portfolio offers a variety of treatment options, facilitating this way the population's access to medicines.

Through our solidarity and involvement we managed in a critical period to carry out our production activity without interruption and, implicitly, we continued to deliver our medicinal products to the foreign markets. Thus, with all the challenges of the pandemic, we continued to strengthen our business abroad, being a major player in the tenders for injectables in Europe and the US, thus ensuring the patients with medicines all over the world.

We also got involved in meeting the needs of the community, supporting the public health system with medicines, material support and donations. Our number one priority is the safety and health of our employees, they are an essential resource for Antibiotice.

With well-defined scenarios and plans, the measures we implemented, through the Crisis Cell set up within the company, proved to be effective in combating and preventing COVID-19 infections.

Because we are concerned about the well-being of our employees, we implemented development and training programs to support colleagues and help increase motivation and satisfaction. We implemented also as a modern motivation system with a robust package of benefits.

We believe that the constant dialogue and transparent communication underpin an ethical behaviour which encourages performance, meritocracy and equal development opportunities for the over 1,400 employees of our company.

In 2020, we continued to develop a business built in over six decades with a long-term vision and a strong commitment to sustainable development.

We have thus put the Strategic Organization and Development Plan at the base of our development strategy for the next years. This Plan aims for a responsible business growth, focused on five strategic pillars. We integrated the social and environmental issues important for our stakeholders who are constantly our dialogue partners, to set our priorities and adapt our business model.

Antibiotice is a mature business, so the responsibility we have for the natural environment in which we operate is integrated into the business model. With an environmental management system aimed at strictly complying with legislative requirements and assuming best practices in the sector, we value natural resources and streamline our production processes, aiming to improve resource management systems to minimize negative effects on the environment.

All this period has shown us once again that we have the ability to adapt quickly, the will and determination to do the things that come to the aid of the people whose health we put first, that science and soul is not just a slogan but a way of feeling and living that we apply in relation to those who depend on our business, community and those who need our products.

Looking back on this whole period, we can't help but wonder: What is the path and attitude that responsible leaders should take from now on? What are the principles and values on which we will have to base our future sustainable construction? Could it be solidarity, empathy, the fact that we have to return to professionalism?

I think that these are topics that deserve to be debated and analyzed by each of us, regarding retrospectively and introspectively, in order to see how we can contribute to the sustainable development of the Romanian economy and society, in general.

Ioan Nani, Economist
General Adirector of Antibiotice SA
Vice President of the Management Board


Antibiotice
Science and soul

About the Report

This is the fourth Sustainability Report of the Antibiotice S.A. (hereinafter referred to as "Antibiotice", „the company"). The report presents the non-financial performance indicators related to our activity during the period 01.01.2020-31.12.2020 and was prepared in accordance with the requirements of Directive 2014/95/ EU, Order of the Minister of Public Finance 1938/2016 and Order of the Minister of Public Finance no. 3456/2018.

The current Report provides information on the sustainability indicators specific to our activity necessary to understand the development, performance and impact of Antibiotice operations. The information presented throughout this report relates to environmental, social and staff aspects, respect for human rights, comprising also a brief description of our business model, a description of our policies on the above issues, the applied due diligence procedures, results of our policies, main risks related to these aspects arising from our operations and key non-financial performance indicators relevant to our activity.

The report was made following the methodology proposed by the Global Reporting Initiative (GRI) standards, the Core Compliance requirements.

The topics analyzed in the reporting process, which formed the basis for developing the content of this report, were determined following a materiality process carried out in July 2021, which involved analyzing the economic, social and environmental impact of the company and consulting the stakeholders.

We thank you to the Antibiotice reporting team who prepared this report with the support of sustainability consultants from CSR Agency.

For any questions, suggestions or complaints abour this report, you can contact us by email office@antibiotice.ro or at the phone numbers bellow:

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* Stakeholders are individuals, groups of people, organizations, institutions, etc. who have an interest in activities and projects of Antibiotice SA (interested parties which may influence or may be influenced by the company).

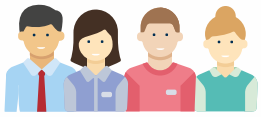
01

Our story

Economic

4 sales offices in 4 countries:
Republic of Moldova, Ukraine, Vietnam and Serbia

Social



1,415 employees:
53.7% women
46.3% men

50% from the management positions are held **by women**

1.1. Our key figures in 2020

>182.1
million lei*
sales revenue
in Romania

>158.2
million lei**
revenue from sales in
the foreign market

48.06
million lei
investments for
strategically develop
the industrial site

>90
million lei,
the amount of
taxes paid to
the state budget

32 hours:
average professional
training hours
per employee

46.26%
share of purchases
from Romanian
suppliers

>648
thousand lei***,
value of
financial support
and donations

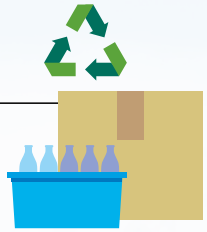
>3.8
million lei,
value of the social
responsibility
projects

* 37.65 million euro, ** 32.72 million euro***, 134 thousand euro (1 euro = 4.8371 lei, the average exchange rate of the National Bank of Romania in 2020)

Environment

316.76 MWh
electricity savings in 2020

60%
recycling/recovery rate for the product packages placed on the Romanian market



710.918 tons
waste diverted from disposal

Zero sanctions for the non-compliance with the environment legislation

1.2. Short history

After more than 6 decades of existence, the first factory producing penicillin in Romania and South-East Europe has currently turned into the most important Romanian generic manufacturer. We are proud that over time, regardless of the challenges we have faced, we have proven to be a successful business model and a reliable company. We have consistently adhered to our mission to manufacture safe, effective and quality pharmaceuticals to give patients hope of a healthy life, and this has allowed us to develop strong, long-term strategic partnerships with all our stakeholders.

Over time, Antibiotice marked several premieres for the pharmaceutical sector in Romania that have strengthened the solid foundation on which our company is built.

1955–1959

The story of Antibiotice began in December 1955, our company becoming the first manufacturer of Penicillin (the antibiotic substance discovered by Alexander Fleming) in Romania and South-East Europe. Four years later, the manufacturing plant of Streptomycin (active substance) started operating and the first finished dosage forms (ointments, creams and suppositories) were manufactured.

1960–1977

New technological flows for manufacturing active substances (erythromycin, oxytetracycline, tetracycline, griseofulvin, sinerdol, lysine) were developed. In that period, Antibiotice became the only producer of sterile parenterals in Romania. In 1977, the American regulatory body Food and Drug Administration (FDA) authorized the manufacturing plant of Streptomycin, this way opening for our company the doors to the international market.

1990–1997

Antibiotice has become a joint-stock company. Amid the macroeconomic changes, the Antibiotice's management team reshaped its production of medicinal products. In our company's portfolio, finished products gained the first position while the active susbtances were used for developing new pharmaceutical forms. In a short amout of time, our company introduced into manufacturing over 30 pharmaceutical products, managing this way to enter the top of the anti-infective manufacturers in Romania.

1997–1999

Antibiotice shares (ATB symbol) started to be traded in the first category of the Bucharest Stock Exchange. In this period, Antibiotice became the first GMP certified pharmaceutical manufacturer in Romania for the injectable powders flow.

2000–2004

The production flow of Nystatin was FDA certified, this allowing the export of this active substance in the United States. Antibiotice has been positioning as a world leader manufacturer, and its Nystatin has become the most exported product.

2005

Antibiotice's economic indicators – profit and turnover – recorded a significant jump, fruit of investments and management policy. A management by objectives system was implemented, designed to increase the performance throughout the company.

Our company launched also its new identity brand in order to visually communicate its modernization and structural changes occurred in the last years.

2006

Antibiotice inaugurated the Center for Medicine Evaluation (CEM), a one million EUR investment. CEM is a clinical research unit conducting clinical studies (phase I and bioequivalence studies). CEM has been authorized by the Ministry of Health, its Bionalytical Laboratory being Good Laboratory Practice (GLP) certified.

2007

Antibiotice obtained the recognition for implementing the Integrated Management System (quality, environment, occupational health and safety) according to the requirements of the EN ISO 9001:2008, EN ISO 14001:2004 and OHSAS 18001:2007 standards, being the first Romanian pharmaceutical company with this performance.

In the same year, our company completed the investment in an ecological waste incineration plant which, together with the modern wastewater treatment plant, significantly have been reducing the impact of the company's activities on the environment.

2009

Antibiotice oriented itself towards the international development.

Our company obtained the FDA authorization to deliver injectable medicines in the United Sates of America; the number of exported medicinal products increased, as well as the number of international partnerships.

The National Association of Romanian Exporters and Importers (ANEIR) designated Antibiotice as the most dynamic export company in the field of medicines.

2010–2011

Antibiotice was FDA certified for the manufacturing flow of penicillins in the form of injectable powders and delivered the first finished medicinal products in the USA, a market in which our company had been already present with the active substance Nystatin.

Our company started the "Summer School a+", a project intended for the professional development of its own employees, and for attracting future specialists in the fields of research, quality control and production of medicines.

Antibiotice continued its investments in the manufacturing technology (an increased production capacity of oral solid dosage forms – tablets) and in research, building a modern Research-Development Center meant to increase the pace of renewing the products in the portfolio.

Our company launched in the market the first central nervous system medicines.

2012–2014

Following the FDA's reapproval of the manufacturing flows of Nystatin and sterile injectable powders (2013) as well as an increased competitiveness, Antibiotice ranked first in the world production of the active substance Nystatin and recorded the first export of Nafcillin (1 g, 2 g) in the American market.

Our company extended its international presence by opening a representative office in the Republic of Moldova and an office in Serbia.

Antibiotice extended also its traditional anti-infectives portfolio with the first carbapenems, enriched its dermatological and central nervous system portfolio and offered new products for prophylaxis and for increasing the life quality (dietary supplements and over-the-counter medications).

Antibiotice have become the first WHO pre-qualified company in Europe for the range of anti-tuberculosis medicines.

2015

US FDA recertified the production flows of sterile finished injectables and active substance Nystatin.

Antibiotice won two gold medals and the Prize at EUROINVENT 2015, the Medicine Section, the largest exhibition of inventions and projects in the South-Eastern Europe.

On December 11, 2015, Antibiotice celebrated 60 years of Romanian continuity and performance.

2016

Antibiotice opened a new international representative office in Hanoi, Vietnam.

Our company started the "Perform a+", a project focused on attracting specialized staff and new collaborators in the research & development field. The project has been dedicated to the young students and residents of the Faculty of Pharmacy within the Gr. T. Popa University of Medicine and Pharmacy Iași.

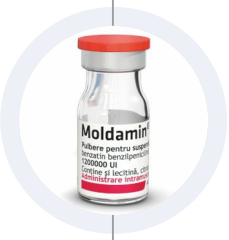
2017–2018

Antibiotice Iași imposes worldwide the quality standard for Nystatin, our product becoming a USP reference standard.

2019

Our third international representative office was opened in Kiev, Ukraine. Antibiotice started the serialization of its medicines, making the first delivery of serialized products in the US.

Antibiotice was the first pharmaceutical company joining the Romanian Investors Relations Association (ARIR).



Laboratory Management System (LMS) has been implemented.

The production of Moldamin, the new formula of benzathine benzylpenicillin was resumed.

2020

The company adapted quickly in the context of the crisis caused by the COVID-19 pandemic, to meet the urgent needs of the medical system and citizens: the production of Paracetamol and Novocalmin was resumed while the surface biocides began to be produced. Antibiotice adopted also important measures for the health and safety of its employees and ensured the continuity of production and the fulfillment of contracts concluded with its business partners.

1.3. About us

Our company has as main activity the manufacture of basic pharmaceutical products, being a trading company with majority state capital, under the tutelary authority of the Ministry of Health.

Over the years, our company produced a diversified range of generic medicines, reaching **a portfolio of 150 finished medicines from 11 therapeutic classes** (anti-infectives, cardiovasculars, dermatologicals, medicines for the digestive system and for the central nervous system, etc.).

Most of the medicines we produce are prescription drugs (Rx), but we also have over-the-counter (OTC) medicines, food supplements and medical devices designed to increase the quality of life. Antibiotice produces also active substances (Nystatin) and since 2020, biocides for surface disinfection.

The Center for Clinical Studies of Antibiotice conducts phase I clinical studies and bioequivalence studies for its own products, as well as for the products of external partners.

We currently produce generic medicines, active substances and biocides using eight manufacturing flows audited and certified by the National Agency for Medicines and Medical Devices of Romania (NAMMDR), according to the Good Manufacturing Practice (GMP) requirements. Finished products (generics for human use, in different pharmaceutical dosage forms: capsules, tablets, sterile powders for injections, ointments, creams, gels, suppositories, pessaries) are manufactured on seven flows while the eighth flow produces the active substance Nystatin, an antifungal made by industrial biosynthesis. In Iași, in the same location of the factory (manufacturing site), our company has its head office and its Center for Clinical Studies.

Our company does not place in the market products or services banned/withdrawn from the market in certain regions or countries.

Domestic market

We are a Romanian company with deep roots in the tradition and history of our country.

Our continuous presence covering more than 65 years in the Romanian market is a proof of our business model performance. The Antibiotice products are sold in almost all the pharmacies in Romania (over 8,000 units – according to INS), in the over 360 public hospitals and more than 160 private hospitals (units with beds).

In **2020**, our company obtained sales revenues in the Romanian market, of about **182.15 million lei**

In **2020**, the amount of Antibiotice finished products provided to patients from Romania through pharmacies was over **26 million units**.*

One of the priorities underlying the way we do business is to ensure continuity in distribution process, so as to ensure the access of patients, doctors and pharmacists to our products. In order to achieve this goal, we conclude commercial agreements with the most important distributors in Romania serving both the hospital and retail segments (the latter including also the main chains of pharmacies with national coverage).

The current context shows us that the distributors have focused on setting up their own channels for sale and for communicating with the patients through the pharmacy chains, while the number of independent pharmacies has decreased year by year. We have adapted our

* According to Cegedim T4/2020, forecast on sales of medicines from pharmacies to patients and consumers, in the Romanian pharmaceutical market (Cegedim – Press release, February 12, 2021)

commercial and portfolio strategies to this context depending on the specifics of the addressability segment (patients) of each partner distributor. We concluded long-term agreements with the main distributors, differentiated by product portfolios, so that patients be assured they will be able to continue the treatment recommended by the prescriber.

As regards the non-prescription medicines, food supplements, dermato-cosmetics, medical devices, we provide the patients with product ranges in different, complete and diversified pharmaceutical forms meant to improve the health status and increase the quality of life.

We developed a strong and competitive team of medical and sales representatives who ensures a two-way flow of information between the company and distributors, prescribers, pharmacists, patients. Thus, we increase the degree of accessibility and satisfaction of the patients towards the medicines manufactured by us. The role of this team is also to be a professional support for the partner distributors, in order to sustain the efficient communication of medical and commercial information in the territory, in as many pharmacies and medical offices as possible.

Also, within the company there is a permanent concern of the mixed team comprising medical representatives, portfolio management and R&D specialists that relates to the key opinion liders (KOL) to define the therapeutic solutions adapted to the current medical trends.

Antibiotice is a reliable partner of the local authorities in the field of health both as a consultant on health policies in the field of communicable diseases (tuberculosis, syphilis) and chronic diseases (heart disease), and as a constant supplier of affordable medicines in hospitals, for some of them being the only provider that complies with European manufacturing and quality standards (EuGMP).

All the food supllements manufactured by Antibiotice are based on the experience of researchers within the company, being manufactured to the same quality standards as those for medicines.

The emphasis we place on quality and performance has helped us all this time to consolidate our leading position in traditional market segments, the company recording notable performances, as follows:

- **Leader** in the hospital segment – anti-infectives for injection – 36.0% market share (data source: CEGEDIM SO)
- **Leader** in the segment of generics and prescription medicines sold to hospitals – 14.84% market share (data source: CEGEDIM SO)
- **Leader in terms of quantity** – injectable powders (65.3% market share), ointments (22.5% market share), suppositories (37.5% market share) (data source: CEGEDIM SO)
- **Ranked 4th** among the 128 manufacturers of generic prescription drugs in the Romanian market (7.6% market share) (data source: CEGEDIM SO)
- **Ranked 7th** in the generics and OTC segment (3.97% market share) and 21st in the total pharmaceutical market (1.76% market share) from a total of 352 companies which operate in the Romanian market (data source: CEGEDIM SO)
- **Ranked 18th** among 243 companies in the top of OTCs and food supplements manufacturers (data source: CEGEDIM SO)
- The Romanian manufacturer of the **complete range** of essential anti-tuberculous drugs

Foreign market

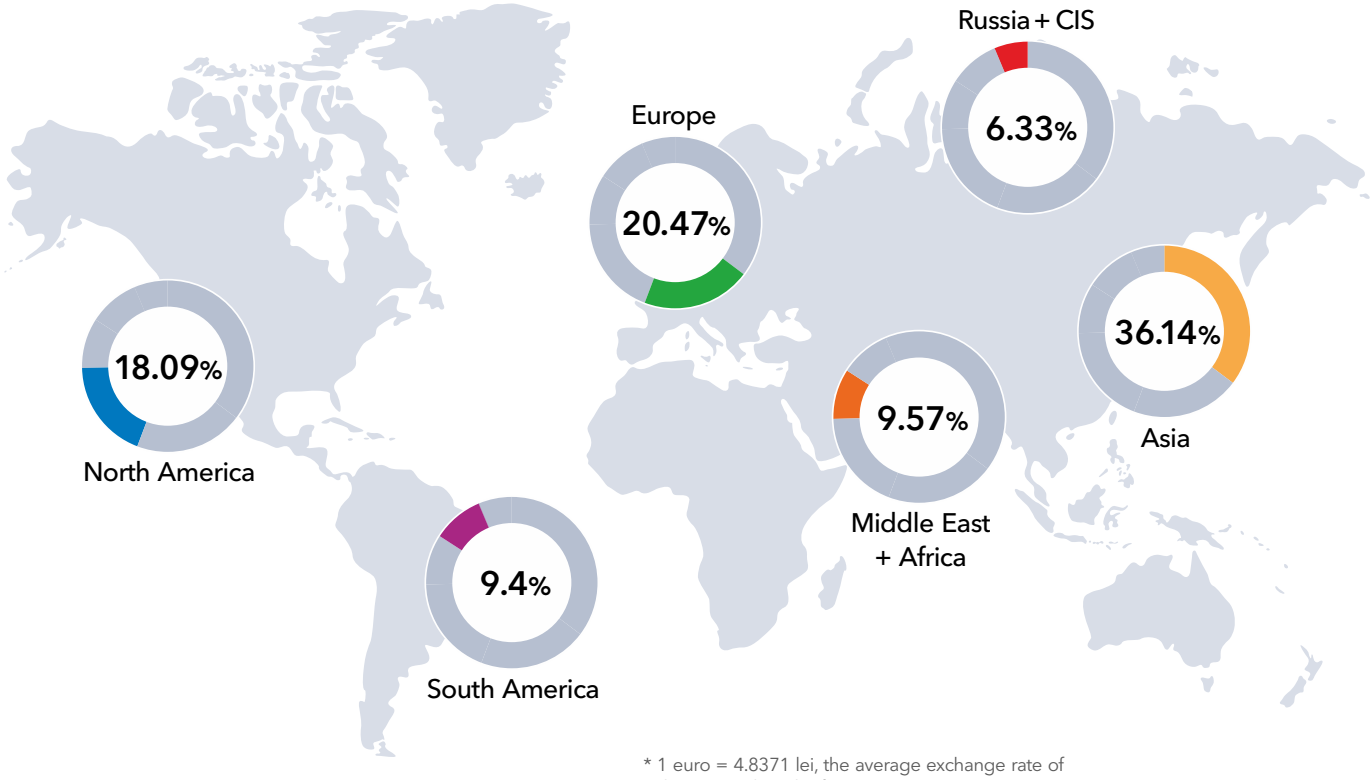
Our products manufactured in Romania have a global impact. Antibiotice trades its products both in Romania and other about 70 countries worldwide. Our company is also the world leader in the production of the active substance Nystatin. Over the past few years, with increasing export in the international markets, Antibiotice opened trading representative offices in other countries: Chișinău – Republic of Moldova, Kiev – Ukraine, Hanoi – Vietnam as well as a sales office in Belgrad, Serbia.

The main markets for the Antibiotice products in terms of share in turnover, growth trend and business security are: Vietnam, the United States, UK, Germany, Denmark, Brazil, Mexico, Republic of Moldova, China, India and Irak.

Known as one of the pioneers of production of penicillin, our company is currently an international supplier of simple and combined penicillins in the markets from the US, Vietnam, Republic of Moldova, Hungary, The Netherlands, Denmak.

The Antibiotice active ingredient Nystatin became USP reference standard in November 2016. Thus, the companies producing the active substance Nystatin or Nystatin-based finished products and willing to sell them in the US market (or in the markets that have adopted USP as a national pharmacopoeia) will use the characteristics of the batch of Nystatin R051D0 manufactured by Antibiotice as a reference standard for testing their products.

In the foreign market, our company recorded sales revenues of 158,274,644 lei (32,720,978 euro*):



* 1 euro = 4.8371 lei, the average exchange rate of the National Bank of Romania in 2020

Share of regional sales of generic medicines for human use (Antibiotice finished products)

Country and sector	Market share by volume of units sold*	Market share by sales value*	Types of customers
Romania*, pharmaceutical sector	**4.21%**	**1.76%**	The finished products (medicines for human use: Rx, which can only be purchased on prescription and OTCs, cosmetics and food supplements) are sold to drug distribution companies. They sell them to hospital pharmacies (where they reach the beneficiaries, inpatients), respectively to independent pharmacies and pharmacy chains (where they are bought by the general public).
Vietnam**, pharmaceutical sector	**51.4%**	**60.7%**	The finished products for human use: (sterile penicillins for injection - Rx medicines) are sold to drug distribution companies. They sell them to hospital pharmacies (where they reach the beneficiaries, inpatients).
Republic of Moldova***, pharmaceutical sector	**3.10%**	**8.26%**	The finished products (medicines for human use: Rx, which can only be purchased on prescription and OTCs, cosmetics and food supplements) are sold to drug distribution companies. They sell them to hospital pharmacies (where they reach the beneficiaries, inpatients), respectively to independent pharmacies and pharmacy chains (where they are bought by the general public).
The United States****, pharmaceutical sector	**8.36%**	**10.39%**	The finished products for human use: (sterile penicillins for injection - Rx medicines) are sold to drug distribution companies. They sell them to hospital pharmacies (where they reach the beneficiaries, inpatients).

* as per Pharma & Hospital Report 2020, Cegedim T4/2020, estimation on the exits of medicines (finished products) from pharmacies to patients in 2020, in the Romanian pharmaceutical market (Cegedim – 12.02.2021 press release)

** as per Pharma & Hospital Report 2020 IQVIA, relevant market of the products registered by Antibiotice in Vietnam (the same active substance, pharmaceutical form, concentration)

*** as per Pharma & Hospital Report 2020 IQVIA, relevant market of the products registered by Antibiotice in the Republic of Moldova (the same active substance, pharmaceutical form, concentration)

**** as per Pharma & Hospital Report 2020 IQVIA, relevant market of the products registered by Antibiotice in the US (the same active substance, pharmaceutical form, concentration).

Beyond the results we get, the professionalism and seriousness that characterize the way we work with international partners are also reflected in their satisfaction, measured annually, according to the requirements of the quality management system. So, in the first semester of each year, we conduct a market research in order to evaluate the satisfaction of our customers. Using the information included in the external sales database, we select the significant customers (customers ensuring over 80% of the sales of the year under analysis and with a minimum sales value of 50,000 USD). To assess their level of satisfaction, a questionnaire is applied, designed in the form of a series of statements, to which the customer gives grades for each topic. In 2020, after the analysis of the results, we obtained values greater than or equal to 94% for all 20 topics in the applied questionnaire.

1.4. Product Portfolio

Our products

We constantly invest in technology, knowledge and in our team, thus guaranteeing the safety, quality and efficiency of the products from our company's portfolio.

Antibiotice manufactures **finished products** *(generic medicines for human and veterinary use, medical devices, food supplements, cosmetics* and, starting with 2020, *biocides for surface disinfection)* and **active substances** *(Nystatin)*. Our company provides also clinical and bioanalytical services for external partners and conducts studies for its own products.

Most generic drugs from our portfolio as well as the active substance Nystatin and biocides are manufactured by the factory located in Iași. Some of the Antibiotice medicinal products are made in cooperation, on the manufacturing sites of our partners. Thus, on the basis of agreements concluded between the parties, Antibiotice buys licenses from partners (in-licensing) and sells licenses to interested partners (out-licensing), manufacturing their products in the factory from Iași.

In 2020, in order to increase the competitiveness and make the activity of the production plants more profitable, the company's management decided to group the eight manufacturing flows in three divisions: Oral Solid Products Division (Capsules Plant and Tablets Plant), Topical Products Division (Ointments & Suppositories Plant) and Sterile Products & APIs Division (Parenteral Products Plant & Biosynthesis Plant).

The divisions are organized and coordinated independently (as production activities, investments in technology and product portfolio) so as to become autonomous profit centers, which adapt their manufacturing and portfolio to the needs and characteristics of the market.

Finished products

The Antibiotice portfolio comprises 150 finished products from 11 therapeutic classes (anti-infectives, cardiovasculars, dermatolgicals, medicines for the digestive system and central nervous system). It includes generic medicines for human and veterinary use (issued on prescription – Rx and OTCs), food supplements (concentrated sources of nutrients, substances with a nutritional or physiological effect), medical devices (used for therapeutic purposes) as well as cosmetics.

I. Generic medicines for human use

In 2020, the year of the SARS-CoV-2 pandemic, Antibiotice reconfigured its manufacturing structure and reintroduced into manufacturing Paracetamol and Novocalmin®, medicines from the central nervous system class, necessary in the therapeutic schemes for patients with Covid.

In the context of increasing the demand for anti-infective drugs associated with

Eight manufacturing flows organized in three divisions:

Sterile Products & APIs Division

penicillin powders for injection, active substances obtained by biosynthesis, as well as biocidal solutions since 2020

Oral Solid Products Division

penicillin capsules, non-beta-lactam capsules, cephalosporin capsules and tablets

Topical Products Division

ointments, creams, gels, suppositories, pessaries

the treatment of Covid-19 in the world's health systems, Antibiotice won several international tenders în the US, Great Britain and European Union for injectable anti-infectives.

Anti-infective medicines

Hospital&Partners is the product portfolio addressed to healthcare professionals for hospital patients. This complex portfolio is made of sterile injectable beta-lactam antibiotics, penicillins, cephalosporins, carbapenems and polymyxins. It also comprises oral solid dosage forms for diseases that are treated initially, in the hospital (the treatment is subsequently continued on an outpatient basis) and medication for chronic conditions (cardiovascular, central nervous system, digestive tract classes).

Antibiotice supports the National Tuberculosis Prevention, Surveillance and Control Program (PNPSCT) of the Ministry of Health, being the producer of the entire range of first-line antituberculosis drugs, as well as of several second-line antituberculosis drugs.

In Romania, Antibiotice is the sole producer of some anti-infectives such as Amoxiplus®, Ampiplus®, Colistina®, Moldamin®, Oxacilina®, Penicilina G®, Tetraciclina Atb® HCL.

The main Antibiotice anti-infectives were Cefort®, Eficef®, Meropenem Atb®, Colistină Atb®, Amoxicilină Atb®, AmpiPlus®, Amoxiplus®, Ampicilină Atb® and Oxacilină Atb® in 2020.

Cardiovascular medicines

Antibiotice has been constantly concerned with developing a complex portfolio of medicines, covering the treatment of the most important cardiovascular diseases: heart failure, hypertension, angina, venous insufficiency, etc. In 2020, the main Antibiotice cardiovasculars were Bisotens® and Nolet®, Hemorzon® range and Fluxiv® range, recommended in chronic venous disease.

Nutriensa® brand of food supplements manufactured by Antibiotice

"Life quality"

For the treatment of various ailments, the "Life quality" concept proposes solutions from various therapeutic areas: cardiovascular, genitourinary, musculoskeletal, dermatology, digestive tract. The concept also brings together prescription and over-the-counter medicines, as well as complementary alternatives, such as food supplements under the Nutriensa® brand.

"Women's health"

Through the "Women's health" concept, Antibiotice aims to strengthen the identity of the portfolio for the prevention and treatment of diseases with a high incidence in women.

II. Generics for veterinary use

The veterinary portfolio contains antibiotics, in the form of ointments, issued only on prescription (Rx). The quality of the medicinal products is demonstrated by the certificate of conformity with good manufacturing practice (GMP), granted by the National Sanitary-Veterinary and Food Safety Authority (NSVFSA). Veterinary medicines are authorized for sale by the Institute for the Control of Biological Products and Veterinary Medicines in Romania (ICPBMV).

III. Biocides

As a result of the Sars-CoV-2 pandemic, in 2020 Antibiotice began to produce biocides for disinfecting surfaces: the products a+Complex and a+Oxy (in bottles of 1 and 5 liters), according to the authorization issued by the Cantacuzino Institute. The formula of a hand disinfectant gel was sent for analysis to an external laboratory for accreditation and inclusion in the company's portfolio, starting with 2021.

Our portfolio provides
45 medicines
(the molecule + the pharmaceutical dosage form for which we have a Marketing authorization) included in the
WHO Model List of Essential Medicines
(medicines that satisfy the health care needs for the majority of the population, used in the treatment of the most common diseases).

Active substances

Since 1975, Antibiotice has been manufacturing the active substance Nystatin by a biosynthesis process, on a dedicated production flow. In 2006, the Nystatin manufacturing process was optimized, which led to a significant increase in productivity. Starting with 2012, Antibiotice has been the world leader in the production of Nystatin. Nystatin API is an antifungal in the form of a yellow powder.

Our services

Through its own Center for Clinical Studies, Antibiotice offers to interested companies clinical and/or bioanalytical services (phase I clinical studies and bioequivalence studies). The studies, which are necessary for the authorization of the products, provide scientific data to confirm the efficacy and safety in the administration of drugs to human subjects. Thus, based on the results of pharmacokinetic and pharmacodynamic analyses, the pharmaceutical equivalence between the generic and the reference medicine (innovative medicine) is tested and demonstrated.

Phase I studies are those studies that are conducted on investigational drugs that are administered for the first time in humans.

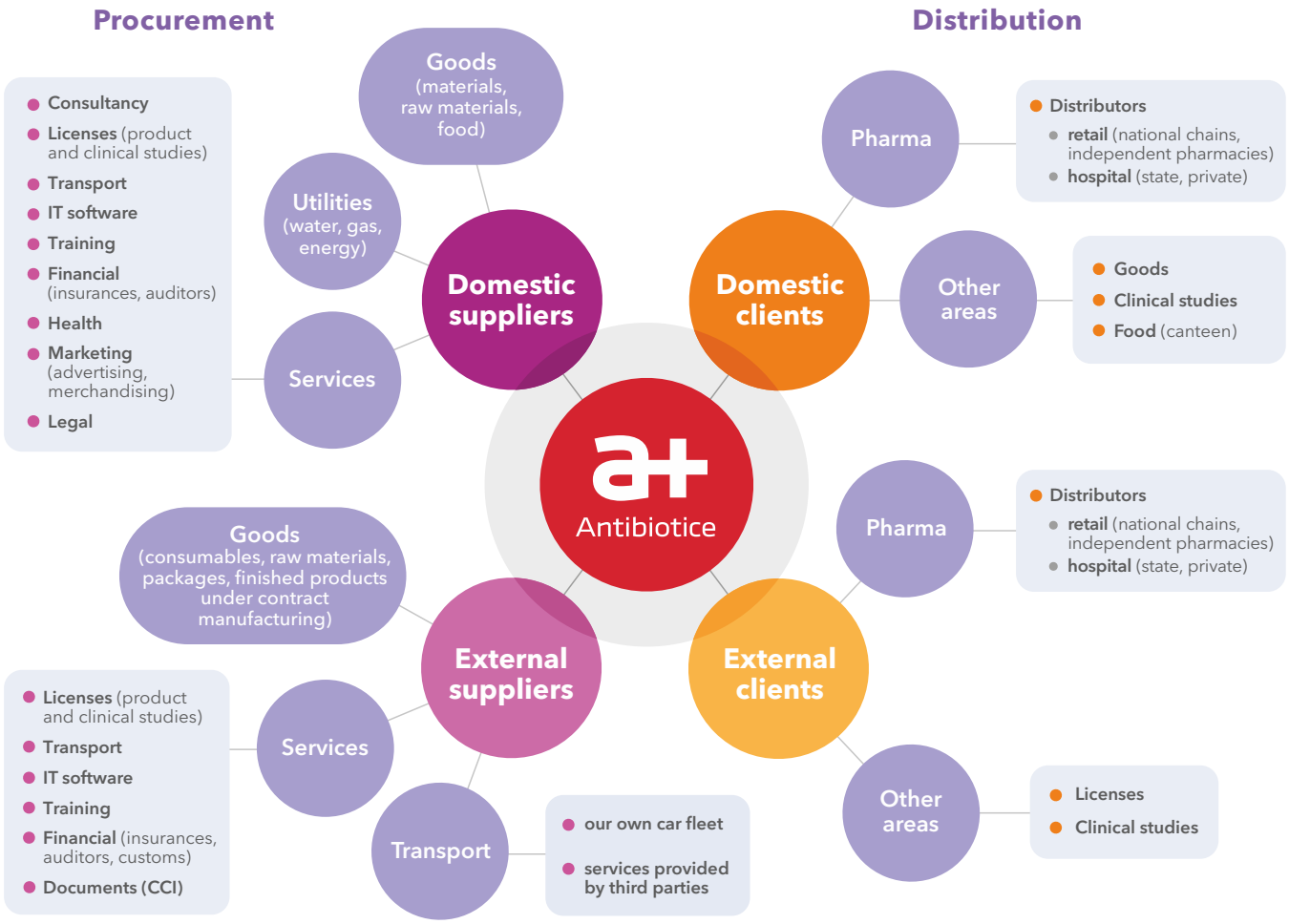
Bioequivalence studies are those studies where the subjects in the study do not suffer from any disease, and the drug administered is not intended to cure, but to provide information on the pharmacokinetics of the test product versus the innovative product.

Our Center for Clinical Studies has a clinical unit with 32 beds, a bioanalytical unit with several laboratories (including a GLP certified bioanalytical laboratory) and a secondary packaging flow of the clinical investigational medicine. The Antibiotice Center for Clinical Studies is a research unit authorized by the Romanian Ministry of Health, established in 2006.

Complete information about the products in our portfolio you can read here or by accessing our page www.antibiotice.ro, Products section.

1.5. Long-term value

Our company's performance and success have allowed us to develop over time strong partnerships with all the actors that are part of the value chain, gaining the trust of all our stakeholders. We constantly invest in research and development and work together with our local and international partners, to create value both for the Romanian society and for the consumers from the over 70 countries where our products reach.



Our processes require that the selection of raw material suppliers be based on the certification of their quality system in accordance with the international requirements of good manufacturing practice (GMP). Thus, in the manufacturing process of the Antibiotice medicines only quality raw materials are used, purchased from authorized producers, who are our partners in our mission to develop and grow sustainably.

As regards the indirect procurement, for services or products that are not directly related to the manufacturing process of medicines, the evaluation of the suppliers is made on the basis of the economic selection criteria, respecting the 3E concept: Economy, Efficiency, Effectiveness.

Throughout the value chain, optimizing the production, packaging, storage and transport processes are constantly pursued, as a guarantee that the Antibiotice medicinal products reach the final consumers in the best conditions.

In the final phase of the value chain, the products arrive from the company's warehouses to the distribution partners, from where they are delivered in the hospital pharmacies (after tenders) and retail pharmacies. From here, the products reach the patients/consumers.

Packaging is recycled through a partnership (service contract), concluded with an organization that implements the obligations of extended liability of the manufacturer, so that the overall objective of recovery/recycling of at least 60% of the quantity of packaging placed on the market is achieved, according to the requirements of Law 249/2015 on the management of packaging and packaging waste. According to the Order of the Ministry of Health No. 119/2014 and Order of the Ministry of Health no. 962/2009, expired medicines from the population will be deposited at pharmacies for final disposal by incineration.

The company's promotion team, through an ethical way of promoting and carrying out continuing medical education programs dedicated to health specialists, aims to increase the degree of accessibility, contributing to the balanced absorption of Antibiotice products in consumption.

The company's specialist teams within the Quality Assurance Department are actively involved, through self-inspection programs to identify in time the elements that could slow down the processes in the value chain, intervening so that risks are minimized and procedures are constantly improved.

1.6. Strategic organization

Our development goals for the next eight-year stage (2020–2028) are planned and organized in the "Strategic Organization and Development Plan" (PODS) which aims to sustainably grow the business and maximize long-term profitability.

PODS has five strategic pillars – the basis of the company's development in the coming years. In the first place it is the strategic adjustment of human resources, followed by the adaptation and diversification of the product portfolio, as well as implementation of a strong internationalization strategy. Development of our industrial site through investments, strengthening the Integrated Management System (quality, environment, occupational health and safety), improving the corporate governance system are also important pillars on which the current generation builds the company's future.

So, in the perspective of 2028, we aim for the following objectives:

- Doubling the turnover: from 341 million LEI to 700 million LEI;
- A gross profit cumulated with the clawback tax of 120 de million LEI;
- Business internationalization by increasing the share of exports to over 50% of the turnover;
- Adjusting the staff to 1,000 employees following the processes of digitization and computerization of the site, as well as as a result of the outsourcing of some services;
- Maintaining the position of world leader for the active substance Nystatin;
- Increasing the value of the average net salary at 1,200 EUR;
- Reaching net assets of 100 million LEI.

and development plan

For achieving and implementing the Strategic Organization and Development Plan, several working groups have been set up to support and monitor the progress in this direction, as follows:

Group	Purpose
G1: Strategic Planning and Performance Management	Implementation of PODS objectives and strategies.
G2: Portfolio policies	Defining the portfolio to support the objectives set out in PODS.
G3: Industrial investments and policies	Defining investments and technologies to support the objectives set out in PODS (involves digitization and computerization strategies of the industrial site).
G4: Legal and Corporate Governance	Defining and maintaining the legal framework and Corporate Governance policy that support the objectives set out in PODS (involves adapting the good practice and corporate governance codes, other codes that define the organization of the company's activities, monitoring of risk management, existence and efficiency of the systems for establishing performance indicators and their monitoring).
G5: Human Resources Policy	Defining the optimal structure of human resources, adapted to the objectives set out in PODS (involves organizational climate strategies, organizational culture, internal communication, payroll systems, organization and functioning regulations, recruitment methods, optimization of roles and assignment sheets, adaptation of the organizational structure).
G6: Integrated Quality Management (including also the Occupational Health and Safety Committee)	Defining the company's policies regarding quality, integrated management, environment, working conditions, health of employees adapted to the objectives set in PODS.

In order to support the activity of the working groups, in our company there are also other work teams in certain support areas, as follows:

- The work team for the implementation of PODS objectives and strategies;
- The team for monitoring performance in implementation of PODS, which aims at the analysis, measurement and control of performance indicators, established in the administration plans and in the management plans that support the implementation of PODS;
- Research work teams (by each division) which will define the product portfolio as well as each stage of development, in the perspective of the coming years;
- Work teams for the portfolio (by each division);
- Work team – Health and Safety Committee;
- Communication work team, which aims to implement and monitor the integrated communication plan of our company;
- Security team of the Antibiotice industrial site, which aims to implement the platform security plans;
- The team for digitization and computerization, which aims to implement the plan for digitization and computerization of the company's activities and processes;
- The work team for defining and implementing investments, which aims to implement the investment plan in the company;
- Technical Approval Commission (CTA), which aims at the technical-economic approval of investments, equipment acquisitions, new constructions, buildings, warehouses, consolidations.

1.7. Materiality analysis

Materiality analysis is the process that underlies the development of the content of the sustainability report. The process consists in identifying the material themes for the company, i.e. those themes that substantially influence the decisions and evaluations of stakeholders and also reflect the economic, social and environmental impact of the company, whether direct or indirect, positive or negative.

Thus, in order to identify the material topics, we consulted, through an online questionnaire, each category of stakeholders identified, but also the managers and specialists within the company. The latter ones evaluated each topic, depending on the size of the economic, social and environmental impact resulting from our activity, stakeholders being asked to evaluate the given topics, depending on how much their decisions are influenced in relation to Antibiotice, on the topic in question.

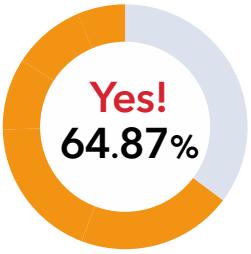
The categories of stakeholders consulted in the process were selected by our company's reporting team, during a meeting, where, together with the process coordinator, the specialists from each department identified each category of partners with whom they communicate and interact in their daily activities.

The process by which this analysis took place took place during the period July–August 2021, recording a total of 354 responses.

Results of the consultation process

Because we want to be close to our stakeholders and have a transparent communication that reaches the main areas of interest for them, we wanted to find out to what extent the sustainability report published in the previous year responds to their needs, in terms of quality, complexity and access to non-financial information about our company.

Q: Have you read the Sustainability Report (2019) of Antibiotice?



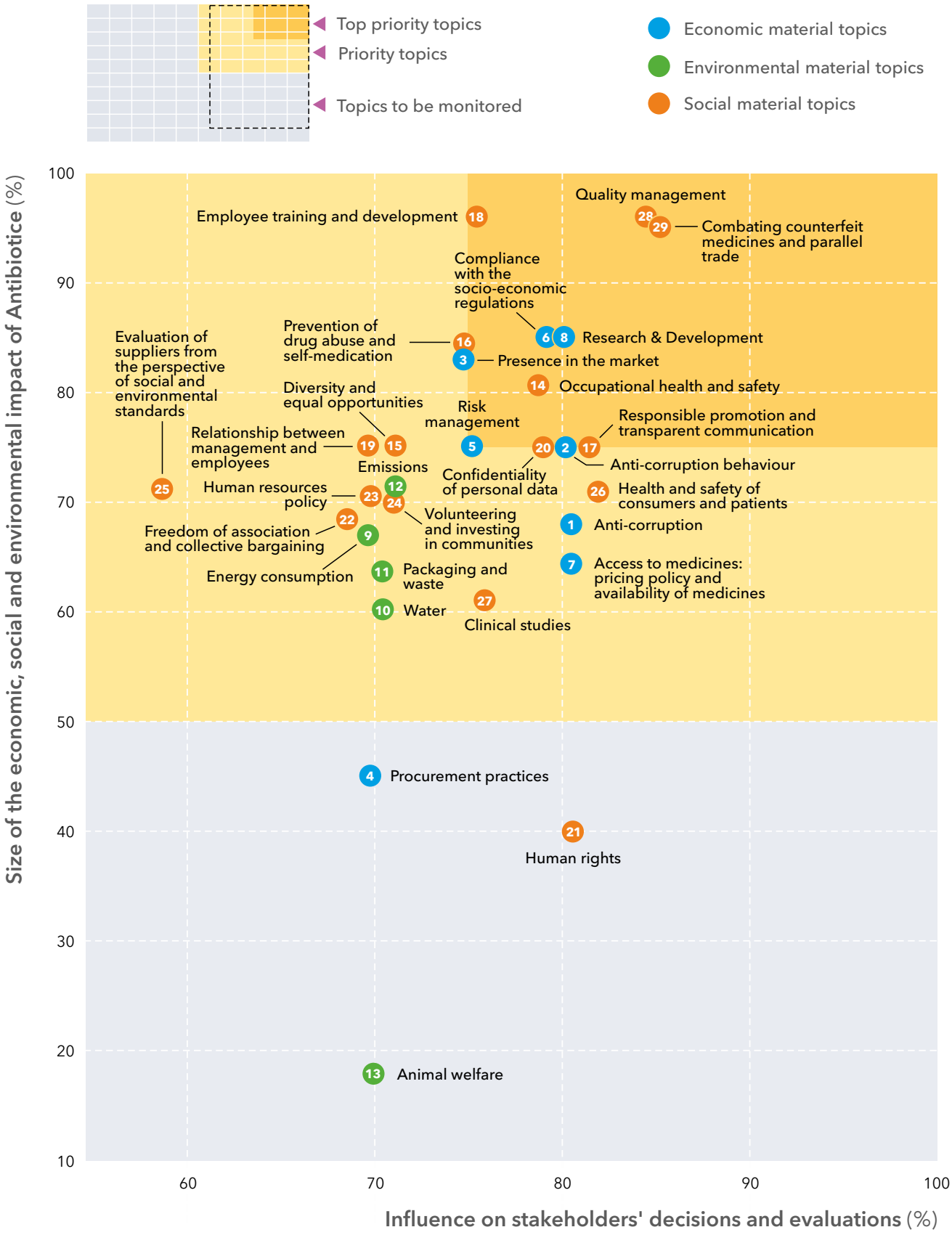
It is also very important for the company that our partners have the opportunity to contribute through effective participation, through the transmission of ideas and improvement solutions to achieve common goals. We were glad to find out that the respondents to the questionnaire consider, in a proportion of over 90%, that there is transparency and clarity in the information communicated through our sustainability report.

Q: Do you think that the information presented in our report is clear and answers your questions about the impact of the company Antibiotice on society, economy and environment?

Material topics

The material topics, as they were evaluated by the stakeholders and company's management, are presented in the materiality matrix in the following figure, with their positioning according to the degree of interest of the stakeholders and size of our company's impact.

Materiality matrix



Material topic boundaries

No.	Topics	Where the impact is generated	
		Inside the company	Outside the company
	Economic matters		
1	Anti-corruption	✔	✔
2	Anti-corruption behaviour	✔	✔
3	Presence in the market	✔	
4	Procurement practices	✔	✔
5	Risk management	✔	
6	Compliance with the socio-economic regulations	✔	
7	Access to medicines: pricing policy and availability of medicines	✔	✔
8	Research & Development	✔	
	Environmental matters		
9	Energy consumption	✔	✔
10	Water	✔	✔
11	Packaging and waste	✔	✔
12	Emissions	✔	✔
13	Animal welfare	–	–
	Social matters		
14	Occupational health and safety	✔	
15	Diversity and equal opportunities	✔	
16	Prevention of drug abuse and self-medication	✔	✔
17	Responsible promotion and transparent communication	✔	✔
18	Employee training and development	✔	
19	Relationship between management and employees	✔	
20	Confidentiality of personal data	✔	
21	Human rights	✔	✔
22	Freedom of association and collective bargaining	✔	
23	Human resources policy	✔	
24	Volunteering and investing in communities	✔	
25	Evaluation of suppliers from the perspective of social and environmental standards	✔	✔
26	Health and safety of consumers and patients	✔	✔
27	Clinical studies	✔	
28	Quality management	✔	✔
29	Combating counterfeit medicines and parallel trade	✔	✔

1.8. Transparent communication with our stakeholders

We want to stay permanently connected to the needs and expectations of our stakeholders, therefore, we constantly communicate with them, through different channels. This requires a continuous and effective engagement with stakeholders, to whom we provide information in a transparent manner, by annually publishing the financial statements and the sustainability report.

The table below shows the categories of stakeholders consulted in the materiality process, the channels and frequency with which we communicate with them, and the topics of interest to them, from an economic, social and environmental perspective, as they were revealed after consultation for materiality analysis.

Our stakeholders	Method of communication	Frequency	Topics that concern them (according to the results of the materiality process)
Shareholders	Email, telephone teleconfererence, General Meeting of Shareholders (GMS)	Whenever they ask us; GMS 4 times a year.	**Economic matters:** Risk management, Research & Development, Anti-competitive behavior, Compliance with the socio-economic regulations; Access to medicines: pricing policy and availability of medicines. **Environmental matters:** Energy consumption, Water, Packaging and waste, Emissions, Animal welfare. **Social matters:** Human resources policy, Health and safety of consumers and patients, Quality management, Confidentiality of personal data, Combating counterfeit medicines and parallel trade
Employees and employee representatives	Email, print, display, internal magazine, social media, polls	Whenever needed or they request it.	**Economic matters:** Access to medicines: pricing policy and availability of medicines, Presence in the market, Risk management, Research & Development , Anti-corruption **Environmental matters:** Animal welfare, Water, Energy consumption, Packaging and waste, Emissions **Social matters:** Diversity and equal opportunities, Human rights, Relationship between management and employees, Employee training and development, Occupational health and safety.
Internal suppliers	Email, telephone, fax	Weekly	**Economic matters:** Anti-competitive behavior, Risk management, Research & Development , Procurement practices, Compliance with the socio-economic regulations **Environmental matters:** Emissions , Energy consumption, Water, Packaging and waste, Animal welfare **Social matters:** Quality management, Combating counterfeit medicines and parallel trade, Evaluation of suppliers from the perspective of social and environmental standards, Human rights, Confidentiality of personal data

Our stakeholders	Method of communication	Frequency	Topics that concern them (according to the results of the materiality process)
External suppliers	Email, telephone, conference calls	Weekly	**Economic matters:** Research & Development , Procurement practices, Access to medicines: pricing policy and availability of medicines , Anti-competitive behavior, Anti-corruption **Environmental matters:** Animal welfare, Emissions, Packaging and waste, Energy consumption, Water **Social matters:** Confidentiality of personal data, Combating counterfeit medicines and parallel trade, Health and safety of consumers and patients, Quality management, Evaluation of suppliers from the perspective of social and environmental standards
Distribuitors	Email, telephone, video conferencing, meetings	Monthly/ quarterly meetings	**Economic matters:** Research & Development, Compliance with the socio-economic regulations, Anti-competitive behavior, Anti-corruption, Access to medicines: pricing policy and availability of medicines **Environmental matters:** Energy consumption, Water, Animal welfare, Packaging and waste, Emissions **Social matters:** Confidentiality of personal data, Responsible promotion and transparent communication, Health and safety of consumers and patients, Combating counterfeit medicines and parallel trade, Quality management
Doctors	Email, telephone, video conferencing, regional and national scientific events	Meetings/visits of medical representatives to quarterly scientific events	**Economic matters:** Presence in the market, Anti-corruption, Research & Development, Anti-competitive behavior, Access to medicines: pricing policy and availability of medicines **Environmental matters:** Animal welfare, Energy consumption, Water, Packaging and waste, Emissions **Social matters:** Prevention of drug abuse and self-medication, Clinical studies, Responsible promotion and transparent communication, Combating counterfeit medicines and parallel trade, Health and safety of consumers and patients, Quality management
Associations or profile bodies/Industry representatives	Email, conference calls	Monthly	**Economic matters:** Risk management, Access to medicines: pricing policy and availability of medicines, Anti-competitive behavior, Anti-corruption, Compliance with the socio-economic regulations **Environmental matters:** Energy consumption, Animal welfare, Water, Emissions, Packaging and waste, **Social matters:** Human rights, Clinical studies, Responsible promotion and transparent communication, Health and safety of consumers and patients, Quality management, Combating counterfeit medicines and parallel trade
Business associations	Email	Quarterly	**Economic matters:** Procurement practices, Risk management, Compliance with the socio-economic regulations, Access to medicines: pricing policy and availability of medicines, Research & Development **Environmental matters:** Energy consumption, Water, Packaging and waste, Emissions, Animal welfare **Social matters:** Evaluation of suppliers from the perspective of social and environmental standards, Health and safety of consumers and patients, Clinic studies, Quality management, Combating counterfeit medicines and parallel trade

Our stakeholders	Method of communication	Frequency	Topics that concern them (according to the results of the materiality process)
Non-governmental organizations	Email, telephone	Quarterly	**Economic matters:** Presence in the market, Research & Development Procurement practices, Anti-corruption Access to medicines: pricing policy and availability of medicines **Environmental matters:** Energy consumption, Water, Packaging and waste, Emissions, Animal welfare **Social matters:** Prevention of drug abuse and self-medication, Responsible promotion and transparent communication, Health and safety of consumers and patients, Human rights, Volunteering and investing in communities
Regulatory and control authorities	Email, telephone	Whenever needed or they request it.	**Economic matters:** Risk management, Access to medicines: pricing policy and availability of medicines, Anti-competitive behavior, Anti-corruption, Compliance with the socio-economic regulations **Environmental matters:** Energy consumption, Animal welfare, Water, Emissions, Packaging and waste **Social matters:** Human rights, Clinical studies, Responsible promotion and transparent communication, Quality management, Combating counterfeit medicines and parallel trade
Central and local authorities	Email, telephone	Whenever needed or they request it.	**Economic matters:** Compliance with the socio-economic regulations, Presence in the market, Access to medicines: pricing policy and availability of medicines, Research & Development, Anti-corruption **Environmental matters:** Animal welfare, Energy consumption, Water Packaging and waste, Emissions **Social matters:** Human rights, Clinical studies, Health and safety of consumers and patients, Quality management, Combating counterfeit medicines and parallel trade
Academic environment	Email, telephone, video conferencing	Monthly	**Economic matters:** Anti-corruption, Anti-competitive behavior, Presence in the market, Access to medicines: pricing policy and availability of medicines, Research & Development **Environmental matters:** Packaging and waste, Water, Energy consumption, Animal welfare, Emissions **Social matters:** Combating counterfeit medicines and parallel trade, Volunteering and investing in communities, Employee training and development, Health and safety of consumers and patients, Responsible promotion and transparent communication
Mass Media	Email, telephone	Bi-monthly	**Economic matters:** Anti-competitive behavior, Risk management, Compliance with the socio-economic regulations, Research & Development, Presence in the market. **Environmental matters:** Animal welfare, Energy consumption, Water Packaging and waste, Emissions. **Social matters:** Volunteering and investing in communities, Health and safety of consumers and patients, Clinical studies, Quality management, Combating counterfeit medicines and parallel trade.

Reporting tools made available to stakeholders

Beyond the constant communication we have with all our stakeholders, we want them to constantly support us and improve our daily work. Therefore, we provide them with various tools through which they can submit recommendations, suggestions and complaints.

The manner in which complaints are handled in our company is set out in the specific internal procedure. Any complaint received is recorded and investigated in order to establish the cause of the non-compliance and decide, as appropriate, the corrective or preventive actions/ opportunities for improvement. The summary of the investigation report, including the conclusion of the complaint (unjustified/justified and the established actions) are sent to the organization/ person who sent the complaint.

The ways in which stakeholders can submit complaints / notifications to Antibiotice:

- telephone: +40 232 209 000, +40 372 065 000
- mail: Antibiotice headquarters, 1 Valea Lupului St., Iași 707410, Romania
- fax: +40 372 065 633
- email: office@antibiotice.ro
- social networks: Facebook www.facebook.com/Antibioticelasi
- on our company's website, in the Contact / Complaints section: www.antibiotice.ro/contact/complaints/

The person receiving the complaint informs the Quality Assurance Department (Quality Assurance Manager – Qualified Person). Depending on the nature of the complaint, the Quality Assurance Manager classifies the complaint in the defect class to which the non-compliance belongs. An internal investigation is initiated by a multidisciplinary team (depending on the nature of the identified non-compliance). Upon completion of the investigation documentation, the Quality Assurance Officer verifies the investigation report, prepares and submits the summary of the investigation report, including the conclusion of the complaint (unjustified / justified and the established actions) to the person making the complaint.

During 2020, 41 complaints were received (38 of them on quality, 2 validated adverse reactions, 1 suggestion for improvement). Following the internal verifications, it resulted that 23 complaints were grounded and 18 unjustified.

The 41 complaints were received from:

- patients: 6 complaints
- pharmacies: 6 complaints
- hospitals: 4 complaints
- distribuitors: 10 complaints
- partners: 15 complaints.

Employee reporting tools

Regarding the complaints / notifications that can be received from employees, according to the internal regulations, they can address directly to the Human Resources Department with the requests, following the specific procedure in order to solve them.

1. The requests / complaints to be analyzed are submitted to Human Resources, which will send them to the commission and the general secretariat.

2. In order to analyze and resolve the individual requests or complaints of our employees, there is a commission composed of:

- the representative of the executive management;
- the representative of the Human Resources Department;
- a legal adviser;
- the representative of the Financial Unit;
- the representative of the activity to which the employee whose request / complaint is being analyzed belongs;
- the representative of the union to which the employee belongs.

3. The committee usually meets at the end of the week, when convened by the representative of the Human Resources department, who transmits to each member of the committee the issue to be analyzed.

4. The analysis committee operates according to the following principles:

- observance of the employees' rights in accordance with the legal provisions, applicable collective labor contract and individual employment contract of each employee;
- promoting the interests of employees regarding salary, working conditions, working time and rest, job stability as well as any other professional, economic and social interests related to labor relations;
- equal treatment for all employees, equal opportunities.

5. Employees who have submitted documents for debate may also participate in the analysis session of the requests/ complaints, as they have the possibility to present pertinent arguments.

6. The result of the analyses is recorded in writing and sent to those interested within a maximum of 30 days by the Human Resources Department.

These notifications/complaints can be also sent to the following e-mail addresses: solicitari.angajati@antibiotice.ro and/or resurse.umane@antibiotice.ro, then following the same settlement procedure described above.

A form is available on the company's website (www.antibiotice.ro), through which such situations can be submitted, in the section Contact – Complaints. The section can be accessed by any interested party who wishes to report/submit complaints (general public, specialized public, etc.).

1.9. Awards and affiliations

Awards for our work in 2020

Romanian Investors Relations Association (ARIR)

Excellent Investor Relations Communication Category: Diploma of Excellence and a perfect 10 mark
January 2020

VEKTOR is the indicator of communication with investors for listed companies and is calculated based on a methodology that includes 15 criteria, in accordance with international best practices in the field.

Our company managed this performance by being transparent and meeting the need of investors, analysts, brokers, journalists to know the Antibiotice business with a greater openness, addressing new and effective communication tools. Antibiotice got a 10 mark and Diploma of Excellence (together with other 4 companies) among 77 listed companies.

Best Company in IR – Retail Choice Category: the 3rd place
October 2020

Antibiotice was awarded at the second edition of the AR&IR 2020 Gala for its performances from the perspective of the communication activity with Investors. For the achievements obtained, Antibiotice was voted, through the ARIR website, in the top 3 companies that communicated the best in the last year with individual investors active on the Romanian capital market, along with big names of companies listed on the Bucharest Stock Exchange. Individual investors appreciated the company's transparency, quality of reporting and communication from the perspective of availability and proactivity of the team responsible for investor relations.

Chamber of Commerce and Industry of Romania

Industry Category – Large Enterprises – Manufacture of basic pharmaceutical products: 1st place National Award
October 2020

The National Top of Companies (TNF) 2020 is organized on the basis of indicators such as net turnover, operating profit, efficiency of human resources use and capital employed.

When making the TNF 2020, 730,998 financial-accounting balance sheets of companies active in Romania were analyzed. 249,128 of these balance sheets entered the competition for the first 10 positions in the national top.

Chamber of Commerce and Industry of Iași

Industry Category – Large Enterprises – Manufacture of basic pharmaceutical products: 1st place
October 2020

Romanian CSR Awards 2020

"Pandemic Community Support" Category – 1st Place: Solidary with the health system
April 2021

"Employee support" – Category Honorable Mention: We take care of the health of our loved ones
April 2021

The event is organized by CSR Media and provides recognition for the best corporate social responsibility projects (CSR) carried out by the companies in Romania. Gala Romanian CSR Awards 2021 lined up at the start over 200 social responsibility projects , carried out by more than 120 national and multinational companies during 2020.

As a gesture of solidarity and responsibility towards the Romanian health system, Antibiotice offered in full pandemic donations worth 134,000 EUR. These donations resulted in medicines, materials and protective equipment offered to hospitals as needed, as well as significant financial resources.

As regards the support of our employees, the most important resource, Antibiotice implemented important measures to protect the health and safety of its employees, but also to reduce the risks of discontinuation of medicine delivery operations.

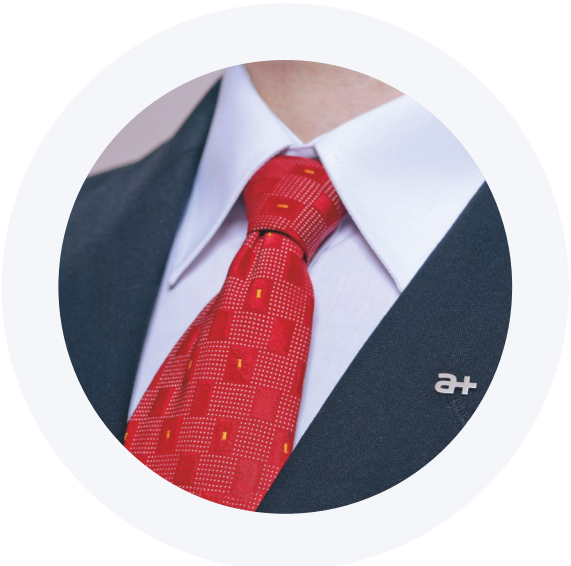
Affiliations

At national level, our company is part of:

- **Chamber of Commerce and Industry (CCI) Iași.** The Chamber represents and supports the interests of member firms and business community in the Iași County. Antibiotice is a member of the Management Board of CCI Iași, and Ioan Nani holds the position of First Vice President.
- **Romanian Association of the Self-Care Industry (RASCI)**, which brings together producers, importers and distributors of non-prescription medicines (OTCs), food supplements and medical devices for personal care.
- **Romanian Association of Industrial Drug Manufacturers (PRIMER)**, which brings together the main manufacturers of medicines with production facilities in Romania.
- **National Association of Romanian Exporters and Importers (ANEIR)** which promotes the interests of member firms.
- **Romanian Investor Relations Association (ARIR)** contributes to the implementation of best practices in communication with investors and corporate governance of companies listed on the Bucharest Stock Exchange.
- **Romanian Organization for Serializing Medicines (OSMR)** was established to implement European legislation on counterfeit medicines and safety rules for packaging of medicinal products for human use issued on prescription (Rx), being responsible for the implementation and administration of the National Medicines Verification System (NMVS), the verification platform , through which pharmacies or other interested parties (wholesale distributors in Romania) can verify the authenticity of an Rx drug.

Internationally, we are part of:

- **European Medicines Verification Organisation (EMVO)**
- **Hungarian Medicines Verification Organisation (HUMVO)**



02

Business ethics and responsibility

2.1. Financial performance

Our company's financial performance trancends the boards of our factory, and its economic impact is reflected along the entire value chain, through purchases from Romanian and foreign suppliers, through the salaries we offer to employees, through the taxes we pay to the state budget, but also through the social involvement projects we implement for the local community.

Financial indicators	2020	2019	2018
Net turnover (lei)	**341,047,668**	390,646,543	365,304,988
Gross profit (lei)	**28,329,456**	35,179,893	35,088,611
Average number of employees	**1,415**	1,415	1,415
Taxes and fees related to salaries	**44,682,282**	40,034,467	36,123,811
Other taxes to the state budget	**15,457,788**	11,716,383	10,258,105
Clawback tax	**27,767,041**	42,210,924	36,484,839
Local taxes and fees	**1,540,300**	1,464,931	1,125,783
Total taxes and fees	**89,447,411**	95,426,705	83,992,538

More information on the company's economic performance at the end of the financial year, 31 December 2020, can be found in the Management Report 2020.

2.2. Corporate governance and management structures

Shareholding structure

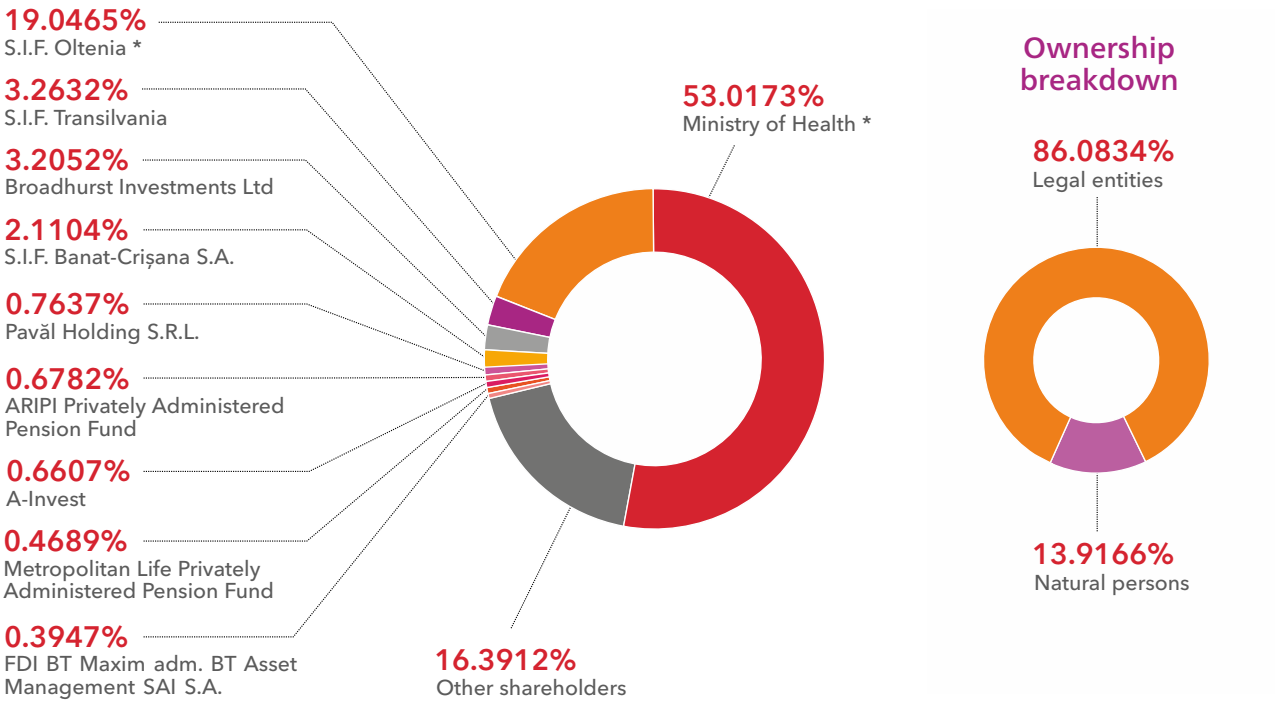
Antibiotice SA is a trading company with majority state capital, in which the majority shareholder, Ministry of Health, holds 53.0173% of the subscribed and paid-up capital. The regulated market on which the securities issued by Antibiotice are traded is the Bucharest Stock Exchange, Premium category.

More details about the company's shareholders can be read in the 2020 Management Report, starting with the page 6.

Main Antibiotice shareholders on December 31, 2020
(extract from the Register of Shareholders)

Ministry of Health (*)	53.0173%
S.I.F. Oltenia (*)	19.0465%
S.I.F. Transilvania	3.2632%
Broadhurst Investments Limited	3.2052%
S.I.F. Banat-Crișana S.A.	2.1104%
Pavăl Holding S.R.L.	0.7637%
ARIPI Privately Administered Pension Fund	0.6782%
A-Invest	0.6607%
Metropolitan Life Privately Administered Pension Fund	0.4689%
FDI BT Maxim adm. BT Asset Management SAI S.A.	0.3947%
Other shareholders (42,285 sghareholders)	16.3912%

* Significant shareholders, according to Law no. 297/28.06.2004, Art. 2, Para 1



Corporate governance

Since 2012, Antibiotice has adopted the principles and recommendations of the Corporate Governance Code of the Bucharest Stock Exchange, which are the basis for meeting the standards of good corporate governance of the company.

Antibiotice is a public enterprise, which complies with the Government Emergency Ordinance no. 109/2011 on the corporate governance of public enterprises. Corporate governance gives Antibiotice shareholders and investors access to accurate, quality, timely information.

At the base of the good governance practices in the company is the Corporate Governance Code of Antibiotice, which outlines the general framework for the activity of the Management Board. Built according to the principles and recommendations of the Corporate Governance Code of the Bucharest Stock Exchange, the code includes, among others, information on the responsibilities of management structures, fair reward and motivation, investor relations, risk management system and internal control. The Corporate Governance Code of Antibiotice was approved by the Management Board January 26, 2017.

Management Board

The Management Board is responsible for the good governance of the company, being the highest form of management and the supreme decision-making authority (except for decisions which, as required by law, must be taken by the General Meeting of Shareholders). The statutory responsilities of the Management Board include setting the company's strategic direction, risk management, etc. Some of the responsibilities are exercised through the advisory committees: The Audit Committee, Nomination and Remuneration Committee and Trade Policy Committee.

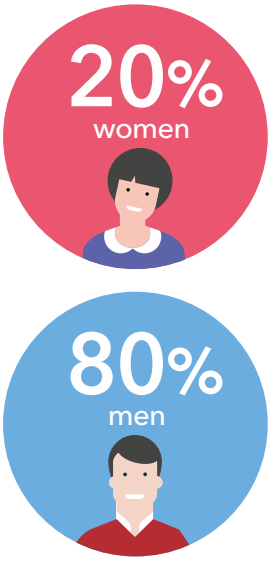
Antibiotice is managed, according to the unitary management system, by a Management Board composed of five members: four non-executive, independent (including the President of the Management Board) and an executive, non-independent administrator, in the person of the Vice President of the Board who is also General Director. The five members of the Board guarantees the efficiency of the capacity to supervise, analyze and evaluate the activity of the directors, as well as the fair treatment of the shareholders.

The term of office of a member of the Mangement Board shall be four years and may be renewed following an evaluation process. A non-executive administrator can be a member of the Antibiotice Management Board, for a maximum of three terms.

The Management Board of Antibiotice delegates the operational management (the current activity of the company) to the executive management, being responsible for monitoring the company's management, on behalf of the shareholders.

The executive management includes the General Director (which has a mandate from the Board) and the specialty directors. There is a clear distribution of responsibilities between the Management Board and executive management. The Management Board seeks to ensure that its own decisions, those of the management, the General Meeting of Shareholders, as well as the internal regulations, comply with the legal requirements and are properly implemented.

Gender diversity in the Management Board of Antibiotice



Composition of the Management Board

Member	Position, representation	Details
Dan-Octavian Alexandrescu*, 44 years old	President of the Management Board Representative of the Ministry of Health	Elected as a member of the Board on September 29,2018 (and then President) for a four-year term (the first term). Primary care physician with competence in laparoscopic surgery and coordinator of the Medicines Policy and Medical Devices Directorate since March 2017. *He has no Antibiotice shares.*
Ioan Nani, 61 years old	Vice President of the Management Board General Director	Reconfirmed as a member of the Board on April 19, 2016 for a four-year term (the third term), was then elected by the members of the Board of Directors to the position of Vice President. Economist specialized in management and chartered accountant, member of the Board since 2009 and General Director between 1998–2008 and since 2009 to the present. *He owns 1,513 Antibiotice shares.***
Cristian Vasile Grasu*, 60 years old	Member of the Management Board Representative of the Ministry of Health	Elected as a member of the Board on September 10, 2019, for a four-year term. Physician, Coordinator of the General Directorate of Public Healthcare of the Department for Monitoring and Coordination of Regional Hospitals to the Ministry of Health, as well as the Coordinator of the Priority Actions of the Ministry of Health. *He has no Antibiotice shares.*
Nicolae Stoian, 64 years old	Member of the Management Board Representative of S.I.F. Oltenia	Elected as a member of the Board on April 19, 2016, for a four-year term (the second term). Chartered accountant, tax consultant, member of the Board of S.I.F. Oltenia. *He has no Antibiotice shares.*
Elena Calițoiu, 57 years old	Member of the Management Board Representative of S.I.F. Oltenia	Elected as a member of the Board on April 19, 2016, for a four-year term (the first term). Mechanical engineer and Director of Placements ad Risk Management Department at S.I.F. Oltenia. *She has no Antibiotice shares*

* Replaced by Ionel Damian, 45 years old, on 16.09.2020
** Number of Antibiotice shares held on 31 December 2020, according to the latest Antibiotice database for 2020
*** Replaced by Lucian Timofticiuc, 49 years old, on 20.05.2020

All members of the Management Board are of Romanian nationality.

Gender diversity in the Management Board

	Men	Women	Total
President	1	0	1
Vice President	1	0	1
Total members	4	1	5
	80%	20%	100%

Generation diversity in the Management Board

	< 30 years	30-50 years	> 50 years	Total
Total members	0	2	3	5
	0%	40%	60%	100%

Advisory committees

1. The Audit Committee supports the Council in carrying out the financial reporting, internal and external audit, risk management and internal control.

Composition:

- **Cristian Vasile Grasu/ Lucian Timofticiuc**
- **Nicolae Stoian**
- **Elena Calițoiu**

Within its responsibilities, the Audit Committee shall carry out an annual evaluation of the internal control system. The evaluation shall take into account the effectiveness and comprehensiveness of the internal audit function, adequacy of the risk management and internal control reports submitted to the audit committee, promptness and accuracy with which the executive management resolves the deficiencies or weaknesses identified by the internal control and then submits reports to the Management Board. The Audit Committee also manages conflicts of interest in connection with the transaction of the company and its subsidiaries with the related parties within the meaning of the Fiscal Code. The Audit Committee monitors the application of generally accepted legal standards and internal audit standards.

2. Nomination and Remuneration Committee supports the Board in nominating the candidates for the Management Board, proposes the remuneration for the members of the Board and Executive Management.

Composition:

- **Dan Octavian Alexandrescu**
- **Elena Calițoiu**

Powers and responsibilities of the Nomination and Remuneration Committee are mainly the following: makes proposals for the positions of directors, draw up and propose to the Board the criteria for selecting candidates for the positions of administrator and director, recommends to the Management Board candidates for the positions listed, makes proposals for the remuneration of administrators and directors, evaluates, at least once a year, the independence of the members of the Management Board, verifies the number of mandates held by members of the Management Board in other companies, perform other tasks in connection with the appointment or removal of Board members, upon its instructions, proposes candidates to the Management Board for appointing, renaming or removing them from the Board.

The Committee may reject candidates who do not meet the criteria for membership of the Board and shall ensure that persons applying for the position of director have the necessary training and experience to perform their duties. It also draws up an annual report on the remuneration of the directors and directors appointed by the Board, as well as other benefits granted to them, a report which will be presented by the Board to the General Meeting of Shareholders.

3. Trade Policy Committee supports the Board in establishing the company's policies and trade relations.

Composition:

- **Cristian Vasile Grasu/ Lucian Timofticiuc**
- **Nicolae Stoian**

The Trade Policy Committee analyzes commercial policies, including marketing and promotion policies, through which the Management Plan and Business Plan are implemented. In order to carry out these tasks, the members of the committee receive reports from the directors of the company in the meetings of the Board and whenever they make requests in this regard.

Antibiotice management

The Antibiotice management team is made up of a general director, executive administrator (who owns also the position of Vice President of the Management Board), together with nine directors.

All members of the management are of Romanian nationality.

Composition of the Antibiotice management team

Member	Position, Department
Ioan Nani	General Director, executive administrator and Vice President of the Management Board *He owns 1,513 Antibiotice shares**
Ovidiu Bățaga	Director Strategic Planning and Business Management Unit *He has no Antibiotice shares.*
Cornelia Moraru	Director Engineering, Investments & Strategic Projects Unit *She owns 1,513 Antibiotice shares**
Paula Luminița Coman	Director Financial Unit *She has no Antibiotice shares.*
Carmen Iustain	Director Research & Development Unit *She has no Antibiotice shares.*
Cristina Diaconescu	Director Quality Unit *She has 1,514 Antibiotice shares**
Liviu Vătavu	Director Human Resources Unit *He has no Antibiotice shares.*
Cristina Pârlog	Director Medical Unit *Nu deține acțiuni Antibiotice*
Darius Georgiani Agafiței	Director Business Development Unit *He has no Antibiotice shares.*
Mihai Stoian	Director Strategic Projects Unit *He has no Antibiotice shares.*

* Number of Antibiotice shares held on 31 December 2020, according to the latest Antibiotice database for 2020

Gender diversity in the Antibiotice management team

	Men	Women	Total
General Director	1	0	1
Specialty directors	4	5	9
Total members	5	5	10
	50%	50%	100%

Generation diversity in the Antibiotice management team

	< 30 years	30–50 years	> 50 years	Total
Total members	0	4	6	10
	0%	40%	60%	100%

More details on corporate governance and management structures within the company are available in the 2020 Management Report or on the Antibiotice website, www.antibiotice.ro, in the section Corporate Governance/Reports.

2.3. Responsible business practices

We are one of the companies with a tradition in Romania, which develops and registers progress from year to year. Culture, values we are guided by and the way we carry out our activity every day have made us a reliable partner for suppliers, customers, but also the health authorities in Romania. All these would not have been possible without a set of strong principles, which are based on an ethical behavior, but also respect and fairness towards those who support us in our work.

In all our activity, as well as in the relations with our partners, state institutions, community, we always put in the foreground the values of the company: efficiency, knowledge, cooperation, responsibility, fairness, respect, loyalty, initiative and transparency.

We make our valuable medicines more accessible to patients, physicians and pharmacists. We always put our strength to the service of those who need support.

We cherish efficiency, knowledge and the cooperation spirit, which allow us to focus on the ever-changing needs of the customers and consumersilor.

In our company, we put the right people in the right place, at the right time. We mutually acknowledge our purpose and value within the company, which creates a sense of connection and gives us the strength to overcome limitattions and obstacles.

As human beings, we care for our fellow beings, do oue best to support them and try to improve the things they find important, such as lifestyle quality.

The hippocratic spirit that guides the practice of medicine and pharmacy also guides our actions. We are honest, compassionate and constantly concerned with modernizing our activity and enhancing our products.

We believe a valuable medicine is not necessarily an expensive one, but a medicine people can afford and which brings the company a reasonable profit. Profit that satisfies our shareholders and allow us to target performance. Moreover, our company has been permanently investing in people, technology and carefully selected partnerships.

In 2020:

Our company did not record corruption incidents or incidents to violate the measures provided in the Integrity Plan of Antibiotice for the implementation of the National Anticorruption Strategy 2016-2020

There were no employees fired or disciplinary sanctioned as a result of their involvement in acts of corruption.

No contractual relations with business partners have been broken due to suspicions of corruption

Anti-corruption policy

Our company developed and implemented a set of reference documents that include, among other aspects, the company's anti-corruption policies and procedures, namely: Corporate Governance Code*, Code of Ethics, Code of good practice in dealing with health professionals, Sponsorship and patronage policy, Internal Regulations*, as well as the Integrity Plan prepared in accordance with the provisions of the National Anticorruption Strategy 2016–2020.

All the documents that make up the framework that regulates the behavior we expect from all employees, regardless of the position they hold in the company, were made known to everyone, and published on the page of the company and accessible to any interested party. The principles and values set out in the above-mentioned regulations are intended to highlight the elements on which the company's policy is based in terms of ethics (integrity, professionalism, accountability, transparency), morality, application and observance of quality standards, integrity, etc.), regulations on economic-financial and fiscal discipline, as well as the regulations on labor discipline and integrity.

As an entity that complies with the principles of corporate governance established by Government Emergency Ordinance 109/2011 on corporate governance of public enterprises, Antibiotice adopted the Declaration of adherence to the fundamental values, principles, objectives and monitoring mechanism of the National Anticorruption Strategy (SNA), thus complying with the provisions of Government Decision no. 583/2016.

* Updated versions can be found on the company's website for 2021.

You can consult the mentioned documents here, or by accessing the company's website, www.antibiotice.ro, section Corporate Governance, Reference documents.

The Integrity Plan elaborated by our company contains measures from the National Anti-Corruption Strategy 2016–2020. The plan includes anti-corruption and transparency measures, including measures regarding the performance of periodic self-assessment on the degree of compliance with the provisions of the plan, as well as recommendations on conducting regular training aimed at increasing the level of education of employees on good anti-corruption practices. Annually, the Integrity Plan is reviewed and updated to be in accordance with the provisions of the normative act on the basis of which it was drawn up, Government Decision no. 583/2015 on the approval of the National Anti-Corruption Strategy 2016–2020, of the sets of performance indicators, the risks associated with the objectives and measures in the strategy and the sources of verification, inventory of institutional transparency and corruption prevention measures, information of public interest.

In order to prevent the occurrence of corruption incidents in contractual relations with business partners, Antibiotice selects responsibly its partners (suppliers, distributors etc.), given both the compatibility of trade objectives and their integrity. Additionally, our company introduced in the commercial contracts clauses to discourage and sanction the attraction of the company and its employees in acts or deeds of corruption. In this way, the partners firmly undertake not to commit, authorize or permit any action that would lead them to violate any of the existing national, European or international anti-corruption laws or regulations., obliging them also to notify the competent judicial authorities if they become aware of any act of corruption related to the negotiation, conclusion or execution of contracts, specialized in preventing and combating corruption.

Additionally, according to the internal policy, our company does not grant sponsorships in any form to political parties and/or candidates.

Code of ethics

The Antibiotice's Code of Ethics is the basis of an organizational culture that respects integrity standards and complies with the specific legislation in force.

The fundamental values of ethics assumed by the company are integrity, professionalism, responsibility and transparency.

Any violation of the code is considered an ethical incident, non-compliance with the Code of Ethics can lead to disciplinary sanctions. Compliance with the provisions of the Code of Ethics is mandatory for all the company (employees, executive management and members of the Management Board). The code of ethics is notified to any new employee or administrator and can be consulted online.

Ethics and Integrity Council

The Ethics and Integrity Council was established in our company through the decision of the General Director. The Council is a consultative body set up within our company with the mission of monitoring the compliance with the Code of Ethics and implementing the principles and rules of ethics specific to the promotion of prescription medicines. The council supports our company's management in making decisions on business conduct and ethical promotion of medicines.

The Ethics and Integrity Council analyses all the ethical incidents in violation of the Code of Ethics and the Integrity Plan drawn up in accordance with with the provisions of the National Anticorruption Strategy 2016–2020, about which it was notified or on which it notified himself. After the analysis of each ethical incident, the Ethics and Integrity Council draws up a written report proposing to the General Director, as appropriate, the measures it deems necessary.

The Ethics and Integrity Council consists of five members, appointed by decision of the general manager of the company, for a four-year term.

The members are appointed from among specialists in the medical, economic and legal fields. A maximum of two board members may be appointed from among persons who have not concluded an individual fixed-term / indefinite employment contract with the company.

We mention some of the attributions of the Ethics and Integrity Council:

- resolves complaints regarding an ethical incident, addressed to our company;
- analyzes the ethical vulnerabilities and proposes to the General Director the adoption and implementation of measures for preventing the ethical incidents;
- analyzes from ethical viewpoint the Internal Regulations of Antibiotice, as well as the Code of Ethics and Good Practice Code for promoting the prescription medicines and managing the interactions with medical and pharmaceutical professionals, with the possibility of proposing changes or additions thereto;
- formulates proposals to reduce the risks of ethical incidents and submits them to the General Director;
- approves the contents of messages addressed to the petitioners, in response to their complaints;
- may formulate an ethically advisory point of view at the request of the General Director or Management Board;
- analyzes cases of violation of ethical norms, and norms of behavior in the relationship of sales/medical representatives with medical professionals;
- analyzes notifications of natural or legal persons in connection with the various types of abuse of the medical or sales representatives;
- notifies the competent state bodies whenever it considers that the aspects of an ethical case may be the subject of an offense and have not been notified by the legal representative of the unit or by the petitioner.

In 2020 no breach of the Code of Ethics was reported.

In 2020 no fines or sanctions were registered for violating the socio-economic legislation

Reporting an ethics incident

Any interested natural or legal person may report an incident of violation of the code of ethics. The notification, which must contain the personal identification data and also the contact data, must be addressed to the General Director. It may be submitted in writing to the registry of the company or may be completed and submitted online, via an ethics form, directly from www.antibiotice.ro, section Corporate Guvernance, Reference documents, Code of Ethics, ethics form.

Conflict of interest

Since 2015, our company implemented an internal procedure regulating the way in which the conflicts of interest and incompatibilities are handled: the situations in which the Antibiotice employees, in the exercise of their duties, they could have a personal interest of a patrimonial nature, which would influence the fulfillme with objectivity of the tasks incumbent on them. The procedure aims to establish the mode of action and the persons responsible for making decisions and endorsing the documents, in connection with professional activities within Antibiotice, in cases of conflicts of interest at the level of persons holding management positions.

In 2020, there were not registered notifications/complaints regarding situations that could constitute conflicts of interests

Competition policy

Anti-competitive, antitrust or monopoly practices have a significant negative impact on consumers, price of products and other factors that are essential for an efficient market. The policies that our company implements in this direction aim at maintaining a healthy economic climate and supporting the responsible competition.

In **2020**, our company **did not record incidents** of anti-competitive conduct or legal proceedings against it for infringement of competition, antitrust or monopoly law.

In Antibiotice, the internal framework governing competition issues, policies and procedures is represented by Corporate Governance Code, Good Practice Code in dealing with health professionals and Sponsorship and Patronage Policy.

The documents are available on the website of the company (section Corporate Governance, Reference Documents) being communicated also to our employees. The purpose of these documents is to highlight the elements on which our company's policy is based in terms of measures to combat unfair Competition.

Assuming these values is essential and, consequently, all the decisions of the Antibiotice management are in accordance with the provisions of the internal regulations.

Cyber security and protection of personal data (GDPR)

The Antibiotice policy on the personal data protection is presented in detail in an internal system procedure "Procedure regarding the processing of personal data in Antibiotice".

In developing this procedure and related internal regulations*, the company complies with the requirements imposed by EU Regulation 2016/679 (GDPR) and national legislation, but also the recommendations stipulated in the good practice guidelines issued by Working Group A29, European Data Protection Supervisor (EDPS), European Data Protection Board (EDPB) or by the national supervisory authorities of personal data in the Member States of the European Union.

The way our company processes personal data depends on the capacity that each person has in relation to Antibiotice. This procedure is described in detail on the company's website, in the section Personal data processing.

The main objective in the field of personal Data protection is the compliance of all our company's activities to the requirements impused by the GDPR Regulation and related legislation. Our company is also concerned with the continuous improvement and awareness of the implemented technical measures and organizational protection and security of personal data.

The internal structure responsible for managing the legal aspects of personal data protection is the Information Security Management Department.

* Related internal regulations refer to the procedure for dealing with situations of personal data security breach, procedure for processing personal data by means of video surveillance, procedure for GPS monitoring of service cars.

During the reporting period, we initiated a variety of projects and initiatives to protect sensitive and personal data, including:

- developing internal procedures for the protection of confidential information and personal data;
- launching training campaigns for employees in the field of data protection;
- concluding confidentiality agreements with all employees and granting access rights to information;
- purchase of a software dedicated to preventing data leakage (Data Loss Prevention).

Periodically (at least annually) our policies, regulations, forms and measures for the security of personal data are reviewed and updated to respond to changes in the organization.

Protecting data when working from home

In order to carry out work from home in conditions of efficiency and safety, the equipment required for our employees was supplemented. The IT Department ensured the creation and functionality of the VPN service, an IT solution that allows employees to work remotely with the company's resources, in conditions of data security and protection.

For adopting new methods which involved the approach of new remote communication tools, the Data Security & Personal Data Protection Department issued a set of rules and recommendations for the use of instant messaging platforms in business activities and supplemented the internal regulations with a chapter dedicated to the VPN security policy.

In 2020, our company
did not record:

> complaints related to breaches on the customer data security and confidentiality

> leakage, loss or theft of personal data

2.4. Product promotion and labeling

The pharmaceutical sector is heavily regulated, both in terms of the promotion of products and medicines, but especially when it comes to their labeling. The products and medicines we place in the market have a direct impact on the health of those who consume them, therefore, the policies and procedures that describe the internal framework for the promotion and labeling of products are based on the legislative regulations in force, both nationally and internationally (with the specifics of each country), but also existing standards and good practices at the industry level.

Promoting our product portfolio

Promotion of the products from the Antibiotice portfolio is done responsibly and ethically, in accordance with the legislation in force. In our company, the coordinator of the promotion activity is the Promotion Manager. Medical Unit ensures the proper registration of materials used in promotions in accordance with applicable laws while the Marketing Unit ensures that employees involved in promotional activities, as well as representatives of companies contracted for promotional activities are trained and familiar with the applicable laws and the provisions of the Code of Good Practice for the promotion of prescription drugs and for interactions with medical professionals.

Training the promotion team is part of the induction process of new employees. Periodically, the quarterly zonal/regional meetings (in which members of the team of the promotion department, consisting of 42 people participate depending on the area) address issues related to ethical behavior in drug promotion activities.

Code of Good Practice for Promoting Prescription Medicines

In our company, the behavior we expect from our colleagues responsible for promotion of Antibiotice product portfolio is contained in the provisions of the Code of Good Practice for the Promotion of Medicines issued on prescription and for interactions with medical professionals.

The Code establishes and implements specific ethical standards for the promotion of prescription drugs, standards to ensure the correct transmission of information on generic medicines to medical professionals.

The legislation that formed the basis for the elaboration of the Code, includes the following categories of normative acts: laws, emergency ordinances, orders, instructions or any similar act issued by the Romanian Parliament, the Government of Romania or by any other competent authority, and any applicable legislation issued by the competent bodies of the European Union and directly applicable to the activities carried out by Antibiotice.

The normative acts taken into account, without any limitations to these, are the following:

- Law no. 95/2006 on health care reform, published in the Official Gazette, Part I, no. 372 of 28.04.2006, as subsequently amended;
- Decisions, instructions, provisions of the National Agency for Medicines and Medical Devices of România (NAMMDR) which regulates the activity of promoting medicines issued on the basis of a medical prescription;
- APMGR Code (Romanian Association for Generic Medicines Producers);
- ARPIM Code (Romanian Association of International Medicine Manufacturers);
- Code of Promotion Practices of the European Federation of Pharmaceutical Industries and Associations;

- European Directive 2001/83/EC on medicinal products for human use, as amended by European Directive 2004/27/EC and Directive 2010/84/EC;
- Code of Pharmaceutical Marketing Practices of the International Federation of Pharmaceutical Manufacturers Associations, when applicable;
- Code of Interactions with Healthcare Professionals of the PhRMA, Pharmaceutical Research and Manufacturers of America.

All employees involved in the promotion activities participate in regular training programs, as well as punctually, when there are significant changes in the applicable laws and regulations. The Code of Good Practice for the Promotion of Prescription Drugs shall be notified to any new medical or sales representative employed, and may be consulted online on www.antibiotice.ro, section Corporate Guvernance, Reference Documents.

Among other things, the Code stipulates that the promotion of prescription drugs should be directed only to medical or pharmaceutical professionals. Our company's medical or sales representatives are not allowed to leave promotional materials in places accessible to the general public, such as pharmacies, waiting rooms, hospital halls and medical clinics.

The promotion activity includes actions:

- to promote products to health professionals: visits by medical representatives to people qualified to prescribe medicines, provision of promotional materials and exhibitions, organization of group presentations, round tables, webinars, participation in scientific event organized by specialized medical societies (according to Order 194/2015 on the approval of the Rules for the evaluation and approval of advertising for medicines for human use).
- promotion of the products made by persons qualified to distribute medicines;
- to promote the products intended for the general public (according to the RASCI Code of Ethics 2021 and Law no. 56/31.03.2021 on food supplements).

In 2020, our employees involved in promotion attended scientific medical events (congresses, conferences, webinars) according to the annual promotion plan. However, in the context generated by the COVID-19 pandemic, the events shifted online, on the platforms agreed by the organizing medical companies. The events had as target audience health professionals, from the medical specialties we addressed with the products from the company's portfolio.

The promotion activity is carried out according to the Promotion Plan which contains:

- details about the target group of health professionals: medical specialties, number of health professionals visited and frequency of visits;
- specific promotion tactics and actions;
- promotion tools (messages, promotional materials);
- monitoring and control of the implementation of the promotion plan by the promotion and sales teams (activity and visit reports, according to the internal reporting platform (CRM));
- regular evaluation of the results and adaptation of the actions according to the set objectives.

In 2020, our company did not record fines, warnings or sanctions for:

– non-compliance with applicable legislation or codes adopted voluntarily, with regard to product promotion.

– non-compliance with applicable legislation or codes voluntarily assumed, with regard to product labeling.

– incidents reported by relevant regulatory authorities (NAMMDs) regarding non-compliance with product labeling/ package leaflet.

The main objectives of the promotion plan are:

- to ensure the access to all categories of patients of the Antibiotice medicines, through a complex distribution, which facilitates the presence of our medicines both in hospitals and pharmacies in Romania and in the foreign markets.
- to ensure the access to correct, concrete information delivered in a timely manner, complying with all existing regulations and ethical standards in the industry.

To evaluate how we handle this topic, in 2020, our company conducted a study for assessing the satisfaction degree in relation to the company's promotion team. The study addressed to health professionals, grouped into five categories: pharmacists, physicians, managers of drug distribution companies, national pharmacy chain managers and pharmacy mini-chain managers.

The analysis of the answers showed an average level of satisfaction for the five categories of 88.9% (scores of over 80% satisfied customers were recorded, in each of the five categories).

Sales and promotion results are evaluated monthly and quarterly. The results of the study are the basis of the plan of measures to correct the indicators that were not met according to the annual plan.

Transparency in the relationship with medical and pharmaceutical professionals and organizations

In 2020 also, Antibiotice reported for 2019, to the National Agency for Medicines and Medical Devices in Romania, all sponsorship activities and any other expenses incurred by the company in the year prior to reporting, for health professionals, professional organizations, patient organizations and any other type of organization engaged in human health activities, medical or pharmaceutical assistance, according to the obligations established starting with 2015, by Law no. 95/2006 on health care reform, article 814 and Order of the Minister of Health no. 194/2015 on the approval of the Norms for the evaluation and approval of advertising for medicines for human use.

Events in 2020

Iasi Dermatological Spring, ninth edition, organized between 13–18 July 2020 by the Association of Dermatologists of Moldova, under the auspices of the University of Medicine and Pharmacy "Grigore T. Popa" Iasi, Romanian College of Pharmacists, Medical College in Romania and the Society of Physicians and Naturalists of Iasi, brought together, in the virtual environment, over 2,800 participants, who were present at the over 20 symposia and at the over 110 courses and workshops and presentations. In the context in which Antibiotice is a leader in the segment of topicals intended in particular for the treatment of dermatological conditions, our company organized a satellite course dedicated to pharmacists and pharmacy assistants, entitled "ABC in Dermatology". The topic was of real interest, the course having an impressive audience of over 800 live participants.

This course brought together teachers from UMF "Grigore T. Popa" Iași and UMF "Carol Davila" (prof. dr. Daciana Elena Brănișteanu, prof. dr. Monica Hăncianu, conf. dr. Cătălin Popescu) as well as dermatologists, practitioners with extensive clinical experience.

Antibiotice Webinars – 65 years of Romanian Continuity and performance a series of online meetings organized by our company in 2020, held from October to December (a month in which Antibiotice celebrated six and a half decades of existence). These virtual conferences were attended by over 1000 health professionals from various medical fields, especially specialists in dermatology, internal medicine, ATI, pneumology, pediatrics, ENT, epidemiology, infectious diseases – to the webinar entitled "Medicines that have made history", pharmacists and family doctors at the webinar "In service of life for a lifetime!", or cardiologists to the webinar "We've been healing people for 65 years. From all our heart."

The v-SRATI 2020 virtual congress organized by the Romanian Society of Anesthesia and Intensive Care, science program comprising in four days, more than 124 conferences, 36 oral communications and e-Posters, 19 satellite symposia, two workshops, sessions held by over 130 readers from 17 countries, from four continents. One of the satellite symposia was organized on November 15 by Antibiotice, in order to promote the antiinfectives portfolio – symposium theme: "Treatment of Gram-negative germ infections – Consecrated options").

We promote responsible antibiotic use

Antibiotics of the Third Millennium is a social responsibility program initiated by Antibiotice and officially launched through the actions carried out in November – December 2018. The program is developed in partnership and under the scientific coordination of the Romanian Society of Microbiology and of the Romanian Society of Epidemiology having as a communication partner the firm "People & companies".

Antibiotics of the Third Millennium supports the judicious use of antimicrobial agents by developing and disseminating best practices in the field of antibiotic use, targeting a community of patients and the general public, physicians, nurses, pharmacists, manufacturers, environmental experts, academics and entrepreneurship representatives.

The program will continue with research and monitoring of the system for reporting and managing infections associated with healthcare and bacterial resistance, in order to outline a concrete plan for balancing and professionalizing this system and improving the way antibiotics are prescribed and the healthcare associated infections are monitored.

In 2020, the Antibiotics of the Third Millennium program took place online through the project platform www.antibioticelemileniuluitrei.ro.

Information was provided to both the general public and health professionals on the responsible use of antibiotics.

Product labeling

Packages of the phramaceutical products manufactured by Antibiotice are carried out in accordance with the national legislation of the country in which the medicinal products are registered and/or marketed.

The package and leaflet of each medicinal product are subject to the approval of NAMMDR, the national regulatory authority for medicinal products or other European and non-European authorities, before placing the medicines in the market and the information is periodically reviewed and aligned with relevant legislative requirements.

Information included in the leaflet, addressed to both healthcare professionals and patients or users, explain to them how to use the medicine correctly. Information includes the composition of the products, indications, dosage and method of administration, mode of action, warnings of possible side effects, recommendations for pregnant or lactating women, possible interactions with other medicinal products, packaging and storage.

If the medicine contains ingredients that could harm the natural environment, then the package, the package leaflet may contain, also information on proper disposal of the product.

All this information is periodically verified and updated to ensure that all our products contain the latest information on quality, safety and quality, as appropriate.

We carefully and systematically monitor legislative changes, reviewing and constantly updating the information on the packaging and package leaflet, to ensure that all our products contain the latest information on quality, safety and quality, as appropriate.

2.5. Quality, our commitment to the health and safety of patients and consumers

Safety and health of the patients and consumers who use our products are the fundamental elements of the way we carry out our activity, an aspect that is also reflected in the results of the materiality analysis, as being the topic of the utmost importance by the company's stakeholders. As a medicine manufacturer, we have a great responsibility, that is why we take all necessary measures to ensure that our production processes comply with the highest national and international quality standards.

Our eight manufacturing flows are audited and certified by the National Agency for Medicines and Medical Devices of Romania (NAMMDR), in compliance with the Good Manufacturing Practice (GMP) requirements. Quality of the medicines in form of sterile injectable powders and of the active substance Nystatin is also confirmed by obtaining from the Food and Drug Administration (FDA) the approval to sell these products in the United States.

Standards, licenses, authorizations and certificates valid on December 31, 2020

Authorization	Description	Recertifications	Date of last certification
Manufacturing authorization 30 F	Manufacturing authorization for medicines for human use, inclusding the clinical investigational medicines, issued by National Agency for Medicines and Medical Devices of Romania (NAMMDR)	Recertification when changing certification conditions	Dec. 2, 2019
Authorization RO 03	Authorization for the manufacture of veterinary medicinal products issued by National Sanitary Veterinary and Food Safety Authority (ANSVSA)	Recertification every 3 years	Apr. 11, 2019
Authorization 7Fsp/2020	Authorization for the manufacture of preparations containing narcotic and psychotropic substances issued by the Ministry of Health	Annual reauthorization	Feb. 4, 2020
Authorization* 861/2018	Authorization to conduct clinical trials in the field of medicine issued by NAMMDR	Reauthorization every 2 years	Jul. 12, 2018 * extended until Dec. 2021 (NAMMD decision 58662E/ 27.07.2020, internally registered 6563P/29.07.2020)
Authorization 1/2011**	Integrated environmental permit issued by ARPM (Regional Environmental Protection Agency) Bacău, revised by the Iași Environmental Protection Agency	Annual approval/revision/re-authorization when changing the conditions of authorization	Jan. 10, 2011 ** revised on Mar. 30, 2018
Authorization 303/2010	Water management permit issued by the Romanian Waters Administration (AAR) Prut-Bârlad	Re-authorization when changing the conditions of authorization	Dec. 20, 2010

Authorization	Description	Recertifications	Date of last certification
GMP Certificate* 023/2018/RO**	Certificate of conformity with good manufacturing practice (GMP) issued by NAMMDR, following the inspections of the manufacturing, packaging and quality control testing of ointments (medicines for human use). Medicines are manufactured in compliance with the Good Manufacturing Practice Guidelines used by NAMMDR when assessing applications for a manufacturing authorization and for inspection of manufacturers of medicines for human use based on quality risk management principles. The manufacturing authorization system ensures that all authorized medicinal products are manufactured only by authorized manufacturers, whose activities are regularly inspected by the competent authority.	Recertification every 3 years	Jun. 5, 2018 *** extended until December 2021 (NAMMD letter no. 58622/ 21.07.2020 with internal registration number 6563P/ 29.07.2020)
GMP Certificate** 040/2017/RO**	Certificate of conformity with good manufacturing practice (GMP) issued by NAMMDR, following the inspections of the manufacturing, packaging and quality control testing of suppositories, capsules and tablets (medicines for human use).	Recertification every 3 years	Aug. 11, 2017 **** extended until Dec. 2021 (NAMMD letter no. 58622/ 21.07.2020, with internal registration no. 6563P/29.07.2020)
GMP Certificate 041/2017/RO	Certificate of conformity with good manufacturing practice (GMP) issued by NAMMDR, following the inspections of the manufacturing, packaging and quality control testing of ointments, suppositories, capsules and tablets (investigational medicinal products for human use).	Recertification every 3 years	Feb. 4, 2020
GMP Certificate 055/2019/RO	Certificate of conformity with good manufacturing practice (GMP) issued by NAMMDR, following the inspections of the manufacturing, packaging and quality control testing of Nystatin, active substance.	Recertification every 3 years	Dec. 2, 2019
GMP Certificate 056/2019/RO	Certificate of conformity with good manufacturing practice (GMP) issued by NAMMDR, following the inspections of the manufacturing, packaging and quality control testing of the sterile products, powders for injectable solutions/ suspensions (medicines for human use).	Recertification every 3 years	Dec. 2, 2019
GMP Certificate 58/2019/RO	Certificate of conformity with good manufacturing practice (GMP) issued by NAMMDR, following the inspections of the manufacturing, packaging and quality control testing of veterinary medicinal products.	Recertification every 3 years	Apr. 2, 2019
GLP Certificate 49***	Certificate of conformity with good laboratory practice (GLP) issued by NAMMDR, following the inspections of the Bioanalytical Laboratory within the Center of Clinical Studies of Antibiotice. GLP is a set of principles to be followed in conducting bioanalytical testing, which provides assurance on the quality and integrity of non-clinical trials.	Recertification every 3 years	Jul. 5, 2017 ***** extended until Dec. 2021 (as per the Decision of NAMMD 59664E/11.08.2020)
US FDA EIR Acceptance	US FDA Establishment Inspection Report Acceptance is the inspection report issued following the inspection of the manufacturing flow of powders for injectable solutions/ suspensions and manufacturing flow of the active substance Nystatin. This inspection was conducted by FDA (the US Drug Regulatory Authority).	Periodic recertification correlated with the risk analysis	Jun. 2, 2017
ISO 9001:2015	The ISO 9001:2015 quality management system is an international standard that specifies the requirements that the quality management system must meet in order for the organization to provide quality products.	Annual surveillance and recertification every 3 years	Jan. 16, 2020

Authorization	Description	Recertifications	Date of last certification
ISO 14001:2015	The ISO 14001:2015 environmental management system is an international standard that specifies the requirements that an environmental management system must meet in order for the organization to increase its environmental performance.	Annual surveilance and recertification every 3 years	Jan. 16, 2020
ISO 45001:2018	The Occupational Health and Safety Management System ISO 45001:2018 is the international standard that sets out the requirements that an occupational health and safety management system must meet in order for the organization to control risks and improve its OHSAS performance.	Annual surveilance and recertification every 3 years	Jan. 22, 2020
R1-CEP 2003-096 Certificate Rev 02	Certificate of Suitability with the European Pharmacopoeia (CEP) for the active substance Nystatin, issued by the European Directorate for the Quality of Medicines (EDQM). CEP confirms that a pharmaceutical substance or a active substance is produced according to the corresponding monographic requirements of the European Pharmacopoeia.	Recertification when the inormation in the Master Record of the Active Substance (ASMF) is changed	Dec. 4, 2018
Certificate10	Certificate of conformity for the aluminium tubes used in the packaging of ointments, creams, gels.	Recertification every 3 years	Mar. 21, 2018
Certificate 11	Certificate of conformity for the screw caps and membrane penetration devices used for closing the aluminium tube filled with ointments, creams and gels.	Recertification every 3 years	Mar. 21, 2018
Certificate 12	Certificate of conformity for the metal cap intended for closing the vials filled with antibiotic products.	Recertification every 3 years	Mar. 21, 2018

Our quality policy

Compliance with the requirements of the quality management system is followed, internally, by the specialists from the Quality Assurance Department (through rigorous policies and procedures), and externally, by the business partners (through periodic audits), respectively by the regulatory authorities in the field in Romania (NAMMDR, ANSVSA) and in the countries where the Antibiotice products are authorized (through inspections).

The Quality Management System implemented by Antibiotice according to the GMP requirements in the European Union (EU GMP) imposed by the European Medicines Agency (EMA) and the ISO standard, is in compliance also with the the good manufacturing practice requirements in the United States of America imposed by FDA (attested by the letter of acceptance obtained in 2017). This recognition has increased the confidence of international partners in the robustness and performance of the quality system implemented by Antibiotice, making it possible to communicate in a common language and be open to the whole world.

In 2020, Antibiotice adapted itself at the request of national and European authorities, as indicated in the guide to regulatory requirements in the context of the COVID-19 pandemic issued by the European Medicines Agency (EMA). So, the EU GMP certificates for the manufacturing flows for non-sterile products, capsules, tablets, coated tablets, suppositories and non-sterile semisolid products were extended until December 2021.

The certificate of conformity with good laboratory practice (GLP) issued for the Bioanalytical Laboratory within the Center of Clinical Studies of Antibiotice, was also extended until the end of 2021.

Following the audit conducted in the period 2-5 December 2019 for certifying the system, the certification body TÜV Rheinland issued at the beginning of 2020 the following certificates: ISO 9001:2015 (quality management system), ISO 14001: 2015 (environmental management system) and ISO 45001:2018 (occupational health and security management system).

Audits conducted by our customers

In view of the COVID-19 pandemic which affected the conduct of the audits, four audits took place during 2020:

- The audit of the manufacturing and control flow of Nystatin, active substance was conducted on-site. Following this audit, our company was requalified as a supplier of active substance (API).
- The other three audits were conducted on the manufacturing and control flow of parenteral products, being remote audits, based on the information requested by customers in the questionnaires sent. Based on the results of these audits, Antibiotice was requalified as a manufacturer of parenteral products.

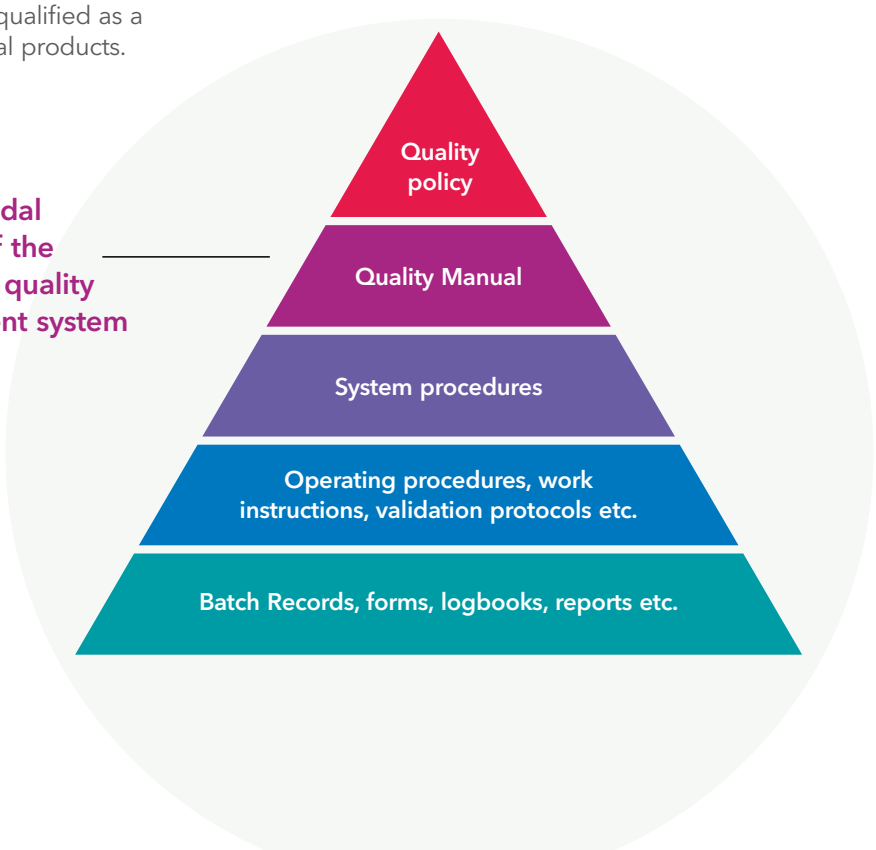
Product quality assessment

Our permanent concern is to provide the population with quality, safe and therapeutically effective medicines. In this respect, we annually carry out an analysis of all the medicines in our portfolio, in accordance with the specific system procedure "Product quality assessment". The purpose of the products quality assessment is to verify the robustness, stability and reproducibility of the existing manufacturing process, corectness of the quality specifications, in order to identify any trend over time. Following the evaluation, corrective actions are proposed and implemented, respectively opportunities for improvement, as appropriate.

Maintaining the quality level of our products is a commitment we have made not only to our patients and consumers, but also to all our value chain partners. Thus, depending on the technological and legislative evolution specific to the pharmaceutical industry, some of the products periodically enter an optimization / reformulation process for complying them with increasingly restrictive legislative requirements.

From the entire Antibiotice portfolio comprising 150 products, seven products underwent an optimization process in 2020.

The pyramidal structure of the Antibiotice quality management system



Research & Development

The main goal of the Research-Development activity is to develop new generic medicines in new pharmaceutical dosage forms: topicals, tablets, capsules, sterile products, biocides, medical devices, dermatocosmetics, cosmetics, in line with the company's strategic development directions.

In 2020, our specialists continued their research activities started in previous years for a significant number of products. At the end of the year, 14 products were under research, as follows:

- 3 products for the Sterile Products and APIs Division
- 7 new products for Topical Products Division
- 4 new products for the Oral Solid Products Division (one of them being a food supplement).

Another 4 research projects for solid oral products were added (3 Rx products and an OTC products) and 9 projects for topical products.

In **2020**, we invested **8.57 million lei** in research-development.

At the end of **2020**, **24 active research projects** (in different stages of development) were in research & development

The reseach activity continued to support the internationalization strategy of the current portfolio with 18 products (10 solid oral products, 4 injectables and 4 topicals), which are to be authorized in various foreign markets.

In March 2020, the American Authority FDA a approved the Active substance master file (ASMF) for the active substance Nystatin, a document that certifies the quality of our product.

The investments that our company made in the research and development activity represent approximately 18% of the total budget of 48.06 million LEI, invested for the strategic development of our site, which included, among other things, investments in new production sites, for modernizing the existing manufacturing sites and for rehabilitating the entire industrial site.

Introducing new products in the market

The proposals for new products are collected and evaluated by the Portfolio Management Department. These proposals resulted from assessing the need to enrich the portfolio in compliance with the strategic directions of development and taking into account the evolution of medical and consumer trends in the period 2025–2030, the market audit per each pharmaceutical dosage and analysis of the main competitors' portfolios.

Each proposal requires initial information on: market analysis highlighting the potential in terms of value, quantity and price/IU (international units), medicale information – presence in therapeutic guidelines, medical advantages, possible evolution of consumption, information on the possibility of in-house development, compatibility with our own technological flows, information on authorization procedures and legislative requirements, information on patents, marketing exclusivity, sales forecasts.

The information for each proposal is centralized by the Portfolio Management Department and then are submitted for validation to the G2 Group (Marketing policies and Portfolio Policies). The selection is based on the following criteria: in line with the development directions of the portfolio, value market size, average price/IU, quantitative market dynamics, number of competitors, portfolio entry speed, share of value added to turnover. When approved, each proposal is assigned the method of assimilation in the portfolio: research-development or business development.

In 2020, 14 projects were evaluated, for including them in our company's future portfolio. These are products for dermatological and gastrointestinal conditions, diabetes, cardiovascular, genitourinary, rheumatic or nervous system diseases, as well as anti-infectives. Both prescription (Rx) and non-prescription products (OTC, food supplements, medical or cosmetic devices) were included. Also in this group of products, we have medicinal products that are first generics.

The company's approach to manage the risk when developing and introducing new products to the market

Each department involved in developing and introducing new products in the market identifies, assesses and manages the risks specific to its field of activity. After the identification of the significant risk, the risk form is completed in which the risk is described, the analysis or the causes that favor the occurrence/recurrence, identifies that the consequences, primarily assesses the consequences and the probable impact, proposes control measures.

Authorization and reauthorization of our products and their registration in new markets

In 2020, the work of our colleagues in the Regulatory Affairs Department included obtaining marketing authorizations or re-authorizations, both in the domestic and international markets, for a number of 35 products from our portfolio (17 authorizations and 18 reauthorizations).

In 2020, one product was authorized in the domestic market while 14 products were reauthorized (5 topicals and 9 solid oral products).

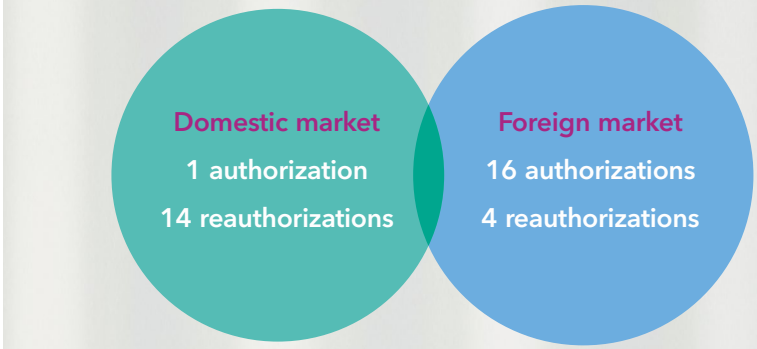
16 products were authorized and 4 were reauthorized in the foreign market in the reporting period.

Authorizations:

- 8 topicals: 7 of them in the Antibiotice territories (4 products in Kosovo and 3 products in Vietnam) and 1 product authorized in Irak
- 5 solid oral products: 4 of them in the Antibiotice territories (1 product in Republic of Moldova and 3 food supplements in Ukraine) and 1 product in Irak
- 3 injectable products: 1 product in the Antibiotice territories (Republic of Moldova) and 2 products in Yemen.

Reauthorizations:

- 3 produse topice în teritorii Antibiotice (Republica Moldova)
- 1 produs injectabil în Hong Kong.



Assessing the risk of nitrosamine impurities in the Antibiotice products

A number of impurities called nitrosamines, which are potentially carcinogenic to humans, have been found in various medicines for human use from various manufacturers. Therefore, globally, medicines regulators have called on manufacturers and traders of medicines for human use to re-evaluate their manufacturing processes in order to eliminate any risk of these impurities occurring.

The presence of nitrosamine impurities in some drugs came to the attention of the authorities in July 2018, when they were first discovered in the active substance valsartan (belonging to the class of sartans, drugs that lower blood pressure). Prior to June 2018, nitrosamines were not among the impurities identified in sartans, so they were not detected by regular tests. As a result, EU, US and Canadian authorities withdrew products containing impurities from the market, and as of 1 February 2019, the European Commission launched a re-evaluation of the production processes of sartan-based medicines in compliance with the Article 31 of Directive 2001/83/EC.

During 2019, nitrosamine impurities were discovered in other products also: in ranitidine-based medicines (to reduce gastric acid production in patients with ulcers or heartburn) and in those containing pioglitazone and metformin, respectively, to lower blood sugar in patients with type 2 diabetes.

Following these findings, the European Medicines Agency (EMA) decided to initiate on 26 September 2019 the process for assessing the risk of nitrosamines for all authorized medicinal products for human use containing active substances obtained by chemical synthesis, including the prescription and non-prescription generics (RXs and OTCs), accros the European Union.

Antibiotice requested data on the presence of nitrosamine impurities from its suppliers of active substances, excipients and primary packaging materials, as well as from partners manufacturing contract products.

Based on these data, the company performed all risk analyzes by the deadline (March 31, 2020), and the conclusions were forwarded to the National Agency for Medicines and Medical Devices (NAMDMR).

Assessment of the presence of nitrosamines in the products from the Antibiotice portfolio was conducted for each medicine by a team of specialists from the following departments: Regulatory Affairs, Center for Clinical Studies, Research-Development, Analytical Unit, Quality, Import, and from the production plants. Testing uses analytical methods developed and validated as required by regulators.

The first risk analyzes were performed at Candesartan Atb® and Ranitidină Atb® (nitrosamine impurities being identified for the first time at European level in several products containing sartans and ranitidine).

Risk analysis for Nystatin, active substance (an antifungal for the treatment of candidiasis), has already been completed, and the analytical test method, developed and validated, according to the partners' requests and the authority's requirements. The summary of the risk analysis sent to the partners shows that no nitrosamine impurities were found in Nystatin.

Withdrawal/recall of products from the market

In 2020, following EMA / 231394/2020, the CHMP (Committee for Medicinal Products for Human Use) recommended the suspension of all marketing authorizations* containing ranitidine hydrochloride due to the low levels of NMDA impurity (N-nitrosodimethylamine).

Thus, all marketing authorization holders must work with manufacturers of active substances and products to assess the risks of formation of nitrosamine impurities in their production processes and to take the necessary measures.

În luna **noiembrie 2020** a avut loc și primul audit de supraveghere pentru cele trei sisteme, calitate, mediu, sănătate și securitate în muncă, ce s-a desfășurat online și **s-a încheiat fără observații.**

* Marketing authorizations (MAs) are licenses issued by regulatory authorities in the field of medicinal products, which prove that products promoted and marketed in a particular market are manufactured in accordance with legal regulations. Holders of MAs are directly responsible for the quality, safety and efficacy of medicinal products, including the quality of the active substances, excipients and raw materials used in the manufacturing process.

Because patient safety is the number one priority of the company, Antibiotice propose to the NAMMDR the voluntary recall of all the batches of Ranitidină Atb® 150 mg, coated tablets from the distribution network (up to the pharmacy level). Upon receipt of the Agency's approval, by July 31, 2020, the recall operations were completed, and by the end of the year all quantities of product and active substances were destroyed by authorized companies.

Serialization of medicines

Counterfeit medicines are a potential risk that could have a significant impact on the health of patients and consumers. Counterfeit products are often products that lack the active ingredient or contain a smaller amount of it. As a generics manufacturer, Antibiotice has been aligned with the requirements of the European Union to reduce counterfeiting of medicines. Starting with February 2019, the process of pharmaceutical serialization of drugs was started on all manufacturing flows.

Serialization involves verifying, in real time, the authenticity of each medicine, wherever it is in the chain between the manufacturer and the patient. Serialization is mandatory for all prescription-only medicines for human use.

Serialization is made in our company in compliance with the Delegated Regulation 2016/161/EU supplementing Directive 2001/83/EC on falsified medicinal products by laying down detailed rules for the safety features on the packaging of medicinal products for human use. Antibiotice succeeded in meeting the above-mentioned regulations and successfully implementing the serialization system at the imposed date, February 09, 2019.

According to the Delegated Regulation 2016/161/EU, drug aggregation is not a mandatory feature, however our company managed to successfully implement this functionality, both for the collective box and for the pallet.

The safety features required by the Delegated Regulation are:

- a unique identifier enabling the authenticity and identification of an individual package of medicinal products to be verified;
- a protection device (tamper evident) gainst unlawful alterations to check if the packaging of a medicine has been modified.

The unique identifier consists of a sequence of numeric or alphanumeric characters that is unique to a particular package of medicinal products and consists of the following data elements:

- a product code (a global unique PC, < 50 characters, according ISO 15459, allowing at least the identification of the name, the international nonproprietary name, pharmaceutical dosage form, concentration, package size and package type of medicine which represent the unique identifier
- a serial number (SN), a sequence of maximum 20 numeric or alpha-numeric characters, (generated by a randomization algorithm)
- expiry date (EXP)
- batch number (BATCH).

In Antibiotice, serialization takes place in the four manufacturing plants:

- Parenteral Products Plant
- Capsules Plant
- Ointments & Suppositories Plant
- Tablets Plant

In our company, the serialization system is organized on five levels:

- **Level 1** – This level includes the hardware devices: printers, print identification and verification rooms, rejection station, sensors for veriying the presence of the product.
- **Level 2** – Dedicated software which manages the serialization and aggregation equipment.
- **Level 3** – Advanco software which assigns the serial numbers to serialization lines, verifies the information received from the serialization equipment and transmits them to level 4; it also allows for changes in the aggregation hierarchy and processing of product deliveries.
- **Level 4** – TraceLink software for data management of serialization and regulatory events, respectively of the processes required for serialization of drugs.
- **Level 5** – A global network allowing the data management of serialization and regulatory events, the connection with partners, customers or any regulatory authority.

Reducing the risk of introducing counterfeit products

In our company, the policies implemented to reduce/meet the risk of introducing counterfeit or compromised products into the supply chain are described in the system procedures. "Serialization and aggregation of medicines in Antibiotice" and "Investigate products that are suspected of being counterfeit".

The policies and control mechanisms implemented by Antibiotice are:

- application of safety elements on the packaging of the products from our portfolio which are issued on medical prescription (unique identifier and sealing system against illicit opening) enabling authentication and identification of the commercial units, to provide evidence on their illicit modification.
- collaboration only with authorized wholesale distributors, holders of a wholesale distribution authorization and a GDP (good distribution practice) certification, issued by the competent authorities following the inspection.

In 2020, the serialization system generated 10 counterfeit alerts, of which:

- 3 alerts were identified as justified, the investigations identified errors in the management of serial numbers (SNs), without impact on quality and safety of the finished product.
- 7 unjustified alerts.

The 10 counterfeit alerts were received from:

- Pharmacies – 7
- Distribuitors – 1
- Romanian Organization for Serializing Medicines (OSMR) – 2

The products suspected of counterfeiting can be identified:

From internal sources: the product suspect suspected of counterfeiting can be identified wihin our company by the Antibiotice staff either at the reception, at the test or after an investigation.

From external surces:

- on the route of the distribution chain (by the distributor, pharmacy, hospital, physician, etc.)
- following the quality complaints received from the market
- following the routine inspections conducted by NAMMDR in the territory (pharmacies, distributors, etc.)
- following the notifications made by the authorities (police, customs authority, etc.)
- by the contract provider.

In Antibiotice, the couterfeit alerts are received:

- in writing
- by telephone
- fax
- email
- social networks
- our company's site.

Pharmacovigilance

Safety of our medicines is monitored through pharmacovigilance, regulated by the requirements of the European Medicines Agency (EMA) and national authorities.

Pharmacovigilance includes all activities for the detection, evaluation, validation and prevention of adverse reactions to medicinal products for which we have a marketing authorization. In the pharmacovigilance activity we have the obligation to communicate and participate actively, at European level, through the following agencies/platforms:

- **European Medicines Agency (EMA)** has as its main responsibility the protection and promotion of public health, by conducting scientific assessments of medicines produced by pharmaceutical companies for the European Union market. EMA facilitates the development of and access to medicines, assesses the marketing authorizations (MAs) of medicines for human and veterinary use, monitors the safety of medicines throughout their life cycle, providing information to health professionals and patients.
- **EudraVigilance** – a system designed to report suspected adverse reactions, a system developed, maintained and coordinated by the EMA.
- **XEVMPD – EMA** platform through which Marketing Authorization Holders (MAs) enter information on medicines in their portfolio, new data appearing/ collected as a result of the use of the products in practice or on the basis of post-marke-ting clinical trials (MAs, summaries of product characteristics (SPC), changes, etc.)
- **MedDRA** – Dictionary of medical terminology that we are obliged to use in drafting documents specific to the Pharmacovigilance Department.

In our company, we evaluate, maintain and communicate to medicinal authorities all information on the safety of the use of medicinal products throughout the life cycle of the products (pre-authorization and post-authorization). Thus, our pharmacovigilance specialists monitor, identify, evaluate, report and establish, through the risk management plans, all potential risks associated with the use of our medicines. Also, as it is known, any drug can have undesirable effects, therefore, according to the law, we carefully monitor, from all sources, the occurrence of such events, respecting the obligation to report to the authorities the information on product safety and to take appropriate measures if the benefit/risk balance changes.

We are connected to the European Pharmacovigilance basis, EudraVigilance and ensure the patients' access to reporting the possible adverse reactions suspected, through forms available on the company's website or promoted through our representatives, to health professionals.

We promote good practices in the field of pharmacovigilance, both internally and through contracts with our business partners, thus contributing, through carefully selected partnerships, to the creation of a network that supports patient safety. As an integral part of the quality assurance system, the pharmacovigilance activity ensures the implementation of the measures established by the European authorities in the field of consumer health, by immediate action, by updating the medical information in the SPC (summary of product characteristics), in the package leaflet and through information letters to healthcare professionals.

In 2020, no adverse effects were reported through the online form, but two complaints were received on the other channels. The adverse reactions received by the Scientific & Pharmacovigilance Departament are registered internally according to specific procedures. These include several steps, including: receipt, registration, analysis, framing, validation, verification of framing (QPPV final supervision). Depending on the severity of the adverse reaction, they must be submitted to EudraVigilance within a maximum of 15 days (serious adverse effects) and 90 days (non-serious adverse effects).

The main activities carried out within the Pharmacovigilance Department are:

- collecting the adeverse effects from doctors, pharmacists and patients to monitor the frequency of adverse effects reported for the Antibiotice medicines;
- analysis and dissemination of information necessary for the correct prescription of our company's medicines for their rational and safe use;
- evaluation and communication of the benefit/risk ratio for all our medicines existent in the market and their transmission to the competent authorities of the territories in which they are placed in the market.

In order to communicate any adverse reactions to our company's medicines, we provide our stakeholders with several channels through which they can report such situations:

- directly, for the collection of any suspected adverse reaction via the Spontaneous Adverse Drug Reporting Sheet, physically transmitted to the health professionals, through our medical/sales representatives/Key Accounts;
- online, on the Antibiotice site, the form for collecting suspected adverse reactions from patients or healthcare professionals, as well as email addresses (sigMedUmane@antibiotice.ro, sigMedVeterinare@antibiotice.ro), for the direct communication of pharmacovigilance situations;
- mobile phone number 0728 199 834, as well as the telephone line, which is routed through the Antibiotice telephone exchange, to which people can communicate any questions/notifications regarding the pharmacovigilance of medicinal products for human use.

During 2020, in addition to the annual actions for updating the company's pharmacovigilance system in compliance with the legislative changes in the field, as well as for maintaining the EudraVigilance database, monitored by the European Medicine Agency, Antibiotice replied to a questionnaire from the German medicine authority, BfArM (Federal Institute for Medicines and Medical Devices) aimed at assessing the potential risk of the company's pharmacovigilance system. This authority did not propose audits/corrective actions.

Clinical Studies Center (CSC)

For conducting the phase I clinical studies and bioequivalence studies, Antibiotice set up its own Clinical Studies Center in 2006. Our Center has the authorization to conduct clinical

Studies, an authorization issued by the National Agency for Medicines and Medical Devices of Romania (NAMMDR), autorizație which is renewed every three years in accordance with the law. Good laboratory Practices (GLP) as well as Good Clinical Studies (GCP) are ensured by the inspection conducted by NAMMDR, once every two years. Following this inspection The regulatory body issues the related compliance certificate.

These certifications and authorizations demonstrate the company's ongoing concern for product quality, which is reflected in its commitment and responsibility to the health of consumers, employees, and environment. In this sense, the processes within the company Antibiotice are carried out according to the Integrated Management System of quality, environment, occupational health and safety.

This framework governs all the processes, from research-development, supply, production, control, to distribution of medicines to patients. Certified for the first time in 2007, the Integrated Management System received its most recent certification in December 2019, following the audit conducted by TÜV Rheinland Cert GmbH.

Antibiotice, an important manufacturer of medicines, conducts clinical studies. Clinical studies is a category of activities that is regulated worldwide. International legislation obliges the manufacturers of medicines to comply with very clearly defined requirements on how clinical studies are conducted.

In accordance with the relevant legislation, prior to the start of the clinical studies, the study protocols must be approved both by the National Agency for Medicines and Medical Devices of Romania (NAMMDR) and National Committee of Medicines and Medical Devices (NCMMD). The latter assesses how the rights of participants in clinical trials are respected and also ensures that ethical standards are respected where the remuneration of the subjects also comes into play. Anyone wishing to participate in a clinical study shall be fully informed by the specialist doctor on the conduct of the study and shall be informed in detail on the administration of the study medicinal product, its potential benefits and risks.

Safety of participants in clinical studies

Fundamental human rights as described in the Helsinki Declaration are ensured for all the participants in the clinical/bioequivalence studies. The participants in the bioequivalece studies receive a monetary remuneration for each clinical stage in which they participate. The calculation of remuneration takes into account the following aspects:

- number of hours of hospitalization
- the molecule studied
- compliance with the pharmaceutical form
- possible adverse effects
- number of biological samples collected
- restrictions during the study.

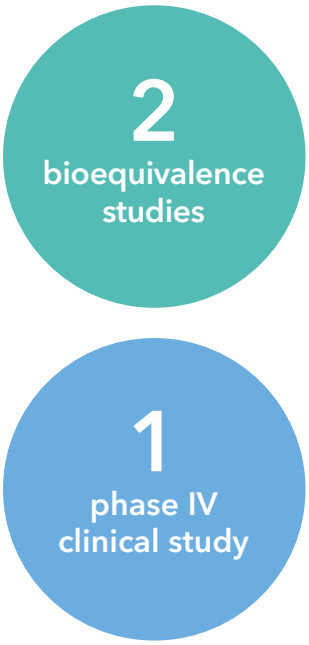
It is important to note that only healthy volunteers are admitted in the bioequivalence studies. At the end of the study, the maintenance of the state of health is ascertained through complete medical analyzes. For the phase I-IV clinical studies, the patients included in the study receive the medication assessed within the clinical study, having access to treatment and medical evaluation throughout treatment.

Remuneration received is also assessed and approved by the Committee on Ethics. Before being included in a clinical study, that person shall receive from the qualified staff all information relating to the study protocol, the drug studied, the associated risks, adverse reactions, etc. Participants may ask any question to qualified medical staff and only after they have been fully informed, sign the informed consent and subsequently can be randoomized in that study. Any participant in a clinical/bioequivalence study has the option to withdraw from that study at any time. Moreover, for any clinical/ bioequivalence study, a health insurance is concluded for each participant in the study.

In 2020, our company' s clinical study plan consisted of starting two bioequivalence studies for oral products, as well as conducting a phase IV clinical study for a topical product, a study which is in progress until the end of 2021.

Animal testing

Quality testing of the products from the Antibiotice portfolio does not involve animal testing. Starting with October 2018, as a result of changes in European and national legislation on the protection of animals used for scientific purposes, the company has replaced animal testing with alternative testing methods.



2.6. Pricing policy and access to medicines

The price of medicines is one of the main factors that influence patients' access to the treatments they need. We know that we, through our activity, have the power to facilitate the citizens' access to medicines. Beside the pricing policy which strictly reflects the national and international provisions, through various products from our portfolio we are present in more than 70 countries. Locally, we get involved whenever we can and distribute products to vulnerable people or groups, to help them get through difficult situations.

Pricing policy

At European level, pricing of medicines for human use is regulated, with the aim of ensuring adequate stocks of medicines at a reasonable cost, in order to maintain public health, support the efficiency of the production of medicines and encourage research and development of new medicines.

As regards the prescription medicines (Rx), the pricing is done in compliance with the legal requirements provided in the Order of the Minister of Health no. 368/2017 for the approval of the Norms regarding the calculation method and the procedure for approving the maximum prices of medicines for human use. The Order transposes into national law the provisions of Articles 1, 2, 3 and 4 of European Council Directive no. 89/105/EEC of 21 December 1988 on the transparency of measures governing the pricing of medicinal products for human use and their inclusion in the scope of the national health insurance system. According to this order, in order to determine the price of a prescription drug, the proposed price is compared with the price of the same drug authorized in the Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Belgium, Italy, Lithuania, Spain, Greece and Germany. The proposed producer price must be less than or equal to the lowest price of the same medicinal product in the list of countries with which the comparison is made. If the medicine has no registered price in the comparison countries, the proposed price is approved. As regards the generic medicines, the price may not exceed the generic reference price. The generic reference price is the maximum producer price that will be approved only once, on the date of application for approval of the price of the first generic medicinal product under the respective International Non-Proprietary Name (INN), concentration and pharmaceutical form.

Prices of over-the-counter medicines (OTCs), food supplements and cosmetics manufactured by Antibiotice c are set and freely changed taking into account market requirements and trends.

For the foreign market, prices of medicines are set by negotiation with external partners, in conditions of competitiveness and in accordance with the legislation in force in the respective countries. Our participation in public medicine tenders, through distributors, ensures the access of all medical institutions to the Antibiotice medicines, in terms of competitiveness and transparency, our company assuming also the flexibility of reducing the price within the limits of profitability. The pricing policy of Antibiotice complies with the specific legislation in force (Law no. 21/1996, republished), respecting competitive practices and ethical conduct in business, according to the internal codes: Code of Ethics and Code of Good Practice for the Promotion of Prescription Drugs and for interactions with medical professionals.

Access to medicines

In 2020, Antibiotice management decided to resume the manufacture of Paracetamol and Novocalmin®, medicinal products for which Antibiotice has Marketing Authorizations (MAs). This decision was taken in order to support the Romanian health system in the context in which most of the national treatment guidelines in the EU recommend paracetamol as a first choice when initiating treatment for fever or pain caused by COVID–19 infection. The introduction of this medicinal product (without a prescription) into the treatment to improve the symptoms of COVID–19 has led to a reduction in stocks of products containing this active substance in the pharmaceutical warehouses and pharmacies. Novocalmin can also be recommended by prescription both in pain and and fever when these symptoms are refractory to another treatment.

Our company won two more tenders, which give it the opportunity to deliver certain products in the United States and Great Britain.

Antibiotice for Europe – În 2020, our company won a tender organized by the European Commission to secure the stocks needed for the second wave of the pandemic, assuming it will deliver within 12 months, 2.7 milllion vials of Amoxiplus®, one of the most widely used antibiotics in the treatment of COVID–19-associated infections.

All these things can only make us proud, because they once again demonstrate the seriousness and professionalism that characterizes us, but also the trust that international partners have in us.

Throughout this period, the company came to the aid of the medical system and, implicitly, of the patients, donating sanitary materials and disinfectants to family doctors and specialists, but also to the hospital wards. More information about our contribution to the community during the COVID-19 pandemic can be found in Chapter 5, "Rapid Reactions in Difficult Conditions: Our Pandemic Actions".

2.7. Risk management

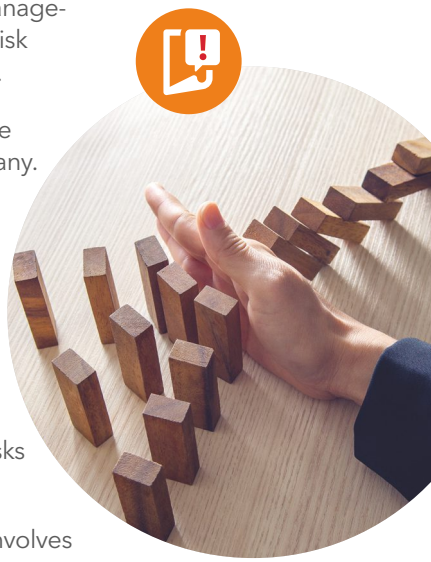
Antibiotice conducts the risk management process in compliance with the legal and regulatory requirements in force. This process involves identifying, assessing, managing and reporting the risks. The main purpose of risk management is to identify the risks to which the company is exposed, so that they can be anticipated and managed without affecting the efficient fulfillment of the company's objectives.

Antibiotice's objectives on risk management:

- understanding the risks to which the company is exposed, the causes, as well as the general and specific objectives
- improving the company's risk profile by managing the process of identifying, assessing and managing risks, and implementing the necessary control measures to maintain the risk exposure in the tolerable area.

Responsibilities related to risk management are performed/fulfilled by the Risk Management Department, together with the risk managers and Antibiotice employees.

Specific risks were identified within the organizational structures of the company. The Risk Management Department annually analyzes and prioritizes the significant risks that may affect the achievement of the general objectives, by setting the risk profile and tolerance, which are approved by the company's management. It also draws up the "Plan for implementing the control measures for significant risks in Antibiotice".



The cyclical review of the main risks involves an assessment of their likelihood of occurrence and their potential consequences in order to confirm the level of exposure and assess their management strategies.

The Internal Audit Office carries out an annual risk management assessment, making recommendations for improvement where necessary, and the findings are presented to the Audit Committee. The Risk Management System and its effectiveness are monitored by the Audit Committee.

The General Risk Register has been prepared and approved in 2020, aiming to minimize the significant risks with an impact on the objectives to which the company is exposed. The relevant risks were synthesized according to their magnitude, using impact and probability.

Financial risks

As regards the financial risk management, the risks to which the company is exposed are:

Commercial (default) risk is generated by the debtor's lack of financial liquidity and by the non-fulfillment of the payment obligation at the fulfillment of its maturity. Circumstances of occuring the default risk: high exposures on the main distributors, long collection terms largely due to delays in settling medical service bills by the National Health Insurance House.

Measures used to control and reduce commercial (non-payment) risk include: monitoring customer creditworthiness, diversifying the portfolio of customers, requesting guarantees.

Liquidity risk refers to the fact that the company may have difficulty in fulfilling short-term payment obligations at any time.

Circumstances of liquidity risk: lack of cash generated by the gap between receipts and payments, determined by the collection of receivables within terms exceeding 300 days, fluctuations of interest rates and foreign exchange rates, volume of investments, fiscal level, price of raw materials.

Our company's policy on the liquidity risk is to maintain, as far as possible, sufficient liquid resources to meet the obligations as they become due, to correlate the payment and collection terms. Financing through credit lines may also be considerd.

Currency risk, a component of the financial risk, frequently occurs in the current conditions of the market economy in which money rates fluctuate according to the law of supply and demand.

Exchange rate fluctuations are reflected both in the costs of imported raw materials and in the selling prices of exported products.

In order to mitigate the exposure to the currency risk, our company took a series of measures such as: synchronizing import and export activities by correlating payment and collection terms, as well as correlating the weight of currencies, so that the time when the payment is to be made is as close as possible or even simultaneously with the of export earnings.

Legislative risks

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

Compliance to these provisions is reflected in additional costs related to updating the documentation, alignment with the latest quality standards.

Our company's strategy for managing these risks involves the constant concern for obtaining international certification of manufacturing flows, updating the authorization documentation for the products in the portfolio, constantly monitoring changes in legislation at international level, continuous adaptation of our policies, rules and procedures to the changes.

Human resources risks

Lack of candidates in the pharmaceutical labour market

For providing the necessary staff, Our Human Resources Unit continued the Perform a+ project, for identifying young talents. Now in its fifth edition, the program aims to provide practical training and selection of employees, through partnerships with the university environment of Iași.

Reputational risk is defined as the current or future risk of adversely affecting profits and capital, caused by the unfavorable perception on the company's image. The Antibiotice strategy is to limit the reputational risks by procedures, rules and flows specially created for this purpose and through sustained, transparent, efficient, proactive communication.

Operational risk is the risk of loss, resulting from the use of inadequate internal processes, persons or systems that have not performed their function properly or from external events. Operational risks may result in equipment malfunctions, human error, malfunction of operational processes, which may ultimately lead to unplanned shutdowns.

Our company constantly monitors the operational risks in order to take measures to maintain them at an acceptable level which does not jeopardize its financial stability, interests of creditors, shareholders, employees and partners.

Environmental risks

Non-compliance with legislation that could have a negative impact on the environment and company's reputation

In order to monitor the environmental risk, a series of measures were taken such as: to maintain and improve the environmental management system according to ISO 14001; to conduct internal audits in order to verify the compliance with the standard's requirements, with the operating procedures; to properly train the staff; to monitor the compliance with the maintenance program; to keep up to date with legislative changes and harmonize with them, to be prepared for responding to emergencies.

Risk of natural disasters (earthquakes, floods, fires)

Antibiotice will apply all the measures at its disposal to reduce these types of risks: Emergency Evacuation Plan, Natural Disaster Response Plan, Fire Response PlanAccident prevention policy involving dangerous substances (acetone, methanol). All these plans aim to protect employees, property and the natural environment.

In addition to the specific risks in the context of the 2020 pandemic of the SARS-CoV-2 virus, there were also identified **risks related to the health and safety of employees.** In order to minimize these risks, organizational and technical measures have been implemented, intended to protect the health of employees, to ensure the continuity of the company's activity.

Difficulties in achieving performance indicators generated by:

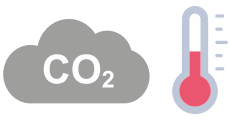
- reduction of productive activities in areas where the distance of employees was not possible
- reducing the number of consumers in open-circuit pharmacies and the number of hospital admissions (only hospital admissions for patients infected with the SARS-CoV-2 virus were recorded)
- limiting the access of our promotion team to doctors and pharmacists.

A number of measures have been taken to minimize the risks, such as:

- orientation towards making sales in the international market
- maintaining a proactive connection with the distributors, extending the online promotion (e-mail marketing campaigns, webinars, videoconferences)
- intensifying the communication with the general public by launching and managing social-media pages for the ranges of food supplements and cosmetics
- careful monitoring of expenditures.

Risks generated by the climate changes

At present, our company has not implemented a formal system for identifying and managing the risks that climate change generates for our activities. However, we are aware that climate change is one of the most important global challenges today. In this regard, in order to anticipate and combat the risks of climate change, the company aims to implement a process to help us identify, analyze and assess these risks and develop plans to mitigate and reduce them, until 2023.



2.8. Procurement practices

By the nature of our business, we seek to develop long-term partnerships with our suppliers, based on transparency, mutual respect and seriousness in business relationships. We are aware of the impact we have on the players in our supply chain, but also of the importance they have for the continuity of our production process.

A fundamental element that underlies the trusting relationships built with suppliers is the timely payment of contractual obligations. Thus, in general, the standard payment term in relation to our suppliers is 60 days from the date of issuing the invoice, except for the utility providers for which the payment term is on average 30 days.

Quality of our products is significantly influenced by the quality of raw materials and equipment used in the manufacturing process. For this reason, the procurement process is heavily regulated in our company. This process is developed with the involvement of three internal departments, as described below:

Technical Department purchases pieces of equipment, laboratory devices, spare parts and services, according to the annual investment and repair programs, approved throughout the company.

In general, there are long-term partnerships with nationally and internationally recognized suppliers of equipment, materials and services. These suppliers comply with the occupational health standards, respect the employees and ensure the environmental protection, all these aspects being ascertained by our specialists during their visits to the suppliers' sites to see and test the quipment and technology provided to Antibiotice.

The COVID-19 pandemic highlighted the seriousness of our partners. Some of the equipment tests were carried out by video conferencing, thus reducing the risks posed by external staff travel.

The relations with our suppliers are defined in the clauses of contracts and procurement orders. Procurement procedure includes all the requirements that our suppliers must meet: occupational health and safety, environment, energy consumption of utilities for the operation of the equipment, compliance with the standards specific to the pharmaceutical industry.

Domestic procurement (Romania)

Pentru desfășurarea în condiții optime a proceselor de producție, cât și a altor activități din organizație, activitatea Achiziții piața internă asigură:

- raw materials: starch, dextrose, sunflower oil, calcium carbonate, etc.
- excipients
- solvents: acetone and methanol
- packaging materials: leaflets, cartons, labels, bands, boxes, polyethylene bags,vials, cans, etc.
- reagents, glassware and laboratory materials
- equipment, spare parts from the domestic market
- DDD services (disinfection, disinsection, deratisation), maintenance, waste collection/disposal, etc.
- car parts and tires
- fuel, lubricants
- construction materials (lime, paint, thinners, etc.)
- general purpose materials (ferrous, non-ferrous and metallurgical materials)
- protective equipment for production and auxiliaries (gowns, overalls, boots, disposable items, etc.)
- IT products, office supplies and consumables
- promotional materials.

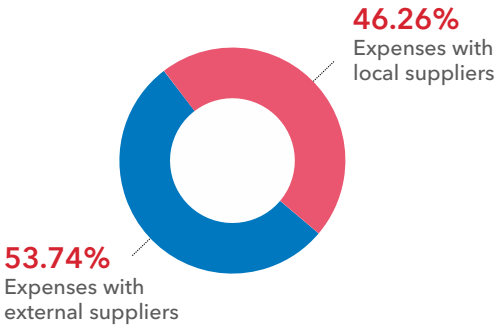
The raw materials, solvents, excipients and packaging materials are purchased only from the qualified suppliers/manufacturers, included in the *List of suppliers accredited in accordance with GMP requirements*. Each supplier/manufacturer is evaluated by the Quality Assurance Departament, based on carefully chosen criteria: audit, evaluation questionnaires, samples, certificates of analysis, quality compliance certification (GMP, ISO standards). In order to ensure continuity in the supply process, the identification and qualification of alternative suppliers/producers is a permanent activity.

Import purchases

The Import Department purchases only from authorized suppliers from the List of authorized suppliers in accordance with the relevant procedures.

The suppliers that meet the criteria required by the company are selected according to the criteria proposed by the following departments: Research-Development, Regulatory Affairs, being subsequently audited and authorized by Quality Assurance, after which they are included in the List of Authorized Suppliers.

Proportion of expenditure with the local and external suppliers



2020 was a tough year, which brought many challenges, from the perspective of the procurement process, generated by the increase in prices, which occurred as a result of the COVID-19 pandemic. Our company did not give up the collaboration with certain suppliers, but there were changes in consumption and orders between authorized suppliers.

Number of suppliers in 2020

Domestic suppliers	External suppliers	Total	New suppliers in 2020
808	219	1,027	10 (Technical Dept.)

Although, at present, the company does not periodically evaluate its suppliers in terms of their social and environmental impact, in the selection process, for specific categories of products/equipment, there are criteria concerning the environmental factors, such as:

- low consumption of utilities required for operation of equipment (electric energy, water, steam, compressed air, cooling agent)
- energy efficiency, according to international standards
- noxious emissions, in accordance with the legal provisions in force.

For instance, in 2020, for the air compressor with the flow rate of 8,649 m³/h, purchased for the Utilities Department, the following aspects were taken into account:

- the compressor must have a variable flow/speed, so that the consumption of electricity during operation varies according to the actual need of compressed air to the consumer (the old, existing compressors had a fixed speed, i.e. they operated at the maximum flow regardless of the consumer's air requirement, which led to high electricity consumption)
- the most efficient type of compressor was selected in terms of electricity consumption required to produce one cubic meter of compressed air
- the equipment with the lowest noise level during operation was selected
- our specialists selected the ompressor in which the cooling of the compression stage and the compressed air is done automatically with water, which ensures a uniform cooling and a longer life of the equipment components.

03

Respecting the natural environment

Preservation of natural resources, consumption efficiency in production processes and reducing our contribution to climate change through the greenhouse gas emissions we generate represent our company' s priorities regarding its impact on the natural environment.

The entire activity in the field of environmental protection is regulated by operating procedures of the environmental management system and by specific work instructions. Starting with 2007, Antibiotice implemented Environmental Management System, in accordance with the ISO 14001:2004 requirements, a component of the Integrated Management System (quality, environment, occupational health and safety). The compliance of the system with the requirements of ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018 standards was recertified by TÜV Rheinland Romania, in January 2020.

We are aware of the responsibility we have for the protection of the natural environment and, as regrds the production processes, we constantly implement measures to reduce our negative contribution. Our policy on quality, environment, occupational health and satefy contains our commitments we are making in this direction.

The activities carried out by the company are regulated by the Integrated Environmental Authorization no. 1/10.01.2011, valid until January 10, 2021. The authorization issued by the Bacău Regional Environmental Protection Agency was revised in March 2018 by the Iași Environmental Protection Agency and has been within the extended period of validity, as a result of the regulations specific to the state of alert established during 2020, during the pandemic.

During 2020 the legal procedural steps regarding the obtaining of the renewed integrated environmental permit were followed, respectively the preparation of the authorization application documentation by an authorized expert and its submission to the Iași Environmental Protection Agency. According to the Law 278/2013 on the industrial emissions (which implementsthe European Directive 2010/75/EU), the main manufacturing activities of basic pharmaceutical products, including intermediate products (industrial biosynthesis of the active substance Nystatin), are subject to authorization, as well as secondary activities technically related to the main activity and carried out on the same site: burning in manufacturing industries, chemical industry, chemicals (storage, handling and transport of chemicals), incineration of hazardous industrial and medical waste resulting from our own activity, treatment of industrial wastewater.

Quality of the environmental factors is monitored according to the requirements of the Integrated Environmental Authorization, both through our own laboratories and through laboratories authorized by the Romanian Accreditation Association (RENAR).

3.1. Energy consumption

All our activities involve energy consumption in various forms (fossil fuels, electricity, heat, etc.). We produce some of the energy we need (steam, thermal energy, energy for cooling), and we buy a part from the external suppliers (natural gases, electricity). Our goal is to reduce consumption by improving the energy efficiency. On the other hand, we aim to increase the proportion of renewable energy used in production processes.
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Energy consumption from fossil fuels

Energy consumption (Tj*)	2020	2019	2018
Diesel**	**18.539**	16.213	18.024
Gasoline**	**0.596**	0.425	0.565
Natural gases***	**170.331**	162.960	187
Total	**189.466**	179.598	205.589

* 1 TJ (terajoule)=10^{12} jouli=1,000 GJ (Gigajoule)

** Heat power of the fuels (PCN) (diesel = 42.63 Gj/ton and gasoline = 43.51 Gj/ton), respectively the emission factors (FE) as per the Annex VI to EC Regulation no. 601/2012 on monitoring and reporting of greenhouse gas emissions in accordance with the Directive 2003/87/CE – http://mmediu.ro/new/wp-content/uploads/2014/04/2014-04-30_Regulament601-2012monitorizare_raportare.pdf)

*** Higher calorific value (PCS) of natural gases = 38.71 Gj/Nmc (according to the information from the supplier)

Electric energy consumption

Total consumption of electrical energy (Tj*)	2020	2019	2018
Total	**55.522**	51.97	53
– from non-renewable sources	**33.339**	25.93	28
– from renewable sources	**22.183**	26.4	25

Energy labels for 2020 were provided by electricity suppliers.

Total consumption of energy

	2020	2019	2018
Total consumption of energy (Tj*)	**244.988**	231.917	258.589

* 1 TJ (terajoule)=10^{12} jouli=1,000 GJ (Gigajoule)

316.76 MWh
electricity savings

Energy consumption from fossil fuels

Fuel consumption occurs in the production processes and in the supply of the company's car fleet:

- diesel is used to power cars and forklifts;
- gasoline is used to power the cars from our fleet;
- natural gas is used in the thermal power plant, in the production of thermal energy, as well as in production, on the purpose of obtaining the active substance Nystatin by the industrial biosynthesis process;
- the steam required for the production process is generated by the combustion of natural gas (methane gas).

Cantitățile de energie au fost calculate pe baza înregistrărilor și informațiilor primite de la furnizorii de utilități și de combustibili, utilizând puterea calorică, dar și factorii agreați de conversie pentru unități de energie, conform literaturii de specialitate.

Energy saved

Fossil fuel consumption increased as a result of the measures taken by our company in order to protect the health of our staff by adapting the transport schedule of the employees (organization of additional car transport trips, with staggered schedules). Another cause of the increase in energy consumption in general is the investment in a new production plant for ointments and suppositories that will become operational in 2021.

So, in 2020, equipment tests were performed, which led to specific utility consumption.

Instead, due to energy efficiency measures, energy savings of 316,76 MWh (1,14 TJ) were achieved. The measures decided upon were the result of a complex energy audit. In addition to the permanent monitoring of the consumption of electricity, natural gas and compressed air, these measures consisted of:

- integration of LED lamps in the indoor/outdoor lighting system and the optimization of outdoor lighting, by including automation systems;
- modernization of the compressed air production system, by purchasing equipment equipped with a variable speed converter;
- installation of frequency converters on certain coolant circulation pumps;
- thermal rehabilitation of some of the buildings;
- control of thermal comfort parameters in ventilation and air conditioning systems (HVAC).

Energy intensity

Energy intensity (GJ*/ 1,000 LEI)	2020	2019	2018
1. Total energy consumption (GJ)	244,988	231,917	258,589
2. Sales revenue (thousand LEI)	340,424 **	390,000	365,000
3. Commodity production (thousand LEI)	360,779	394,418	360,242
Energy intensity at 1,000 LEI sales revenue (1:2)	0.72	0.59	0.70
Energy intensity at 1,000 LEI commodity production (1:3)	0.68	0.59	0.72

* 1 GJ (Gigajoule) =10^9 jouli

** Energy intensity value calculated and reported in the Non-Financial Statement 2020 (June 30, 2021) was derived from the unaudited financial statements

Energy intensity increased during 2020, due to the increased energy consumption (as explained above), respectively the decrease of the production volume, in a year marked by the Covid-19 pandemic.

3.2. Emissions

In the activity of Antibiotice, direct greenhouse gas emissions come from:

- Its own thermal power plant, by burning natural gas;
- Incineration of dangerous, industrial, medical waste, in its own incinerator;
- Our own car hood, almost entirely powered by diesel, but also gasoline;
- industrial wastewater treatment
- intallation for extracting the active substance Nystatin, which emits volatile organic compounds (VOC)
- discharges directed from the manufacturing plants of the finished products and from warehouses

96 tons CO_2 eq
reducing the amount of greenhouse gases

Direct and indirect emissions of greenhouse gases

The calculation of emissions is performed according to the standard methodology set out in Regulation EC 601/2012 on monitoring and reporting greenhouse gas emissions in accordance with the Directive 2003/87/EC (calculation made by multiplying the activity data corresponding to the category of fuel used, based on net heat output, with appropriate emission factors, according to IPPC guidelines, 2006).

GHG emissions (tons CO_2 eq*)	2020	2019	2018
Purpose 1 – direct emissions, of which:	**10,561**	10,033	10,768
– from natural gas combustion**	**9,129**	8,787	9,378
– from the combustion of diesel and gasoline***	**1,432**	1,246	1,390
Purpose 2 – indirect emissions (electricity consumption from suppliers)****	**2,980**	3,604	3,608
Total greenhouse gas emissions Purpose 1 + Purpose 2 (tons CO_2 eq)	**13,541**	13,637	14,376

* CO_2 eq = Equivalent carbon dioxide (or carbon dioxide equivalent) is a unit based on the global warming potential (GWP) of different greenhouse gases. CO_2 eq measures the environmental impact of one tonne of these greenhouse gases compared to the impact of one tonne of carbon dioxide.

** Higher calorific value (HCV) of natural gas = 38,71 Gj/Nmc (according to the information from the supplier).

*** Fuel calorific value (FCV) (diesel fuel = 42.63 Gj/ton and gasoline = 43.51 Gj/ton), respectively the emission factors (FE) (as per the Annex VI to EC Regulation no. 601/2012 on monitoring and reporting of greenhouse gas emissions in accordance with the Directive 2003/87/CE – http://mmediu.ro/new/wp-content/uploads/2014/04/2014-04-30_Regulament601-2012monitorizare_raportare.pdf)

**** Value of emission factors (EF) for electricity is in accordance with the energy labels for 2020, issued by utility providers.

The reduction in the amount of greenhouse gases during 2020 compared to the previous year was 96 tons CO_2 eq representing 0.7%. Although, during 2020, the reduction of greenhouse gases (GHGs) was below expectations for the reasons described in the chapter "Energy consumption", our efforts to minimize GHGs has been continuing in the long term.

Intensity of greenhouse gas emissions (GHG) (tons CO_2 eq/1,000 LEI)	2020	2019	2018
1. Total GHG emissions (tons CO_2 eq)	**13,541**	13,637	14,376
2. Sales revenues (thousand LEI)	**340,424**	390,000	365,000
3. Commodity production (thousand LEI)	**360,779**	394,418	360,242
Intensity of GHG emissions at 1,000 LEI sales revenue (1:2)	**0.040**	0.035	0.039
Intensity of GHG emissions at 1,000 LEI commodity production (1:3)	**0.038**	0.035	0.040

The increase in GHG emissions can be explained by the increase in the amount of fossil fuels used and the decrease in production volume in the context of the pandemic.

Other emissions

The industrial biosynthesis installation uses in the process of obtaining the active substance Nystatin organic solvents: acetone (C_3H_6O) and methanol (CH_3OH), belonging to the group of volatile organic compounds (VOCs).

This installation it is monitored according to the best available techniques (BAT), which set emission limit values for the environment so that, under normal operating conditions, they do not exceed the emission levels associated with the best available techniques (according to IPPC Directive 96/61/EC on integrated pollution prevention and control and VOC Directive 1999/13/EC on the reduction of emissions of volatile organic compounds, both of which are also implemented in national legislation).

In 2020, the amount of total emissions of non-methane volatile compounds (VOCs) increased by 11% compared to 2019, due to the 23% increase in the productio of the active substance Nystatin.

Quality of the air in the Antibiotic's perimeter is monitored by determinations made in its own laboratory and in a third-party laboratory. The certificates of analysis shows that the concentrations of gaseous pollutants emitted into the air are within the maximum permissible limits for protecting the human health: nitric oxide (NOx), sulfur oxide (SOx), carbon monoxide (CO), ammonia (NH_3), non-methane volatile organic compounds (NMVOCs), suspended powders (PM) etc., in compliance with the conditions established by the regulatory acts held and the legal requirements in force, applicable to the activities carried out at Antibiotice. No exceedances of the maximum permitted concentrations provided for in the integrated environmental permit were recorded.

Other significant emissions in the air (tons COV nm*/year)	2020	2019	2018
Volatile organic compounds (VOC) non-methane (t COV nm/year)**	382,977	310,583	unreported

* COV nm = non-methane volatile organic compounds
** According to the balance of solvents drawn up taking into account the values measured by a third-party laboratory, accredited by RENAR.

Our company fleet in 2020

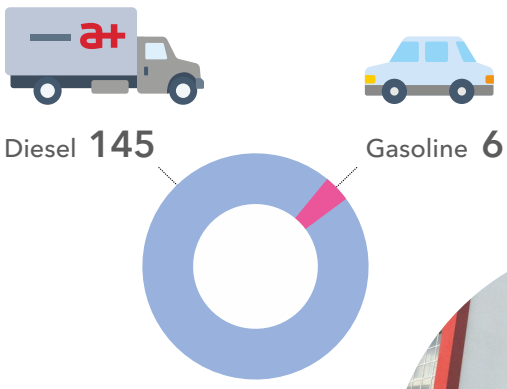
The fleet, which transports people and goods outside the company, is composed of means of transport such as service cars, buses for employee transport, minibuses, vans, tractors. Inside the factory, the goods are transported by forklifts and electric trucks.

The fleet also includes a special vehicle that participates in extinguishing fires inside and outside the company (Fire Department) and a car used to transport people to the hospital and tests to various laboratories (Medical Office).

Antibiotice car fleet (motor vehicles in circulation)

Number of vehicles	151
Mileage (km)	2,683,276

Types of vehicles in our fleet



3.3. Water consumption management

Management of water supply and drainage, as well as the monitoring of water quality, is done in accordance with the requirements of the Water Management Authorization no.303/20.12.2010, issued by the National Administration of Romanian Waters, Prut Bârlad Water Basin Administration, which was valid until December 31, 2020, being subsequently extended during the alert state.

In 2020, our company went through all the legal stages regarding the obtaining of the new water management authorization, finalized with the obtaining of the Water Management Authorization no.20/31.03.2021, with a validity period of up to 01.04.2026.

Water captured and consumed

Our production processes require a large amount of water. The largest amount of water is used as raw material in the technological process of obtaining the active substance Nystatin through industrial biosynthesis, water is the major component of the biosinthesis broth (in the stage of obtaining the industrial vegetative, in the intermediate bio-reactors with volumes of 3300 l and 2500 l, then in the stage of cultivation of the industrial vegetative on nutritious medium, in the bioreactors with volumes of 70,000 liters).

	2020	2019	2018
Total volume of captured water, by source (Ml*):	**159,6**	146,7	141,9
– from surface waters (rivers, lakes, etc.)	0	0	0
– from groundwater	0	0	0
– from the direct collection of rainwater and its storage	0	0	0
– from the wastewater of another organization	0	0	0
– from public water supply systems	**159,6**	146,7	141,9

* 1 Ml (megalitre) = 1,000,000 liters = 1,000 m³ (cubic meters)

The water entering production is demineralized and stored in a tank, before distributed. Part of the water supply is intended for domestic water consumption and for the maintenance of green spaces being.

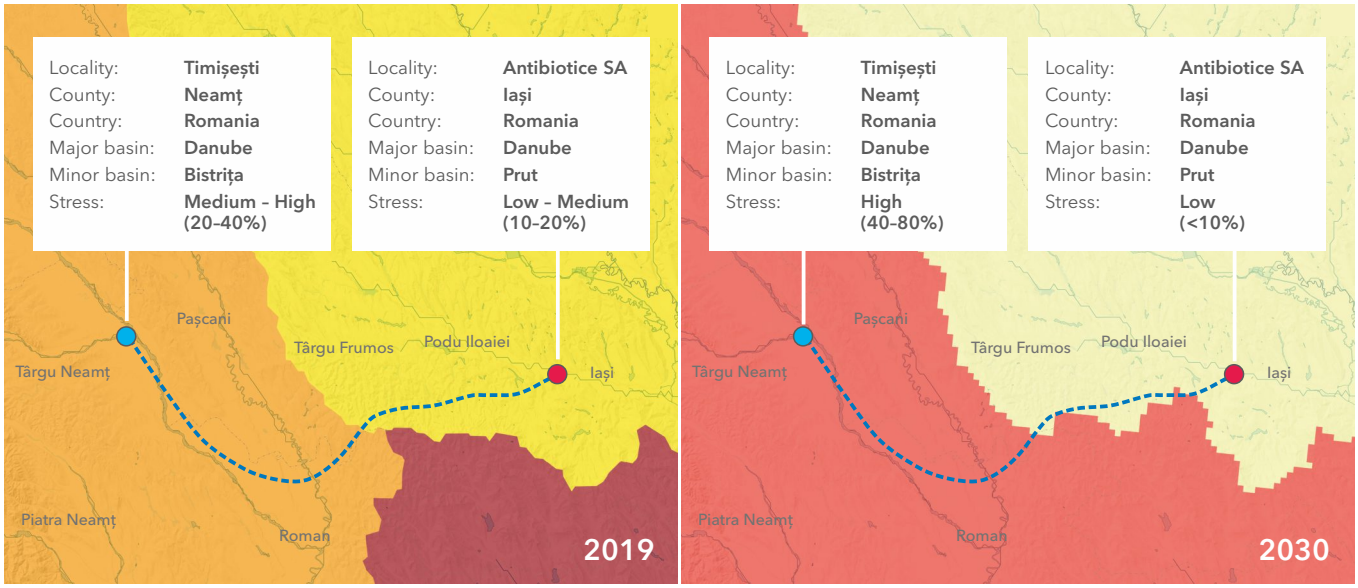
The increase in water consumption by about 8.8% recorded in 2020 is mainly due to the additional use of water for personal hygiene and additional cleaning and disinfection of contact surfaces in the context of the pandemic, as well as due to the extended irrigation of green spaces compared to 2019, amid weather conditions (drought).

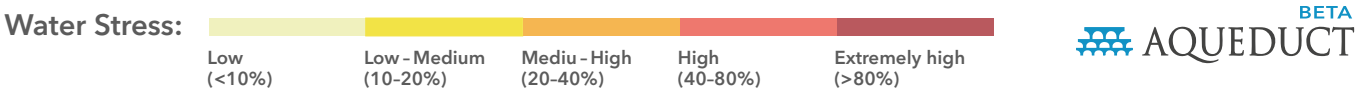
We constantly monitor water consumption in our company. Because our main operations, i.e. production (factory of medicinal products), clinical services (Center for Clinical Studies) and the administrative area (the head office) are located in the City of Iași, Iași County, the entire volume of water is provided by ApaVital (the regional public operator of water and sewerage services in the Iași County). The operator supplies the city of Iași with drinking water from two sources: Timișești (since 1911) and the Prut River (since 1957).

The water used in the production processes comes from the Iasi municipal network, being drinking water, which has as its source the underground springs of Ozana (Neamț River). In the spring water extracted by the operator ApaVital at the foot of the mountains, near the commune of Timișești, Neamț county, additional surface water is injected from the river Moldova, to compensate the water deficit during droughts.

We say that an area is under water stress if it does not have the capacity to meet the demand for ecological and human water (availability, quality or access to water). In order to evaluate if the Timișești area, Neamț, where our water source comes from, is or is not an area with water stress, we used the tools provided, free of charge by the Global Resources Institute (GRI), namely Aqueduct Water Risk Atlas. Aqueduct 3.0 use the terminology of risk elements used by the United Nations Office for Disaster Risk Reduction (danger, exposure and vulnerability) and each indicator is assigned a risk element.

Evaluation of water stress in the Timișești area, Neamț County, in the present (2019) and in the future (2030)





From the category of physical risks, we used basic water stress**, an indicator required by the GRI 303 standard. Basic water stress is calculated as the ratio of the total water captured (extracted) in one year to the total available renewable water resources.

Water is collected for domestic, industrial, irrigation and animal use (drinking water and non-drinking water), and available renewable water reserves include surface and groundwater reserves and take into account the impact on which consumers of water and large dams located upstream, have on the availability of water downstream.

Higher indicator values show more competition between users for the same water sources. If the indicator values are high (40–80%) or extremely high (>80%), the area is under water stress.

Thus, the map of the Timișești area, Neamț (left of the diagram) shows that the indicator has a medium to high value in 2019 (20–40%), so the area was not yet under water stress. Aqueduct 3.0 also allowed us a projection in the future, so we made an estimate of the water stress of the Timișești area, until the 2030.

Unfortunately, in all three allowed simulation scenarios (pessimistic, business as usual or optimistic), the indicator values are high (40–80%), so the area will probably be under water stress (the right of the diagram, the year of 2030, the optimistic scenario).

It should be noted that 2020 was a dry year in Eastern Europe, with little rainfall, drought affecting also the County of Iași.

Although the Timișești area, where the water we use in our company comes from, is not under water stress, we are aware that, in the future, water resources will be diminished.

** Indicator used in the Aqueduct Water Risk Atlas, accessed on October 1, 2021.

Recovered/recycled water

Water recovery/recycling takes place within the steam production and distribution system. The resulted condensate is recovered and reintroduced into the water supply circuit of the steam boilers. In 2020, 8,507 m³ de of water from the steam condensate were reused for heating and preheating.

Intensity of water consumption

Intensity of water consumption (specific water consumption)	2020	2019	2018
1. Total water consumption (m³)	**159,600**	146,700	141,900
2. Sales revenue (thousand LEI)	**340,424**	390,000	365,000
3. Commodity production (thous. LEI)	**360,779**	394,418	360,242
Intensity of water consumption at 1,000 LEI sales revenue (1:2)	**0.47**	0.38	0.39
Intensity of water consumption at 1,000 Lei commodity production (1:3)	**0.44**	0.38	0.39

Discharged water

The following categories of water are discharged from the company's site:

- technological wastewater
- wastewater
- rainwater.

Technological (industrial) wastewater is treated locally in existing pre-treatment plants. Technological wastewater, partially pre-treated, as well as domestic and rainwater from the Biosynthesis Plant area are routed through the internal sewer to the factory's pre-treatment plant.

Discharged water	2020	2019	2018
Total volume of water discharged by destination (Ml*)	**257.4**	249.2	208.4
– in surface water (brook)	**134**	134	85.4
– in groundwater	**0**	0	0
– to suppliers or other organizations	**123.4**	115.2	123

* 1 Ml (megalitre) = 1,000,000 litres = 1,000 m³ (cubic meters)

Antibiotice receives also in its sewerage network wastewater from economic and administrative units in the area, for which it provides pre-treatment and evacuation services in the sewerage ApaVital, on a contract basis (these quantities have been included in the declared volumes of e fl uents). The pre-treatment plant works in two treatment stages: a mechanical one, with the role of retaining floating coarse matter, sand, grease, and a biological one with activated sludge, which reduces the organic load and other pollutants such as ammonia nitrogen (NH_4-N), sulphides etc.

Conventional clean meteoric or rainwater, which comes from atmospheric precipitation, is discharged into the natural emissary (Cantacuzoaia brook, a tributary of the Bahlui river). Domestic wastewater is routed through the sewer system to its own pre-treatment plant.

The volumes of effluents were measured with the help of measuring equipment and the records are based on the minutes concluded with the authorized operator.

At Antibiotice, water quality monitoring was done according to the requirements of the Water Management Authorization. Quality of the pre-treated wastewater in its own treatment plant and of the rainwater discharged into the emissary falls within the parameters established by the environmental legislation. Antibiotice performs determinations of quality indicators for discharged water by the mass flow method, in its own laboratory, as well as in third-party, RENAR accredited laboratories. In 2020 there were no exceedances of the maximum permitted concentrations established by the Integrated Environmental Authorization and Government Decision no.352/2005 (NTPA 001 and NTPA 002).

3.4. Materials, packaging and waste

For manufacturing and packaging the active substance Nystatin in the form of bulk powder, the biocides for disinfecting the surfaces and the finished products from our portfolio (generic medicines for human and veterinary use, medical devices, food supplements, cosmetic products), we use non-renewable materials (minerals, oil, gas, etc.) and renewable materials (wood, water, etc.). Both renewable and non-renewable materials used by Antibiotice are almost all virgin materials. Most raw materials and packaging are used for producing mediicnes in the factory from Iași, where most of the waste is generated.

The two major activities carried out in the pharmaceutical factory from Iași are the manufacture of active substances, on the technological flow of industrial biosynthesis which produces the active substance Nystatin in bulk (a powdered antifungal) and manufacture of finished products in pharmaceutical dosage forms (parenterals, capsules, tablets, ointments, creams, gels, suppositories and pessaries), on seven manufacturing flows.

The drug is a substance with certain properties, used in the treatment or prevention of diseases. A drug consists of the active substance and excipients. The active substance or active pharmaceutical ingredient (API) is the most important part of the medicine, the biologically active principle that determines the therapeutic effect on the body.

The industrial biosynthesis process of the active substance Nystatin begins with the seeding of bacterial microorganisms Streptomyces noursey on a nutritious medium. Fermentation follows in industrial bioreactors, where, under certain environmental conditions, microorganisms biosynthesize Nystatin. Then, the active substance is separated from the biosynthetic fluid and purified (extraction phase). A yellowish, loose powder is obtained, which is packed in plastic (polyethylene) bags and then in cardboard boxes. The whole process is in line with good manufacturing practices (GMP) in the pharmaceutical industry.

The industrial technological flow of production through biosynthesis of the active substance Nystatin is, by its nature, the most important consumer of raw materials, respectively, a waste generator. The main raw materials used are the organic and inorganic substances that make up the nutrient medium needed to feed microorganisms, and water, the major component of the biosynthesis broth. In the last phase of the technological process, Nystatin is extracted by using the solvents acetone and methanol. Solvents are 95% recovered from the mother solutions (water mixed with solvents resulting from extraction), and then reintroduced into the technological process.

When a medicine is formulated, in addition to the active substance, excipients are added. Excipients are inert substances that have no biological activity against the body and can have several roles: they ensure the aggregation of the active substance, long-term stability of the medicine, increase the absorption and solubility of the medicine, and so on.

The generic medicine is a drug developed to be similar to the original, innovative medicine. When the patent for the innovative drug expires, usually after 10-15 years, its manufacturers lose their exclusive manufacturing and marketing rights, and generic manufacturers can enter the market with drugs equivalent to the original, but at lower prices. The generic medicine contains the same active substance, is in the same pharmaceutical form and is used in the same doses as the original medicine to treat the same condition.

The Antibiotice finished products are generic medicines in various pharmaceutical dosage forms developed through own research. The Antibiotice finished medicines are manufactured in accordance with good manufacturing practices (GMP) in the pharmaceutical industry. Each manufacturing flow has different operations specific for each pharmaceutical form obtained, but, as a general description, the main operations are: weighing of active substances and excipients, mixing until homogenization, filling in finished forms, then the primary, secondary and tertiary packaging.

Primary packaging of the finished products obtained by Antibiotice is made as follows:

- sterile powders for injection (parenteral products) are introduced in labeled vials and sealed with stoppers and caps.
- capsules, tablets and medical devices in the form of suppositories (including the pessaries) are packaged in printed blister strips made of aluminium foil, plastic (polyethylene, PVC) foil, composite materials (aluminium and plastic).
- ointments, creams and gels are inserted in printed aluminum or plastic tubes, sealed with plastic (polyethylene) lids.

In the secondary packaging, each individually packaged pharmaceutical form is inserted in its own box, together with the leaflet, and then sealed (usually, the vials with sterile powder are not individually packaged, but in boxes of 10, 12 or more pieces).

The tertiary packaging process involves grouping several units of medicines into cardboard boxes, which are then sealed and labeled. They are transported on wooden pallets (tertiary packaging for transport), depending on the quantity ordered. For the integrity of the transport, the pallet loaded with medicines is sealed with stretch film.

Some of the primary packages are produced in our company, by the Microproduction Plant. Aluminium tubes for ointments, aluminium caps for sealing the vials with sterile powders for injectable solutions, plastic caps for sealing the aluminium tubes for ointments and plastic extensions (elongated tips used to apply certain ointments) uses aluminium as a raw material (strips și round disks), respectively polyethylene (plastic granules). Aluminium tubes are inscribed with typography paints.

Biocidal products are clear liquid solutions, packed in 1 liter plastic containers, labeled with spray head or in 5 litre labeled cans.

Type and amount of materials used by our company in the production process in 2020

In 2020 only the inputs of raw materials, materials, packaging, intended for the medicine production operations were estimated quantitatively. Starting with the next year we will monitor also the inputs of materials used in the activities carried out by the Center for Clinical Studies, by the head office (from Iași), as well as by our commercial representative office in Bucharest.

In general, the quantities of raw materials, materials, packaging consumed in 2020 were measured directly. However, in some cases, only estimates were made, due to the very large number of products purchased, their varied nature and characteristics, the different units of measurement used, etc. For example, for a number of products, we considered paper and cardboard packaging to be identical, although in reality they differ in size and weight in each product. In the next reporting cycles, we will implement data collection systems to obtain the most accurate information possible.

We estimated that, in 2020, the total weight of raw materials and auxiliary materials used in the production and packaging of the active substance Nystatin and finished products (generic medicines for human and veterinary use, medical devices, food supplements, cosmetic products and biocides) was 5,970.543 tons, of which 3,857.216 tons were non-renewable materials and 2,113.327 tons were renewable materials.

Of the total raw materials and materials purchased, 64.6% were purchased from the domestic suppliers (from Romania) and 35.4% from external (international) suppliers.

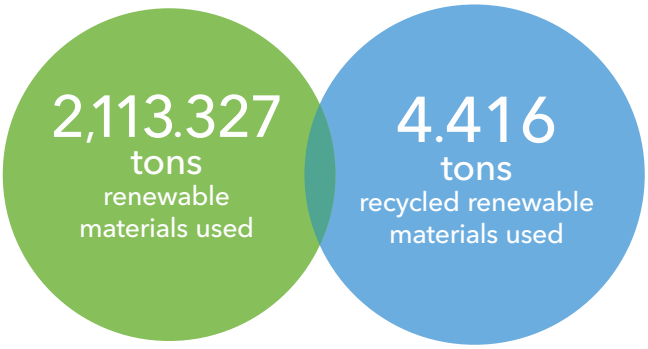
The data was provided by the following departments: Domestic Procurement Department for the suppliers from Romania and Import Department for the international suppliers. Some contextual data were taken from the 2011-2020 Antibiotice Integrated Environmental Authorization (updated in 2018), from the website of the Iași Environmental Protection Agency, section Regulations, Integrated Environmental Permits, respectively from the 2020 Antibiotice Annual Environmental Report, section Regulations, 2020 Annual Environmental Report.

The amount of materials used in 2020

i) Non-renewable materials	tons
i.1) Virgin non-renewable materials	
Raw materials (active substances in bulk, excipients, organic and inorganic chemical substances etc.)	2,253.084
Materials used in the manufacturing process, but which are not part of the final product or packaging of the product (diesel and gasoline*, industrial lubricants, solvents, gas, aluminium, polyethylene, etc.)	682.273
Products or semi-finished parts, including all the types of materials and components, other than the raw materials entering the final product (typewriter ink, paint, electrodes, parts of various metals, glass and plastic, other than packaging, etc.)	332.764
Materials used as packaging (glass, plastic of different types, rubbers, aluminium/plastic caps, blisters of aluminum foil, plastic or composite materials)	589.095
Total non-renewable virgin material	**3,857.216**
i.2) Recycled non-renewable materials	
Total recycled non-renewable materials	**0**
Total non-renewable materials used in 2020	**3,857.216**
ii. Renewable materials	**tons**
ii.1) Virgin renewable materials	
Raw materials (natural resources transformed into products and services)	0
Materials used in the manufacturing process, but which are not part of the final product or packaging of the product (paper and paperboard, other than packaging, natural rubber)	2.495
Materials used as packaging (paper and cardboard, wood)	2,106.416
Total virgin renewable materials	**2,108.911**
ii.2) Recycled renewable materials (recycled cardboard)	
Total recycled renewable materials	**4.416**
Total renewable materials used in 2020	**2,113.327**
Total non-renewable and renewable materials used in 2020	**5,970.543**

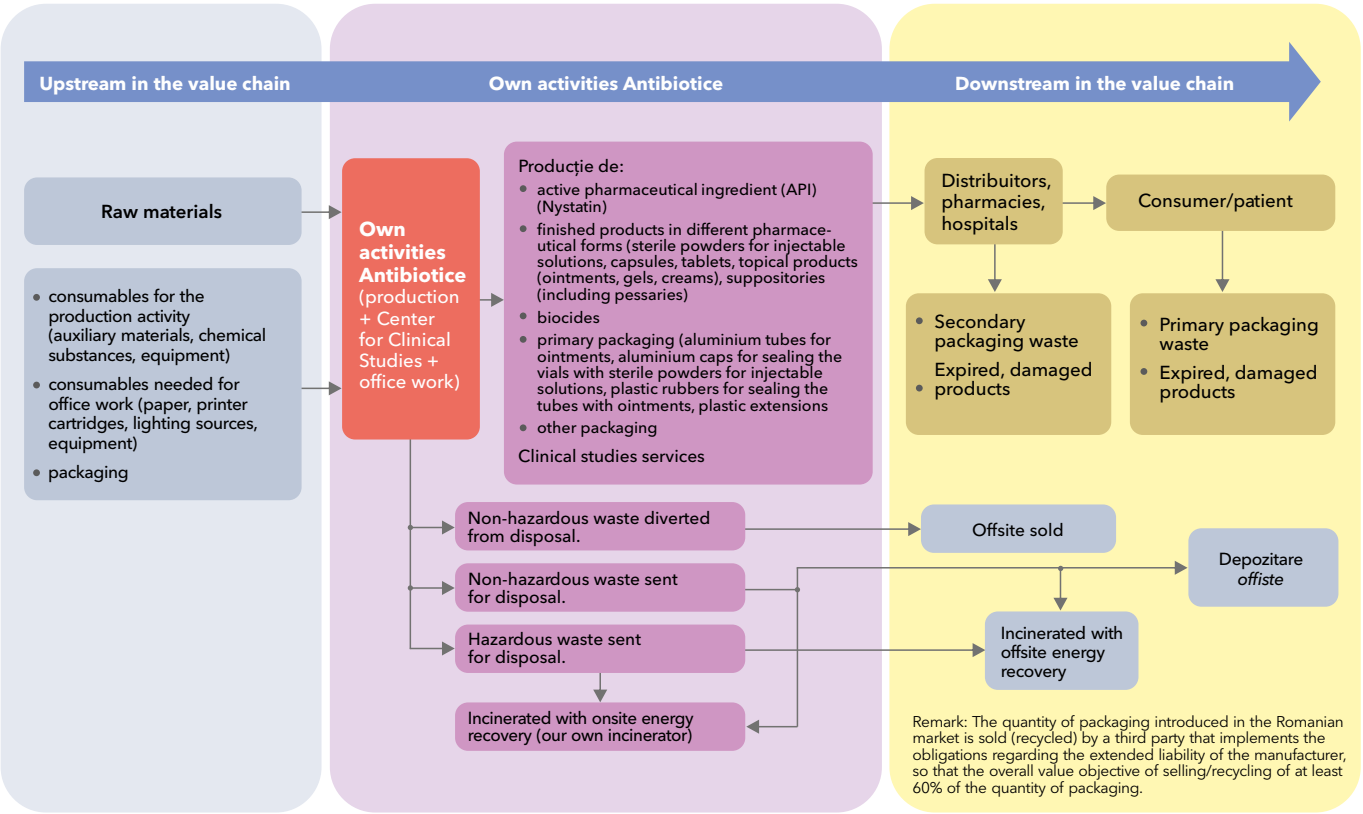
Recycled input materials

Due to the specifics of the pharmaceutical and medicine industry, there is a limit to recycled materials that can be used in production. Therefore, the percentage of recycled materials used in the manufacture of the main Antibiotice products is very small, only 0.074% (the cardboard used to separate the products in their shelf on the pallet, in the tertiary packaging). The ratio of the amount of materials used to make the Antibiotice products in 2020 and the waste generated in the same period was 4.26.



Packaging and waste

Materials and waste flow



Cur company constantly improves the waste management by reducing the total amount of waste and collecting it separately. Each manufacturing plant and producție și auxiliary structure is equipped with containers for separate collection. According to the plan, all employees are regularly trained on specific topics, including waste management.

Recyclable waste was sold to the authorized economic operators based on contracts and the non-valuable waste was incinerated in our own incineration plant (with energy recovery) or sent for storage to the municipal landfill or disposed by authorized economic operators on a contract basis.

We present below the quantities of waste generated by Antibiotice from the manufacturing operations in 2020, and how they were removed or diverted from disposal.

The data were extracted from the records of the Environmental Department and from the environmental audit carried out in 2020. In 2020, the amount of waste decreased compared to the previous year, due to the decrease in production volume (in the context of the pandemic) but also to their more efficient management.

Waste (tons)	2020	2019	2018
The total amount of waste generated, of which:	1,400.910	1,760	738
- hazardous waste	21.714	17	17
- non-hazardous waste	1,379.196	1,743	722

Types of waste and method of disposal

Waste management by category and methods of disposal/recovery (tons)	2020	2019	2018
Total waste generated in 2020	**1.400,910**	1.760	738,46
Total amount of hazardous waste, according to the method of recovery/disposal (where applicable)	**21,714**	17	16,86
Hazardous waste for reuse	0	0	0
Hazardous waste for recycling	0	0	0
Hazardous waste for compost	0	0	0
Hazardous waste for recovery, including energy recovery	0	0	0
Hazardous waste for incineration	21,714	17	16,86
Municipal landfill	0	0	0
Storage on the company's site	0	0	0
Total amount of non-hazardous waste, according to the method of recovery/disposal (where applicable)	**1.000,628**	1.743	721,6
Non-hazardous waste for reuse	0	0	0
Non-hazardous waste for compost	0	0	0
Non-hazardous waste for recycling	0	0	0
Non-hazardous waste for recovery, including energy recovery	710.918	1112	96
Non-hazardous waste for incineration	54,209	36	26,2
Municipal landfill	213,500	215	221
Storage on the company's site*	400,282	407	499

* This non-hazardous waste is temporarily stored on site before their selling or disposal by authorized economic operators.

Types of waste generated in 2020 (tons)

No.	Types of waste generated	Waste code	Amount of waste generated in the factory	Waste diverted from disposal (recovered)	Disposed waste (incineration, storage)
1	Iron and steel	*17 04 05*	593.769	593.759	0.000
2	Aluminium cables	*17 04 11*	6.600	6.600	0.000
3	Scrapped equipment	*16 02 14*	2.267	2.025	0.000
4	End-of-life tires	*16 01 03*	0.805	0.805	0.000
5	Expired chemical substaces	*16 05 09*	5.800	0.000	5.800
6	Expired medicines, non-compliant products	*20 01 32*	35.250	0.000	35.250
7	Fire ash and slag from incineration in the factory incinerator	*19 01 12*	1.595	1.595	0.000
8	Sludge from pre-treatment plant (sludge from biological treatment of industrial wastewater)	*19 08 12*	13.282	0.000	0.000

No.	Types of waste generated	Waste code	Amount of waste generated in the factory	Waste diverted from disposal (recovered)	Disposed waste (incineration, storage)
9	Exhausted mycelium cakes after depletion/ composting (sludges from wastewater treatment in the pre-treatment plant)	*07 05 12*	387.000	0.000	0.000
10	Residues from solvent distillation and recovery (other residues from the reaction column blaze)	*07 05 08**	14.800	0.000	14.800
11	Exhausted absorbents, filter materials, polishing materials, protective clothing contaminated with dangerous substances	15 02 02*	3.036	0.000	3.036
12	Used oil (other engine, transmission and lubricating oils)	*13 02 08**	0.750	0.000	0.750
13	Solid wastes containing hazardous substances	*07 05 13**	2.950	0.000	2.950
14	Mixture of acetone, varnish, inks from the printing of ointment tubes (waste from the removal of paints and varnishes containing organic solvents or other dangerous substances)	*08 01 17**	0.107	0.000	0.107
15	Medical waste subject to special measures	*18 01 03**	0.07145	0.000	0.07145
16	Sharp objects (medical waste)	*18 01 01*	0.00862	0.000	0.00862
17	Rubber waste (plastics)	*20 01 39*	0.464	0.000	0.464
18	Mixed municipal waste	*20 03 01*	213.500	0.000	213.500
19	Paper and cardboard packaging	*15 01 01*	67.735	65.450	2.285
20	Wood packaging	*15 01 03*	11.195	11.160	0.000
21	Plastic packaging (PVC foils, polyethylene and aluminium)	*15 01 02*	17.759	7.358	10.401
22	Glass packaging	*15 01 07*	14.770	14.770	0.000
23	Aluminium (metal) packaging	*15 01 04*	7.396	7.396	0.000
Total			**1.400.910**	**710.918**	**289.423**

* hazardous waste (the others ones are non-hazardous)

In 2020, out of the total of 1,400.910 tons of waste generated by Antibiotice, 28.57% (400.282 tons) were stored in composting basins arranged at the factory's pre-treatment plant (filter cakes of depleted mycelium and sludge from the pre-treatment plant). Of the remaining amount, of 1,000.628 tons, 1,000.341 tons were removed and diverted from disposal, representing 71.40% of the total waste generated in 2020. Of the 1,000.341 tons, 29% (289.423 tons) were disposed, and the rest of 71% were diverted from elimination (710.918 tons).

Of the total waste generated in 2020, iron and steel accounted for 43%. A small part was generated in production, the rest resulting from decommissioning work on our industrial site in 2020. All the decommissioning and demolition works of physically and morally worn-out buildings were carried out after obtaining the necessary authorizations from the competent institutions. The released land surfaces were returned to the natural circuit, to be arranged as green spaces or used as locations for future industrial purposes.

Of the total hazardous waste,68% represented the waste resulting from the production of the active substance Nystatin (14.8 tons of residues resulting from the distillation and recovery of solvents, disposed by incineration). The same production flow generated 28% of the total non-hazardous waste (387 tons of depleted mycelium cakes). Also, mixed municipal waste accounted for 15% of the total non-hazardous (213,500 tons).

Waste diverted from disposal in 2020 (tons)

Types of diversion	Waste code	Onsite	Offsite	Total
Hazardous waste				
Preparing for reuse		**0**	**0**	**0**
Recycling (downcycling, upcycling, composting, anaerobic digestion)		**0**	**0**	**0**
Another method of recovery (repurposing, refurbishment)		**0**	**0**	**0**
Total hazardous waste diverted from disposal		**0**	**0**	**0**
Non-hazardous waste				
Preparing for reuse		**0**	**710.918**	**710.918**
Iron and steel	*17 04 05*	0	593.759	593.759
Scrapped equipment	*16 02 14*	0	2.025	2.025
End-of-life tires	*16 01 03*	0	0.805	0.805
Paper and cardboard packaging	*15 01 01*	0	65.450	65.450
Plastic packaging (PVC, polyethylene and aluminum foil)	*15 01 02*	0	7.358	7.358
Glass packaging	*15 01 07*	0	14.770	14.770
Aluminium cables	*17 04 11*	0	6.600	6.600
Fire ash and slag from incineration in the factory incinerator	*19 01 12*	0	1.595	1.595
Wood packaging	*15 01 03*	0	11.160	11.160
Aluminium(metal) packaging	*15 01 04*	0	7.396	7.396
Recycling (downcycling, upcycling, composting, anaerobic digestion)		**0**	**0**	**0**
Another method of recovery (repurposing, refurbishment)		**0**	**0**	**0**
Total non-hazardous waste diverted from disposal		**0**	**710.918**	**710.918**

Due to the specific quality requirements of the production process and the regulations specific to the pharmaceutical industry, packaged products in various pharmaceutical forms, obtained on the seven manufacturing flows, are also the main sources of waste in the form of packaging (especially paper, cardboard, plastic and wood).

The total amount of paper, cardboard, plastic and wood packaging waste was 111.459 tons, representing 7.24% of the total waste generated in 2020, of which 111.424 tons were recovered.

Waste removed in 2020 (tons)

Location	Waste code	Onsite	Offsite	Total
Dangerous waste				
Incineration (with energy recovery)		**18.693**	**3.02145**	**21.71445**
Residues from solvent distillation and recovery (other residues from the container of the reaction columns)	*07 05 08**	14.800	0	14.800
Solid wastes containing hazardous substances	*07 05 13**	0	2.950	2.950
Exhausted absorbents, filter materials, polishing materials, protective clothing contaminated with hazardous substances	*15 02 02**	3.036	0	3.036
Used oil (other engine, transmission and lubricating oils)	*13 02 08**	0.750	0	0.750
A mixture of acetone, varnish, inks for printing tubes for ointments (wastes from the removal of paints and varnishes containing organic solvents or other dangerous substances)	*08 01 17**	0.107	0	0.107
Medical waste subject to special measures	*18 01 03**	0	0.07145	0.07145
Incineration (no energy recovery)		**0**	**0**	**0**
Storage		**0**	**0**	**0**
Total dangerous waste disposed		**18.693**	**3.02145**	**21.71445**
Non-hazardous waste				
Incineration (with energy recovery)		**20,28022**	**33,92862**	**54.20884**
Paper and cardboard packaging	*15 01 01*	2.285	0	2.285
Expired drugs, non-compliant products	*20 01 32*	7.13022	28,120	35.250
Plastic packaging (PVC, polyethylene and aluminum foils)	*15 01 02*	10.401	0	10.401
Expired chemical substances	*16 05 09*	0	5.800	5.800
Rubber waste (plastic material)	*20 01 39*	0.464	0	0.464
Medical waste, sharp objects	*18 01 01*	0	0.00862	0.00862
Incineration (no energy recovery)		**0**	**0**	**0**
Storage		**0**	**213.500**	**213.500**
Mixed municipal waste	*20 03 01*	0	213.500	213.500
Total non-dangerous waste disposed		**20.28022**	**247.42862**	**267.70884**

Of the total of 67.735 tons of paper and cardboard packaging generate, 2,285 tons were incinerated as a result of contamination.

In 2020, we recorded an increase in the amount (up to 35.250 tons) of non-dangerous waste (expired medicines and non-compliant products, including Ranitidină Atb® withdrawn from the market). We recorded also an increase in the amount of dangerous waste (2,950 tons) in the form of solid wastes containing dangerous substances (disposal of an amount of Ranitidine, active substance). This increase was due to the decision of the Romanian National Agency for Medicines and Medical Devices to withdraw from sale, starting with January 2020, all ranitidine-based medicines from the Romanian market. The decision followed that of the European Commission, which in September 2019 called on Member States to re-evaluate medicines containing ranitidine as a result of the discovery in some of them of nitrosamine impurities with a potential carcinogenic risk.

Recycling of products and their packaging materials

Packages (tons)	2020	2019	2018
1) Total packaging recycled or diverted from disposal	380	523	597
2) Total packaging placed in the market	623	872	998
Percentage of packaging recycled/ diverted from disposal of those placed on the market (1:2)	60%	60%	60%

The quantity of packaging placed in the Romanian market was diverted from disposal (recycled) through a service contract concluded with an organization that implements the obligations regarding the extended liability of the producer, so that the global value objective of recycling of at least 60% of the amount of packaging placed in the market was achieved, in accordance with the requirements of the (updated) Law 249/2015 on the management of packaging and packaging waste.

Our company verified/controlled if the authorized contractor fullfiled the packaging waste recycling targets by requesting monthly reports and centralized annual reports stating the degree of achievement of these targets.

Antibiotice fulfilled its payment obligations to the Environmental Fund Administration for placing in the marketing the quantity of packaging, according to the legislation in force.

Packaging materials recovered from the Romanian market in 2020	Quantity of packaging of the products placed in the Romanian market (tons)	Percent of packaging recovered from the quantity placed in the market through third parties
Glass packaging	272.111	60.58%
Aluminiun packaging	37.203	21.93%
Plastic packaging	60.150	55.82%
Paper/cardboard packaging	240.024	66.07%

Recovery of organic solvents used for obtaining the active substance

Acetone and methanol are volatile organic solvents (VOCs) used in the final phase of the technological process of industrial biosynthesis, for the isolation and purification of the product: the active substance Nystatin.

Solvent-containing waters resulting from isolation and purification of Nystatin are directed to solvent recovery facilities, where they are heated until the solvents evaporate. Captured, condensed and recovered solvent vapors (in liquid form) are then reintroduced into the technological process. The resulting wastewater reaches a neutralization basin, where it is treated to become neutral (pH=7), and then discharged to the pre-treatment plant. The recovery yield of the organic solvents, acetone and methanol is approximately 95%.

04

Responsibility to our people and the local community

The history and tradition of more than 65 years have made Antibiotice more than just an economic player: we are an important part of the community and one of the largest employers in Iași. Beyond the contribution and positive impact we bring to the health and well-being of patients and consumers through our medicines and products, we want the way we do business to add value to our team and local communities. Our long-term success depends on them and the sustainable growth of the company can only be achieved if those around us grow with us. That's why we're committed to always being more than just a business – we want to be a reliable partner and part of the solution – to work together to overcome the biggest challenges, walking together on the same path, under the umbrella of a common goal.

Guaranteeing respect for fundamental human rights is an essential principle that characterizes the relationship with our employees. Our company ensures, through applicable policies and procedures, a work environment that encourages team spirit, personal and professional development, offering our employees decent working conditions, an adequate remuneration system, based on the principle of meritocracy, operating in conditions of high quality standards, safety and performance. We guarantee free expression, freedom of association and collective bargaining for all employees, combating any form of discrimination as well as balancing personal and professional life.

4.1. Our people

Our organizational culture is geared towards innovation, performance and the satisfaction of all those who are our business partners. We know that our mission to do more and better for people's health is not an easy one, but we are convinced that we can achieve our goals year after year, along with highly motivated and involved employees.

The team of specialists working in the research, development and manufacture of medicines and active substances includes pharmacists, biologists, chemists, chemical engineers, laboratories, chemical operators, as well as high-quality specialists who manage the support activities: quality assurance and control, engineering and service, economic, marketing, sales, procurement and logistics. Out of the 1,415 employees who are part of the Antibiotice team, 46,5% are graduates of higher education (of which 2.5% have a doctoral degree), and 53.5% are high school graduates.

At Antibiotice, all activities are performed by staff employed under a contract of employment. Thus, most of the employees carry out their activity in the significant location of operations in Romania, in the pharmaceutical company located in the City of Iași, Iași County, with the head office in the same location. A small part of the staff works at the zonal representation in Bucharest, the capital of Romania, and the staff with responsibilities in sales and promotion work in different cities from all regions of Romania. Internationally, our company has employees in the commercial representative offices from Chișinău, Republic of Moldova, Kiev, Ukraine and Hanoi, Vietnam, as well as in the sales office in Novisad, Serbia.

The data presented refer only to the employees from Romania.

Number of employees by gender, type of contract and working hours, in 2020

	Men	Women	Total
Permanent employment contract	630	745	1,375
Fixed-term employment contract	25	15	40
Full-time employees (8 hours/day)	654	759	1,413
Angajați cu normă parțială (4 hours/day)	1	1	2

All employees of the company are covered by the provisions of the collective employment agreement.

According to the company's internal regulations, the employer has the obligation to consult with the union regarding the decisions likely to substantially affect the rights and interests of employees, in accordance with the term provided in the Labor Code, section 5. If the company is put in a position to make collective redundancies, it has the obligation to initiate in due time and under the conditions provided by law consultations with the union in order to reach an agreement, at least on the methods and means of avoiding collective redundancies or reducing the number of employees to be dismissed, mitigating the consequences of dismissal through the use of social measures aimed at, inter alia, support for the conversion or retraining of dismissed employees. The notice periods and the provisions for consultation and negotiation are governed by the collective employment agreement.

In Romania, collective bargaining between the union (representing the interests of employees) and the employer (representing the interests of the employer) to establish working and employment conditions, etc. is a legal obligation. At Antibiotice, the results of negotiations between the Free Trade Union and the employers' association are included in the Collective Employment Agreement of the company.

Each employee of our team is entitled to the provisions of the collective agreement, regardless of the type of his employment contract, the norm of work or membership or not in the union. The Collective Employment Contract is valid for two years (with the possibility of extending it only once, for a maximum of 12 months). The Free Union in Antibiotice is the social dialogue partner of the company's management, participating, as a representative of the employees, in the negotiation of the clauses contained in the Collective Employment Agreement. Any employee of the company can become a member of the Union. The Antibiotice Free Union is part of the Federation of Free Trade Unions in Chemistry and Petrochemistry (that is also the member of the National Trade Union Confederation "Cartel ALFA").

Percentage of employees who are union members

	2020	2019	2018
Percentage of union members, out of the total number of employees	**73.52%**	78%	77%

The management of the company has discussions in advance, with the union representatives, about the decisions that may affect the rights of the employees or that create new obligations for them, discussions that end with notifications agreed by both parties (respecting the methodologies imposed by the applicable legislation).

Antibiotice, in Top 100 of most desired employees

Antibiotice ranked 91st in the preferences of respondents to the "Most Desired Employers in 2020" a study conducted by Catalyst Solutions, a company with over 15 years of experience in recruiting, attracting talent and employer branding.

The top 10 most important factors in choosing an employer in 2020, according to this study, were:

1. recognizing employee performance
2. pleasant, friendly working atmosphere
3. managers/leaders who encourage and support employee development
4. ensuring a secure job
5. specialists, experts in the field, from whom you can learn
6. attractive salary package
7. attractive package of benefits
8. performance bonuses
9. a good reference foa future career
10. overtime is paid or compensated with free time.

These factors are among our major concerns, our company has been carrying out several projects in this regard over time. An example is given by the study of culture and organizational climate, through which we constantly assess employees' perception of the work environment, the company's values, as well as satisfaction of our employees with the positions they hold. In 2020, the best results were obtained in the area of impact of managers on team members, in that of interdepartmental collaboration and employee satisfaction.

4.2. Diversity and equal opportunities

Diversity in the workplace means respecting and valuing skills, highlighting the different potential that each team member brings to internal processes. We want all our employees to enjoy a diverse and inclusive work environment that gives them equal rights and opportunities.

According to the Internal Regulations, within the labor relations in our company operates the principle of equal treatment and opportunities for all employees. In order to respect the principle of non-discrimination in Antibiotice the following acts are forbidden:

- to publish a job advertisement that shows a preferences or discourages someone for applying for a job because of his or her race, nationality, ethnicity, religion, social or disadvantaged category, age, sex or sexual orientation, beliefs
- to discriminate against any employee on the grounds of race, nationality, ethnicity, religion, social status, belonging to a disadvantaged category, or due to his or her beliefs, age, gender or sexual orientation
- any conduct aimed at creating an atmosphere of intimidation, hostility, discouragement or negatively affecting the situation of employees in the workplace, in terms of professional promotion, remuneration or income of any kind, or access to training and professional development, in case of their refusal to accept unwanted behavior related to sexual life.

44 years old
The average age of employees

Labour force – age, gender and position in our company

	Men				Women			
	< 30 years	30-50 years	> 50 years	Total men	< 30 years	30-50 years	> 50 years	Total women
Top management (executives)	0	4	1	**5**	0	1	4	**5**
Middle management (managers who report directly to executive management)	4	48	30	**82**	5	72	36	**113**
Specialists	45	322	201	**568**	46	363	233	**642**
Total	49	374	232	**655**	51	436	273	**760**

Number of employees with disabilities

	Men	Women	Total
Specialists	6	3	9
Total employees with disabilities	**6**	**3**	**9**

50% from management positions **are held by women**

In 2020, there were no incidents of discrimination in our company

Remuneration of our employees

Remuneration policy is an extremely important element in our company, as it underpins the way our employees are rewarded for the work they perform. Remuneration policy allows us also to clearly articulate the criteria and the way in which the salaries are established within Antibiotice, taking into account the company's values and fundamental principles, such as fairness and equity.

For work performed under the conditions provided in the Collective Labor Agreement, every employee has the right to a basic salary established at the conclusion of the Individual Employment Contract. The basic salary is established for each employee, in relation to the quality, importance, complexity of the job, with professional training and competence.

Salary income includes basic salary, allowances and bonuses. The salary within the company is made taking into account the fulfillment of the performance indicators, established by reference to the Management Plan of the company and by correlation with the specific attributions of each job.

Any discrimination based on sex on the basis of all elements and conditions of remuneration is prohibited for work of equal value.

Attracting new employees, able to support the company's vision, as well as the low availability of specialists on the labor market, determined the Antibiotice management to create a unitary and modern salary system, with effects in the period 2019–2022.

The new system, structured around predictable pay levels for each position in the organizational hierarchy, aims to align the package of financial and non-financial benefits with the level of performance and individual contribution made by each employee to the company's objectives.

Recruitment policy and employee retention

Recruitment and the measures we take to ensure the retention of employees are essential aspects of our human resources policy, identifying and selecting the most suitable employees for open positions within the company, but also maintaining them in the long term, leading to processes with significant impact on our capacity as an employer and implicitly on the growth and success of the company.

At Antibiotice, recruitment for vacancies is carried out in accordance with the internal procedure for the recruitment and selection process, which sets out the methods and channels for recruitment. The objectives of the recruitment process are set out in the annual staff recruitment plan. Our company provides the necessary labor force through legal methods: competition, (written exam, interview), as the case may be. Recruitment is done in compliance with the legal provisions in the field, through the Human Resources department and/or through specialized recruitment companies.

In 2020, 106 people were hired (57 employees with higher education and 49 with secondary education), while 111 employees ceased their activity. Staff turnover rate was 3.00% (under the planned level of 5% and significantly less than the percentage recorded in 2019, i.e. 4.6%).

Ratio between gross basic salary*/gross remuneration** of women vs men by function and category of staff (%)	Ratio between the basic salary of women and that of men	Ratio of women's pay to men's pay
Top management (executives)	95.42%	116.00%
Middle management (managers who report directly to executive management)	98.28%	95.13%
Specialists	102.64%	95.22%
Total employees	**102.46%**	**95.40%**

Calculation = average gross basic salaries*/gross remuneration** of women in the category divided by average gross basic salaries / gross remuneration of men in the category

* Gross base salary is the amount paid by the company for work performed (does not include payment for additional work or bonuses).

** Gross remuneration is the basic salary, to which the additional amounts paid to the employee are added (seniority, overtime, bonuses, benefits, transportation, allowances, etc..)

The employees who have left the company fall into the following categories:

- retirement (56)
- resignation (34)
- termination – individual fixed-term employment contract (2)
- termination of individual employment contract during the probationary period (5)
- termination of the contract with the agreement of the parties (5)
- death (3)
- medically unfit for fulfilling the job (3)
- annulment of the job (3)

In Antibiotice three generations of people work together harmoniously, the oldest having 40 years of activity. The concern for handing over the torch from seniors to the youngest, as well as attracting new talent, are the basis of recruitment and internal mentoring programs.

We want to give young people the opportunity to choose a career in our company, so we develop partnerships with schools to facilitate their access to the information they need to make the best decisions when it comes to their future.

Perform a+ is a partnership program initiated since 2016, in collaboration with the Grigore T. Popa University of Medicine and Pharmacy Iasi - Faculty of Pharmacy, Alexandru Ioan Cuza University Iasi – Faculty of Chemistry and Gheorghe Asachi Technical University Iasi – Faculty of Chemical Engineering, part of the continuing education and communication platform that Antibiotice develops with educational institutions in the areas of research, pharmaceutical marketing, career guidance and responsibility towards patients, the environment and the community.

Perform a+ aims to instill in the final year students/graduates (residents, PhD students) a passion for the pharmaceutical industry and activities involved in a career in this field. The project offers participants the opportunity to complete the knowledge acquired during the years of university study, with theoretical and practical sessions, supported by mentors appointed from among the company's employees. At the end of the courses, integration and application of the acquired knowledge is materialized in the presentation in front of colleagues and company representatives, of an individual science project that highlights the knowledge, passion and inventiveness of young people aspiring to a career in the pharmaceutical field.

Perform a+ program has been a successful cooperation with academia and a way to attract and develop pharmacists (final year students, residents and PhD students) in the industry of generic medicines. As a result of the development of the five editions of the Perform a+ program, 24 graduates were hired in the following departments: Research-Development, Regulatory Affairs, Portfolio Management, Quality as well as in the manufacturing plants.

Partnersiphs with pre-university education institutions – "Petru Poni" Technological High School Iași and Technological High School of Mechatronics and Automation: since 2020 we have introduced a new form of partnership with pre-university education institutions – the dual education – through which we follow the 3-year training of 15 pupils for the profession of chemical operator – medicines and cosmetics and 10 pupils for the profession of electrician – low voltage networks. Collaboration in this project involves facilitating practical training, but also material support for students through scholarships awarded according to the performance criteria included in the contracts and encouraging them to avoid dropping out of school.

Fluctuația de personal raportată la plecările voluntare

	2020	2019	2018
Fluctuația de personal	3%	4,6%	4,37%

Categorie	Angajați noi		Angajați care au plecat din companie	
Gen	**Nr.**	**Rată (%)**	**Nr.**	**Rată (%)**
Femei	38	2,69%	59	4,17%
Bărbați	68	4,80%	52	3,67%
Total	106	7,49%	111	7,84%
Grupă de vârstă	**Nr.**	**Rată (%)**	**Nr.**	**Rată (%)**
<30	19	1,34%	6	0,42%
30-50	80	5,65%	38	2,68%
>50	7	0,49%	67	4,73%
Total	106	7,49%	111	7,84%

* Fluctuația de personal a fost calculată prin raportarea numărului de angajați care au plecat voluntar din firmă 42 (cu excepția celor ce s-au pensionat la termen), la numărul total mediu de angajați din anul respectiv 1415

4.3. Occupational Safety and Health

All our achievements along the years would not have been possible if it had not been for our team's everyday contribution, involvement and dedication. That is why, the concern for our employees' health and safety is more than a legal obligation for us. It is a firm commitment that we take and for which we implement strict measures each year. We want our employees to work in a safe environment and have the certainty they will return to their homes safe and healthy at the end of each working day.

The occupational health and safety management system (OHSMS) is a fundamental part of the risk management strategy. The implementation of our OHSMS is designed to:

- protect both Antibiotice team and the people engaged in different activities on the site
- ensure strict compliance with the current relevant regulations
- facilitate improvement
- enhance the motivation of the organization and acceptance of occupational health and safety inside the company
- reduce the number of incidents by the systematization of all the activities relevant relating to occupational health and safety
- reduce health risks, and implicitly the associated costs
- reduce material loss as a result of the decrease of the number of incidents and accidental shutdowns
- reduce insurance costs.

Our company pays special attention to the safety and security of both the employees and the visitors. The Internal Prevention and Protection Department that is subordinated to the CEO of the company, ensures that the directives of the Law 319/2006 on safety and health at work.

Maintaining and developing an effective occupational health and safety management system in Antibiotice guarantees the creation of an optimal framework for the management and elimination of occupational risks and hazards as well as for improving the work environment and human relations.

In 2007, the company achieved the official certification in conformity with the international standards 9001/14001/18001 for its integrated management system (quality/environment/occupational health and safety).

In 2019, the occupational health and safety management system of the company was awarded the certification to SR ISO 45001 by the certifying body TÜV Rheinland Romania.

The principles and actions of the occupational safety system are defined in the Prevention and Protection Plan, while their implementation is followed by the company's Occupational Health and Safety Committee (OHSC).

Occupational Health and Safety Committee

In the company, there is an Occupational Health and Safety Committee. The Committee consists of a number of employees with duties related to their fellow workers' health and safety, an equal number of legal representatives of the employer and the occupational health physician.

A designated employee or an employee from the Occupational Health and Safety Office is the secretary of the Committee. The president of the Committee is a legal representative of the employer.

The members of the Committee are nominated by written decision by the president of the Committee, and their

names are communicated to the employees. The Committee convenes on a quarterly basis or any time it is necessary.

According to the Government Resolution no. 1425/2006 and subsequent amendments, the Committee has the following responsibilities:

- analyzes the employees' health status, the record of the days of incapacity for work, and proposes measures for the improvement of the work conditions
- analyzes and makes suggestions in relation to the occupational health and safety policy and the prevention and protection plan, according to the internal regulations
- follows the implementation of the prevention and protection plan, including the allocation of means that are required for its implementation, as well as their effectiveness in terms of working conditions improvement
- analyzes the addition of new technologies, the selection of equipment, taking into consideration the potential consequences on the employees' health and safety, and makes proposals when deficiencies have been identified
- analyzes the selection, acquisition, maintenance and use of the working equipment, the collective and individual protective equipment
- proposes ways of fitting out the workplaces, taking into account the presence of employee groups susceptible to specific risks
- analyzes the requests formulated by the employees related to the working conditions and how the designated persons fulfill their duties
- follows the manner in which the legal requirements concerning occupational health and safety, the labor and health inspectors' directives are applied and respected
- analyzes the employees' proposals for the prevention of work accidents and occupational diseases as well as for the improvement of the working conditions and recommends their incorporation in the prevention and protection plan
- analyzes the cause of work accidents, occupational diseases and incidents, and can propose the adoption of technical measures in addition to the actions to be taken formulated after the investigation
- carries out its own checks on the implementation of both its own and the working instructions and prepares a written report with the findings
- debates upon the written report on the current status of occupational health and safety, taken actions and their effectiveness, that is received from the head of the unit at least once a year, as well as the proposals for the next prevention and protection plan.

Risk Identification

The assessment of the risks of workplace accidents is carried out in conformity with the provisions of the internal procedure and is aimed at identifying the occupational health and safety risks for each workplace and job and establishing actions to control risks, which will result in a continuous improvement of the occupational health and safety management system. The company employees have the obligation to immediately inform the employer and/or designated employees on any work-related situation that they have reasons to believe that may pose a danger to the employees' health and safety, as well as on any deficiency in the production systems.

In 2020, the Committee identified new professional risks and the following measures were taken:

- purchase of additional equipment designed to reduce the employees' physical effort, for the Topical Products Unit and the Logistics Department;
- purchase of a multi-gas detector and a pump for toxic gas measurement/ detection tubes, for the Occupational Health and Safety Office, to prevent and limit risks.

The company has an Occupational Health and Safety Office, which handles prevention and protection operations. The Office is organized by the employer, as follows:

- the employees working for the Office must meet at least the requirements of Art. 49 of the Government Resolution no. 1425/2006 and subsequent amendments
- the Office coordinator must meet the requirements of Art. 50. of the Government Resolution no. 1425/2006 and subsequent amendments
- the Office personnel have individual full-time labor contracts concluded with the employer
- the Office personnel perform only prevention and protection activities
- the Occupational Health and Safety Office has available the necessary material and human resources to carry out prevention and protection operations in the company.
- the employer provides the Office with the appropriate means for performing the specific activities;
- the Occupational Health and Safety Office handles also the monitoring of the employees' health status with the help of the team of healthcare professionals working at the in-house, adequately equipped Occupational Medicine Center.

Occupational Health and Safety Training

In the company, all employees are periodically informed and trained on occupational health and safety, according to the specificity of their jobs, as follows:

- new employee onboarding
- trainings on maintenance and repair works
- trainings on career-specific certification/ certification renewal, according to the legislation in force (abrasive stone mounting, work at height)
- trainings on the authorization issued by the National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment, Rom. ISCIR (for stockers, riggers, forklift drivers, a.s.o).

Moreover, the company carries out periodical occupational health and safety (OHS) training sessions and concludes OHS agreements with all external partners performing different works on Antibiotice's site, according to the relevant internal procedure.

Type of Training	Number of employees	Total number of hours
New employee onboarding	106	848
Maintenance and repair works	140	280
Career-specific certification / certification renewal, according to the legislation in force the (abrasive stone mounting, work at height)	128	256
Authorization by National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (stockers, riggers, forklift drivers)	415	415
OHS trainings and agreements concluded with external partners performing works on the site, according to the internal procedure	663	663

Antibiotice awards benefits to the employees working in extreme temperature conditions, i.e. below –10 °C or exceeding +32 °C (while the legally defined limits are –20 °C and +37 °C).

The company has an in-house Occupational Medicine Center with a team of physicians specialized in occupational health and nurses. The Center is open 24 hours and appropriately equipped for:

- pre-employment medical examinations;
- first aid in case of medical emergencies;
- employees' periodical medical examination, according to the occupational health regulations and the requirements for the quality and safety of medicinal product manufacturing.

In addition, the Center includes a dental clinic, which provides specialized medical assistance in case of emergencies, and a psychology clinic that makes the psychological evaluation of the employees subject to different risks, according to the relevant legislation in force.

Moreover, the psychological clinic offers psychological counselling to the employees free of charge, ensuring the confidentiality and integrity of the personal information.

During the reference year, there were two workplace accidents in the company, which resulted in ten days of absence altogether.

In the company, workplace accidents are recorded and investigated in conformity with the requirements of the Law no. 319/2006 – Chapter VI – Notification, Investigation, Recording and Reporting of Events, Government Resolution no. 1425/2006 – Methodological Norms for the Implementation of Law no. 319. – Chapter VII – Notification and Investigation of Events, Recording and Evidence of Workplace Accidents and Dangerous Incidents, Notification, Investigation, Declaration and Reporting Occupational Diseases, and the in-house standard procedure for workplace accident investigation.

To eliminate risks and dangers causing the recorded workplace accidents, in conformity with the internal standard procedures, the company decided to reevaluate the occupational health and safety risks and to provide further training sessions to the employees.

	Employees		Workers	
	Men	Women	Men	Women
No of deaths caused by workplace accidents	0	0	0	0
No. of workplace accidents with serious consequences on the employee's life (requiring more than 6 months of recovery)	0	0	0	0
Total no. of workplace accidents	1	1	0	0
Main types of accidents:	Commuting accidents		–	

In 2020, **there were NO:**

- deaths caused by diseases following exposure to dangers at the workplace
- diseases caused by exposure to dangers at the workplace.

4.4. Development and Integration of employees

Employee training and development are essential for the long-term success of the company. In addition to the fact that all such professional training programs are designed to improve employees' knowledge and skills, they help boosting the company's productivity and good performance as well as the employees' motivation and satisfaction. With an impact also on the retention of the employees, the training and development programs we have been implementing come to reaffirm our commitment, i.e. to invest in our employees, to continually give them opportunities that would allow them to grow along with the company.

The company's training programs designed for the employees include both training sessions taught by in-house trainers (specialists in different areas of competence) and professional development programs carried out by external trainers.

In the company, the employees' training and coaching are performed in conformity with the internal standard operating procedure for the training provided by external lecturers (prepared by the Human Resources Unit) and the system operating procedure on employees' training (prepared by the Quality assurance Dept.). The latter focuses on the compliance with the Good Manufacturing Practice regulations and the requirements of the quality, environmental and occupational health and safety management systems (i.e. ISO 9001:2015, ISO 14001:2015, ISO 45001:2018).

The primary targets of the 2020 plan for training with external trainers were continuing professional development, acquisition of further knowledge and specific skills for the field of activity. For instance, the Medical and R&D teams received training runs on the following subjects: "Authorization of Biocidal Products. Updates to the Legal Requirements and Practical Aspects", "Nitrosamine Impurities", "Notification and Advertising of Food Supplements. Legal and Practical Approaches", "Pharmaceutical Sterilization", "Genotoxic Impurities" a.s.o. The Engineering and Quality teams received training covering the following areas: "Computer-assisted Validation", "Qualification of Pharmaceutical Systems and Equipment", "Maintenance Management".

Moreover, job-specific courses and webinars, designed to improve manufacturing processes and focused on the concept of "Lean Leadership & Management" were offered.

Taking into account the specific requirements in this industry, employees responsible for the technical equipment and facilities undergo specific training runs and certification exams (by ISCIR*, ANRE**, INSEMEX***) every month.

In addition, there is a dedicated team of in-house trainers who are qualified persons and offer training in GMP-related matters to each unit or department of the company.

In 2020, as a result of the COVID-19 pandemics, which forced the authorities to declare a state of emergency and then a state of alert, together with the internal measures taken by the company to protect the employees, one of our already recognized programs, i.e. "Summer School a+", could not take place. Furthermore, part of the training sessions that were normally carried out in person, were shifted to on-line. Therefore, the employees were given free personal and professional development webinars provided by different professional training suppliers. The webinars focused on subjects that would aid people adapt to the pandemic conditions: tele-work, change management, situational leadership, emotional intelligence, beliefs and convictions, creativity and problem-solving in change management, a.s.o.

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* ISCIR – National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment

** ANRE – Romanian Energy regulatory Authority

*** INSEMEX – National Institute for Research and Development in Mine Safety and Protection to Explosion

Hours of Training in 2020

Average hours of professional training/coaching per employee	**32**
Hours of professional training/coaching for specialists	**26,5**
Hours of professional training/coaching for middle management	**21**
Hours of professional training/coaching for top management (executives)	**20**

Exemples of training sessions

	Total no. of hours	Number of attendees
Biocidal Products Authorization	119	**9**
Biocidal Products – Updates to Legal Requirements and Practical Aspects (online)	48	**6**
Understanding Pharmaceutical Sterilization (online)	223	**12**
Notification and Advertising of Food Supplements	10	**2**
Genotoxic and elementar impurities (online)	15	**4**
Updated INCOTERMS 2020 (webinar)	24	**6**
Communication and Writing	108	**9**
Clinical Studies	15	**3**
Risk Management and Vulnerable Positions. Corporate Governance.	16	**1**
Employer Branding	9	**1**
Formulation and Manufacturing of Tablets	202	**31**
Computer validation basics	172	**23**
Pharmaceutical Equipment System qualification	210	**30**
General Data Protection Regulation (GDPR)	180	**1**

Percentage of Employees Who Received Performance Assessment and Career Development Plan Revision (by gender and category)

	Men		Women	
	No.	%	No.	%
Top Management (the executives)	5	0.41%	5	0.41%
Middle Management (managers reporting directly to the executives)	68	5.62%	97	8.02%
Specialists	488	40.36%	546	45.16%
Total no. of employees	**561**	**46.40%**	**648**	**53.60%**

During the reporing period, 1,209 employees (85.44% of the total number of employees) received performance assessment. No evaluation was carried out for a number of employees in the following circumstances: termination of the employment contract during the reporting period (111 employees), less than 6 months on the job in 2020 (67 employees) and suspension of the employment contract (22 employees).

71
employees were promoted to higher positions in 2020, of which 36 were women (50%).

Benefits for employees

In Antibiotice, the benefits package we offer to our employees comes to reinforce the belief that people are crucial elements and the most precious resource we have in our way towards a sustainable development. Be it bonuses, additional days to the legal holiday period or financial support on important events, we constantly invest in Antibiotice's people thus proving once again that we do care for their well-being in the present, but also for their future.

Our company grants to all employees, irrespective of the type of employment contract or seniority (of less or more than 1 year), a standard package of fringe benefits, some of which are negotiated and included in the company's Collective Labor Agreement.

The standard package of fringe benefits includes:

- the Easter bonus
- the Christmas bonus
- the 8 March bonus for women employees (on the International Women's Day)
- profit-sharing (share of the net profit of the company), as an annual performance bonus, awarded to the employees according to criteria such as work results, objective achievement, discipline
- meal tickets
- protective foodstuff

Parental Leave	Men	Women
Total no. of calendar days	448	10,704
No. of employees entitled to have a parental leave	3	19
No. of employees who got a parental leave	3	19
No of employees who returned to work at the end of the parental leave	2	6
No of employees who returned to work at the end of the parental leave and were still employed after 12 months	4	31
Rate of return to work* (%)	100%	100%
Retention** (%)	100%	88.57%

* Rate of return to work = (Total no. of employees who returned to work in 2020, after parental leave / Total no. of employees expected to return to work in 2020, after parental leave) x 100

** Retention = (Total no. of employees who had a parental leave in 2017, returned to work in 2019 and were still employed in 2020/ Total no. of employees who returned to work in 2019 at the end of the parental leave) x 100

- free transport by the company buses from/to work within the city limits
- free access to the parking space at the company's headquarters, for the employees using their personal or a company car
- additional days to the annual leave (depending on the seniority, working conditions, staff category)
- paid days off for special private events (marriage, birth, death) or other circumstances
- financial support on personal events (death of a family member, a child's birth – for women employees, and starting October 2020, when the new Collective Labor Agreement for 2020–2022 came into force, for every employee becoming a parent.

Additional benefits

Depending on the performance criteria or the particularities of the performed job, some employees receive additional benefits such as:

- performance bonus for the employees included in the MBO system, according to the level of fulfillment of the assigned indicators
- private health insurance for 252 employees selected based on established criteria (a pilot program initiated in 2018 for 136 employees)
- life and accident insurance
- cell phone
- laptop
- company car
- professional training programs paid by the employer

The standard package is offered to the employees irrespective of their type of employment contract (full time or part time).

Bookster Books on “Biblioteca a+” Shelves

Starting October 2020, Antibiotice has given the opportunity to access the Bookster.ro platform to all the employees who are passionate about knowledge, free of charge.

The project entitled "Bookster Books on the Shelves of Biblioteca a+ Library" aims at encouraging reading and the acquisition of further knowledge by facilitating access of Antibiotice's employees and their family members to books, articles, podcasts (focused on personal and professional development, hobbies, fiction). Bookster is a public library that lends books to corporate employees using its online platform. The borrowed books are then delivered to the employees at their offices, free of charge.

At the end of 2020, a number of 211 employees (15%) had a Bookster.ro account.

Organizational Climate Improvement and Culture Orientation towards Innovation and High Performance

Because we aim at improving the work environment and transforming our organization in a company that most of the current employees and potential employees would consider worth working for, every two years, an extensive organizational climate survey is conducted. The survey focuses on the work environment, managers' concern for creating a climate encouraging cooperation and performance improvement, and desired /actual system of values in the company.

In June 2020, the Human Resources Dept. carried out an organizational climate survey on the managers' role in creating an organizational climate encouraging orientation towards high performance and satisfaction of the human resources. 62 per cent of the employees participated in the survey. The survey was conducted during the state of alert and its objective was the assessment of the employees' perception of the managers' profiles from the perspective of their capability of and concern for providing a climate that promotes orientation towards organizational performance and employees' personal satisfaction.

Conducting the survey during the state of alarm, one month after the state of emergency had ended, resulted in a series of mutations in relation to the perception of different aspects of the organizational climate, interpersonal cooperation for the fulfillment of professional duties and the degree of satisfaction concerning the positions held. Compared to the previous years, the employees considered the work performed by each one more important and their own results as impacting the others. Interpersonal cooperation was seen as improved in comparison to past years. There were also
a series of changes to the manner in which the employees perceive their immediate superior's activity and behaviors.

The employees' indicators for climate and satisfaction showed an increase from 7.51 in 2018 to 8.5 in 2020 (10 was the maximum).

The additional measures taken to create a climate oriented towards the motivation and protection of the employees, the limitation of the stress level and adaptation to the new conditions generated by the pandemics also contributed to this good result.

Following the survey, a skills development plan was created aiming at the optimization of the organizational climate and enhancement of teamwork and cooperation thus supporting the achievement of the objectives and orientation of the organizational culture towards innovation and high performance.

4.5. Community investing

We would like people around us grow and develop along with us. To this end, we get involved in different community projects any time we can by investing and directing funds to meet the urgent needs of the community. Our projects are set up on four strategic pillars, i.e health, education, environment and social involvement. Antibiotice organizes its own charity events, humanitarian projects, as well as educational and cultural programs by means of the "Science and Soul" Foundation.

The sponsorships are granted in conformity with the Corporate Sponsorship Policy. Its requirements are mandatory for all the employees, executives and members of the Board, in accordance with the provisions of the Law no. 32/1994 on Sponsorship.

3.822.823 lei invested in community by CSR projects

Modul de acordare a sponsorizărilor este stabilit prin Politica de sponsorizare și mecenat. Prevederile sunt obligatorii pentru toți angajații, precum și pentru membrii Consiliului de administrație și ai conducerii executive, în conformitate cu prevederile Legii nr. 32/1994 privind sponsorizările.

Projects for Our Communities

In 2020, the company invested, by the social responsibility projects run, a total amount of **3,822,823 lei** as follows:

- **1,505,759 lei** for projects under the Health pillar
- **46,621 lei** for projects under the Education pillar
- **1,960,000 lei** for projects under the Environment pillar
- **310,443 lei** for projects under the Social Involvement pillar

"Prieteniei a+ Park"

On December 1, 2020, on Romania's National Day, Antibiotice inaugurated "Prieteniei a+ Park" (n.t. Friendship a+ Park), a social; responsibility project, part of the program entitles "Antibiotice, a Friendly and Responsible Brand".

The project required the remodeling of the shelterbelt adjacent to the national road DN28 (next to the town of Valea Lupului). Covering a total surface of 25,000 sqm in front of the company, the park has more than 1,000 trees and shrubs, turf, lanes, a sportsground, and a modern playground.

The initial shelterbelt was planted in 1955 by the first employee of the company. The beneficiaries of the park are both the local community and Antibiotice's employees. The development works were carried out between March and October 2020 and consisted in setting up irrigation systems, landscaping and gardening, tree and shrub planting, lane building, provision of street lighting and street furniture. The total value of the investment amounted to 2 million lei.

In the Park, there is a statuary, a public monument (assembly made up of a water fountain and a statue), named "Fântâna Maternității" (n.t. "Maternity Fountain"), made by the sculptor Constantin Baraschi, one of the most important sculptors in Romania in the interwar period. The monument was professionally restored by Antibiotice from own resources with the help of the specialists from the "Moldova" National Museum Complex in Iași, the Center for Restoration and Conservation of the National Heritage.

Donate blood! Put your heart and soul into protecting life!

Despite the difficulties generated by the COVID-19 pandemics, on June 16 (few days apart from the World Blood Donor Day, which is celebrated on June 14 each year), the "Antibiotice – Science and Soul" Foundation succeeded in conducting the 19th edition of the "Donate Blood! Put Your Heart and Soul into Protecting Life!" campaign, in which a number of 70 employees took part voluntarily.

The volunteers donated 32 liters of blood altogether, which helped saving the lives of 150 people. By their example, Antibiotice's employees convey a message to the community about the need for more active involvement of the population in the process of voluntary blood donation in order to save lives.

To meet the permanent need for life-saving blood in hospitals, the "Antibiotice – Science and Soul" Foundation in partnership with the Regional Blood Transfusion Center have been organizing blood donation campaigns twice a year since 2010.

"Science and Soul" Scholarships

For 19 years, Antibiotice has been supporting the "Pro Ruralis" Association and contributing to the education of children with special skills, abilities and academic potential but with insufficient material means and coming from rural areas by granting the "Science and Soul" scholarships. The offered scholarships provide the necessary support for the children to continue their secondary and high school education as well as opportunities for their personal and professional development.

The conditions in which the pupils conducted their classes during the pandemic (online) determined the "Antibiotice – Science and Soul" Foundation to donate to the five Pro Ruralis scholarship students supported by the foundation, five tablets to be able to participate in online courses and access the necessary digital resources and tools. The five pupils in the 7th grade of the V. Lupu Pedagogical High School from Iași had very good school results in previous years, with general averages over 9.00.

"Be generous! Be Santa Claus!"

DFor eight years, the "Antibiotice – Science and Soul" Foundation has been running the campaign "Be generous! Be Santa Claus!", actively involving the company's employees who turn into Santa's elves.

Around the winter holidays, the Antibiotice's employees brought a glimmer of hope, as well as the spirit of Christmas to the homes of children from disadvantaged families. Following an internal corporate social responsibility (CSR) campaign, approximately 100 employees of our company got involved as volunteers in this project. Each volunteer involved in the campaign received a letter from a child (which was addressed to Santa Claus) and purchased gifts from their own funds. The "Antibiotice - Science and Soul" Foundation added a consistent packet of sweets and fruit for each child.

Thus, on December 17 and 18, 2020, the "Antibiotice – Science and Soul" distributed gifts for 78 children from needy families, aged between a few months and 15 years, with limited material possibilities, from the counties of Iași and Neamț. Santa Claus and his elves loaded the sleigh with the long-awaited gifts and wandered from house to house, well equipped with masks and disinfectants, safely, handing out these gifts to the children in the villages Dumbrava, Rădeni, Valea Arini, Timișești, Drehuța, Munteni, Belcești, Dumești, Cucuteni and Dancu.

05

Fast reactions under difficult conditions: our actions during the pandemic

2020 was a long and challenging road that few of us could have imagined at the beginning of the year. Faced with the new reality, the coronavirus pandemic and with the restrictions imposed by the authorities to limit the spread of the virus, we had to adapt and react quickly, trying to make the best decisions in a short time. From the very beginning, our number one priority has been to ensure the protection of our employees. They have been and continue to be the essential resource in our company.
Despite all the difficulties, the efforts of the whole team were incredible. We managed to come to the aid of those around us, both by rethinking and relaunching the production of some important medicines for treating COVID-19 and by supporting the health system.

We took proactive measures to protect employees and the company from the effects of the SARS-CoV-2 epidemic, starting with February 3, 2020, in the context in which the first case of coronavirus was reported in Romania on February 26, 2020, and the pandemic with the new coronavirus was decreed by the WHO on March 11. The first measures taken in our company referred to limiting the access of foreigners to the company's territory, restricting travel to states where cases of COVID-19 were reported and initiating steps to provide masks, gowns and disinfectant solutions.

With the onset of national emergency state, to prevent the spread of SARS-CoV-2 virus among employees, a Crisis Cell was nominated on March 10, 2020, which was later integrated into the Health and Safety Committee.

These two bodies had as their main objective, during the state of emergency and later during the state of alert, the elaboration and follow-up of the implementation of the Plan of action to limit and prevent the spread of infection with the new coronavirus. These structures included executives, operations managers and managers with responsibilities in the field of occupational health and safety at work and logistics.

Through the activity of the crisis cell, the impact and evolution of the pandemic were permanently monitored, the links with the competent medical and government authorities were activated so that the most problems be anticipated and the most appropriate organizational and technical measures be taken to maintain activity on the site and health of our staff. These measures ensured that the company's business was carried out safely, so that there was no risk of discontinuing the delivery of essential medicines for the national health system or failure to comply with the terms of external contracts.

During the state of emergency (March 16 – May 14, 2020), the Crisis Cell monitored daily the evolution of the health of its employees (employees suspected of being infected or quarantined), taking measures in real time to ensure their safety and activated the links with the competent medical and governmental authorities so that they can anticipate and address the most appropriate strategies, in line with the national evolution of the pandemic.

So, on March 15, 2020, the Crisis Cell made three work scenarios, accompanied by step-by-step action plans against COVID-19 (adopted by an internal decision), which were to be activated according to the evolution of the pandemic. The aim of these scenarios was to clarify the steps to be taken, depending on the evolution of the pandemic, so as to minimize the risks of discontinuation of drug deliveries on the domestic and foreign markets, with effects on the business and the Romanian healthcare system.

Scenario 1, applied from March 16, involved limiting the on-site activity for employees in indirect production areas by starting work from home. Employees working in production/utilities/delivery areas continued their activity on site.

To carry out work from home in conditions of efficiency and safety, the endowment of employees with remote work equipment was supplemented. The IT Department ensured the creation and functionality of the VPN service, an IT solution that allows employees to work remotely with the company's resources, in conditions of security and data protection. In adopting new ways of working with new remote communication tools, the Department of Data Security and Personal Data Protection issued a set of rules and recommendations for the use of instant business messaging platforms in and supplemented the internal regulations with a chapter dedicated to the VPN Security Policy.

In order to increase the security and health of the employees who continued to come on our site, the Crisis Cell adopted new measures, such as:

- daily disinfection of our own buses for employee transport and common areas (access roads, hallways, locker rooms)
- limiting the access of visitors to our site and the obligation of those who visit us to fill out forms for identifying their state of health
- limiting work meetings inside and outside the company and replacing them with means of distance communication (video conferencing, email, telephone)
- randomly periodic medical examinations among our employees performed by the medical staff from the medical office of the company.

Scenario 2 In the second scenario, simultaneously with the limitation of administrative activities, we initiated the cessation of other non-production activities for which it was not possible to work from home for a long period of time. The main production activities continued both for achieving the manufacturing plans prior to the onset of the pandemic and for responding to the new demands coming from the Romanian health system.

In the month of April, as a matter of urgency, Antibiotice resumed the production of Paracetamol and Novocalmin®, in order to be able to provide the pharmacies and hospitals with two antipyretic medicines used in the symptomatic treatment of SARS-CoV-2 infection.

In May 2020, Antibiotice produced a limited amount of hydroxychloroquine, an antiviral drug that was then required by medical staff and authorities to treat the new coronavirus infection.

Our company responded also to the requests of the international health systems, supporting them with medicines associated with the COVID-19 treatment, although the export conditions were not favorable. The restrictive measures applicable to export activity through legislation specific to the states of emergency and alert, disruption of ground and air transport, changes in bureaucratic procedures called for new and swift solutions to the above-mentioned issues. In the period of alert we made emergency exports requested by the governments of Lithuania, Latvia and the Netherlands au fost and we mobilized resources to respond positively to the demand for medicines needed in hospitals from developing countries, such as Irak and Yemen.

Development of these production activities on the Antibiotice site required an increase in the level of safety measures to protect the health of employees. Thus, the wearing of masks and gloves at work became mandatory, as well as the regular disinfection of hands and surfaces, strict monitoring of our employees' health and physical distance measures in means of transport and at work.

In the context of an increased pressure and emotional stress on employees, our company took the following measures for employees:

- daily communication through the available means of the state of the company's activity, of the measures taken to ensure their health and safety
- a new email address alăturidetine@antibiotice.ro was created to provide employees with information and psychological support from a psychologist, employed by the company for employees emotionally overwhelmed by the stress generated by the pandemic, so that they can continue their work with high morale and emotional comfort
- internal communication campaign #TotulVaFiBine, carried out through the internal publication ATB News.

Scenario 3 meant the total cessation of activities conducted by Antibiotice and continuing only the maintenance and security activities on site. This scenario, provided that the central authorities would request the temporary closure of the business as a result of the evolution of the pandemic or in the event of a major internal infection, was not implemented.

In order for all employees, including those who worked from home to resume safely their activities on site, the Health and Safety Committee issued in May 2020 an internal procedure "Preventive measures to limit COVID-19 infections" which established employee rules of conduct and applicable safeguards to limit COVID-19 infection in our company. This procedure was brought to the attention of all our employees in a hierarchical and communicative manner, persuasively and through alternative means of communication.

The procedure has been updated 6 times since its issuance until the date of publication of this report, in order to respond to the new contexts to which the company has been exposed since the beginning of the pandemic.

Among the measures that implemented the legislative requirements imposed by the authorities due to the pandemic, but also the additional measures, which exceeded the legal obligations, taken in our company when all the activities were resumed, after the state of emergency, we can list:

- constant monitoring of the health of employees, by the specialized staff from the Office of Occupational Medicine
- testing of directly productive personnel, both with rapid antigen tests and with RT-PCR tests, to check that the health status of employees after periods of leave / suspicion of infection
- installing disinfecting devices and mats in the access areas
- installing thermal scanners for measuring temperature of our employees when entering the company
- distributing sanitary and protective materials (masks, gloves, visors, hand and surface disinfectants, etc.) in compliance with a daily norm
- periodic disinfecting the contact surfaces in the areas with heavy traffic (doors, handles, taps, railings, etc.), means of transport of persons and goods
- organizing work at workplaces (offices, laboratories, production areas, dining rooms) so that the 1.5 m distance rule be ensured (including installation of Plexiglas partition panels, where applicable)

- limiting the circulation on site by encouraging the use of the virtual environment: online meetings, video conferencing and acquisition of Microsoft teams licenses
- catering delivery of the meals, at work, by the canteen located inside the factory, Bistro "Lunch break", to avoid the movement of staff on site
- differentiated work schedule of staff, in conjunction with measures for distancing and safe transport of employees and their monitoring
- a permanent communication with our employees, providing them with information on the evolution of the pandemic and scenarios experienced by the company during the pandemic.

In order to help our employees change their attitude and put into practice their new behaviors on distancing, breath management and hygiene, the following materials and internal communication campaigns were carried out:

- a guideline in print and online format for a safe return to work, including distancing, breathing and hygiene management
- a guideline on our employees' behaviour at work in pandemic conditions, including video movies communicated online
- posters containing the rules applicable to the workplace, posted in buses / internal spaces / access routes / common areas

- audio spot for employees, broadcast on internal radio and in company buses, with special measures to be observed at work, during the pandemic
- a guideline with useful tips for the period of isolation or quarantine, "9 questions on the path from a positive test to back to work".

All these measures allowed the company's activity to be carried out fluently, in safe conditions (production processes, delivery of medicines, research and development, quality control, etc.) without major discontinuities, during 2020.

In addition to the protection measures listed above, Antibiotice also implemented measures to motivate and support its employees during the pandemic, such as:

- providing a bonus and free meals to employees who worked on site during the state of emergency
- providing the free COVID-19 testing for employees in directly productive activities, on returning to work from the emergency state, vacation or after an infection
- offering additional days off to employees who did not have the opportunity to justify quarantine/ isolation days.

In 2020, in our company 201 employees were infected with COVID-19. In order to support them, the company implemented measures, in addition to the legal obligations, constantly monitoring their health, providing them with medical support from the doctors at our own doctor's office, as well as additional days off, post-illness and free RT-PCR testing upon return to the company.

In solidarity with the health system

In the early months of the COVID-19 pandemic, Antibiotice provided financial support and donations of medicines, worth 134,000 EUR, for 12 hospitals from Romania, as a gesture of solidarity with the medical system. Thus, along with eight hospitals in Iași (including the Regional Institute of Oncology and the Hospital for Infectious Diseases), hospitals from Pașcani, Onești and Brașov were also supported.

Also, the main pole for treating people infected with the new virus, the National Institute of Infectious Diseases "Matei Balș" in Bucharest received support from the company, both financially and in medicines.

Antibiotice also supported the Romanian Society of Anesthesia and Therapy which acquired 4,000 protective equipment (suits and visors), as well as 5,000 de FFp2 masks for 43 AIC units in the country.

At the Romanian CSR Awards Gala 2021, the project won 1st place in the category "Pandemic Community Support."".

Respect for the forerunners

In the midst of the COVID-19 pandemic, starting in April 2020, Antibiotice took care of 31 of the former retired employees. Through the "Antibiotice – Science and Soul" Foundation, Beneficiaries of the project, people with disabilities, medical conditions or who cannot travel, received basic food aid, delivered every two weeks or on request. Protective masks were purchased and offered to the Antibiotice seniors.

At the end of the year, another 50 seniors received traditional food packages offered by our company.

The support provided by the "Antibiotice – Science and Soul" Foundation reached the homes of some people who, over the years, secured the Antibiotice's roots and contributed over the years to its success and implicitly to the saving of human lives. It is a human, natural gesture to be close and in solidarity with those who are in need and for whom health and safety are the most important. There are those who were our mentors and pioneers, things for which we are grateful.

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	102-51 Date of most recent report		The most recent Sustainability Report of Antibiotice was elaborated for the period 01.01.2019-31.12.2019.	
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	403-9 Work-related injuries	3, 8	95	
Diversity and equal opportunity				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 89, 90	
	103-2 The management approach and its components		89, 90	
	103-3 Evaluation of management approach		39, 89, 90	
GRI 405: Diversity and equal opportunity 2016	405-1 Diversity of governance bodies and employees	5, 8, 10	38-38	
	405-2 Ratio of basic salary and remuneration of women to men		90	
Prevention of drug abuse and self-medication				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 49	
	103-2 The management approach and its components		30, 49	
	103-3 Evaluation of management approach		49	
	Initiatives to promote responsible drug use	3	49	
Responsible promotion and transparent communication				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 46-49	
	103-2 The management approach and its components		46-49, 56, 57, 59	
	103-3 Evaluation of management approach		30, 47, 59	
GRI 417: Marketing and labeling 2016	417-2 Incidents of non-compliance concerning product and service information and labeling		47	
	417-3Incidents of non-compliance concerning marketing communications		47	
Employee training and development				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 96, 99	
	103-2 The management approach and its components		96, 99	
	103-3 Evaluation of management approach		30, 88, 96	
GRI 404: Training and professional development 2016	404-1 Average hours of training per year per employee	4, 5, 8, 10	97	

Standard GRI	Information	Sustainable Development Goal	No. of page (s)	Omission
GRI 404: Training and professional development 2016	404-3 Percentage of employees receiving regular performance and career development reviews		97	
The relationship between management and employees				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 87, 88	
	103-2 The management approach and its components		87, 88	
	103-3 Evaluation of management approach		30, 88	
GRI 402: Labor/ management relations 2016	402-1 Minimum notice periods regarding operational changes		88	
Customer privacy				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 44, 45	
	103-2 The management approach and its components		44, 45	
	103-3 Evaluation of management approach		30, 45	
GRI 418: Customer privacy 2016	418-1 Substantiated complaints concerning breaches of customer privacy and losses of customer data		45	
Human rights				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26	
	103-2 The management approach and its components		31, 89	
	103-3 Evaluation of management approach		30, 89	
GRI 412: Human rights assessment 2016	412-2 Employee training on human rights policies and procedures	In 2020, there were no human rights training programs for employees.		
Freedom of association and collective bargaining				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26	
	103-2 The management approach and its components		66	
	103-3 Evaluation of management approach		30, 66	
GRI 407: Freedom of association and collective bargaining 2016	407-1 Operations and suppliers in which the right to freedom of association and collective bargaining may be at risks	In 2020, there were no assessments at the level of the supply chain regarding the observance of the right to association and collective bargaining.		
Human resources policy				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 87, 88, 91	
	103-2 The management approach and its components		87, 88, 90, 91, 98, 99	
	103-3 Evaluation of management approach		30, 88, 91	
GRI 401: Employment 2016	401-1 New employee hires and employee turnover		91	
	401-2 Benefits provided to full-time employees that are not provided to temporary or part-time employees		98, 99	
	401-3 Parental leave		98	

Standard GRI	Information	Sustainable Development Goal	No. of page (s)	Omission
Volunteering and investing in communities				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 100	
	103-2 The management approach and its components		100, 101, 106	
	103-3 Evaluation of management approach		100	
GRI 413: Local communities 2016	413-1 Operations with local community engagement, impact assessments and development programs		In 2020, there were no assessments of the company's impact on local communities.	
Evaluation of suppliers from the perspective of environmental and social standards				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 66, 67	
	103-2 The management approach and its components		66, 67	
	103-3 Evaluation of management approach		30, 66, 67	
GRI 414: Supplier social assessment 2016	414-1 New suppliers that were screened using social criteria			Currently, the company does not monitor these indicators.
GRI 308: Supplier environmental assessment 2016	308-2 New suppliers that were screened using environmental criteria			
Health and safety of consumers and patients				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 50	
	103-2 The management approach and its components		50-52, 59, 60	
	103-3 Evaluation of management approach		53	
GRI 416: Customer health and safety 2016	416-1 Assessment of the health and safety impacts of product and service categories		53, 55	
	416-2 Incidents of non-compliance concerning the health and safety impacts of products and services	There were no incidents of non-compliance with the impact of products and services on consumer health and safety.		
Clinical studies				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		20, 21, 26, 60, 61	
	103-2 The management approach and its components		60, 61	
	103-3 Evaluation of management approach		60, 61	
	Number of clinical studies started in the reporting period		61	
Quality management				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 50	
	103-2 The management approach and its components		50–52	
	103-3 Evaluation of management approach		53	
	Valid standards, licenses, authorizations and certificates at the end of the reporting period			
Combating counterfeit medicines and parallel trade				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		26, 57, 58	
	103-2 The management approach and its components		30, 57, 58, 64	
	103-3 Evaluation of management approach		30, 57, 58	
	Counterfeit alerts generated by the serialization system		58	

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