Antibiotice
Science and soul

2021
Integrated Annual Report

In service of life for a lifetime!

Contents

Message of the General Director of Antibiotice SA

Dear partners,

I am honored to present you the 2021 Integrated Annual Report of Antibiotice which includes both the financial and non-financial statements. This transition from the separate to the integrated reporting of financial performance is a natural step by which we support our stakeholders by transparently presenting to them the financial results, impact of our company on the economy, environment and society as well as our contribution to the community development.

Antibiotice has taken important steps on the path to sustainability, integrating in a balanced way the business objectives with the principles of sustainable development throughout the company's operations.

During this year we continued the efforts of consolidating our business, efforts materialized in total revenues of 389 million lei and a 13% higher profit compared to the previous year, given that our international business accounted for 39% of the entire business.

Our experience of almost 70 years as well as our way of organization, with international representative offices and consolidated collaboration agreements with over 200 partners from all over the world, with a sustained research and development activity, with 8 GMP certified manufacturing flows, allowed us to act promptly, honoring domestically and internationally all our contractual obligations, even in the restrictive conditions of the pandemic. We are glad that our international partners have been with us for over 30 years, giving us the opportunity to develop strategies for the benefit of patients in all territories where the Antibiotice medicines are marketed.

Looking back, we appreciate that we already have a great ability to develop a product from just a molecule until the medicine launched in the market. In difficult times, we mobilized ourselves with maximum efficiency, adjusting our offer to the needs of the market and contributing to the restoration of the people's health. We have been standing in solidarity with the people, with the Romanian health system and last but not least, with our partners.

Our company has been developing based on a well-defined business plan which covers the next 8 years, with strategic pillars and targets to be achieved each year, a tool for continuous adaptation to the domestic and international market, for developing our business and increasing its profitability.

A major objective of the business plan pursued in 2021 as well is developing a sustainable, complex and accessible product portfolio to meet the needs of patients. Consequently, adapting our product portfolios through innovative operational research but also through license acquisitions is a sustained activity in Antibiotice.

Our knowledge and expertise in the production of medicines have allowed us to win important tenders abroad. Thus, Antibiotice has been enjoying the recognition of health systems in the United Kingdom, United States, Vietnam where we won major tenders for the sterile injectable antiinfectives.

We are aware of the effects of climate changes and, for this reason, we intend to conduct a complex audit in 2022 along the entire value chain on the risks posed by these changes that will allow us to take concrete measures to reduce emissions.

In our business model we integrated also the social and environmental issues of interest for our stakeholders and the results obtained in 2021 with zero environmental incidents, zero incidents regarding anti-corruption practices, 47 new marketing authorizations which facilitate the access of patients from all over the world to valuable therapeutic solutions, access to benefits and development opportunities for all employees represent a confirmation of our ethical and responsible way of conducting our business and of the values that guide our activity.

We are aware that our valuable and high-performing employees, who embrace the company's values represent the source of our success. Our mission of doing more and better for people's health is not an easy one, but together with our highly motivated and involved employees, we have been fulfilling it year after year. Through the continuing education programs (e.g. Perfom a+ for identifying and attracting new colleagues), motivational programs (e.g. Club a+ which offers employees both opportunities to practice sports in appropriate spaces and pursue personal development programs) we make sure that our people are ready to build the company's vision in the perspective of the coming years.

Antibiotice encourages the team spirit, personal and professional development, offering employees optimal working conditions, a good incentive system and career development opportunities, so that "a company worth working for" is not just a phrase.

The year of 2021 was again about solidarity and how closely this solidarity is related to the responsibility with which we carry out our daily activities. Thus, in the context of the second year of the COVID-19 pandemic, at the beginning of 2021, Antibiotice showed its readiness to support national immunization efforts by making the Vaccination Center a+ available to employees and members of neighboring communities. Our effort resulted in approximately 24,000 doses of vaccine administered at the Vaccination Center a+.

I am proud when the Antibiotice team's efforts are recognized as good practices and when, through our work, we are a good example. Thus, the performance and transparency of the business ranked the Antibiotice company in the GOLD category within the most important, complex and unique assessment of sustainability performance: Romania Corporate Sustainability & Transparency Index (CST Index) for the 2020 Sustainability Report.

We will continue to improve our activities to reduce our carbon footprint and align ourselves to the new sustainability regulations. We are also very focused on increasing economic performance and meeting our business objectives in line with sustainable development objectives, continuing to remain a reliable, ethical and transparent partner for all our stakeholders and to have a positive impact on the community, on economy and environment.

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

About the report

This is the first Integrated Annual Report of the Antibiotice SA (hereinafter referred to as "Antibiotice" or the "company"). The report presents the financial indicators of the previous reporting years included in the Annual Report and the non-financial performance indicators related to our company's activity during the period 01.01.2021–31.12.2021. The non-financial information contained in this report complies with the requirements of the Directive 2014/95/EU, Order of the Minister of Public Finance 1938/2016, Order of the Minister of Public Finance 3456/2018, Order of the Minister of Public Finance no. 1.239/2021 and with the requirements provided in art. 8 of Regulation (EU) 2020/852 of the European Parliament and of the Council of June 18, 2020 on the establishment of a framework to facilitate sustainable investment and amending Regulation (EU) 2019/2088.

The current report provides information on the sustainability indicators specific to our activity, necessary for understanding the development, performance and impact of Antibiotice operations. The non-financial information presented throughout this report relates to environmental, social and staff aspects, respect for human rights, fighting corruption and bribery, 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 audited financial statements* included in the report were prepared in accordance with the International Financial Reporting Standards (IFRS) while the non-financial data were prepared according to the methodology proposed by the Global Reporting Initiative (GRI) standards 2016 (Core option).

The topics analyzed in the process of reporting non-financial information 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 Antibiotice stakeholders.

We thank all those who made possible this report developed by the Antibiotice's reporting team.

For questions, suggestions or complaints about this report, you may contact our company by email at: **office@antibiotice.ro** or at the following address:

Antibiotice SA
head office:
1 Valea Lupului St.,
707410 Iași, Romania,
www.antibiotice.ro

Telephone:
+40 232 209 000
+40 232 220 040
+40 372 065 000
+40 372 065 633

* The Independent Auditor's Report on the financial statements can be found on page130 of the current report.

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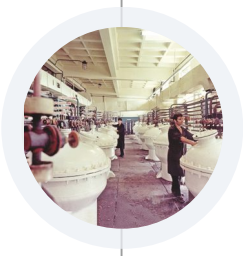
Company profile

1.1. Short history

After more than six and a half decades of existence, Antibiotice is today the most important Romanian generic medicine manufacturer. Over the years, our company has remained true to its mission to manufacture safe, effective and quality pharmaceuticals to give patients the hope of a healthy life. Antibiotice has an active global presence and exports its products to all continents, managing to make the valuable medicines more affordable to the patients both from Romania and from abroad.

1955–1959

The first factory producing in the South-Europe the Penicillin discovered by Alexander Fleming was established in Romania in December 1955. Four years later, the Streptomycin Plant 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, Nystatin) were developed. In that period, Antibiotice became the only producer of sterile parenteral products (injectables) in Romania. Food and Drug Administration (FDA), the American regulatory body authorized the manufacturing plant of strempto-mycin (active substance) in 1997, this way opening for our company the doors to the international market.

1990–1997

Antibiotice has become a joint-stock company. The macro-economic changes determined the Antibiotice's management team to reorient the production of medicines, finished products ranking first in the Antibiotice portfolio while the active substances being used for developing new pharmaceutical dosage forms. Shortly after, our company has entered the top of antiinfectives manufacturers in Romania.

1997–1999

Antibiotice entered the capital market, our company's shares (ATB symbol) starting to be traded in the first category of the Bucharest Stock Exchange. Our company became the first manufacturer of medicines in Romania which obtained the Good Manufacturing Practice (GMP) certificate for the flow manufacturing medicines for injection.

2000–2004

Antibiotice has been positioning itself as a world leader manufacturer of Nystatin after obtaining the FDA authorization for the manufacturing flow, this allowing the export of this active substance in the United States which has become the most exported product.

2005

The impact of investments and efficient management policy materialized in an important jump of economic indicators (profit and turnover). Antibiotice implemented a management by objectives system, designed to increase the performance throughout the company. On its 50th anniversary, a new brand identity was launched to visually communicate the company's modernization and structural changes.

2006

Antibiotice inaugurated the Center for Medicine Evaluation (CEM), a one million investment. CEM is a clinical research unit conducting non-therapeutic clinical studies (phase I and bioequivalence studies). CEM has been GLP certified and authorized by the Ministry of Health.

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. Our company completed the investment in an ecological waste incineration plant which, together with the modern wastewater treatment plant significantly reduce the impact of the company's activities on the environment.

2009

Antibiotice oriented itself towards the international development and obtained the first Marketing Authorizations issued by FDA for injectables in the United Staes of America. The number of exported products as well as the number of international partnerships increased. 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 audited by FDA which certified the manufacturing flow of penicillins in the form of injectable powders and delivered the first finished medicinal products in the US market, a market in which our company had already been 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 research, quality control and production of medicines.

Antibiotice continued the investments in manufacturing technologies (the capacity to obtain compressed oral solid forms increased) as well as in research, completing the investment in a modern Research & Development Center, increasing this way the pace in which the product portfolio has been renewed.

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 sterile powder for injection 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, diversified its dermatological and central nervous system portfolios and offered new products for prophylaxis and for increasing the life quality (food supplements and over-the-counter medicines).

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

2015

FDA reapproved the production flows of the sterile finished products for injection and the 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-East Europe.

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 Grigore 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 company opened a new international representative office in Kyiv, Ukraine. Antibiotice started the serialization of its medicines, making the first delivery of the serialized products in the US.

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

Implementation of the Laboratory Management System (LMS) was initiated.

2020

The crisis caused by the Covid-19 pandemic imposed the reintroduction of two products into production, Paracetamol and Novocalmin, for treating the symptoms of Covid-19. Our company started also to produce biocides for hand and surface disinfection. Antibiotice won the tender organized by the European Commission for one of the most widely used antibiotics in the treatment of Covid-19: AmoxiPlus®.

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

Laboratory Management System (LMS) has been implemented.

2021

Antibiotice established a Vaccination Center within its own Research & Development Center, facilitating the access to vaccination for its employees as well as for the community. Our company organized also Caravan + for 6 weeks which facilitated the access to Covid-19 immunization for 420 people in rural areas.

For the second year in a row, Antibiotice won a 11 million EURO tender organized by the health authorities in the UK and Wales for 5 injectable antiinfectives.

1.2. About Antibiotice

Antibiotice has as its 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 which has 53% of the subscribed and paid-up capital. It has been present on the capital market for 24 years, being listed since 1997 on the Bucharest Stock Exchange (BVB), in the Premium category.

With a tradition of over 66 years, Antibiotice is one of the most important Romanian manufacturers of generic medicines, the most significant producer of antiinfectives and one of the most important suppliers of medicines for the Romanian hospitals.

Antibiotice currently develops and produces generic medicines for human use (150 products in 11 therapeutic classes), veterinary medicines, active substances and biocides on the eight manufacturing flows verified and certified by the National Agency for Medicines and Medical Devices of Romania (NAMMDR), in accordance with the Good Manufacturing Practice (GMP) requirements.

The active substance Nystatin made by a biosynthesis process unique in Romania has become the USP reference standard starting with 2017. Our Nystatin manufactured in Iași is exported to over 60 countries around the world and ranks Antibiotice first in the world top of this segment.

Most of the medicines we produce are prescription drugs (Rx), but we also have over-the-counter medicines, food supplements and medical devices designed to prevent the diseases and increase the quality of life. The generics produced by Antibiotice are mainly addressed to patients with infectious diseases, but also to cardiovascular, dermatological, digestive and central nervous system pathologies.

Antibiotice produces valuable and affordable medicinal products both for the Romanian and foreign markets worldwide. Over time, it has developed strong business relationships with over 70 partners worlwide and opened representative offices in Vietnam, Moldova, Ukraine and Serbia.

The continuous development of the company and the expansion in the international markets were made possible by investments and by implementing internationally recognized quality standards:

- **Good Manufacturing Practice (EU-GMP)**
- **Certificate of Suitability with the European Pharmacopoeia (COS)**
- **Food and Drug Administration (FDA) authorization**

Antibiotice has 8 manufacturing flows, organized in three divisions:

Sterile Products & APIs Division

penicillin powders for injection, active substances obtained by biosynthesis, biocidal solutions

Oral Solid Products Division

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

Topical Products Division

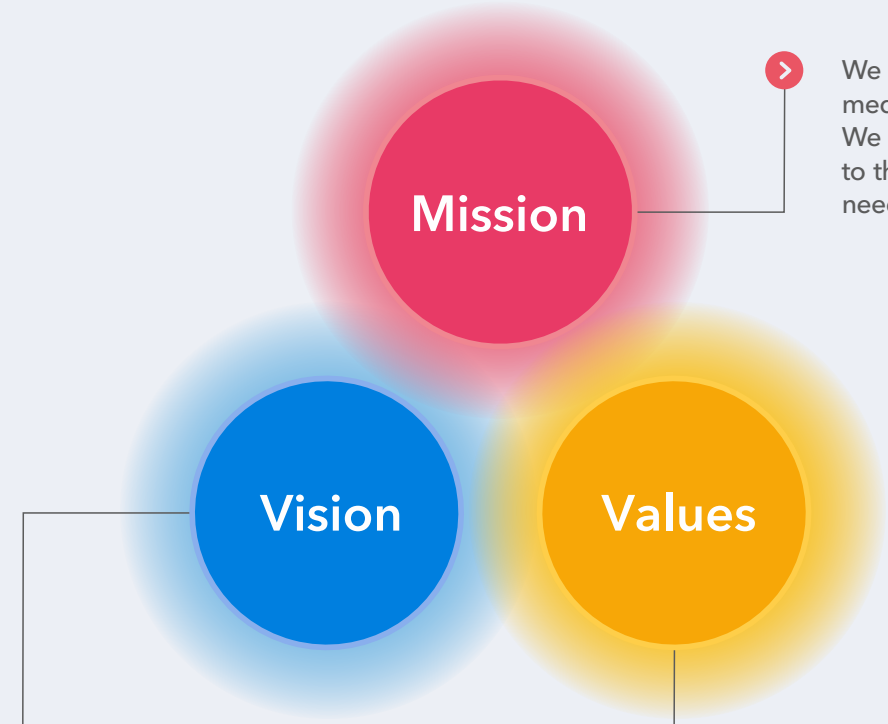
ointments, creams, gels, suppositories, pessaries and biocides

Beyond the global recognition, the Antibiotice brand remains firmly committed to its mission of improving the health and lives of people from Romania and abroad.

In Iași, in the same location of the factory (manufacturing site), our company has its head office and its Research-Development Center including the Center for Clinical Studies.

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

Antibiotice is one of the companies with a rich tradition in Romania. Its organizational culture, values and the way in which it carries out its activity on a day-by-day basis have made the company a reliable partner for suppliers, customers, but also for the health authorities in Romania and in the states where it conducts its business.



We make our valuable medicines more accessible. We always put our strength to the service of those who need our support.

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 allows us to target performance, permanently investing in people, technology and carefully selected parterships.

We cherish efficiency, knowledge and spirit of cooperation which allow us to focus on the ever-changing needs of our customers and consumers. In our company, we put the right people in the right place, at the right time. We mutually aknowledge our purpose and value, which create a sense of connection and gives us the strength to overcome limitations and obstacles.
As human beings, we care about our fellows, we seek to be close to them and we always think about how to improve things that are important to them.

1.3. Our 2021 figures

Economic matters

388.93
million lei – total income

59 **million lei** –
business performance

>90 **million lei** –
taxes paid to the state budget

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

Social matters

1,370
employees,
of which
54.3% are women and
45.7% are men

60%
of the management positions are held by women

34.4 hours –
average hours number of professional training per employee

77.8%
Romanian suppliers

Environmental matters

440.554
MWh – electricity savings in 2021

60%
the recovery rate of packaging placed in the Romanian market

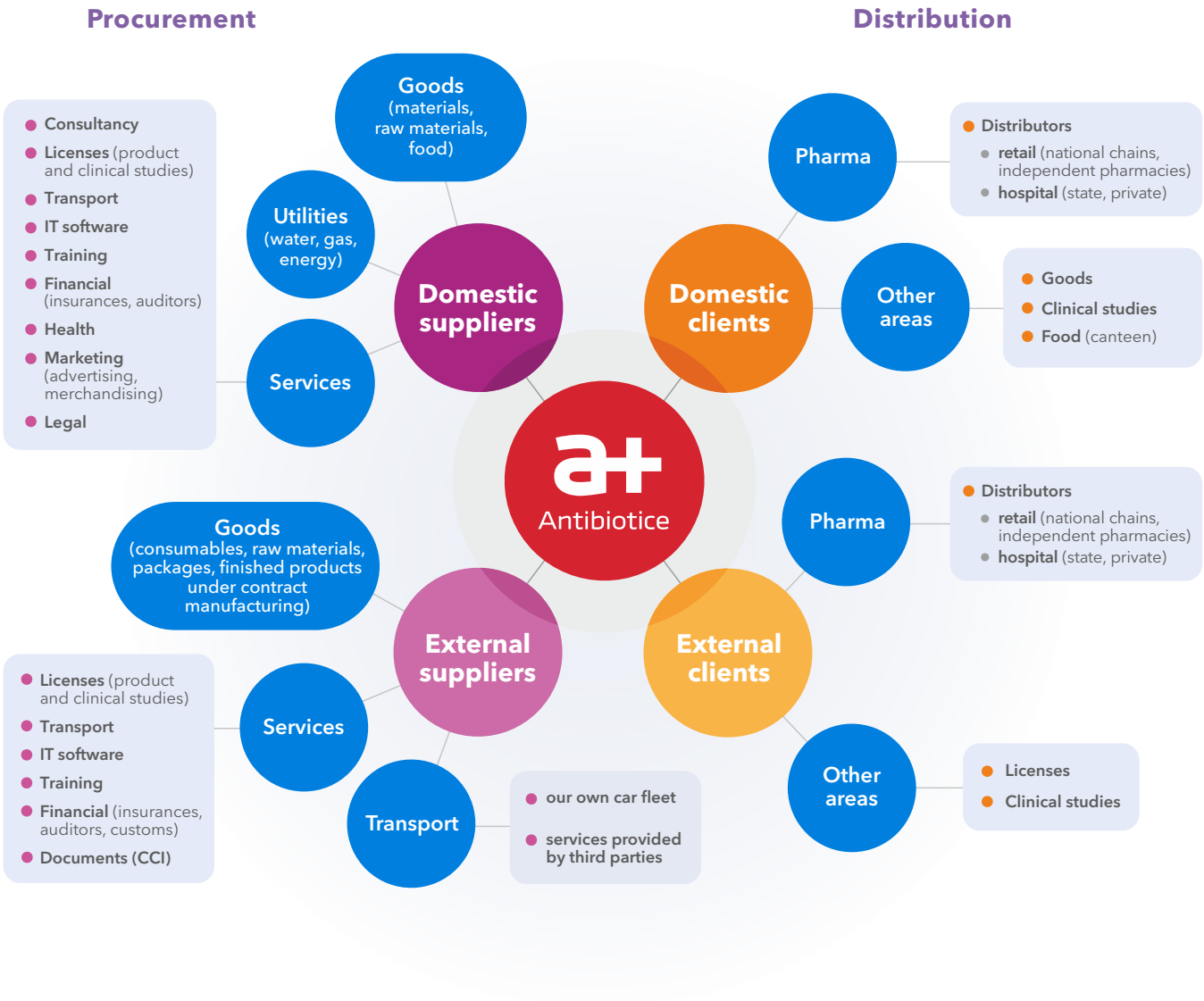
770.235
tons – waste diverted from disposal

ZERO
sanctions
caused by environmental incidents

1.4. Long-term value

Our company's performance and success have allowed us to develop over time strong partnerships with all the players within the value chain, gaining the trust of all our stakeholders.

Antibiotice constantly invests in Research & Development and works together with its local and international partners to create value both for the Romanian society and for the consumers from the external markets where its products are sold.



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

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

Throughout the value chain, optimizing the production, packaging, storage and transport processes is constantly pursued, as a guarantee that the Antibiotice medicines 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 tender-based to hospitals and retail pharmacies. From here, the products reach the patients/consumers.

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

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

By self-inspection programs, our Quality Assurance specialists teams are actively involved in identifying in due time the elements that could slow down the processes throughout the value chain. They intervene to minimize the risks and improve constantly the procedures.

1.5. Strategic Organization & Development Plan

With a long-term vision and a strong commitment to responsible business growth, the foundations of the Strategic Organization & Development Plan (PODS) have been laid for the period 2021–2028. Our development goals for this period are included in the PODS which aims to sustainably grow the business and maximize the long-term profitability.

The Strategic Organization & Development Plan has five strategic pillars which represent the foundation of the company's development in the years to come, including objectives, strategies and measures specific to the main functions of the company. These pillars, on which the current generations build the future of the Antibiotice business, aim at strategically adapting human resources to the realities of the period 2021–2028, strategically adapting the product portfolio, business sustainability by improving the integrated management system (quality, environment, occupational health and safety), strategic planning and performance management as well as the corporate governance.

Currently, our company has been conducting an internal analysis process which will be, together with the stakeholder consultation, the basis for developing the sustainability strategy. Our sustainability strategy will be established and completed by the end of 2022.

By **2028**, Antibiotice intends to double its turnover to **700 million lei**

So, in the perspective of 2028, Antibiotice has the following objectives:

- doubling the turnover up to 700 million lei;
- a gross profit plus the clawback tax of 120 million lei;
- internationalization of our business 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 by outsourcing certain services;
- maintaining the position of world leader for the active substance Nystatin;
- increasing the value of the average net salary at 1,200 Euro;
- reaching a net asset of 1,000 million lei.

A number of working groups have been set up to support and monitor the achievement and implementation of the PODS objectives:

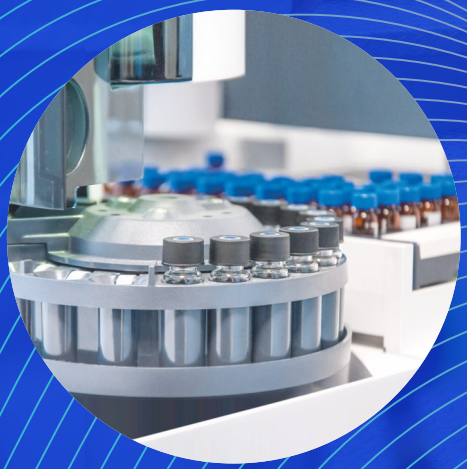
Group	Purpose
G1: Strategic Planning and Performance Management	Implementation of the PODS objectives and strategies.
G2: Portfolio policies	Defining the product portfolio to support the objectives set in the PODS.
G3: Industrial investments and policies	Defining investments and technologies to support the objectives set out in the PODS (involves digitization and computerization strategies of the site).
G4: Legal and corporate governance	Defining and maintaining the legal framework and corporate governance policy meant to sustain the objectives included in the PODS (involves the adaptation of good practice and corporate governance codes, other codes that define the organization of the company's activities, monitoring risk management, existence and efficiency of systems for establishing performance indicators and their monitoring).
G5: Human resources policy	Defining the optimal human resources structure adapted to the objectives included in the PODS (involves organizational climate strategies, organizational culture, internal communication, payroll systems, organization and functioning regulations, recruitment methods, optimization of roles and job descriptions, adaptation of the organizational structure).
G6: Integrated quality management (including 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 working groups, other teams operate in our company for certain support areas, such as:

- **the team for implementing the PODS objectives and strategies;**
- **the team for monitoring the performance in implementing PODS** which aims to analyze, measure and control the performance indicators established in the management plans that support the implementation of the PODS;
- **research work teams** (by each division) that will define each stage of development for the following years;
- **the work teams for the portfolio** (by each division) that will define the product portfolio, in the perspective of the coming years;
- **the work team - Occupational Health and Safety Committee;**
- **the work team for communication,** which aims to implement and monitor the company's integrated communication plan;
- **the team for securing the Antibiotice industrial site** which aims to implement the security plans;
- **the digitization and computerization team** 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;
- **the technical approval commission** that aims at the technical-economic approval of investments, acquisitions of equipment, new constructions, buildings, warehouses, consolidations.

02

Our company performance



2.1. Strategic evolution

Product portfolio renewal

In 2021 also, one of the strategic objectives of Antibiotice was to secure a sustainable and marketable portfolio by introducing new medicines in the domestic and international markets.

- **14 projects – new, completely evaluated products** which will be introduced in the future portfolio through own research or business development;
- **24 projects under research**, in various stages of development, in our own research center;
- **15 purchased licenses for new products;**
- **47 products that obtained marketing authorizations or notifications:**
  - 7 products in the domestic market (Romania);
  - 40 products in the international market

Antibiotice top products

Top 20 best selling Antibiotice brands*

The first 20 brands (in terms of sales value) traded by Antibiotice in 2021 recorded sales of 264.47 million lei.

No.	Brand	International non-proprietary name (INN)	Therapeutic class and form of administration	Main competitors
1	**Cefort®** 250 mg, 1 g and 2 g	ceftriaxonum	Antiinfectives for systemic use Other beta-lactam antibacterials Injectables	Medaxone® (Medochemie)
2	**Meropenem Atb®** 500 mg and 1 g	meropenemum	Antiinfectives for systemic use Other beta-lactam antibacterials Injectables	Meropenem Kabi (Fresenius)
3	**Eficef®** 100 mg și 200 mg	cefiximum	Antiinfectives for systemic use Other beta-lactam antibacterials Capsules	Xifia® (Alkaloid AD),
4	**Colistina Atb®** 1,000,000 UI	colistini sulfas	Antiinfectives for systemic use Other antibacterials. Injectables	Sole product
5	**Nidoflor®**	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatological preparations Corticosteroids in combination with antibiotics Ointments	Triderm® (Organon)
6	**Amoxiplus®** 1,000 mg/200 mg	amoxicillinum + acidum clavulanicum	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Injectables	Sole product
7	**Hemorzon®** ointment	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoids for topical use Ointments	Procto Glyvenol (Recordati), Prestogel (Hip Pharma), Proctinum (Natur Product Zdrovit)
	Hemorzon® suppositories	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoids for topical use Suppositories	Cicatridina (NaturPharma), Prosto Glyvenol (Recordati)
8	**AmpiPlus®** 1,000 mg/500 mg	ampicillinum + enzyme inhibitor	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Injectables	Sole product
9	**Amoxicilină Atb®** 250 mg and 500 mg	amoxicillinum	Antiinfectives for systemic use Beta-lactam antibiotics, penicillins Capsules	Ospamox® (Novartis)
10	**Bisotens®** 5 mg and 10 mg	bisoprololum	Cardiovascular system Beta blockers Tablets	Concor® (Merck Kgaa), Bisogamma® (Wörwag Pharma), Sobyc® (Krka D. D.)
11	**Nolet®** 5 mg	nebivololum	Cardiovascular system Beta blockers Tablets	Nebilet® (Menarini) Nevivolol Actavis (Teva)
12	**Silithor®**	food supplement	Digestive tract and metabolism Hepatoprotectors Capsules	Essentiale Forte® (Sanofi), Essentiale Max® (Sanofi), Lagosa® (Wörwag Pharma) Liv 52® (Himalaya), Fortifikat® (Sun Pharma),
13	**Glycerin suppositories for adults** and **Glycerin suppositories for children**	glycerolum	Digestive tract and metabolism Laxatives Suppositories	Dulcolax® (Sanofi), 4Lax® (Solacium Pharma), Glycerin suppositories (Dr. Max)
14	**Kanamicina H** 5 mg/10 mg/g ophthalmic ointment	kanamycinum + hydrocortisonum	Sensitive organs Anti-inflammatories and anti-infectives with corticosteroids. Ointments	Tobradex (Novartis) Betabioptal (Farmila)
	Kanamicina Atb® 10 mg/g ophthalmic ointment	kanamycinum	Sensitive organs Ophthalmic antiinfectives Ointments	Sole product

* Data source: Cegedim Romania 2021

No.	Brand	International non-proprietary name (INN)	Therapeutic class and form of administration	Main competitors
15	**Clotrimazol Atb®** 10 mg/g cream	clotrimazolum	Dermatological preparations Antifungals Ointments	Canesten (Bayer AG), Clotrimazol (Slavia Pharm) Clotrimazol MK (Fiterman Pharma)
16	**Paracetamol Atb®** 500 mg tablets, 125 mg suppositories, 250 mg suppositories	paracetamolum	Central Nervous System Antipyretic analgesics Suppositories and tablets	Paracetamol (Zentiva), Paracetamol (Terapia), Paracetamol LPH (Labormed)
17	**Ampicilină Atb®** 250 mg, 500 mg and 1 g	ampicillinum	Antiinfectives for systemic use Other beta-lactam antibiotics, penicillins.Capsules and injectables	Ampicilina® (Novartis), Ampicilina® (Farmex Company), Standacillin (Novartis)
18	**Fluocinolon N Atb®** 0.25 mg/5 mg/g	fluocinoloni cetonidum + neomycinum	Dermatological preparations Corticosteroids in combination with antibiotics. Ointments	Fluocinolon Acetonid (Laropharm),
19	**Ceftamil®** 1 g	ceftazidimum	Antiinfectives for systemic use Beta-lactam antibacterials Injectables	Sole product
20	**Fluxiv®** tablets	food supplement	Cardiovascular system Tonic for venous capillaries Tablets	Detralex® (Servier), Devaricid® (Biofarm), Endolex® (Sun Wave Pharma)
	Fluxiv® cream	cosmetic product	Cardiovascular system Varicose veins therapy Ointments	Troxevasin (Teva), Endolex® (Sun Wave Pharma), Ruscoven (Aboca)

Top of the products for which Antibiotice is the sole manufacturer

The products for which Antibiotice is the sole manufacturer recorded sales worth 155.8 million lei in 2021.

No.	Product	International non-proprietary name (INN)	Therapeutic class and form of administration
1	**Aceclofen®**	diclofenacum + paracetamolum	Musculoskeletal system Suppositories
2	**Amoxiplus®** 1,000 mg/200 mg	amoxicillinum + acidum clavulanicum	Antiinfectives for systemic use Powder for injection
3	**Ampiplus®** 1,000 mg/500 mg	ampicillinum + sulbactamum	Antiinfectives for systemic use Powder for injection
4	**Cicloserină Atb®** 250 mg	cycloserinum	Antiinfectives for systemic use, tuberculosis treatment. Capsules
5	**Clo-Ekarzin®** 0.5 mg/10 mg/g	bethametasonum + clotrimazolum	Dermatological preparations Cream
6	**Colistină Atb®** 1,000,000 UI	sodium colistimethate	Antiinfectives for systemic use Powder for injection
7	**Cutaben Bebe®**	zinc oxide + ichthammol + Vital ET®	Dermatological preparations Emollient and protective cream
8	**Cutaden®**	ichthammol + zinc oxide + hamamelis virginiana extract	Dermatological preparations Protective cream
9	**Fezivit®**	vitamin C + iron + zinc	Dermatological preparations Other dermatological preparations Capsules
10	**Fluocinolon N Atb®** 0.25 mg/5 mg/g	fluocinoloni acetonidum + neomycini sulfas	Dermatological preparations Topical corticosteroid in combination Ointment
11	**Fluxiv®**	diosminum + hesperidinum + troxerutin + acidum ascorbicum	Cardiovascular system Food supplement with a role in the normal functioning of blood vessels Coated tablets
12	**Fluxiv® tonic cream**	troxerutin + D-pantenol	Cardiovascular system Varicose vein therapy, topical product Cream

No.	Product	International non-proprietary name (INN)	Therapeutic class and form of administration
13	**Hemorzon®** suppositories	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoids for topical use Suppositories
14	**Hemorzon®** ointment	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system Antihemorrhoids for topical use Ointment
15	**Hidrocortizon Atb®** 10 mg/g	hydrocortisonum	Dermatological preparations Ointment
16	**Lejer®**	senna + rhubarb + ginger + hibiscus	Digestive tract and metabolism, laxatives Capsules
17	**Lisinopril Atb®** 40 mg	lisinoprilum	Cardiovascular system Angiotensin converting enzyme inhibitors Tablets
18	**Moldamin®** 1,200,000 UI	benzathini benzylpenicillinum	Antiinfectives for systemic use, broad-spectrum penicillins. Powder for injection
19	**Nidoflor®** 15 g	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatological preparations Cream
20	**Nistatină Atb®** 100,000 UI	nystatinum	Gynecological antiinfectives Pessaries
21	**Nistatină Atb®** 500,000 UI	nystatinum	Intestinal anti-infectives Coated tablets
22	**Oxacilină Atb®** 1 g	oxacillinum	Antiinfectives for systemic use, penicillins Powder for injection
23	**Penicilină G potasică Atb®** 1,000,000 UI and **Penicilină G sodică Atb®** 400,000 UI and 1,000,000 UI	benzylpenicillinum	Antiinfectives for systemic use, broad-spectrum penicillins Powder for injection
24	**Piafen®**	metamizolum natricum + pitofenonum + fenpipramidum	Digestive tract and metabolism, antispasmodics in combination with analgesics. Tablets
25	**Pirazinamidă Atb®** 500 mg	pyrazinamidum	Antiinfectives for systemic use, tuberculosis treatment. Tablets
26	**Saliform Forte®**	methylis salicylas + levomentholum	Musculoskeletal system Cream
27	**Silithor®**	silimarinum + L-methioninum + L-cisteinum	Digestive tract and metabolism Hepatoprotective food supplement Capsules
28	**Sinerdol®** 300 mg	rifampicinum	Antiinfectives for systemic use, tuberculosis treatment. Capsules
29	**Sinerdol® ISO**	rifampicinum + isoniazidum	Antiinfectives for systemic use, tuberculosis treatment. Capsules
30	**Soriso®**	rhodiola rosea + ocimum basilicum	Central Nervous System Adaptogen food supplement Coated tablets
31	**Tetraciclină Atb®L** 30 mg/g	tetracyclinum	Dermatological preparations Ointment
32	**Tinero® Gel**	nicotinamidum	Dermatological preparations, anti-acne products. Ointment
33	**Triamcinolon S Atb®**	triamcinolonum + chlorquinaldolum	Dermatological preparations Cream
34	**Zifex® Complex**	metronidazolum + nystatinum + neomycini sulfas + hydrocortisonum	Gynecological antiinfectives Pessaries

Data source: Cegedim Romania 2021

Our company's performance in the domestic market*

- **ranked 1st** in the relevant market** of the generic prescription medicines (Rx) and non-Rx products (OTCs, food supplements and medical devices), with a 13.6% market share;
- **ranked 4th** in the segment of prescription (Rx) and over-the-counter (OTC) generic medicines, with a 4% market share;
- **leader** in terms of quantity of the following pharmaceutical dosage forms: ointments (20.4% market share), suppositories and pessaries (32,9% market share), powders for injection (63% market share);
- **leader** in the segment of generic medicines with medical prescription (Rx) and without medical prescription (OTC) sold in hospitals, with a 14.5% market share;
- **leader** in the segment of generic antiinfectives, with a 29.3% market share;
- **the Romanian manufacturer** of the complete range of essential antituberculosis medicines.

* According to District Sell-Out, Cegedim Customer Information, December 2021.

** According to the competition rules, the relevant market for a product comprises all the products/services that the consumer considers interchangeable or substitutable taking into account the characteristics, use and price of the product (according to Competition Council's Order no. 388 for the implementation of the instructions on defining the relevant market, published in the Official Gazette 553/ August 5, 2010).

Our company's performance in the external market

- strengthening our company's position as a **world leader** in the production of the active substance Nystatin;
- our Nystatin is the **USP reference standard** for more than 4 years;
- **representative offices** in the Republic of Moldova, Ukraine and Vietnam and a commercial office in Serbia;
- **the main Romanian exporter** of generic medicines in the Vietnamese market;
- the quantities of 6 products (sterile penicillins for injection) exported in the US **tripled**;
- **supplier of sterile antibiotics for injection** for the National Health System (NHS) by winning the tender organized in the Great Britain and Wales (the second year in a row) for 5 injectable antiinfectives.

Awards and affiliations

Awards

Romanian Investors Relations Association (ARIR)

"Excellent Investor Relations Communication" category: Diploma of Excellence and a perfect 10 mark – VEKTOR 2021, January 2022

For the third year in a row, Antibiotice Iași obtained the maximum grade in the VEKTOR ranking, made up of the Romanian Investors Relations Association (ARIR), which evaluates the communication with investors of the companies listed in the Romanian Regulated Market.

VEKTOR is the indicator of communication with investors of the listed companies and is calculated based on a methodology that includes 15 criteria according to the best international 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 among 77 listed companies.

Chamber of Commerce and Industry of Romania

Category: "Industry – Large enterprises – Manufacture of basic pharmaceutical products" – National Prize, 1st place, November 2021

The National Business Rankings (TNF) 2021 was organized taking into accounts indicators such as turnover, operating profit, efficiency of use of human resources and the capital employed. In achieving the TNF 2021, 768,372 financial–accounting balance sheets of companies active in Romania were analyzed, an increase of over 5% over the previous year. Antibiotice has been in the elite Romanian companies for over 20 years, ranking first in its field of activity, for excellence in business.

Chamber of Commerce and Industry of Iași

Category: "Industry – Large enterprises – Manufacture of basic pharmaceutical products" – National Prize, 1st place, November 2021

Romania Corporate Sustainability & Transparency Index 2021

Gold Level Recognition, December 2021

Antibiotice ranked GOLD in Romania Corporate Sustainability & Transparency Index (CST Index) 2021 with the 2020 Sustainability Report. Our company obtained a score of 93 points out of a maximum of 100 points, awarded on the basis of a complex analysis starting from a scorecard with 10 categories and 70 sustainability indicators. Romania CST index ranking organized by The Azores within the Best Practices in Corporate Sustainability event is the most important and complex ranking in the field of sustainability in Romania which assesses public information on sustainability and aims to identify the companies with the highest level of performance and transparency from the perspective of sustainable development.

Romanian CSR Awards 2021

Category: "Employee support" – Second place "Let's get back to normal", April 2022

The event is organized by CSR Media and offers recognition to the best corporate social responsibility (CSR) projects carried out by Romanian companies. The Romanian CSR Awards 2021 Gala initially lined up over 300 social responsibility projects, carried out by more than 120 national and multinational companies during 2021. The award rewards and recognizes the Antibiotice's efforts to protect the health of employees in the pandemic and to provide the people with the appropriate information in order to make the right decision on COVID vaccination. While,

for some industries, working from home was possible, Antibiotice continued to operate on its production site, without interruptions, protecting the health and safety of its employees.

Evaluation from the perspective of ESG indicators (environmental, social and governance). Bucharest Stock Exchange
February 2022

Antibiotice ranked 17th in the top 5%, at the pharmaceutical sub-industry level out of a total of 442 companies, at the international level, from the perspective of ESG (Environmental, Social, Governance) performance, a set of non-financial criteria used by investors to assess the activity and environmental and social impact, but also the governance of companies. The analysis based on ESG criteria was initiated by the Bucharest Stock Exchange, together with Sustainalytics, one of the global main providers of ESG ratings and analyses.

The ESG score obtained by Antibiotice in 2021 can be accessed on the BVB website, at https://bvbresearch.ro/ReportDashboard/ESGScores. ESG analysis reports are conducted independently by Sustainalytics, based on a collaboration with the Bucharest Stock Exchange initiated in 2020, and scores are calculated based on publicly available reports and information.

Affiliations

Chamber of Commerce and Industry (CCI) of Iași
The Iași Chamber of Commerce and Industry represents and supports the interests of the member firms and business community in Iași County. Antibiotice is a member of the Management Board of CCI Iași and Ioan Nani, our General Director, holds the position of First Vice President.

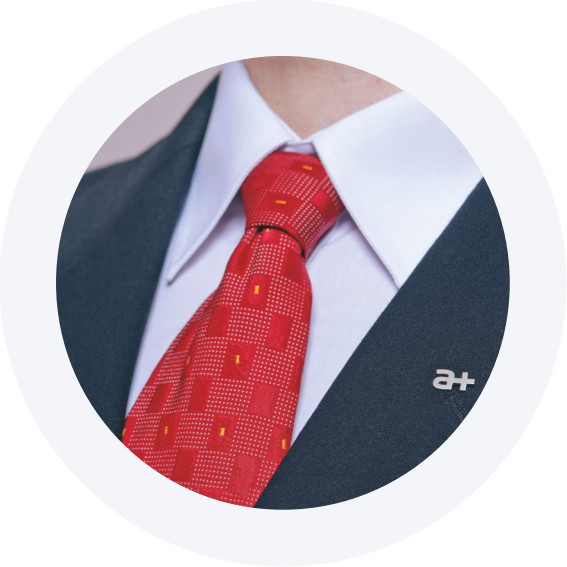
Romanian Association of the Self-Care Industry (RASCI)
RASCI brings together producers, importers and distributors of non-prescription medicines (OTC), food supplements and medical devices for personal use, active on the Romanian market.

Romanian Association of Industrial Drug Manufacturers (PRIMER)
PRIMER brings together the leading manufacturers of medicines with production facilities in Romania.

National Association of Romanian Exporters and Importers (ANEIR)
ANEIR promote the interests of the member firms.

Romanian Investor Relations Association (ARIR)
ARIR contributes to the implementation of best practices in communication with investors and corporate governance of the companies listed on the Bucharest Stock Exchange.

Romanian Medicines Serialisation Organisation (OSMR)
OSMR was established to implement the European legislation on falsified medicines and safety rules for packaging of medicinal products for human use issued on medical prescription (Rx), being responsible for implementing and managing the National Medicines Verification System (NMVS), a verification platform through which pharmacies or other stakeholders, such as wholesalers in Romania, can verify the authenticity of a product. At the regional level, Antibiotice is a member of the European Medicines Verification Organisation (EMVO) and Hungarian Medicines Verification Organisation (HUMVO).



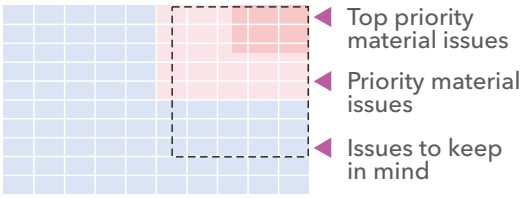
Materiality analysis

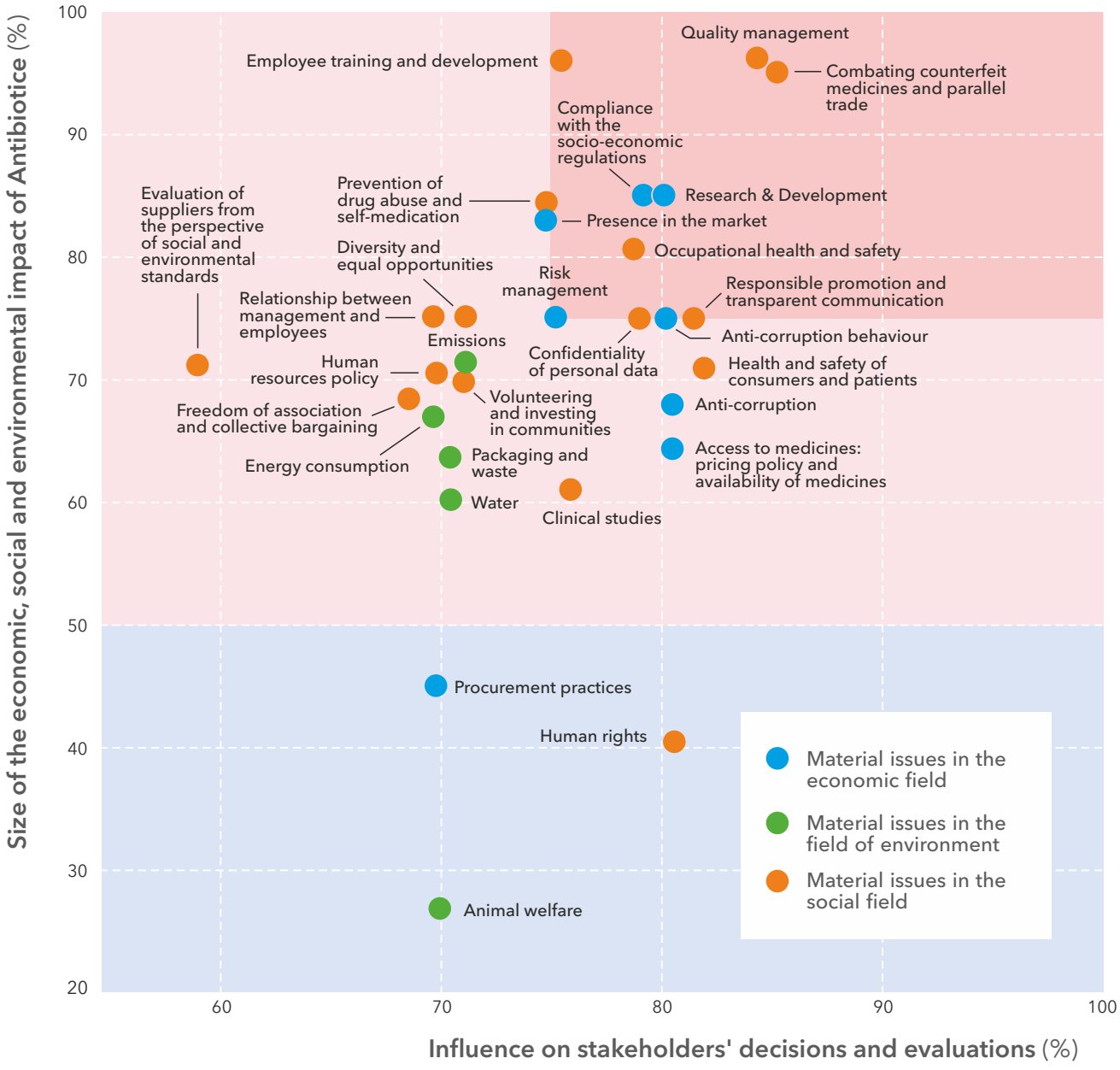
Materiality analysis is the process based on which the content of the sustainability report is developed. The process consists in identifying those issues/topics that substantially influence the decisions and evaluations of stakeholders and also reflect the economic, social and environmental impact of our company, whether direct or indirect, positive or negative. It is very important for the company that its partners have the opportunity to contribute, through effective participation, to the consultation process, with the transmission of ideas and solutions to achieve the common goals. The last materiality analysis was done in the period July – August, recording a total of 354 answers.

Material topics

Material topics, as they were evaluated by the stakeholders and Antibiotice management, are presented in the materiality matrix, with the positioning of these topics according to the degree of interest of the stakeholders and the scale of the company's impact.

Materiality matrix





Transparent communication with our stakeholders

Antibiotice wants to stay permanently connected to the needs and expectations of the company's stakeholders and therefore constantly communicates with them, through different channels. This requires a continuous and effective engagement with stakeholders, to whom our company provides information in a transparent manner, through the annual publication of its financial statements and sustainability report.

The tools and the frequency with which our company communicates with all the types of stakeholders as well as the issues of interest to them from an economic, social and environmental perspective, as they were revealed by the materiality analysis, can be found in the following table.

Our stakeholders	Communication channel	Frequency	Issues that concern them (as per the results of the materiality process)
Shareholders	Email, phone, teleconference, General Meeting of Shareholders (GMS)	Whenever they request it; GMS – 2 times a year	**Economic issues:** risk management, research & development, anti-competitive behaviour, compliance with the socio-economic regulations, access to medicines: pricing policy and availabilty of medicines **Environmental issues:** energy consumption, water, packaging and waste, emissions, animal welfare **Social issues:** 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 issues:** access to medicines: pricing policy and availabilty of medicines, presence in the market, risk management, research & development, anti-corruption **Environmental issues:** animal welfare, water, energy consumption packaging and waste, emissions **Social issues:** diversity and equal opportunities, human rights, relationship between management and employees, employee training and development, occupational health and safety
Internal suppliers	Email, phone, fax	Weekly	**Economic issues:** anti-competitive behaviour, risk management, research & development, procurement practices, compliance with socio-economic regulations **Environmental issues:** emissions, energy consumption, water, packaging and waste, animal welfare **Social issues:** 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	Communication channel	Frequency	Issues that concern them (as per the results of the materiality process)
External suppliers	Email, phone, teleconference	Weekly	**Economic issues:** research & development, procurement practices, access to medicines: pricing policy and availabilty of medicines, anti-competitive behaviour, anti-corruption **Environmental issues:** animal welfare, emissions, packaging and waste, energy consumption, water **Social issues:** confidentiality of personal data, combating counter-feit medicines and parallel trade, health and safety of consumers and patients, quality management, evaluation of suppliers from the perspective of social and environmental standards
Distributors	Email, phone, videoconference, meetings	Monthly/ quarterly meetings	**Economic issues:** research & development, compliance with socio-economic regulations, anti-competitive behaviour, anti-corruption, access to medicines: pricing policy and availabilty of medicines **Environmental issues:** energy consumption, water, animal welfare, packaging and waste, emissions **Social issues:** 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, phone, videoconference, regional and national scientific events	Meetings/visits of the medical representatives to quarterly scientific events	**Economic issues:** presence in the market, anti-corruption, research & development, anti-competitive behaviour, access to medicines: pricing policy and availabilty of medicines **Environmental issues:** animal welfare, energy consumption, water, packaging and waste, emissions **Social issues:** 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 bodies in this field/ industry representatives	Email, videoconfe-rences	Monthly	**Economic issues:** risk management, access to medicines: pricing policy and availabilty of medicines, anti-competitive behaviour, anti-corruption, compliance with socio-economic regulations **Environmental issues:** energy consumption, animal welfare, water, emissions, packaging and waste, **Social issues:** 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 issues:** procurement practices, risk management, compliance with socio-economic regulations, access to medicines: pricing policy and availabilty of medicines, research & development **Environmental issues:** energy consumption, water, packaging and waste, emissions, animal welfare **Social issues:** evaluation of suppliers from the perspective of social and environmental standards, health and safety of consumers and patients, clinical studies, quality management, combating counterfeit medicines and parallel trade

Our stakeholders	Communication channel	Frequency	Issues that concern them (as per the results of the materiality process)
Non-governmental organizations	Email, phone	Quarterly	**Economic issues:** presence in the market, research & development, procurement practices, anti-corruption, access to medicines: pricing policy and availabilty of medicines **Environmental issues:** energy consumption, water, packaging and waste, emissions, animal welfare **Social issues:** prevention of drug abuse and self-medication, responsible promotion and transparent communication, health and safety of consumers and patients, human rights, volunteering and investment in communities
Regulatory and control authorities	Email, phone	Whenever needed or they request it	**Economic issues:** risk management, access to medicines: pricing policy and availabilty of medicines, anti-competitive behaviour, anti-corruption, compliance with socio-economic regulations **Environmental issues:** energy consumption, animal welfare, water, emissions, packaging and waste **Social issues:** human rights, clinical studies, responsible promotion and transparent communication, quality management, combating counterfeit medicines and parallel trade
Central and local authorities	Email, phone	Whenever needed or they request it	**Economic issues:** compliance with socio-economic regulations, presence in the market, access to medicines: pricing policy and availabilty of medicines, research & development, anti-corruption **Environmental issues:** animal welfare, energy consumption, water packaging and waste, emissions **Social issues:** human rights, clinical studies, health and safety of consumers and patients, quality management, combating counterfeit medicines and parallel trade
Academic environment	Email, phone, videoconferences	Monthly	**Economic issues:** anti-corruption, anti-competitive behaviour, presence in the market, access to medicines: pricing policy and availabilty of medicines, research & development **Environmental issues:** packaging and waste, water, energy consumption, animal welfare, emissions **Social issues:** combating counterfeit medicines and parallel trade, volunteering and investment in communities, employee training and development, health and safety of consumers and patients, responsible promotion and transparent communication
Mass-Media	Email, phone	Bi-monthly	**Economic issues:** anti-competitive behaviour, risk management, compliance with socio-economic regulations, research & development, presence in the market **Environmental issues:** animal welfare, energy consumption, water packaging and waste, emissions **Social issues:** volunteering and investment in communities, health and safety of consumers and patients, clinical studies, quality management, combating counterfeit medicines and parallel trade

Communication channels available to stakeholders

Beyond the constant communication Antibiotice has with all its stakeholders, our company wishes them to constantly support it to improve its day-by-day activity. Therefore, we provide our stakeholders with various instruments through which they can send us recommendations, suggestions and complaints. The way in which our company handles the complaints is set out in the specific internal procedure. Any complaint is recorded and investigated to establish the cause of the non-compliance and to decide, as appropriate, the corrective or preventive actions needed for improvement. The summary of the investigation report, including the conclusion of the complaint (justified/unjustified and the set actions) are sent to the entity/person who sent the complaint.

At Antibiotice, the stakeholders can submit complaints/notifications:

- by phone: +40 232 209 000, +40 372 065 000
- in writing: at the Antibiotice headquarters, str. Valea Lupului nr. 1, 707410 Iași, România
- by fax: +40 372 065 633
- email: office@antibiotice.ro
- by Facebook: www.facebook.com/Antibioticelasi
- on our company website, www.antibiotice.ro, Contact/Complaints section: www.antibiotice.ro/contact/reclamatii/

Complaints received in 2021:

- **Quality – 84 complaints** (details in the chapter Business Sustainability by Improving the Integrated Management System);
- **Pharmacovigilance – 3 complaints** (details in the chapter Business Sustainability by Improving the Integrated Management System);
- **Serialization – 12 falsification alerts** (details in the chapter Business Sustainability by Improving the Integrated Management System);
- **Environment – 0 complaints** (details in the chapter Respect for the Natural Environment);
- **Governance – 0 complaints** (details in the chapter Strategic Planning and Performance Management);
- **Human Resources – 0 complaints** (details in the chapter Strategic Adaptation of Human Resources).

2.2. Financial evolution

In 2021, the turnover recorded by Antibiotice amounted to 368,422 thousand lei, by 8% higher than the value recorded in 2020.

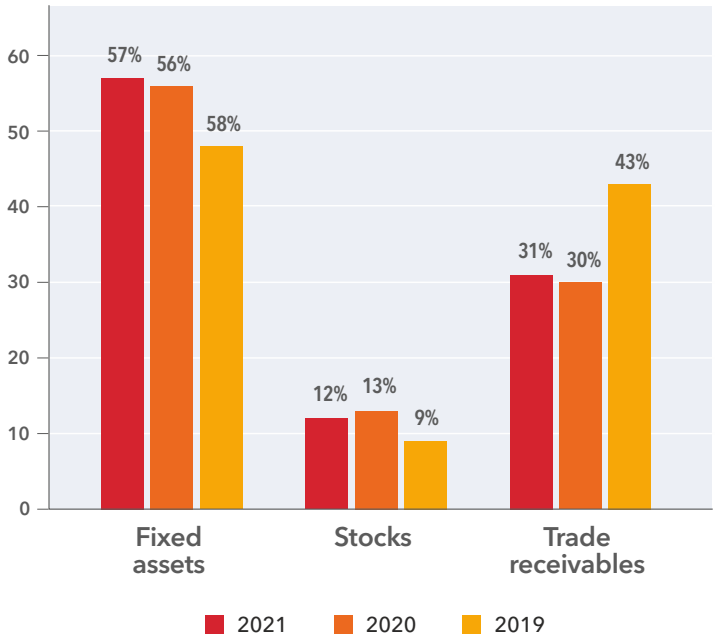
Our company continued in 2021 to strengthen internationaly its presence, so that from the whole turnover, the amount of 142,448 thousand lei represented the revenues from selling abroad our products.

Total assets recorded on 31.12.2021 were 895,338 thousand lei, by 4% higher than the value recorded on 31.12.2020, i.e. 863,000 thousand lei. The specifics of the activity carried out by our company involve the acquisition of state-of-art equipment and installations for the production areas which makes as the fixed assets to have a significant share in the patrimony. The increased share of fixed assets in total assets, the effect of investments made correlated with the increase in turnover reflected a favorable situation. Out of these, about 5% represented intangible assets, respectively know-how, research and development projects, software licenses.

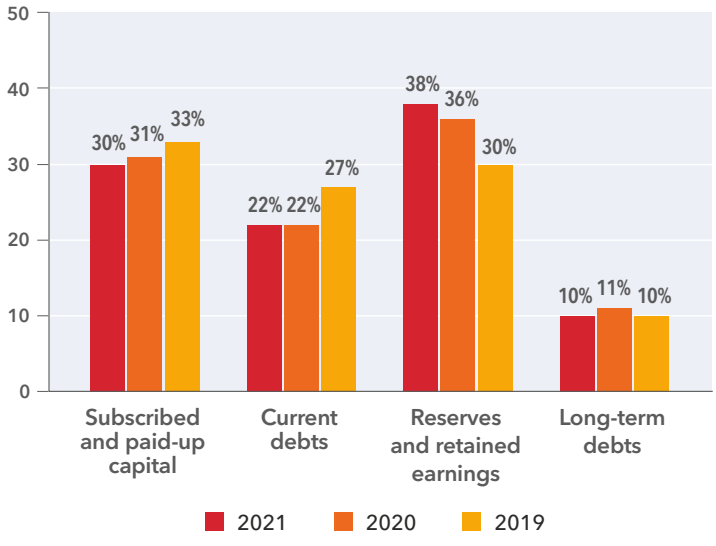
Stocks were correlated with the production and sales, taking into account the difficulties in their transport at the international level.

Correlated with the value of assets, the value of liabilities recorded on 31.12.2021 was 895,338 thousand lei, by 4% higher than the value recorded on 31.12.2020, i.e. 863,000 thousand lei. The share of current and long-term debt decreased by reducing the amount from the credit used to finance the working capital, from 87,522 thousand lei to 76,432 thousand lei, and by repaying the installments of the long-term loan contracted to finance the investments made in the new Ointments & Suppositorries Plant and for purchasing serialization equipment.

Evolution of the structure of patrimonial asset items



Evolution of the structure of patrimonial liability items



The activities carried out by Antibiotice have an impact on the entire value chain, from the consumption of raw materials, materials and utilities from strategic partners to the remuneration of employees, taxes and fees paid to the state and local budgets, as shown below:

Cash flow

Receipts and payments from **operating activities** generated a surplus of 44.4 million lei. Cash inflows from operating activities amounted to 373.3 million lei while the payments made for the operating activity amounted to 328.8 million lei, of which:

- payments to suppliers of goods and services worth 181 million lei;
- payments in connection with staff worth 106.6 million lei;
- payments of taxes, fees and assimilated payments in the amount of 37.7 million lei;
- bank interest payments amounting to 3.5 million lei..

From the investment activity in 2021, payments amounting to 29.05 million lei were recorded.

As regards the financing activity, long-term bank loan repayments and dividend payments of 2.1 million lei were recorded.

As regards the cash flow, the company's objective is to reduce the credits for financing the operational activity from one year to another. So that, on January 1, 2021, their value was 87.5 million lei. On 31.12.2021, we recorded a value of 76.4 million lei. In the years to come, our company intends to continue this strategy.

Taxonomy

An integral part of the European Commission's Action Plan for Financing Sustainable Growth, the Regulation (EU) 2020/852 establishes a European Union classification system for ecologically sustainable economic activities (taxonomy), which is being implemented in stages, in the years 2022 and 2023.

The Regulation is a key tool for the European Union to direct the capital flows towards sustainable investments and to create transparency in the capital market. It encourages an increased channeling of investments by companies, investors to the areas and activities where they are most needed for sustainable development. Therefore, the EU Taxonomy Regulation will play an important role in boosting the sustainable investments. According to the EU Taxonomy, Antibiotice SA has to identify how and to what extent its activities are classified as sustainable, as defined in the EU Taxonomy Regulation.

The EU Taxonomy Regulation sets six environmental objectives:

1. Climate change mitigation
2. Climate change adaptation
3. Sustainable use and protection of water and marine resources
4. Transition to a circular economy
5. Pollution prevention and control
6. Protection and restoration of biodiversity and ecosystems

On July 6, 2021, the European Commission formally adopted the Delegated Regulation 2078/2021, setting out the criteria defining the activities that contribute substantially to climate change mitigation and adaptation, the first two of the six environmental objectives.

Consumption efficiency in production processes, conservation of natural resources, reduction of carbon emissions are priority objectives of our company in terms of environmental protection and sustainable development.

Relative to the environmental objectives of climate change mitigation and adaptation, in 2021, the eligible activities and their value impact are summarized by the key performance indicators such as turnover, operating expenses (OPEX) and capital expenditures (CAPEX) presented below.

Eligible activities	Key performance indicators		
	Turnover	CAPEX	OPEX
Water supply, sewerage, waste management	4.05%	2.95%	1.1%
Transport	1.4%	-	1.4%
Total	5.45%	2.95%	2.5%

2.3. Stock market evolution

Shareholding

Antibiotice SA is a trading company in which the Romanian state is the majority shareholder, holding through the Ministry of Health 53.0173% of the subscribed and paid-up capital. Its main activity is the manufacture of basic pharmaceutical products as per the NACE 2110. The Antibiotice shares (ATB symbol) are traded in the Premium category of the Bucharest Stock Exchange (BVB).

Antibiotice SA became a public company in April 1997, when it issued at BVB dematerialized, freely transferable shares for trading. The first transaction of the ATB shares was recorded on April 16, 1997, at a reference price of 0.3500 lei/share. The historical maximum was reached on July 10, 2007, at the price of 2.1700 lei/share while the historical minumum of 0.0650 lei/share was recorded on June 8, 2000.

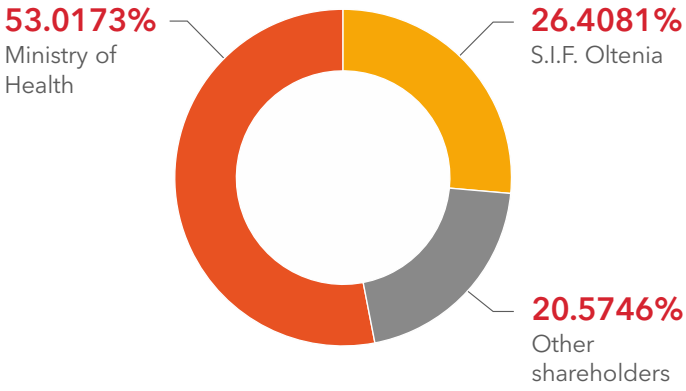
The register of shareholders and Antibiotice shares has been maintained by Depozitarul Central SA Bucharest.

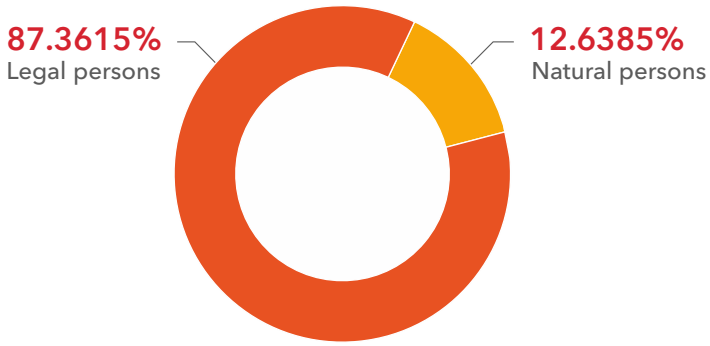
Top Antibiotice shareholders as of December 31, 2021
(extract from the Register of Shareholders)

	Percentage of shares held (%)
Ministry of Health (*)	**53.0173**
S.I.F. Oltenia (*)	**26.4081**
Other shareholders (42,285 shareholders)	**20.5746**

* Significant shareholders, according to the Law no. 297 of 28.06.2004, Art. 2, Par. 1

Ownership breakdown





Antibiotice in the 2021 capital market

Stock market capitalization of Antibiotice on December 31, 2021 was 406,830,852.24 lei. The minimum price of an ATB share was 0.4800 lei in 2021. The share price rose up to a maximum price of 0.6080 lei/share.

In 2021, Antibiotice and BRK Financial Group, one of the most active brokers in the structured products segment traded on BVB, concluded a market making contract. Colaboration with the BRK Financial Group aims to create added value for the Antibiotice shareholders by improving liquidity and minimizing volatility.

The Antibiotice shares are included in BET-BK index (which includes the shares of the 30 most liquid companies admitted to trading on the regulated market managed by BVB), and BET-Plus index (which includes the Romanian companies listed on the BVB market - with the exception of financial investment companies – which meet the minimum selection criteria).

Antibiotice shares – ATB / Regular Market

	2017	2018	2019	2020	2021
Number of shares	671,338,040	671,338,040	671,338,040	671,338,040	671,338,040
Stock market capitalization (thousand LEI)*	361,180	326,942	341,040	326,270	406,831
Stock market capitalization (thousand EUR)*	77,511	70,100	71,370	66,935	82,211
Stock market capitalization (thousand USD)*	92,813	80,259	79,873	82,163	93,022
Total traded value (million LEI)	12	9	15	14	44
No. of traded shares	21,113,565	17,109,263	30,364,292	27,085,005	80,534,368
Opening price (LEI/share)	0.5200	0.5780	0.4800	0.5120	0.4940
Maximum price (LEI/share)	0.5920	0.5780	0.5260	0.5550	0.6080
Minimum price (LEI/share)	0.5200	0.4550	0.4500	0.4130	0.4800
Price at the end of the period (LEI/share)	0.5380	0.4870	0.5080	0.4860	0.6060
Average price (LEI/share)	0.5585	0.5028	0.4851	0.5079	0.5913
Earnings/share (LEI/share)***	0.0500	0.0511	0.0459	0.0418	0.0446
Gros dividend/share (LEI/share)**	0.026552598	0.009991506	0.029879738	0.00330631	0.00319809
Dividend yield****	4.59%	2.05%	6.20%	6.5%	0.65%
Dividend distribution rate*****	53%	20%	65%	8.4%	7.2%

* Calculation based on the share price in the last trading day of that year
** Proposed dividend
*** Calculation of the earnings per share is based on the net profit of each year
**** Dividend per share/price of the share in the first trading day of each year
***** Dividend distribution rate = (total number of shares x gross dividend per share)/total net profit

Dividends

From the accounting profit worth 29,939,404 lei in the fiscal year 2021, the amount of 27,792,403 lei will be allocated to other profit reserves, of which 25,302,090 lei representing fiscal facilities for the profit invested in technological equipment, electronic computers and peripheral equipment, as well as in computer programs, according to art. 22, para. 5 of Law no. 227/2015 on the Fiscal Code, and 2,490,313 lei representing fiscal facilities for research & development activities.

Total dividends for the financial year 2021 which are to be distributed, in value of 2,147,001 lei, represents the difference between the accounting profit in the amount of 29,939,404 lei and other profit reserves provided by law, in the amount of 27,792,403 lei. The dividends for the fiscal year 2021 will be paid starting with 03.10.2022.

According to the dividend policy, Antibiotice is consistent with the policies of increasing the turnover, reducing costs and launching in the market new products at more affordable prices, leading to savings both for the population and to the state budget, with a special focus on the investment program.

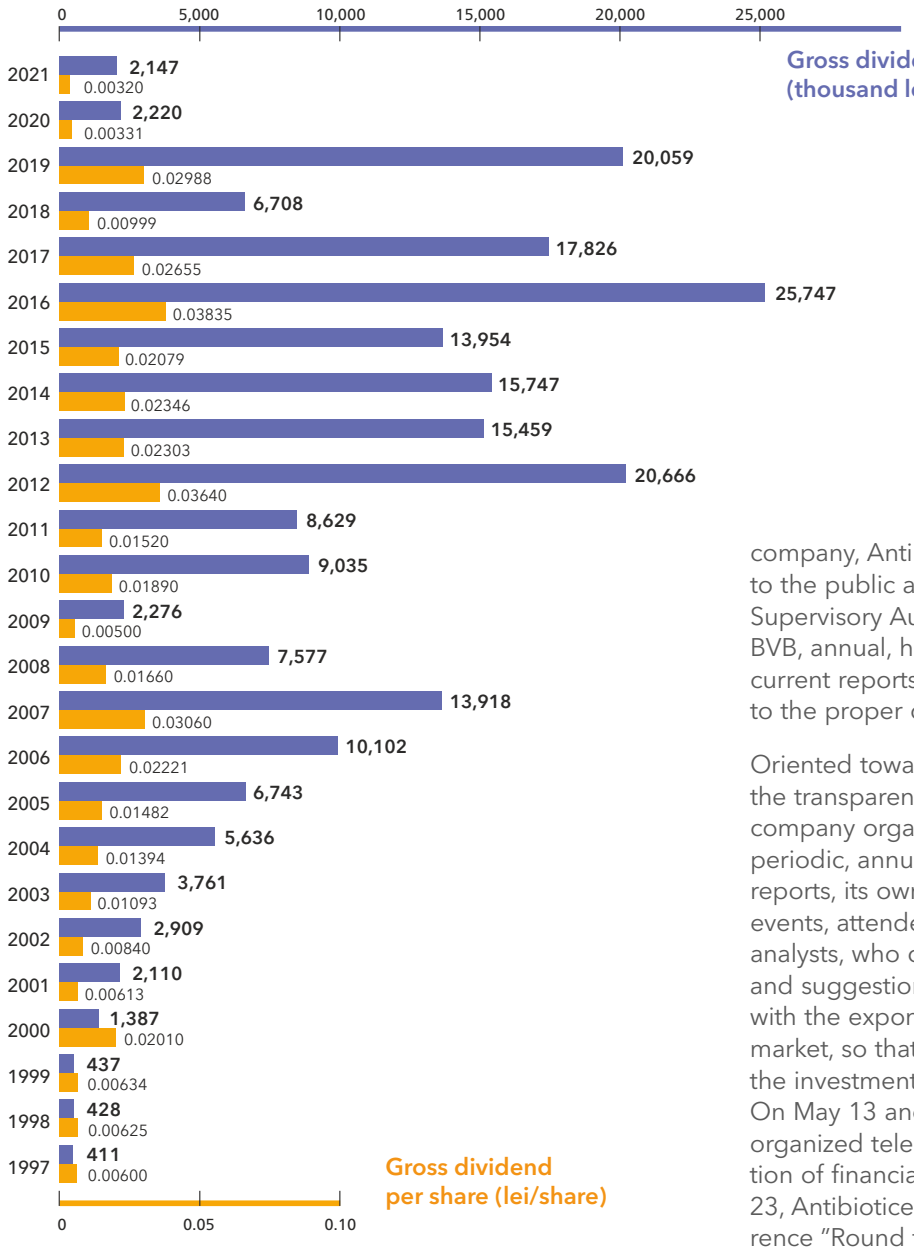
During 2021, a number of 80,534,368 shares in value of 43.65 million lei (8.87 million Euro, 10.51 million USD) were traded, with an average price of 0.5420 lei/share. In 2021, our company paid dividends in value of 2,102,442.59 lei for the fiscal years 2017, 2018, 2019 and 2020.

Dividend history (2017 – 2018 – 2019 – 2020)

Period	Net dividends							Date on which the payment of dividends ceases
	Due	Paid (lei)				Unclaimed dividends on 31.12.2021		
		Until 31.12.2020	01.01÷31.12 2021	Total	%	lei	%	
2017	17,588,680	16,160,171.48	15,528.83	16,175,700.31	91.97	1,412,979.79	8.03	13.09.2021
2018	6,612,624.05	6,069,182.87	14,293.79	6,083,476.66	92.00	529,147.39	8.00	in progress
2019	19,811,039.75	18,114,220.03	60,504.82	18,174,724.85	91.74	1,636,314.90	8.26	in progress
2020	2,840,868.50	–	2,012,115.15	2,012,115.15	70.83	828,753.35	29.17	in progress

Payment of the dividends for the fiscal years 2017, 2018, 2019 and 2020 has been made through the Depozitarul Central SA – Bucharest and, implicitly, through the CEC Bank – the Paying Agent.

Volume of gross dividends and gross dividend per share



Investor Relations

The constant communication between our company and its investors is maintained through the Investor Relations Department. This process allows the knowledge of the operational activity, strategy and the perspectives of the business, in order to carry out, in an informed way, a fair evaluation of the company. Being a listed company, Antibiotice makes available to the public and submits to the Financial Supervisory Authority (ASF), respectively BVB, annual, half-yearly, quarterly and current reports, as well as documents related to the proper conduct of general meetings.

Oriented towards developing and increasing the transparency towards shareholders, the company organizes immediately after the periodic, annual and half-yearly financial reports, its own meetings and presentation events, attended by interested investors and analysts, who can send questions, opinions and suggestions. This ensures a dialogue with the exponents of the Romanian capital market, so that they gain a sufficient basis for the investment decision-making process. On May 13 and July 30, 2021 our company organized teleconferences for the presentation of financial statements. On November 23, Antibiotice organized also the conference "Round table with the Antibiotice management" to maintain a permanent dialogue between management, investors and analysts. All the documents related to the smooth running of the mentioned events were published in accordance with the legislation in force.

The maximum grade obtained in the evaluation of the VEKTOR indicator of the Romanian Investor Relations Association (ARIR) for the third year in a row in 2021 is a recognition of the active, transparent and constant communication of our company with the investors.

03

Actions and results in 2021

3.1. Strategic adaptation of the human resources

The long-term success of the company depends equally on its valuable employees and on ensuring a sustainable growth that can only be achieved when those around it grow with the organization. That is why Antibiotice is committed to being more than just a business – to being a reliable partner and part of the solution – working together with stakeholders to overcome the biggest challenges, working together on the same path, under the umbrella of a common goal.

Guaranteeing the respect for the fundamental human rights is an essential principle of Antibiotice that characterizes the relationship with its employees. The company ensures, through the applicable policies and procedures, a working environment that encourages the team spirit, the personal and professional development, offering employees decent working conditions, an adequate salary system, operating in conditions of high standards of quality, safety and performance. Antibiotice guarantees the right to free speech, the freedom of association and collective bargaining for all employees, fighting any form of discrimination and ensuring a balance between the personal life and the professional life.

Antibiotice's people

The organizational culture of Antibiotice is oriented towards innovation, performance and the satisfaction of all those who are business partners. Our mission of doing more and better for people's health is not easy, but together with highly motivated and involved employees, this mission is supported every year by the achievement of the set goals.

Within Antibiotice, the following pillars of the organizational culture have been identified, which define the way in which the company collaborates both internally, with employees and externally, with its partners as well as with the community:

1. "A company worth working for" and "We live healthy in a healthy company";
2. "Working for life for a lifetime";
3. Antibiotice, a friendly and responsible brand;
4. A company oriented towards knowledge and performance;
5. Romanian tradition and continuity.

45
the average age of Antibiotice employees

64%
of the top management positions are held by women

In 2021, there were no incidents of discrimination

The indicators of the Human Resources Unit in 2021, aligned with the directions of the Strategic Organization and Development Plan, were established taking into account the adaptation of human resources to the medium- and long-term development strategy. These objectives aimed at:

- completing the staffing schemes, training the employees to get the skills needed to achieve goals and increasing the employee involvement;
- optimizing the salary-related expenses;
- the continuous development of employees through training programs;
- improving the organizational climate and orienting the organizational culture towards innovation and performance;
- modernizing and implementing the digitization programs in the Human Resources Unit.

In 2021, the contract was signed for the acquisition of a human resources software that represents a single application with several modules, for the most important activities in the company. It manages the complete evolution cycle of the employee, from the recruitment to the retirement: data management, time management, payroll, career management, performance management, training and coaching.

The application streamlines the work of the human resources specialists and helps digitize the processes of recruitment, staff management, timekeeping and payroll by using modern technologies in the field of human resources management tools.

During 2021, after signing the contract, the important stages were planned and a project implementation schedule was made.

Also, in 2021, the specific processes of human resources were audited, the technical specifications for each module were drawn up. In 2022 the data export and implementation will be done.

The team of specialists working in the research, development and manufacture of medicines and active substances includes pharmacists, physicists, biologists, chemists, chemical engineers, laboratory operators, chemical operators, as well as highly qualified specialists who manage the support activities: quality assurance and control, regulatory affairs, engineering and service, economics, marketing, sales, procurement and logistics.

Of the 1,370 Antibiotice employees at the end of 2,021, 48.3% are higher education graduates, 51.7% are secondary education graduates and 2.4% have completed doctoral studies. At Antibiotice, all activities are performed by employees with a contract of employment. Thus, most of the employees (1,277) work in the significant location of operations in Romania, at the medicines factory in the City of Iași, Iași County, where the headquarters are located (92.3%).

Some of the staff works at the area representative office in Bucharest, the capital city of Romania, and the staff with sales and promotion duties (93 employees) works across the country, in different cities from all regions of Romania (6.8%). A total of 7 people work in the international sales offices in Chisinau, the Republic of Moldova, in Kyiv, Ukraine and Hanoi, Vietnam, as well as in the sales office in Novisad, Serbia.
The data herein relate only to the company's employees in Romania.

Number of employees by gender, type of contract and working hours, on December 31, 2021

	Men	Women	Total
Employees with an indefinite employment contract	604	735	1339
Employees with a fixed-term employment contract	22	9	31
Full-time employees (8 hours/day)	626	742	1368
Part-time employees (4 hours/day)	2	0	2

According to the provisions of the company's internal regulations, the employer commits to consult with the union regarding the decisions that may substantially impact the rights and interests of the employees, in accordance with the term provided in the Labor Code, section 5.

If the company has to carry out collective redundancies, it also has the obligation to initiate consultations with the union, in due time, under the conditions provided by law in order to reach an agreement, at least on the methods and means of avoiding collective layoffs or reducing the number of laid-off employees, mitigating the consequences of layoffs by applying some social measures aimed, inter alia, at supporting laid-off employees, offering them training for requalification. The notice periods and the provisions for consultation and negotiation are regulated by the collective labour agreement.

In Romania, the collective negotiations between the trade union (representing the interests of employees) and the employer to establish the working conditions, employment, etc., is a legal obligation. At Antibiotice, the results of the negotiations between the Free Antibiotice Union and the employer are included in the Collective Labor Agreement concluded at company level. Each employee of our team is the beneficiary of the provisions of the collective agreement, regardless of the type of the employment contract, the work schedule or whether or not he or she belongs to the union. The Collective Labor Agreement is valid for two years (with the possibility of its extension only once, for a maximum period of 12 months).

The Free Antibiotice Union is the social dialogue partner of the company's employer, participating, as a representative of the employees, in the negotiation of the clauses included in the Collective Labor Agreement. Any employee of the company can become a member of the union. The Free Antibiotice Union is part of the Federation of Free Trade Unions in Chemistry and Petrochemistry (which is a member, in turn, in the National Trade Union Confederation "Cartel ALFA"). 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 (in compliance with the methodologies required by applicable law). All the employees of the company benefit from the provisions of the Collective Labor Agreement.

Percentage of the union members

	2021	2020	2019
The percentage of the union members, out of the total employees	68.61%	73.52%	78%

Diversity and the equal opportunities

Diversity in the workplace means respecting and capitalizing on skills, valuing the potential each team member brings to the internal processes. Antibiotice wants all employees to benefit from a diverse and inclusive work environment, which provides them with equal rights and opportunities.

Distribution of staff by age, gender and position in the company, on December 31, 2021

	Men				Women			
	< 30	30-50	> 50	Total	< 30	30-50	> 50	Total
Top management	0	4	1	5	0	1	4	5
Middle management	0	14	6	20	0	29	12	41
Specialists/professionals	43	351	207	601	64	414	220	698
Total	43	369	214	626	64	444	236	744

Number of employees with disabilities, on December 31, 2021

	Men	Women	Total
Specialists	4	2	6
Total employees with disabilities	4	2	6

In 2021, there were no complaints regarding human resources issues

According to the Internal Regulations, the principle of equal treatment and equal opportunities for all employees operates in the company's labor relations.

In order to comply with the principle of non-discrimination at Antibiotice, the following deeds are prohibited:

- conditioning the filling of a position, by announcement or competition, by belonging to a race, nationality, ethnicity, religion, social category or disadvantaged category, age, gender or sexual orientation or by the convictions of the candidates;
- the discrimination against any employee on the grounds that he or she belongs to a race, nationality, ethnic group, religion, social group, or disadvantaged group, or because of his or her beliefs, age, gender, or sexual orientation;
- any conduct aimed at creating an atmosphere of intimidation, hostility, discouragement or negatively impacting the situation of employees in the workplace, in terms of professional promotion, remuneration or income of any kind, or the access to the professional training and to the further education, in case of their refusal to accept an unwarted behavior related to sexual life.

Reporting tools for employees

Antibiotice intends also to implement, starting in 2022, the regulation and policy on the equal opportunities and treatment between women and men in the field of harassment at work. By implementing these documents, measures will be put in place to prevent and fight discrimination and harassment in the workplace.

Regarding the complaints/notifications that can be received from the employees, according to the internal regulations, they can contact directly the Human Resources Department concerning the requests, the specific procedure being applied for solving them.

1 The requests/complaints to be analyzed are submitted to Human Resources Department, which will forward them to the commission and the General Secretariat.

2 In order to analyze and resolve the individual requests or complaints of the employees, a commission is set up in the company composed of:

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

3 The Commission usually meets at the end of the week when convened by the representative of the Human Resources Department, who forwards to each member of the committee the issues to be considered.

4 The analysis committee operates according to the following principles:

- observance of employees' rights in accordance with the legal provisions, the applicable collective labor agreement and the individual employment contract of each employee;
- promotion of the employees' interests in relation to wages, working conditions, working time and rest, job stability and any other professional, economic and social interests related to employment relationships;
- equal treatment for all employees and equal opportunities.

5 The employees who have submitted documents for debate may also attend the meeting for the analysis of requests/complaints, as they have the opportunity to present relevant arguments.

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

The anonymous complaints are considered and analyzed according to the same procedure as the signed complaints.

These notifications/complaints can also be sent to the following e-mail addresses: solicitari.angajati@antibiotice.ro and/or resurse.umane@antibiotice.ro . They follow then the same settlement procedure described above. On the company's website, www.antibiotice.ro, a form is available through which such notifications can be submitted, in the section Contact – Reclamații. The section can be accessed by any interested party wishing to report or submit complaints (general public, specialized public, etc.).

Remuneration of the employees

Remuneration policy is an extremely important element in our company, as it is the basis of the way in which employees are rewarded for the work they perform.

Remuneration policy allows also the articulation of the criteria and the way in which the salaries are established within Antibiotice by taking into account the company's philosophy, values and fundamental principles,, such as fairness and rectitude. For the work performed under the conditions provided in the Collective Labor Agreement, each 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 qualification, importance, complexity of the duties that belong to the position in which he or she is employed, with the training and professional competence.

The salary income includes the basic salary with the related allowances and bonuses. The salary within the company is made in direct agreement with the fulfillment of the performance indicators, established by reference to the Management Plan of the company and by correlation with the specific duties of each job.

Any discrimination based on gender on all elements and conditions of pay is prohibited for equal work or work of equal value. Attracting and retaining employees, able to support the company's vision in the medium and long term, as well as the low availability of specialists in the labor market, led the Antibiotice management to create a unitary and modern payroll system, with effect from 2019–2022.

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

Ration between gross basic salary*/ gross remuneration of women compared to men, by positions and categories of staff (%)**

	The ratio between the basic salary of women and men	The ratio between the remuneration of women and men
Top management (executive management)	90.92%	90.98%
Middle management (managers that report directly to executive management)	90.90%	89.24%
Specialists	92.40%	86.42%
Total employees	104.32%	98.55%

The calculation method = Average gross basic salary*/gross remuneration** of women in the category, compared to the average gross basic salary/ gross remuneration of men in the category

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

** The gross remuneration is the base salary, plus the additional amounts paid to the employee (seniority, overtime, bonuses, benefits, transportation, allowances, etc.).

Recruitment policy and employee retention

The recruitment and the measures taken by Antibiotice to ensure the employee retention are key aspects of the human resources policy. Identifying and selecting the most suitable employees for open positions within the company, but also maintaining them in the medium and long term are processes with a significant impact on the quality of employer and, implicitly, on the growth and success of the company.

Within Antibiotice, the recruitment and selection for vacancies is carried out according to the specific internal procedure, which provides in detail the methods and channels of recruitment. The objectives of the recruitment process are set out in the annual staff recruitment plan.

The company ensures its necessary workforce through a transparent process: competition (written exam, interview), as appropriate. The recruitment is done in compliance with the legal provisions in the field, through the Human Resources Department and/or through specialized recruitment companies.

In 2021, 105 people were employed (64 higher education employees and 41 secondary education employees), and 117 employees ceased their activity. The staff turnover rate was 4.89% (below the planned level of 5%). The employees who left the company are included in one of the following categories:

- retirement (32)
- resignation (58)
- termination upon expiration – individual fixed-term employment contract (3)
- termination of individual employment contract during probationary period (8)
- termination of contract with the agreement of the parties (8)
- death (1)
- disciplinary termination of the employment contract (7)

Staff turnover, related to voluntary departures

	2021	2020	2019	2018
Staff turnover*	4.89%	3%	4.60%	4.37%

* The method of calculation = the ratio between the number of employees who voluntarily left Antibiotice without full-term retirement (69) and the average number of employees in 2021 (1410).

Category	New employees		Employees who left the company	
Gender	**No.**	**Rate (%)**	**No.**	**Rate (%)**
Women	55	52.38	52	44.44
Men	50	47.62	65	55.56
Total	105	100	117	100
Age group	**No.**	**Rate (%)**	**No.**	**Rate (%)**
<30	36	34.3	18	15.4
30-50	57	54.3	59	50.4
>50	12	11.4	40	34.2
Total	105	100	117	100

* The rate for each category is calculated at the average number of staff for 2021 (1,410 employees)

Antibiotice actively collaborates with three generations of employees who share their experience and knowledge in the coaching and mentoring programs, established internally, in all areas of the company's activity. Young people are also given the opportunity to develop a successful career in the company. In this respect, partnerships are being developed with pre-university and university education units to facilitate their access to the information they need to make the best decisions when it comes to their future.

4.89%
Staff turnover rate

Perform a+

The Perform a+ program is a partnership program initiated in 2016, in collaboration with the "Grigore T. Popa" Iași University of Medicine and Pharmacy, the Faculty of Pharmacy, which was expanded in 2020 by collaborating with the Faculty of Chemistry within the "Alexandru Ioan Cuza" University of Iași, and with the Faculty of Chemical Engineering within the "Gheorghe Asachi" Technical University of Iași. This project is part of the platform of education and continuous communication that Antibiotice develops with educational institutions in the areas of research, pharmaceutical marketing and responsibility towards patients, the environment and the community.

Perform a+ promotes and instills in the final year students / graduates (residents, doctoral students) the passion for the pharmaceutical industry and the activities involved in a career in the field. At the same time, the project offers the possibility to complete the knowledge acquired during the years of university study, with theoretical and practical sessions, supported through mentors appointed from among the company's employees. The integration and application of the acquired knowledge materialize at the end of the courses in the presentation, in front of colleagues and company representatives, of an individual scientific project that highlights the knowledge, passion and inventiveness of young aspirants to a career in pharmacy.

The Perform a+ program was a successful cooperation with academia and a way to attract and develop pharmacists (final year students, residents and PhD students) in the generic medicine industry in 2021. In the Perform a+ program, 6th edition, since 2021, 21 young people participated, and 7 of them were subsequently employed in Antibiotice. As a result of the 6 editions of the Perform a+ program, a total of 32 graduates were hired, who completed the teams of specialists in Research and Development, Regulatory Affairs, Portfolio Management, Quality Control and production departments.

Partnerships with pre-university education institutions – "Petru Poni" Technological High School Iași and Technological High School of Mechatronics and Automation

Since 2020, Antibiotice has concluded a new form of partnership with pre-university education institutions – dual education – which aims to train for a period of 3 years, 15 pupils for the profession of chemical operator for medicinal products and cosmetics and 10 pupils for the profession of electrician for low voltage networks. The collaboration in this project involves facilitating practical training, but also material support for pupils through scholarships awarded according to the performance criteria included in the contracts and encouraging them to avoid dropping out of school. In 2021, with all the constraints related to managing pandemic conditions, the company focused on the online pupil participation in the schooling program and the part of the program involving the organization was adapted to the new study conditions of the pupils.

Employee development and integration

The employee training and development are essential for the company's medium and long-term success. Beyond the fact that all programs are meant to improve the knowledge and skills of the team, the professional training of employees contributes significantly to increasing the productivity and performance of the company, but also to motivating and improving their satisfaction. The training and development programs that Antibiotice implements come to support the commitment to invest in people and to constantly offer them career development opportunities that will allow them to grow with the organization. This also impacts the employee retention.

The training programs made available to the company's employees include internal training programs, carried out with the help of internal lecturers, specialists in their field of competence and also professional development programs carried out through external lecturers. Within the company, the training and formation of employees is carried out according to the provisions of the internal procedure for training with external lecturers (through the Human Resources department) and the procedure for staff training (system procedure performed by the Quality Assurance department).

The latter aims to comply with the rules of the good manufacturing practice (GMP) and the requirements of quality management systems – ISO 9001: 2015, the environment – ISO 14001: 2015 and occupational health and safety – ISO 45001: 2018. For 2021, the training plan with external lecturers had as priority objectives the specialized professional development, the acquisition of knowledge and the deepening of the specific knowledge in their field of activity.

As the restrictions caused by the COVID-19 pandemic and the state of alert were in place in 2021, some of the trainings were organized online. Thus, a series of programs for employees were organized online by various training providers, and allowed them to adapt to the context of the pandemic: telecommuting, change management, situational leadership, emotional intelligence, training beliefs and convictions, creativity and solving problems in change management, etc.

Strategies and measures to increase the employee motivation

Adapting the reward system and creating a policy of financial and non-financial motivation for the employees have the role of increasing the employee satisfaction and improving the staff retention. The job ranking project initiated in 2019, which is the basis of a modern salary system was followed by the salary level alignment program, in several stages.

The compensation and benefits system is analyzed and adapted annually according to the realities of the labor market and includes both the fixed component, based upon ranking and the variable component, directly correlated with performance for certain categories of employees (top management, internal and international sales).

In 2021, the company started a reconsideration analysis of the evaluation criteria of the company's positions, in order to update the ranking system in correlation with the changes in the organizational structure and with the duties established according to the changes in technology and procedures. Our company established the positions for which the salary packages with a variable component and other benefits correlated with objectives, indicators and performance criteria arising from company-level objectives will be applied since 2022.

Employee benefits

At Antibiotice, the benefits package offered to employees strengthens the belief that the company's people are the essential elements and the most valuable resource our company has on its way to sustainable growth. Whether we are talking about bonuses, extra days off or financial support

in case of important events in the employee's lives, we cons-tantly invest in the company's people to support their present and future well-being.

The company grants each employee, regardless of the type of contract or seniority (under or over 1 year) a standard package of extra salary benefits (some of which are negotiated and established by the Collective Labor Agreement (CCM) at company level.

The standard package of benefits is offered to employees regardless of the type of contract (full-time or part-time):

- Easter bonus;
- Christmas bonus;
- March 8 bonus for the female employees, on the International Women's Day;
- profit sharing (a share of the company's net profit), as a performance bonus granted to employees, annually, according to criteria such as work results, achievement of objectives and discipline;
- meal vouchers;
- special meals or drinks necessitated by exceptional working conditions;
- free transport by company buses, within the municipality of Iași, to/from work;
- free access to the parking spaces at the company's head-quarters, for the employees who drive their personal or company car as a means of transport;
- additional days off (according to criteria such as seniority, working conditions, staff categories)
- paid days off for special events in the family of the employee (marriage, birth, death) or in other situations;
- financial support on the occurrence of events in the employee's private life (death of a family member, birth of a child (both for women and men).

Additional benefits

Depending on the performance criteria or the specifics of the activities carried out, some employees receive additional benefits, such as:

- performance bonus, for employees included in the objective management system (MBO), according to the degree of fulfillment of the indicators;
- private health insurance for 252 employees, according to pre-established conditions (a pilot program started in 2018, with 136 employees)
- life insurance and accident insurance;
- company mobile phone;
- company laptop;
- company car;
- professional training programs paid for by the employer.

Bookster Read'n'Roll! books on the shelves of the Library a+

Antibiotice offered as a benefit, free of charge, to its employees passionate about knowledge, the possibility to access, starting with October 30, 2020, the Bookster.ro platform. The objective of the project „Bookster Read'n'Roll! books on the shelves of Library a+" is to encourage reading and gain new knowledge, by facilitating the access of the Antibiotice employees and their families to books, articles, podcasts (from personal and professional development to hobbies and fiction). Bookster is a public library that lends books to company employees through its online platform. The borrowed books are then delivered to employees free of charge at the office. At the end of 2021, 219 employees (15.98%) had an account opened on Bookster.ro.

Improving the organizational climate and orienting culture towards innovation and performance

Because the organization wants to improve the work environment and its transformation into a company that most employees and potential employees consider to be worth working for, every two years, an extensive study on the organizational climate is conducted. Thus, the evolution of the indicators regarding the workplace atmosphere, the concern of the managers for ensuring a favorable climate for collaboration, the improvement of the results and, last but not least, the system of desired/practiced values at company level are followed.

In 2021, between the months of June and July, the Human Resources department conducted an organizational climate study called "Implications of managerial activities on strengthening performance-oriented organizational culture, improving the working atmosphere and the satisfaction of the human resources during the pandemic. Questionnaire-based opinion research", attended by 66.8% of the employees.

The main objectives of the study were to assess the perception of the Antibiotice employees regarding:

- the specific measures adopted by the Antibiotice management during the pandemic and comparisons with the situation of Romanian companies;
- the identification of particular aspects related to the recruitment process and the abilities of the selected candidates at Antibiotice compared to the situation of Romanian companies
- promoting the value system, an essential part of the organizational culture
- the managers' profiles in terms of their capacity and concern to ensure, during the pandemic, a work climate that allows the orientation towards the organizational performance and the personal satisfaction of the employees;
- what do the employees at Antibiotice appreciate compared to what other Romanian companies' employees appreciate about those companies and whom do they want to work for?
- the employees' satisfaction with the positions held;
- the quality of the interpersonal collaboration among employees of the same department or among different divisions, units and departments.

As compared to the evaluations of the previous years, the employees perceived the work carried out by each of them as important as their own results have an impact on the others. The indicator of the managers' profiles in terms of their capacity and concern for ensuring a climate that allows the orientation towards organizational performance and human resources satisfaction increased in 2021 compared to 2020, from 8.1 to 8.4. In 2021, the degree of satisfaction with the positions occupied decreased slightly compared to 2020, from 8.5 to 8.3, but it is above the target value of at least 8.

In addition to the study, a plan to strengthen the organizational culture was developed, with measures planned until the end of 2023, grouped in the following areas:

- the development of interpersonal collaboration in order to achieve, in the best conditions, the job duties;
- the internal communication of the objectives and performance indicators to the teams involved in achieving them;
- increasing the degree of employee satisfaction with the positions held;

- the development of skills oriented towards the optimization of the organizational climate, mainly in the management area, which should ensure the orientation towards performance and the satisfaction of the human resources;
- updating the values of the company's organizational culture and adopting measures to consolidate them and promoting among employees the fundamental principles underlying the managerial guidelines.

The employees who did not work for at least six months during the year (63) and the employees with a suspended employment contract (20) were not assessed. In 2021, 57 employees were promoted, of which 26 were women (46%).

The professional development of the employees is especially important for the company, so the objective regarding the number of hours of continuous professional training is 34 hours/employee.

Proportion of employees (out of the total number of employees) who benefited from a performance evaluation and a review of the career development plan, by gender and category of employees

Performance appraisal and career development plan	2021*				2020			
	Men		Women		Men		Women	
	No.	%	No.	%	No	%	No.	%
Top management (executive management)	5	0.36	5	0.36	5	0.35	5	0.35
Middle management (managers reporting directly to the executive management)	18	1.31	40	2.92	82	5.79	113	7.98
Specialists	507	37.01	595	43.43	568	40.14	642	45.37
Total employees	530	38.69	640	46.72	655	46.29	760	53.71

* To the purpose of adapting the human respurce to the long-term strategic paln of the company, the hierarchy levels were reconsidered, which led, starting with 2021, to a new staff resizing, particularly of the top and middle management.

Continuous professional training in 2021

Average professional training hours per employee	34.4
Professional training hours for secondary education employees	39.3
Professional training hours for higher education employees	30.9
Professional training hours for employees in management positions	19.8

34.4
hours of continuous professional training/ employee

Examples of training offered to employees in 2021	Total number of hours	Number of participants
Process extension, validation, technology transfer	650	50
Notions of GMP	465.5	133
Change control, investigation and deviation	357.5	55
Data integrity	264	44
Out-of-specification results	180	30
Presentation skills	120	10
Negotiation and contracting in the procurement process	104	13

Parental leave in 2021	Men	Women
Total number of days	762	6,739
Number of employees who were entitled to parental leave	6	10
Number of employees who have taken parental leave	6	10
Number of employees who returned to work after the end of the parental leave	5	23
Number of employees who returned to work (in 2019/2021) after the end of parental leave and were still employed after 12 months	9	51
Return to work rate* (%)	125%	110%
Retention** (%)	100%	85.7%

* Return to work rate = (Total number of employees who returned to work in 2020, after the end of the parental leave compared to the total number of employees who should have returned to work in 2020, after the end of the parental leave) x 100;

** Retention = (The total number of employees who took parental leave in the previous period, 2017, returned to work in 2019 and were still employed in 2020 compared to the total number of employees who returned to work in 2019, after the end of the parental leave) x 100

The health and safety of the Antibiotice employees is a firm commitment made by the company to ensure a safe and healthy working environment. Detailed information on Occupational Health and Safety can be found in the chapter Business Sustainability by improving the Integrated Management System (page 76).

3.2. Strategic portfolio adjustment

Antibiotice's current portfolio

The Antibiotice portfolio includes finished products (generic medicines for human and veterinary use, medical devices, food supplements, cosmetics and, with the emergence of the COVID-19 pandemic, biocides for surface and hand disinfection), active substances (Nystatin), clinical and bioanalytical studies conducted for our own products and for our external partners' products. The most generic medicines in our portfolio as well as the active substance Nystatin and the biocides are produced on our manufacturing sites. Some of the Antibiotice 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 its factory located in Iași.

Finished products

The Antibiotice portfolio consists of over 150 finished products from 11 therapeutic classes (antiinfectives, cardiovasculars, dermatologicals, medicinal products for digestive tract, central nervous system, etc.), including generic medicines for human and veterinary use (prescription medicines (Rx) and over-the-counter (OTC) medicines), food supplements (concentrated sources of nutrients, substances with a nutritional or physiological effect), medical devices (for therapeutic purposes) as well as cosmetics.

Strategic development of the Antibiotice portfolio focuses on the following main directions: antiinfectives – maintaining the leading position in this market; topical products; medicines for the treatment of chronic diseases in order to support the health system; sterile solutions; Nystatin – development of the vertical integration project of this active substance in the domestic and international market; products to support the life quality; biocides – the development of the disinfectants portfolio.

Generic prescription medicines

Through the portfolio segment which includes generic prescription drugs, our company aims to strengthen the therapeutic classes with a significant contribution in turnover, in order to support the health system (antiinfectives, cardiovasculars, dermatologicals, gastrointestinals, medicinal products for muscular and osteoarticular diseases).

Antiinfective medicines

Hospital & Partners is the product portfolio addressed to the healthcare professionals for patients in public and private hospitals. This complex portfolio is made of sterile anti-infectives for injection, beta-lactam antibiotics: penicillins and cephalosporins, also carbapenems and polymyxins. The category of anti-infective drugs also includes oral solid forms from beta-lactam classes: penicillins, cephalosporins and carbapenems, fluoroquinolones, macrolides and tetracyclines. Antibiotice is the main partner of the Ministry of Health within the National Tuberculosis Prevention, Surveillance and Control Program (PNPSCT), being the manufacturer of the whole range of first-line antituberculosis drugs, as well as

several second-line antituberculosis drugs. In Romania, Antibiotice is the only manufacturer of some anti-infectives such as Amoxiplus®, Ampiplus®, Colistina, Moldamin®, Oxacilina, Penicilina G, Tetraciclina Atb®, Eritromicină Atb®. In 2021, the main Antibiotice antiinfectives were: Meropenem Atb®, Eficef®, Colistină Atb®, Cefort®, Amoxiplus®, AmpiPlus®, Amoxicilină Atb®, Imipenem/ cilastatin Atb®, Ceftamil ® and Oxacilină Atb®.

Cardiovascular medicines

Medicines intended for the treatment of cardiovascular diseases are part of the development of the portfolio for chronic diseases with increasing incidence. Antibiotice has been constantly concerned with developing a complex portfolio of medicines to cover the treatment of the most important cardiovascular diseases: hypertension, angina pectoris, heart failure, venous insufficiency, etc. In 2021, the main Antibiotice cardiovasculars were: Bisotens®, Nolet®, Almacor® and the Hemorzon® range.

Dermatological products

The dermatological drugs from the Antibiotice portfolio are intended for treating the most important skin diseases with increasing incidence and prevalence (psoriasis, atopic dermatitis, bacterial skin infections, skin eczema), with a complex portfolio of topical corticosteroids, topical antibacterials and antifungals. In 2021, the main Antibiotice dermatologicals were Nidoflor® and Fluocinolon N Atb®.

Non-prescription products

This portfolio segment includes non-prescription products, such as food supplements, medical devices, cosmetics, OTCs which addresses the needs of various categories of target audience, contributing mostly to developing the life quality and topicals portfolios. The main therapeutic areas to which these types of products are addressed are: dermatological diseases, diseases or physiological conditions specific to women, cold and flu, pain, supporting the health of the following systems: osteo-articular system, cardiovascular system, digestive tract.

Nutriensa® represents the natural orientation of our company's concern for the well-being and health of its public. The Nutriensa® food supplements are manufactured by Antibiotice in compliance with the quality and safety requirements imposed by the GMP standards.

"Women's health"

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

Nutriensa® food supplements, maufactured by Antibiotice

Derma+

This concept includes products intended for the treatment of fungal skin infections and products intended for daily skin care, adjuvants of drug treatments. Cutaden® and Tinero® brands as well as Clotrimazol cream belong to this category.

Generic medicines for veterinary use

The veterinary portfolio contains antibiotic drugs, in the form of ointments, issued only on prescription (Rx). 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. Veterinary medicines are authorized for sale by the Institute for Control of Biological Products and Veterinary Medicines (ICPBMV) from Romania.

Biocides

In the context of the SARS CoV-2 pandemic, Antibiotice introduced in its portfolio TP1 biocidal products (for human hygiene) and TP2 biocidal products (for surface disinfection). Biocidal products were tested for microbiological efficacy in the accredited laboratories Chemila (Czech Republic) and Hamilton (Spain) and subsequently were approved by the National Committee for Biocidal Products within the Ministry of Health. The biocidal products in our portfolio are:

Sanygel is a hand sanitizer based on ethanol and glycerol used as a TP1 product for the hygienic disinfection of hands in the non-medical field and the hygienic and surgical disinfection of hands in the medical field.

a+Oxy is a disinfectant solution for hands and surfaces used as a TP1 product for the hygienic disinfection of hands in the non-medical field and as a TP2 product for the disinfection of surfaces in the non-medical and medical fields.

Active substances

Since 1975, Antibiotice has been manufacturing by an industrial biosynthesis process, on a dedicated manufacturing flow, the active substance Nystatin. In 2006, the Nystatin manufacturing process was optimized which led to a significant increase in productivity. Currently, our company has been developing 4 forms of this active substance: standard, micronized, compacted, feed-grade. Antibiotice has been the world leader manufacturer of Nystatin since 2012. In 2017, our product has become the USP reference standard. Nystatin is an antibiotic used in the treatment of fungal infections, which is marketed by Antibiotice in over 60 countries worldwide.

Services

Antibiotice provides for interested companies, through its own Center for Clinical Studies, clinical and/or bioanalytical services specific to phase I clinical and bioequivalence studies. These studies provide scientific data to confirm the efficacy and safety of drugs in human subjects. Thus, based on the results of pharmacokinetic and pharmacodynamic analyzes, the pharmaceutical equivalence between the generic and the reference drug (the innovative drug) is tested and demonstrated.

Phase I studies are those studies that are performed on 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, respectively the innovative one.

Our Center for Clinical Studies has a clinical unit with 32 beds, a bioanalytical unit with several laboratories, including a bioanalytical laboratory authorized according to the Good Laboratory Practice (GLP) requirements and a secondary packaging flow for the investigational medicinal product. The Center for Clinical Studies is a research unit established in 2006 and authorized by the Ministry of Health.

Starting with January 2021, when the second stage of vaccination against COVID-19 started in Romania, Antibiotice made the Center for Clinical Studies available to its employees and the community for the purpose of setting up the Vaccination Center a+ on its premises. This measure taken by Antibiotice for supporting the Romanian sanitary system determined the limitation of conducting clinical studies in 2021.

Complete information on the products in the Antibiotice portfolio can be read here or by accessing our page www.antibiotice.ro, Products Section.

Our portfolio provides **49 medicines included in the WHO Model List of Essential Medicines** (molecule + pharmaceutical form, for which we have a Marketing Authorization). According to the World Health Organization, these medicines meet the health care needs of the majority of the population, used in the treatment of the most common diseases.

Developing the future product portfolio through our own research and license purchases

Assimilation of new, high-quality, safe and effective pharmaceuticals that increase patients' access to valuable treatments and support an active lifestyle is the backbone of the strategy to renew our company's product portfolio. Closely following the therapeutic trends worldwide, using our knowledge and expertise for developing the portfolios which brought us awareness, our company has been developing its offer to patients and health partners, taking into account the latest requirements of medical and pharmaceutical authorities. Our own research and purchasing licenses for new products are the two strategic directions towards which Antibiotice has been focusing for developing its portfolio. All these projects contribute to achieving the objectives, such as doubling the turnover up to 2030, being operable starting with the period 2022–2025 in the target markets with a significant share in total revenues.

Evaluating proposals for new products

The proposals for new products are centralized and evaluated by the Portfolio Management Department and represent the results of the actions for completing the portfolio in line with the strategic development directions, taking into account the evolution of the medical and consumption trends in the period 2025–2030, market audit for each pharmaceutical form and the analysis of the main competitors'portfolios.

For each proposal, information is required on:

- analysis of the consumption market, with the highlighting of the value, quantitative and price potential;
- medical data (inclusion in therapeutic guidelines, medical advantages, evolution of consumption);
- the possibility of in-house development, on our own production flows;
- authorization procedures and legislative requirements;
- legal aspects related to patents/ commercial exclusivity;
- estimated sales in the market, data on profitability of products.

As part of the process of analyzing new product proposals, meetings of the portfolio teams composed of representatives of the departments involved, take place. The proposals qualified in the intermediate stages of analysis are subject to validation in working groups G2 (Portfolio Policies) and G1 (Strategic Planning & Performance Management), the selection being based on the following criteria:

- to be in line with the development directions of the portfolio;
- therapeutic importance;
- the value size of the market, average price/IU;
- quantitative market dynamics, number of competitors;
- portfolio entry speed;
- the share of the value contribution to the turnover, profit.

Each department involved in developing and launching new products in the market identifies, evaluates and manages the risks specific to the field of activity. After identification, the risk form in which the risk is described is filled out, the analysis or causes that favor its occurrence/ recurrence are set out, the consequences and likely impact are identified and control measures are proposed. Once approved, each proposal for a new product is assigned a method of assimilation in the portfolio:

- through own research-development conducted by the Research-Development Center of Antibiotice;
- by purchasing manufacturing licenses (business development).

In 2021, our specialists completed the evaluation of **14 new products** that are to be introduced in the future portfolio of our company. These have as main indications maintaining the health of the body's systems, complications of metabolic disorders, treatment of musculoskeletal disorders, treatment of skin infections and disinfection of surfaces. In the process of evaluating new product proposals, at the end of 2021, 72 proposals which are in line with the strategic directions of portfolio development, remained in the analysis, in different (from early to advanced) stages. These include prescription (Rx), over-the-counter (OTC) products, food supplements, medical devices or cosmetics and biocidal products. Also, this group includes products that can have the status of first generics. Evaluation and selection of the new products that will be part of the Antibiotice's future portfolio form the basis of the multi-annual research-development plans.

14

products were evaluated for inclusion in the future portfolio

8.7
million lei invested in the research-development activity in 2021

Our on-site Research & Development Operations

The Research-Development activity has as its main objective the development of medicines, both generics and unique combinations from the categories: topicals, tablets, capsules, injectables which have gone through the previous stages of selection and evaluation in order to renew the portfolio.

Along with the well-known pharmaceutical forms, in the last two years, other categories of products have entered the research-development process, such as: biocidal products, medical devices and cosmetics in accordance with the company's medium- and long-term strategic development directions. Our research specialists will enrich the Antibiotice portfolio with products from the following classes: antiinfectives, dermatologicals, cardiovasculars, non-steroidal anti-inflammatory drugs, medicines for the digestive system, medicines for women's health and biocides.

Researching and developing a new product is a multi-annual project, which is why, in 2021, we continued the research activities for 28 new products whose development was started in previous years. To these products, we added two others that passed the selection stage managed by the Portfolio Management Department. Following biannual reassessments of research projects in relation to the relevant market for these products, potential suppliers of active substances and excipients and global alerts on possible impurities of the active substances used, therapeutic restrictions, etc., our specialists continued their research for 24 projects.

These projects develop the portfolios of our company's three divisions, as follows:

- **Topical Products Division:**
  11 new product projects in research (6 medical devices, 2 OTCs, 2 prescription-only-medicines and one biocidal product, hand sanitiser);
- **Oral Solid Products Division:**
  10 new product projects in research (2 OTCs and 8 prescription-only-medicines, of which one project started in 2021);
- **Sterile Products & APIs Division:**
  3 new product projects in research (2 prescription-only-medicines – one injectable product and one oral suspension (a project started in 2021) and one biocidal product for surfaces).

On-site research for supporting our business internationalization

The research activity continued to support the process of internationalizing our company's portfolio. To this end, 13 products were included in the process of optimizing their formulas and updating their documentation in accordance with current guidelines in order to authorize them in various external markets:

- **Topical Products Division:**
  8 topicals
- **Sterile Products & APIs Division:**
  5 injectables

In 2021, our company completed activities to update documentation for internationalizing two prescription-only medicines (products for injection). In 2022, another 11 products (8 topicals and 3 injectables) will be optimized.

Antibiotice is the world 's largest producer of Nystatin, therefore more attention is paid to supporting the industrial synthesis of this active substance, through research of the microbiological and analytical components. Various projects were conducted in the laboratory for the synthesis of active substances, other than Nystatin, and for obtaining nano-structured medicines as a research base for future product categories to be included in the company's portfolio. Our company is going to put into

operation a new manufacturing plant for topicals. As a result, throughout 2021, the research activity also supported the process of technological transfer of topical products from the current portfolio, on the new manufacturing site, through risk assessments, mathematical equivalences of manufacturing processes and analysis of critical process parameters.

Authorized surface disinfectants, hand sanitizer in the process of authorization

Research and testing of new disinfectants started in the context of the COVID-19 pandemic, continued also in 2021. The current portfolio of biocidal products, consisting of a surface disinfectant and a hand sanitizer, will be completed with new products which are in the development-research stage. In 2021, our company invested 8.7 million lei in the R&D operations.

In-licensing projects

Antibiotice has been developing its medicine portfolio also through in-licensing projects, assimilating those products of interest which can be brought into the portfolio in a short period of time or which cannot be manufactured on the company's current facilities. In this context, in 2021, Antibiotice concluded agreements for 15 products belonging to the following therapeutic classes: alimentary tract and metabolism – probiotics (3 products), injectable antiinfectives (4 products), cardiovasculars (5 products), dermatologicals (3 products), antidiabetics (2 products). The first sales of these products are planned starting with 2022, by launching in the market the probiotic products from the Simbiflora range.

Obtaining and maintaining the marketing authorizations (MAs)

In 2021, the Regulatory Affairs Department supported obtaining and maintaining the Marketing Authorizations for products that are marketed both in the domestic and international markets. For developing our portfolio in the domestic market, in the reporting period, 2 injectable antiinfectives were authorized while new procedures were initiated for authorizing 2 oral solid products from the digestive tract class. Three dietary supplements with probiotics were notified: Simbiflora Complex, Simbiflora Forte, Simbiflora Kids and 2 (two) biocides, Sanygel and a+Oxy, TP1 type (skin disinfection) and TP2 type (surface disinfection), for medical and non-medical use, in various forms of presentation. Also, 5 products were reauthorized for the domestic market.

In order to support the internationalization strategy, 40 new Marketing Authorizations were obtained in 2021 (14 injectables, 25 oral, solid products and one product with topical administration) in countries from the European Union, Europe, Africa. Our company initiated also 35 new authorization procedures in countries from the European Union, Asia and Europe. 29 reathorization procedures were completed and another 20 were initiated in order to maintain the current products in the market.

Risk assessment of nitrosamine impurities in the Antibiotice medicinal products

Starting from the requirements of the EU, US and Canadian regulators regarding the limitation of nitrosamine impurities in medicines, in 2021, the activity of evaluating the occurrence of these impurities in the products from our portfolio continued through the theoretical study of the synthesis process of the active substances used, overlapped with the manufacturing process of our products. During 2021, risk analyses were completed for 62 products from our company's current portfolio.

15
products introduced in the portfolio through in-licensing projects

40
MAs in the foreign markets

There were no voluntary or recommended withdrawals of the Antibiotice products from the market in 2021.

Following these risk analyzes, 12 products were declared as presenting a risk of containing nitrosamines. These products passed to the "Step 2", which involves advanced tests for confirming or disproving the presence of nitrosamines:

- **8 products from the portfolio of the Oral Solid Products Division**
  - Candesartan Atb 8 mg, tablets
  - Candesartan Atb 16 mg, tablets
  - Eritromicină Atb 200 mg, tablets
  - Ibufen 400 mg, coated tablets
  - Indapamidă Atb 1.5 mg, prolonged-release tablets
  - Sinerdol 150 mg, capsules
  - Sinerdol 300 mg, capsules
  - Sinerdol Iso 300 mg/150 mg, capsules
- **3 products from the portfolio of the Topical Products Division**
  - Cicatrol 10 mg/g, cutaneous paste
  - Naftifină Atb 10 mg/g, cream
  - Neopreol 2.5 mg/5 mg/g, ointment
- **1 product from the portfolio of the Sterile Products & APIs Division**
  - Tigeciclină Atb 50 mg, powder for solution for infusion (contract manufacturing)

The testing also involved developing and validating analytical methods according to the requirements of the regulatory authorities, thus ensuring the certainty of the quality of the pharmaceutical products from the Antibiotice portfolio. Our company collaborated with an external analytical laboratory for the analysis and development of methods for identifying and quantifying the nitrosamines. To date, Step 2 statements have been submitted to regulators:

- **the "NO RISK" conclusion** for 2 of the mentioned products (Ibufen 400 mg, coated tablets, Tigeciclină Atb 50 mg, powder for solution for infusion);
- **the "WITH RISK" conclusion**, for 6 products analyzed (Candesartan Atb 8 mg tablets, Candesartan Atb 16 mg tablets, Sinerdol 150 mg capsules, Sinerdol 300 mg capsules, Sinerdol Iso 300 mg/150 mg capsules, Neopreol 2.5 mg/5 mg/g, ointment). For the six products, variations will be initiated regarding the introduction of the analysis of Nitrosamines in the specifications of the active substances and finished products. Marketing authorization holders should complete confirmatory testing and submit requests for variations by September 22, 2022.

As regards the active substance Nystatin, the risk analysis was performed, the conclusion being the absence of nitrosamine impurities in this product, a conclusion supported by analytical measurements. The summary of this analysis was forwarded to our business partners, further supporting the distinctive quality of this active substance included in our company's portfolio.

Withdrawal of products from the market

As a result of the strict quality and pharmacovigilance policies implemented by Antibiotice which closely monitors all legislative changes and international alerts, there were no voluntary or recommended withdrawals of the company's products from the market in 2021.

Promotion and labeling of the Antibiotice products

Pharmaceutical industry benefits from a strong regulatory framework, both in terms of promoting the pharmaceutical products and their labeling. Policies and procedures that describe the internal framework for carrying out product promotion and labeling processes are based on the legislative regulations in force, both at national and international level (specific to each country), as well as good practice standards specific for this industry.

Promotion strategies

The promotion of the products from the Antibiotice portfolio is a priority activity from the long-term development strategy of the company, which is achieved through:

- strengthening partnerships with health professionals through promotion actions;
- identifying new consumers for the products in the portfolio through screening programs;
- identifying the prescribing habits and treatment behaviors of physicians through testing programs;
- partnerships with pharmacy chains for promoting our non-RX product portfolio in their catalogs;
- accessing alternative promotion channels: online, TV; e-commerce – partner pharmacies for non-RX products.

In 2021, the promotion of the Antibiotice portfolio was focused on medical visits to various medical specialties and pharmacists, as well as on the participation in scientific events organized mostly online and also in-person, when the context was favorable.

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

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

The communication to the health professionals, physicists and pharmacists aims to increase the awareness of product brands in the portfolios of therapeutic classes: antiinfectives, dermatological preparations, genitourinary system, musculoskeletal system and the range of Nutriensa® food supplements.

The gradual abandonment of the restrictions during the state of alert made it possible to resume the direct visits of the team of medical representatives to various medical specialties and the organization of local scientific events (presentations of portfolios and products or round tables).

They aimed to reconnect our company with opinion leaders and the medical and pharmaceutical community and to bring to attention the therapeutic solutions manufactured by Antibiotice that have proven their efficiency in administration, as well as accessibility for patients. There were over 500 presentationsin offices, dispensaries and hospitals and over 25 round tables that addressed relevant topics

for participating doctors and pharmacists, adapted to seasonal diseases (respiratory infections, dermatological diseases, chronic venous disease and so on).

In 2021, the company participated in national and regional scientific events (congresses, conferences, webinars) in partnership with the Romanian Society of Pneumology, the Romanian ENT Society, the Romanian Society of Infectious Diseases, the Romanian Society of Urology, the Romanian Society of Obstetrics – Gynecology, the Romanian Society of HPV, the Romanian Society of Ultrasonography in Obstetrics and Gynecology, the Romanian Society of Vascular Surgery, the Romanian Association for Pediatric Education in Family Medicine, aiming to strengthen partnerships with representatives of the medical and pharmaceutical communities in Romania, thus supporting continuing medical education by facilitating access to conferences, as well as proposing therapeutic solutions manufactured by Antibiotice.

Emphasis was also placed on the recommendation of pharmaceutical solutions manufactured by Antibiotice in magazines, books and specialized treatises (advertising models and articles in: Revista Viata Medicală, Revista Galenus, Revista Ginecologia.ro, Treatise on malignant pathology of the endometrium – Romanian Academy Publishing House). Also, the communication was continued through multiple information channels, respectively online, the selection of platforms that facilitate the transmission of information to health professionals.

Through communication platforms, webinars dedicated to health professionals were organized (webinar dedicated to pharmacy assistants with granting credits) and national and regional scientific events (Congresses, Conferences held by Professional Associations) held online or hybrid (participation both in-person and online) were attended.

The communication to the general public was achieved through numerous actions, including: TV campaign to promote the Fluxiv® range, the launch of the nutriensa.ro website, the promotion on social media (Nutriensa® – community development and influencer marketing campaigns; Fluxiv® range – promotion on Youtube, Google Search, Mobile and OLV Programmatic; Cutaden® and Tinero® – Facebook, Instagram promotion). Another channel of communication to the general public is the radio, where promotional radio spots were broadcast on national and local channels for brands in the Nutriensa® range: Imunofix®, Fluxiv®, Silithor®, Fezivit C®, Equilibra®, Lejer®. On the occasion of World Patient Safety Day, which in 2021 focused on the safety of the newborn, an e-mailing campaign was conducted with information about the benefits of using Cutaden®Babe, while providing samples of this product to mothers in the "Cuza Voda Iași" Maternity Hospital.

Accessing the e-commerce sales channel, through partner pharmacies, involved carrying out promotion and sales projects on e-commerce sites: Farmacia Tei (Tei Pharmacy), Farmacia Bella Donna (Bella Donna Pharmacy) and Farmaciile Dona (Dona Pharmacies).

The main objectives of the promotion plan are to ensure:

- **the accessibility of all categories of patients to Antibiotice brand medicines, through a complex distribution, which facilitates the presence of our medicines both in hospitals and pharmacies in Romania and on international markets where we are present;**
- **ensuring the access to accurate, concrete and real-time information by observing all the existing legislative regulations and ethical standards at industry level.**

Other promotion campaigns for the general public which were carried out in 2021:

- offers in pharmacy chain catalogs for non-RX products;
- the identification of new consumers for the products in the portfolio through screening programs (Pletix – Screening project for Chronic Venous Disease, carried out in pharmacies and family medicine offices);

- educational campaigns (campaigns for Tinero® "132 moments of vulnerability" and "Adolescent challenges in skin care" – a complex approach to adolescent problems, with the involvement of the dermatologist and the psychologist);
- influencer marketing campaigns, through bloggers, for the Fluxiv®, Tinero® and Cutaden® range, by recommending products by public persons and offering samples for testing and creating their own experience with these products.

Legislative framework for product promotion

Antibiotice takes all the measures to ensure that the promotion of the products in the company's portfolio is carried out responsibly and ethically, in accordance with the legislation in force. Within the company, the coordinator of the promotion activity is the promotion manager. The Medical Department ensures the proper registration of materials used in promotional activities in accordance with the applicable laws, and the Marketing Department ensures that company employees involved in promotional activities as well as representatives of companies contracted for promotional activities are trained and familiar with the applicable laws and with the provisions of the Code of Good Practice for the Promotion of Prescription Drugs and for Interactions with Medical Professionals.

The training of the promotion team is part of the induction process of new employees. The issues related to the ethical behavior in drug promotion activities are addressed in quarterly area or regional meetings. These meetings are attended by 42 members of the promotion department team, depending on the area for which it was organized.

Code of Good Practices for the promotion of prescription drugs

The Code of Good Practice for the promotion of prescription drugs and for interactions with medical professionals defines and implements specific ethical standards for the promotion of prescription drugs. They will ensure the correct transmission of information on generic medicines to medical professionals.

The legislation that formed the basis for the drafting of the Code includes the following categories of normative acts: laws, emergency ordinances, orders, instructions or any similar document issued by the Romanian Parliament, the Government of Romania or by any other competent authority, as well as any applicable normative act 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, are the following:

- Law no. 95/2006 on the health care reform, published in the Official Gazette Part I, no. 372, of 28.04.2006, with all subsequent amendments;
- Decisions, instructions, provisions of the National Agency for Medicines and Medical Devices of Romania (NAMMDR) which regulates the activity of promoting medicines issued on the basis of medical prescription;
- The APMGR Code (Romanian Association of Generic Drug Manufacturers);
- The ARPIM Code (Romanian Association of International Drug Manufacturers);
- The Code of Promotion Practices of the European Federation of Pharmaceutical Industries and Associations;
- The European Directive 2001/83/EC on medicinal products for human use, as amended by the European Directive 2004/27/EC and the Directive 2010/84/EC;

In 2021, the company did not register fines, warnings or sanctions for:

- **the non-compliance with the current legislation or codes adopted voluntarily, with regard to product promotion;**
- **the non-compliance with the applicable legal regulations or voluntarily adopted code with regard to product labeling;**
- **incidents reported by relevant regulatory authorities (NAMMDR) regarding the non-compliance with product labeling/package leaflet.**

- The Code of Pharmaceutical Marketing Practices of the International Federation of Pharmaceutical Manufacturers Associations, where applicable;
- The Code of Interactions with Healthcare Professionals of the PhRMA, a Pharmaceutical Research and Manufacturers of America).

The behavior that the company expects from the people responsible for promoting the products in the Antibiotice portfolio is included in the provisions of this Code. All the employees involved in promotion activities participate regularly in training programs, but also when significant changes take place in the applicable laws and regulations.

The code of good practice for the promotion of prescription drugs is brought to the attention of each new medical or sales representative employed, and it can be read online, on www.antibiotice.ro, Corporate Governance, Reference Documents section. The Code stipulates, inter alia, that the promotion of prescription-only medicines should be directed only to medical or pharmaceutical professionals. At the same time, the 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 of:

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

Transparency in the relationship with medical and pharmaceutical professionals and organizations

According to the duties established starting with 2015, by the Law no. 95/2006 on health care reform, the article 814 and the 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, Antibiotice reported, also in 2021, to the National Agency for Medicines and Medical Devices in Romania, all sponsorship activities and any other expenses incurred by the company during the year 2020, prior to reporting, for health professionals, professional organizations, patients and any other type of organizations carrying out activities related to the human health, healthcare or pharmaceuticals.

The level of customer satisfaction

In order to evaluate the way we manage this topic, Antibiotice also carried out a market research in 2021, which is carried out annually, for the past 15 years, regarding the evaluation of the level* of customer satisfaction, in accordance with the requirements of ISO 9001/2015 for the implementation of the quality management system. For 2021, the research "Customer Satisfaction Assessment" was conducted between October and December 2021. The data collection was done by applying questionnaires to key Antibiotice customers: physicists, retail pharmacists (independent pharmacies), distribution managers, national chain managers and mini-chain managers.

The average level of satisfaction for the 5 categories of customers in 2021 is 88.4%. For all the representative customers, scores of over 80% were registered which,

* The level of satisfaction is calculated in the form of absolute marks, from 1 to 5, and relative marks, as percentages from 1% to 100%.

according to the classification of customers according to the level of satisfaction, places them in the category of "satisfied customers". The sales and promotion results are evaluated monthly and quarterly. The results of the study are the basis of the plan of measures to rectify the indicators that were not met according to the annual plan.

Antibiotice promotes the responsible use of antibiotics

The antimicrobial resistance is a major public health problem, which requires global actions to inform the population about the promotion of responsible consumption of antibiotics, so that future generations can be treated effectively. Antibiotice's response to this need is the "Antibiotics of the 3rd millennium" – a social responsibility program initiated in 2018, under the scientific coordination of the Romanian Society of Microbiology and the Romanian Society of Epidemiology, having as communication partner the company "People and Companies".

The "Antibiotics of the 3rd millennium" supports the judicious use of antimicrobial agents by developing and disseminating good practices in the field of antibiotic use, addressing a community of patients and the general public, health professionals, manufacturers, environmental experts, representatives of academia and entrepreneurship. In 2021, the program took place online through the project platform, www.antibioticelemileniuluitrei.ro. The pages of the platform were accessed during this period 20,038 times, and the 1,828 subscribers received 5 newsletters and 1 special report, dedicated to the European Antibiotic Awareness Day.

Also, on the occasion of the European Antibiotic Awareness Day, the webinar "During the COVID-19 pandemics, we are united in preventing the bacterial resistance" was organized, which brought together 273 participants – physicists and pharmacists from all over the country. For the general public, Antibiotice achieved, on the occasion of Antimicrobial Resistance Awareness Week 2021, the social media campaign "Antibiotics, use them wisely!", which had an impact on 13,000 people.

Product labeling

Packaging of the Antibiotice pharmaceutical products is done in accordance with the national legislation of the country where the medicines are registered and/or marketed. The packaging and package leaflet of each medicinal product shall be subject to the approval of the national medicinal product regulatory authority, NAMMDR or other European or non-European authorities before being placed on the market, and the information shall be reviewed regularly and aligned with relevant legislative requirements.

The information included in the package leaflet, addressed to both healthcare professionals and patients or users, explains the correct way to use the medicine. Information on the composition of the products, indications, dosage and route of administration, the mode of action, warnings of possible side effects, the recommendations for pregnant or lactating women, the possible interactions with other medicinal products, packaging and storage are provided.

The labeling of other pharmaceutical products (medical devices, food supplements, cosmetics) manufactured and marketed by Antibiotice is carried out in accordance with the relevant legislation. If the pharmaceutical products contain ingredients that could affect the natural environment, then the packaging and package leaflet may also contain information on the proper disposal of the product. All this information is regularly checked and updated, to ensure that all our products contain the latest information on quality, safety and efficacy, as appropriate.

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

Pricing policy and access to medicines

Pricing policy

The Antibiotice pricing policy complies with the specific legislation in force (Law no. 21/1996, republished), by observing the competitive practices and the ethical conduct in business, according to the company's internal codes: the Code of Ethics and the Code of Good Practice for the promotion of medicines issued on prescription and for interactions with the medical professionals.

- On the Romanian market, for the medicines from the Antibiotice portfolio that are issued on the basis of medical prescription (Rx), the establishment of prices 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 the European Council Directive no. 89/105/EEC of December 21, 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 medicinal product, the proposed price is compared with the price of the same medicinal product authorized in 12 countries: 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 medicinal product is not priced in the comparison countries, the proposed price is approved. In the case of generic medicinal products (such as medicinal products produced by Antibiotice), the price may not exceed the generic reference price which is the maximum producer price to be approved once, on the date of application for approval of the price of the first generic medicinal product in the international common name (INN), strength and pharmaceutical form.
- The prices of the Antibiotice over-the-counter (OTC) medicines, the medical devices, food supplements and the cosmetics are set and change freely, taking into account the market requirements and trends.
- For the international market, the prices of medicines are established by negotiation with external partners, in conditions of competitiveness and according to the legislation in force in the respective countries. The participation in medicines public tenders, through distributors, ensures the access of all medical institutions to the medicinal products manufactured by Antibiotice, in conditions of competitiveness and transparency, while the company assumes flexibility in terms of reducing the price within the limits of profitability.

Access to medicines

The mission of Antibiotice is to make valuable medicines more accessible as a means of health care for patients, physicists and pharmacists. This mission is fulfilled through a complex distribution, which facilitates the presence of Antibiotice medicines both in hospitals and pharmacies in Romania, and in international markets where the company is present.

The access to medicines for human use is achieved on the domestic market through a network of 7 national distributors, and for the veterinary use medicines, through 4 distributors.

In 2021, still during the pandemic, Antibiotice added to its portfolio the hand sanitizer Sanygel, thus completing the range of biocides (launched in 2020, together with the solutions for surface

disinfection). Sanygel either follows the same path to reach the market, as in the case of medicines for human use, namely through distributors, or is marketed through a support department that runs spot contracts with each institution or company concerned.

On the international market, the medicines from Antibiotice Iași reach through the 40 distributors in the territories where we export products for which we hold marketing authorizations, but also through tenders in which we participate either in our own name or through our external partners. In 2021, in order to strengthen the ties with the traditional partners on the foreign market, but also to find new business opportunities and development of new pharmaceutical products, Antibiotice was represented by a delegation composed of specialists in the fields of research-development, import, export, marketing-sales and business development at CPhI Worldwide (Fiera Milano) – an event that brings together thousands of health professionals.

Portfolio development, increasing the access to valuable medicines

The development of the product portfolio is consistently supported by the Business Development department which contributes to the achievement of the objectives of the Organization and Strategic Development Plan of the company through in-licensing projects.

40 marketing authorizations in international territories

In order to increase the degree of accessibility to the Antibiotice brand products and for the sustainability of the territorial expansion plan, the product registration procedures have been initiated in our company's international territories of interest. Thus, 40 MAs (marketing authorizations) were obtained in the Scandinavian countries (Denmark, Sweden, Norway and Finland) as well as in Moldova, Ukraine, South Africa and Serbia.

Recognition from international health systems

The quality standards that Antibiotice meets have allowed the company to access international tenders. Thus, Antibiotice enjoys recognition from the health systems of Great Britain (tender won worth of 11 million euros for a period of two years), the United States of America, Denmark and Vietnam where the company won important tenders for sterile injectable anti-infective drugs intended for hospitals.

Ensuring access to medicines by fulfilling orders

During 2021, the second year of the Covid 19 pandemic, Antibiotice responded positively to all the drug requests in Romania and in international markets, by mobilizing the suppliers of raw materials, the efficient organization of manufacturing and fulfilling orders on time. Particular attention was paid to orders from hospitals where Antibiotice tendered, to the contracts in its own markets and, last but not least, to the applications for tuberculostatic drugs and injectable penicillins from developing countries in the Middle East, or Africa.

Antibiotice has thus managed to ensure a dispersed, balanced access to the exported medicinal products, while ensuring the consumption needs of the patients in Romania. The company thus becomes an internationally recognized, competitive player in the segment of sterile injectable anti-infective medicines (single penicillins and combined penicillins), a long-term partner of health systems in the UK, USA, Hungary and the Baltic states.

3.3. Business sustainability by improving the Integrated Management System

Quality – our commitment to the health and safety of patients and consumers

Quality policy

As a manufacturer of medicinal products, Antibiotice is responsible for the quality, safety and efficacy of the manufactured products, which is why all the necessary measures are taken to ensure that the production processes comply with the highest national and international quality standards. The quality, environment and occupational health and safety policy can be found on the company's website.

Quality assurance in the pharmaceutical factory

Antibiotice's portfolio includes a wide range of products: generic medicines for human and veterinary use with and without a prescription, food supplements and cosmetics, active substances (Nystatin) and biocides. The factory is organized into eight dedicated manufacturing flows for the manufacture of medicines; all of them are inspected and certified periodically, according to the requirements of the Good Manufacturing Practice (GMP), by NAMMDR and has implemented a quality management system that integrates Good Manufacturing Practice (GMP), as they are defined by the European (EU GMP) and the US (cGMP) legislation or by the legislation of other countries where the Antibiotice brand products are authorized.

The quality management system complies with the requirements of the ISO 9001:2015 standard, and together with the environmental standards (ISO 14001:2015) and the occupational health and safety standards (ISO 45001: 2018), they form the integrated management system, which contributes to the growth of the product quality. The functioning of the management system is permanently verified, both internally, by specialists in each field (quality, environment, occupational health and safety) and externally, by national (NAMMDR, ANSVSA) and international bodies (US-FDA), by certification bodies (TÜV Rheinland, SRAC) and by business partners.

The pyramidal structure of the quality management system at Antibiotice

* Extension of the GMP certificates by NAMMDR, until December 2022.

** Supervisory audit ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018, carried out by TÜV Rheinland.

Inspections and audits in 2021

In 2021, Antibiotice adapted to the requirements of national and European authorities on audits and inspections during the COVID-19 pandemic.

May 18, 2021
Third party audit of the Nystatin active substance carried out by Rephine Ltd.

May 19, 2021
Third party audit for parenteral products carried out by Rephine Ltd. for the partner Intrapharm, UK.

June 7, 2021
The audit performed remotely (online) for parenteral products by SQA Services Inc. for Sagent Pharmaceuticals, USA.

27–28.10.2021
Surveillance audit, to verify the compliance of the Integrated Management System: quality, environment, occupational health and safety with the requirements of the standards ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018, carried out by ISO TÜV Rheinland.

14.12.2021
Audit for the Nystatin active substance, carried out by R&S Beratung, for Pharma Greven GmbH, Germany.

Product quality control

Antibiotice is concerned with providing quality, safe and therapeutically effective medicines, this is the reason why all the raw materials and manufactured products are tested to ensure that they meet the quality specifications. In addition, all the results are evaluated annually, along with the manufacturing records for each product in the portfolio.

Its purpose is to verify the stability and reproducibility of the manufacturing process and the correctness of the quality specifications, in order to identify any trend occurred over time. Following the evaluation, corrective actions are proposed and implemented, as well as opportunities for improvement, as appropriate, according to the internal procedures.

Maintaining the quality level of our products is a commitment not only to patients and consumers, but also to all our partners in the value chain. Thus, depending on the technological and legislative evolution specific to the pharmaceutical industry, periodically, a part of the products enters the optimization / reformulation process, as the purpose is the framing with more and more restrictive legislative requirements.

Regarding the quality complaints, the internal procedure specifies that the person receiving the complaint notifies the Quality Assurance department (at the address **asigurarea.calitatii@antibiotice.ro**). Depending on the nature of the complaint, the Quality Assurance Officer places the complaint in the defect class to which the non-conformity belongs.

An internal investigation is initiated, carried out 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 sends the summary of the investigation report, including the conclusion of the complaint (unjustified/justified, as well as the established actions), to the complainant.

During 2021, 84 complaints were received. Of these, following internal audits, it turned out that 64 complaints were substantiated and 20 were unjustified. The 84 complaints were received from:

- **Patients:** 9 complaints;
- **Pharmacies:** 25 complaints;
- **Hospitals:** 4 complaints;
- **Distributors:** 27 complaints;
- **International partners:** 19 complaints

The complaints concern product quality issues such as:

- Product quantity issues: the lack of capsules, tablets, blisters, tubes, commercial units;
- Issues with the physical appearance of the product: broken capsules, chipped tablets, consistency/texture, powder on the outside of the bottle, etc.;
- Packaging issues: broken blisters, leaky tubes, damaged boxes, stained packaging, erased printed data, etc.

Following the investigations, depending on the nature of the primary cause identified, corrective measures of various types were proposed such as:

- Technical solutions: procurement of new equipment, additional sensors, optimizations of the equipment operation mode;
- The reassessment of raw materials/ primary packaging materials: change of tube length, selection of raw materials to reduce their natural variability;
- The optimization of the manufacturing process: revision of work procedures and instructions, additional process controls, restriction of the operating field, product reformulation;
- Training and awareness of the staff involved.

Standards, licenses, authorizations and certificates valid on December 31, 2021

Authorization type	Description	Recertification	Date of the latest certification
Manufacturing authorization 30 F	Manufacturing authorization for the production of medicines for human use, including medicines for clinical investigation, issued by NAMMDR (National Agency for Medicines and Medical Devices in Romania).	Recertification when changing certification conditions	December 2, 2019
Authorization RO 03	Authorization for the manufacture of veterinary medicinal products issued by ANSVSA (National Sanitary Veterinary and Food Safety Authority).	Recertification every 3 years	April 11, 2019
Authorization 7Fsp/2020	Authorization for the manufacture of preparations containing narcotic and psychotropic substances issued by the Ministry of Health.	Annual reauthorization	January 4, 2021
Authorization 861/2018	Authorization to conduct clinical trials in the field of medicine issued by NAMMDR.	Reauthorization every 2 years	July 12, 2018, extended until December 2021 (according to the decision of NAMMD 58662E / 27.07.2020, internally registered 6563P / 29.07.2020)
Authorization 3/2021	Integrated environmental permit issued by ARPM (Regional Environmental Protection Agency) Bacău, revised by the Iași County Environmental Protection Agency	Annual endorsement/ revision/reauthorization when changing the conditions of authorization	September 29, 2021
Authorization 20/2021	Water management permit issued by AAR (Romanian Waters Administration) Prut-Bârlad.	Reauthorization when changing the authorization	March 31, 2021, validity conditions 01.04.2026
GMP certificate 023/2018/RO	Certificate of conformity with the Good Manufacturing Practice (GMP) issued by NAMMDR, following the inspection of manufacturing operations, packaging and testing, for quality control, of ointments (medicines for human use). The manufacture of medicinal products is carried out in accordance with the guideline on good manufacturing practice, used by NAMMDR for the assessment of manufacturing authorization applications and for the inspection of manufacturers of medicinal products for human use, based on the principles of quality risk management. The manufacturing authorization system ensures that all the authorized medicinal products are manufactured only by authorized manufacturers, whose activities are regularly inspected by the competent authorization body.	Recertification every 3 years	June 5, 2018, extended until December 2022 (NAMMDR notice no. 67912E / 22.12.2021 registered internally 111P / 05.01.2022)
GMP certificate 040/2017/RO	Certificate of conformity with the Good Manufacturing Practice (GMP) issued by NAMMDR, following the inspection of manufacturing, packaging and testing operations, for quality control, of suppositories, capsules and tablets (medicines for human use).	Recertification every 3 years	August 11, 2017, extended until December 2022 (NAMMDR notice no. 67912E / 22.12.2021 registered internally 111P / 05.01.2022)
GMP certificate 041/2017/RO	Certificate of conformity with the Good Manufacturing Practice (GMP) issued by NAMMDR, following the inspection of manufacturing, packaging and testing operations, for quality control, ointments, suppositories, capsules and tablets (medicines for human use for clinical investigation).	Recertification every 3 years	August 11, 2017, extended until December 2022 (NAMMDR notice no. 67912E / 22.12.2021 registered internally 111P / 05.01.2022)
GMP certificate 055/2019/RO	Certificate of conformity with the Good Manufacturing Practice (GMP) issued by NAMMDR, following the inspection of manufacturing, packaging and testing, for quality control, of Nystatin active substance.	Recertification every 3 years	December 2, 2019

Authorization type	Description	Recertification	Date of the latest certification
GMP certificate 056/2019/RO	Certificate of conformity with the good manufacturing practice (GMP) issued by NAMMDR, following the inspection of manufacturing, packaging and testing operations, for quality control, sterile products, powders for injectable solutions / suspensions (medicines for human use).	Recertification every 3 years	December 2, 2019
GMP certificate 58/2019/RO	Certificate of conformity with the good manufacturing practice (GMP) issued by NAMMDR, following the inspection of manufacturing, packaging and testing, for quality control, of veterinary medicinal products.	Recertification every 3 years	April 11, 2019, extended until December 2022 (ANSVSA address 27505 / 30.12.2021)
GLP 49 certificate	The certificate regarding the conformity with the good laboratory practice (GLP), issued by NAMMDR, following the inspection of the Bioanalytical Laboratory within the Antibiotice Center for Clinical Studies. The GLP represents the principles that are followed in conducting bioanalytical testing, which provides assurance on the quality and integrity of non-clinical trials.	Recertification every 3 years	July 5, 2017, extended until December 2021 (according to the decision of NAMMDR 59664E / 11.08.2020)
US FDA EIR Acceptance	US FDA Establishment Inspection Report Acceptance is the inspection report issued after the FDA (US Medicines Regulatory Body) inspected the powder manufacturing flow for injectable solutions/ suspensions and the manufacturing flow of the Nystatin active substance.	Periodic recertification correlated with risk analysis	June 2, 2017 VAI statement from US FDA / 02.03.2021
ISO 9001:2015	Quality management system ISO 9001: 2015 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 supervision and recertification every 3 years	January 16, 2020
ISO 14001:2015	Environmental management system ISO 14001:2015 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 supervision and recertification every 3 years	January 16, 2020
ISO 45001:2018	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 supervision and recertification every 3 years	January 22, 2020
R1-CEP 2003-096-Rev 03 Certificate	The certificate of compliance with the European Pharmacopoeia (CEP) for the Nystatin active substance, issued by the EDQM (European Directorate for the Quality of Medicines & HealthCare). The CEP confirms that a pharmaceutical substance or an active substance is produced according to the requirements of the corresponding monograph in the European Pharmacopoeia.	Recertification when changing the information in the Active Substance Master File (ASMF)	July 02, 2021
Certificate 10	The certificate of conformity for aluminum tubes used in the packaging of ointments, creams and gels.	Recertification every 3 years	March 21, 2018
Certificate 11	The certificate of conformity for screw caps and membrane penetration devices used for closing aluminum tubes with ointments, creams and gels.	Recertification every 3 years	March 21, 2018
Certificate 12	The certificate of conformity for the metal cap for closing vials containing antibiotic products.	Recertification every 3 years	March 21, 2018

Serialization of medicines

The counterfeit medicines are a potentially important risk for any public health system in the world, with a significant impact on the health of patients and consumers, impacting not only the patients but also the pharmaceutical industry. Since February 2019, as a manufacturer of medicines, Antibiotice has aligned itself with the European and national legislative requirements to reduce the counterfeiting of medicines by serialization, which allows the real-time verification of the authenticity of any medicine, wherever it is on the legal supply chain between the manufacturer and the patient.

Thus, all the finished medicinal products for human use, issued on prescription (Rx), have, on the outer packaging, two mandatory safety elements, which allow to check their authenticity: a computer-generated element (a unique code printed on the packaging) and a physical element (a seal that is destroyed upon any attempt to unwrap the package).

Reducing the risk of introducing counterfeit products into the supply chain

Within our company, the policies implemented to reduce the risk of introducing counterfeit or compromised products into the supply chain are described in the system procedures "Serialization and aggregation of medicines at Antibiotice" and "Investigation of suspected counterfeit products" and specify:

- the application of security features to the packaging of products in the portfolio which are issued on the basis of a prescription (unique identifier and sealing system against unlawful opening) allowing the verification of the authenticity and the identification of commercial units in order to provide evidence of their illicit modification;
- the collaboration only with authorized wholesale distributors of medicinal products, who hold wholesale distribution authorizations and certification according to the good distribution practices (GDP) issued by the competent authorities following an inspection.

During 2021, the serialization system generated 12 falsification alerts, of which 6 alerts were substantiated alerts (following the investigations, they were identified as errors in the management of serial numbers, without impact on the quality and safety of the finished product), and 6 alerts were unjustified. The 12 falsification alerts were generated by:

- pharmacies – 3 falsification alerts;
- distributors – 2 falsification alerts;
- the Romanian Medicines Serialization Organization – 5 falsification alerts;
- the National Agency for Medicines and Medical Devices in Romania – 2 falsification alerts.

Pharmacovigilance

The pharmacovigilance covers all the activities of detection, evaluation, validation and prevention of adverse reactions or any problems associated with the use of medicinal products for which there are marketing authorizations.

The pharmacovigilance is the legal obligation by which each manufacturer of medicines guarantees the safe use of the medicines that company manufactures, according to the requirements of the regulatory authorities in the field of medicines at European level (European Medicines Agency – EMA) and at national level (National Agency for Medicines and Medical Devices in Romania –NAMMDR). Thus, the pharmacovigilance contributes to the protection of public health and patients.

Pharmacovigilance for medicinal products for human use

At Antibiotice, all the information on the safety of the use of medicines is evaluated, maintained and communicated to the regulatory authorities throughout the life cycle of the products (including in the pre-authorization and post-authorization stages). Any medicine can also have side effects, so Antibiotice closely monitors the occurrence of such events, by using all sources and by observing the obligation to report to the authorities the information on the safety of our medicines and to implement appropriate measures, if the benefit– risk ratio* of a medicine changes.

The pharmacovigilance specialists monitor, identify, assess, report and establish, through risk management plans, the potential risks associated with the use of Antibiotice branded medicinal products for human use. The main activities of the Scientific and Pharmacovigilance Department (the internal pharmacovigilance structure of Antibiotice) are:

- the collection of adverse reactions from physicians, pharmacists and patients to monitor the frequency of known adverse reactions to the medicines in the portfolio;
- the analysis and dissemination of information necessary for the correct prescription of the company's medicines for the rational and safe use of medicinal products;
- the evaluation and communication of the risk – benefit ratio for all the company's medicines on the market and their transmission to the competent authorities of the territories where they are placed on the market.

Antibiotice promotes good practices in the field of pharmacovigilance, both internally and through contracts with business partners, thus contributing to the creation of a network that supports the patient safety.

As an integral part of the Antibiotice Quality Assurance System, the pharmacovigilance activity ensures the introduction of immediate actions and measures established by the authorities, as well as the updating of medical information on the Antibiotice medicines, through information letters and a summary of product characteristics (SPC) for healthcare professionals (physicists, pharmacists) and through the package leaflet of each medicine, which is made available to patients and consumers.

Antibiotice is connected to the European Pharmacovigilance database, EudraVigilance, providing patients with access to reporting of suspected adverse reactions, through available forms, promoted to healthcare professionals through medical and sales representatives, or on the company's website.

Thus, for the reporting of suspected adverse reactions on medicinal products for human use produced by Antibiotice,

* The benefit-risk ratio refers to the weighting of the benefits of a medicine (positive effects) in relation to the associated risks (side effects). Sometimes known as the risk- benefit ratio, it must be considered favorable for a medicinal product to be authorized. The benefits and risks associated with medicines are constantly monitored to confirm that the benefits outweigh the risks (Eudra Vigilance Glossary, https://www.adrreports.eu/ro/glossary.html a link accessed on April 19, 2022).

several channels of communication and collection are made available to patients and consumers, as well as to physicians and pharmacists:

- directly, through the spontaneous adverse medicines reporting form, provided by the Antibiotice medical and sales representatives, to physicians and pharmacists;
- online, on the website www.antibiotice.ro, through the form for collecting suspected adverse reactions or by e-mail at **sigMedUmane@antibiotice.ro**
- by phone, at **+40728 199 834** or through the telephone switchboard, at **+40 232 209 501**

The adverse reactions, received by Antibiotice through these channels, by the Scientific and Pharmacovigilance Department, are recorded internally, according to specific procedures. Depending on their severity, the adverse reactions received must be transmitted to the European EudraVigilance database within a maximum of 15 days for the severe adverse reactions and 90 days for the non-severe adverse reactions.

During 2021, for the medicines for human use, 3 non-severe adverse reactions were reported (online) to Antibiotice.

The 3 adverse reaction reports were received from:

- health professionals (physicists and pharmacists) – 2 adverse reactions;
- patients – 1 adverse reaction.

Over the past year, Antibiotice responded to a questionnaire from the German drug authority, Federal Institute for Medicines and Medical Devices (BfArM), which aimed to assess the potential risk of the company's pharmacovigilance system without proposing audit / corrective actions by the authority.

During 2021, no external audit of Antibiotice's own pharmacovigilance system was carried out, which our company implemented according to the European legislation, as a holder of marketing authorizations for medicinal products.

Veterinary medicines

The suspected adverse reactions to veterinary medicinal products manufactured by Antibiotice are reported via:

- online, on www.antibiotice.ro, via the form for collecting suspected adverse reactions or by email at **sigMedVeterinare@antibiotice.ro**
- by phone, at **+ 40 232 209 501** or **+ 40 232 209 536**

During 2021, no adverse reactions to veterinary medicinal products were reported to Antibiotice SA.

Clinical studies

The clinical studies plan of Antibiotice for 2021 included 2 bioequivalence studies (for own products which are to be included in the portfolio) and 2 clinical studies of phase II / III, respectively phase IV.

Bioequivalence studies are performed to demonstrate the pharmaceutical bioequivalence between the generic medicine under study and the innovative reference medicine. In this case, the medicine under study is not intended to treat a disease, therefore, only healthy subjects (volunteers) take part in the bioequivalence studies (who are assured that the health condition is maintained after the study, by performing a complete set of medical tests).

Phase I clinical trials test medicines administered in humans for the first time in order to cure a particular disease, Phase II and III clinical studies test the drug to investigate efficacy and safety in adminis-tration, and Phase IV studies aim to achieve additional information on the safety, efficacy and optimization of the administration after the medicine has received a marketing authorization. Therefore, only patients (who thus have access to treatment with the studied drugs and to medical evaluation throughout the clinical studies) are included in the phase I, II, III and IV studies.

Safety of participants in clinical studies

Like any drug company, Antibiotice conducts clinical studies, which are regulated internationally. The legislation imposes very clear requirements, which drug manufacturers must comply with in conducting clinical studies. The study protocols are approved by NAMMDR and the National Commission for Bioethics of Medicines and Medical Devices.

The Commission assesses how fundamental human rights are respected as described in the Helsinki Declaration (the rights of participants in clinical studies), ensuring that, ethical standards are followed if the study subjects are paid.

Before being included in a clinical study, the subject receives from the qualified staff (investigating physicians), all the information regarding the study protocol, the tested medicine, associated risks, adverse reactions, etc. Study participants can ask any question to the medical staff and they sign the informed consent only after they are fully informed.

Volunteers included in the bioequivalence clinical studies receive a monetary remuneration for each clinical stage in which they participate. The calculation of remuneration takes into account the number of hospitalization hours, the tested molecule, compliance with the pharmaceutical form, possible adverse reactions, the number of biological samples, restrictions during the study.

The remuneration received is evaluated and approved by the National Commission for Bioethics of Medicines and Medical Devices. Any participant in a clinical or bioequivalence study has the possibility to withdraw from the study at any time. Moreover, for each study participant, Antibiotice SA takes out an insurance policy.

Animal testing

The quality testing of products in the portfolio does not involve animal testing. As a result of European and national legislative changes regarding animal protection used for scientific purposes, starting with October 2018, Antibiotice has replaced animal testing, used until then, with alternative methods.

Occupational health and safety

The occupational safety and health management system (OSH) is a fundamental part of the risk management strategy. The objectives targeted by the implementation of the OSH management system are:

- protection of the Antibiotice team and of those who carry out their activity on the company's territory;
- strict compliance with the legislative regulations in force;
- facilitating improvement;
- improving the organization's motivation and acceptance of occupational safety and health within the company;
- reducing the number of accidents by systematizing all activities relevant to occupational safety and health;
- reduction of health risks, and implicitly, the reduction of the associated costs;
- reduction of material losses due to the number reduction of accidents and accidental stops;
- reduction of insurance costs

Antibiotice pays special attention to the safety and security of employees as well as visitors. The Internal Prevention and Protection Service, subordinated to the General Director, ensures the observance of the regulations contained in the Law no. 319/2006 on safety and health at work.

Maintaining and developing an effective occupational safety and health management system for Antibiotice is the guarantee of creating an optimal framework for managing and eliminating work-related risks, improving the working environment and employee relations.

Since 2007, the company has obtained the certification of the Integrated Management System (quality / environment / occupational health and safety), according to international standards 9001/14001/18001.

In November 2019, the company obtained a new certification of the occupational health and safety management system, SR ISO 45001, granted by the certification body TÜV Rheinland Romania, which conducted in 2021 a surveillance audit to verify the compliance of the system.

The principles and measures of the occupational safety system are established and followed through the Prevention and Protection Plan by the Occupational Safety and Health Committee (OSHC) organized at company level.

Occupational Safety and Health Committee

There is an Occupational Safety and Health Committee within the company. The Committee is composed of worker representatives with specific responsibilities for the safety and health of workers, on one hand, and employer or his legal represen-tative and his representatives in equal numbers as the workers' representatives and the occupational physician, on the other.

The coordinator of the occupational health and safety activity is the secretary of the Occupational Safety and Health Committee. The employer or his legal representative is the chairman of the Occupational Safety and Health Committee. The members of the Occupational Safety and Health Committee shall be nominated by the written decision of its chairman and all members shall be informed regarding the composition of the committee. This committee meets quarterly or whenever necessary.

The responsibilities of the OSHC according to GD.1425/2006, with subsequent amendments, are:

- analyzes the health of staff, the situation of the days of incapacity for work, proposing measures to improve working conditions;
- analyzes and makes proposals regarding the occupational safety and health policy and the prevention and protection plan, according to the internal regulation;
- pursues the implementation of the prevention and protection plan, including the allocation of the necessary means to achieve its provisions and their efficiency in terms of improving working conditions;
- analyzes the introduction of new technologies, the choice of equipment, taking into account the consequences on the safety and health of workers and makes proposals when certain deficiencies are found;
- analyzes the choice, purchase, maintenance and use of work equipment, collective and individual protection equipment;
- proposes measures for the arrangement of workplaces, taking into account the presence of groups sensitive to specific risks;
- analyzes the requests made by the workers regarding the working conditions and how the designated persons fulfill their attributions;

- monitors the manner in which the legal regulations on safety and health at work are applied and observed as well as the measures ordered by the labor inspector and the health inspectors;
- analyzes workers' proposals for the prevention of accidents at work and occupational diseases, as well as for the improvement of working conditions and proposes their inclusion in the prevention and protection plan;
- analyzes the causes of work accidents, occupational diseases and events and may propose technical measures in addition to the measures ordered following the investigation;
- performs its own checks regarding the application of its own instruction and work instructions and makes a written report on the findings;
- discusses the written report submitted to the occupational safety and health committee by the head of the unit at least once a year, regarding the occupational safety and health situation, the actions taken and how effective they are in the year ended, and proposals to be implemented next year within the prevention and protection plan.

Identifying risks

The assessment of risks related to accidents at work is carried out in accordance with the provisions of the internal procedure and aims to identify the risks to safety and health at work for each workplace and job and to establish measures to control the risks to health and safety at work, which is useful for the continuous improvement of the occupational health and safety management system.

The company employees have the obligation to immediately communicate to the employer and / or the designated workers any work situation which is considered to be danger to the safety and health of the workers, as well as any deficiency of the production systems. Within OSHC, in 2021, new occupational risks were identified and the following measures were taken:

- through the 2021 Prevention and Protection Plan, a number of 11 technical measures, 4 organizational and 4 hygienic-sanitary measures were planned. The measures aimed at reducing physical effort by purchasing 3 manual pallet trucks in the Biosynthesis plant, purchasing a forklift for the Topical Products plant, purchasing an electric pallet truck for the Logistics Department, purchasing 2 cleaning systems for class B clean rooms for the Parenteral plant and 1 cleaning system for class B clean rooms for the Quality Assurance department;
- purchase of an audiometer and 3 automatic defibrillators, within the Medical Office;
- the professional risks for the Tablets, Transports, Biosynthesis plants were re-evaluated, in order to correlate with the events that occurred in 2021

The Occupational Health and Safety (OSH) activity is organised within the company to deal with prevention and protection activities, according to a structure established by the employer, as follows:

- consists of workers who meet at least the requirements provided in art. 49 of GD 1425/2006 with subsequent amendments;
- the coordinator of the OSH activity must meet the requirements provided in art. 50. of GD 1425/2006 with subsequent amendments;
- workers within the OSH activity have a full-time individual employment contract signed with the employer;
- OSH workers only carry out prevention and protection activities;
- has at its disposal the material and human resources necessary to carry out the prevention and protection activities within the company;
- the employer provides the appropriate means for the OSH activity to be able to carry out the specific activities;
- also ensures the supervision of the workers' health through the Occupational Medicine Office that has a professional staff and adequate material means, in accordance with the law.

Occupational health and safety training

Within the company, all employees are informed and receive training on occupational health and safety periodically, depending on the specifics of each activity they carry out, as follows:

- general introductory training instructions;
- instructions on overhaul and repair work;
- instructions on authorization/reauthorization per occupations according to the legislation in force (abrasive stone installers, working at height);
- training instructions according to ISCIR (boiler firemen, load binders, forklift operators, etc.).

Our company conducts also OSH training and concludes agreements in this regard with all external partners who carry out various works on the Antibiotice site according to the internal procedure.

The employees of Antibiotice benefit from the facilities granted for work in conditions of extreme temperatures, starting with temperatures of -10 degrees (compared to the legal limit of -20 degrees) and from +32 degrees Celsius (compared to the legal limit of +37 degrees).

An adequately equipped medical office, as well as a team of occupational physicians and nurses, operate within the company.

The medical office with a permanent program (24 hours a day) has the necessary medical equipment for:

- ensuring medical checks upon employment;
- ensuring the provision of first aid in case of medical emergencies;
- ensuring medical checks for the permanent assessment of the health of employees, according to the legislation of occupational medicine, but also to the requirements regarding the quality and safety of the medicine manufacturing.

The medical office also has a dental office that provides specialized medical assistance for emergencies and a psychological office that ensures the performance of psychological assessments of employees at risk, according to current legislation.
In addition, the psychological office provides, for employees, psychological counseling free of charge, with the protection of confidentiality and protection of personal data.

In 2021, starting with February, a vaccination center with 2 vaccination flows was authorized and operated within the Center for Clinical Studies (Pfizer and Moderna vaccines were used). Subsequently, the vaccination center was relocated inside the Medical Office, where it operated with a vaccination flow (Pfizer vaccine), 7 days / week / 12 hours a day.

Type of training conducted in 2021

	Number of Employees	Total number of hours
General introductory training instructions	107	856
Instructions on overhaul and repair work	133	266
Instructions on authorization/reauthorization for each type of job according to the legislation in force (abrasive stone installers, working at height)	32	32
Authorization instructions according to ISCIR (boiler firemen, load binders, forklift operators)	145	145
OSH training (external partner conventions carrying out various works on the Antibiotice site according to the internal procedure)	405	405

The own vaccination center provided easy access to immunization both for Antibiotice employees (about 80% of employees were vaccinated in 2021) and for their families, former employees and members of neighboring communities. During 2021, 23,603 doses of Pfizer BioNTech and Moderna vaccine were administered, with no severe adverse reactions.

During the reporting period, the company recorded three accidents at work (road accidents), totaling a number of 46 days of temporary incapacity for work.

The registration and investigation of work accidents in the company is carried out in accordance with the provisions of Law 319/2006, Chap. VI – Communication, research, registration and reporting of events, GD 1425/2006 Methodological norm for applying the provisions of Law 319. Chap. VII – Communication and investigation of events, recording of work accidents and dangerous incidents, investigation, declaration and reporting of occupational diseases and the company's Incident Investigation Procedure.

In order to eliminate the risks and dangers that are the sources of work accidents, according to the internal procedures, the company ordered the reassessment of the risks regarding safety and security at work (OSH) and the additional training of the workers.

Accidents at work in 2021

	Employees		Workers	
	Men	Women	Men	Women
Number of deaths caused by accidents at work	0	0	0	0
Number of accidents at work with serious consequences for the employee (needs more than 6 months of recovery)	0	0	0	0
Total number of accidents at work (with temporary incapacity for work / road accident)	1	2	0	0

The main types of accident: work accident with temporary incapacity for work; road accident

In 2021 **there were not registered:**

- deaths caused by illness as a result of exposure to hazards in the workplace;
- illnesses caused by exposure to hazards in the workplace.

Measures taken in 2021 during the COVID-19 pandemic

In the second pandemic year, our company maintained the preventive and safety measures to protect employees' health from infection with the new coronavirus. Measures were also adopted to stimulate the process of vaccination against COVID-19, to provide our employees with post-vaccination protection and adequate information on the effects and benefits of vaccines for immunization against SARS-CoV-2. Starting with February 2021, information on the effects and benefits of COVID-19 vaccines was provided on internal channels, video messages and testimonials were broadcast with internal leaders (during the 1st and 3rd wave of the pandemic) and an intensive prevention campaign was conducted by communicating anti-COVID-19 protection measures at the each workplace. In order to elucidate the doubts on vaccination among employees, an internal study was conducted to assess perceptions of anti-COVID-19 immunization, with a 37% attendence, followed by two workshops "The specialist explains. You decide.", internally conducted by an infectious disease specialist. At the end of 2021, about 78% of our employees were immunized against the SARS-CoV-2 coronavis. To these actions, the measures initiated in 2020 and continued in 2021 were added to protect employees from SARS-CoV-2 infection, supplemented by new ones:

- the working procedure SOP-SSO-017, revision 06 – Preventive measures to limit COVID-19 infections was revised;
- the Vaccination Center a+, with two flows (Pfizer and Moderna vaccines) located inside the Center for Clinical Studies was authorized and put into operation since February 2021. Subsequently, the Vaccination Center a+

was relocated inside the Medical Office, where it operated with one vaccination flow (Pfizer vaccine), 7 days a week / 12 hours a day;

- our employees were constantly trained and their and visitors's health was monitored;
- plexiglass panels were used where the 1.5-meter social distancing could not be ensured;
- medical masks, gloves, visors, hand sanitizers and surfaces were freely provided;
- our company's management nominated a Health & Safety Committee that monitored nationally and internationally the evolution of the pandemic in order to take appropriate measures in the company;
- our employees had to measure their temperature with the help of thermal scanners, to disinfect their hands and wear the medical mask, being subjected to medical examinations when necessary;
- the high-traffic contact surfaces (doors, handles, taps, railings, etc.) and company buses were periodically disinfected;
- our company maintained the work at home for employees who had been able to do so.

Program for testing and diagnosing uterine cervical cancer

Given the limited access to medical investigations due to the pandemic, in October, Antibiotice hosted for its employees, a testing and diagnosis campaign for cervical cancer, within the national project ONCOPREV. This project was carried out by the Iași Regional Institute of Oncology and the Enable Romania Foundation, Antibiotice supporting the project by organizing the testing within the Mobile Screening Unit. Through this campaign, 255 women employees (34% of the eligible women) benefited from free Babeș-Papanicolau and HPV testing. Our women employees who needed additional investigations benefited from a special circuit of programming for investigations and treatment, in the specialized medical unit from Iași.

Respecting the natural environment

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

The entire activity on the environmental protection is regulated by operating procedures of the environmental management system and by specific work instructions.

Starting with 2007, Antibiotice has obtained the certification of the Integrated Management System (quality/environment/ occupational health and safety), according to the 9001/14001/18001 international standards.

Since November 2019, our company has obtained a new certification of the occupational health and safety management system, SR ISO 14001, granted by the certification body TÜV Rheinland Romania, that conducted in 2021 a supervisory audit to verify the compliance of the system.

We are aware of the responsibility we have for protecting the natural environment and we have been constantly implementing measures to diminish the negative contribution generated by the production processes. Our policy on quality, environment, occupational health and safety contains the main commitments we make in this direction.

The activities developed by our company are regulated by the Integrated Environmental Authorization no. 3/29.09.2021, valid with annual approval, issued by the Iași Environmental Protection Agency, as well as by the Water Management Authorization no. 29/31.03.2021 issued by the Romanian Water Administration, Prut-Bârlad Branch, valid until 01.04.2026.

In accordance with the requirements of Law 278/2013 on industrial emissions (which implements the European Directive 2010/75/EU), the following activities has to be authorized: the main manufacturing activities of basic pharmaceutical products, including intermediate products (industrial biosynthesis of Nystatin) as well as the secondary activities technically related to the main activities 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 own activity, industrial wastewater treatment generated by the manufacturing activity.

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

Energy consumption

All our activities involve energy consumption in various forms (fossil fuels, electricity, thermal energy). Our company produces a part of the energy (steam, thermal energy, energy for cooling) and purchases another part from external suppliers (natural gas, electricity). Our company's objective is to reduce the consumption by improving the energy efficiency. To this end, Antibiotice aims at increasing the proportion of renewable energy used in the production processes.

Energy consumption from fossil fuels

In our company, fuel consumption occurs in the production processes and for refueling the vehicle fleet:

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

The energy quantities were calculated based on records and information received from utility and fuel suppliers, using calorific value, but also the agreed conversion factors for energy units, according to the literature.

Fossil fuel consumption

Energy consumption (Tj*)	2021	2020	2019
Diesel**	**19.97**	18.539	16.213
Gasoline**	**0.57**	0.596	0.425
Natural gas***	**171.42**	170.331	162.960
Total	**191.96**	189.466	179.598

* 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 (EF) according to Annex VI to Regulation (EU) no. 601/2012 on the monitoring and reporting of greenhouse gas emissions, according to Directive 2003/87/EC – http://mmediu.ro/new/wp-content/uploads/2014/04/2014-04-30_Regulament601-2012monitorizare_raportare.pdf)

*** The higher calorific value (PCS) of natural gas is 38.59 Gj/Nmc, according to the information provided by the supplier.

Electric energy consumption

Total consumption of electrical energy (Tj*)	2021	2020	2019
Total	**45.442**	55.522	51.97
– from non-renewable sources	**27.302****	33.339	25.93
– from renewable sources	**18.140****	22.183	26.40

* 1 TJ (terajoule)=10^{12} jouli =1,000 Gj (gigajoule);

** The energy labels for 2021 will be made available by the electricity suppliers after July 1, 2022, according to the applicable regulations in the field. Thus, in the energy consumption calculations, the values from the energy labels corresponding to 2020, available at the date of preparation of this report were used. Energy consumption will be recalculated after the energy labels for 2021 are provided.

Total energy consumption

	2021	2020	2019
Total energy consumption (Tj*)	**237.393**	244.988	231.917

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

Increase in fossil fuel consumption was due to supplementing the number of cars in the company's fleet, correlated with the increase in the number of kilometers travelled. Due to the social distancing rules imposed by the pandemic, the transport fleet adapted to a differentiated work schedule, thus making additional trips.

Energy saved

440.554 MWh electricity savings

Due to energy efficiency measures resulting from a complex energy audit, energy savings of 440.554 MWh (MegaWatt hour), i.e. 1.59 TJ were achieved.

In addition to the permanent monitoring of the consumption of electricity, natural gas and compressed air, the measures consisted of:

- modernizing the compressed air production system with compressors with variable frequency drives by purchasing a new compressor with variable speed;
- replacing old transformers with new, dry, more efficient transformers;
- replacement of fluorescent lighting in the Raw Materials Warehouse with LED lighting.

Energy intensity

Energy intensity (GJ*/ 1,000 lei)	2021	2020	2019
1. Total energy consumption (GJ)	237,393	244,988	231,917
2. Sales revenue (thousand lei)	366,209	340,424	390,000
3. Commodity production (thousand lei)	381,259	360,779	394,418
Energy intensity at 1,000 lei sales revenue (1:2)	0.64	0.72	0.59
Energy intensity at 1,000 lei commodity production (1:3)	0.62	0.68	0.59

* 1 GJ (Gigajoule)=10^9 jouli

Following the implementation of measures to streamline energy consumption, energy intensity (relative to the value of production) decreased by 8.8% compared to the previous year.

Emissions

Direct greenhouse gas emissions are generated by Antibiotice through:

- its own thermal power plant, by burning natural gas;
- incineration of dangerous, industrial and medical waste in its own incinerator;
- its own vehicle fleet almost entirely powered by diesel and gasoline;
- industrial wastewater treatment;
- installation for extracting the active substance Nystatin, which emits volatile organic compounds (VOC);
- discharges routed from the manufacturing plants of the finished products and from warehouses.

Direct and indirect emissions of greenhouse gases

Emissions are calculated according to the standard methodology set out in the Regulation (EU) No. 601/2012 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC (calculation made by multiplying the activity data corresponding to the category of fuel used, based on the net heat output, with the corresponding emissions factors, according to the 2006 IPPC Guidelines).

GHG emissions (tons of CO_2 eq)	2021	2020[1]	2019[1]
Scope 1 – direct emissions, of which:	**8,430**	8,314	8,849
– from natural gas combustion*	**6,944**	6,882	7,603
– from the combustion of diesel and gasoline**	**1,486**	1,432	1,246
Scope 2 – indirect emissions (electricity consumption from suppliers)***	**2,773**	2,980	3,604
Total greenhouse gas emissions Scope 1 + Scope 2 (tons of CO_2 eq)	**11,203**	11,294	12,453

* The higher calorific value (HCV) of natural gas was 38.59 Gj/Nmc, according to the information provided by the supplier

** Calorific value (CV) of fuels: diesel 42.46 Gj/ton and gasoline 43.51 Gj/ton; the values used represent the national values of the emission factors and the net calorific values, specific to the fuels and the category of activity, according to the IPPC Guidelines (information valid for 2019) – http://www-old.anpm.ro/docfiles/view/214864.

*** The value of emission factors (EF) for electricity was in line with the energy labels for 2020, issued by utility providers. The energy labels for 2021 will be made available by the electricity suppliers, after July 1, 2022, according to the applicable regulations in the field. Thus, in the energy consumption calculations, the values from the energy labels for 2020, available at the date of preparation of this report, were used. Energy consumption will be recalculated after the energy labels for 2021 are provided.

Intensity of greenhouse gas emissions (GHG) (tons of CO_2 eq/ 1.000 lei)	2021	2020[1]	2019[1]
1. Total GHG emissions (t of CO_2 eq)	**11,203**	11,294	12,453
2. Sales revenues (thousand lei)	**366,209**	340,424	390,000
3. Commodity production (thousand lei)	**381,259**	360,779	394,418
Intensity of GHG emissions at 1,000 lei sales revenues (1:2)	**0.030**	0.033	0.032
Intensity of GHG emissions at 1,000 lei commodity production (1:3)	**0.029**	0.032	0.032

Compared to the value of commodity production, the intensity of emissions from Scope 1 and Scope 2 decreased by 9% compared to 2020. The decrease in the intensity of GHG emissions can be explained by the decrease in electricity consumption.

Other significant emissions in the air (tons of NMVOC*/year)	2021	2020	2019
Non-methane volatile organic compounds (tons of NMVOC/year)**	**285,476**	382,977	310,583

* NMVOC = non-methane volatile organic compounds

** according to the solvent balance drawn up taking into account the values measured by a RENAR accredited third-party laboratory

[1] In the 2020 Report, the Scope 1 emissions were calculated using emission factor values and net calorific value for methane gas according to the 2006 IPPC guidelines. For 2021, Scope 1 was calculated using data from the List of National Emission Values and Net Calorific Values: available for consultation here https://bit.ly/3Q8WbqD

Thus, the value of Scope 1 emissions and intensity of GHG emissions for 2020 and 2019 were recalculated using these values.

Compared to the previous year, greenhouse gases emitted in 2021 decreased by 91 ton of CO2eq, representing 0.8%. The amount of the greenhouse gas emissions was calculated on the basis of the information available at the reporting date and will be updated later, after the suppliers will provide the labels.

Other emissions

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

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

In 2021, the amount of total emissions of non-methane volatile compounds (VOCs) decreased by 25% compared to 2020 due to the production structure.

Quality of the air in the Antibiotice's perimeter is monitored by determinations made in its own laboratory and in a third-party laboratory. The certificates of analysis show that the concentrations of gaseous pollutants emitted into the air fall within the maximum acceptance limits for protecting the human health: nitric oxide (NO_x), sulfur oxide (SO_x), carbon monoxide (CO), ammonia (NH_3), non-methane volatile organic compounds (NMVOC), 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 by Antibiotice.
No exceedances of the maximum admissible concentrations foreseen in the Integrated Environmental Authorization were recorded.

In 2021, following the issuance of the Law no. 123/2020 known as the "Law of Smells", we initiated specific actions, in order to apply the legislative requirements in the field, as follows: we elaborated an Olfactory Discomfort Management Plan, we have started the collaboration with a third-party laboratory to determine odor emissions, in order to evaluate the values of these indicators as accurately as possible and we intend, in the future, to ensure the self-monitoring of these emissions.

We have been constantly concerned with improving the technological performance of installations / equipment, as well as with identifying the applicable solutions, in order to prevent any discomfort for the neighboring community.

Vehicle fleet in 2021

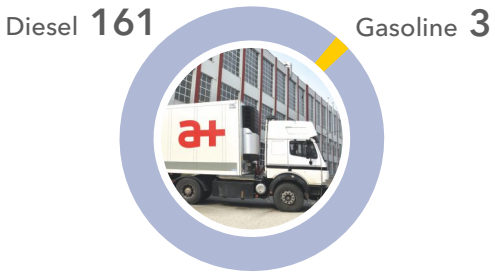
Our company's fleet consists of means of transport such as service cars, buses for employee transport, minibuses, vans, tractors. Inside the factory, the transport of goods is done with forklifts and electric trucks.

Antibiotice vehicle fleet (motor vehicles in circulation)

Number of vehicles	**164**
Distance traveled (km)	**3,427,850**

Our fleet also includes a special vehicle that participates in extinguishing fires inside and outside the company, used by the Fire Department and a car for transporting people to the hospital and analysis laboratories, used by the Medical Office.

Types of vehicles in the fleet



Water consumption management

Management of water supply and drainage, as well as the monitoring of water quality are done in accordance with the requirements of the Water Management Authorization no. 20/31.03.2021 valid until 01.04.2026, issued by the National Administration "Romanian Waters", Prut-Bârlad Water Basin Administration.

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 by industrial biosynthesis, water being the major component of the biosynthesis broth (in the stage of obtaining the industrial vegetative, in 3300 l and 2500 l intermediate bioreactors and then in the growth stage of the industrial vegetative on the nutritious medium, in bioreactors with volumes of 70,000 liters).

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

	2021	2020	2019
Total volume of water captured, by source (Ml*):	**149.0**	**159.6**	**146.7**
– 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	149.0	159.6	146.7

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

In 2021, water consumption decreased by about 7%, mainly due to the measures applied to improve water management, by ensuring the monitoring of consumption.

Our company has been constantly monitoring water consumption. Because our main operations, i.e. production (the pharmaceutical factory), clinical services (Center for Clinical Studies) and the administrative area (our headquarters) are located in the City of Iași, Iași County, the entire volume of water is supplied by ApaVital (the regional public operator of water and sewerage services in the Iași County). This operator supplies the City of Iași with potable water from two sources: Timișești (since 1911) the Prut River (since 1957).

Water used in the production processes comes from the Iași municipal network, being potable water from the underground springs of Ozana (Neamț River). In the spring water extracted by the operator ApaVital from the foot of the mountains, near the Timișești Commune, Neamț County, additional surface water is injected from the Moldova River to compensate the water deficit in times of drought.

Water stress risk

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). We used the tools provided free of charge by the Institute of Global Resources (WRI), namely the Aqueduct Water Risk Atlas to evaluate if the Timișești area, Neamț, where our water source comes from, is or is not a water stress area.

Aqueduct 3.0 uses the risk element terminology used by the United Nations Office for Disaster Risk Reduction (danger, exposure and vulnerability) and each indicator is assigned a risk element.

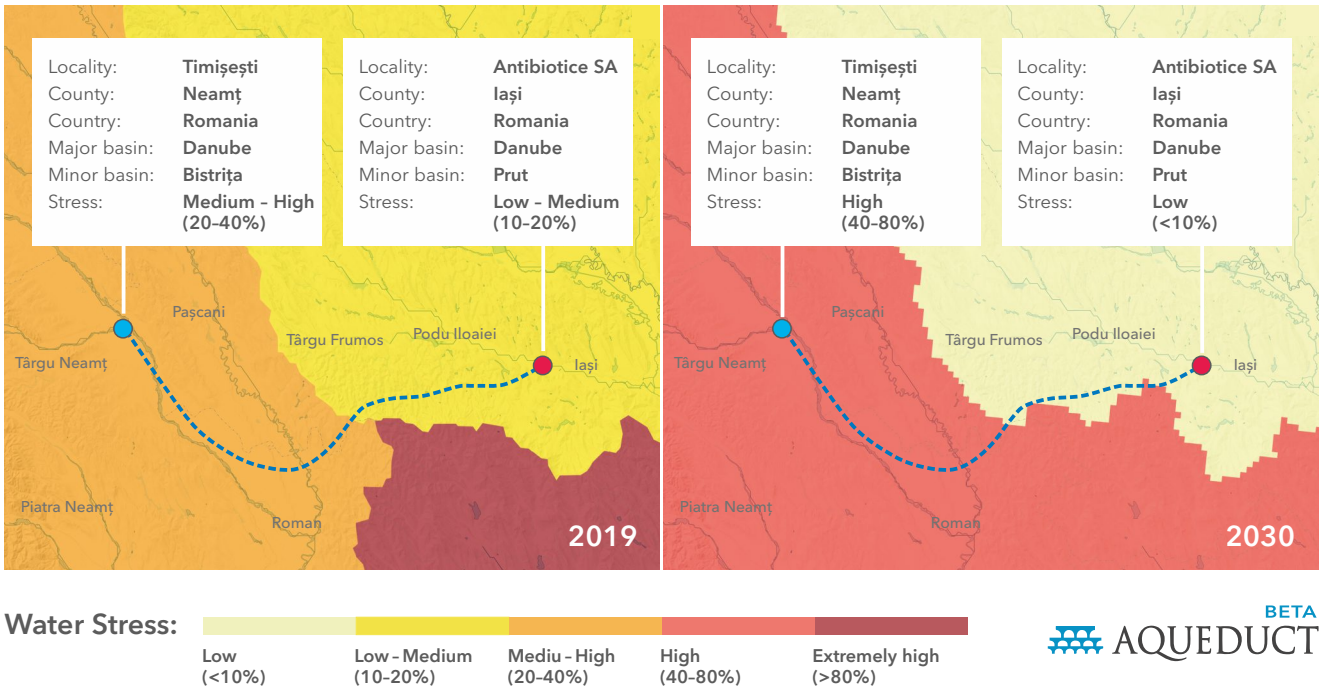
From the category of physical risks, we used basic water stress**, an indicator required by the GRI 303 standard. Basic water stress is calculated as the ratio between the total water captured (extracted) during a year and the total renewable water resources available.

Water is collected for domestic and industrial use, for irrigation and for animals (drinking and non-drinking water), and available renewable water reserves include surface and ground water reserves and take into account the impact of the

> "For the commissioning of the city's first large industrial unit, Penicillin Factory (1955), the necessary water was provided from the Timisesti source."
>
> (*"Iași, the city saved with the living water from Timișeștii Neamțului"*, Grigore Radoslavescu, Studis Publishing House, 2018)

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

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



water consumers and large dams located upstream on the availability of water downstream.

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

Thus, the map of Timișești area, Neamț, (left on the diagram) shows that, in 2019, water stress had a medium to high value (Medium-High, 20–40%), so the area was not yet under water stress. The Aqueduct 3.0 tool also allowed us a projection into the future, so we made an estimate of the water stress in the Timișești area up to 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 (see on the right side of the figure, optimistic scenario for 2030).

It should be noted that 2021 was not a dry year in Eastern Europe. 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.

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 circuit for supplying the steam boilers. 10,012 m3 of water from the steam condensate were reused for heating and preheating in 2021.

Intensity of water consumption

Intensity of water consumption (specific water consumption)	2021	2020	2019
1. Total water consumption (m³)	**149,000**	159,600	146,700
2. Sales revenue (thousand lei)	**366,209**	360,800	390,000
3. Commodity production (thousand lei)	**381,259**	360,779	394,418
Intensity of water consumption at 1,000 lei sales revenue (1:2)	**0.41**	0.47	0.38
Intensity of water consumption at 1,000 lei commodity production (1:3)	**0.39**	0.44	0.38

Discharged water

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

- technological wastewater
- wastewater
- rainwater.

Technological (industrial) wastewater is treated in each plant in existing pre-treatment installations. Partially pre-treated, technological wastewater as well as domestic and rain water in the area of the Biosynthesis Plant are directed through the internal sewer to the pre-treatment plant of the factory.

Antibiotice receives also in its sewerage network wastewater from economic and administrative units from the area, for which it provides pre-treatment services and drainage in the ApaVital sewerage, on a contract basis (these quantities were included in the declared volumes of effluents).

The pre-treatment plant works in two treatment stages: a mechanical one, with the role of retaining floating coarse matter, sand, fats, and a biological one with

-11.2%

Intensity of water consumption, relative to the value of production, decreased by 11.2% compared to 2020

Discharged water	2021	2020	2019
Total volume of discharged water, by destination (Ml*)	**243.3**	**257.4**	**249.2**
– in surface water (brook)	134	134	134
– in groundwater	0	0	0
– discharged water to suppliers or other organizations	109.3	123.4	115.2

* 1 Ml (megaliter) = 1,000,000 liters = 1,000 cm (cubic meters)

activated sludge, which reduces the organic load and other pollutants such as ammonia nitrogen (NH4-N), sulfides etc..

Conventionally clean meteoric water, 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 sewerage system to our own pre-treatment plant.

The effluent volumes 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 performed according to the requirements of the Integrated Environmental Authorization and Water Management Authorization. Quality of wastewater pre-treated in our own treatment plant and discharged into the municipal sewerage network, conventionally clean rainwater discharged into the emissary, as well as groundwater fell within the parameters established by environmental legislation. Antibiotice performs determinations of quality indicators for discharged water, in its own laboratory, as well as in third-party laboratories accredited by RENAR. In 2021, there were no exceedances of the maximum allowed concentrations set in the Integrated Environmental Authorization, Water Management Authorization and G.D. no. 352/2005 (NTPA 001 and NTPA 002).

Materials, packaging and waste

For manufacturing and packaging the active substance Nystatin in the form of bulk powder, the biocides for disinfecting surfaces and finished products from our portfolio (generic medicines for human and veterinary use, medical devices, food supplements, cosmetics) we use non-renewable materials (minerals, petroleum, 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 medicines in the factory located in Iași, where most of the waste is generated.

The two two major activities carried out in our pharmaceutical factory from Iași are the production 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 production activity is carried out in accordance with the Good Manufacturing Practices (GMP) in the pharmaceutical industry.

The process of industrial biosynthesis of the active substance Nystatin begins with the inoculation of bacterial microorganisms *Streptomyces noursey*, on a nutrient medium. Fermentation follows in industrial bioreactors, where, under certain environmental conditions, microorganisms biosynthesize Nystatin. The active substance is then separated from the biosynthetic fluid and purified (extraction phase). A yellowish powder in bulk is obtained, which is packed in plastic (polyethylene) bags and then in cardboard boxes.

Industrial technological flow of production by 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 organic and inorganic substances that make up the nutrient medium needed to feed microorganisms, and water, the major component of biosynthesis broth. In the last phase of the technological process, the extraction of Nystatin is done with the help of acetone and methanol solvents. The solvents are recovered in a proportion of 95%, from the mother solutions (waters mixed with solvents resulting after extraction), being then reintroduced in the technological process.

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

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

Each manufacturing flow has different operations, specific to the pharmaceutical form obtained, but, as a general description, the main operations are: weighing of active substances and excipients, mixing to homogenization, filling, then the primary, secondary and tertiary packaging.

Primary packaging of finished products manufactured by Antibiotice takes place as follows:

- sterile powders for injectables (parenterals) are placed in vials labeled and sealed with stoppers and caps;
- capsules, tablets, suppositories, pessaries (medicines and medical devices) are packed in printed blisters of aluminum foil, plastic (polyethylene, PVC), composite materials (aluminum and plastic);
- ointments, creams and gels are introduced in printed aluminum or plastic tubes, sealed with plastic (polyethylene) lids.

In the secondary packaging, each individually packaged pharmaceutical form is introduced in its own box, together with the leaflet, and then sealed.

Tertiary packaging process involves grouping several drug units into cardboard boxes, which are then sealed and labeled. Their transport is done on wooden pallets (tertiary packaging for transport), depending on the quantity ordered. For transport integrity, the pallet loaded with drugs is sealed with stretch film.

Some of the primary packages are produced in our company by the Microproduction Plant. Aluminum tubes for ointments, aluminum caps for sealing the vials filled with sterile powders for injectable solutions, plastic caps for sealing the aluminum tubes for ointments and plastic extensions for applying certain ointments use aluminum as a raw material (strips and round disks) and polyethylene (plastic granules). Aluminum tubes are printed with printing paints.

Biocidal products are in the form of clear liquid solutions packed in 1-liter labeled, plastic containers with spray heads or in 5-liter labeled cans, or in the form of translucent gel packaged in 50 ml, 100 ml labeled lidded plastic containers, in 500 ml and 1-liter labeled containers with dosing pump and in 5-liter labeled cans.

The type and quantity of materials that our company used in the production process, in 2021

For 2021, the inputs of raw materials, materials and packaging were estimated for the production operations carried out in the pharmaceutical factory from Iași. In the following year we will monitor the inflows of raw materials, materials, etc. used in the activities carried out at the Center for Clinical Studies, at our headquarters (located in the same premises with the manufacturing site) as well as at our Representative Office in Bucharest.

In some cases, the quantities consumed were measured directly, but due to the very large number of products purchased,

The data were provided by the Domestic Procurement Department for the Romanian suppliers and by the Import Department for the external suppliers, and some contextual data were taken from the 2011–2020 Integrated Environmental Authorization held by Antibiotice (updated in 2018 with extended validity during the alert state) and Integrated Environmental Authorization no. 3/29.09.2021 which can be found on the website of the Iași Environmental Protection Agency, in the Regulations section, Integrated Environmental Authorizations and the 2021 Annual Environmental Report of Antibiotice which can be consulted on our company's website, in the Responsibility section, Environmental Protection.
For the following reporting periods, we will implement reporting systems able to obtain data as accurate as possible.

different characteristics and units of measurement as well as due to the lack of data required in the calculations, only estimates were made in many cases (for example, in the case of secondary and tertiary packaging made of paper and cardboard, such as the medicine box, label, band, leaflet which we considered identical in size and weight for all products).

We thus estimated that, in 2021, the total weight of raw materials and auxiliary materials used for production and packaging of the active substance Nystatin and finished products (generic medicines for human and veterinary use, medical devices, food supplements, cosmetics and biocides) was 5,953.9 tons, of which 3609.2 tons were non-renewable materials and 2344.7 tons were renewable materials.

Of the total raw materials and consumables purchased, we purchased 65% from the domestic suppliers and 35% from the external suppliers.

The amount of materials used in 2021

i) Non-renewable materials	Tons
i.1) Non-renewable virgin materials	
Raw materials (active substances in bulk, excipients, organic and inorganic chemical subtances etc.)	2050.3
Materials used in the production process but which are not part of the final product or packaging of the product (diesel and gasoline*, industrial lubricants, solvents, gases, aluminum, polyethylene, etc.)	637.4
Products or semi-finished parts, including all types of materials and components, other than raw materials included in the final product (printing ink, paint, electrodes, parts of different metals, glass and plastic, other than packaging, etc.)	281.6
Materials used as packaging (glass, plastic of various types, stoppers, aluminum and plastic caps, blisters of aluminum, plastic or composite material foil)	639.9
Total non-renewable virgin materials	**3609.2**
i.2) Recycled non-renewable materials	
Total recycled non-renewable materials	**0**
Total non-renewable materials used in 2021	**3609.2**
ii. Renewable materials	**tons**
ii.1) Renewable virgin rmaterials	
Raw materials (natural resources turned into products and services)	0
Production process-related materials used in the manufacturing process, but not part of the final product or product packaging (paper and paperboard, other than packaging, natural rubber)	2.0
Materials used as packaging (paper and cardboard, wood)	2338.2
Total renewable virgin materials	**2340.2**
ii.2) Recycled renewable materials (recycled cardboard)	
Total recycled renewable materials	**4.5**
Total renewable materials used in 2021	**2344.7**
Total non-renewable and renewable materials used in 2021	**5953.9**

Recycled input materials

Due to the specifics of the pharmaceutical and medicine industry, there is a limit of the 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 0.075 % (the cardboard used to separate the products when placed on the pallet, in the tertiary packaging).

The ratio between the amount of materials used to manufacture the Antibiotice products in 2021 and the waste generated in the same period was 5.25.

Packaging and waste

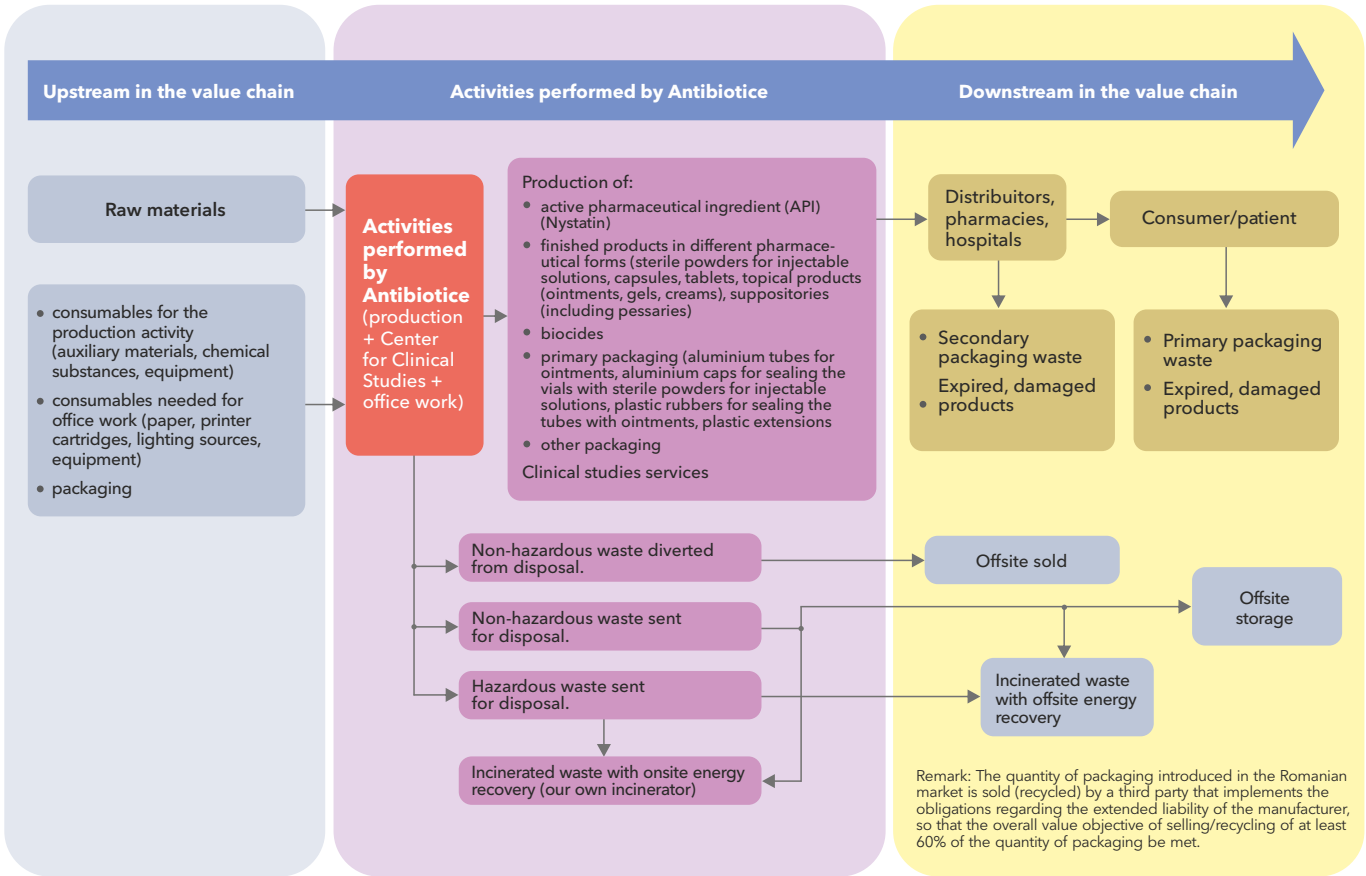
Our company has been constantly improving the management of the waste generated, by reducing the total quantities of waste and collecting them separately. Each manufacturing plant and each ancillary activity has separate waste collection containers. As planned, all our employees have been periodically trained on specific topics, including waste management.

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

We present below the quantities of waste generated in 2021 by Antibiotice from the manufacturing operations and how they were disposed of or diverted from disposal.

These data were extracted from the records held by the Environmental Department, including also the environmental audit conducted in 2021.

Materials and waste flow



Waste (tons)	2021	2020	2019
Total amount of waste, of which:	**1132.758**	**1400.910**	**1760**
- hazardous waste	16.218	21.714	17
- non-hazardous waste	1116.54	1379.196	1743

Due to the fact that our site has been in a continuous modernization, in 2021, according to the legal regulations, old production plants were demolished because they were unsuitable for safe use and no longer corresponded to the current manufacturing norms. Waste generated from demolition, namely mixtures of concrete, bricks, tiles and ceramic products, other than those specified in 17 01 06 – code 17 01 07 – amounted to **15,049.062 tons**. The demolition stage was specific to 2021. Therefore, in order to have a clear picture of the comparative evolution of the quantities of waste generated from manufacturing operations, we will not include this type of waste in the statistics.

The reduced waste from the manufacturing activity in 2021, compared to the previous year, was both due to the beginning of implementing the sustainability principles in our processes and strategies, and to improving the waste management in our company.

Types of waste and method of disposal

Waste management by types and methods of disposal /recovery (tons)	2021	2020	2019
Total waste generated	**1,132.76**	1,400.91	1,760
Total amount of hazardous waste, according to the method of recovery/disposal (where applicable)	**16.22**	21.71	17
Hazardous waste for reuse	0	0	0
Hazardous waste for recycling	0.38	0	0
Hazardous waste for compost	0	0	0
Hazardous waste for recovery, including energy recovery	0	0	0
Hazardous waste for incineration	15.84	21.714	17
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)	**998**	1000.63	1743
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	769.86	710.92	1112
Non-hazardous waste for incineration	34.7	54.2	36
Municipal landfill	188.5	213.5	215
Storage on the company's site*	**118.53**	400.22	407

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

Types of waste generated in 2021 (tons)

No.	Waste type	Waste code	Total amount of waste generated	Waste diverted from disposal	Disposed waste (incineration, storage)
1	Packaging paper, cardboard	15 01 01	72.92	71.13	1.75
2	Iron and steel	17 04 05	642.52	642.05	0
3	Aluminum, packaging	15 01 04	8.95	8.5	0
4	Aluminum dismantling, demolition	17 04 02	0.07	0	0
5	Copper waste	17 04 01	2.39	2.39	0
6	Mycelium, filter cakes	07 05 12	113.1	0	0
7	Sludge – industrial water treatment plant	19 08 12	5.43	0	0
8	Engine oil for lubrication, transmission	13 02 08*	0.58	0	0.58
9	Mixed municipal waste	20 03 01	188.5	0	188.5
10	Wood packaging	15 01 03	21.71	21.88	0
11	Glass packaging	15 01 07	10.59	7.19	0
12	Plastic packaging	15 01 02	16.78	7.29	9.13
13	Rubber waste	20 01 39	0.23	0	0.23
14	Expired medicines, non-compliant products	20 01 32	23.52	0	23.52
15	Electronic, electrical waste	16 02 14	1.42	1.28	0
16	Acetone mixture with inner varnish, enamel, inks	08 01 17*	0.22	0	0.22
17	Solvent distillation and recovery residue	07 05 08*	12	0	12
18	Exhausted absorbents	15 02 02*	2.61	0	2.61
19	Ash waste, burning slag	19 01 12	0.17	0	0
20	Expired reagents, laboratory substances	16 05 06*	0,09	0	0.09
21	Aluminum cables	17 04 11	2.9	2.9	0
22	(Sharp) medical waste	18 01 01	0.06	0	0.06
23	(Infectious) medical waste	18 01 03*	0.29	0	0.29
34	Exhausted chemicals	16 05 09	0.0036	0	0.0036
25	Solid waste with hazardous substances	07 05 13*	0.042	0	0.02
26	Paper	20 01 01	5.26	5.26	0
27	Abandoned CFC-containing equipment	20 01 23*	0.13	0.13	0
28	Lead acid batteries	16 06 01*	0.25	0.25	0
			1,132.76	**770.24**	**239.04**
** mixtures of concrete, bricks, tiles and ceramic products, other than those specified in 17 01 06		17 01 07	15,049.06		

* hazardous waste (the others are non-hazardous)

In 2021, out of the total of 1,132.7577 tons of waste generated by Antibiotice from the manufacturing process, 10.47% (118.53 tons) were stored in the composting basins arranged at the factory's pre-treatment plant (exhausted mycelium filter cakes and the sludge from the pre-treatment plant). Of the remaining quantity of 1,014.2277 tons, 1,009,274 tons were removed and diverted from disposal, representing 90% of the total waste generated in 2021.

Out of the 1,014.2277 tons, 21% (239.0387 tons) were disposed of, 76% were diverted from disposal (770.235 tons) and the rest of 3% (4.954 tons) were temporarily stored to be diverted from disposal.

Of the total waste generated in 2021, the metal ones (iron and steel) represented 57%. A small part was generated in production, the rest resulting from decommissioning on the industrial site.

769.86 tons
of waste diverted from disposal

Waste diverted from disposal (tons)

		2021			2020		
Location	**Waste code**	**Onsite**	**Offsite**	**Total**	**Onsite**	**Offsite**	**Total**
Hazardous waste							
Preparing for reuse		0	0	0	0	0	0
Recycling (downcycling, upcycling, composting, anaerobic digestion)		0	0.38	0.38	0	0	0
Abandoned CFC**-containing equipment	20 01 23*	0	0.13	0.13			
Waste – lead acid batteries	16 06 01*	0	0.25	0.25			
Another recovery method (repurposing, refurbishment)		0	0	0	0	0	0
Total hazardous waste diverted from disposal		0	**0.38**	**0.38**	0	0	0
Non-hazardous waste							
Preparing for reuse		0	769.86		0	710.92	710.92
Iron and steel	17 04 05	0	642.05	642.05	0	593.76	593.76
Scrapped equipment	16 02 14	0	1.28	1.28	0	2.025	2.025
End-of-life tires	16 01 03	0	0	0	0	0.81	0.81
Paper and cardboard packaging	15 01 01	0	71.13	71.13	0	65.45	65.45
Plastic packaging (PVC, polyethylene and aluminum foils)	15 01 02	0	7.29	7.29	0	7.36	7.36
Glass packaging	15 01 07	0	7.19	7.19	0	14.77	14.77
Aluminum cables	17 04 11	0	2.90	2.90	0	6.60	6.60
Hearth ash and slag from burning waste in the factory incinerator	19 01 12	0	0	0	0	1.59	1.59
Wooden packaging	15 01 03	0	21.88	21.88	0	11.16	11.16
(Metal) aluminum packaging	15 01 04	0	8.50	8.50	0	7.396	7.396
Paper	20 01 01	0	5.30	5.30	0		
Copper	17 04 01	0	2.39	2.39	0		
Recycling (downcycling, upcycling, composting, anaerobic digestion)		0	0	0	0	0	0
Another recovery method (repurposing, refurbishment)		0	0	0	0	0	0
Total non-hazardous waste diverted from disposal		0	**769.86**	**769.86**	0	**710.92**	**710.92**

* hazardous waste (the others are non-hazardous) ** CFC = chlorofluorocarbon (freon)

Waste sent for disposal (tons)		2021			2020		
Where waste is disposed of	Waste code	Onsite	Offsite	Total	Onsite	Offsite	Total
Hazardous waste							
Incineration (with energy recovery)		15.42	0.42	15.84	18.69	3.02	21.71
Other residues from the reaction column vessel	07 05 08*	12.00	0	12.00	14.80	0	14.80
Solid wastes containing hazardous substances	07 05 13*	0	0.04	0.04	0	2.95	2.95
Exhausted absorbents	15 02 02*	2.61	0	2.61	3.04	0	3.04
Other engine, transmission and lubrication oils	13 02 08*	0.58	0	0.58	0.75	0	0.75
Wastes from the removal of paints and varnishes containing organic solvents or other hazardous substances	08 01 17*	0.22	0	0.22	0	0	0.11
Medical waste subject to special measures	18 01 03*	0	0.29	0.29	0	0.07	0.07
Expired reagents, laboratory substances	16 05 06*	0	0.09	0.09			
Incineration (without energy recovery)		0	0	0	0	0	0
Storage		0	0	0	0	0	0
Total hazardous waste sent for disposal		**15.42**	**0.42**	**15.84**	**18.69**	**3.02**	**21.71**
Non-hazardous waste							
Incineration (with energy recovery)		18.39	16.31	34.70	20.28	33.93	54.21
Paper and cardboard packaging	15 01 01	1.75	0	1.75	2.29	0	2.29
Expired medicines, non-compliant products	20 01 32	7.28	16.25	23.52	7.13	28.12	35.25
Plastic packaging	15 01 02	9.13	0	9.13	10.40	0	10,40
Exhausted chemicals	16 05 09	0	0	0	0	5.80	5.80
Plastics	20 01 39	0.23	0	0.23	0.46	0	0.46
Medical waste, sharp objects	18 01 01	0	0.06	0.06	0	0.01	0.01
Incineration (without energy recovery)		0	0	0	0	0	0
Storage		0	188.50	188.50	0	213.50	213.50
Mixed municipal waste		0	188.50	188.50	0	213.50	213.50
Total non-hazardous waste sent for disposal		**18.39**	**204.81**	**223.20**	**20.28**	**247.43**	**267.71**

All decommissioning and demolition works of old, physically and morally worn out buildings were carried out after obtaining the necessary permits from the competent institutions. The released land areas were returned to the natural circuit, to be arranged as green spaces or used as locations for future industrial purposes.

The manufacturing flow for obtaining the active substance Nystatin by biosynthesis generated the largest amount of hazardous waste, 76% out of the total amount, i.e. 12 tons of residues from the distillation and recovery of solvents (from the vessel of the reaction columns). The same production flow generated also 10% of the total non-hazardous waste (113.1 tons of depleted mycelium cakes).

Mixed municipal waste accounted for 17% of total non-hazardous waste (188.5 tons).

Due to the specific quality requirements of the production process and the specific regulations of the pharmaceutical industry, the finished products packaged in different pharmaceutical forms, obtained on the seven manufacturing flows are also the main sources of packaging waste (especially paper/cardboard, plastic and wood). The total paper /cardboard, plastic and wood packaging waste was 111,414 tons, representing 9.84% of the total waste generated in 2021, of which 100,29 tons were recovered.

Out of a total of 72.924 tons of paper and cardboard packaging, 1.749 tons were incinerated on site with energy recovery.

The amount of hazardous waste disposed of decreased by 27% in 2021 compared to 2020. In January 2020, the National Agency for Medicines and Medical Devices of Romania ordered the withdrawal of ranitidine-based medicines from sale in the Romanian market, this contributing to an increased amount of waste, while, in 2021, it was no longer the case.

The decrease of the quantities of hazardous waste disposed of in 2021 is correlated with the decrease of the generated quantities, result of implementing the sustainable development strategy, of continuously improving the waste management procedure, by monitoring and reviewing it, annually.

The quantity of packaging introduced in the Romanian market was harnessed (recycled) through a service contract concluded with an organization that implements the obligations on the extended liability of the manufacturer, so that the overall objective of recovering/recycling at least 60% of the quantity of packaging placed in the market was achieved, according to the requirements of Law 249/2015 on the management of packaging and packaging waste (updated), as well as the GEO no. 196/2005 on the Environment Fund.

In order to be able to verify/control if the authorized provider meets the objectives of recycling the packaging waste, our company asks for and the authorized organization sends monthly reports as well as the annual centralized report on the achievement degree of these objectives.

The goals set for the entire portfolio of clients (Antibiotice included) of OIREP, the authorized service provider were met.

In 2021, Antibiotice Iași did not register outstanding amounts of payment to the Environmental Fund Administration, the global objective of recycling/recovering 60% of packaging waste being fulfilled.

Recovery of organic solvents used in the process of obtaining the active substance

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

Recycling the products and their packaging materials

Packaging (tons)	2021	2020	2019
Total recycled/recovered packaging	**360**	380	523
Total packaging placed in the market	**597**	623	872
Percentage of recycled/recovered packaging from those placed in the market	**60%**	60%	60%

Packaging materials recovered from the Romanian market in 2021	Quantity of packaging of the products placed in the market in Romania (tons)	Percentage recovered from the quantity placed in the market by third parties (%)
Glass packaging	271.012	60.11
Aluminum packaging	35.933	20.76
Plastic packaging	67.680	43.77
Paper/cardboard packaging	222.261	70.62

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

With regard to complaints concerning environmental issues, they can be made to the address: office@antibiotice.ro and will be sent to the Environmental Protection Department.

The Coordinator of the Environmental Protection Department informs the top management and evaluates which departments are responsible for the reported issues.

An internal investigation is initiated by a multidisciplinary team (depending on the nature of the identified non-compliance). After the investigation is completed, the investigation report is verified, including the conclusion of the complaint (unjustified/justified and the established actions) and a reply is sent to the complainant.

There were no notifications and complaints related to environmental issues in 2021.

60%
recycled packaging

95%
Recovery yield of organic solvents

3.4. Strategic planning and performance management

Strengthening our company in the domestic market

Our company's presence of over 66 years in the Romanian market is a testimony that the Antibiotice business model is a performing one. Our products are sold in over 8,000* pharmacies in Romania, in 360 public hospitals and 150 private hospital units (bed units).

Antibiotice Iași is included in the list of entities of strategic importance for the defense of the country. The way the company is organized, with representative offices in international territories and collaboration contracts with partners from all over the world, allows it to act in the shortest time, from the moment of receiving an order until the moment of honoring it. Thus, in critical periods, such as the two years of the pandemic or when there was a likelihood of a danger affecting the entire population of the country, Antibiotice mobilized with maximum efficiency and responsibility and manufactured life-saving medicines.

In 2021, the Antibiotice's domestic sales revenues amounted to 388.3 million lei **

One of the priorities underlying the way Antibiotice operates is to ensure continuity in the distribution process, so as to ensure the access of patients, doctors and pharmacists to the company's products. This happens by concluding commercial contracts with the most important distributors in Romania that serve the hospital and retail segments, including the main chains of pharmacies with national coverage.

The current context shows us that distributors have focused their development by setting up their own sales and communication channels with patients, through pharmacy chains, and the number of independent pharmacies has decreased from year to year. Therefore, Antibiotice has adapted its commercial and portfolio strategy, our company's actions being oriented towards adapting the product portfolio according to the specifics of the addressability segment of each partner distributor (patients). Long-term contracts have been concluded with the main distributors, by product portfolios, so that patients be assured of continuity of treatments with the drugs recommended by the prescriber. Antibiotice provides patients with over-the-counter (OTC) medicines, food supplements, dermato-cosmetics and medical devices, in various pharmaceutical forms, complete and diversified product ranges that contribute to improving health and increasing quality of life. Antibiotice has developed a strong and competitive team of medical and sales representatives, which ensures a two-way information flow between the company and distributors, prescribers, pharmacists, patients, ensuring an increased satisfaction and accessibility of patients to the products they need. Another role of this team is to be a support for the partner distributors, efficiently communicating the medical and commercial information in the territory, in as many pharmacies and medical offices as possible. Also, in our company, there is a permanent concern of the mixed team of medical representatives, specialists in portfolio management and research &development specialists, who relate with the Key Opinion Leaders (KOL) to define

* According to the National Institute of Statistics (INS).

** According to Pharma & Hospital Report 2021, Cegedim Customer Information, forecast on the outflows of medicines from pharmacies to patients in the Romanian pharmaceutical market (published on February 1, 2022).

therapeutic solutions adapted to current medical trends. Antibiotice is a trusted partner of local health authorities, 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 medicines (Antibiotice being the only manufacturer for some of them) at affordable prices, medicines that meet EU GMP standards. All the food supplements manufactured by Antibiotice are based on the experience of the company's researchers and are manufactured to the same quality standards as medicines.

Antibiotice SA does not place in the market products or services prohibited or withdrawn from markets in certain regions or countries.

Evolution of the pharmaceutical market in Romania***

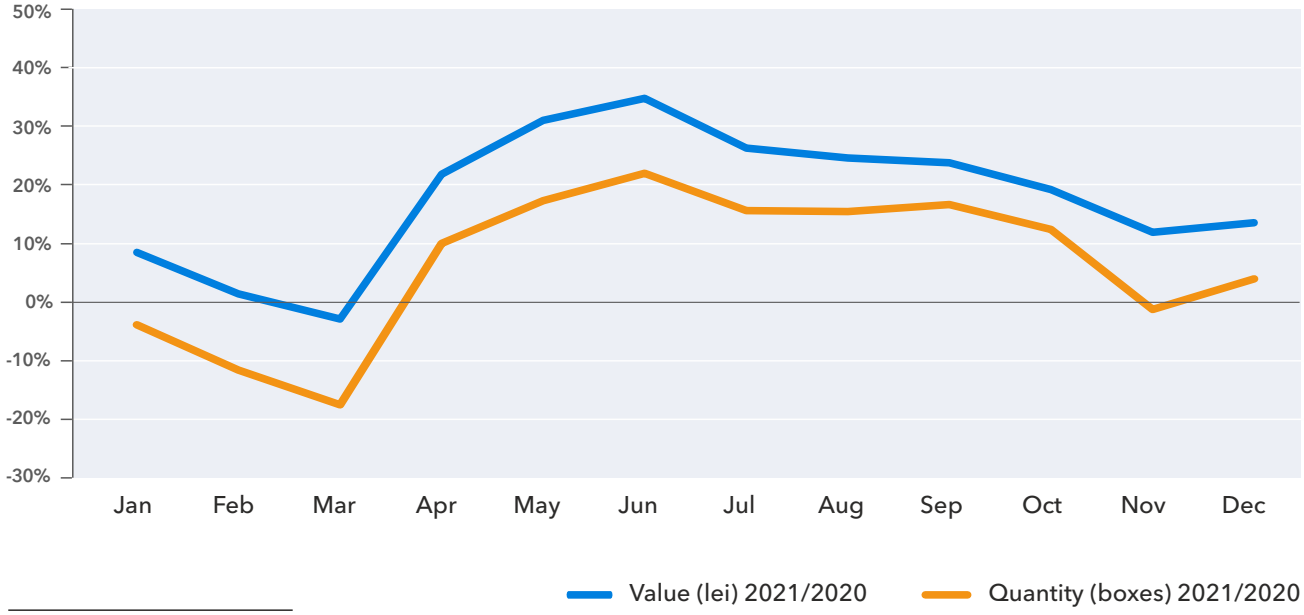
In 2021, the total value of the Romanian market (medicines released from pharmacies to patients and consumers) was 21.15 billion lei at the distribution price, higher by 17.1% compared to 2020, meaning a total consumption volume of medicines (units) of 658.6 million boxes, higher by 5.3 % compared to the consumption recorded in 2020.

The Romanian pharmaceutical market is dominated by prescription drugs (Rx), which represent 73.9% of total value sales and 61.7% of total drug consumption in terms of quantity (reported as number of boxes).

In 2021, prescription drugs (Rx) had a value increase of 16.4%, up to 15.6 billion lei (compared to 13.4 billion lei in 2020) while the products without prescription (OTCs, food supplements, medical devices) had an increase in value of 19.5%, up to 5.5 billion lei (compared to 4.6 billion lei in 2020). The first five therapeutic classes, grouped according to the share of value sales in 2021, were the digestive tract, antineo-plastics, cardiovascular system, central nervous system, blood and organs and represented 72.2% of total sales in the Romanian pharmaceutical market.

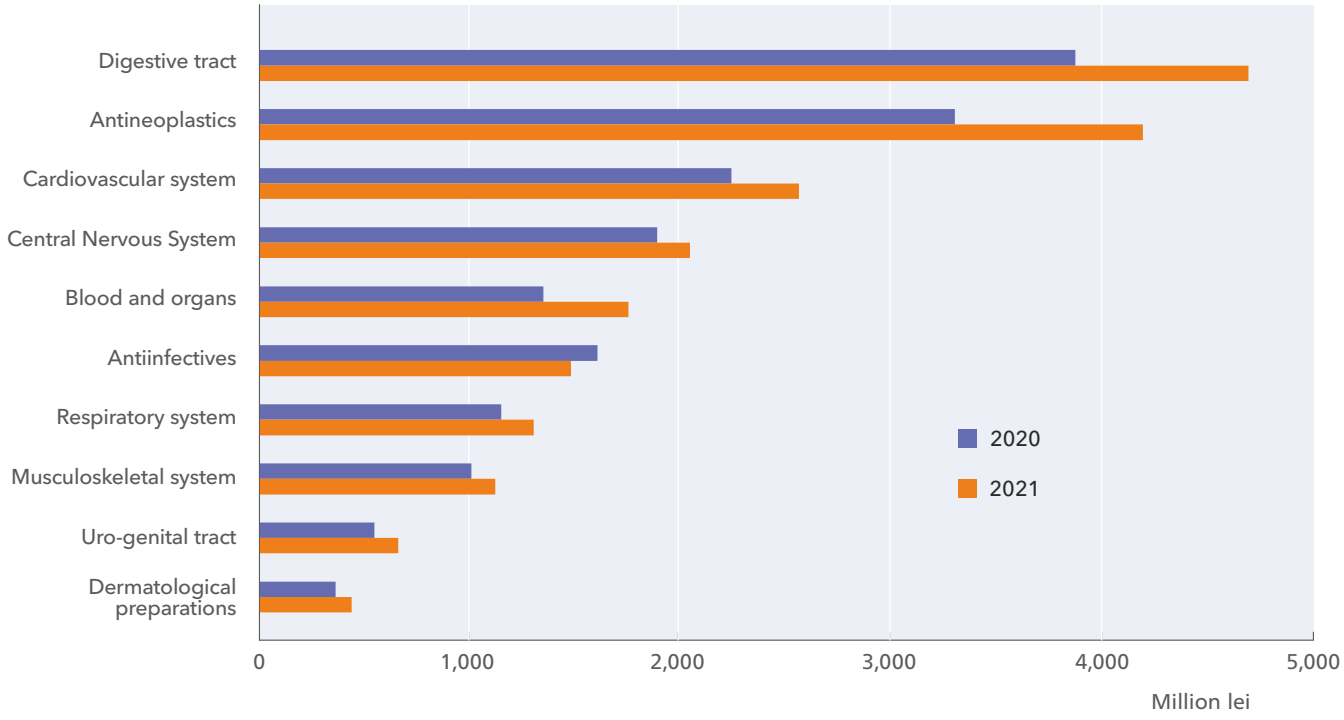
Leader in terms of quantity
for the following pharmaceutical dosage forms: ointments, suppositories and pessaries

Monthly evolution of the total market (2021 vs 2020)



*** According to District Sell-Out, Cegedim Customer Information, December 2021.

Value evolution – Top 10 therapeutic classes (2021 vs 2020)



Evolution of the pharmaceutical market relevant for Antibiotice

The relevant market for the medicinal products made by Antibiotice, according to the competition rules, comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer by reason of the products' characteristics (e.g. therapeutic indication, active ingredient, dosage form, strength), their prices and their intended use.

No. 1
in the relevant market, with a 13.6% market share by value of sale.

The relevant market of the products manufactured by Antibiotice recorded, in the analyzed period, a value of 2,858,695 thousand lei, a 19% increase compared to 2020 (i.e. 2,402,430 thousand lei). In 2021, consumption, in terms of quantity, grew by 5.2% (168.8 million boxes were released to the pharmacies compared to 160.5 million boxes in 2020).

In 2021, prescription medicines (Rx) accounted for 48.3% of the total value sales and 54.7% of the total consumption of medicines (as no. of boxes), with a 14% increase in value (from 1.21 billion lei in 2020, to 1.38 billion lei) and a 4.8% quantitative increase (from 88,060 thousand boxes in 2020, to 92,334 thousand boxes).

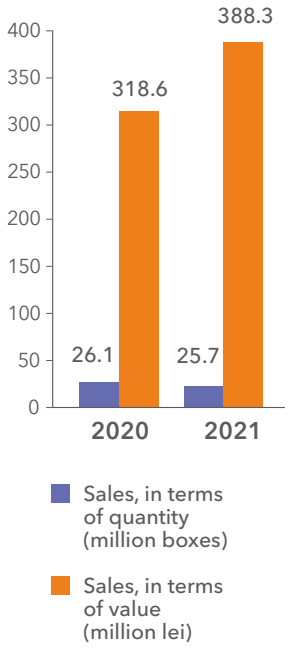
Over-the-counter (OTC) medicines accounted for 51.7% of the total value sales and 45.3% of the total consumption of medicines (as no. of boxes), with a 24.1% increase in value (from 1,189,831 thousand lei in 2020, to 1,476,745 thousand lei) and a 5.6% quantitative increase (from 72.4 million boxes in 2020, to 76.5 million boxes).

Antibiotice in the Romanian pharmaceutical market

In 2021, the sales made by Antibiotice to pharmacies and hospitals on the local market amounted to 25.7 million units (boxes) in terms of quantity and 388.3 million lei, in terms of value.

The value of the 2021 sales to the distributors was 346.2 million lei, while the value of the sales made by the distributors

Evolution of Antibiotice's sales in Romania in 2020–2021



to the hospitals and pharmacies was 393.7 million lei (123.6 million lei in hospitals and 270.1 million lei in pharmacies). Of the total sales to pharmacies, the value of the sales to pharmacy chains was 90.5 million lei and the value of the sales to independent and small-chain pharmacies was 179.6 million lei.

In 2021, the products with significant increase of the sales from distributors to pharmacies (sell-out), in terms of value, were: Meropenem Atb® for injection, 1 g, Colistin Atb® for injection, 1.000.000 IU***, Cefort® for injection, 1 g, Amoxiplus® for injection, 1000 mg/ 200 mg, Eficef® capsules, 200 mg, Nidoflor® cream, 15 g, Ceftamil® for injection, 1 g, Rosuvastatin Atb® tablets, 20 mg, Silithor® capsules, Imipenem/Cilastatin Atb® 500 mg/ 500 mg.

*** IU = in pharmacology, the international unit (IU) is a unit of measurement for the effect, not mass of a substance; the variance is based on the biological activity or effect. Despite its name, International units as used in pharmacology are not part of the International System of Units used for physics and chemistry (source: Wikipedia).

Antibiotice consolidated its core business component, i.e. antiinfectives for systemic use, and developed also the ranges of dermatological and cardiovascular products, two therapeutic classes for which the company has important sales in the market. Antibiotice kept its communication with the distributors very active to prevent potential discontinuities in the supply of the hospitals and pharmacies with medicines and to create optimal stocks that would allow the delivery of orders in the shortest time possible. The company adapted to the market demand and succeeded to fully cover the need of injectable antibiotics, such as carbapenems, cephalosporins and penicillins.

Consolidation of the company in the international market

300%
Triple sales of sterile products for injection in the United States

200%
Double sales of sterile products for injection in Great Britain

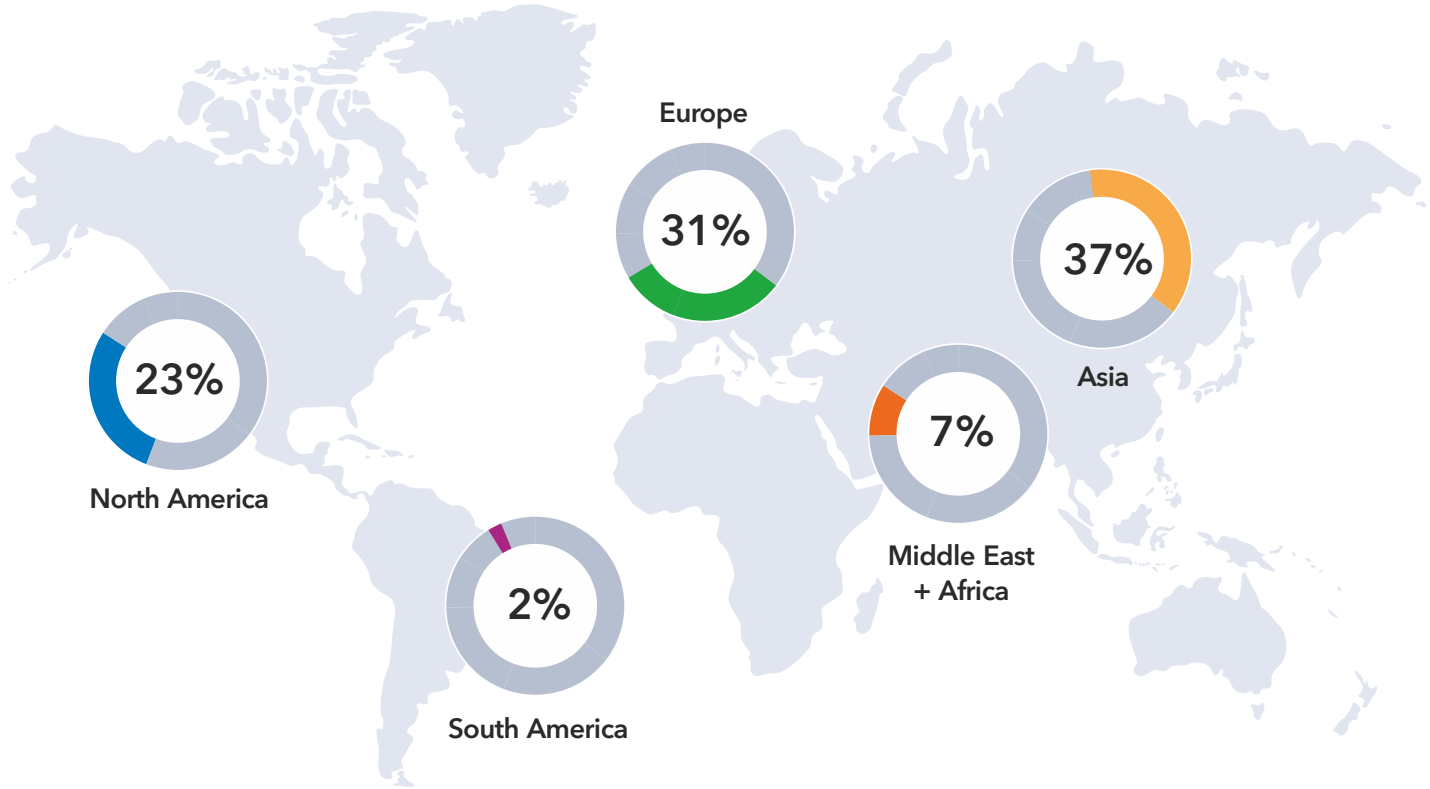
In 2021, the export turnover amounted to 143.3 million lei, accounting for 39% of the company turnover. Moreover, during the last years, with the increase of its exports, Antibiotice opened representative commercial and business offices in Vietnam, Republic of Moldova, Ukraine, and Serbia.

The strategy for developing the international business took into consideration the fact that the external markets were more dynamic and had higher levels of consumption as well as long-term development potential. Antibiotice's entry in the very competitive and highly regulated international markets required superior quality products with high added-value. Thus, in 2021, Antibiotice sold in Romania and in more than 60 countries worldwide, consolidating its traditional business partnerships and developing numerous representation agreements for the marketing and sale of its finished products and API.

Internationalization of the finished products business

The territorial expansion plan developed to achieve the company's business objectives for 2030 is based on a strategy for the internationalization of the current finished products portfolio, and especially the sterile injectable antiinfectives and topicals (a new manufacturing facility for topical products will start operating by the end of 2022), as well as for accessing new markets such as Australia, Brazil, Norway, Finland, Sweden, Germany, Italy, Spain, Poland, Philippines, Mexico.

International Sales Breakdown



Representative territories to which finished products are delivered

Representative Territories	Sector	Customers
Romania	pharmaceutical	Medical prescription (Rx) medicines for human use, OTCs (non-prescription medicines), cosmetics and food supplements are sold to distribution companies. Then the distribution companies sell them to hospital pharmacies to reach the beneficiaries (i.e. hospitalized patients) as well as to independent and chain pharmacies to be sold to the general public.
Vietnam	pharmaceutical	Sterile penicillins for injection (Rx medicines for human use) are sold to pharmaceutical distributors, which sell them to hospital pharmacies for the hospitalized patients.
Republic of Moldova	pharmaceutical	Rx medicines for human use are sold to distribution companies. Then the distribution companies sell them both to hospital pharmacies to reach the. hospitalized patients and to independent and chain pharmacies to be sold to the general public.
Serbia	pharmaceutical	Medical prescription (Rx) medicines for human use, cosmetics and food supplements (non-prescription products) are sold to distribution companies. The distribution companies take part in hospital tenders and sell them to hospital pharmacies as well as to retail pharmacies to reach the beneficiaries (i.e. patients or general public).
UK	pharmaceutical	Sterile penicillins for injection (Rx medicines for human use) are sold to pharmaceutical distributors, which sell them to hospitals based on successful tender award, to reach the hospitalized patients.
Denmark	pharmaceutical	Sterile penicillins for injection (Rx medicines for human use) are sold to pharmaceutical distributors, which sell them to hospitals based on successful tender award, to reach the hospitalized patients.
United States	pharmaceutical	Finished products for human use (sterile penicillins for injection – Rx medicines) are sold to pharmaceutical distribution companies, which afterwards sell them to hospital pharmacies to reach the beneficiaries (i.e. hospitalized patients).

The effects of the pandemics on the pharmacy sales, felt ever since 2020, continued also in 2021. The volumes of topical and solid oral products sold internationally decreased due to the circulation and free movement restrictions, measures for social distancing, quarantine or isolation of population. The structure of consumption in pharmacies showed a focus on the medication for chronic diseases and COVID-19 therapy.

The main international markets of the medicinal products made by Antibiotice, in terms of turnover, growth trend and business security, are the US, Canada, UK, The Netherlands, Denmark, Serbia, Republic of Moldova, Vietnam and Iraq.

Strengthening the position of world leading manufacturer of Nystatin API

The product portfolio designed for international markets includes, besides finished products, the active pharmaceutical ingredient Nystatin with antifungal action. The manufacturing of Nystatin on Antibiotice's site began in 1975, but the interest for this ingredient started to increase only in the 2000s, when, following the inspection conducted by the US FDA (2002), the manufacturing plant for Nystatin was granted the approval which would allow the export of the API to the US market. From that moment, Antibiotice became of the top international manufacturers of Nystatin and shortly afterwards, the world leading manufacturer of this substance.

Nystatin API is manufactured by a biosynthesis process that cannot be found anywhere else in Romania. In 2017, the Nystatin made by Antibiotice became the United States Pharmacopoeia's reference standard for this substance. Thus, other companies manufacturing nystatin API or finished products containing nystatin and intend to sell such products on the US market (or other markets that have adopted the USP as their national pharmacopoeia), will use the characteristics of Nystatin made in Antibiotice as reference when conducting quality tests on their products. The Nystatin manufactured by Antibiotice is delivered to producers from all the continents and used as raw material for the manufacture of tablets, capsules, oral suspensions, topicals (creams, ointments), and pessaries. The production and sales of Nystatin in 2021 followed the trend of the last 3 years of consolidation of the international business, our product reaching North America, South America, Europe, Asia and Africa. In the US, Antibiotice is the market leader for Nystatin.

39%

Export accounts for 39% of the turnover

International customers' satisfaction level

The financial results of Antibiotice, the professionalism and reliability of the manner in which the company works with the international partners are reflected also in the business partners' level of satisfaction, which is measured each year, according to the requirements of the quality management system in place. Thus, every year, during the first quarter, a market survey is conducted to evaluate the level of satisfaction of the significant customers (i.e. international customers which ensure more than 80% of the sales of the reviewed year and with sales not lower than 50,000 USD). The survey contains a series of statements which the customers are invited to grade. In 2021, the results of the survey showed, for each of the 20 topics, levels equal or higher than 95.44% and an overall level of satisfaction of 97.68% (exceeding the level obtained in 2020, i.e. 96.65%).

97.68%

customer satisfaction level

Complex manufacturing structure adapted to international quality standards

The main activity of Antibiotice is the manufacturing of basic pharmaceutical products (CAEN code 2110). Most of the generic medicines included in the company's portfolio, the active pharmaceutical ingredient Nystatin and biocidal products are manufactured on the company's site in Iasi, on 8 production lines. The lines are inspected and authorized by the Romanian National Agency of Medicinal Products and Medical Devices in conformity with the requirements of the good manufacturing practices. Seven of the production lines manufacture finished products (i.e. generic medicines for human and veterinary use in different dosage forms: capsules, tablets, sterile powders for injection, ointments, creams, gels, suppositories, pessaries), while the eighth is dedicated to the industrial biosynthesis of the active pharmaceutical ingredient, Nystatin (an antifungal product) and to the manufacturing of biocidal products.

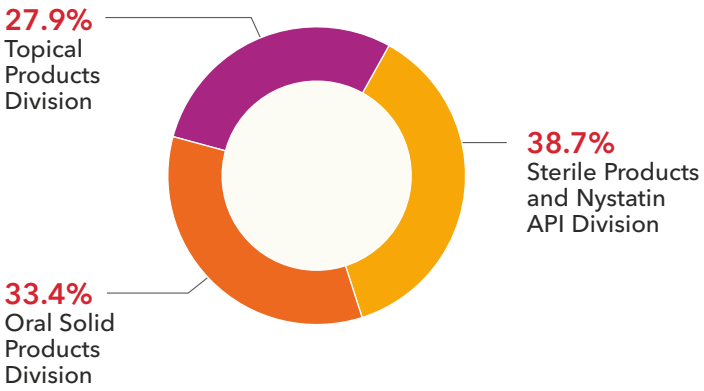
The manufacturing processes are carried out in five production plants grouped under three divisions:

- **Oral Solid Products Division** (Capsules and Tablet Plants)
- **Topical Products Division** (Ointments and Suppositories Plant)
- **Sterile Products and Nystatin API Division** (Injectables and Biosynthesis Plants).

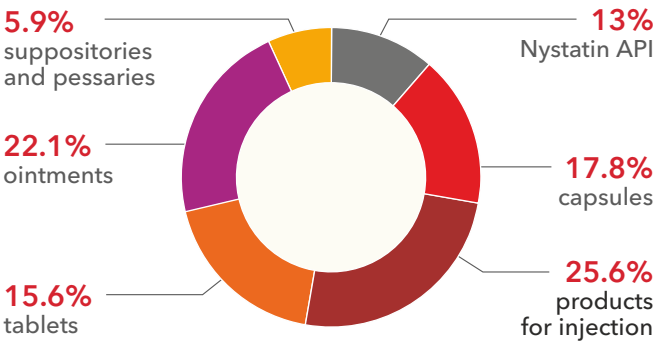
In 2021, the manufacturing capacity utilization rate was around 63%, the volume of manufactured finished products amounted to 371.88 million units while the total production value was 381.26 million lei.

In 2021, a new biocidal product started to be manufactured, i.e. Sanygel®, a hand sanitizer gel packed in 50-ml, 100-ml, 200-ml, 500-ml, 1-l and 5-l bottles. In addition, the company's two surface sanitizers a+ Oxy and a+ Complex received the appropriate notification for medical and non-medical used from the Committee for Biocidal Products of the National Institute for Public Health.

Production value breakdown by division in 2021
(as percentage of total production value)



Production value breakdown by finished dosage form or API
(as percentage of total production value)



Operating costs optimization and increase of operating efficiency

The Strategic Organization and Development Plan of the company is based on a sustainable development, as a comprehensive approach that links three directions: environment, social material and governance. Their integration requires a compliance between environmental and economic development over a long period of time.

2021 represented the first stage of the Strategic Organization and Development Plan during which Antibiotice focused heavily on the continuous adaptation to the conditions in the local and international markets to the purpose of enhancing the company's presence in the market and increasing business profitability.

Statement of comprehensive income 2021

Indicators	U.M.	2019	2020	2021	2021/ 2020	2020/ 2019
Total income	K lei	407,781	380,393	388,925	102%	93%
Total expenditure	K lei	372,601	352,064	358,622	102%	94%
Turnover	K lei	390,647	341,048	368,422	108%	87%
– Internal	K lei	237,924	182,773	225,974	124%	77%
– International	K lei	152,723	158,275	142,448	90%	104%
Export share in turnover	%	39%	46%	39%	83%	119%
Gross profit	K lei	35,180	28,329	30,303	107%	81%
Clawback	K lei	42,211	27,767	28,669	103%	66%
Gross profit + clawback	K lei	77,391	56,096	58,972	105%	72%
Total assets (TA)	K lei	794,015	863,000	895,388	104%	109%
Equity	K lei	502,377	577,272	604,992	105%	116%
Total liabilities (TL)	K lei	291,638	285,728	290,397	102%	98%
Indebtedness (TL/TA*100)	%	37%	33%	32%	98%	88%
Solvability (TA/TL*100)	%	2.72	3.02	3.08	102%	111%
Total expenses per 1,000 lei income	Lei	914	926	922	100%	101%
Average no. of employees		1,415	1,415	1,410	99%	100%
Work productivity (operating income/ total no. of employees)	Lei	284,056	264,342	272,217	103%	93%
Taxes and fees, of which:	K lei	95,427	89,447	89,078	100%	94%
– clawback	K lei	42,211	27,767	28,669	103%	66%
– taxes and fees related to salaries	K lei	40,034	44,682	47,358	106%	112%
– other taxes and fees to state budget	K lei	11,716	15,458	11,438	74%	132%
– local taxes and fees	K lei	1,465	1,540	1,613	105%	105%
Added value	K lei	210,868	200,200	184,594	92%	95%
Profitability of gross profit	%	9.01%	8.31%	8.22%	99%	92%
Profitability of gross profit + clawback	%	19.81%	16.45%	16.01%	97%	83%

The total income resulted from the operations carried out by Antibiotice in 2021 amounted to 388,925 thousand lei, by 2% higher than the income of 2020. The activities performed during 2021 were focused on measures aiming at the strategic adaptation of the human resources, strategic adaptation of the product portfolio, business sustainability by continuous improvement of the integrated management system (quality, environment, occupational health and safety), strategic planning and performance management, improvement of the corporate governance system, and generated expenses amounting to 358,622 thousand lei, by 2% higher than in the previous year. The efficiency of the entire activity is reflected by the indicator Total expenses per 1,000 lei of total income, which by the end of December 2021, amounted to 922 lei, lower than in the previous year (926 lei). On December 31, 2021, the gross profit was 30,303 thousand lei, by 7% higher compared to the gross profit of 2020. The gross profit consolidated with the clawback value resulted in a profitability of the business of 16%. The clawback has been paid by the pharmaceutical product manufacturers as a tax to the state budget since 2011.

3.5. Improving the corporate governance system

Antibiotice SA is a public enterprise established in conformity with the provisions of the Government Emergency Ordinance no. 109/2011 on corporate governance of public enterprises. The management of the company is organized to meet the expectations of the shareholders in terms of competitiveness, profitability and long-term value generation.
A well-defined, traceable decision-making system is in place and the delegations of responsibilities and competences are made commensurably with the granted prerogatives and the existing control system.

The good corporate governance rules in the company are defined by the Corporate Governance Code of Antibiotice, which establishes the general framework of the Management Board's activity and was created according to the principles and recommendations of the Corporate Governance Code of the Bucharest Stock Exchange. The Code, approved by the Board in January 2017, contains information on the responsibilities of the management structures, fair reward and motivation, relationships with the investors, risk management system and internal control.

The management of Antibiotice SA believes that the Corporate Governance Code is an important tool for achieving sustainable performance, ensuring the accuracy and transparency of the company's decision-making process through equal access of all the shareholders to relevant information about the company.

Management Board

The Management Board of Antibiotice SA is responsible for the good governance of the company and is the highest decision-making body of the company (except for the decisions provided by law for the General Meeting of the Shareholders). Among other statutory responsibilities, the Board sets the strategic direction of the company and is involved in the risk management.

Antibiotice is managed according to the unitary system of administration, by a Management Board consisting of five members: four are independent* non-executive** directors (including the president of the Board) and a non-independent executive director (the vice-president of the Board, who is also the CEO of the company). The term of office for the Board members is four years are can be renewed following an evaluation process.

All Board members are of Romanian nationality.

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* Non-executive member of the Board: who has not been appointed as manager in the company (Law no. 31/1990 on companies).

** Independent member of the Board: who has not been a manager or employee of the company, has not been remunerated, has not been a financial auditor or non-executive director of the company, has not been engaged in business relationships with the company, is not related in kinship to the manager or main shareholder of the company, etc. (Law no. 31/1990 on companies).

Members of the Management Board of Antibiotice SA, as of December 31, 2021

Director	Representation	Details
Lucian Timofticiuc President of the Board	Non-executive, independent director, term of office: 16.09.2020 –18.04.2024	Physicist General manager and administrator of Vremea Nouă SRL, Vaslui. Nationality: Romanian No shared owned in Antibiotice*.
Ioan Nani Vice-president of the Board, CEO	Non-independent, executive director since 2009, term of office: 1.06.2020 –18.04.2024	Economist CEO of Antibiotice SA Iași since 1998 (between 1998 – 2008 and since 2009 to present). Nationality: Romanian. 1,513 shares owned in Antibiotice*.
Ionel Damian	Non-executive, independent director, term of office: 21.04.2021 –18.04.2024	Lawyer Executive director – Tax Inspection at the General Directorate of Public Finance Iași Nationality: Romanian. No shared owned in Antibiotice*.
Cătălin Codruț **Popescu**	Non-executive, independent director, term of office: 26.08.2021 – 18.04.2024	Engineer General manager of Medimfarm SA, Ploiești, Prahova County. Nationality: Romanian. No shared owned in Antibiotice*.
Mihai Trifu	Non-executive, independent director, term of office: 26.08.2021 – 18.04.2024	Economist Vice-president and deputy general manager of SIF Oltenia, Craiova, Dolj County Nationality: Romanian No shared owned in Antibiotice*.

* Number of shares in Antibiotice owned as of December 31, 2021, according to the latest data base of Antibiotice for 2021.

Gender diversity in the Management Board

	Men	Women	Total
President	1	0	1
Vice-president	1	0	1
Members	3	0	3
Total	5	0	5
%	100%	0%	100%

Age diversity in the Management Board

	30-39 y.o.	40-49 y.o.	50-59 y.o.	>60 y.o.	Total
Members	1	2	1	1	5
%	20%	40%	20%	20%	100%

Advisory committees

The Management Board exercises part of its responsibilities through the three existing advisory committees, i.e. the Audit Committee, the Trade Policy Committee, and the Nomination and Remuneration Committee. The specialized advisory committees carry out investigations and analyses, issue recommendations and submit periodic reports on their actions to the Board.

Audit Committee

The Audit Committee has the responsibility to make an annual evaluation of the internal control system and to provide assistance to the Board in preparing the financial statements, the internal and external audits, risk management and internal control. In addition, it manages the conflicts of interests in relation to the transactions of Antibiotice SA and its subsidiaries with affiliated parties in the meaning of the Fiscal Code, and monitors the application of the legal standards and generally accepted internal audit standards.

Trade Policy Committee

The Committee supports the Board in establishing the commercial policies and relationships of the company by analyzing the trade, marketing and promotion policies based on which the Management Plan (the business plan) and its management component are applied. In order to fulfill these duties, the members of the committee receive reports from the company directors during the Board meetings or any other time upon request.

Nomination and Remuneration Committee

The Nomination and Remuneration Committee nominates candidates for the Board and proposes the remuneration of the members of the Board and the company directors. Its main responsibilities also include the evaluation of the Board members' independence and the verification of the number of mandates they held. The Committee drafts an annual report on the remunerations and other benefits granted to the members of the Board and directors. The report is presented by the Board to the General Meeting of the Shareholders.

Members of the Advisory committees of the Management Board of Antibiotice SA
as of December 31, 2021

Advisory committee	Members
Audit Committee	Ionel Damian, Cătălin Codruț Popescu, Mihai Trifu
Nomination and Remuneration Committee	Lucian Timofticiuc, Ionel Damian, Mihai Trifu
Trade Policy Committee	Lucian Timofticiuc, Ionel Damian, Cătălin Codruț Popescu

Executive management

The executive management includes a Board-mandated Chief Executive Officer (CEO) and nine directors (seven executive directors and two specialty directors). The Board delegates to the executive management the responsibility for the ordinary business operations of the company (operations management). All the members of the executive management are Romanian nationals.

Members of the executive management of Antibiotice SA

Director	Position	Details
Ioan Nani	CEO	Ioan Nani, an economist, has been the CEO of Antibiotice SA Iași since 1998 (between 1998–2008 and from 2009 to date). Nationality: Romanian 1,513 shares owned in Antibiotice*
Ovidiu Bățaga	Executive Director, Marketing & Sales	Ovidiu Bățaga, an economist, was appointed on May 5, 2008. Nationality: Romanian No shares owned in Antibiotice*
Cornelia Moraru	Executive Director, Production and Industrial Strategies	Cornelia Moraru, an engineer, was appointed on May 1, 2003. Nationality: Romanian 1,513 shares owned in Antibiotice*
Paula Luminița Coman	Executive Director, Financial	Paula Luminița Coman, an economist, was appointed on June 6, 2011. Nationality: Romanian No shares owned in Antibiotice*
Daniela Pascariu	Executive Director, Quality Assurance	Daniela Pascariu, a pharmacist, was appointed on October 8, 2021. Nationality: Romanian No shares owned in Antibiotice*
Liviu Vatavu	Executive Director, Legal Affairs and Corporate Governance	Liviu Vatavu, a lawyer, was appointed on September 1, 2019. Nationality: Romanian No shares owned in Antibiotice*
Mihaela Denis Gălățanu	Executive Director, Human Resources	Mihaela Denis Gălățanu, an engineer, was appointed on September 1, 2021. Nationality: Romanian No shares owned in Antibiotice*
Darius Giorgiani Agafiței	Executive Director, Business Development	Darius Giorgiani Agafiței, an economist, was appointed on September 2, 2020. Nationality: Romanian No shares owned in Antibiotice*
Carmen Iustain	Specialty Director, Research & Development	Carmen Iustain, a physicist, was appointed on May 1, 2020. Nationality: Romanian No shares owned in Antibiotice*
Ionel Susanu	Specialty Director, Logistics	Ionel Susanu, an economist, was appointed on March 30, 2021. Nationality: Romanian No shares owned in Antibiotice*

* Number of shares in Antibiotice owned as of December 31, 2021, according to the latest data base of Antibiotice for 2021.

Gender diversity in the executive management team

	Men	Women	Total
CEO	1	0	1
Directors	4	5	9
Total	5	5	10
%	50%	50%	100%

Age dsiversity in the executive management team

	40-49 y.o.	50-59 y.o.	>60 y.o.	Total
Members	5	4	1	10
%	50%	40%	10%	100%

Anti-corruption policy

All documents may be found on the company website www.antibiotice.ro, section Corporate Governance / Reference Documents.

Antibiotice has created and implemented a set of reference documents which include also the anti-corruption policies and procedures of the company, namely: Corporate Governance Code, Code of Ethics, Code of Good Practice for Promotion of Medical Prescription Medicinal Products and Interraction with Healthcare Professionals, Sponsorship and Patronage Policy, Internal Regulations, as well as the Antibiotice SA's Integrity Plan for the Implementation of the National Anti-corruption Strategy for 2016–2020.

All documents that make up the framework regulating the expected behavior of the employees, irrespective of their position in the company, were brought to the attention of all the employees and published on the company website to be available to any interested party.

The principles and values set out in the above-mentioned regulations are designed to highlight the elements on which the company policy is based in terms of ethics (integrity, professionalism, responsibility, transparency), morality, application and observance of standards (of quality, integrity, etc.) and regulations on economic, financial or taxation discipline as well as on discipline at workplace and integrity.

As an entity which complies with the principles of corporate governance established by the Government Emergency Ordinance no.109/2011 on the corporate governance of public enterprises, Antibiotice adopted the Declaration of Adherence to the Fundamental Values, Pronciples and Objectives and Monitoring Mechanism of the National Anti-corruption Strategy for 2016–2020, thus complying with the provisions of the Government Decision no. 583/2016.

Moreover, Antibiotice SA's Integrity Plan for the implementation of the National Anti-corruption Strategy for 2016-2020 contains anti-corruption and transparency measures including some pertaining to the performance of periodic self-assessment of the extent of compliance with the provisions and dispositions of the plan as well as recommendations on conducting periodical training for increasing the employees' level of education about good anti-corruption practices.

In 2021, there were no corruption incidents or violations of the measures indicated in the Integrity Plan of Antibiotice for the Implementation of the National Anti-corruption Strategy for 2016-2020 reported in the company.

The anti-corruption policies and procedures, the Code of Ethics, Code of Corporate Governance and Integrity Plan on the National Anti-corruption Strategy for 2016–2020 were presented to the Management Board and the executive management.

In 2021, there were no disciplinary dismissals or sanctions following the involvement of employees in acts of corruption. Moreover, no contractual relationships with business partners were discontinued due to suspicions of corruption acts. The training plans in the company specify the communication of the anti-corruption policies and procedures in force and applied in the company as well as of the periodical training of relevant employees in topics such as ethics, anti-corruption and conflict of interest management.

To prevent the occurrence of corruption incidents in contractual relationships with business partners, Antibiotice selects its partners (suppliers, distributors etc.) responsibly taking into consideration both the compatibility of the trade objectives and the integrity of such partners.

In addition, the company's procedures for contract negotiation and preparation have clauses which discourage and sanction the attracting of the company and its employees into corruption acts or deeds. Thus, the partners undertake not to commit, authorize or allow any act that would violate the national, European, or international anti-corruption laws and regulations in force and to inform the competent legal authorities specialized in the prevention of and fighting corruption, if they become aware of any act of corruption in relation to the negotiation, conclusion or execution of contracts.

Moreover, the Integrity Plan of the company was communicated both to the supervising authority (i.e. Minister of Health), and to the Technical Secretariat of the National Anti-corruption Strategy of the Minister of Justice (i.e. the competent authority which supervises the implementation of the GD 583/2016 in the country).

Code of Ethics

The Code of Ethics of Antibiotice SA lies at the foundation of an organizational culture which respects the integrity standards and complies with the specific legislation in force. The fundamental ethical values assumed by the company are: integrity, professionalism, responsibility and transparency.

Any violation of the code is considered an ethical incident and the non-compliance with the Code of Ethics may lead to disciplinary sanctions. Compliance to the provisions of the Code is mandatory for everybody in the organization (i.e. employees, members of the executive management and of the management Board). The Code of Ethics is communicated to each new employee or manager and can be consulted online.

Ethics and Integrity Committee

The company's Ethics and Integrity Committee was established by the CEO's decision. The Committee is an advisory body created for monitoring the conformance with the provisions of the Code of Ethics and application of the ethical principles and rules specific to the promotion of medical prescription medicinal products. The Committee supports the company management in making decisions related to business conduct and ethical promotion of medicines.

The Ethics and Integrity Committee analyzes all the ethics incidents made by the violation of the Code of Ethics or the Integrity Plan prepared in conformity with the terms of the National Anti-corruption Strategy for 2016-2020, about which it has been informed or has taken itself notice. Following the analysis of each ethics incident, the Committee prepares a written report, which contains recommendations for the CEO for the necessary actions to be taken.

The Ethics and Integrity Committee consists of 5 members appointed by the CEO's decision for a 4-year term. The members are selected from among specialists in the medical, economic or legal field. Maximum two Committee members are allowed not to have a fixed or indefinite-term individual labor contract with the company.

The Ethics and Integrity Committee:

- handles the notifications of ethics incidents received by the company
- analyzes ethical vulnerabilities and recommends to the CEO the adoption and implementation of measures for preventing ethical incidents
- examines from ethical viewpoint, the Internal Regulations of the company, Code of Ethics, and Code of Good Practice for Promotion of Medical Prescription Medicinal Products and Interaction with Healthcare Professionals and makes suggestions for changes or additions to them
- formulates and submits proposals for reducing the risk of ethical incidents to the CEO
- approves the contents of the communications addressed to petitioners, in response to their notifications
- formulate an advisory opinion upon the CEO's or Board's request
- examines the cases of violation of ethical norms and conduct rules in the interaction of the medical and sales representatives with the health professionals
- analyzes the natural or legal persons' notifications of different types of abuse made by the medical or sales representatives
- informs the competent state authorities whenever it considers the aspects of an ethics-related case may be the subject of lawbreaking and such aspects have not been notified by the legal representative of the company or by petitioner.

In 2021, no violation of the Code of Ethics was reported

In 2021, no fines or sanctions for violating the socio-economic regulations were reported

Reporting an ethics incident

Any interested natural or legal person can report an incident of violation of the Code of Ethics. The notification must be addressed to the CEO and should contain personal identification data and contact information. It can be submitted in writing to the company registry office or online, by completing an ethics form which can be accessed on **www.antibiotice.ro**

In 2021, there were no notifications or complaints of situations that could be considered conflicts of interests.

In 2021, there were no incidents of anti-competitive conduct.

In 2021, there were no legal proceedings against the company for infringement of the competition, antitrust or monopoly law.

Conflict of interest

Since 2015, the company has had in place an internal procedure for handling the conflicts of interest and incompatibilities, i.e. the situations in which the company employees, while performing their professional duties, could have a personal interest of patrimonial nature that would affect the objective fulfillment of their tasks. The procedure was reviewed and updated in 2019. Its purpose is to establish the line of action and the persons responsible for taking decisions and endorsing the documents pertaining to the professional activities in the company in cases of conflicts of interest for people holding managerial positions.

Competition policy

Anti-competitive or monopoly practices have a significant negative impact on consumers, price of products and other elements essential for an effective market. The policies implemented by the company aim at maintaining a healthy economic environment and supporting responsible competition.

In Antibiotice, the internal framework regulating competition-related aspects, policies and procedures is represented by the Corporate Governance Code, Code of Good Practice for Promotion of Medical Prescription Medicinal Products and Interaction with Healthcare Professionals, Sponsorship and Patronage Policy. The documents are available on the company website, and are also communicated to the employees.

The purpose of such documents is to highlight the fundamental elements of the company policy on fighting unfair competition. Embracing theses values is essential and consequently, all the decisions taken by the management of the company are in accordance with the provisions of the internal regulations.

Cyber security and personal data protection

In Antibiotice, the policy of general data protection (GDPR) is described in the internal operating procedure created for this purpose and implemented throughout the company. The procedure was developed in conformity with the national and European legal requirements (Law no. 190/2018, EU Regulation 2016/679) and guidelines for good practices. The main objective is that all activities carried out in Antibiotice comply with the requirements of the relevant legislation in the field. The company processes personal data depending on the quality each individual has in relation with Antibiotice. The internal structure responsible with personal data protection is the Information Security Management department.

In order to protect confidentiality and personal data, several projects and initiatives were carried out in Antibiotice in 2021, such as:

- sessions of training and testing of knowledge in data protection for 1,378 employees
- specialized assistance for appropriate processing of personal data, for all activities in Antibiotice
- promotion of materials raising awareness of the ways to protect and process personal information, for the employees and third parties (business partners, clients, visitors etc.)
- conclusion of agreements with business partners on data management
- start of necessary actions to comply with the requirements of the Law no. 362/2018 implementing the European Directive on the security of network and information systems (NIS – Network and Information Security): forming the NIS working team, preparation of the action plan to achieve conformity with the minimum requirements of the cybersecurity standards, acquisition of softwares to ensure the security of the IT infrastructure.

1.378
employees trained in data protection

The policies, regulations, forms, and personal data security measures are periodically reviewed for effectiveness (at least once a year) and updated to respond to the changes in the company.

- No related to breaches on the customers data security and confidentiality regulations (personal data protection)
- No leakage, loss or theft of personal data

Risk management

In Antibiotice, risk management is conducted in conformity with the legal and regulatory requirements in force. This process involves risk identification, assessment, management and reporting. The main objective of risk management is to identify the risks the company is exposed to, so that such risks can be anticipated and controlled without affecting the efficient fulfillment of the company's objectives.

Antibiotice SA's objectives on risk management are:

- understanding the risks to which the company is exposed, the causes and the general and specific objectives
- improving the company's risk profile by managing the process of risk identification, assessment, and control and implementing the necessary control measures to maintain the risk exposure within tolerable levels.

In Antibiotice, the activities pertaining to risk management are carried out by the Risk Management Dept., together with the risk officers and company employees. Each year, the Risk Management Dept. analyzes and prioritizes the significant risks that may affect the fulfillment of the general objectives, creates the Plan for the Implementation of Risk Control Measures, and establishes the risk profile of the company and the tolerance level. The periodic review of the main risks includes an assessment of their likelihood and potential consequences to confirm the level of exposure and evaluate the strategies for their management.

Every year, the Internal Audit Office assesses the performance of the Risk Management Dept. and makes recommen-dations for improvement, where necessary. The findings of the assessment are presented to the Audit Committee of the Board.

Risks identified in 2021

The standard procedure on the risk management was revised to include also the sustainability risks. In all the organizational structures, the specific risks were identified and the relevant risks were synthesized according to their magnitude, using impact and probability. Based on the identified risks, a General Risk Record was created and approved. The purpose was to minimize the significant risks (which impact the business objectives) the company is exposed to.

Financial risks

The **commercial risk** or non-payment risk occurs when a business partner is unable to fulfill the contractual obligations, which results in financial loss for the company. Antibiotice is mainly exposed to the commercial risk arising from the sales to its customers. To reduce the risk, a series of measures are taken, such as continuing evaluation of the customers' financial performance and history of payments, requesting guarantees, securing receivables.

The **liquidity risk** occurs when the company may face difficulties in fulfilling its short-term payment obligations at any time. The circumstances in which the liquidity risk can occur include the lack of cash-flow due to gap between receipts and payments, long terms for debt collection, fluctuation of the interest rates and currency rates, volume of investments, level of taxation, price of raw materials and utilities. The judicious management of the liquidity risk involves a series of measures such as the retainment of sufficient liquidities to cover the payment obligations when they are due, correlation of the payment and encashment terms, and availability of financing using credit lines.

The **currency risk** is a component of the financial risk which often occurs in the current conditions of the market economy, in which the exchange rates fluctuate according to the law of demand and supply. Such fluctuations impact both the cost of imported raw materials and the export selling prices of the products. In order to diminish the exposure to the currency risk, measures were taken to synchronize the import and export operations by correlating the payment and collection terms and currency ratios so that the date when payments are made be as close as possible, or even the same, to the date of collections from export sales.

Legislative risks

he pharmaceutical market is a highly regulated one, with clear legislative requirements created to the purpose of controlling the quality and therapeutic efficiency of the medicinal products in the market and of preventing counterfeit. The adaptation to such requirements results in additional costs generated by the documentation updating and alignment to the latest quality standards. The company strategy for managing such risks involves the constant concern for obtaining the international quality certifications for the manufacturing lines, updating the documentation for the marketing authorization of the products, continual monitoring the international legislative changes and adaptation of the policies, rules and procedures to such changes.

Human resource risk

The human resource risk refers to the shortage of qualified candidates for the pharmaceutical industry in the labor market. The circumstances in which these risks occur include the retirement of the company specialists and migration of the qualified personnel due to the development of the North-East region and the competing companies in the area.

Reputational risk

The reputational risk is defined as the current or future risk for the profits or capital of the company to be adversely affected due to the unfavorable perception of the company's image. The strategy of the company is to limit the reputational risk by procedures, rules and information flows designed for this purpose, and by efficient, proactive, transparent and sustained communication. Several measures were taken by the company to diminish such risks, such as the development and implementation of the Code of Ethics, preparation and implementation of the

Integrity Plan, implementation of warning instruments, transparent communication of the Code of Ethics and the Integrity Plan to increase awareness, drafting and implementation of the conflict of interest procedure.

Operational risks

The operational risk is the risk of loss due either to inadequate processes, people or internal systems that have not operated or function properly or to external events. Operational risks include equipment malfunctions, human errors, defective operational processes, which may ultimately result in unplanned shutdowns. The company constantly monitors such risks to be able to take measures to maintain them at an acceptable level that does not jeopardize the financial stability of the company or the interests of the creditors, shareholders, employees and business partners.

Occupational health and safety risks

The following measures were taken to control the risk of work accidents and occupational diseases occurrence: checking whether the occupational health and safety procedures and equipment operation instructions are appropriately followed, continuous training of the employees on occupational health and safety according to the established training program, use of safety signs, supply of individual protective equipment, checking whether the personal protective equipment is used and the preventive maintenance program is followed, conducting the periodical medical examination.

Environmental risks

The environmental risks are the result of the company's failure to comply with the applicable legislation and regulations. This failure may have a negative impact on the environment and company reputation. To control such risks, the following measures were taken: maintenance and improvement of the environmental management system ISO 14001, internal audits to identify the status of compliance with the requirements of the standard, observance of the operating procedures, personnel training, observance of the maintenance program, monitoring of legislative changes and their harmonization to the existing measures, preparedness and response plan for emergency situations.

Antibiotice SA will take all measures necessary to diminish physical risks in case of natural hazards (e.g. earthquakes, floods, fires), and therefore has in place the following: Emergency Evacuation Plan, Natural Disaster Action Plan, Fire Emergency Action Plan, policy for preventing the occurrence of incidents involving hazardous substances (e.g. acetone, methanol). Tall these plans are designed to protect the employees, the material assets and the environment.

Risks generated by climate change

Antibiotice believes that climate change is one of the most important global challenges nowadays. Therefore, to anticipate and prevent risks associated with climate change, the company intends to implement a process that will help it identify, analyze and assess such risks and develop plans to reduce them by 2023. In 2021, the company identified a supplier of specific services that will lead to the conformance with the requirements related to the climate change and transition to a low-carbon economy.

Internal control

In Antibiotice, the specialized internal control is carried out according to the legislation in force, by means of the preventive financial control, financial inventory control and control of management of activities, which are periodically evaluated by the Internal Audit office. The findings of and recommendations following the internal audit and internal control actions are submitted to the Audit Committee of the Board on a quarterly and yearly basis. The Committee assesses their activity and effectiveness.

Internal audit

In 2021, a number of 11 audit actions were conducted, with the following objectives: examination of compliance with the set of specific principles, rules of procedure and methodology, internal memos and decisions, review of work organization and assessment of the management and control of activities in Antibiotice. The actions were carried out in conformity with the rules of procedure and going through all the stages specific to internal auditing. The findings were included in internal audit reports which were submitted to the company's CEO for approval. The conclusions and recommendations formulated in the reports were assimilated by the audited organizational structures and were followed through up to their implementation. Thus, by the end of 2021, out of the 37 recommendations, 23 were implemented, 3 were partially implemented, and 11 were within their established deadline.

Internal audit scope and actions conducted in 2021, audited structures and findings:

1 Evaluation of the procurement of goods and services

During 2021, three audit actions were conducted to examine the process of goods and services procurement and the performance of the contracts concluded by the Technical & Production Dept. (equipment procurement), Investments Dept. (construction works procurement), and Internal & International Acquisitions Dept. (goods and services procurement).

The procurement activities were found to comply with the approved internal regulatory and procedural framework.

2 Evaluation of the patrimony administration – sale, pledge concession of goods

The internal audit conducted to review the work of the Patrimony Management Dept. found that the activities were carried out in conformity with the legal and procedural provisions.

3 Evaluation of the income generation process

The audits targeted the work of the Marketing & Sales Unit (evaluation of the sales income), Research & Development Unit (evaluation of the income from intangible assets), and Technical & Production Unit (evaluation of the income from production). Their findings showed that the activities were carried out according to the procedural framework and appropriately controlled.

4 Evaluation of the expense budgeting

The conclusion of the analysis of the company's budget was that the activity was efficient, compliant with the approved Income & Expenditure Budget for 2021 and met the established financial performance indicators.

5 Evaluation of the corruption prevention system

The evaluators found that the measures for preventing conflicts of interest and incompatibilities indicated under Annex no. 3 to the Government Decision no. 583/2016 were implemented.

6 Evaluation of the decision-making system and internal control system

The audit targeted the Financial Management Control Dept., Preventive Financial Control Dept, and Risk Management Dept. The evaluators found that the activities were organized and operated in accordance with the internal regulatory and procedural framework.

7 Evaluation of the human resources management

The evaluation of the human resources management found that the specific activities of personnel selection and recruitment, employee training, employee disciplinary investigation, human resources management were carried out in conformity with the legal and procedural requirements, and that the salary budget and number of employees were within the approved limits.

8 Evaluation of the activity of the Information Technology Dept.

The auditors found that the information and communication resources were in control, an internal procedural framework for the use, confidentiality, monitoring, security and access to such resources was created and that measures were taken to improve the information and communication system.

Financial management control

In 2021, according to the legal provisions of the Government Decision no. 1152/2012, the financial management control had the following specific objectives:

- to verify the compliance with the legal provisions in substantiating the 2021 Drat Income and Expenditure Budget
- to verify the compliance with the legal requirements and internal regulations on conducting the annual inventory of the assets, liabilities and equity for 2020
- to verify the compliance with the legal requirements and internal regulations on the receipts and payments in LEI and foreign currency, of any nature, in cash or by bank transfer
- to verify the compliance with the legal requirements on the execution of the Income and Expenditure Budget for 2020
- to verify the compliance with the legal requirements on the preparation, circulation, storage and archiving of primary accounting records technical-operative documents
- to verify the implementation of the company's liquidity improvement plan
- to verify the compliance with the legal requirements and the provisions of the approved Accounting Policy Manual on the registration of the financial-accounting operations in the accounting records
- to verify the compliance with the legal requirements on the existence, integrity, preservation and use of the means and resources on any account.

The control actions resulted in control reports, which included the findings and recommended measures for improving the reviewed activities. The control reports were approved by the company's CEO, who gave dispositions for the application of the recommended measures. All the measures were implemented.

Inventory control

In 2021, a number of 25 inventory actions were carried out, covering the warehouses for raw materials, materials and finished products, areas in which the raw materials and materials are used and have stock inventory management in place, and inventory locations where the inventory manager was changed. The inventory control was conducted in conformity with the legal and regulatory framework established by the Accounting Law no. 82/1991, republished and updated, the Law no. 22/1969 on the recruitment of inventory managers, establishment of guarantees and liability in assets management, Order of the Minister for Public Finance no. 2861/ 9.10.2009 for the approval of the Provisions regarding the inventory of assets, liabilities and equity items, as well as other operating procedures, internal memos and decisions issued by the company's management. The control findings confirmed the factual existence of the written stocks in the financial-accounting records. In addition, no deficiencies, damages or shortages were identified.
The control reports were submitted to the Accounting Dept. to be used for the annual inventory of the company's patrimony.
The internal control exercised by the specialized structures and the hierarchical control exercised by the executive and non-executive directors and managers ensures both the economical, efficient and effective use of the company's resources and the achievement of the set objectives.

04

Investments and related activities for strategic development

4.1. Investments for medium and long-term development

Investments represent the driving force for the consolidation and strategic development of Antibiotice. The twofold increase of the turnover and augmentation of the business profitability by 2030 are the main targets of the company. To achieve such ambitious objectives, the company focuses its investments on two important areas: strategic development and business consolidation. Thus, Antibiotice periodically reinvests its profit in developing the product portfolio, applicative research, acquisition of portfolios, quality assurance equipment, upgrading of manufacturing technologies and digitalization.

In 2021, Antibiotice continued to invest in the research of new products, quality assurance equipment, upgrade of the manufacturing technologies and digitalization. This shows the company's interest for the prompt support of the national health system, making investments for a sustainable development. In 2021, the value of the investment projects developed amounted to 47.23 million lei, according to the contracts concluded with the partners and agreed working schedules. Antibiotice continued its investment policy in conformity with the management plan approved by the General Meeting of the Shareholders in April 2021 and focused on the following:

Development of manufacturing, research, utilities, transport and storage infrastructures

The investments in the new manufacturing site for topical products and suppositories continued in 2021. The new production site will have a double capacity compared to the existing one and will boost the company's turnover by the future sales of the products both in Romania and international markets. At present, the company is the national leading manufacturer of topical products (ointments, creams, gels) and suppositories. In 2021, the planned investment in the site amounted to 6.48 million lei. The new manufacturing site will be authorized by the National Agency for Medicines and Medical Devices in 2022.

The company's research & development activities focus on adapting the product portfolio to the new therapeutic trends and on providing healthcare professionals and patients alike with affordable and therapeutically valuable medicinal products.

In 2021, the investments in research & development amounted to 9.4 million lei. The investments were oriented towards the product portfolio development and procurement of R&D-specific laboratory equipment.

Investments for updating existing manufacturing sites

An amount of 9.7 million lei was invested for revamping the production sites of the three manufacturing Divisions, in equip-ment procurement, installations, fittings and laboratory devices. For adapting the infrastructures of service, utility supply and distribution, transport and connection to the national road network, storage of raw materials and finished products to the trend of development of the entire industrial site, 15.7 million lei were invested in 2021. In 2021, the investments required to support the Integrated Management System (Quality, Environ-mental Protection, Occupational Health and Safety), amounted to 0.62 million lei, while the investments in the information technology, telecommunication and process digitalization amounted to 4.5 million lei. Operating in the extremely competitive pharmaceutical industry, Antibiotice invests also in long-lasting international business partnerships and in maintaining the quality standards required for international market access and recognition.

4.2. Procurement, an important link in the value chain

Procurement is an important link of the value chain and is organized to meet the company's needs of developing a long-term sustainable business with suppliers both from Romania, and intra- and extra-community areas. The COVID-19 pandemics remained the biggest world challenge also in 2021 triggering many changes in the pharmaceutical companies due to the dynamics of the supply chain and operating manners and to the efforts to diminish the risks that may occur in the supply chain, to avoid discontinuities. In the pharmaceutical industry, the supply chain management is extremely important for meeting the market demands in the best conditions possible.

The consolidated business relationships developed by the company's management with international partners in time were a considerable advantage for the company in 2021, too. Through them, the company succeeded to procure protective materials and equipment and thus ensured the continuity of the company's operations. Nevertheless, the pandemics impacted the procurement process and many manufacturers reduced their activity due to human resources or material resources shortages. To be able to cope with such challenges and efficiently manage the risks related to the procurement practices, the company increased the number of its suppliers and identified new suppliers for raw materials and materials, which are to be qualified. In 2021, Antibiotice focused on operational stability, securing the supply chain, adaptation of the production to the reality of the market, and formulation of strategies for the long-term development of the product portfolio. The pro-active risk management and risk sharing with the suppliers, the planning, forecasts and deliveries made together with the business partners, the use of "what-if" scenarios to identify possible solutions are only but a few actions taken to ensure the successful procurement with raw materials and materials.

Procurement practices

Antibiotice seeks to develop long-term partnerships with the suppliers, based on principles of transparency, mutual respect and reliability. The company is aware of the impact it has on the players in its supply chain and of the importance such players have for the continuity of the production process. A fundamental element for trustworthy relationships with the suppliers is the timely payment of contractual obligations. Thus, in general, the standard payment term in the relation with the suppliers is 60 days from the date of invoice, except for the utility suppliers, which have an average payment term of 30 days. Taken into account the long-term partnerships, Antibiotice is always receptive to the suppliers facing difficulties, which require the payment of the invoice before the due date, and helps them in this regard. The quality of the raw materials and of the equipment used in manufacturing can significantly influence the quality of the products. For this reason, the procurement process is heavily regulated.

77.8%
of suppliers are local

In the company, there are three departments which carry out procurement operations:

1 Technical department

The Technical department purchases pieces of equipment, laboratory devices, spare parts and services, according to the approved annual investment and maintenance programs. The company has long-term partnerships with suppliers of equipment, materials or services which are known both in the country and internationally, comply with the occupational health regulations, respect their employees and protect the environment, things that our company's specialists ascertained during their visits to the suppliers' premises for testing the pieces of equipment and technologies supplied by them to Antibiotice. The relationships with the suppliers are defined in clauses of the supply and procurement contracts and orders, while the requirements pertaining to occupational health and safety, environmental protection, consumption of utilities for the equipment operation, compliance with the standards specific to the pharmaceutical industry are included in the procurement procedure.

2 Local procurement (Romania)

The Internal acquisitions dept. carries out the procurement from the Romanian market of the following raw materials and materials required either for manufacturing or operations in the company:

- 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, laboratory glassware and materials
- spare parts, devices (from the country and abroad)
- services of disinfection, disinsection, deratization (DDD), 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 materials for manufacturing activities and auxiliary materials (gowns, overalls, boots, disposable items etc.)
- IT products, office supplies, consumables
- promotional materials.

2 International acquisitions

The department makes purchases only from authorized suppliers included on the List of Authorized Suppliers, in conformity with the appropriate procedures. The approved suppliers which meet the requirements of the company are selected based on criteria formulated by the R&D and Regulatory Affairs departments, then audited and authorized by the Quality Assurance and afterwards, included on the List of Authorized Suppliers. Last year was very challenging for the procurement process taking into account the increase in the prices. The company did not discontinue the cooperation with any supplier, but there were some changes in consumption amounts and orders among the authorized suppliers. The pharmaceutical industry is constantly evolving and the company adapts to be able to meet the future trends in procurement promptly.

Although at present, the company does not make periodical evaluation of its suppliers in terms of their social and environmental impact, it intends to create a code of conduct and a supplier evaluation questionnaire by 2022. Thus, the company aims at aligning to the supply chain sustainability standards and therefore it is important to act responsibly in connection to its suppliers by applying social and environmental standards that would help develop long-term sound business relationships with its partners.

Number of suppliers in 2021

Year	No. of local suppliers	No. of international suppliers	Total no.
2020	808	219	1027
2021	**831**	**237**	**1068**

Breakdown of procurement from local and international suppliers

Year	Percentage of procurement		Total
	Local suppliers	International suppliers	
2020	46.26%	53.74%	100%
2021	**48.95%**	**51.05%**	**100%**

The current process for selecting suppliers of specific types of products/equipment includes environmental criteria, such as:

- low consumption of utilities required for equipment operation (electrical power, water, steam, compressed air, cooling agent)
- energy efficiency, according to the international standards
- exhaust emissions according to the regulatory requirements in force.

05

Responsibility for our community

Community investment

Along with our contribution to and positive impact on the patients and consumers' health and wellbeing through the medicines and products we manufacture, we want our operations to bring added value also to the local communities and thus, we invest and provide financial assistance to cover their pressing needs. Our projects are set up on four main pillars, i.e. health, education, environment and social involvement. The company organizes its own charity events, humanitarian projects as well as educational and cultural programs through the "Antibiotice – Science and Soul" Foundation. Because the company intends to bring added value to the local communities, it recognizes the importance of the dialogue with the representatives of such communities in identifying their main needs. In 2021, Antibiotice organized a meeting with representatives of the local authorities, At the same time, one-to-one meetings were arranged with some categories of stakeholders. Sponsorships are granted in conformity with the Corporate Sponsorship and Patronage Policy. Its requirements are mandatory for all employees, executives and Board members, in accordance with the provisions of the Law no. 32/1994 on sponsorship.

Projects for our communities

In 2021, the company invested 731,125 lei in corporate social responsibility projects.

Vaccination Center a+

In the second year of the COVID pandemics, on January 18, 2021, Antibiotice Iași set up and made available to the employees and members of the neighboring communities a vaccination center located in its own Center for Clinical Studies. The center had two separate dedicated access flows, a capacity of 32 beds arranged in 4 rooms, included a medical assistance office, refrigeration units for optimal preservation of the immunization vaccines, a reception, restrooms, and qualified medical and auxiliary staff (i.e. physicians and nurses). The medical doctors and nurses working in the Vaccination Center a+ were employees of the company. The Center was opened 7 days a week, from 8 a.m. to 8 p.m. for 6 months. Starting July 2021, the Center was relocated to the company's medical assistance office due to the lower and lower vaccine demand, and since August 2021, it operated once a week, on Fridays.

Vaccination Caravan a+

Besides the stationary anti Covid-19 vaccination center, Antibiotice joined the national immunization efforts also by arranging, in cooperation with the local authorities, mobile caravan units to reach rural communities in the county of Iasi that had limited access to vaccination. Thus, in partnership with the Iasi Department of Public Health and Iasi County Prefecture, Antibiotice organized Vaccination Caravan a+ campaigns each Sunday for 6 weeks in a row, from May 16 to the end of June 2021. The Vaccination Caravan a+ facilitated the access to vaccination of 420 residents from 7 villages from the county of Iași, namely Hălăucești, Stolniceni-Prăjescu, Mogoșești-Siret, Fântânele, Gropnița, Movileni, and Oțeleni. By December 31, a number of 23,603 vaccine doses were administered in the stationary and mobile centers altogether. Antibiotice constantly involved in and supported the authorities' efforts and actions to fight the pandemics and to return to normality.

Back to normality

While working for home was possible for some departments, the manufacturing operations were not interrupted, but appropriate measures were taken to protect the employees' health and safety. Throughout 2021, the company ran the project entitled "Back to Normality Together" with the purpose of providing

the employees with accurate information on the pandemics and stimulating vaccination. The project included a series of events, such as internal information and awareness campaigns, in-house inquiries, and workshops held by health professionals. An information campaign entitled "The Specialist Recommends, You Decide" was also part of the project, in which Prof. Dr. Egidia Gabriela Miftode, an epidemiologist and infectious disease doctor was invited to clarify for the employees different aspects related to COVID vaccination effects and to answer to their questions on the subject. By the end of 2021, 78% of the employees were vaccinated.

The project won second place at the Romanian CSR Awards 2022 Gala, for the "Employee Support" category.

"Call for Life"

By means of its campaign entitled "Call for Life", Antibiotice showed its support to the national healthcare system, by its employees who voluntarily took part in actions intended to limit the spread of the SARS-CoV-2 virus by early detection of the infected individuals (PCR testing) as well as by delivering COVID-19 vaccines to family physicians and home vaccination of people physically incapable of moving or being moved for the Iasi county. The campaign represents the company's prompt response to the request of the Iasi Department of Public Health (DPH) for vehicles and volunteer drivers to manage and handle the more and more increasing number of SARS-CoV-2 infection cases both in the country and nationally. Several employees of the company expressed their availability and willingness to help the authorities overwhelmed by the large number of requests for testing during the 4th wave of the pandemics. Thus, in October and November 2021, a number of 14 employees with civic sense volunteered to help, by turns the DPH. They spent more than 600 hours driving the DPH medical staff either to the homes of over 2,500 people to be tested or vaccinated, or to the offices of family physicians from all over the county, to deliver vaccines. During the entire project, Antibiotice supplied the volunteers with professional protective equipment generally used by Intensive Care staff and disinfecting solutions for their cars.

"Donate Blood! Put Your Heart and Soul into Protecting Life!", 20th edition

More than 70 employees of the company donated almost 35 liters of blood during the blood donation campaign organized by the "Antibiotice – Science and Soul" Foundation in cooperation with the Regional Center for Blood Transfusion on October 14, 2021. Last year's edition of the project was possible because the mobile vaccination unit of the Regional Center for Blood Transfusion started operating again due to the acute lack of blood from the city hospitals.

"Science and Soul" Scholarships, 20th edition

Each year, the company, through the "Antibiotice – Science and Soul" Foundation, supports the "Pro Ruralis" Association, offering 5 scholarships to children from rural areas. In this way, Antibiotice makes its contribution to the education of children with special skills and abilities, high IQ, but with limited material means, and supports them to continue their secondary and high-school education, thus providing them the opportunity of a successful professional career and personal development.

"We Plant Oxygen in the Community", 2nd edition

Part of the environmental protection program entitled "Be Pro Nature! Get Involved!", "We Plant Oxygen in the Community" is a tree planting project addressed to the employees and consisted in the greening of a parcel of land on the site of the company. Thus, on April 22, 2021, on the occasion of the International Earth Day, 50 employees took part voluntarily in the planting of maple trees.

"Power of Deed", a charity action program at Easter

Around the Easter holidays, the "Antibiotice – Science and Soul" Foundation made a humanitarian gesture for 23 needy families with 121 children living in remote villages of the Iasi county (Zmău, Lungani, Dumești, Cosițeni). Each family received a package containing staple foods, traditional dishes, hygiene and cleaning products and school supplies for the children.

"Be Generous! Be Santa Claus!", 9th edition

The joy of a Christmas with fulfilled wishes was lived by 80 children from needy families from the county of Iasi (Bogonos, Dumești, Costești, Buhalnița, Deleni, Poiana Deleni). On December 14 and 15, 2021, the "Antibiotice – Science and Soul" Foundation distributed gifts for children aged between 1 and 15 years old from families with limited material possibilities living in rural areas. The letters sent to Santa Claus by the children reached the kind-hearted "elves", i.e. employees of the company, who generously fulfilled every dream laid out on paper with great hope by the children.

Club a+

The Club a+ is a sports and recreational facility intended for the employees of the company, where several social responsibility projects designed to maintain a healthy life style and increase wellbeing are carried out. The aim of the Club a+ is to become a valuable non-financial motivation and loyalty improvement instrument for the company's employees interested in sports and a healthy life style as well as a hub for the Iași community engaged in sports or educational activities, and a center for training and formation programs. Starting May 24, 2021, under the slogan "Let's Start Exercise", the employees were invited to the Club a+ to practice, free of charge, team sports or instructor-assisted aerobics and Pilates classes. In 2021, the company's employees could also opt for self-defense classes and, for a fee, ballroom dancing. On November 23, 2021, under the auspices of the Club a+, Antibiotice organized the first edition of "Healthy Living Workshop", a CSR program that gathered health professionals who promoted to the employees the concept of a healthy lifestyle, both through sports practicing and nutrition. The specialists in nutrition and pharmacists from the "Gr. T. Popa" University of Medicine and Pharmacy of Iași offered important information on how a balanced diet can become our ally and an unexpected resource during the pandemic times. The participants also learned the general principles of nutrition, were give recommendations on how they could arrive to have a well-balanced diet, and found out information on the foods providing protection against SARS-CoV-2 virus.

06

Report on the audit of financial statements

To the Antibiotice shareholders

Report on the audit of financial statements

Our opinion

We audited the attached individual financial statements of ANTIBIOTICE S.A. ("The Company") with its registered office in Iași, 1 Valea Lupului St., tax identification number RO1973096, comprising the financial position statement as of December 31, 2021, statement of comprehensive income, statement of changes in equity and cash flow statement for the financial year ended on the above-mentioned date as well as a summary of the significant accounting policies and other explanatory notes.

The individual financial statements as of December 31, 2021 are identified as follows:

- Net assets/total equity: 604,991,800 Lei
- Net profit of the fiscal year: 29,939,404 Lei

In our opinion, the attached individual financial statements give a true and fair view, in all significant aspects, of the financial position of Antibiotice company on December 31, 2021, as well as of the financial performance and cash flows for the fiscal year ended on the above-mentioned date in accordance with the Order of the Minister of Public Finance (OMPF) no. 2844/2016 for approving the accounting regulations compliant with the International Financial Reporting Standards adopted by the European Union ("IFRS-UE").

We conducted our audit in accordance with the International Standards on Auditing (ISAs), Regulation (EU) no. 537 of the European Parliament and of the Council ("The Regulation") and Law no. 162/2017. Our responsibilities are described in detail in the section *Auditor's responsibilities in an audit of financial statements* in our report. We are independent of the Company, in accordance with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants (the IESBA code), according to the relevant ethical requirements for the audit of financial statements in Romania, including the Regulation and Law no. 162/2017 and we fulfilled our ethical responsibilities according to these requirements and to the IESBA code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Key issues

Key audit issues are those issues that, based on our professional judgement, had the greatest importance for auditing the financial statements of the current period. The following key issue was approached in the context of the audit of the financial statements as a whole and in forming our opinion on them and we do not offer a separate opinion on this key issue.

Key issue – Value of trade receivables

Presentation value of trade receivables according to IFRS depends significantly on the calculation and estimation process of the trade discounts as well as on the process of estimating their recoverability. The company presented in the financial statements in the explanatory note no. 4 – "Sales Income" the value of the granted trade discounts and, in the explanatory note no. 15 – "Trade and other receivables" the company presented the trade receivables in net value of 270 million LEI, adjusted with the estimated depreciation.

During our mission, we conducted the following audit procedures that included, but were not limited to these:

- We assessed the compliance of the policies for recognizing the income and trade receivables;
- We conducted analytical review procedures and detail tests for verifying the amount of granted discounts, including through extending the verifications on the discounts granted in the next fiscal year related to the sales in the audited fiscal year;
- We conducted procedures for direct confirmation of trade receivable balances;
- We evaluated the internal procedures and methods used by the management team for estimating the probable amount to be collected;
- We verified the consistency of applying the accounting policies related to the adjustment of trade receivables.

Other information – Management Report

The administrators are responsible for drafting and submitting other information. This other information includes the Management Report and Remuneration Report but it does not include the financial statements and auditor's report related to these statements. The Management team is responsible for this other information. Our audit opinion on the financial statements does not cover other information and we do not express any form of assurance conclusion on them. In connection with our audit on the financial statements, our responsibility is to read this other information and, in this approach, to evaluate whether this information is significantly inconsistent with the financial statements or with the knowledge we gained from the audit or if it appears to include significant errors. If, based on the performed activity, we come to the conclusion that there are significant errors in this information, we must report this. We have nothing to report on this matter.

Additionally, in accordance with the provisions of OMPF no. 2844/2016, we read the Management Report and Remuneration Report and report the following:

- In the Management Report we did not identify information that is not consistent in all significant aspects with the information presented in the financial statements as of December 31, 2021;
- The above-identified Management Report includes, in all the significant aspects, the information requested by OMPF no. 2844/2016 to the para 15–19 of the Annex no. 1;
- The Management Report does not include the non-financial declaration specified to the paragraphs 39–42 from OMPF no. 2844/2016 which will be subsequently presented in a separate report;
- Based on our knowledge and our understanding gained during the audit of the financial statements drafted on December 31, 2021 about the Company and its environment, we did not identify significant erroneous information presented in the Management Report;
- The Remuneration Report, identified above, includes, in all material respects, the information required by Article 107 para. (1) and (2) of Law 24/2017 (republished) on issuers of financial instruments and market operations.

Responsibility of the management team and other persons responsible for the governance related to the financial statements

The Management team is responsible for drafting and fair presentation of these financial statements in accordance with

OMPF no. 2844/2016 and for the internal control which is considered relevant by the management for elaborating the financial statements without significant misstatements due to fraud or error.

When drafting the financial statements, the management is responsible for assessing the company's ability to continue its activity, presenting, if needed, the aspects related to continuation of the activity and using the accounting based on the going concern principle unless the management plans to either liquidate the company or stop the operations or has no realistic alternative except for these.

The persons responsible for administering the company are also responsible for supervising the financial reporting process.

Auditor's responsibility

Our objectives are to obtain reasonable assurance that the financial statements as a whole do not include material misstatements, whether due to fraud or error, and to issue an auditor's report that includes our opinion. The reasonable assurance represents a high level of assurance but it is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement, if it exists. Misstatements can arise from either fraud or error and are considered material if they reasonably can be expected, individually or cumulatively, to influence the users' economic decisions based on these financial statements.

As part of an audit in accordance with the ISA standards, we exercise our professional judgement and maintain our professional skepticism during the audit. Moreover:

- We identify and evaluate the risks of material misstatements in the financial statements caused either by fraud of by error, establish and perform audit procedures to respond to these risks and we get enough and appropriate audit evidence to form a basis for our opinion. The risk of not detecting a material misstatement caused by fraud is greater than the risk of not detecting a material misstatement caused by error, as fraud may include complicity, forgery, intentional omissions, false statements, or avoidance of internal control.
- We consider the internal control as relevant to the audit to establish the audit procedures appropriate in the given circumstances, but not to express an opinion on the effectiveness of the Company's internal control.
- We assess the appropriateness of the used accounting policies and reasonableness of accounting estimates and of the related information presented by the management team.
- We formulate a conclusion on the appropriateness of using the going-concern principle by the company and determine, based on the obtained audit evidence, whether there is a significant uncertainty related to events or conditions that could raise significant doubts about the Company's ability to continue its activity. If we conclude that there is a significant uncertainty, we need to draw attention in the audit report on the related presentations from the financial statements or, if these presentations are inappropriate, we must change our opinion. Our conclusions are based on the audit evidence obtained by the date of our audit report. However, future events or conditions may determine the Company not to continue operating on the going-concern principle.
- We evaluate the presentation, structure and overall content of the financial statements, including the information submissions and the extent to which the financial statements reflect the transactions and basic events in a manner that lead to the accurate presentation.

We communicate to those responsible for the administration, among other things, the planned objectives and timing of the audit, as well as the significant audit findings, including any significant internal control deficiencies that we identify during our audit.

Report on other legal and regulatory requirements

We were appointed by the General Meeting of Shareholders held on April 9, 2020 to audit the financial statements of ANTIBIOTICE S.A. Iași for the fiscal years 2020 - 2022. The uninterrupted total duration of our commitment is 5 years, covering the financial exercises 2017-2021.

We confirm that:

- Our audit opinion is in accordance with the additional report submitted to the Audit Committee of the Company which we issued on the same date to which we issued this report. Also, in conducting our audit, we remained independent of the audited entity.
- We did not provide for the company the non-audit services that are prohibited according to the article 5, para. (1) from the Regulation (EU) no. 537/2014.

In the name of,

Accounting, Expertise & Accounting Consultancy Company - SOCECC Ltd.

headquartered in Bucharest, registered in the Electronic Public Register with the no. FA227

through Zegrea Laurențiu, registered in the Electronic Public Register with the no. AF2666

Bucharest, March 15, 2022

GRI Content Index

GRI Standard	Information	Sustainable Development Goal	No. of page (s)	Omission
GRI 101: Foundation 2016				
General Information				
GRI 102: General Disclosures 2016	**Organizational profile**			
	102-1 Name of the organization		7	
	102-2 Activities, brands, products and services		9-13, 53-60	
	102-3 Location of headquarters		7	
	102-4 Location of operations		12, 13	
	102-5 Ownership and legal form		12, 36	
	102-6 Markets served		12, 25, 103	
	102-7 Scale of the organization		12-15, 22-25, 33, 34, 42, 98, 99	
	102-8 Information on employees and other workers	 	42-44	
	102-9 Supply chain		16, 124	
	102-10 Significant changes to the organization and its supply chain		11	
	102-11 Precautionary principle or approach		56-72	
	102-12 External initiatives		Antibiotice has not signed and/or adhered to the book, principles or other economic, environmental or external social initiaties.	
	102-13 Membership of associations		27	
	Strategy			
	102-14 Statement from President		4, 5	
	102-15 Key impact, risks and opportunities		59, 73, 78, 87	
	Ethics and integrity			
	102-16 Values, principles, standards and norms of behaviour		61-65, 71, 72	
	Governance			
	102-18 Corporate governance structure		19, 108-110	
	102-22 Composition of the highest governance body and its committees	 	108-111	
	102-25 Conflict of interest		114	
	Stakeholder engagement			
	102-40 List of stakeholder groups		29-31	
	102-41 Collective bargaining agreements		43	
	102-42 Identifying and selecting stakeholders		Sustainability Report 2020, page 24	
	102-43 Approach to stakeholder engagement		29-31	
	102-44 Key topics and concerns raised		29-31	

GRI Standard	Information	Sustainable Development Goal	No. of page (s)	Omission
GRI 102: General Disclosures 2016	**Reporting practice**			
	102-45 Entities included in the consolidated financial statements		7	
	102-46 Defining report content and topic boundaries		28. For material topic boundaries, check page 26 of the 2020 Sustainability Report	
	102-47 List of material topics		28	
	102-48 Restatements of information		85	
	102-49 Changes in reporting		7. This is the first Integrated Annual Report of Antibiotice.	
	102-50 Reporting period	12 CONSUM SI PRODUCTIE RESPONSABILE	7	
	102-51 Date of most recent report	12 CONSUM SI PRODUCTIE RESPONSABILE	The most recent Sustainability Report of Antibiotice was elaborated for the period 01.01.2020–31.12.2020.	
	102-52 Reporting cycle	12 CONSUM SI PRODUCTIE RESPONSABILE	Annualy	
	102-53 Contact point for questions regarding the report		7	
	102-54 Claims of reporting in accordance with the GRI standards	12 CONSUM SI PRODUCTIE RESPONSABILE	7	
	102-55 GRI content index		135-142	
	102-56 External assurance		Non-financial data has not been externally verified.	
Significant (material) topics				
ECONOMIC TOPICS				
Anticorruption				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 112	
	103-2 Management approach and its components		32, 112, 118	
	103-3 Evaluation of management approach		112	
GRI 205: Anticorruption 2016	205-2 Communication and training about anticorruption policies and procedures	16 PACE, JUSTITIE SI INSTITUTII EFICIENTE	112	
	205-3 Confirmed incidents of corruption and actions taken	16 PACE, JUSTITIE SI INSTITUTII EFICIENTE	112	
Anti-competitive behaviour				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 62-64, 114	
	103-2 Management approach and its components		32, 62-64, 114	
	103-3 Evaluation of management approach		62, 64, 114	
GRI 206: Anti-competitive behaviour 2016	206-1 Legal actions for anti-competitive behaviour, anti-trust and monopoly practices		61-64, 114	
Market presence				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28	
	103-2 Management approach and its comp.		18, 32	

GRI Standard	Information	Sustainable Development Goal	No. of page (s)	Omission
GRI 103: Management approach 2016	103-3 Evaluation of management approach		25	
GRI 202:Market presence 2016	202-1 Standard entry level wage rates by gender compared to local minimum wage		45	
	202-2 Proportion of the Romanian nationality staff in the management team		108	
Procurement impacts				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 123-125	
	103-2 Management approach and its components		32, 123	
	103-3 Evaluation of management approach		124, 125	
GRI 204: Procurement impacts 2016	204-1 Proportion of spending on local suppliers		125	
Risk management				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 73, 74, 76, 78, 87, 115-119	
	103-2 Management approach and its components		32, 73, 74, 76, 78, 87, 115-119	
	103-3 Evaluation of management approach		73, 118, 119	
Socio-economic compliance				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 113	
	103-2 Management approach and its components		32, 113	
	103-3 Evaluation of management approach		113	
GRI 419: Socioeconomic compliance 2016	419-1 Non-compliance with laws and regulations in the social and economic area		In 2021, no fines or sanctions were registered regarding the violation of legislative regulations in the socio-economic field.	
Access to medicines: pricing policy and availability of medicines				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 66	
	103-2 Management approach and its components		32, 66, 67	
	103-3 Evaluation of management approach		66, 67	
	Number of essential medicines in the company's portfolio		56	
Research and development				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 56-60, 121, 122	
	103-2 Management approach and its components		32, 56-60, 121, 122	
	103-3 Evaluation of management approach		56-60, 121	
	Active research projects at the end of the reporting period		58	
	Value of investments in research and development		59, 121	

GRI Standard	Information	Sustainable Development Goal	No. of page (s)	Omission
ENVIRONMENTAL TOPICS				
Energy consumption				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 83, 84	
	103-2 Management approach and its components		32, 83, 84, 97	
	103-3 Evaluation of management approach		83, 84	
GRI 302: Energy 2016	302-1 Energy consumption within the organization		83	
	302-3 Energy intensity		84	
	302-4 Reduction of energy consumption		83, 84	
Apă				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 86-89	
	103-2 Management approach and its components		32, 86-89, 97	
	103-3 Evaluation of management approach		86, 88	
GRI 303: Water and efluents 2018	303-1 Interaction with water as a shared resource		86-88	
	303-2 Managing the impact of effluents		86-88	
	303-3 Water withdrawal		86	
	303-4 Water discharge		88, 89	
	303-5 Water consumption		86	
Packaging and waste				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 89-97	
	103-2 Management approach and its components		32, 89-92, 97	
	103-3 Evaluation of management approach		91, 93-97	
GRI 306: Waste 2020	306-1 Waste generation and significant waste-related impacts		89-92	
	306-2 Management of significant waste-related impacts		89-92	
	306-3 Waste generated		93-97	
	306-4 Waste diverted from disposal		95, 97	
	306-5 Waste directed to disposal		96	

GRI Standard	Information	Sustainable Development Goal	No. of page (s)	Omission
Emissions				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 84-86	
	103-2 Management approach and its components		32, 84-86, 97	
	103-3 Evaluation of management approach		85	
GRI 305: Emissions 2016	305-1 Direct (Scope 1) GHG emissions		85	
	305-2 Indirect (Scope 2) GHG emissions		85	
	305-4 GHG emissions intensity		85	
	305-5 Reduction of GHG emissions		85	
Animal welfare				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 76	
	103-2 Management approach and its components		32, 76	
	103-3 Evaluation of management approach		76	
SOCIAL TOPICS				
Occupational health and safety				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 76-80	
	103-2 Management approach and its components		32, 76-80	
	103-3 Evaluation of management approach		80	
GRI 403: Occupational health and safety 2018	403-1 Occupational health and safety management system		76-78	
	403-2 Hazard identification, risk assessment and incident investigation		77, 78	
	403-3 Occupational health services		79-81	

GRI Standard	Information	Sustainable Development Goal	No. of page (s)	Omission
GRI 403: Occupational health and safety 2018	403-4 Topics related to occupational health and safety, regulated by special agreements, concluded with trade unions	8	76-78	
	403-5 Worker training on occupational health and safety	8	79	
	403-6 Promoting health services for workers	8	48, 49, 80, 81	
	403-7 Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	8	123-125	
	403-9 Work-related injuries	3, 8	80	
Diversity and equal opportunity				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 41-45	
	103-2 Management approach and its components		32, 43-45	
	103-3 Evaluation of management approach		44, 45	
GRI 405: Diversity and equal opportunity 2016	405-1 Diversity of governance bodies and employees	5, 8, 10	42, 43	
	405-2 Ratio of basic salary and remuneration of women to men		45	
Prevention of drug abuse and self-medication				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 65	
	103-2 Management approach and its components		32, 65	
	103-3 Evaluation of management approach		64, 65	
	Initiatives to promote responsible drug use	3	65	
Responsible promotion and transparent communication				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 61-65	
	103-2 Management approach and its components		32, 61-65	
	103-3 Evaluation of management approach		64	
GRI 417: Marketing and labeling 2016	417-2 Incidents of non-compliance concerning product and service information and labeling		64	
	417-3 Incidents of non-compliance concerning marketing communications		64	
Employee training and development				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 48-51	
	103-2 Management approach and its components		32, 48-51	
	103-3 Evaluation of management approach		32, 46	
GRI 404: Training and education 2016	404-1 Average hours of training per year per employee	4, 5, 8, 10	51	

GRI Standard	Information	Sustainable Development Goal	No. of page (s)	Omission
GRI 404: Training and education 2016	404-3 Percentage of employees receiving regular performance and career development reviews		51	
The relationship between management and employees				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 41-43	
	103-2 Management approach and its components		32, 41-43	
	103-3 Evaluation of management approach		32, 43	
GRI 402: Labor/management relations 2016	402-1 Minimum notice periods regarding operational changes		43	
Customer privacy				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 114	
	103-2 Management approach and its components		32, 114	
	103-3 Evaluation of management approach		114	
GRI 418: Customer privacy 2016	418-1 Substantiated complaints concerning breaches of customer privacy and losses of customer data		114	
Human rights				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 41, 43	
	103-2 Management approach and its components		32, 41, 43	
	103-3 Evaluation of management approach		41, 43	
GRI 412: Human rights assessment 2016	412-2 Employee training on human rights policies and procedures	In 2021, 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		28, 41, 43	
	103-2 Management approach and its components		32, 41, 43	
	103-3 Evaluation of management approach		43	
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 2021, 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		28, 41, 42, 44-46, 48	
	103-2 Management approach and its components		32, 41, 42, 45, 46, 48, 50	
	103-3 Evaluation of management approach		44, 50	
GRI 401: Employment 2016	401-1 New employee hires and employee turnover		46	
	401-2 Benefits provided to full-time employees that are not provided to temporary or part-time employees		48, 49	
	401-3 Parental leave		52	

GRI Standard	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		28, 127-129	
	103-2 Management approach and its components		32, 127-129	
	103-3 Evaluation of management approach		127-129	
GRI 413: Local communities 2016	413-1 Operations with local community engagement, impact assessments and development programs		In 2021, 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		28, 123-125	
	103-2 Management approach and its components		16, 17, 32, 123-125	
	103-3 Evaluation of management approach		124, 125	
GRI 414: Supplier social assessment 2016	414-1New 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		28, 68, 69	
	103-2 Management approach and its components		32, 68-72, 74, 75	
	103-3 Evaluation of management approach		69, 73	
GRI 416: Customer health and safety 2016	416-1 Assessment of the health and safety impacts of product and service categories		69, 73-75	
	416-2 Incidents of non-compliance concerning the health and safety impacts of products and services		75	
Clinical studies				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 55	
	103-2 Management approach and its components		32, 75, 76	
	103-3 Evaluation of management approach		75	
	Number of clinical studies started in the reporting period		75	
Quality management				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28, 68	
	103-2 Management approach and its components		32, 68-72	
	103-3 Evaluation of management approach		73	
	Valid standards, licenses, authorizations and certificates at the end of the reporting period		71,72	
Combating counterfeit medicines and parallel trade				
GRI 103: Management approach 2016	103-1 Explanation of the material topic and its boundary		28,73	
	103-2 Management approach and its components		28,73	
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	Counterfeit alerts generated by the serialization system		73	

Antibiotice SA

1 Valea Lupului St.
707410 Iași, Romania
Phone: +40 (232) 209 000
Fax: +40 (372) 065 633
office@antibiotice.ro

www.antibiotice.ro