

## MANAGEMENT REPORT 2018

### Management Report

Yearly report according to:

|   |  |
|---|--|
| For the financial year:                                       | IFRS<br>2018                               |
| Report date:  | March 13, 2019                             |
| Company name:   | Antibiotice SA                             |
| Head office:  | Iasi, Strada Valea Lupului nr. 1           |
| Phone number:   | 0232/209000, Fax 0232/209633               |
| Fiscal registration code:                                     | RO 1973096                                 |
| Regulated market which trades shares:                         | Bucharest Stock Exchange                   |
| Subscribed and paid up capital:                               | 67.133.804 LEI                             |
| Main characteristics of the securities issued by the company: | Nominative shares, nominal value: 0.10 LEI |

In this Administrators' Report, the management plan for the period 2016 - 2020 is assessed at the level of the year 2018.

#### **The corporate governance**

The corporate governance is defined by the set of rules and regulatory norms whereby a Management Board demonstrates the responsibility, fairness and transparency of the company's relationship with all stakeholders, impacting upon the management, administration and control of a company.

Applying the principles embodied in the Corporate Governance Code ensures the transparency and efficiency of the activities and processes, thus providing the framework for maximizing the value of the company's long-term shareholdings and increasing the attractiveness of the company in relation to investors.

Antibiotice adopted the principles and recommendations of the Corporate Governance Code of the Bucharest Stock Exchange (CGC-BVB); these principles underpin the fulfillment of the good corporate governance standards of the company.

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

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The structures on which the Antibiotice governance system is based are:

- The General Meeting of Shareholders
- The Management Board
- The Advisory Committees
- The Executive Management

### Code of Ethics

The Code of Ethics of Antibiotice SA sets out the ethical standards of conduct that establish and regulate the corporate values, the business responsibilities and obligations of the organization and how they work.

The Code of Ethics provides rules in key areas relating to employees, human rights, environmental management, social responsibility and corporate governance.

The code is binding and applies to all the structures and activities of the company. The Code of Ethics is a fundamental commitment to strive for the compliance with high ethical standards and applicable legal requirements wherever Antibiotice operates.

The Code of Ethics is presented in detail on the website of the company ([www.antibiotice.ro/Investitori/ Guvernanta Corporativa / Documente de referinta /Cod de etica](http://www.antibiotice.ro/Investitori/Guvernanta_Corporativa/Documente_de_referinta/Cod_de_etica))

### Code of Corporate Governance

The Code of Corporate Governance of Antibiotice SA retrieved the principles and recommendations of the BSE and represents the tool through which Antibiotice implements these principles and recommendations by observing the rules of corporate governance.

The Code of Corporate Governance creates the framework for establishing strong relationships with our company's shareholders and with other interested parties, as well as an effective and transparent communication, based upon trust.

The Code of Corporate Governance of Antibiotice SA is divided into four chapters:

- Chapter I - Responsibilities of the Management Board
- Chapter II - The Risk Management and Internal Control System
- Chapter III - Fair reward and motivation
- Chapter IV - Investor relations.

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It also contains two annexes, namely:

Annex I - Operating Rules of the Management Board

Anexa II - Rules for assessing the Antibiotice SA administrators

In **Chapter I - Responsibilities of the Management Board**, the role of this body is defined alongside the guidelines in terms of competence, experience, knowledge and independence of its members, enabling them to effectively perform their specific duties and responsibilities.

In **Chapter II - The risk management and internal control system** shows that the activity of the company is subject to the supervision exercised by certain risk management and internal control systems set up for this purpose. Also, internal audits are organized in order to assess independently and periodically the safety and effectiveness of the risk and internal management control systems.

The **Chapter III - Fair reward and motivation** establishes the general principles and conditions that are the foundation of the method for setting the level of remuneration of the Management Board and the company management members.

The **Chapter IV - Investor Relations** establishes that Antibiotice should make constant efforts in order to provide shareholders with updated information on events of interest to them (ex.: general meeting of shareholders, payment of dividends, etc.).

In conclusion, the Code of Corporate Governance of Antibiotice SA and its annexes outline the general framework under which the Management Board operates, complying with the rules and principles of corporate governance set by the BSE in order to create an attractive capital market, based upon the best practices, transparency and trust.

The state of compliance with the provisions of the new Code of Corporate Governance of the BSE <sup>1</sup> on December 31 2018 is presented in Annex no.1 of this report.

### General Meeting of Shareholders

The General Meeting of Shareholders (GMS) is the highest decision-making body of the company, where shareholders participate directly and make decisions. Among other duties, the GMS decides upon the distribution of the profit, elects the Management Board, appoints auditors and establishes the remuneration of the Management Board.

During the year 2018, the Board convened three Ordinary General Meetings of Shareholders and three Extraordinary General Meetings of Shareholders, on *March 5 2018*, on *April 26 2018* and on *September 25 2018*.

All the necessary documents relating to the smooth conduct of the General Meetings were published on due time and as required by the law.

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During the general meetings of March 5 2018 the following were approved:

During the Ordinary General Meeting of Shareholders:

- 
- the revenue and expenditure budget for 2018;
- the increase of the monthly fixed indemnities and gross variables of the members of the Management Board and the General Manager as well as the conclusion of the addendums according to this approval, in view of the application of GEO no. 79/2017 for amending and supplementing the Law no. 227/2015 regarding the Fiscal Code and GEO no. 90/2017 regarding some fiscal-budgetary measures, the amending and supplementing some normative acts and extending some deadlines.

During the Extraordinary General Meeting of Shareholders the establishment of two representative offices of the company, one in the Republic of Moldova and the other in Ukraine was approved.

On *April 26, 2018*, the Management Board of the company convened two General Meetings of Shareholders, one Ordinary Meeting and one Extraordinary Meeting.

The Ordinary General Meeting of Shareholders approved the following:

- the financial statements of the company for the financial year 2017, based upon the Administrator's Report and the Financial Auditor's Report;
- the registration of the unsolicited and non-requested dividends for the financial year 2013 as income;
- the degree of achievement of the objectives and performance criteria for the year 2017 for the members of the Management Board;
- the release from administration of the administrators, for the activity carried out during the financial year 2017, upon the basis of the reports submitted;
- the objectives included in the management plan for the members of the Management Board for 2018;
- the remuneration of the members of the Management Board according to the provisions of Law no. 111/2016 for the approval of the Government Emergency Ordinance no. 109/2011 on the Corporate Governance of Public Enterprises;
- the election of Mr. Dan-Octavian Alexandrescu as temporary administrator of the Management Board, according to the provisions of art. 64<sup>1</sup> of GEO no. 109/2011, following the termination of the mandate contract of Ms Adela-Petrinia Neagoe.

The Extraordinary General Assembly of Shareholders approved the following:

- extending the validity of the multi-currency multi-product limit of 30 million LEI contracted by SC Antibiotice SA from the Export Import Bank of Romania - EximBank SA for a period of 12 months;

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- maintaining the guarantees related to the multiproduct multi-currency limit in the amount of 30 million LEI for the entire validity period resulting from the extension under item 1 of the agenda of the meeting;
- the issuance of a decision of SC Antibiotice SA not to divide, not to merge and not to decide on the early dissolution during the entire validity of the multi-product multi-currency limit without the prior consent of the Export Bank of Romania - EximBank SA ;
- the empowerment of the General Manager Ioan Nani and the Economic Director Paula Luminita Coman to sign on behalf of the company all the documents related to the extension, according to the agenda items 1 and 2, as well as the documents related to the obligations assumed by the company according to point 3 of the agenda;
- Contracting a long-term investment facility (10 years) in the amount of 15,406,300 EUR from UniCredit Bank;
- guaranteeing the investment credit facility in the amount of 15,406,300 EUR to be contracted from UniCredit Bank;
- the empowerment of the General Manager Mr. Ioan Nani and Mrs. Paula Luminita Coman as Economic Director to sign on behalf of the company all the documents/credit agreements and their accessories, necessary and related to the contracting and implementation of the investment credit facility, according to points 1 and 2;
- Establishing the headquarters of the Antibiotice Representative Office in the Republic of Moldova at the following address: mun. Chisinau, Grenoble Street, 259/2, 259/3, Republic of Moldova.

The General Meetings of *September 25, 2018* have submitted for approval and approved the following items on the agenda:

The Ordinary General Assembly of Shareholders:

- the company's financial statements for the first half of 2018, based upon the Administrators' Report and the Financial Auditors' Report;
- the modification of the Management Board by appointing Mr. Dan-Octavian Alexandrescu as non-executive director for a four-year term, starting with 25.09.2018;
- the form of the mandate contract to be concluded by the company with the non-executive administrator appointed on 25.09.2018, as well as the annexes to the contract including the objectives and performance criteria, the fixed indemnity and the variable component.

The Extraordinary General Meeting of Shareholders:

- the increase of the cash-non cash multi-currency credit, contracted to UniCredit Bank from the amount of 30,000,000 RON to the amount of 50,000,000 RON;

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- the securing of the credit amounting to 50,000,000 RON contracted to UniCredit Bank;
- the empowerment of Mr. Ioan Nani as General Manager and Mrs. Paula Luminita Coman as Economic Director to sign on behalf of the company all the documents/credit agreements and their accessories, necessary and related to the contracting and implementation of the credit facility in the total amount of 50.000.000 RON from UniCredit Bank;
- the confirmation, ratification and assuming of the mortgage and real estate mortgage contracts under the Credit Agreement no. IAS3-42-2016 dated 17.08.2016, signed with UniCredit Bank S.A.
- the ratification of access to the credit facility of 4.000.000 EUR granted to the company under the article 44 of the Articles of Association, by the additional act no. 8 of 26.03.2018 to the Credit Facility Contract no. 12239/22 May 2012, as well as by the Additional Act no. 4 of 26.03.2018 to the Mortgage Contract no. 12239 / G1 / 22 May 2012 concluded with ING Bank N.V., a facility that was fully reimbursed on 29.06.2018.
- the establishment of the headquarters of the Antibiotice Representative Office in Ukraine at the following address: Kiev, 6 Mikhaila Dontsa Street, Ukraine.
- the registration date 10.10.2018, in order to identify the shareholders on whom the effects of the adopted decisions are reflected, according to the provisions of art. 86, paragraph 1 of the Law 24/2017 regarding the issuers of financial instruments and market operations and set ex-dates for 09.10.2018.

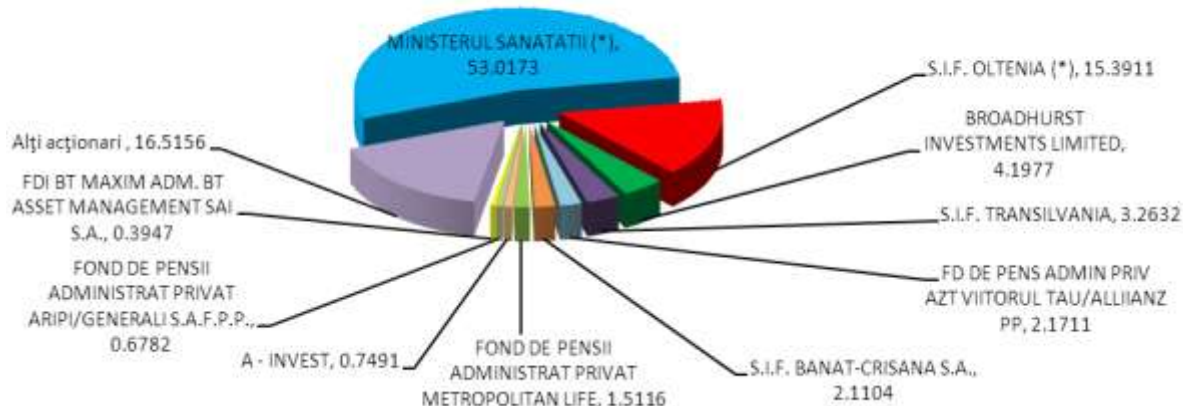
### Antibiotice SA on the capital market

#### Investors (*according to the Shareholders' Registry on 31.12.2018* )

- The Ministry of Health (\*) - 53.0173%,
- S.I.F. Oltenia (\*) - 15.3911%
- Broadhurst Investments Limited - 4.1977%
- S.I.F. Transilvania - 3.2632%
- Fondul de Pensii Administrat Privat AZT Viitorul Tau/Allianz - 2.1711%
- S.I.F. Banat-Crisana S.A - 2.1104%
- Fondul de Pensii Administrat Privat METROPLITAN LIFE - 1.5116%
- A-Invest - 0.7491%
- Fond de Pensii Administrat Privat ARIPI/GENERALI S.A.F.P.P. - 0.6782%
- FDI BT MAXIM ADM. BT ASSET MNAGEMENT SAI S.A. - 0.3947%
- Other individuals and legal entities - 16.5156%.

NOTA: (\*) - Significant shareholders, according to Law no. 297 of 28.06.2004, Art. 2, Paragraph 1

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### Classes of shareholders

- Legal entities - 8.,8571%,
- Individuals - 13.1429%.

### Dividends

During the year 2018 dividends were paid for the financial years 2014, 2015, 2016 and 2017 amounting to 16.232.891, 48 lei, as follows:

| Period | Net dividends |                  |                  |               |       |                             |      | Dividend payment suspending date |   |
|--------|---------------|------------------|------------------|---------------|-------|-----------------------------|------|----------------------------------|---|
|        | Due           | Paid             |                  |               |       | Not collected on 31.12.2018 |      |                                  |   |
|        |               | lei              |                  |               |       | % (total paid)              | lei  |                                  | % |
|        |               | Until 31.12.2017 | 01.01÷31.12.2018 | Total         |       |                             |      |                                  |   |
| 0      | 1             | 2                | 3                | 4             | 5     | 6                           | 7    | 8                                |   |
| 2014   | 15.061.293    | 13.939.429.39    | 26.266.58        | 13.965.695.97 | 92.73 | 1.095.597.03                | 7.27 | 22.10.2018                       |   |
| 2015   | 13.753.343    | 12.620.174.10    | 33.033.48        | 12.653.207.58 | 92.00 | 1.100.135.42                | 8.00 | Payment in progress              |   |
| 2016   | 25.401.595    | 23.260.934.12    | 80.042.72        | 23.340.976.84 | 91.89 | 2.060.618.16                | 8.11 | Payment in progress              |   |
| 2017   | 17.588.679.97 | -                | 16.093.548.70    | 16.093.548.70 | 91.50 | 1.495.131.27                | 8.50 | Payment in progress              |   |

### **Dividend history (2014 -2015- 2016 -2017)**

For the years 2014, 2015, 2016 and 2017 the payment of dividends was performed through the Central Depository Bucharest and implicitly, through the CEC Bank.

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### The evolution of the price per share

The titles issued by Antibiotice have been listed in the PREMIUM category of the Bucharest Stock Exchange under the ATB symbol since 1997.

The first transaction was registered on April 16, 1997, at a reference price of 0.3500 LEI / share. The historic maximum was reached on July 10, 2007, with the price of 2.1700 LEI / share, and the historical minimum of 0.0650 LEI / share was registered on June 8 2000.

Both the business plans and the financial results from the company have been a strong guarantee that Antibiotice has strengthened its position on the national medicines market.

The shares of Antibiotice (ATB), traded on the Bucharest Stock Exchange are included in the BET-Plus index, which includes the Romanian companies listed on BSE market that meet the minimum selection criteria except for the financial investment companies.

In 2018, the minimum price for an ATB share was 0.4550 LEI. The share price increased to a maximum of 0.5780 LEI / share.

The stock exchange capitalization of Antibiotice on December 31 2018 (the last trading day of the year) was 326.942 thousand LEI.

### Antibiotice shares - ATB / Regular Market

|  | 2014        | 2015        | 2016        | 2017        | 2018        |
|--|-------------|-------------|-------------|-------------|-------------|
| Number of shares                             | 671.338.040 | 671.338.040 | 671.338.040 | 671.338.040 | 671.338.040 |
| Stock market capitalization (thousand lei)*  | 390.719     | 357.152     | 349.096     | 361.180     | 326.942     |
| Stock market capitalization (thousand euro)* | 87.173      | 78.868      | 76.875      | 77.511      | 70.100      |
| Stock market capitalization (thousand \$)*   | 105.978     | 86.167      | 81.123      | 92.813      | 80.259      |
| Total value traded (million lei)             | 16          | 11          | 6           | 12          | 9           |
| No. of traded shares                         | 27.467.454  | 18.844.935  | 12.555.866  | 21.113.565  | 17.109.263  |
| Opening price (lei/share)                    | 0.5520      | 0.5850      | 0.5320      | 0.5200      | 0.5780      |
| Maximum price (lei/share)                    | 0.6170      | 0.6170      | 0.5420      | 0.5920      | 0.5780      |
| Minimum price (lei/share)                    | 0.5410      | 0.5240      | 0.4200      | 0.5200      | 0.4550      |



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|  |        |        |        |             |             |
|--|--------|--------|--------|-------------|-------------|
| Price at the end of the year (lei/share) | 0.5850 | 0.5320 | 0.5270 | 0.5380      | 0.4870      |
| Average price (lei/share)                | 0.5845 | 0.5836 | 0.5032 | 0.5585      | 0.5028      |
| Earnings/share (lei/share)***            | 0.0464 | 0.0405 | 0.0452 | 0.0500      | 0.0511      |
| Gross dividend/share (lei/share)**       | 0.0235 | 0.0197 | 0.0384 | 0.026552598 | 0.009991506 |
| Dividend yield ****                      | 4.03%  | 3.69%  | 4.05%  | 4.59%       | 2.05%       |
| Dividend distribution rate *****         | 51%    | 49%    | 52%    | 53%         | 20%         |

- \* Calculated based on the share price on the last trading day of the year,
- \*\* Proposed dividend,
- \*\*\* The calculation of earnings per share is based upon the net profits of each year
- \*\*\*\* Dividend per share/share price on the first trading day of each year
- \*\*\*\*\* The dividend distribution rate = (total number of shares x gross dividend per share)/total net profit.

During the year 2018, 17,109,263 shares were traded, worth 8.6 million LEI (1.8 million euros, 2.2 million dollars), with an average price of 0.5028 LEI / share.

### The rights of the holders of financial instruments

The corporate governance framework adopted and applied:

- protects the shareholders' rights,
- ensures the fair treatment of all shareholders,
- recognizes the role of third parties with interests in the company
- guarantees the provision of information and its transparency
- assures the responsibility of the Management Board towards the company and the shareholders.

On the company's website at [www.antibiotice.ro/investitori/informatii\\_actionari](http://www.antibiotice.ro/investitori/informatii_actionari), there is a section dedicated to shareholders, where one can access and download documents related to the General Meetings of Shareholders: procedures regarding the access and participation in the meetings, the notice to attend, additions to the agenda, informative materials, special representation proxies, correspondence voting forms, decision drafts, decisions, voting results, etc.

The company makes available to all interested the periodical and annual financial statements prepared according to the legislation in force. The company also complies with all disclosure requirements under the laws of commercial companies and the capital market.

Within the company there is a structure specialized in the relationship with the existing and potential investors, called Capital Market, which has the main role of

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ensuring a good communication with the shareholders of the company. The persons appointed to keep in touch with the investors deal with shareholders' requests with maximum efficiency and facilitate the dialogue with the management of the company. The company creates and develops an appropriate policy to promote effective communication with investors and shareholders.

### Management Board

Antibiotice SA is administered by a Management Board responsible for fulfilling all the tasks necessary to achieve the object of the company, except as provided by law for the General Meeting of Shareholders. There is a clear division of responsibilities between the Management Board and the Executive Management.

The Management Board seeks to ensure that its own decisions, those of the company's management, the General Meeting of Shareholders as well as the internal regulations comply with the legal requirements and are properly implemented. The Board is responsible for monitoring the company's management on behalf of the shareholders.

The duties of the Management Board are described in the company's Articles of Association and the relevant internal regulations available on the website of the company under the Corporate Governance section.

During the year 2018, the Management Board met in 10 sessions, each time with 100% presence and adopted decisions that enabled it to carry out its tasks in an effective and efficient manner.

Thus, on the monthly meetings the Management Board has discussed in detail about the financial results in the reporting period and cumulatively since the beginning of the year as well as the economic performance relative to the budget and the same period last year. The Board requested, as appropriate, detailed explanations from the executive management in connection with the plans to increase production efficiency, the investment plans, the provisions made, the liquidity management, the operational profitability and of the overall activity. Following the detailed analysis of the results for the period, the Board decided the approval thereof for the publication and submission to the Bucharest Stock Exchange and the Financial Supervision Authority fitting every time the Financial Communication Calendar.

The five members of the Board shall ensure the effectiveness of the ability to monitor, analyze and assess the work of the managers as well as the fair treatment of the shareholders.

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### Management Board of Antibiotice SA on 31 December 2018

**Legal adviser, IAVOR Ionuț-Sebastian, 43 years old**

**Chairman of the Board and representative of the Ministry of Health**

At the Ordinary General Meeting of Shareholders of April 30 2015 Mr. Iavor was elected a member to the Management Board of the company and then appointed by the Board members as Chairman.

Mr. Ionuț Sebastian Iavor is currently General Manager of the General Directorate of Human Resources and Legal Department within the Ministry of Health.

**Number of Antibiotice SA shares owned - 0\***

**Ec. Ioan NANI, 59 years old**

**Vice Chairman of the Board and CEO**

At the Ordinary General Meeting of Shareholders of April 19 2016, Mr. Nani was reconfirmed as a member of the Board of Directors, for a period of four years; Mr. Nani was appointed then by the members of the Board as Vice-President. Mr. Nani is an economist specialized in management, a chartered accountant and a member of the Board since 2009 as well as CEO (1998-2008 and 2009 - present day).

**Number of Antibiotice SA shares owned - 1.513\***

**Dr. Dan-Octavian Alexandrescu, 44 years old**

**Member of the Management Board and representative of the Ministry of Health**

At the Ordinary General Shareholders Meeting of September 29, 2018, Mr. Dan-Octavian Alexandrescu was elected to the Management Board for a four-year term.

Mr. Dan-Octavian Alexandrescu is a primary care laparoscopic surgeon and secretary of state in the Ministry of Health and has been coordinator of the Medicines and Medical Devices Policy Division since March 2017.

**Number of Antibiotice SA shares owned - 0\***

**Ec. Nicolae STOIAN, 62 years old**

**Member of the Board and representative of the SIF Oltenia shareholding and other corporate shareholders**

At the Ordinary General Meeting of Shareholders of April 19 2016, Mr. Stoian was re-elected as a member of the Management Board for a period of four years. Mr. Stoian is a chartered accountant, a tax consultant and financial auditor, as well as a representative of the Internal Control Department with SIF Oltenia.

**Number of Antibiotice SA shares owned - 0\***

**Eng. Elena CALIȚOIU, 55 years old**

**Member of the Board and representative of SIF the Oltenia and other corporate shareholders**

Mrs. Calițoiu was confirmed during the Ordinary General Meeting of Shareholders on April 19, 2016, for a period of four years.

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Mrs. Calițoiu is a mechanical engineer and Director of Investments and Risk Management with SIF Oltenia; Mrs. Calițoiu has been a member of the Board since 2016.

**Number of Antibiotice SA shares owned - 0\***

*\*The number of Antibiotice shares (ATB) held on September 1 2016 according to the latest database held by Antibiotice for the year 2016.*

### **The advisory committees**

During the year 2018, the specialized advisory committees had the following membership:

- the Audit Committee: Mr. Ionuț Sebastian IAVOR - President and Mr. Nicolae STOIAN and Mrs. Elena CALIȚOIU;
- the Nomination and Remuneration Committee: Ionut Sebastian Iavor - President and Mrs. Elena CALIȚOIU;
- the Trade Policies Committee: Mr. Dan Octavian Alexandrescu - President and Mr. Nicolae STOIAN.

The advisory committees have conducted investigations, analyzes and have developed recommendations for the Management Board in specific areas and submitted periodic reports upon their activity.

The Audit Committee met during the year 2018 in four sessions in order to fulfill its responsibilities with regard to financial reporting, external and internal auditing, risk management and internal control.

### **Internal control**

The specialized internal control activities provided by the legislation in force are carried out through our company's own Internal Audit Office, which carries out the following activities: internal audit, financial management control, management control and is carried out in a methodological and procedural framework regulated by laws, norms and codes of professional conduct specific to each activity.

The way of setting and achieving the objectives of the Internal Audit Office, the findings and recommendations resulting from all internal control actions were submitted quarterly to the Audit Committee in the Management Board, for the assessment of the activity and the internal control exercised in the company.

During the year, 9 missions were carried out according to the approved Annual Plan 2018, which had the following general objectives adapted to the areas, according to the specifics of the audited organizational structures:

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- the examination of compliance with all principles, specific procedural and methodological rules, internal notes and decisions;
- the examination of the way in which the activity is organized;
- the evaluation of the management and control system of the activity;
- other objectives specific to the activity.

The missions were carried out in compliance with the procedural audit procedures, by going through all the stages of an internal audit mission and materialized in internal audit reports, which were approved by the General Manager. The conclusions and recommendations of the audit reports for each audit mission were acknowledged by the audited structures.

The monitoring method of the implementation of the recommendations made within the internal audit missions is provided in the operational procedure, code: AI-021 "Follow-up of recommendations". After the implementation deadline is exceeded, it is required to communicate in writing the implementation status of the recommendations by the audited structures. Thus, out of the 48 recommendations from the audit reports drawn up in 2018, 30 recommendations had a deadline for implementation on December 31, 2018 and we found that they were implemented.

Within the Internal Audit Office, the activity of inventory and control of the management with personnel with attributions in this respect is carried out. During the year a number of 15 inventory actions were carried out, which included the following entities' management:

- the company's central deposits of the raw materials and consumables;
- the places of consumption of raw materials and consumables where stock management is organized.

The inventory activity was aimed at observing the legal framework established by the following normative acts:

- the Accounting Law no. 82/1991, republished and updated;
- Law no. 22/1969 on the employment of managers, the provision of guarantees and the liability for the management of goods;
- the M.F.O.2861/09.10.2009 for the approval of the Norms regarding the organization and performance of the inventory of assets such as debts and equity;
- Operating procedures, internal notes, internal decisions of the company's management.

The findings following the control actions are: the legal regulations and the internal decisions regarding the stock management are observed, there is a consistency between the factual and the scriptic stocks as a result of the periodical checking during the year between the quantitative evidence held at the level of the management and the quantitative-value within the Accounting Office.

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In 2018, within the Internal Audit Office, the personnel with the function of financial controller also carried out financial control actions in accordance with the provisions of H.G. 1151/2012, which had as objectives:

- the verification of the compliance with the legal provisions regarding the recording of the economic and financial operations in the accounting records;
- the verification of the compliance with the legal provisions regarding the execution of the income and expenditure budget for the year 2017;
- the verification of the compliance with the legal provisions in the substantiation of the company's income and expenditure budget for the year 2018;
- the verification of the legal provisions and the internal regulations regarding the manner of carrying out the annual inventory of the assets, liabilities and equity for the year 2017;
- the verification of the observance of the legal provisions and of the internal regulations regarding the receipts and payments in LEI and foreign currency, of any kind, in cash or by transfer;
- the verification of the observance of the legal provisions and of the internal regulations regarding the drawing up, circulation, keeping and archiving of the primary, accounting and technical-operative documents.

The financial control actions of management were finalized by drawing up control reports, in which the findings and proposed measures for improvement of the verified activities were presented. The control reports issued were approved by the General Manager who ordered the application of the measures.

### **The risk management**

The risk management is the continuous identification and monitoring/evaluation of the risks to which the activity of the company is or may be exposed and which may affect the achievement of the objectives. These aim at achieving indicators that ensure both the continuity of the activity and the protection of the interests of shareholders and clients.

The risk management by the company observes the legal and regulatory requirements in force for the identification, assessment, management and reporting of risks:

- The Order of the General Secretariat of the Government (OGSG) no. 400/2015 modified and completed by OGSG no. 200/2016 and OGSG 600/2018;
- The requirements of the Code of Corporate Governance of the Bucharest Stock Exchange.

The main purpose of the risk management is to help understand and identify the risks to which the organization is exposed so that they can be anticipated and managed without adversely affecting the organization's performance goals.

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The running of the risk management processes ensures the identification, analysis, assessment and management of risks in order to keep them at acceptable levels based upon the company's risk tolerance and the ability to cover (absorb) these risks.

In 2018, the General Risk Register was developed and approved, aiming to minimizing the significant risks with impact on the objectives to which the company is exposed.

The Risk Management activity analyzes and prioritises significant annual risks that may affect the achievement of the overall objectives of the company's operations.

For 2018, at the level of the company, 14 significant risks have been identified and ranked, which may affect the achievement of the general objectives of the company.

At the level of organizational structures within Antibiotice SA specific risks were identified, which were presented to the Audit Committee.

The objectives of Antibiotice SA concerning the risk management are as follows:

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

The main categories of risks identified:

### 1. Financial risks

From the viewpoint of the financial risk management, the risks to which the company is exposed are: the currency risk, the liquidity risk and the commercial (non-payment) risk.

1.1. **The currency risk**, a component of the financial risk, often occurs in the current market economy conditions in which currency rates fluctuate under the rule of demand and supply.

The exchange rate fluctuations are reflected both in the costs of the imported raw materials and in the export prices of finished products.

During 2018 there were periods with higher volatility, with depreciation rates of the leu. At the end of 2018 the exchange rate earnings amounted to 7.373.362 LEI, the expenses to 7.109.232 LEI, resulting in a net gain from the exchange rate difference of 264.130 LEI.

1.2. **The liquidity risk** is the risk according to which the company may encounter difficulties in honoring any short-term payment obligations at any time.

The circumstances of the liquidity risk: the lack of cash-flow generated by the gap between receipts and payments, the collection of receivables over deadlines exceeding 300 days, the unpredictability and the lack of transparency for the calculation of the clawback tax, the increase in the price of utilities, raw materials and services.

## MANAGEMENT REPORT 2018

In 2018, the cash demand of the company was higher than in 2017, both for the payment of the clawback tax, dividends to shareholders and for the support of the acquisitions in the investment plan, which led to greater use of credit lines.

The company's liquidity risk policy is to maintain, to the extent possible, sufficient liquidity to meet the obligations as they mature and the availability of funding through funding lines.

**1.3. *The commercial (non-payment) risk*** - is defined as the risk of loss or of the failure to achieve the expected profits because of the debtor's lack of financial liquidity and the failure to meet the payment obligation at the due date.

The circumstances of the occurrence of the non-payment risk: large exposures to the major distributors, the long payment periods due largely to delays in the settlement of health care bills by NHIH.

The measures used by the company to control and reduce the commercial (non-payment) risk include: the monitoring of the customer creditworthiness, the diversifying of the client portfolio and the request of warranties.

### **2. The legislative risks**

The legislative changes aimed at the pharmaceutical market lead to the emergence of the legislative risk, which must be continuously managed.

The pharmaceutical market is a regulated market, with clear legislative provisions, designed to control the quality and therapeutical efficiency of the medicines present on the market, as well as to avoid counterfeiting.

The adaptation to these provisions is reflected both in additional costs related to the updating of the documentation, in aligning to the latest quality standards, in influencing the peak sales prices as well as in delays in product marketing.

The company's strategy for managing these risks involves the permanent concern for obtaining international certifications for the manufacturing lines, the updating of the authorization documentation for portfolio products, the carrying out of bioequivalence and stability studies, the constant pursuing of the legislative changes at international level and the continuous adapting of policies, rules and procedures to the latest changes.

### **3. The human resources risks**

#### **3.1. The labor shortage of candidates trained in specific fields of the pharmaceutical industry**

The measures used to control and reduce this risk are: organizing the "Summer School a+", promoting the company within the faculties, organizing study visits of the students in the company, carrying out the "Perform a+" project, partnerships with pre-university education units.



## MANAGEMENT REPORT 2018

4. **The reputational risk** refers to the possibility of occurrence of negative events, as well as of unfavorable opinions or perceptions, which can negatively impact upon the company's revenue, brand and public image.

In order to effectively identify and manage the situations that could create a reputational risk, the following measures are envisaged: the monitoring of the company's image in the media, the constant communication to the media and the relevant public of the positive information about the company's performance and development prospect, the control of risks, the continuous training of the employees, the adaptation to the legislative requirements in the field and the compliance with the procedures.

5. The company also carries out a permanent surveillance of **the operational risks** in order to take measures to maintain them at an acceptable level that does not threaten its financial stability, the interests of creditors, shareholders, employees and partners.

The risk assessment process has also identified a number of **external risks**, namely:

- the risk of natural disasters (earthquakes, floods, fires, etc.);
- the risk of wars or interethnic conflicts;
- the risk of national and international economic instability;
- the risk of legislative instability;

### Nomination and Remuneration Committee

During the year the Nomination and Remuneration Committee met in meetings where it evaluated the activity of the administrators and performed tasks related to the appointment of a member of the Management Board.

The remuneration granted to the Management Board and the Executive Management (General Manager) is presented in the table below:

| Description                    | For the year ending on |                  |
|--------------------------------|------------------------|------------------|
|                                | 31.12.2018             | 31.12.2017       |
| Salaries                       | 2.223.909              | 1.014.017        |
| Taxes and social contributions | 50.038                 | 227.308          |
| <b>Total</b>                   | <b>2.273.947</b>       | <b>1.241.325</b> |

The administrators and directors with a mandate contract (the general manager) receive, for their work, a fixed monthly indemnity and a variable indemnity.

The variable indemnity is granted depending on the fulfillment of the performance indicators and criteria established in the management contracts and the mandate contract.

The monthly fixed indemnity is established in accordance with the legal provisions, respectively the provisions of Article I.33. paragraph (3) of the Law no. 111/2016 for the approval of the Government Emergency Ordinance no. 109/2011 on the Corporate Governance of Public Enterprises.

## MANAGEMENT REPORT 2018

The fixed and variable indemnity for the members of the Management Board is approved by the General Meeting of Shareholders. The general limits on the remuneration of directors with a mandate contract are approved by the General Meeting of Shareholders; based upon these general limits, the Management Board sets the amount of the directors' remuneration (with a mandate contract).

### Executive management

Antibiotice is represented by the General Manager, according to powers provided by law and the company's Articles of Association. The Management Board retains the duty of representing the company in relationship with the directors whom it has appointed. The executive management of Antibiotice is ensured by one General Manager, who is also the Vice-Chairman of the Management Board and nine specialized managers.

### Executive Management of Antibiotice SA on December 31, 2018

**Ec. Ioan NANI, 59 years old**

**CEO and Vice Chairman of the Board**

Mr. Nani has graduated from the Faculty of Economics, the "Alexandru Ioan Cuza" University of Iași. Mr. Nani is an economist specialized in management and a chartered accountant.

Mr. Nani began working as an economist at Antibiotice in 1987. Between 1991 and 1993 he worked as a financial control inspector with the General Directorate of Public Finance Iași and then with the Court of Auditors of Romania. In 1994 Mr. Nani returned to Antibiotice as a financial executive and in 1998, Mr. Nani became CEO. In February 2009 Mr. Nani was appointed Deputy Chairman of the Authority for State Assets Recovery (AVAS), and in the month of June of the same year Mr. Nani became CEO of Antibiotice.

Mr. Nani has been CEO since 2009.

**Number of Antibiotice SA shares owned - 1.513\***

**Eng. Cornelia MORARU, 53 years old**

**Technical and Production Manager**

Mrs. Moraru graduated from the Faculty of Chemical Technology, the Technical University "Gheorghe Asachi" of Iași. After graduation, Mrs. Moraru worked as a chemical engineer at the Fălticeni Chemical Factory. Mrs. Moraru has been working at Antibiotice since 1990. Until 1998 Mrs. Moraru has worked at the Penicillin II Plant and then at the Biosynthesis compartment for a year. From July 1999 until January 2001 Mrs. Moraru has worked as a biosynthesis technologist at the Penicillin II Plant. In January 2001 she became Head of the Tablets Plant and in May 2003 Mrs. Moraru was appointed Director of the Pharmaceutical Division.

Mrs. Moraru has been the Technical and Production Manager since 2005.

## MANAGEMENT REPORT 2018

**Number of Antibiotice SA shares owned - 1.513\***

**Ec. Paula Luminița COMAN, 51 years old**

**Economic Manager**

Mrs. Coman has graduated from the Faculty of Economics and Business Administration, the “Alexandru Ioan Cuza” University of Iași and has been a Chartered Accountant since 2006 and a tax consultant since 2007.

After graduation, Mrs. Coman has worked as an economist at the County Iași Tourism Office. Mrs. Coman has been working at Antibiotice SA since 1991 as an economist in the Rates Efficiency Office. In 1998 Mrs. Coman has become Head of the Economic Analysis Compartment and in 2003 Head of the Financial-Accounting Department.

Mrs. Coman has been the Economic Manager since 2011.

**Number of Antibiotice SA shares owned - 0\***

**Ec. Vasile CHEBAC, 64 years old**

**Commercial and Logistics Director**

Mr. Chebac has graduated from the Faculty of Economics, the “Alexandru Ioan Cuza” University of Iași, has been an active member of the Body of Chartered Accountants, Iași Branch since 1993 and a financial auditor and has been a member of the Chamber of Auditors of Romania since 2008.

Mr. Chebac has started working at Antibiotice SA in 1972. In 1987 Mr. Chebac became an economist at the Planning and Development Department within the Investment Compartment. In February 1991 Mr. Chebac has worked as a financial controller at the Directorate General of Public Finance and in July 1993 Mr. Chebac has worked as a financial controller at the Chamber of Accounts Iași, and in July 1993 the Chamber of Auditors financial controller in Iași. In January 1998 Mr. Chebac was appointed Chief Commissioner at the Fraud Squad of Iași. In September 2001 Mr. Chebac returns to Antibiotice SA to the position of Chief Commercial Officer and General Services.

Mr. Chebac has been the Commercial and Logistics Director since 2005.

**Number of Antibiotice SA shares owned - 0\***

**Ec. Gica RUSU, 55 years old**

**Human Resources Director**

Mrs. Rusu, a graduate of the “Alexandru Ioan Cuza” University of Iași, the Faculty of Economics, was granted in 2003 a master's degree in management and business administration by the same university.

Mrs. Rusu has been working at Antibiotice since 1981. In 1986 Mrs. Rusu was an economist at the Penicillin Plant and in 1996 was working in the Financial Department. In 1999 Mrs. Rusu has become the Head of the Human Resources Department.

Mrs. Rusu has been the Human Resources Director since 2004.

**Number of Antibiotice SA shares owned - 1.510\***

**Ec. Ovidiu BĂȚAGA, 41 years old**

**Marketing and Domestic Sales Director**

Mr. Bățaga, a graduate of the Faculty of Economics and Business Administration (FEAA), the “Alexandru Ioan Cuza” University of Iași holds three titles of Masters in Financial

## MANAGEMENT REPORT 2018

Management (awarded by the same university in 2001), Pharmaceutical Marketing (from the “Grigore T. Popa” University of Medicine and Pharmacy in 2003) and Project Management (awarded by the “Gheorghe Asachi” Technical University in 2007).

After graduation Mr. Bățașă worked as a junior in the Currency and Credit Chair, Finance specialty, within the FEAA. Mr. Bățașă has been working at Antibiotice SA since February 2001 as an economist in the Economic Analysis, Accounting and Marketing Department. In January 2006 Mr. Bățașă was appointed Head of Market Analysis and Strategic Planning Department.

Mr. Bățașă has been the Marketing and Domestic Sales Director since 2010.

**Number of Antibiotice SA shares owned - 0\***

**Dr. Mihaela MOȘNEGUȚU, 49 years old**

**Medical Director**

A graduate of the Faculty of Medicine, the “Grigore T. Popa University of Medicine and Pharmacy of Iași, Dr. Moșneguțu is a specialist in family medicine.

Dr. Moșneguțu began work as a doctor working in County Iași. Dr. Moșneguțu has been working at Antibiotice since 2000. In 2000 she was working at the Promotion Office and in 2001 Dr. Moșneguțu becomes the Head thereof. In 2005 Dr. Moșneguțu became the Head of the Pharmacovigilance and Medical Consultancy Department and in 2009 she was appointed Medical and Retail Promotion Manager.

Dr. Moșneguțu has been Medical Director since 2011.

**Number of Antibiotice SA shares owned - 0\***

*\* Number of Antibiotice Company shares (ATB) owned on September 1 2016 according to the latest database held by Antibiotice on the year 2016.*

**Ec. Mihai STOIAN, 43 years old**

**International Business Director**

A Graduate of the Faculty of Economic Sciences at the “Alexandru Ioan Cuza” University of Iași, the International Economic Relations specialization.

Mr. Stoian has been working at Antibiotice SA since May 2005 as Export Area Sales Manager for active substances.

In July 2008 Mr. Stoian was appointed Head of Intracommunity Deliveries and Export, within the Marketing and International Relations Unit.

In August 2009 Mr. Stoian was appointed Export Manager and in June 2011 he was appointed Business Development Manager.

Mr. Stoian has been an International Business Director since 2012.

**Number of Antibiotice SA shares owned - 0\***

**Eng. Mihaiela Stoenescu, 51 years old**

**Communication Director**

A graduate of the Faculty of Chemical Technology of the “Gheorghe Asachi” Technical University of Iași, in 1999 Mrs. Stoenescu obtained the title of Master in Business

## MANAGEMENT REPORT 2018

Management, the Faculty of Economics and Business Administration within the “Alexandru Ioan Cuza” University of Iași.

In 2010 Mrs. Stoenescu became an Expert in Public Relations, following the international certification in Public Relations of the Chartered Institute of Public Relations UK. Mrs. Stoenescu worked as an economic journalist, and then for about 20 years she has worked in the field of communication and public relations. Mrs Stoenescu has also worked for Antibiotice as a Public Relations Director, during which she coordinated the rebranding of the company.

Mrs Stoenescu currently holds the position of Communication Director.

**Number of Antibiotice SA shares owned - 0\***

**Eng. Cristina Diaconescu, 51 years old**

**Director of the Research and Development Unit**

A graduate of the Faculty of Industrial Chemistry of the “Gheorghe Asachi” Technical University of Iași, Mrs Diaconescu holds two master’s degrees in business management at the Faculty of Economics and Business Administration, the “Gheorghe Asachi” University of Iași and a master’s degree in Pharmaceutical Management and Marketing of the “Gr. T. Popa” University of Medicine and Pharmacy of Iași - the Faculty of Pharmacy.

Mrs Diaconescu has been working at Antibiotice since 1994. In 2005 she was appointed Deputy Director of Marketing and Domestic Market. In January 2008 Mrs Diaconescu became Promotion & Retail Sales Manager and as of February 2015 she was appointed Quality Control Manager.

Mrs Diaconescu currently holds the position of Director of the Research and Development Unit within Antibiotice.

**Number of Antibiotice SA shares owned - 1514\***

### The activity analysis

In 2018, Antibiotice - Romania's leading manufacturer of generic medicines - continued its mission to deliver valuable, therapeutically affordable medicines, thus contributing to a better health for millions of patients in Romania and in other countries of the world.

The characteristics of the sales on the international markets in 2018 were:

*The export increased by 10% compared to 2017 (31.5 million USD/124 million LEI)*

| Value situation (USD) |             |             | 2018/2017 |
|-----------------------|-------------|-------------|-----------|
| Category              | YEAR 2017   | YEAR 2018   |           |
| Nystatin              | 15.061.872  | 16.462.078  | 109.3%    |
| Finished products     | 13.670.017  | 15.024.748  | 109.9%    |
| Total (USD)           | 28.731.889  | 31.486.826  | 109.6%    |
| Total (LEI)           | 117.419.062 | 124.056.552 | 105.7%    |

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### *The main markets where Antibiotice SA has experienced growth:*

|                   |  |
|-------------------|--|
| Finished products | Vietnam (37%)<br>(share in the export value of finished products)                      |
| Nystatin          | North America (31%) and South America (16%)<br>(share in the export value of Nystatin) |

### *Top finished products sold for export:*

Ampicillin & Sulbactam injectable (Vietnam)  
Amoxicillin capsules (Vietnam)  
Glycerin adults (Russia)  
Nafcillin injectable 2 g (USA)

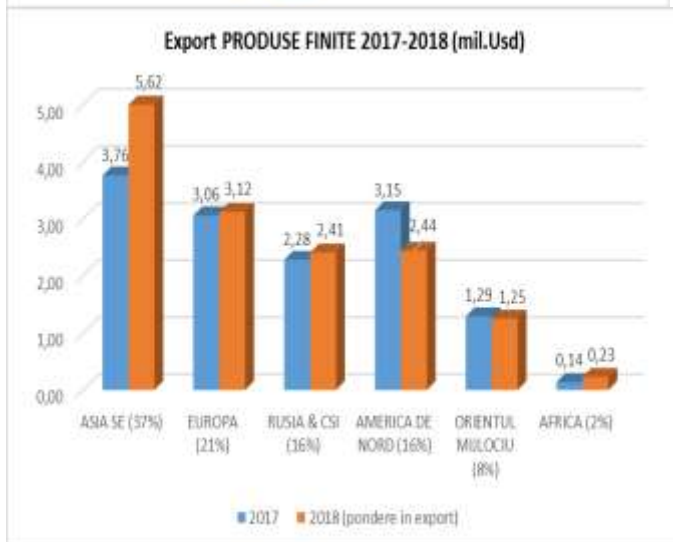
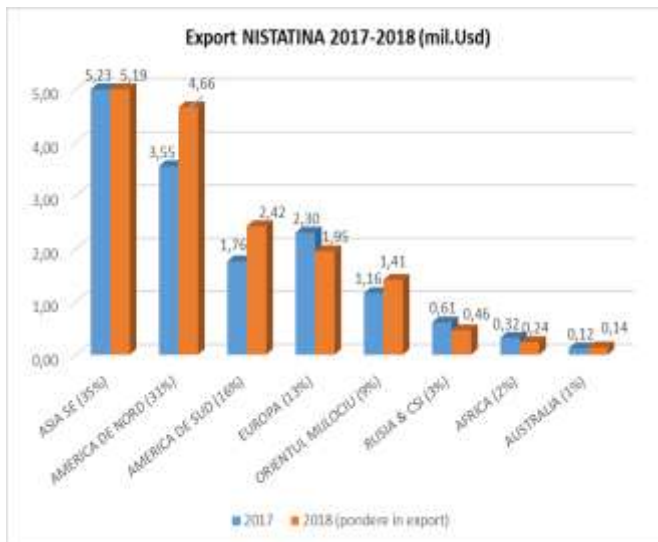
In 2018, Antibiotice's strategy on international markets has pursued:

- To maintain the world leadership for Nystatin active substance;
- To increase the market share on the regulated markets, especially in the US market;
- To develop/strengthen the presence of the company on the current markets and to identify new potential markets;
- To focus the export growth efforts on strategic markets;
- To develop new business models and partnerships in foreign markets to accelerate the company's development internationally;
- To adapt the portfolio of products traded on foreign markets according to the local specific consumption.

Antibiotice is present in 75 countries of the world with finished products made on its 8 manufacturing lines.

The export of Nystatin and finished products in 2018 has the following structure per areas - in progress compared to 2017:

## MANAGEMENT REPORT 2018



- Asia remains the main destination for finished products, up by 50% (+1.9 million USD) compared to 2017, as the sales of finished products in Vietnam increased.
- North America has become the main growth pole for micronized Nystatin, with a + 31% increase (+1.1 million USD).
- Most South American markets (excluding Colombia) experienced the tripling of their orders for Nystatin ATB Standard.

The top 10 countries where 80% of finished product sales were made in 2018 are: Vietnam - 37%, the US - 14%, Iraq 6%, Moldova 6%, The Netherlands 4%, Russia 5%, Lithuania - 4%, Ukraine - 2%, Canada - 2%, Bosnia Herzegovina - 1%.

The top 10 countries that achieved 80% of the Nystatin sales in 2018 are: the US - 28.3%, China - 12.4%, Brazil - 8.3%, Germany - 5.5%, India - 5.5%, Vietnam - 5.4%, Colombia - 4.7%, Iran - 3.7%, Pakistan - 2.9%, the Netherlands - 2.5%, Taiwan - 1.8%.

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For the 16th consecutive year, Antibiotice participated in the most important event in the world pharmaceutical industry - the international fair CPhI Worldwide, which took place from 9 to 11 October in Madrid, Spain. The fair brought together 2.500 exhibitors from 153 countries.

Along with the world's elite pharmaceutical industry, Antibiotice has presented over 25 representative products from the perspective of the pharmaceutical forms existing in its portfolio, i.e. sterile injectable powders, ointments, suppositories, capsules, tablets and supplements.

In addition to the anti-infective products, the promotion of medicines from the cardiovascular and dermatology therapeutical classes was considered.

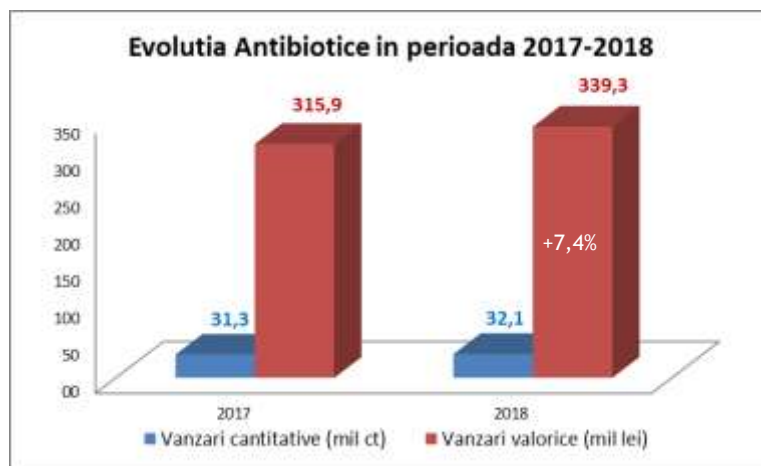
### Pharmaceutical market evolution in Romania

In 2018, the value of medicines released to patients amounted to 16.07 billion LEI (distribution price), higher by 13.8% compared to 2017. From quantitative viewpoint, the market grew by 5.9% compared to the previous year, 612.7 million of boxes being sold by the pharmacies.

In terms of prescribing, the pharmaceutical market was dominated by prescription medicines (RX) representing 78% of total value sales and 66% of the total consumption of medicines (reported as a number of boxes) in Romania. This category of products recorded a 13.6% increase in value, from 11 billion LEI in 2017 to 12.5 billion LEI in 2018.

### Antibiotice SA in the pharmaceutical market in Romania

In the context of the pharmaceutical market in Romania, Antibiotice recorded a sales growth of 7.4% (339.3 million LEI) in pharmacies and hospitals compared to 2017.

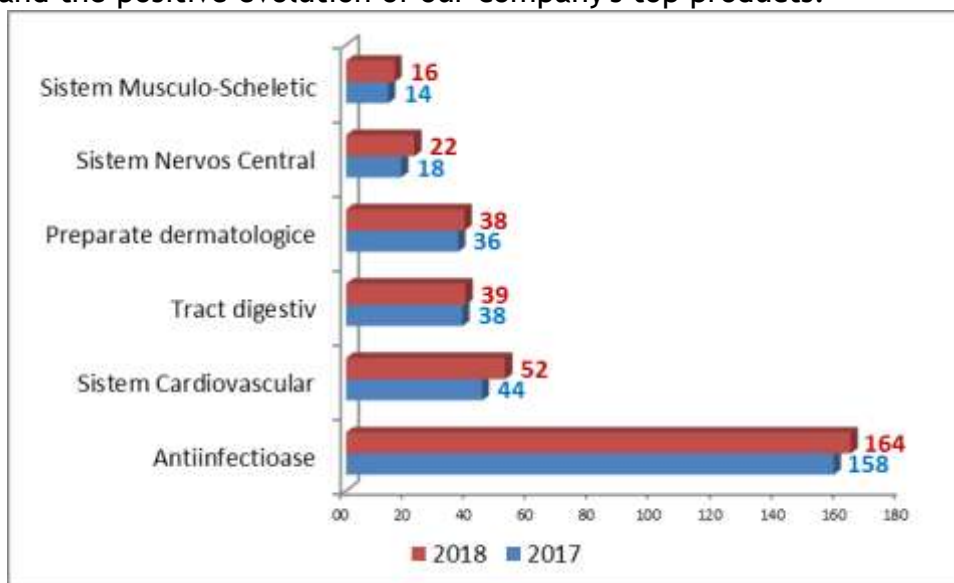




## MANAGEMENT REPORT 2018

The retail pharmacy segment was up 7.3 % compared to the previous year, from 236.3 million LEI to 253.5 million LEI, while the hospital segment grew by 7.9%, from 79.5 million LEI in 2017 to 85.8 million LEI in 2018.

The main therapeutic classes which recorded significant value increases compared to 2017 were: antiinfectives (+5.5 million LEI), cardiovascular system medicines (+7.5 million LEI), digestive tract medicines (+1 million LEI), dermatological preparations (+2.1 million LEI), central nervous system medicines (+ 4.3 million LEI) and musculoskeletal system medicines (+2,1 million LEI). The increases were generated by both new products input and the positive evolution of our company's top products.



The products from our company portfolio that generated more than 1 million LEI in 2018 were: Fluxiv® range (+4.3 million LEI), Meropenem® for injection range (+2.4 million LEI), Ampiplus® (+1.9 million LEI), Nolet® (+1.9 million LEI), Glycerin range (+1.9 million LEI), Colistina Atb® (1.8 million LEI), Sprinten® (+1.7 million LEI), Memantina Atb® range (+1.6 million LEI).

In the generics and OTCs segment, Antibiotice SA ranked third, with a 5.1% market share while in terms of total pharmaceutical market, it ranked 16<sup>th</sup>, with a 2.11% market share.

In 2018, Antibiotice maintained its leading position in the segment of generics and OTCs sold in hospitals, with a 18.01% market share, higher than the percent recorded in the previous year (17.5%).

In the top of non-prescription medicines (OTCs) and dietary supplements, Antibiotice ranked 13<sup>th</sup> in a total of 221 companies, higher by one position compared to 2017. In 2018, the percentage of growth recorded by Antibiotice in this segment was 14.4%, being equal to the one recorded by the total market (14.4%).

During 2018, actions for promoting the products from our portfolio were carried out in the main therapeutic areas: antiinfectives, dermatological preparations, medicines for cardiovascular system, digestive tract and metabolism, central nervous system and musculoskeletal system. These actions aimed at increasing the reputation of the

## MANAGEMENT REPORT 2018

company brand and product brands as well as the loyalty of the target audience. Among them we mention:

- Participation in the most important national and regional scientific events;
- Organizing working meetings with independent pharmacies and mini-chain pharmacies;
- Launching the social responsibility program “Antibiotics of the 3<sup>rd</sup> Millennium” by bringing together local and international experts as well as professionals who consistently support the judicious use of antibiotics;
- Social media campaigns for Cutaden Bebe®, Sprinten®, Fezivit C® for the general public;
- National radio campaigns for Spaverin®, Sprinten®, Fezivit C® which aimed at increasing the reputation of the product brands;
- Risk awareness campaign for the chronic venous insufficiency - for promoting the product Fluxiv;
- Merchandising campaigns for our products on the shelves of open circuit pharmacies.
- Promoting information to the general public on bacterial resistance and correct use of antibiotics at the European Antibiotic Awareness Day (EAAD).

### Research-Development

The Research & Development activity had as main objectives to develop new products and optimize the current company portfolio (topicals, tablets, capsules, injectables, new pharmaceutical forms). These objectives derived from the company's strategic development directions in line with the sales plan until 2025.

The research pipeline in 2018 included 33 projects, of which: solid oral forms (18 projects), medicines for injections (5 projects) and topical forms (10 projects) in different stages of development, covering the therapeutic classes that define our company's portfolio: oral antiinfectives, injectable antiinfectives, dermatologicals, cardiovasculars, non-steroidal anti-inflammatory medicines, medicines for digestive system and for women's health. One of our goals is to strengthen the portfolio of dietary supplements, cosmetics and prophylaxis products.

As an integral part of the Research & Development activity, Biotechnology Research has been geared towards identifying the stability conditions of the product Nystatin, in parallel with works for maintaining the strains in the company's industrial culture collection laboratory.

In order to maintain the current portfolio, we aligned ourselves to the changes in pharmacopoeias in force for a number of 11 products from our portfolio and we updated the authorization documentation. We completed 7 national re-authorization procedures and reauthorized 21 international products.

In 2018, the antiinfective and cardiovascular portfolios, representative for our company both nationally and internationally, were complemented with a new product from the beta-lactam antibiotic class in combination with beta-lactamase inhibitors (in

## MANAGEMENT REPORT 2018

two concentrations) and a selective beta blocker, for which the decentralized authorization procedures (Romania and EU countries) were initiated in 2016. Two new cosmetic products were notified in 2018.

39 new Marketing Authorizations for medicines and Notifications for dietary supplements produced by Antibiotice were obtained for 8 countries from Asia, Africa, CIS area and Europe.

An ISO inspection was conducted in 2018 for recertifying the Center for Drug Evaluation in which two bioequivalence clinical trials were conducted, one of them for a product from the Antibiotice portfolio and the other one for an external sponsor.

Also, the procedures for conducting other clinical trials (preparation of the study protocols, submission of documentation to the National Agency for Medicines and Medical Devices and to the National Bioethics Commission for Medicines and Medical Devices) were initiated for other two products, one of them for a product from our own portfolio and the other one for an external sponsor.

Permanent monitoring of efficacy and safety in administration of the medicines manufactured by Antibiotice, proactive activities and risk management over the life cycle of each medicinal product are carried out by the Pharmacovigilance Department, connected to the European data-processing network for medicines safety - EudraVigilance.

### Production

In 2018 Antibiotice produced 525 million pharmaceutical units in the form of tablets, capsules, parenterals, topicals (ointments, creams, gels) suppositories and pessaries, higher by 3 million pharmaceutical units compared to 2017.

Our company produced also the active substance Nystatin in a quantity higher by 4% in 2018 as compared to the previous year. The total value of our 2018 production amounted to 326.2 million LEI, by 12.7% higher than in the previous year.

Value of production for export in 2018 (Nystatin and finished products) was by 13% higher than in 2017 and represented 28% from the total value of products manufactured on the Antibiotice site. The production of parenteral products for export represented 36% out of the total value of the products for external markets, by 5% higher compared to 2017.

Through the environmental protection program, actions were taken to reduce emissions of volatile organic substances during the extraction phase of Nystatin and specific consumption of solvents in the technological process.

The manufacturing plants were equipped with new filling and packaging equipment leading to an increase in productivity by more than 22%.

One of our important concerns in 2018 was to equip the manufacturing flows with equipment for serialization of finished prescription products in accordance with Directive 2011/62/EU as well as to start this process.

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### New products in 2018

- Antiinfectives for systemic use: **Perasin®** 2.25g and 4.5 g (Piperacillin with tazobactam);
- Topical preparations for joint and muscle pains, at high doses: **Saliform® forte**, cream, 50 g and 100 g (Methyl salicylate);
- Cosmetics: **Fluxiv®** tonic cream, 20 g, 40 g and 100 g (Trolox), **Tinero®** (Nicotinamide) gel, 15 g and 40 g.

### Medium and long-term development through investments in new facilities

The approved planned value of the investment program for 2018 was 116,280,727 LEI that was rectified at 112,432,068 LEI through a justified renunciation to a series of investment objectives. The negotiated and contracted value of the investment objectives was 103,260,918 LEI of which 75,295,060 LEI represent fully achieved objectives and 27,965,858 LEI represent the objectives in progress which are to be completed by the end of 2019. The difference between the rectified and contracted value, i.e. 9,171,151 LEI were savings generated by a good negotiation of the offers with our suppliers of goods and services.

Out of the value of the objectives under execution, the amount of 22,607,501 LEI represents equipment, clean rooms and utility installations for the new Ointment & Suppository Plant, the difference of 5,358,357 LEI being represented by service contracts and contracts for purchasing equipment for manufacturing plants, Quality Control and Research & Development.

Through the investment objectives included in the program, we aim at:

- building a new, performing manufacturing capacity equipped with modern production installations for manufacturing ointments and suppositories, which can be GMP and FDA authorized.
- modernizing and revamping the existing manufacturing flows for increasing the production capacities, quality of products and for reducing the production costs;
- modernizing the utility installations within the entire enterprise;
- attaining the objectives included in the strategy for reducing the pollution and protecting the environment.

The main investments made in 2018 were:

#### I. A new production capacity for ointments and suppositories

Our objectives for this investment:

- to build and properly equip a new Ointment & Suppository Plant which can be EU GMP and FDA authorized;
- to obtain a GMP certification for this new plant issued by our national regulatory body (National Agency for Medicines and Medical Devices);
- to provide proper conditions for manufacturing medicines in compliance with the legislative requirements and pharmacopoeias in force for registering and

## MANAGEMENT REPORT 2018

selling them in all the regulated markets, especially in Europe, the US and Canada.

### Substantiation of investment

A new modern manufacturing plant for manufacturing semisolid medicines filled in tubes (ointments, creams, gels) and suppositories represents for Antibiotice SA the guarantee for a long-term business development.

The company's development strategy focuses on maintaining and expanding the portfolio of semisolid products filled in tubes and suppositories.

This strategy is based on developing the portfolio for the domestic market but also on diversifying and penetrating new important markets in Europe, North America, Asia and Africa.

In order to ensure the main characteristics of medicines (quality, efficiency, safety), their manufacturing must be made in facilities with high-performing equipment and critical utilities compliant with the GMP requirements.

The first stage of this investment completed in 2017 consisted of the construction of the manufacturing plant (without clean rooms and the related installations) and the technical-administrative building.

In 2018, we developed the second stage of this important investment consisting of:

1. design and construction of clean rooms and related installations;
2. design and construction of utility installations: compressed air system, industrial cold system, electricity supply, purified water system, cold water supply system (industrial cold), demineralized water supply, steam supply, technological hot water, drinking water, thermal station;
3. assembly of technological equipment correlated with the assembly of the clean rooms and all the installations.

### **II. Equipment for the manufacturing plants, Quality Control and Medical Unit**

The purchased manufacturing equipment and laboratory devices are of latest generation, with high productivity, low energy consumption and high operational safety. Manufacturing equipment replaced the equipment with significant physical wear which generated high maintenance costs and low productivity. The purchase of modern laboratory equipment was required by the continuous revisions of pharmacopoeial monographs and increased accuracy of analysis methods in the pharmaceutical laboratories.

Taking into account that, starting with 2019, all the pharmaceutical products which are to be traded both in the domestic and external markets (the US, EU) must be serialized, it is necessary that, starting with this year, the products manufactured by Antibiotice be serialized. For this purpose, we purchased serialization equipment and included them in the manufacturing flows in all the manufacturing plants and in the Finished Product Warehouse. In compliance with the requirements of European Directive 2011/62/EU and Drug Quality and Security Act to combat the counterfeit medicines.

**III. Intelligent Energy Monitoring System in Antibiotice** - a project co-funded by European funds, through the Large Infrastructure Operational Program, Axis 6.2, entitled "Monitoring Energy Consumption of Industrial Consumers".

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The overall objective of this project is to reduce by 1 %, on average the specific energy consumption (kgep / 1000 EUR) in our company, in a 5-year period after implementing the project as a result of monitoring consumption by implementing a smart metering system for energy consumption.

The specific objectives are as follows:

- monitoring the electricity and natural gas consumption and storing the data in the manufacturing plants and for other users for which the energy is monthly paid;
- drafting daily reports for the monitored energy consumption or, as the case may be, reports by work shifts, seasons, manufacturing cycles;
- performing energy consumption / cost analyzes per each consumer / installation / equipment;
- calculation of specific consumptions based on which measures / strategies for making the equipment / installations more effective can be established with the technical support for future upgrading projects.

### Optimizing the operating costs and increasing the operating efficiency

In 2018, following its strategic objectives with a special emphasis on the business internationalization, Antibiotice marked an 8% increase in the sales revenue (27,671,799 LEI) compared to 2017. Our company recorded also a net profit higher by 2% compared to 2017, reaching the value of 34,303,788 LEI.

The 2018 financial results reflect a wide-ranging activity management program meant to reduce the considerable impact generated by the **claw-back tax** which **increased by 25%** compared to 2017, reaching the value of **36,484,667 LEI**.

The company's performance was highlighted in a 8% increase in the sales income, in absolute value of 27,671,799 LEI compared to 2017. This increase is mainly due to sales in the international market, which recorded values higher by 6 %.

The production made in 2018 was higher by 13% compared to the previous year and determined expenditures with raw materials and consumables higher by 9%, an increase caused also by the increase in import prices for acquisitions.

In 2018, faithful to a responsible employer policy, our staff expenses were higher by 6% compared to 2017 as a result of wage increases made in 2017 with effect in 2018.

Amortization and depreciation expenses increased by 18% as a result of the commissioning of the equipment purchased according to the investment plan, for modernizing the company's activity.

Other operating expenses recorded a 8% increase due to the increase in the clawback tax up to 36,484,667 LEI and due to the increased utility tariffs in 2018 (electricity 29%, methane gas 7%, water 6%).

## MANAGEMENT REPORT 2018

Operating profit had a value of 39,312,791 LEI, higher by 5% compared to 2017.

After-tax profit was worth 34,303,788 LEI, higher by 2% compared to 2017.

|  | Financial year    |                   | 2018/2017   |
|--|-------------------|-------------------|-------------|
|  | 31.12.2017        | 31.12.2018        |             |
| A  | 1                 | 2                 | 3=2/1       |
| <b>Revenue from sales</b>                      | 336,904,666       | 364,576,466       | 1.08        |
| Other operating income                         | 37,796,667        | 45,405,000        | 1.20        |
| Income related to the cost of product stocks   | 4,235,363         | -1,259,715        | -0.30       |
| Income generated by the entity and capitalized | 1,850,831         | 3,489,144         | 1.89        |
| Expenditure on raw materials and consumables   | 127,072,000       | 138,844,375       | 1.09        |
| Staff costs                                    | 85,897,194        | 90,864,735        | 1.06        |
| Amortization and depreciation expenses         | 17,098,098        | 20,237,870        | 1.18        |
| Other operating expenses                       | 113,395,172       | 122,951,124       | 1.08        |
| <b>Operating profit</b>                        | <b>37,325,063</b> | <b>39,312,791</b> | <b>1.05</b> |
| Net financial income                           | -1,963,633        | -4,224,180        | 2.15        |
| <b>Pre-tax profit</b>                          | <b>35,361,430</b> | <b>35,088,611</b> | <b>0.99</b> |
| Income tax expenses                            | 1,803,076         | 784,823           | 0.43        |
| <b>Profit</b>                                  | <b>33,558,354</b> | <b>34,303,788</b> | <b>1.02</b> |

### Assets

The 2018 current assets are higher than the short-term liabilities while the permanent capital (equity + long-term liabilities) exceeds the fixed assets, which show that the company meet the principle of aligning the maturity of assets and liabilities.

- **Fixed assets** recorded a 38% increase compared to the previous year as a result of both the investment process in 2018 and the result of the reevaluation of the buildings (according to the Fiscal Code Art. 460 and the Company's Accounting Policy).

## MANAGEMENT REPORT 2018

- **Inventory** value slightly decreased by 3%; these are managed according to the stock regulations established within our company.
- **The receivables** increased by 18%, of which the trade receivables related to the turnover increased by 14%, the difference representing advance payments for the acquisition of fixed assets according to the investment plan.

### Liabilities

The financing policy for the investments made within our company in 2018 led to a 32 % growth in the current liabilities, from 135,386,417 LEI to 178,917,540 LEI, influencing the economic indicators as follows:

- an increase in indebtedness degree (amounts owed to credit institutions / equity) from 17% to 27%, up to the level budgeted at the beginning of the year;
- a 13% increase in equity compared to 2017;
- a supraunitary current liquidity (2.12), which falls within the recommended limits

|                                     | 31.12.2017         | 31.12.2018         |             |
|-------------------------------------|--------------------|--------------------|-------------|
| <b>ASSETS</b>                       |                    |                    |             |
| <b>FIXED ASSETS</b>                 |                    |                    |             |
| Tangible assets                     | 223,242,890        | 310,640,665        | 1.39        |
| Intangible assets                   | 13,107,622         | 15,028,716         | 1.15        |
| <b>TOTAL FIXED ASSETS</b>           | <b>236,350,512</b> | <b>325,669,381</b> | <b>1.38</b> |
| <b>CURRENT ASSETS</b>               |                    |                    |             |
| Stocks                              | 67,264,546         | 64,964,661         | 0.97        |
| Trade and other receivables         | 264,212,743        | 313,094,458        | 1.18        |
| Cash and cash equivalents           | 5,107,743          | 2,376,682          | 0.47        |
| <b>TOTAL CURRENT ASSETS</b>         | <b>336,585,032</b> | <b>380,435,802</b> | <b>1.13</b> |
| <b>TOTAL ASSETS</b>                 | <b>572,935,544</b> | <b>706,105,183</b> | <b>1.23</b> |
| <b>LIABILITIES</b>                  |                    |                    |             |
| <b>CURRENT LIABILITIES</b>          |                    |                    |             |
| Trade and similar liabilities       | 55,535,974         | 67,181,084         | 1.21        |
| Amounts owed to credit institutions | 69,731,310         | 100,729,229        | 1.44        |
| Tax and current tax liabilities     | 9,792,887          | 10,421,393         | 1.06        |
| Investment subsidies                | 326,246            | 637,008            | 1.95        |
| <b>TOTAL CURRENT LIABILITIES</b>    | <b>135,386,417</b> | <b>178,958,714</b> | <b>1.32</b> |



## MANAGEMENT REPORT 2018

### LONG-TERM LIABILITIES

|                                     |                    |                    |             |
|-------------------------------------|--------------------|--------------------|-------------|
| Investment subsidies                | 2,498,889          | 2,489.791          | 1.00        |
| Deferred tax                        | 18,172,398         | 25,266,930         | 1.39        |
| Amounts owed to credit institutions |                    | 26,662,433         |             |
| <b>TOTAL LONG-TERM LIABILITIES</b>  | <b>20,671,287</b>  | <b>54,419,154</b>  | <b>2.63</b> |
| <b>TOTAL LIABILITIES</b>            | <b>156,057,704</b> | <b>233,377,868</b> | <b>1.50</b> |

### Share capital and reserves

|                                     |                    |                    |             |
|-------------------------------------|--------------------|--------------------|-------------|
| <b>Share capital</b>                | <b>264,835,156</b> | <b>264,835,156</b> | <b>1.00</b> |
| Revaluation reserves                | 14,556,141         | 53,459,596         | 3.67        |
| Legal reserves                      | 13,426,761         | 13,426,761         | 1.00        |
| Other reserves                      | 162,134,513        | 190,422,002        | 1.17        |
| Reported result                     | -71,633,085        | -83,719,989        | 1.16        |
| Current result                      | 33,558,354         | 34,303,788         | 1.02        |
| <b>TOTAL EQUITY</b>                 | <b>416,877,840</b> | <b>472,727,315</b> | <b>1.13</b> |
| <b>TOTAL ASSETS AND LIABILITIES</b> | <b>572,935,544</b> | <b>706,105,183</b> | <b>1.23</b> |

|                               |  | 31.12.2017  | 31.12.2018  |
|-------------------------------|--|-------------|-------------|
| <b>ROE (Return on Equity)</b> | = Net profit/Equity                          | 8,05%       | 7,26%       |
| <b>ROA (Return on assets)</b> | = Net profit /Total Assets                   | 5,86%       | 4,86%       |
| <b>EPS (LEI/SHARES)</b>       | = Net profit/share                           | 0.050       | 0.051       |
| <b>NET TURNOVER RATE</b>      | = Profit/Sales income                        | 9,96%       | 9,41%       |
| <b>GENERAL LIQUIDITY</b>      | = Current assets/Current liabilities         | 2,54        | 2,12        |
| <b>FAST LIQUIDITY RATE</b>    | =(Current assets-Stocks)/Current liabilities | 2,02        | 1,76        |
| <b>Degree of indebtedness</b> | = Liabilities/Total assets                   | 25,94%      | 33,05%      |
| <b>No. of shares</b>          |  | 671,338,040 | 671,338,040 |

### AMOUNTS OWED TO CREDIT INSTITUTIONS

#### Amounts owed to credit institutions at 31.12.2018

Short-term contract no. IAS3-42-2016/ 17.08.2016 concluded with Unicredit Bank S.A.

|                                     |  |
|-------------------------------------|--|
| Objective                           | Credit line - working capital                        |
| Amount                              | 50,000,000 LEI                                       |
| Maturity                            | 16.08.2019   |
| <b>Balance at December 31, 2018</b> | <b>40,398,127 LEI</b>                                |
| Guaranties                          | Mortgage contract for buildings, land / Contract for |

## MANAGEMENT REPORT 2018

assignment of receivables

Contract no. IAS3-20-2018/03.05.2018 concluded with Unicredit Bank S.A.

|                                     |  |
|-------------------------------------|--|
| Objective                           | Capital investment loan  |
| Amount                              | 15,406,300 EUR   |
| Maturity                            | 02.05.2028   |
| <b>Balance at December 31, 2018</b> | <b>5,709,266.17 EUR (26,627,446.49 LEI)</b>                                    |
| Guaranties                          | Mortgage contract for buildings, land / Contract for assignment of receivables |

Short-term contract no. 12/01.07.2013 concluded with Export-Import Bank of Romania-EXIMBANK S.A.

|                                     |  |
|-------------------------------------|--|
| Objective                           | Credit line - working capital  |
| Amount                              | 30,000,000 LEI   |
| Maturity                            | 26.06.2019   |
| <b>Balance at December 31, 2018</b> | <b>24,158,985.50 LEI</b>   |
| Guaranties                          | Mortgage contract for buildings, land / Contract for assignment of receivables |

Short-term contract no. 12239/22.05.2012 concluded with ING BANK N.V. AMSTERDAM - Romania Branch

|                                     |   |
|-------------------------------------|---|
| Objective                           | Credit line - working capital   |
| Amount                              | 9,500,000 EUR   |
| Maturity                            | 22.05.2019  |
| <b>Balance at December 31, 2018</b> | <b>11,711,390.09 LEI<br/>5,132,454.91 EUR ( 23,937,256.45 LEI)<br/>128,503.05 USD ( 523,470.02 LEI)</b> |
| Guaranties                          | Mortgage contract for buildings, land / Contract for assignment of receivables                          |

SC Antibiotice SA did not lodge guarantees and did not pledge or mortgage its own assets to guarantee certain obligations in favor of a third party.

### Cas flow

Cash and cash equivalents at the beginning of the period were -64.62 million LEI, representing credit lines amounting to 69.73 million LEI of which 5.1 million LEI remained

## MANAGEMENT REPORT 2018

available in the bank accounts from the same credit lines. Cash receipts from operating activities were 342.16 million LEI. Cash payments to suppliers of goods and services were 196.18 million LEI, and those to and on behalf of employees were 82.49 million LEI.

Payments of 64.6 million LEI were made for purchasing fixed assets. Our company paid also 6.73 million LEI, representing income tax, VAT, local taxes and bank interest and 35.89 million LEI representing contributions to the Ministry of Health (clawback tax).

Our company paid dividends under financing activities amounting to 16.23 million LEI.

At the end of the period the cash and cash equivalents were -98.35 million LEI representing credit lines for the current activity (100.72 million LEI) of which 2.37 million LEI remained available in the bank accounts from the same credit lines.

The Company did not record unpaid obligations to the state and local budget.

2019 is under the sign of further internationalizing our business, strengthening our sales in Romania and elaborating a supportive plan for the coming years as there are no legislative measures to lower the claw back tax, this burden having a high potential risk of lowering the company's medium and long-term development potential.

### **Imports of raw materials**

Acquisitions of raw materials, packaging and finished products are a support activity on the value chain of our company, with specific objectives. These include monitoring the procurement structures and negotiating the prices on raw materials and goods, managing relationships with suppliers of raw materials and goods by negotiating contracts (supply contracts based on quality specifications), identifying and managing alternative sources of active substances, with the objectives of securing the supply or obtaining lower prices, as well as meeting the deadlines set for the research development projects.

We correlated the program for procuring raw materials, secondary packaging, substances/ reference medicines, finished products with the sales structure generated both by the domestic market and by various international markets, so as to achieve the objectives proposed at the beginning of the year. We also sought to keep the existing partnerships and develop new strategic partnerships, a mandatory condition in the context of increasing the complexity and competitiveness of the pharmaceutical market worldwide.

### **Human Resources**

The human resources policy promotes the diversity and equal opportunities in recruiting, selecting and integrating the employees. Our employees benefits from all the rights deriving from the law, our company offering fair and equitable conditions of work and professional development.

#### **The average staff number on December 31, 2018 - 1415**

By nature of the specific activities carried out in Antibiotice, the staff breakdown by education and professional training is the following:

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|   |             |
|---|-------------|
| Higher education - 600 employees, of which:           | 42.40%      |
| - 32 employees with completed doctoral studies (5.3%) |             |
| Secondary education - 851 employees                   | 57.6 %      |
| <b>Total 1415</b>                                     | <b>100%</b> |

The activities of the Human Resources Management Unit in 2018 aimed at achieving the specific objectives:

### **1. Identification of the staff needed in each structure for achieving the objectives**

In order to put into practice an integrated vision of all the company's units regarding the provision of personnel corresponding to the needs generated by the proposed strategic objectives, the *Human Resources Commission* operates within the company, being responsible for establishing the necessary staffing to ensure an optimal operating structure, but also to maintain the balance of the indicators assumed and approved in the Income and Expense Budget.

During the meetings of the commission held in 2018, the results of the analyzes regarding the personnel needs for each organizational structure were presented taking into account the following:

- the need to fill vacancies
- creating teams in the priority areas
  - o quality assurance
  - o research-development
  - o medical unit
  - o automation and investment
  - o production

Staffing was performed by going through the specific recruitment and selection stages, established by procedures as well as through specific projects for attracting and selecting new employees.

### **Perform a+, 3rd edition**

The project aims at developing the practical skills among pharmacists (residents and final year students) in the specific activities carried out by the Medical Unit and Research & Development Unit and also to creating a foundation for a long-term communication and collaboration with the *Grigore T.Popa* University of Medicine and Pharmacy in order to train and attract specialized personnel.

**Perform a+** project run its 3<sup>rd</sup> edition in 2018, in collaboration with the Faculty of Pharmacy Iași for selecting graduates for pharmaceutical research & development. The theoretical and practical program was supported by mentors chosen among the company's specialists.

### **Summer School a+, 9<sup>th</sup> edition**

The external component of this project seeks to identify and train specialists in pharmacy, biology, chemistry, chemical engineering and select them to fill the vacancies in Pharmaceutical Research & Development, Quality Assurance, Quality Control,

## MANAGEMENT REPORT 2018

Production. The candidates become familiar with the working environment, concepts and regulations in the pharmaceutical industry.

30 participants were selected in this project well-known in the academic environment in Iași and among the final year students of the Iași universities. They were properly trained by our specialists. The topics covered by the courses of the Summer School a+ presents information in the fields of quality assurance in a pharmaceutical company, pharmacovigilance, Regulatory Affairs, specific laboratory techniques in quality control, pharmaceutical research and formulation. The courses were held in the period July - August 2018.

**So far, our company employed 40 participants in the courses held in the 9 editions of the Summer School a+.**

### **Partnerships with pre-university education institutions**

Within the partnerships established with Petru Poni Technological High School and Technological High School of Mechatronics and Automation Iași in the school year 2017 - 2018, 70 pupils from the grades XI and XII, with the specializations of laboratory chemist technician / chemist operator in the pharmaceutical and cosmetics industry, practiced their internships in our company. As regards the pupils with the specialization of mechatronist / electromechanic, Antibiotice was a partner in running the projects and events organized to encourage them to practice the chosen profession.

The program aims at building the pupils' practical skills and enhancing their knowledge in order to attract them as future employees for replacing our employees with retirement opportunities.

Under the "Școala Altfel" (Doing School Differently) program, Antibiotice opened its gates to more than 350 pupils from pre-university education institutions in Iași presenting itself as one of the most famous landmarks in the industry from Iași, presenting its history and future development perspectives.

### **2. Running of professional skills training programs**

In order to achieve the professional objectives and performances necessary to increase the competitiveness and quality of the business, we carry out, on a yearly basis, human resources development projects, with training programs for each unit, according to the needs identified for each organizational structure and in close correlation with the applicable EC and national legislative changes.

Training programs with internal lecturers, established for each structure according to the specifics of the activity, are complemented by the continuous professional training by accessing professional training programs with external lecturers, according to the Annual Training Plan approved and budgeted for the current year.

In 2018, a number of 665 employees attended the scheduled training sessions, by specialization fields, resulting in an average of 35.2 hours of training / employee.

Also in 2018, to its 9<sup>th</sup> edition, through its internal component, Summer School+ offered employees, the opportunity to benefit from training aiming at developing specialized competencies in quality assurance, regulatory affairs, serialization, new requirements in validating the manufacturing processes and requalifying the equipment

## MANAGEMENT REPORT 2018

as well as at the organizational development through topics related to the employer brand, employee retention, legislative provisions on health and safety at work.

### **3. Setting the 2018 objectives for the staff included in the Management by Objectives (MBO)**

Based on the indicators approved in the Income & Expenditure Budget 2018 and starting from the company's Business Plan for the period 2018-2020, Antibiotice established the annual general objectives which generate the specific objectives for each activity for the employees included in the MBO system.

The Management Performance Monitoring & Evaluation Committee analyzed the individual forms for setting the 2018 objectives of the MBO staff in all the company's structures to determine whether they subscribe to the objectives set out in the Management Plans, if they are established in accordance with the synergy principles, interdependence, standardization and to make recommendations on how to formulate and measure the indicators.

The objectives validated by the Committee were the basis for issuing the decisions of setting the objectives for 2018 and additional acts to individual labour contracts for the 340 employees included in the MBO system.

### **4. Strategies and measures to increase employee motivation**

In 2018, our company started a new, unitary and modern wage system which aims to align the revenues to each employee's level of performance, having as a consequence to increase the motivation and loyalty of the employees, respectively the attractiveness of the employer brand. Defined in line with the business development plan and labor market trends, the new system is a perfectible one that will undergo improvements over the coming years. This project implies:

- *Analysis of the higher and secondary education jobs, taking into account:*
  - *monthly net income;*
  - *calculation of the existing coefficients for the analyzed jobs in relation to the minimum wage.*
- *Setting the maximum coefficients of the net revenues by job groups, taking into account the following factors:*
  - *the level of professional training and experience required to fill the job;*
  - *the holders' responsibilities;*
  - *complexity and importance of the activity ;*
  - *availability on the labor market;*
  - *labour conditions;*
  - *other specific factors (working with confidential data, etc.).*
- *Sizing the maximum coefficients by groups of jobs with higher/ secondary education*
- *Calculation of the financial implications of implementing the new coefficients*

## MANAGEMENT REPORT 2018

- *Validation of the job hierarchy process in a team made up of directors, managers, consultants and employee representatives (trade union) - the stage completed in December 2018.*

### 5. Strategies and measures for increasing the employer brand attractiveness

In 2018 our company initiated a program to increase its attractiveness for recruiting and retaining the staff. The planning for implementing this program was established and the necessary instruments were also chosen:

- Conducting the impact study on the perception and attractiveness of the employer brand among the employees and public targeted for recruitment;
- Setting a plan to increase the employer brand awareness and to ensure the compliance of the HR practices based on the impact analysis results.

In trim IV 2018 a fost aplicat chestionarul privind perceptia angajatilor asupra In the fourth quarter of 2018 the employee perception questionnaire was applied on Antibiotice as an employer. In 2019 we will continue to measure the perception of the external public, to establish the main pillars on which the internal and external communication will be developed.

### 6. Ensuring a favorable working climate and an organizational culture geared towards innovation and performance

The employees' representatives together with the company's management identify the best solutions for maintaining a beneficial climate for the professional activities.

In 2018 an analysis study on the organizational climate was conducted for identifying the solutions to ensure a higher level of employees' performance and satisfaction. Based on the conclusions of the study, action plans will be established starting with 2019.

In its activity, Antibiotice applies ethical standards based on principles of honesty, integrity, fairness and transparency, and equally focuses on all shareholders, employees, business partners, authorities and community.

our company, there is a balanced distribution of employees by gender and age:

| Age range        | 20-30       | 30-40        | 40-50        | 50-55        | over 55      | Total (%)  |
|------------------|-------------|--------------|--------------|--------------|--------------|------------|
| Women (%)        | 5.13        | 12.89        | 21.65        | 8.19         | 7.19         | 55.05      |
| Men (%)          | 3.56        | 9.05         | 18.45        | 5.34         | 8.55         | 44.95      |
| <b>Total (%)</b> | <b>8.69</b> | <b>21.94</b> | <b>40.10</b> | <b>13.53</b> | <b>15.74</b> | <b>100</b> |

From a confessional point of view, 96% of our employees belong to the Orthodox confession, 4% to the Catholic confession. This proportion is in line with the confessional structure at national level. This characteristic, as well as those related to gender, age, nationality or the presence of disabilities are not limiting criteria for employment.

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Our company ensures a fair and non-discriminatory treatment at work. 11 of our employees are people with disabilities and benefit from the legal provisions.

### Quality policy

#### Certified quality

The increase of the confidence in the quality, efficiency and safety of our company's products is achieved by keeping under control and improving the Integrated Management System, attested by the results of the following inspections / audits in the period 01-12.2018.

#### Inspected conducted by authorities

In the period 13-14.02.2018 the National Agency for Medicines and Medical Devices conducted the inspection for evaluating the GMP compliance of the Quality Management System of Antibiotice S.A. and manufacturing flows for ointments and ophthalmic ointments. Our company obtained the GMP certificate for the above-mentioned manufacturing flows and the updated Manufacturing Authorization.

#### Audits conducted by the certifying bodies

In the period 29-30.09.2018 SRAC conducted the surveillance audit for aluminum tubes, polyethylene caps and metal caps manufactured by the Microproduction Plant.

In the period 12-15.11.2018, Lloyd's Register Quality Assurance conducted the ISO surveillance audit in accordance with ISO 9001:2015 and ISO 14001:2015 (new standards) and in accordance with OHSAS 18001:2007. The audit report was transmitted without critical nonconformities.

#### Audits conducted by customers

During 2017 there were audits carried out by specialized firms or external clients for qualifying Antibiotice as a finished product supplier - an audit for parenteral products and 2 audits for the manufacturing flow of Nystatin - active substance, for requalifying the company as an API supplier.

A pre-audit was also conducted before the audit of the Agency from Russia for certifying the manufacturing flow of suppositories to support the reauthorization of products in Russia. The audit was completed without critical nonconformities and the CAPA Plan was submitted.

#### Audits conducted by our specialists to suppliers of raw materials/ primary packaging materials / finished products

In accordance with the annual Audit Plan 2018, 5 external audit missions were conducted to the producers of raw materials and primary packaging materials from Germany, Spain, France and Italy (suppliers of primary packaging - foils, non-sterile active substances, suppliers of glass vials).

Also, within the Audit Campaign in India, missions to verify the compliance of Quality Management Systems with the EU GMP requirements were conducted in 9 companies, to



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determine whether these companies can be our suppliers of various active substances necessary for the manufacturing process.

Auditing the suppliers of active substances, primary packaging materials, finished products manufactured under contract is a mandatory requirement at European level for marketing authorization holders of pharmaceuticals. The current legislation obliges all the Marketing Authorization Holders to periodically verify ( a period not exceeding 3 years) the compliance of manufacturers / distributors of active substances with the EU GMP requirements.

### Labour health and safety

At the end of 2018, LRQA monitored the compliance of the Occupational Health & Safety Management System with the International Standard 18001, integrated with Quality and Environmental Management Systems.

In order to reduce professional risks and to continuously improve the labour conditions, the implementation of measures went on for:

- reducing the physical effort by completing the endowments within the Biosynthesis Plant with electrical equipment for transport and lifting the raw materials and finished products;
- reducing the exposure to chemical agents by ensuring the storage of chemical reagents in the Medical Unit's laboratories in reagent cabinets with vapor filtration system and purchasing a chemical niche for granulometric determinations.

In order to help our staff become aware of our current concerns in the field of health and safety at work:

- we promote a healthy and safety work from the very beginning of the professional life;
- we take measures for preventing the health problems during professional life.

Maintaining and developing an effective Occupational Health and Safety Management System is the guarantee for:

- creating a unique and coherent framework to eliminate the dangers and risks related to work;
- a more effective control of risk factors for injury and / or occupational disease;
- improving the work environment and interpersonal relationships at the workplace;
- higher performances obtained by our employees;
- helping our staff become aware about the **value** our company gives to its human capital.

### Responsibility for environment

Our company' s activity in the field of environmental protection is regulated by the Integrated Environmental Authorization no. 1 / 10.01.2011 issued by the Regional Environmental Protection Agency Bacau, revised on 03.2018 (valid until 10.01.2021) and by the Water Management Permit no. 303 / 20.12.2010 issued by the National

## MANAGEMENT REPORT 2018

Administration of Romanian Waters, the Prut-Barlada Water Basin Administration (valid until 31.12.2020).

In order to comply with the environmental protection legislation, Antibiotice ensured the specific endowments and qualified personnel. The whole activity is regulated by specific procedures of the environmental management system as well as by operating procedures and working instructions.

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

### **Specific consumptions and energy use**

The activity of the Biosynthesis Plant which produces Nystatin, active substance is covered by the European Integrated Pollution Prevention and Control (IPPC) Directive. In 2018, the Biosynthesis Plant fell within the planned specific consumptions, with respect to the quantities of used solvents, the legal condition for fugitive solvents emissions being observed (less than 15% of the amount of solvents used during the year).

### **Air quality**

In 2018, air pollutant emissions/immisions analyzes were conducted by our own laboratory for the indicators: nitrogen oxides, ammonia, suspended particulates and sedimentable powders for air quality monitoring. There were no exceedances of the maximum admissible concentrations stipulated in the Integrated Environmental Authorization. Also, the determinations made by third laboratories showed that the values of the pollutants emitted in the air complied with the legal requirements established by the Integrated Environmental Authorization obtained by Antibiotice SA.

### **Water quality**

Water quality monitoring required analyzes on the quality of the water entering our own water treatment plant and discharged into the municipal sewage system, conventionally clean water discharged into the natural emissary as well as underground water. No exceedances of the maximum admissible concentrations established by the Integrated Environmental Authorization, Water Management Permit, and by NTPA 001 and NTPA 002 - 2005 were recorded.

### **Soil and groundwater protection**

Out of the total area of the land owned by Antibiotice, about 40% is covered by green spaces.

The quality of groundwater was monitored by monthly analyses of samples obtained from the perimeter drilling and drilling downstream of the landfill site. There was no accidental pollution or environmental incident leading to degradation of soil quality in the area of influence of the company's activity.

### **Waste management**

Antibiotice SA implemented a selective waste collection system, each manufacturing plant and auxiliary workplace being equipped with suitable containers for collection.

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Recyclable waste was sold to authorized economic operators on the basis of contracts. Unusable waste was incinerated in our own facility or stored at the municipal waste disposal site.

Our company complies with the packaging waste management requirements (corresponding to the quantity of products that the company introduced in the Romanian market). The overall objective set for 2018, as well as the minimum objectives of recovery by recycling, by each type of material, (according to Law No. 249/ 2015, with subsequent amendments and completions) were achieved.

### **Antibiotice - a responsible brand that supports community development**

#### *CSR projects implemented in 2018*

Antibiotice takes responsibility for contributing as a "good citizen" to the community life, being directly involved in developing a better society and a cleaner environment.

The Corporate Responsibility Strategy fundamentally supports our company's mission and vision. We produce medicinal products with science but we also put our hearts in what we do to stay always close to people.

We underline our mission to act in a sustainable way and we are committed to creating a long-term value for our company and our stakeholders, respecting the environment and supporting the communities in which we operate.

We are involved in the community's life through social responsibility programs based on four strategic pillars: health, education, social and environmental protection.

#### **Health**

*We develop social responsibility programs to improve the health of our employees, but also the health of the community in which we operate. These programs have been developed to educate and inform the population about health prevention.*

#### **Antibiotics of the 3<sup>rd</sup> Millennium**

Antibiotice launched on November 9, 2018 the social responsibility program *Antibiotics of the 3<sup>rd</sup> Millennium* by bringing together international and local experts as well as professionals who consistently advocate the judicious use of antibiotics in human and veterinary medicine. The event took place in the week ahead of the World Health Organization's World Antibiotic Awareness Week. The debate brought together different perspectives on antibiotic use and resistance, a theme with a wide social addressability.

Antimicrobial resistance is a priority for many European countries, but also worldwide, being considered a threat to public health. Antibiotice's involvement in limiting the antibiotic resistance phenomenon is a responsible approach, natural to a pharmaceutical

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producer in a continuous international development, because this is a global crisis that can not be ignored.

The Antibiotics of the 3<sup>rd</sup> Millennium program aims at drawing attention to the phenomenon, supporting the development and dissemination of good practices in the use of antibiotics, addressing a community of patients and general public, doctors, nurses, pharmacists, manufacturers, environmental experts, academic and entrepreneurial representatives.

**” Donate blood! Put your soul to life! ”**

The acute blood crisis in the Romanian hospitals determined our company's employees to involve, starting with 2010, in the blood donation campaigns initiated by the Antibiotice - "Science and Soul" Foundation, in partnership with the Regional Blood Transfusion Center (CRTS) Iasi.

On the occasion of the World Health Day, 60 employees donated 30 liters of blood to save more than 150 lives. The second round of the campaign took place on October 11, 2018, when 50 Antibiotice employees donated 25 liters of blood, saving 130 lives.

### Education

*We invest, with science and soul, in the education of young people who, like our employees, can be highly performant in their career and become responsible behavior models. We recognize the role the local community and we support it in forming and developing the company's main source of value - well-trained people.*

#### **100 Antibiotice employees were trained to provide the first aid**

Antibiotice SA is constantly preoccupied with the safety of its employees and organized first aid courses for its employees on the occasion of the World Heart Day.

In the period 16-17.10.2018, 100 Antibiotice employees participated in first aid courses organized by the company in partnership with UPU-SMURD Iasi and Emergency Medicine specialists from the Grigore T. Popa University of Medicine and Pharmacy Iasi. The project titled "Everyone Can Save a Life!" aimed at promoting basic first-aid measures among the company's employees but also raising their awareness in emergency situations to support their peers.

The course was supported by doctors from SMURD Iasi and consisted in the theoretical and practical presentation of first aid notions. All employees of the company were provided with flyers containing important first aid information.

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### **Antibiotice employees support 70 pupils with a high risk of school dropout**

For the second consecutive year our company's employees supported the programme "Home in the community - after school at Valea Lupului School".

The After School Program includes orphaned children, children in grandparents' care, or children with sick parents but talented and intelligent who benefit from personal development programs with a psychologist and the support of volunteer teachers.

On May 30, 2018, in the company's festive hall, our employees attended a charity theater show "Poem in clay" put into the stage by the Cantalup theater troupe from the Valea Lupului School.

The amount collected from the employees' donations was doubled by the Antibiotice's "Science and Soul" Foundation. So, 12,000 LEI were donated for this project supporting 70 students enrolled in this program in order not to drop out of school.

After a year of running this program, the learning results of the children included in the project improved significantly, and that's why we decided to extend this project.

### **Environment**

*Antibiotice develops a sustainable partnership with the community by carrying out activities meant to protect the environment, being permanently concerned with the improvement of its environmental performance.*

### **"Orchard at school" gets roots in three schools from the Iași County**

In the second year of the "Orchard at school" project, the Antibiotice volunteers together with their families planted in two stages, 300 fruit trees at schools in the neighboring localities.

The first stage of planting took place on April 21, 2018. 70 volunteers got involved and planted 200 fruit trees at the schools in Letcani and Cogeasca localities.

The second stage of planting took place on November 3, 2018 when over 50 volunteers from Antibiotice got involved in this project run by the "Science and Soul" Foundation. They planted 100 fruit trees at the school from the Rediu locality.

The management of the Gymnasium School Rediu decided that in the centennial year, the 100 trees planted to be named after 100 heroes of the First World War. The trees will be cared for by the pupils until the end of the gymnasium studies and then handed over to the future generations.

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The "Orchard at school" project is run by the "Science and Soul" Foundation through which the Antibiotice employees voluntarily engage and try to inspire the younger generation for protecting the environment, maintaining a healthy lifestyle and cultivating the civic spirit in the community.

Through the power of the example offered by Antibiotice employees, this project grew and got roots in eight schools in Iasi County contributing to the health and a better life of the community.

### **Antibiotice supports Earth Hour**

Our company participated in the Earth Hour action, the largest environmental event of all times, which draws attention to the effects of global warming. On March 24, 2018, between 20:30 and 21:30 our company symbolically switched off the lights in areas where this was possible (e.g. the administrative buildings) in the tenth consecutive participation of the company in this action.

Such actions are meant to demonstrate the importance of rational consumption of natural resources and our commitment to protecting the environment both to our employees and the communities in which we operate.

### **Doors Open Day at Antibiotice**

Antibiotice uses the resources responsibly, meets the highest quality standards for manufacturing medicines and protecting the environment.

Responsibility for the environment is a constant concern of our company and, in this respect, it opened its doors to facilitate a dialogue between the company and the communities in its neighborhood on environmental issues.

On July, 2018, in collaboration with the Valea Lupului City Hall, Antibiotice organized the Doors Open Day for the inhabitants of this community.

The company's specialists presented to all the participants how Antibiotice protects the environment. They had the opportunity to learn about the investments of more than 5 million EUR made in the recent years in modern manufacturing technologies to protect the environment:

- Antibiotice's **Wastewater Treatment Plant** that transforms technologically wastewater from production areas into pre-cleaned, odorless and non-environmentally harmful water that is then transported to the city's wastewater treatment plant;
- **Waste incineration plant** - storage, recycling and incineration in conditions of minimal impact of waste resulting from the company's activity on the environment.

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Through such actions, Antibiotice aims to convey to the community, through the power of example, responsibility for the environment.

### Social matters

*Antibiotice, through the "Science and Soul" Foundation engages itself in the community life by supporting disadvantaged groups through social programs, some of which have become traditional.*

#### **„Be generous, Be Santa Claus!”**

For the sixth consecutive year, the "Science and Soul" Foundation organized „Be generous, Be Santa Claus!” campaign in partnership with Pro Vita Department of the Iasi Archdiocese Mission District.

In the centennial year, the campaign was organized a number of 100 children from families with reduced material opportunities in rural areas from Iași and Botoșani Counties.

The toddlers aged between 1 and 13 lay their dreams in enthusiastic letters. Their emotional, lewd or elaborate, precise or idealistic ranges animated this year also our colleagues who became Santa Claus's elves.

On December 14, 2018 Santa Claus rushed to appear at a festivity organized in our company. The kids enjoyed meeting him, many of them for the first time. As a sign of thanks, the little ones played short artistic moments, singing Christmas carols.

Within the legal deadline imposed by the Order of the Minister of Public Finance 1938/2016, Antibiotice SA undertakes to elaborate - within 6 months of the publication of this document - the Non-Financial Report for 2018. It will be made available to the public on the company's website.

#### **Conclusions:**

- a 8% increase in the sales revenue compared to 2017
- a 6% increase in the international sales compared to 2017
- a 2% increase in the net profit compared to 2017

**VicePresident of Management Board**  
**Ioan Nani**

**Financial Director,**  
**Paula - Luminita Coman**

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