

**S.C. ANTIBIOTICE S.A. IASI**  
**THE MANAGEMENT BOARD**  
**THE AUDIT COMMITTEE**  
**No. 1/14052018**

**REPORT**

**On the annual assessment of the effectiveness of internal audit and internal control reports  
and of the risk management system**

Under the provisions of the capital market legislation, the Audit Committee established within the Management Board of Antibiotice S.A. Iasi, proceeded to prepare a report on the annual evaluation of the effectiveness of internal audit and internal control reports and of the risk management system. In 2017, the Audit Committee had the following composition:

- Stoian Nicolae
- Calitoiu Elena
- Iavor Ionut Sebastian

The Audit Committee has been operating in accordance with the provisions of the capital market legislation and regulations and the following aspects were analyzed:

- a) the monitoring of the effectiveness of the internal audit and risk management systems;
- b) the monitoring of the statutory audit, the verification and monitoring of the independence of the external financial auditor.
- c) the monitoring of the financial reporting process;

Following the analysis and audits carried out, the Audit Committee noted the following:

**The internal audit**

The Internal Audit's Office has been operating in accordance with:

- the multi-annual strategic internal audit plan approved by the Management Board;
- the annual internal audit plan endorsed by the Audit Committee and approved by the Management Board in November 2016, which provided the audit missions to be carried out during 2017;
- the Law 672/2002 republished, regarding the public internal audit;
- the G.O. no.1086/11.12.2013 for the approval of the General Norms regarding the exercise of the public internal audit activity;

- the own methodological norms approved by the Management Board of Antibiotice S.A. Iasi.

The **internal audit missions** carried out in 2017, according to the Internal Audit Plan, were as follows:

1. The assessment of the Capsule Plant activity within the Technical and Production Unit;
2. The evaluation of the activity of the Technical and Production Department, within the Technical and Production Unit;
3. the evaluation of the activity of the Investment Office within the Engineering and Investment Unit;
4. the evaluation of the Utility and Micro-production Department activity within the Engineering and Investment Unit;
5. the evaluation of Storage and Internal Transport activity, within the Commercial and Logistics Unit;
6. the evaluation of the Domestic Market Sales activity, within the Marketing, Sales and Domestic Market Unit;
7. the evaluation of the Economic Unit's activity;
8. the evaluation of the Quality Unit's activity;
9. the evaluation of the International Business Unit's activity.

The missions were carried out in accordance with the procedural audit norms, by going through all the stages of an internal audit mission and resulted in internal audit reports that were approved by the General Manager.

All the recommendations were integrated by the structures audited and approved by the General Manager.

The way of implement the recommendations formulated in the internal audit missions is provided in the operational procedure, code: AI-. 021 "Follow-up of Recommendations" by requesting the written communication of the status of implementation of recommendations by the audited structures. Thus, out of the 41 recommendations from the audit reports drawn up during 2017, 35 recommendations had the implementation deadline until 31.12.2017 and we found that they were implemented.

During 2017, within the Internal Audit Office, the staff carrying out the function of financial controller performed **managerial financial control activities** in accordance with the provisions of G.O. 1151/2012, which had the following objectives:

- the verification of the compliance with the legal provisions regarding the accounting activity in the economic and financial operations;
- the verification of the compliance with the legal provisions concerning the execution of the revenue and expenditure budget for the year 2016;
- the verification of the compliance with the legal provisions in substantiating the draft of the company's income and expenditure budget for the year 2017;

- the verification of the legal provisions and the internal regulations regarding the method of performing the annual inventory of the elements of the assets, debts and equity for the year 2016;
- the verification of the observance of the legal provisions and the internal regulations regarding the receipts and payments in RON and currency of any kind, in cash or by transfer;
- the verification of the compliance with the legal provisions and internal regulations regarding the preparation, circulation, keeping and archiving of primary, accounting and technical-operative documents.

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

In order to preserve the objectivity of the auditors, the staff of the office involved in the management inventory and managerial financial control activities was different than the one involved in internal audit missions.

The Internal Audit Office also carried out the activity of inventory and management control alongside the staff with attributions in this respect. During the year 2017 a number of 15 inventory actions were carried out, which included the following management units of the company:

- the central warehouses of the raw materials and consumables of the company;
- places for the consumption of raw materials and consumables where stock management units are organized (manufacturing plants).

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

- the Accounting Law no. 82/1991, republished and updated;
- the Law no. 22/1969 on the employment of managers, the provision of guarantees and the responsibility for the management of assets;
- the Order of the Minister of Public Finance no. 2861/09.10.2009 for the approval of the Norms regarding the organization and performance of the inventory of assets, debts and equity;
- the 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 conformity between the factual and the script entry stocks as a result of the periodical checking throughout the year between the quantitative evidence held at the level of the management and the quantitative value evidence within the Accounting Office.

All these specific forms of internal control (internal audit, financial management control and management control) organized and carried out according to the legal requirements within the Internal Audit Office together with the Risk Management Office carried out by the organizational structure with the same name within the Economic Unit represent forms of **subsequent control**.

The other forms of **internal control** exercised within the company are: the **preventive financial control** exercised by the staff designated by the Internal Decision no. 216/10993P of 07.10.2014 on the organization and exercise of the company's own preventive financial control. The activity of organizing and exercising of the company's own preventive financial control provides:

- organizing its own preventive financial control,
- control procedure,
- visa refusal,
- the quarterly reporting on the activity of its own preventive financial control;

During the year 2017 there was no refusal of the operations subject to the preventive financial control visa.

The Audit Committee noted the existence of procedures for organizing the management of material and monetary values and the analytical and synthetic evidence of the patrimonial elements. The organization of the management of the material and monetary values is in accordance with the Law no. 22/1969, ensuring the coverage of all the patrimonial elements in the synthetic and analytical records of the company.

### **The risk management**

Within SC Antibiotice SA, the risk management is a process that involves the identification of significant risks that can affect the company as a whole or one of its component structures, the assessment, ranking and prioritization thereof, as well as the establishment of measures to reduce the exposure in accordance with the limits of tolerance to risk, to provide a reasonable assurance that the objectives and activities are being met.

In the process of risk management, during 2017, the following actions were carried out:

The "Tolerance Limits" were approved to be used in the risk analysis. Thus, after applying the control measures, the residual growths must fall within the following tolerance limits:

- The risks that have the effect of lowering revenue and turnover/increasing of expenditures – in the "Tolerance" area; The risks that impact the image of the company – in the "Tolerance" area.
- The human resources risk – in the "Average tolerance" area.

Within each structure, the risk manager has identified and assessed the significant risks associated with the company's own objectives and activities and formulated the risk response strategy and completed the risk alert form;

On the basis of the risk alert form, at the Risk Management Meeting, the risks identified in each of the structures were analyzed and the management measures were established;

- Each risk manager completed the Risk register, which was approved by the Head of the Unit and sent to the Risk Management Activity;
- On the basis of the Risk Registries received, the General Risk Register was developed;

After the risk assessment and the establishment of the risk response strategy, the monitoring of the

implementation of the management measures at each level was carried out;

- The process continued with the risk review, the stage where it was analyzed whether the risks persisted, whether new risks occurred, the impact and probability emerged, it had been changed, in which case the risk exposure was revised; whether new measures are needed or new deadlines for their implementation are needed; the addressed risks can be closed;

The entire process ended by the completion in the Risk Register of the residual risk, its approval by the Head of the Unit, its submission to the Risk Management Activity the update of the General Risk Register. Following this process:

*13 general risks have been identified* (risks that impact upon the general objectives of the company).

They are grouped under the following categories:

**1. Financial risks:**

- The liquidity risk;
- The currency risk;
- The commercial (non-payment) risk.

**2. Economic risks:**

- Loss of the source of raw materials/finished product;
- Difficulties in achieving the export turnover;
- Decrease of turnover on the domestic market
- Decrease of profit.

**3. Technological risks:**

- Exceeding the planned technical and economic indicators - specific consumption, returns

**4. Image risks:**

The deterioration of the image of the company through the appearance of negative information in the written and on-line media.

**5. Human resources risks:**

The lack of high-performance, higher education and secondary education candidates on the labor market.

The impossibility of achieving professional development and the correlation of wages,

according to the hierarchy of positions.

## 6. Legislative risks:

The identification of critical deficiencies during audits performed by the national, European audits or audits performed by the company's authorities on the beneficiaries of contracts,

- The delayed enforcement for protection/ sanctioning of the protected infringed right.

Prior to applying of control measures, 9 inherent risks are found in the "Average Tolerance" area and 4 in the "Intolerable" area.

After applying the control measures 8 residual risks are found in the "Tolerance" area, 4 in the "Average tolerance" area and one in the "Intolerable" area.

The risks left unresolved after applying control measures:

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

*The fluctuations in the exchange rate* are reflected both in the costs of the imported raw materials and in the prices for the export of the finished products. During 2017 there were periods when higher volatility periods were recorded, with depreciation intervals of the leu against the background of domestic and international events.

Since the beginning of the year, the national currency has depreciated by 2.56% against the EUR and has appreciated by 9.9% against the USD, which since August dropped below the RON 4 threshold.

In 2017, the exchange rate earnings amounted to RON 4.787.767, while the expenditures amounted to RON 8.047.855. The general impact of the exchange rate differences generates a loss of RON 3.261.088.

The difficulties encountered in solving the risk: the chains have their own product portfolios, which have priority on recommendation; increasing the demand for genuine cardio products, given the low price difference compared to the generic product; the stock discontinuity products manufactured in cooperation; additional commercial offers to short BBD stocks; the awareness campaign of the use of antibiotics, intensively applied at hospital level, leads to prescription discounts on some products in the portfolio; the provision of anti-TB drugs, especially for the treatment of TB MDR from external sources, whose quantities, assortments, values, delivery times are difficult to estimate even by TB Program Coordinators; the competitors' bids require sales below the minimum profitability level set at the company level; the National Auction requires sales at priced lower than expected, given that there is no possibility of immediate purchase price cuts; the increasing of price differences for the sale of antibiotics at the National Auction above those provided, with the need to carefully monitor the overall budget and decrease of other budget items.

In order to diminish/control the risk, a series of actions were taken:

- The updating of quality agreements for contract manufacturing with the inclusion of

mutually agreed legal requirements;

- The elaboration and updating of specific documentation related to contract manufacturing;
- The contracts are maintained within the pre-established validity term;
- To comply with the audit plan, a system procedure was implemented;
- The compliance certificates have been issued for all the finished product batches manufactured under contract;
- Any batches manufactured in a non-EU country must be tested at in our company, so ATB issues certificates of analysis.

***On each unit, the situation is as follows:***

#### **The Marketing and Domestic Market Sales Unit**

44 risks were identified, of which 36.36% are found in the “Tolerance” area, 43.18% in the “Average Tolerance” area, 20.45% are in the “Intolerable” area.

After applying the control measures, 61.36% of the residual risks are found in the “Tolerance” area, 34.09% in the area “Average tolerance” area and 4.55% in the “Intolerable” area.

#### **The Engineering and Investment Unit**

41 risks have been identified: 65.85% are found in the “Tolerance” area, 31.70% are found in the “Average Tolerance” area and 2.44% in the “Intolerable” area.

After applying the control measures, 92.68% of residual risks are found in the “Tolerance” area and 7.32% in the “Average Tolerance” area.

#### **The Technical and Production Unit**

39 risks were identified: 61.53% in the “Tolerance” area, 35.90% in the “Average tolerance” area and 2.56% in the “Intolerable” area.

After applying the control measures, 92.31% of the residual risks are found in the “Tolerance” area and 7.69% in the “Average Tolerance” area.

#### **The Medical Unit**

22 risks were identified out of which: 59.09% in the “Tolerance” area and 40.91% in the “Average Tolerance” area.

After the application of the control measures, 90.48% of the residual risks are found in the “Tolerance” area and 9.52% in the “Average Tolerance” area.

### **The Quality Unit**

8 risks were identified out of which: 75% in the “Average Tolerance” area, 25% in the “Intolerable” area.

After the application of the control measures 50% the residual risks are found in the “Tolerance” area and 50% in the “Average Tolerance” area.

### **The Human Resources Management Unit**

8 risks were identified of which: 12.5% are in the “Tolerance” area, 62.50% in the “Average Tolerance” area and 25% in the “Intolerable” area.

After the application of the control measures 62.5% of the residual risks are found in the “Tolerance” area and 37.5% in the “Average tolerance” area.

### **The Economic Unit**

23 risks were identified, of which 69.56% are in the “Tolerance” area, 26.09% in the “Average Tolerance” area and 4.35% in the “Intolerable” area.

After applying the control measures, out of the 23 risks 22 are found in the “Tolerance” area and one in the “Intolerable” area.

### **The Logistics and Acquisition Unit**

19 risks were identified: 36.85% in the “Tolerance” area, 63.15% in the “Average Tolerance” area.

After applying the control measures, 84.21% of the residual risks are found in the “Tolerance” area and 15.79% in the “Average Tolerance” area.

### **The International Business Unit**

21 risks were identified, out of which: 33,330% in the “Tolerance” area, 52.38% in the “Average tolerance” area and 14.29% in the “Intolerable” area.

After the application of the control measures, 66,67% of the residual risks are found in the “Tolerance” area and 33,33% in the “Average Tolerance" zone.

### **The General Unit**

17 risks were identified, of which: 58.82% in the “Tolerance area” area, 29.41% in the “Average tolerance” area and 11.76% in the “Intolerable” area.

Three risks were identified within the *Import Office*.

After applying the control measures, a residual rise is found in the “Tolerance” area, 2 are located in



the “Average Tolerance” area. The emergence of these risks is determined by external factors - international pharmaceutical and national legislation, the environmental legislation in certain countries (China) - are beyond the control of ATB.

### **The Legal Department**

After applying the control measures 11 residual risks are found in the “Tolerance” area.

### **The Communication Office**

After applying the control measures 2 residual risks are found in the “Tolerance” area.

During 2017, in the process of risk management, the following actions were carried out:

- meetings were held with the risk managers of each structure;
- the specific, general objectives and the activities carried out to achieve them have been identified;
- the risks to the objectives for the year 2017 have been identified;
- the growth response strategy for each risk was established;
- measures have been proposed to mitigate the effects of risk manifestation;
- the risk registers have been prepared for the risks specific to each structure and for the general risks;
- at the end of the year the risk update and review took place;

The risk management continuously evaluates the risks to which the company's activity is or may be exposed, which may affect the achievement of the objectives. They aim to achieve the predicted indicators under controlled growth conditions, ensuring both the continuity of the activity and the protection of the interests of shareholders and clients.

### **The Financial Reporting**

The Audit Committee analyzed the compliance with the legal provisions and regulations of FSA and BSE regarding the manner of *drafting, reporting and informing the public* about:

- the annual financial statements (31.12.2016),
- the financial statements (first and third quarters of 2017),
- the half-year financial statements (30.06.2017).

The Audit Committees found that the annual, half-yearly and quarterly reporting activity was conducted in accordance with the capital market legislation, with the established methodology and forms and includes all the documents stipulated in the FSA regulations. and the BSE Code.

The financial reports were submitted to the FSA and BSE and were made available to the public in due time. The transmission of documents to the FSA and the BSE and for informing the investors was done both in Romanian and in English.

### **The External Financial Auditor**

- By the Decision no. 1 of June 28<sup>th</sup> 2017, the Ordinary General Meeting of the Shareholders approved a financial audit contract with the Accounting, Expertise and Accounting Consultancy company SOCECC S.R.L Bucuresti for three years.

The economic and financial statements ended on 31.12.2016 were audited by the financial auditor company BDO AUDIT SRL.

The Accounting, Expertise and Accounting Consultancy Company - SOCECC S.R.L Bucuresti has audited the economic and financial situations concluded during the first semester of 2017.

The Accounting, Expertise and Accounting Consultancy Company SOCECC SRL Bucuresti meets the requirements for independence of Antibiotice SA in accordance with the Ethics Code of Accounting Professionals issued by the Council for International Ethics Standards for Accountants, in accordance with the ethical requirements relevant to the audit of financial statements in Romania.

In S.C. Antibiotice SA Iasi the accounting records was conducted in accordance with the legal norms in force; the recordings are made upon the basis of supporting documents as the accounting policies are being observed.

The company ensures the evidence and the keeping of all mandatory registers, observing the method of filling-in, storage and archiving thereof.

The Annual Report of the Audit Committee will be submitted to the Management Board of ANTIBIOTICE S.A. for approval and will be published on its website within the period provided by the regulations in force.

**THE AUDIT COMMITTEE,**

**Nicolae STOIAN**

**Elena CALITOIU**

**Ionut IAVOR**