

CURRENT REPORT

According to:

- Law no. 297/2004 republished and CNVM regulations issued for applying this law,
- National Securities Commission Regulation no. 1/2006 on issuers and securities transactions,
- Law no. 31/1990 republished, with all subsequent amendments,

Report date: **28.01.2013**

Name of issuing entity: **Antibiotice SA**

Registered office: Iași, 1 Valea Lupului St., postal code 707410,

<http://www.antibiotice.ro>

E-mail: actionariat@antibiotice.ro

Phone/fax: **0372 065633 / 0232 209633**

Unique Registration Code in the Trade Register Office: **R01973096**

Number in the Trade Register: **J22/285/1991**

Subscribed and paid-up capital: **56,800,710 RON**

Regulated market on which the securities issued are traded: **Bucharest Stock Exchange**

Number of shares: **568,007,100**

The main characteristics of the securities issued by the trading company: **registered shares nominal value: 0.10 RON.**

Significant event to be reported:

Successful US FDA Inspection on Antibiotice premises, a business card for new outlets

In December 2012 and January 2013, three American investigators audited the manufacturing lines of Antibiotice in order to extend the partnerships on the US market.

Thereby, in the period 14 - 22 January 2013, Food & Drug Administration, the American regulatory authority conducted on Antibiotice premises a follow-up inspection, compulsory for the manufacturers delivering medicines on the American market.

The FDA inspection was completed without issuing the form 483, „Inspectional Observation” intended to report any non-compliance, which is the best result of an FDA inspection according to the rules of the American authority.

„Our continuous concern to meet the quality, safety and effectiveness requirements for the medicines produced by our company is reflected in the improvement of the Quality System and keeping it under control. Only through hard work and devotion our professional team could demonstrate the compliance of the Quality System of Antibiotice with the GMP requirements and the US FDA inspection which lasted for 7 working days ended without issuing the Inspectional Observation form no. 483. Starting with 2002 when the FDA approval was received for the pharmaceutical active substance Nystatin, this one is the third inspection out of a total of 4, which ended up with this exceptional result.

The result of the US FDA inspection consolidates our position on the U.S. market for sterile, solid products for injection and for Nystatin. The confidence in a compliant and sound quality system creates the favorable framework for the registration process, meaning the presence of Antibiotice products on very regulated markets and not only”, explained Lavinia Dimitriu - Quality Director.

At the same time, in December, two major distributors of medicines on the American market audited the quality system from the sterile injectable products line with a view to concluding new commercial partnerships with Antibiotice, both audits being finalized in a favourable way.

Currently, Antibiotice delivers on the U.S. market the following products : Ampicillin, sterile powder for injection (4 strengths) and the active substance Nystatin while Nafcillin, powder for solution for injection will be exported starting with the first semester of 2013 (2 strengths).

„The worldwide recognized FDA approval will allow us also to extend our business on other highly regulated markets such as Australia, South America, Canada and South Africa. At the same time, this favourable opinion represents an excellent promoting tool on the emerging markets in Asia, the Middle East ” declared Mihai Stoian, Business Development Director with Antibiotice.

The export of medicines, one of the strategic development directions of Antibiotice, recorded in 2012 a turnover of 20 million USD, four times higher compared to 2007,

when the figure was 5 million USD. For 2013, Antibiotice estimates export sales will be higher by 17% than in the previous year.

Currently, Antibiotice exports finished pharmaceutical products and the active substance Nystatin in 60 countries of the world, through more than 100 partners.

Chief Executive Officer,
Ec. *Ioan NANI*