



Antibiotic

CODE OF GOOD PRACTICES OF ANTIBIOTICE SA

ON THE PROMOTION OF PRESCRIPTION - ONLY MEDICINES
TO AND INTERACTION WITH HEALTHCARE PROFESSIONALS

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CHAPTER I - RECITALS

Taking into consideration that Antibiotice S.A. is a Romanian legal person where the state holds a majority stake, having as its main activity the production and marketing of generic medicines;

Taking into account that, in all the activities related to the medical field, representatives of the pharmaceutical industry believe that high standards need to be defined and met while the ethical criteria are considered as a basis for an appropriate legally and morally behavior in the activities of promoting medicines;

Following the general framework set at the European level through the Directive 2001/83/EC of the European Parliament and of the Council relating to medicinal products for human use, act which recognizes the role of the voluntary control of advertising and promoting the medicinal products by the self-regulatory bodies and appeal to these bodies when complaints arise; Antibiotice S.A. Iași adopts this Code of Good Practice for the promotion of prescription medicines and interactions with healthcare professionals. This Code, together with the Company's Code of Ethics and Internal Regulations, will provide support to ensure a legal and moral framework in which the promoton activities of our company's representatives take place.

The Code defines and implements ethical standards specific for promoting prescription medicines, standards to ensure the correct transmission of information about generic medicines to the healthcare professionals.

The Code does not intend to limit or regulate the provision of medical, scientific or non-promotional factual information nor does it intend to limit or regulate the activities for the general public related to those medicines distributed exclusively without prescription.

This Code reflects the requirements of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, Romanian Association of International Drug Producers (ARPIM) Code, Romanian Association of Generic Drug Manufacturers (APMGR) Code as well as the Council Directive 2001/83/EC, as amended, in connection with the medicines of human use.

At the same time, legislation which established the guidelines for elaborating the current Code includes the following categories of normative acts: laws, emergency ordinances, instructions and any similar document issued by the Parliament of Romania, Government of Romania or by any other competent authority as well as any applicable normative act issued by the competent authorities of the European Union and directly applicable to the activities developed by Antibiotice.

The normative acts taken into consideration, without being limited to them, are the following:

- Law no. 95/2006 on health reform, as republished in the Official Gazette, Part I, no. 372 of 28.04.2006, with all subsequent amendments;
- Order no 194/2015 of the Ministry of Health approving the Norms on evaluation and approval of advertising the medicinal products for human use;

- Decisions, instructions provisions of the National Agency for Medicines and Medical Devices (NAMMD) which regulates promotion activity of prescription medicines;
- Code of Promotion Practices of the European Federation of Pharmaceutical Industries and Associations;
- European Directive 2001/83/EC on medicinal products for human use, amended by the Directive 2004/27/EC and amended by the Directive 2010/84/EC;
- Code of Pharmaceutical Marketing Practices, International Federation of Pharmaceutical Manufacturers Associations, when applicable;
- Code of Interactions with Healthcare Professionals, Pharmaceutical Research and Manufacturers of America.

CHAPTER II - GLOSSARY

Articles of Incorporation – represents the act underlying the establishment of Antibiotice S.A. and regulates the organization, operation and performance of the company's activity.

Authority – means any national, regional or local public authority, agency, council, commission, including any departments or subdivisions thereof, having regulatory and supervisory powers in the pharmaceutical field and, implicitly, jurisdiction over Antibiotice S.A. Iași.

Healthcare Professionals – are the physicians, stomatologists, nurses and pharmaceutical assistants who, in the course of their professional activities, carry out specific activities in collaboration with the Antibiotice employees.

Ethics – represents all the deontological and moral principles for the operation of the health system, which are assumed by Antibiotice S.A. in the relationship with the healthcare professionals, in accordance with the legislation in force.

Incident of ethics – represents any act of violation of deontological and moral principles in the operation of the health system committed by a medical representative or sales representative of Antibiotice S.A.

Medical representative – means a representative, an Antibiotice's employee who contacts the staff in the medical and pharmaceutical field for promoting the medicinal products manufactured by Antibiotice S.A.

Sales representative – means a commercial officer, an Antibiotice's employee having the task of selling, prospecting, informing the current and potential clients about the company's products and services.

Ethics & Integrity Council – represents the forum set up within Antibiotice S.A. in order to guarantee implementing the deontological and moral principles for the operation of the health system.

Ethical case – represents any complaint with ethical character relating to the activity of a medical or sales representative of Antibiotice S.A. which requires an analysis within the Ethics & Integrity Council followed by a decision formulated by this forum;

Decision of the Ethics & Integrity Council – represents the conclusion based on the legal provisions and those of the current Code, formulated by the members of the Council related to an ethical case in the activity of Antibiotice S.A. by which it is established whether the issues raised are or not an ethical issue.

Ethical vulnerability – represents any factor which, by its action or inaction, may cause or encourage the occurrence of an ethical issue.

Medicinal product/ medicine – means any substance or combination of substances presented as having properties for treating or preventing disease in human beings, as well as any substance or combination of substances which can be used for healing, correcting or modifying

physiological functions in human beings by exerting a pharmacological, immunological or metabolic action.

Prescription-Only Medicine – means a medicinal product that legally requires a medical prescription dispensed by a qualified medical practitioner.

Medical prescription – any prescription of medicinal products dispensed by a qualified medical practitioner.

Promotion and advertising – means any activity made by Antibiotice S.A. in order to directly or indirectly inform as well as any other form of promotion intended to stimulate the prescription, distribution, sale or consumption of medicinal products.

These forms of promotion include: visits made by medical or sales representatives to the healthcare professionals, printing of promotional materials (brochures, leaflets, posters, invitations), supply of samples, organizing–financing the attendance of the healthcare professionals to scientific events, including the payment of accommodation costs in connection with these events, press releases when new products are launched, use of audio-video materials, internet promotion, e-mails, newsletters, forums, blogs and any other electronic media, promotional gifts as well as any other promotional activities.

Summary of product characteristics (SPC) – means the summary of characteristics of a medicinal product as provided by the laws in force.

Sample – means a medicinal product supplied free of charge by Antibiotice S.A. to the healthcare staff to let them get acquainted with that product and gain experience with it.

Reasonable – this term can refer to the specific interactions among the medical or sales representatives and the healthcare professionals, meaning that all these interactions must be within the legal limits, without exaggerations; or it can refer to the values of the contracts used by the medical or sales representatives of Antibiotice S.A. meaning that these must be directly proportional to the services covered by the contract.

CHAPTER III – SCOPE OF THE CODE

Art.1 The current Code regulates the promotion of prescription medicines made by the Antibiotice representatives as well as their interactions with the health professionals.

Art.2 The current Code neither intends to limit or regulate the provision of medical, scientific information nor does it intend to limit or regulate the activities to the general public that are related to those medicines distributed exclusively without prescription.

Art.3 The scope of this Code covers the promotion and advertising activities carried out by the Antibiotice employees, medical or sales representatives regarding the prescription-only medicines for human use and which have been officially licensed for marketing on and off the territory of Romania.

Art.4 This Code also regulates the minimum ethical standards which will be met in the interactions between Antibiotice representatives and the healthcare staff.

Art.5 In addition to complying with the provisions of the current Code, Antibiotice representatives must comply with the applicable laws and if any conflict occurs between the provisions of this Code and those of the applicable law, the most restrictive from the provisions in conflict will be applied.

Art.6 The Code covers all methods of promotion used in the interactions with the healthcare professionals and medical institutions, with the exceptions below:

- summaries of product characteristics as provided in the relevant legislation, labeling of medicines and leaflets of the medicinal products, insofar as they are not promotional;
- correspondence, possibly accompanied by non-promotional materials, in response to individual questions from health professionals, decision-makers or in response to their specific communications, questions or comments, including letters published in specialty magazines but only if they refer to the subject of the letter or to the question and are not promotional;
- announcements and factual, accurate, informative reference materials with regard to the authorized medicinal products and which relate, for example, to changes in packaging, warnings about the side effects as part of the general precautions, commercial catalogues and price lists provided that they do not include promotional statements about the product;
- non-promotional information related to health or illness status, provided there are no direct or indirect references to specific medicinal products;
- activities related to medicinal products dispensed without medical prescription;
- general, non-promotional information about the company (such as information for investors or current/potential employees) including financial data, description of the research & development programs and discussions on the regulations concerning the company and its products.

CHAPTER IV – GENERAL PRINCIPLES OF THE CODE

Art.7 The Code of Good Practices sets out certain principles and rules that must be met by all the Antibiotice representatives. No exception to these principles and rules is allowed, unless they are expressly provided for in the Code.

Art.8 When a medical representative, a sales representative or any other Antibiotice employee receives as a task carrying out promotional activities, the regulations of the current Code will be met whenever a specific contract is concluded with a health professional.

Art.9 A medicinal product must not be promoted prior to the grant of the marketing authorization, allowing its sale and distribution. Promotion must be in accordance with the provisions stipulated in the summary of characteristics of the approved medicinal product and must comply with the terms of the marketing authorization issued by National Agency for Medicines and Medical Devices or modified through the Decision of the European Commission.

Art.10 Under no circumstances it is allowed to offer, promise or give to healthcare professionals any remuneration, including gifts, pecuniary benefits, benefits in kind, in return for prescribing, dispensing, selling or administering a medicine. Remunerations for medical or pharmaceutical professionals will only be granted for genuine, grounded and necessary services.

Art.11 Subject to the provisions of the article 814 of Law no. 95/2006 on health reform, Antibiotice has the obligation to declare to the Ministry of Health and National Agency for Medicines and Medical Devices all the sponsorship activities as well as any other expenses incurred for the healthcare professionals.

Art.12 Promotion practices aims at bringing a benefit for patients and healthcare system.

Art.13 Information provided to the healthcare professionals in the promotion activities must be accurate, ethical, trustworthy from medical viewpoint and based on the summary of product characteristics (SPCs) as confirmed by the competent authorities.

Art.14 Antibiotice representatives must permanently maintain high ethical standards in the promotion activities. These activities must not lead to discrediting the pharmaceutical industry or offend the competitors in the pharmaceutical market.

Art.15 Within the specific tasks, Antibiotice representatives must comply with the provisions of the current Code, taking also into account the provisions of the company's Internal Regulation and Code of Ethics.

CHAPTER V - RULES IN PROMOTION ACTIVITY

SECTION I – INTERNAL REQUIREMENTS

Art.16 Medical Unit ensures the appropriate recording of the materials used in the promotion activities according to the applicable laws.

Art.17 Marketing Unit makes sure that the Antibiotice staff involved in the promotion activities, as well as the representatives of the companies contracted for promotion activities are trained and familiar with the applicable laws and with the provisions of the Current Code on activities for promoting medicines.

SECTION I – MAKING THE PROMOTION

Art.18 Promotion of prescription-only medicines, made by the Antibiotice representatives must be directed only to the healthcare professionals.

Art.19 The medical and sales representatives of Antibiotice S.A. are not allowed to display promotional materials in places accessible to the general public such as pharmacies, waiting rooms, hospital halls and medical clinics.

Art.20 If the medical and sales representatives of Antibiotice S.A. are to carry out operations involving the processing of personal data belonging to the medical and pharmaceutical staff they will get agreement of the healthcare staff in this respect.

Art.21 Using the fax, e-mail, text messages and any other means of electronic communications is not allowed unless the healthcare staff has previously granted their permission.

SECTION II - PROMOTIONAL INFORMATION

Art.22 According to the applicable laws, the promotion activity focused on the medical and pharmaceutical staff, qualified to prescribe and provide medicinal products will include, without being limited to these, the following information:

- essential information compatible with the leaflet of the medicine such as name of the medicine, pharmaceutical form, dosage and route of administration, warnings and special precautions, drug interactions, side effects, name and address of the marketing authorization holder and other essential information.
- classification of medicinal product according to the type of prescription.
- date of the last revision of the reference material.

Art.23 Where appropriate, information can include the sales price or the informative price of different medicines and the reimbursement conditions granted by the social health insurance bodies.

Art.24 Promotion information must be accurate, updated, objective, verifiable and sufficiently complete to allow medical staff to form their own opinion on the therapeutic quality of that medicinal product.

Art.25 Promotion must encourage the rational use of medicines, presenting them objectively and without exaggerating their properties. Promotion messages should not imply that one medicine has a certain merit, value or property unless they can be substantiated with truthful medical records.

Art.26 The words "safe" or "risk-free" and other similar phrases should not be used for describing a medicine without a proper justification. Also, it is not to be supposed that a medicine has not adverse effects.

Art.27 Any comparisons among different medicines must be based on relevant and comparable aspects. Comparative promotion is allowed only if it is fully supported by clinical study data. Data sources must be clearly identified and available to be accessed on request.

SECTION IV – PROMOTION ON THE INTERNET

Art.28 Taking into account that the promotion on the internet could be accessed by the general public, promotion addressed to the healthcare professionals through the internet is permitted provided that the requirements established in the applicable laws and the current Code are met.

Art.29 Promotion via internet of the prescription-only medicines must be restricted only to the access of the healthcare professionals through a valid and verifiable system, accessed with the user name and password.

Art.30 The promotion website must include the identity and address of Antibiotice S.A., information sources and specific target audience. The content of the promotion site must be updated if the marketing authorization undergoes changes.

Art.31 Web pages may also contain non-promotional information related to the health education, characteristics of diseases, prevention, screening and treatment methods as well as other information meant to promote the public health. These may refer to medicinal therapeutic options, they can offer relevant information about therapeutic alternatives including, if necessary, surgery, behavioral change and other interventions that do not require use of medicines.

Art.32 The web pages containing health education information must always recommend to visitors to consult a medical or pharmaceutical professional for more information.

Art.33 Any information of promotional nature (according to the definition from the Code) on the websites addressed to the healthcare professionals must comply with the regulations in force regarding the advertising content and format and promotion procedure of medicinal products. This type of information must be clearly identified as information for the healthcare professionals and should not be accessible to the general public.

Art.34 The website may suggest to the healthcare professionals, patients and the large public to send e-mail messages asking for further information on the company's products or other issues. The company may respond to such messages in the same way they would respond to inquiries received by mail, telephone or other media.

Art.35 In communicating with the patients or large public, discussing personal medical issues must be avoided. If personal medical information is disclosed, it should be kept confidential.

Art.36 Where applicable, the answers must recommend consulting a healthcare professional for more information.

Art.37 Links to a website sponsored by other company can be created but links from web-pages intended for the general public must not be created towards web pages sponsored by the company which are intended for the healthcare professionals.

Art.38 The links must lead to the initial page (home) of the webpage or they have to be treated in such a way that the reader to be aware of the identity of the webpage sponsor.

Art.39 In accordance with the applicable laws and regulations, addresses of web pages sponsored by the company meeting the current recommendations can be written on the packaging of the medicinal products.

Art.40 Antibiotice S.A. will ensure the compliance between the information which will be included on the promotion website and the regulations of the current Code.

Art.41 The provisions of this Code do not apply to the presentation site of Antibiotice S.A.

SECTION V - TRANSPARENCY REQUIREMENTS

Art.42 Promotion of medicines should not be masked. All the promotional and advertising materials must clearly indicate their advertising nature. Any material with regard to medicinal products and their uses, if it is a promotional one must clearly indicate that it is sponsored by Antibiotice S.A. The only exception is represented by the materials from market research. In this case, it is not necessary as the name of the company to be disclosed, in order to avoid influencing the respondents.

CHAPTER VI - COMPANY'S REPRESENTATIVES

Art.43 Medical and sales representatives of Antibiotice S.A. will study and retain the relevant principles of the Code of Good Practices, gaining also sufficient scientific knowledge in order to be able to supply accurate and complete information on the medicinal products they promote.

Art.44 The general principles governing the activity of Antibiotice representatives are as follows:

- the company's representatives must meet all the requirements of the internal Code of Good Practices and all the Romanian relevant laws and regulations;
- the company's representatives must fulfil their professional duties in a responsible and ethical manner;
- the company's representatives must immediately send to the Pharmacovigilance Department any information in connection with the use of medicines, their use during pregnancy, reports on adverse reactions or reports on quality deficiencies of the medicinal products manufactured by Antibiotice S.A., using standardized forms recommended by the National Agency for Medicines and Medical Devices;
- the company's representatives will act in accordance with the provisions of the annual marketing plan without causing inconveniences to the medical or pharmaceutical staff;
- the company's representatives must not use unprincipled means to get a meeting. No fee can be paid for a meeting. During a meeting or when requesting an appointment for a meeting, the company's representatives must take all the reasonable measures to make sure they do not mislead the healthcare professionals with respect to their identity or to the company they represent.

Art.45 Antibiotice S.A. will implement a training program for all the employees involved in promotion activities both when they are hired and whenever significant changes in the Romanian and European regulations take place.

CHAPTER VII - RELATIONS WITH THE HEALTHCARE PROFESSIONALS

SECTION I - EVENTS AND HOSPITALITY

Art.46 Subject to meeting the relevant requirements of the applicable laws and this Code, Antibiotice S.A. has the right to sponsor or finance various events with the aim of supporting development and professional knowledge of the healthcare professionals.

Art.47 Certain basic principles about organizing the events will be observed:

- the main purpose of any event must be of a scientific or educational nature;
- hospitality associated with the scientific or educational events must be limited to the main objective of the meeting, it must not damage the image of Antibiotice S.A. and be disproportionate to what the healthcare specialists want and can pay. Thus, the professional content of an event should represent most of the duration of the event compared to the time of hospitality and entertainment;

- hospitality granted to the healthcare professionals will be at a reasonable level and strictly limited to the duration of the event;

- hospitality granted in connection with the events will be limited to travel, meals, travel medical insurance, accommodation and registration fees. Hospitality will not be extended to husband/wife, relatives up to grade IV included or any other accompanying persons, unless that person is a member of the medical staff and qualifies himself/ herself with full rights as a delegate or participant in the event;

- the venue of the events must serve the main purpose of the event, so the tourism, sports or entertainment only places will be avoided;

- the events outside Romania must not be organized unless they are appropriate and necessary from logistical or security reasons (for example: a visit to a manufacturing plant/research center abroad, etc.)

- 3-star and 4-star hotels for accommodation or as a venue of the scientific events are recommended.

Art.48 Maximum limits to be met for the hospitality related to the events organized, sponsored or financed by Antibiotice S.A. are the following:

- air travel (internal or external): economic class, business class is not allowed;

- hotel accommodation (România): up to the equivalent in LEI of EUR 150 per night (VAT and breakfast included);

- meals: up to LEI 150 (VAT and coffee break included) per person/meal for the local events and up to EUR 150 per person/meal for the international events. This limit does not apply to the "gala dinners" organized as a part of the international events;

- Antibiotice representatives have the obligation to conclude a written contract with the person receiving the sponsorship so that the above requirements to be recorded and respected.

SECTION II – SPONSORSHIP CONTRACTS AND GIFTS

Art.49 Sponsorship contracts are agreements concluded according to the law, in compliance with the provisions of the article 814 of the Law no. 95/2006 on health reform, describing the purpose and value of sponsorship.

Art.50 Activities to be covered by sponsorship contracts are, but are not limited to, the following:

- rental of stands during the events;

- acquisition of advertising space;

- payment of participation fees at symposiums and congresses;

- sponsoring the speakers during events;
- costs of meals and lodging provided by the Company for certain scientific events.

Art.51 In order to support the efforts for technical & medical and scientific development, donations and sponsorships to hospitals and clinics from the public medical sector are allowed (private medical institutions excluded) or to NGOs (affiliated to the public health institutions) in the following cases:

- sponsorships and donations with a specific destination (which will be demonstrated by contract) for the renovation and adaptation of clinical spaces;
- this type of support will be unconditional and must be directly related to medical activities and for the direct or indirect benefit of patients.

Art.52 Sponsorships (in cash and in nature) granted by Antibiotice S.A. to public institutions, organizations and associations of healthcare professionals, are allowed if they:

- are meant to support the healthcare or research in the medical field;
- are documented and archived by the sponsor;
- are not an urge to recommend, prescribe, purchase, distribute, sell or administer certain medicinal products;
- are based on an express written request.

Art.53 Sponsorships and donations individually granted to the medical or pharmaceutical professionals are not allowed. They are only granted to the institution, medical office or other form of organization in which the healthcare professional works.

Art.54 Sponsorship contracts concluded by Antibiotice S.A. will prohibit the beneficiary's employees from using the sponsored equipment for personal purposes or for obtaining material benefits. The beneficiary undertakes to use the equipment obtained by sponsorship or donation exclusively for the free-of-charge benefit of patients.

Art.55 Contracts concluded between the Company and the institutions, organizations or associations of the healthcare professionals according to which these bodies provide any kind of services in favor of Antibiotice S.A. are allowed if these services:

- are provided with the aim of supporting the healthcare or research;
- are not an urge to recommend, prescribe, purchase, distribute, sell or administer certain medicinal products;

Art.56 In order to help developing the healthcare professionals and enhancing their knowledge in the therapeutic areas in which they operate, Antibiotice S.A. can sponsor different events but with the obligation of complying with the following conditions:

- the main purpose of the event is of a medical and scientific nature;
- sponsoring a medical event or the participation of a medical or pharmaceutical professional to a medical event is a public information;
- sponsoring the event or the participation of the healthcare professionals to a medical event must not be subject to any obligation to promote, recommend or purchase the Antibiotice products.

Art.57 Free commodity contracts for medical equipment concluded with hospitals, clinics from public medical sector or NGOs (affiliated to public health institutions) are allowed. This type of contracts must be strictly unconditional and must be directly connected with the medical activities. Free commodity contracts will be concluded as a result of a simple request of the applicant and will be archived.

Art.58 Promotional articles, whether they are related to a particular product or have a general purpose can be distributed to the healthcare professionals provided they are inexpensive and relevant for the medical practice. Used as promotional items, general utility objects can include pens, agendas, callendars, office clocks and other similar items, according to the Romanian regulations in force.

Art.59 Cash payments or their equivalent, jewelry, tobacco products or exclusive private use gifts can not be offered as gifts.

Art.60 Offering articles of domestic use and which are not used in the usual practice of medicine or any other health professions is not allowed.

Art.61 Promotional articles can be personalised only with the name and logo of medicinal product, dosage and pharmaceutical form and, if it is necessary, only a mention of the indications to designate the therapeutic category of medicine.

Art.62 Names of medicines from the Antibiotice portfolio cannot be written on the medical robes offered to the medical and pharmaceutical staff.

Art.63 By way of exception, in certain special cases (Easter, Christmas, New Year, National Day etc.), recognized by the applicable laws, gifts can be offered, even if they are not relevant for the medical practice.

Art.64 Healthcare professionals can also receive as a sponsorship, scientific works and other educational materials with a reasonable value. If the real educational purpose is justified, payment of membership fees in the Romanian or international professional associations and fees for accessing specialized publications may also be additionally supported.

Art.65 Antibiotice S.A. has the right to transparently sponsor the healthcare professionals for elaborating and editing professional works. A certain work will mention the granted sponsorship.

Art.66 The company's representatives can also interact in their activity with public servants, including decision makers in the sanitary field.

Art.67 The agreements concluded with the professionals from the sanitary field and decision makers will include mentions related to the obligations of the sanitary professionals and decision makers to comply with all legal provisions on the issues of incompatibility or conflict of interest, if any. Therefore, the agreements will include clauses regarding the status assumed by these professionals proving that they are not in a situation of incompatibility as defined by the applicable legislation and by which they declare and are committed to observe the obligations regarding the interest conflicts stipulated by the laws in force.

Art.68 The contract can also specify that the healthcare professionals/ decision makers guarantee that they will fill out and forward to the unit in which they operate or to any other interested authorities and entities, all the declarations indicated by the applicable legal provisions specifying the mandatory transmission of declarations of interests, declarations of incompatibility, property declarations or any other similar obligations.

SECTION III - CONSULTANCY PROVIDED BY THE HEALTHCARE PROFESSIONALS

Art.69 Antibiotice S.A. can conclude contracts according to the legislation in force, in compliance with the provisions of the article 7991 of the Law no. 95/2006 on health reform with the healthcare professionals for consultancy and related services, such as: lectures, consultation and / or counseling and involvement in medical/ scientific activities and studies, training, participation in market research, both in groups and individually.

Art.70 All formalities covering these consultancy services or other services must meet the following criteria:

- the conclusion of a contract or a written agreement is mandatory prior to the commencement of providing the services. It specifies the nature of the services to be rendered and is the basis for payment of these services;
- a legitimate need for these services was clearly identified before requesting services and concluding agreements with the future consultants;
- selection criteria of the consultants are directly connected with the identified need and the persons responsible for selecting the consultants have the necessary experience to appreciate if the selected healthcare professionals meet these criteria;
- number of the healthcare professionals is not greater than the number reasonably required to meet the identified need;
- Antibiotice S.A. will keep records on the services provided by the consultants and will use them accordingly;
- hiring a healthcare professional to provide the relevant service do not oblige him/her to recommend, prescribe, purchase, distribute, sell or administer a medicinal product;
- compensation for services is reasonable and reflects the fair market value of the provided services.

Art.71 For the provided services, reasonable compensations will be offered to the external consultants, including reimbursement of reasonable travel expenses, meals and accommodation (if applicable).

Art.72 In the written contracts concluded with the consultants, Antibiotice S.A. will include provisions relating to the obligation of the consultant to declare that he/she is a consultant for the company whenever they write or speak in public in relation to a matter which is the subject of the agreement or any other matter relating to the company.

Art.73 If Antibiotice S.A. hires part-time healthcare professionals who continue to practice their profession, the company will require them to publicly affirm their employment agreement with the company whenever they write or speak in public in relation to a matter which is the subject of the current employment or any other matter relating to the company.

Art.74 The company will internally establish the maximum net amounts reasonable for such services that can be paid individually to a healthcare professional in the course of a fiscal year.

Art.75 Starting from the public information with reference to the activities developed by the healthcare professionals within private clinics or pharmacies as well as from the amounts assessed by the ARPIM and APMGR members, the following maximum net hourly fees for the preparation, documentation and presentation of the works elaborated by medical or pharmaceutical staff are recommended as a fair market value:

- 80 €/ hour for the professionals in the following situations: lecturers or moderators of medical events; presidents of medical societies or professional associations at a national level; professors or university lecturers, primary doctors;
- 65 € net/hour for the professionals in the following situations: lecturers at medical events; presidents of medical societies or professional associations at a local level; heads of works (university lecturers); specialist physicians; principal pharmacists;
- 50 € net/ hour for the professionals in the following situations: lecturers at medical events, family doctors, university assistants, pharmacists;
- 12 € net/hour for the professionals in the following situations: lecturers at medical events, other categories of professionals not found in any of the above categories.

Art.76 For other categories of specialists in the sanitary field, such as but not limited to: psychologist, economist in the medical or pharmaceutical field, specialist in medical devices, the above hourly fees can be applied based on their experience and level of training, without exceeding the maximum limits for the work done.

Art.77 Based on the training efforts, duration of the event and experience level, Antibiotice S.A. can internally define the maximum reasonable net limits for such services which can be paid to a healthcare professional during a fiscal year.

Art.78 In order to conclude a service and/or consulting agreement, the following are required:

- a written contract specifying the nature of services to be provided and the basis for payment of these services;
- documentation of the services provided which must be kept by the company's specialized department.

Art.79 Essential elements taken into account when concluding such a contract will be following:

- legitimate need for these services (which was certainly established in advance)
- criteria for selecting the consultants (which must relate to the identified purpose);
- persons responsible for selecting the consultants (who must have the experience needed for evaluating if a certain healthcare professional meet these criteria);
- number of selected healthcare professionals (which must not be greater than the number reasonably required to achieve the identified purpose).

SECTION V – PROMOTION CONTRACTS

Art.80 Promotion contracts are written agreements concluded in accordance with the legislation in force, in compliance with the provisions of article 814 of Law no. 95/2006 on health reform, with healthcare professionals, describing promotional activities and their purpose.

Art.81 The activities which must be covered by promotion contracts are, but are not limited to, the following:

- any actions developed within the established legal limits, aiming at facilitating the access of consumers to medicines and accurate information on the products from the Antibiotice portfolio.

Art.82 Promotion of medicinal products must be correct and accurate, balanced and objective and must not mislead through distortion, exaggeration, omission or otherwise.

Art.83 When promotional activities refer to published studies, clear references to them should be included. All the illustrations in the promotion materials, including charts, pictures, photos and tables must indicate the exact source and to be faithfully reproduced, except the cases when these must be adapted or changed, in which case it should be noted that they were adapted or modified.

Art.84 In their promotion activities, medical and sales representatives of Antibiotice S.A. will not use methods likely to discredit or reduce confidence of the healthcare professionals in the company's products. Also, they will not launch injurious information about the competitors' products.

Art.85 Promotion activity must be transparent.

SECTION V – SERVICE CONTRACTS

Art.86 Service contracts are agreements concluded with the healthcare professionals in compliance with the provisions of the article 814 of the Law no. 95/2006 on health reform, concluded in a written form, describing the services provided by these healthcare professionals in the benefit of Antibiotice S.A. as well as the value of these services.

Art.87 Activities to be covered by service contracts are, but not limited to, the following:

- participation of the healthcare professionals to the events generically called scientific manifestations or round tables, events for which preparation, documentation and presentation activities are performed.

Art.88 Conclusion of the service contracts with healthcare professionals is allowed only if these services are provided with the aim of supporting Antibiotice S.A. in the scientific activities developed in accordance with its object of activity.

Art.89 Service contracts will not be concluded with the healthcare professionals in order to encourage them to recommend, prescribe, purchase, distribute or administer medicines from the Antibiotice portfolio.

SECTION VI – GRANTING SAMPLES

Art.90 Taking into account the national and European legislation, samples can not be given as part of a promotion process. So, according to the EU-Directive 2001/83/EC medical samples cannot be given as inducement to recommend, prescribe, purchase, distribute, sell or administer certain medicinal products.

Art.91 Medical samples are provided to healthcare professionals so that they can get acquainted and acquire experience with the medicines.

Art.92 According to the national laws and regulations, a limited number of medical samples of some new medicinal products can be provided to the healthcare professionals in exceptional cases and for a limited period of time.

Art.93 Pentru produsele tranzacționate în baza unei autorizații de punere pe piață emisă înainte de această dată, nu pot fi acordate mostre. Number of samples granted for each prescription medicine will be limited by internal rules of Antibiotice S.A. to the equivalent of a treatment for 10 patients in the lowest dosage available in the Antibiotice portfolio, according to the applicable legal provisions. For the products traded on the basis of a marketing authorization issued before this date, no samples can be given.

Art.94 Antibiotice S.A. will develop appropriate control and management systems for the samples it distributes and for all medicines given by the medical representatives as samples.

Art.95 Each sample will not be larger than the smallest form of traded presentation and will be printed as "free medical sample - not for sale" or other formulation with the same meaning and will be accompanied by a copy of the summary of product characteristics.

Art.96 Samples can only be given in response to a written request, signed and dated by the applicant. An applicant can be only the physician empowered to prescribe that product. Samples must be handed directly to the healthcare professionals requesting them or to the persons authorized to receive them on their behalf.

Art.97 Delivery of samples is not allowed for the following medicinal products:

- those containing substances defined as narcotic drugs or psychotropic substances, in the meaning of international conventions;
- those for which the delivery of samples is inappropriate, according to the updated periodically regulations of the competent authorities.

SECTION VII – COLLABORATION WITH THE PATIENT ORGANIZATIONS

Art.98 Pharmaceutical industry has mutual interests with the organizations of patients which represent and support the needs of the patients and persons who care them and, on this line, the collaboration of Antibiotice S.A. with the patient organization is inherent and will meet the following ethical standards;

- will ensure the independence of the patient organizations from viewpoint of their political options, strategies and activities;
- all the partnerships between the patient organizations and the Company will be based on mutual respect, opinions and decisions of each partner having equal value;

- Antibiotice will not ask for and the patient organizations will not assume the promotion of a certain prescription medicinal products;
- the objectives and scope of any partnership with this type of entities will be transparent. Financial and non-financial support granted by Antibiotice will always be made known clearly to the general public.

Art.99 The company will conclude a written contract when offering, directly or indirectly, financial or non-financial support to the patient organizations. That act must specify the amount and purpose of the funding.

Art.100 The contracts on services provided by the patient organizations in the favor of the company are allowed only if the services concerned are necessary for supporting the healthcare or research.

Art.101 Contracts concluded with the patient organizations must not suggest in any way recommendation and / or use of a certain medicinal product.

Art.102 Taking into consideration that the patient organizations have limited funds for financing their activities, they can be supported through a general financing (to cover the daily operational costs of the organizations) or a project financing (for a specific project or a series of projects in the company's attention)

Art.103 The contract will stipulate the obligation of the patient organization to make the statements provided by the relevant legislation in force, including the statement of income arising from these interactions with the company.

CHAPTER VIII - COUNCIL OF ETHICS AND INTEGRITY

Art.104 The Ethics & Integrity Council is an advisory forum within Antibiotice S.A., having the mission to guarantee and monitor in which way the company's medical and sales representatives implement the principles and deontological norms specific to promotion activities of the prescription medicines, so as to ensure the correct transmission of the information on medicinal products to the healthcare professionals.

Art.105 The Ethics & Integrity Council is made up of 5 members, appointed by the decision of the General Director of Antibiotice S.A. for a 4-year term. The members of the Council will be chosen from among the medical, economic and legal specialists. Maximum 2 members of the Council can be appointed from among those who have not signed an employment contract with Antibiotice S.A. for a determined / indefinite period.

Art.106 Membership in the Ethics & Integrity Council is incompatible with the following positions within the organizational chart of Antibiotice S.A.: General Director and / or executive director.

Art 107 Members of the Ethics & Integrity Council must specify, prior to their appointment by the decision of the General Director of Antibiotice S.A., the existence of a direct or indirect connection, of a family, professional or financial nature, with the natural or legal persons involved in the cases subject to the analysis of the Council. If a member is in one of these situations, he / she can not participate in the analysis sessions of the respective case, being replaced by an alternate member.

Art 108 The Ethics & Integrity Council is headed by a president elected by secret ballot from among its members. If the President is absent, the present members shall appoint a meeting president by secret ballot.

Art 109 The attributions of the Ethics & Integrity Council are the following:

- solves complaints regarding the incidents of ethics addressed to Antibiotice S.A.
- analyzes the ethical vulnerabilities and proposes to the company's general director measures for preventing the ethical incidents;
- analyzes from ethical viewpoint the Internal Regulations of Antibiotice S.A. as well as the Code of Ethics and Code of Good Practices to promote the prescription-only medicines to and interactions with the healthcare professionals, with the possibility of proposing amendments or completions to these documents;
- formulates proposals for diminishing risks of ethical incidents and submits them to the General Director;
- approves the content of the communications addressed to the complainants in response to their notifications;
- can formulate an ethical advisory viewpoint at the request of General Director or Management Board of Antibiotice S.A.;
- analyzes the cases of breaching the ethical and behavioral rules between medical/sales representative – healthcare professional;
- analyze the notifications of natural or legal entities in connection with the different types of abuses of the medical/sales representatives;
- notifies the competent bodies of the state whenever it considers that issues from an ethical case may be the subject of a infringement and have not been notified by the legal representative of the organization or of the claimant.

Art 110 The Ethics & Integrity Council can request documents and information in connection with the ethical case subject to analysis and may invite to its meetings persons who can help solve it.

Art 111 Attributions/ powers of the President of the Ethics & Integrity Council are the following:

- chairs the Council meetings;
- convokes the Council's members whenever necessary;
- endorses, by signature, the documents issued by the Council as well as the quarterly reports;

Art 112 The Ethics & Integrity Council meets quarterly or whenever necessary at the convocation of the General Director, Management Board or at least three of its members. Meetings are chaired by the President or, in his/her absence, by the person elected by the secret ballot of the present members. The quorum for the meetings is ensured by the presence of at least three of the Council members, including the president of the meeting. Decisions of the Council shall be adopted by simple majority vote.

Art 113 An ethical incident can be notified by any interested natural or legal person. Notification will be addressed to the General Director of the company and will be sent to the Registry Office of Antibiotice S.A. or by filling out the on-line form which can be found on the company website.

Art 114 The following situations, without being limited thereto, may be subject to the notifications on the existence of an incident of ethics:

- Antibiotice representatives promote prescription medicines to people other than medical or pharmaceutical professionals;
- medical or sales representatives of Antibiotice S.A. let promotional materials in places accessible to the general public such as pharmacies, waiting rooms, hospital halls and medical clinics;
- medical or sales representatives of Antibiotice S.A. perform operations involving processing of personal data of the healthcare staff, without their prior consent;
- medical or sales representatives of Antibiotice S.A. give inaccurate and incomplete information; in this way the healthcare staff may form an erroneous opinion on the therapeutic quality of a medicine;
- promotion by internet of the prescription medicines without restricting the access only to the healthcare professionals, by means of a valid and verifiable system, accessed with a user name and a password;
- organizing events at which the hospitality granted to the healthcare professionals exceeds the expense limits on travel, meals, medical insurance during travel, accommodation, registration fees or will be extended to husband/wife as well as to relatives up to grade IV inclusive or any other accompanying persons;
- granting illegally individual sponsorships and donations to the healthcare professionals.

Art 115 The Ethics & Integrity Council analyzes the notifications and make a decision taking the following steps:

- the General Director will submit to the President of the Council all the complaints and notifications regarding an incident of ethics as well as any other documents issued in connection therewith;
- the Council will analyze the documentation related to that particular case;
- following the analysis, the Council will adopt by secret ballot a decision on the ethical case;
- the decision will be communicated immediately after its adoption to the company's General Director;
- The General Director will ensure the communication of the result to the person who made the complaint and will dispose the necessary measures.

CHAPTER IX - SANCTIONS

Art.116 In the event of a breach of the provisions of the current Code, depending on its seriousness and circumstances found by qualified individuals within Antibiotice S.A., taking into account the provisions of Law no. 53/2003 - Labor Code as well as those of Internal Regulations and Code of Ethics, appropriate sanctions will be applied.

Art.117 Sanctioning of the Antibiotice representatives guilty of violating this Code, will be followed by the application as soon as possible in the entire company, of the administrative measures necessary to remedy the effects of acts that led to applying a sanction (e.g. withdrawal of promotional materials, retraining of the staff that have to comply with the provisions of the current Code).

Art.118 In accordance with the provisions of the article 308 of the Penal Code, if an Antibiotice representative violates a provision of the current Code by committing one of the offenses in connection with the job stipulated in the articles 289-292 (taking and giving bribes, traffic of influence, buying influence), 295 (embezzlement), 297-301 (abuse of service, negligence in service, abusive use of the function for sexual purposes, usurpation of the function, conflict of interest) and 304 (disclosure of classified or non-public information) of the Penal Code this will result in referral to the competent judicial bodies in implementing legal measures that might be required.

CHAPTER X - FINAL PROVISIONS

Art.119 The Code of Good Practices of Antibiotice S.A. on the promotion of prescription-only medicines to and interaction with the healthcare professionals is applicable starting with 01.01.2015.

Antibiotice **at**

