Association of Foreign Innovative Pharmaceuticals Manufacturers Representatives

CODE OF FARMABREND NOVA'S CONDUCT DURING PROMOTION OF DRUGS ISSUED UNDER A PRESCRIPTION AND COMMUNICATION TOWARDS THE HEALTHCARE PROFESSIONALS

Adopted by the General Assembly of FARMABREND NOVA on _____ and ratified by the General Assembly of FARMABREND NOVA on _____ harmonized with the EFPIA HCP Code, 24.06.2013

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INTRODUCTION

The Association of Innovative Pharmaceuticals Foreign Manufacturers Representatives FARMABREND NOVA Skopje is a voluntary, non-governmental and non-profitable association, founded for an indefinite period of time for the purpose of achieving goals in the field of the validity of protected (patented) drugs and promotion of the industry of patented drugs and their decisive importance for achieving the highest level of public health in the Republic of Macedonia.

The membership is composed of representatives of foreign pharmaceutical companies in the Republic of Macedonia involved in the production, trade and promotion of innovative drugs, whose activity is based on research and development of new chemical compounds.

Authorities of this Association are: Assembly, Executive Board and President of the Assembly.

The purpose of the Code of FARMABREND NOVA's conduct during promotion of drugs issued under a prescription and communication towards the healthcare professionals is to established visible and clear rules and procedures, which the members of FARMABREND NOVA are obliged to observe during the promotion of their drugs before the healthcare professionals, in a manner that provides professional and ethical behavior as well as transparency in the procedures all in order to achieve rational pharmacotherapy and ensuring high quality healthcare protection for the patients' common good.

FARMABREND NOVA

FARMABREND NOVA and its members are aware how important it is to provide correct, true and objective information about the medical products in order to be able to make rational decisions regarding the use thereof.

Having this in mind, FARMABREND NOVA adopted the Code of FARMABREND NOVA's conduct during promotion of drugs issued under a prescription and communication towards the healthcare professionals ("Code of FARMABREND NOVA's conduct towards the Healthcare professionals".

The Code of FARMABREND NOVA's conduct during promotion of drugs issued under a prescription and communication towards the healthcare professionals is in compliance with the

EFPIA code for promotion of drugs issued under a prescription and interaction with healthcare professionals and the local laws in the Republic of Macedonia.[1, 2].

FARMABREND NOVA encourages the competition among the pharmaceutical companies. The Code of FARMABREND NOVA's conduct towards the healthcare professionals does not try to limit the drugs promotion or to limit the interactions with the healthcare professionals in a manner which hurdles the fair competition. Instead, FARMABREND NOVA tries to make sure that the members of FARMABREND NOVA as representatives of the pharmaceutical companies carry out promotion and have interactions with the healthcare professionals in a proper manner and in compliance with the existing and current laws and regulations in R. Macedonia, avoiding unethical practices and potential conflict of interests with the healthcare professionals.

Hence, the Code of FARMABREND NOVA's conduct towards the healthcare professionals aims to encourage an environment in which the general public can be sure that the choices made regarding their prescribed drugs and medical devices are made on the basis of the characteristics of each product and the medical needs of the patients regarding such drug.

[1] Law on drugs and medical devices http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-lekovi-i-medicinski-pomagala.pdf

[2] Healthcare Protection Act, Official Gazette No.10, 17 January 2013.

PURPOSE OF THE CODE OF FARMABREND NOVA'S CONDUCT TOWARDS THE HEALTHCARE PROFESSIONALS

The Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals covers the promotion of dugs issued under a prescription and the interactions between the healthcare professionals and the pharmaceutical companies. The Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals shall be applied by the members of FARMABREND NOVA ("**Member Companies**").

The member companies shall bear responsibility of the obligations imposed under the applicable code (defined herein below) even when they authorize other parties (eg. When they hire sales persons, consultants, market research companies, advertising agencies) to create, implement or to involve themselves in activities covered by the applicable code (defined herein below) on their behalf. In addition, the Member companies shall take reasonable measures to make sure that the other parties they have authorized to create, implement or to be involved in activities covered with the applicable code (defined herein below), however not act on behalf of the Member company (for example joint ventures, holders of licenses), have complied with the applicable codes (defined herein below).

„**Promotion** " is any type of providing correct information about the drug to the general and professional public, and covers all the activities undertaken, organized or sponsored by the pharmaceutical companies or third parties on their behalf which encourage the prescription, the supply, the sale, the administration, the recommendations or the use of drugs. The drugs may not be promoted before they obtain Drug Marketing Authorization issued by the Competent authority allowing thereby sale, supply or promotion of the drug out of such authorization.

Drug is any substance or a combination of substances formulated in a manner in which they treat or prevent diseases in people. Furthermore, drug is any substance or a combination of substances which may be used by or given to people for recovery, correction or modification of the physiological functions by triggering pharmacological, immunological or metabolic activity, or for establishing medical diagnosis.

The Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals covers the promotion and the communication towards and the interactions with any healthcare worker in the field of medicine, dentistry and pharmacy, medical nurses or any other person who during the carrying out of his/her professional activities may issue a prescription, buy, purchase or manage the drugs ("**healthcare** professional").

The Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals covers all promotion methods including, without limitation to, oral and written promotional activities and communications, advertisement in newspapers or by electronic mail, the activities of the medical representatives responsible for drugs promotion (defined in Article 18 paragraph 1), the use of internet and other electronic communication, the use of audio-visual systems as films, videos, data storage services etc., and the provision of informational or educational materials, hosting events and free samples.

The Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals also covers the interaction between the representatives of the Member companies and the healthcare professionals including, but not limited to those in the context of research or contract signature (including certain aspects of clinical trials, non-intervention trials and consulting and advisory services). The interactions between the representatives of the Member companies and the patients associations will be covered in the Code of FARMABREND NOVA's conduct and the patients associations.

The purpose of the Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals is not to limit or regulate the provision of non-promotional medical, scientific and factual information; nor to limit or regulate the activities aimed at the general public referring solely to the medical products issued without a prescription.

The Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals does not cover the following:

The information contained in the summary report on the drug characteristics, the patient information leaflet and the packaging of the drugs and medical devices and the accompanying brochures, which are subject of the provisions of the Law on Drugs and Medical Devices,

The correspondence, if possible accompanied by material of non-promotional character, necessary for answering a specific question about a certain drug,

Factual, informative releases and reference material related, for example, with changes in the packaging, warning about the side effects as part of the general precautions, catalogues and pricelists, providing they contain no complaints about the products,

Non-promotional information related to the human health or diseases,

Activities related to the promotion of drugs issued without a prescription, or

Non-promotional, general information about the companies (as well as information intended for the investors or current/future employees) including financial data, descriptions of research and developmental programs and discussions on subjects related to the regulative which affect certain company and its products.

CODE APPLICATION

The Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals sets the minimum standards which FARMABREND NOVA considers necessary to be applied. In a manner compatible with its respective national laws and regulations, FARMABREND NOVA must, at a minimum, adopt in its code provisions no less rigorous that the provisions contained in the EFPIA HCP Code.

In order to avoid any doubt, the term "company" in the form used in this Code of FARMABREND NOVA's Conduct towards the Healthcare Professionals , shall mean any legal entity organizing or sponsoring promotion or is involved in interactions with the healthcare professionals included in the code, regardless of whether such entity is a parent company (for example headquarters, main office or a controlling company of the commercial enterprise), branch office or any other form of enterprise or an organization.

PROVISIONS OF THE CODE OF FARMABREND NOVA'S CONDUCT TOWARDS THE HEALTHCARE PROFESSIONALS

ARTICLE 1

Drug Marketing Authorization.

1.01. Drugs may not be promoted before they receive Marketing Authorization issued by the Competent Authority thereby enabling the sale, supply or promotion of the drug within the frames of the approved indications.

1.02. The promotion must be consistent with the particulars indicated in the Summary of product characteristics of the relevant Medicinal product.

ARTICLE 2

Information to be published

Drugs promotion intended for the healthcare professionals shall be conducted by the holders of the drug marketing authorizations through an announcement in a professional literature, professional periodical magazines and other professional publications, as well as through direct provision of information to the healthcare professionals prescribing or issuing the drugs.

2.01. All promotional materials must contain the following clear and legible information:

- Essential information consistent with Summary of product characteristics (protected name, international unprotected name, indications, contraindications, use, special precaution measures and warning and side effects), indicating the date of the last approved or revised Summary of product characteristics;

- Manner of issuing the drug;
- Indication that the promotional material is intended for healthcare professionals ;
- List of reference;
- Date and number of the valid drug marketing authorization;
- Information that if any side effect/reaction is noticed it should be reported to the holder of the authorization and the competent authorities for pharmacovigilance;
- Reference number (code) and date of authorizing the promotional material;
- Information on the availability of the entire Summary of product characteristics and other information about the drug with the Holder of the authorization.

The drug promotion may also contain data on the sales price of the drug i.e. the medical device and the information whether the drug is on the list of drugs the costs for which are covered by the Macedonian Health Insurance Fund.

If the promotion is to serve as a reminder, in such case it shall only include the information on the drug protected name and/or its international unprotected name (if any) and/or the name of the company/ Holder of the Drug Marketing Authorization.

ARTICLE 3

Promotion and supporting with evidence

3.01. The promotion must be correct, precise, balanced, fair, objective and comprehensive enough to enable the recipients to form their own opinion on the therapeutic value of the drug subject of promotion. The promotion must be based on updated evaluation of all relevant evidence and it must clearly reflect such evidence. The promotion must not be misleading caused by misrepresentation, distortion, exaggeration, , undue emphasis, and omission or in any other way.

3.02. The promotion must be supported by information which must be made available immediately as a reply to the requests made by the healthcare professionals. In particular, the promotional claims regarding the side effects must r reflect the available evidence or supported by clinical experience. However, supporting by facts shall not be necessary for the elements approved under the drug marketing authorization.

3.03. Promotion must encourage rational drug use through their objective presentation and without exaggerating of their properties. Claims used in the promotion may not imply that the drugs or their active ingredients have any special characteristic, quality or property unless this can be substantiated.

3.04. When the promotion makes reference to published studu, clear reference of such papers must be provided.

3.05. Any comparison made between different drugs must be made on the basis of relevant and comparable aspects of the products. Comparative advertising must not mislead or underestimated.

3.06. All illustrations, including diagrams, drawings, pictures and tables, taken from already published research papers, included in the promotional material shall:

a. Clearly indicate the concrete source(s) of such illustrations;

b. Be authentically reproduced, except in cases when adaptation or modification is necessary, and in such case it must be clearly indicated that the illustration has been adapted and/or modified. Special attention must be paid in order to make sure that the illustrations included in the promotion leave no wrong impression about the drug's nature (for example, whether the drug is appropriate for use in children) or leave wrong impression with the representations or comparisons (for example, use of incomplete and statistically irrelevant information or use of unusual units of measurement).

3.07. The word "**safe**" may not be used for the description of a drug without the necessary qualification.

3.08. The word "new" may not be used for the description of the drug, pharmaceutical form or therapeutic indication which have been generally available to the wide public and have been marketed for a period longer than one year from its local launch.

3.09. It may not be indicated that the product has no side effects, risk of poisoning or risks from addiction.

ARTICLE 4

Using quotes during the promotion

4.01. The quotes of the medical or the scientific literature or from the personal communications must be authentically reproduced (except in cases when adaptation or modification is necessary and in those cases it must be clearly indicated that the quote has been adapted and/or modified) and the source must be precisely identified.

ARTICLE 5

Acceptability of the promotion

5.01. Companies must maintain high ethical standards at all times. Promotion must:

- never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry;

- be of a nature which recognizes the special nature of medicines and the professional standing of the recipient(s); and

- not be likely to cause offence.

ARTICLE 6

Distribution of promotion

6.01. The promotion shall be intended only for those who are reasonably assumed to have a need of or an interest in certain information.

6.02. The list of recipients' addresses must be updated at all times. The healthcare professionals' requests to be removed from the lists of recipients for promotional purposes, must be met.

6.03. Pursuant to the applicable national laws and regulations, the use of fax, electronic mail, automatic dialing systems, text messages and any other type of electronic communication and sending data for promotional purposes is prohibited, unless there is a previously obtained consent given by the recipient or the recipient requests such action.

ARTICLE 7

Transparency of promotion

7.01. The promotion must not be disguised.

7.02. Clinical assessments, post-marketing surveillance and experience programs and post-marketing trials and studies (including the retrospective ones), may not represent disguised promotion. Such assessments, programs and studies shall be conducted primarily for scientific and educational purposes.

7.03. When a company pays for or otherwise provides for or organizes publishing of promotional material in specialized medical magazines, such promotional material may not look like an independent editorial and should be labeled as "commercial text".

7.04. The material referring to drugs and their use, regardless of whether they are promotional or not, which are financed or provided by the company, must clearly indicate the sponsor company.

ARTICLE 8

Advice on personal medical questions

8.01. In case individuals from general public request advice on personal medical questions, the requesting person shall be advised to consult a healthcare professionals.

ARICLE 9

Information or educational materials and items for medical utility

9.01. Distribution of informational or educational materials shall be permitted only if: (i) they are inexpensive, (ii) they directly refer to the medical or pharmaceutical practice; and (iii) they pose direct benefit to the patients' healthcare protection. The distribution of such materials or products shall not construe inducement for recommendation, prescription, buying, procurement or application of a certain drug.

9.02. The products for medical use which are directly aimed at education of the healthcare professionals may be provided if "inexpensive" and if they do not disrupt the recipient's routine practice.

9,03. The members of the Association shall provide instructions regarding the meaning of the term "inexpensive" used in this article 9. The companies must comply with all the relevant instructions provided pursuant this paragraph 9.03, with regard to all applicable codes.

ARTICLE 10

Events and hospitality

10.01. All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events (including, but not limited to, meetings of advisory bodies, visits to research or manufacturing facilities, and planning, training or meetings of investigators for clinical studies and non-intervention studies) organized or sponsored by or on behalf of the company must be held at an appropriate location that serves the main purpose of the event and hospitality can be offered only when it is appropriate and in accordance with the provisions of the applicable Code.

10.02. No company may organize or sponsor an event that occurs outside its country of origin unless:

a. most of the invited persons are coming from a country other than the country of origin of the company, so keeping in mind the countries of origin of most of the invited persons, it makes more sense to hold the event in another country, or

b. taking into account the location of the relevant source or expertise that is the object of the event, it makes more sense to hold the event in another country (an "international event").

10.03. Hospitality for events should be limited to covering the expenses for travel, meals, accommodation and registration fees. The cost of air travel as part of a hospitality / sponsorship shall be allowed for economy class only.

10.04. The member companies will not provide or offer meals (food and beverages) i.e. hospitality to healthcare professionals, except for in exceptional situations where there is a clearly defined professional or scientific content when organizing professional or business meetings and they are to be of moderate value.

10.05. Hospitality may be provided to individuals who are qualified to participate in the event (whether passively or actively) but not to the individuals accompanying him/her (family members or any other third party).

10.06. All forms of hospitality offered to the healthcare professionals shall be reasonable and strictly limited to the main purpose of the event. As a general rule, hospitality must not exceed what healthcare professionals, would be normally prepared to pay themselves.

10.07. Hospitality shall not include sponsoring or organizing entertainment events (eg. sporting or recreational events). Companies should avoid locations that are known for their recreational facilities or that is extravagant (such as buildings intended primarily for relaxation, spas, wineries, etc.). Accommodation is allowed only in hotels with up to 4 stars i.e. hotels of no entertaining character, except for in exceptional situations (e.g. organizer of the congress decided on the venue of the Congress, if the capacity of the 4 star hotels do not meet the conditions for organizing the event).

ARTICLE 11

Donations and grants supporting the healthcare protection and the research

Donations and grants in material goods and financial assistance to institutions, organizations or associations which are made up of health professionals and / or providing health services or conduct research are allowed only if:

a) they are made in order to support the healthcare services or the research;

b) there is a written request made by the institution, organization or association;

c) they are documented and the donator keeps records thereof;

d) represent no inducement for recommendation, prescription, buying, offering, sale or administration of certain drugs.

Donations granted to individual health professionals are not permitted under this article.

The donation may not be offered to the association nor necessitated by the association. It is recommended that companies publicly disclose information for donations (in material goods or financial assistance).

ARTICLE 12

Service fees

12.01. The agreements concluded between companies and healthcare, institutions, organizations or associations of healthcare professionals under such institutions, organizations or associations provide any type of services to companies (or any other type of funding that is not covered by Article 11 or elsewhere by this code) shall be permitted only if such services (or other funding):

a) are offered in order to support health services or research; and

b) do not represent an inducement to recommend, prescribe, supply, offer, sell or administer certain drugs / medical devices.

ARTICLE 13

Sponsorship of healthcare professionals

13.01. Companies must adhere to the criteria for the selection and sponsorship of healthcare professionals attending training or events. The criteria will be further defined in the Guidelines.

No financial funding may be offered to compensate for the time that healthcare professionals spent attending events. In case of international events for which the company is sponsoring the participation of healthcare professionals, if they provide any sponsorship of healthcare professionals this should be in accordance with the provisions of paragraph 1 of this Article, the costs coverage by the companies must be pursuant to Article 10 of this Code.

ARTICLE 14

Using consultants

14.01. The services of healthcare professionals may be used as consultants and advisors, whether in groups or individually, for services such as presentation at or convening meetings, involvement in medical / scientific studies, clinical trials or training, participation in meetings of advisory boards and participation in market research where such participation involves remuneration and / or travel. The agreement which covers such consultancy or other services must, to the extent relevant for the corresponding contract, meet the following criteria:

a) before ordering the services, written contract or agreement shall be signed which specifies the nature of the services to be provided and pursuant to clause (g), the payment basis for such services shall be specified,

b) before asking for a service and entering into a contractual relationship with the potential consultants, a legitimate need for the services has been identified,

c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants who possess the expertise necessary to assess whether certain healthcare professionals meet these criteria or not,

d) the number of healthcare professionals is not greater than the number reasonably necessary to meet the identified need,

e) the company to which the contract was signed keeps records of and properly uses the services provided by the consultants,

f) the engagement of healthcare professionals to provide the relevant service is not an incentive to recommend, prescribe, purchase, supply, sell or administer a particular drug, and

g) the fee payable for the services is reasonable and reflects the fair market value of the service offered. In this regard, the arrangements for smaller consulting services should not be used to justify compensation to the healthcare professionals.

14.02. In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, healthcare professionals that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare his/her employment arrangement with the company whenever he/she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company. The provisions of this Section 14.02 apply even though the EFPIA HCP Code does not otherwise cover non-promotional, general information about companies (as discussed in the "Scope of the EFPIA HCP Code" section 2)

14.03. Limited market research, such as one-off phone interviews or questionnaires delivered by mail / e-mail / Internet, are excluded from this article, provided that the healthcare professionals are not consulted in a way that repeats (either in terms of the frequency of calls, or in terms of calls related to the same research) and the fee is minimal and reasonable.

14.04. If a healthcare professionals attends an event (an international event or otherwise) as a consultant or advisor, in such case the relevant provisions of Article 10 shall apply.

ARTICLE 15

Non-intervention studies of drugs with marketing authorization

15.01. Non-intervention studies of drugs for which marketing authorization has been issued is defined as a study / research in which the drug is prescribed in the usual manner in accordance

with the drug authorization. The indication of applying a certain treatment for the patient shall not be decided in advance with the examination protocol but falls within the current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. The patients shall not be subject to any additional diagnostic procedures, and epidemiological methods shall be applied for the analysis of the collected data.

15.02. The non-intervention studies which are prospective by their nature and which include collection of patient data by or on behalf of individuals or groups of healthcare professionals specifically for the implementation of the study, must comply with the following criteria:

- the study shall be conducted for a particular scientific purpose;

- (a) there is a written plan (or protocol) for research and b) there are written contracts between healthcare professionals and / or institutions in which the study is to be conducted on the one hand and the company that is sponsoring the study, on the other hand, specifying the nature of the services to be provided and under the clause that follows, the payment basis for these services;

- any compensation provided is reasonable and reflects the fair market value of the work performed,

- The study protocol together with other required documents must be submitted to the ethics committee for review and approval under the Regulations on the manner and procedure for clinical trials of drugs and the contents of the documentation,

- the local laws, regulations and rules for the personal data privacy must be complied with (including the personal data collection and use),

- the study may not be an incentive for a recommendation, prescription, purchase, supply, sale or administration of a particular drug,

- the study protocol must be approved by the medical / scientific research department of the company, and the study must be conducted under the supervision of the scientific - research, medical department of the company,

- the study results must be analyzed by or on behalf of a company with which a contract has been signed and then a summary thereof must be made available within a reasonable period of time (maximum 6-12 months upon the preparation of the final study report) that is given to the scientific - research department of the company that keeps records of such reports over a reasonable period of time. The company must send the report to all healthcare professionals who participated in the study and the resulting report shall be submitted to the regulatory authorities under the relevant regulations. If the study shows results that are relevant for the assessment of the correlation between benefits and risks, in such case the report should immediately be submitted to the relevant competent authorities.

The medical representatives responsible for the promotion of drugs may be involved only in administrative capacity and such involvement must be under the supervision of the scientific

service of the company that will ensure that representatives are adequately trained. Such participation should not be associated with the promotion of a drug.

15.03. To the extent applicable, companies are encouraged to apply paragraph 2 of this article for all kinds of studies that are covered by paragraph 1 of this Article, including epidemiological studies and registries and studies which are retrospective by nature.

ARTICLE 16

Free samples

16.01. In principle, no medical samples should be given, except on an exceptional basis.

Medical samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products, and should not be given for the sole purpose of treating patients.

Medical samples are provided to health professionals so that they may familiarize themselves with the medicines and acquire experience in dealing with them.

In accordance with national and/or EU laws and regulations, a limited number of medical samples may be supplied on an exceptional basis and for a limited period. A reasonable interpretation of this provision is that each health professional should receive, per year, not more than 4 medical samples of a particular medicine he/she is qualified to prescribe for 2 years after he/she first requested samples of each particular medicine.

In this context, a new medicine is a product for which a new marketing authorization (MA) has been granted, either following an initial MA application or following an extension application for new strengths/dosage forms that include a new indication. Extensions of the MA to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new medicines.

Without prejudice to the ban on medical sampling of medicines containing psychotropic and narcotic substances, medical samples can only be given in response to a written request from health professionals qualified to prescribe that particular medicine. Written requests must be signed and dated by the recipient.

On an exceptional basis, member associations may allow, through additional guidance, a longer period than 2 years if required by local healthcare conditions.

Section 16.02. Companies must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by its representatives. This system shall also clearly establish, for each health professional, the number of samples supplied in application of the provisions in Section 16.01 (i.e. the “4x2” standard).

Section 16.03. Each sample shall be no larger than the smallest presentation of that particular medicine in the relevant country.

Each sample must be marked “free medical sample – not for sale” or words to that effect and must be accompanied by a copy of the summary of product characteristics.

ARTICLE 17

No gifts allowed

17.01. No gifts or pecuniary advantage (in cash or benefit in kind) may be supplied, offered or promised to a healthcare professional.

ARTICLE 18

Liability of the pharmaceutical company’s employees

18.01. Every company needs to ensure that its medical representatives, including employees who are hired under a third party agreement and all other employees working with the healthcare professionals, pharmacies, hospitals or other healthcare facilities regarding the promotion of drugs and medical devices, are familiar with the relevant requirements imposed by the applicable Code and all applicable laws and regulations and are properly trained and have sufficient scientific knowledge to be able to provide accurate and complete information regarding the drugs they promote.

- Medical representatives must work in accordance with all the relevant requirements defined in the applicable codes and all applicable laws and regulations, and the companies are responsible for ensuring their compliance.
- Medical representatives shall responsibly and ethically perform their duties.
- During each visit, and in compliance with the current laws and regulations, medical representatives must provide the person they are visiting with or have available summary of product characteristics of the drug i.e. the medical device they are promoting.
- Medical representatives must forward to the medical department in their company any information not included in the summary report on the drug characteristics they have received regarding their company’s drug which is particularly mandatory if the information refers to side effects.
- Medical representatives must ensure that the frequency, timing and duration of visits to healthcare professionals, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.

- Medical representatives may not apply any inducements or frauds to come to a meeting. During the meeting or when seeking to schedule a meeting, medical representatives shall not make misleading representations with regard to their identity or the identity of the company they are representing.

The provisions shall apply for all activities of the medical representatives for drugs promotion.

18.02. The entire personnel of the company and any personnel engaged under an agreement with a third party, which deals with the preparation or approval of promotional material or activities must be fully familiar with the requirements imposed by relevant laws and regulations.

- Every company must establish a medical department which will be managed by a medical doctor or least pharmacist where appropriate and will be responsible for issues related to their drugs that are not covered by the summary of product characteristics and for the approval and supervision of non-intervention studies. The companies have the freedom to decide what is the best way to establish this department i.e. if there is a department which is in charge of both duties or there are different departments for duties that are clearly differentiated, taking into account its resources and organization. The Medical department is responsible for the medical review of the promotional material before it is issued and responsible person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance of Applicable code and any applicable advertising laws and regulations, is consistent with summary of product characteristics and is a fair and truthful presentation of the facts about medicine.

- Each company must appoint at least one experienced employee who will be responsible for supervision of the operations of the company and its subsidiaries to ensure that the standards of the Code have been met.

ARTICLE 19

Procedure in case of violation of the Code

19.01. The members of FARMABREND NOVA are recommended to settle all cases of alleged violation of the code, referring only to those two companies, amicably and with direct negotiations. In general, amicable resolution is recommended also in case of a dispute between a member of FARMABREND NOVA and non-member pharmaceutical companies.

If no amicable resolution can be achieved, it is possible to file a complaint for violation of the Code against a member of the association FARMABREND NOVA and at the same time in writing to the President of the Association and to the President of the Ethics Committee. The work of the Ethics Committee and the possible sanctions are defined in the Procedure in case of violation of the FARMABREND NOVA's codes and the Statute of FARMABREND NOVA.

ARTICLE 20

Final provisions

20.01. The Assembly of FARMABREND NOVA adopted this Code on _____ and it shall become effective as of _____

20.02. Under the Code all members of the Association FARMABREND NOVA are obliged to fully abide to and observe its provisions.