ASSOCIATION OF THE RESEARCH-BASED PHARMACEUTICAL MANUFACTURERS IN BULGARIA

ARPharM

CODE OF ETHICS
OF THE RESEARCH-BASED PHARMACEUTICAL INDUSTRY IN BULGARIA

Adopted May 2006, in force since 5th of June 2006;
Amended July 2008, in force since 31st of July 2008;
Amended September 2011, in force since 1st of January 2012;
Amended November 2013, in force since 1st of January 2014;
Amended on 22nd of October 2014, immediate effect;
Amended on 16th of April 2019, effect from 1st of January 2020;

INTRODUCTION

The Association of the research-based pharmaceutical manufacturers in Bulgaria (**ARPharM** or **the Association**) is a representative body of the research-based pharmaceutical industry in Bulgaria. The Association unites the manufacturers and marketing authorization holders, operating on the Bulgarian market which have signed this Code of Ethics and invest in the development of the pharmaceutical industry through synthesis and formulation of medicinal products containing innovative active pharmaceutical substances.

The main priority of the Association and its members is to contribute to the provision and protection of health and human life, ensuring access for Bulgarian patients to quality, safe and effective medicinal products for prevention, diagnostic testing, and treatment of diseases.

In order to provide for accurate, objective and fair information which ensures rational prescription and reasonable use of medicinal products, the pharmaceutical manufacturers and the marketing authorization holders distribute among the representatives of the healthcare profession specialized information about the products, collected in the process of the research and development activities, as well as from the experience obtained during the treatment of diseases. The aim of this promotional activity is introduction to the merits and characteristics of the specific medicinal product through appropriate educational and marketing means.

The pharmaceutical manufacturers and marketing authorization holders organize their advertising and promotional activities regarding medicinal products, subject to prescription, as well as regarding their interactions with the healthcare professionals, in compliance with the regulations of the Bulgarian legislation in effect. While the trial, manufacturing, marketing and control on pharmaceuticals are subject of extensive regulation, the advertising and promotion of medicinal products cannot be extensively arranged through legal regulations. Due to that reason, the pharmaceutical companies are brought together around a Code of Ethics (**the Code of Ethics** or **the Code**) and oblige themselves to conduct their activity relating to the advertising and promotion of pharmaceuticals, subject to prescription, as well as regarding their interactions with the healthcare professionals, in compliance with the provisions of the present Code.

The Code, reflecting the requirements of Council Directive 2001/83/EC, as amended, enhances the role of voluntary control of advertising and promotion to healthcare professionals of prescription medicinal products, as well as regarding the interactions of the pharmaceutical industry with the healthcare professionals, by self-regulatory bodies and recourse to such bodies when complaints arise.

ARPharM encourages competition among pharmaceutical companies. The Code of ARPharM is not intended to restrict promotion and advertising of medicinal products or the interactions of the pharmaceutical industry with the healthcare professionals in a way which is detrimental to the fair competition but to guarantee that the pharmaceutical companies carry out their promotional and advertising activity, as well as their interactions with the healthcare professionals, in a truthful manner and in accordance with the high ethical and moral principles and values, as well as with the provisions of this Code. The Code of ARPharM therefore aims to foster an environment where the general public can be confident that the prescribing and dispensing of pharmaceutical products is performed according to the merits of each product and the healthcare needs of the patients.

The member-companies of the association are bound not to perform or encourage activities directed towards inducement of healthcare professionals to prescribe particular pharmaceuticals for material benefits (items, money and services). Items, subsidies, financial support, scholarships, grants, invitations to participate in conferences, should not be offered or

provided to healthcare professionals against prescription or undertaking of engagement to prescribe definite medicinal products.

The members of ARPharM are obliged to observe both the regulations of the Bulgarian legislation in place, the legislative norms of the European Union legislation, the EFPIA Code on promotion of medicines, the IFPMA Code on pharmaceutical marketing practices, and the provisions of the present code as long as they do not contradict the abovementioned.

PREAMBLE

The Code of Ethics herein stipulates the principles and the rules that the Companies are obliged to observe during performance of promotion and advertising activities with respect to prescription-only pharmaceuticals intended for healthcare professionals and permitted by the Bulgarian law, as well as the principles and the rules, which the Companies are obliged to observe in their interactions with the healthcare professionals.

The adoption and observance of this Code of Ethics is a mandatory condition for membership to the association and each member is liable not to violate the regulations and the spirit of this code. The member-companies of ARPharM are obliged to acquaint with the Code of Ethics the authorised by them legal entities or natural persons, which perform promotion or advertising of their medicinal products.

Any natural person, being a representative of a Company, shall confirm to the obligation to follow the Code of Ethics by placing his/her signature. Other pharmaceutical manufacturers or the marketing authorization holders, not being members of ARPharM, could adopt and adhere to the regulations of the present Code.

The application and observance of the Code is an obligation of any and all companies that have adopted it. The observance of the Ethical Code is controlled by the Ethics Commission at ARPharM (**The Commission**). Any claims related to probable violations of the Code shall be referred to the Commission. The Commission could issue decisions intended to assist in interpretation of the provisions of the Code when required or when the Commission has been approached. The interpretative decisions are obligatory concerning the meaning of the interpreted provision since the date on which the Companies are informed or since the date provided in it.

A key principle of the Code is that any statement or message connected with advertising and promotion of pharmaceuticals should be compliant with the Summary of product characteristics (**SPC**) approved in Bulgaria.

The proceedings taken to determine a violation and impose sanctions are held before the Commission in line with the procedure and the rules established in the Code.

The adherence to the regulations of this Code of Ethics shall not relieve the members of ARPharM and the companies towards which it is compulsory, from the responsibility to observe the regulations of the Bulgarian legislation, the legislation of the European Union and other relevant codes of international organizations and/or companies.

SCOPE OF THE CODE

The ARPharM Ethics Code regulates the promotion and advertising of prescription-only medicinal products to healthcare professionals as well as the interaction between the pharmaceutical industry and the healthcare professionals.

The Companies are responsible under the Code also for the activities of their subcontractors – third parties (for example consultants, advertising agencies, market-research agencies, contracted sales force) whereas these activities are regulated of the Code of Ethics.

"**Promotion and advertising**", as used in the ARPharM Code of Ethics, includes any activity undertaken, organized or sponsored by a pharmaceutical company, or performed with its authority and on its behalf, which promotes the prescription, supply, sale, application or consumption of its medicinal product(s).

"Medicinal product", as used herein**,** is any substance or combination of substances that are presented at having curative or prophylactic action on human diseases or any substance or combination of substances that can be used or administered with a view to restoring, correcting or modifying physiological functions of human beings through pharmacological, immunologic or metabolic action or for medical diagnosis.

The Code covers promotion and advertising directed towards all of the listed herein: doctors, doctors of dental medicine, master pharmacists, nurses, midwives, medical laboratory technicians, paramedics, doctor's assistants, assistant-pharmacists or any other person who in the course of his/her professional activity could prescribe, purchase, supply or administer medicinal products and whose main practice, practice address or place of registration is in Europe (each of them called a "**healthcare professional**").

In order to avoid any doubt or ambiguity, the term "healthcare professional" includes any official or government agency employee or employee of any organisation (both in the public and private sectors) who could prescribe, purchase, supply or administer medicinal products and any Company employee whose main activity is of a practicing healthcare professional but excludes all the other employees of a Company or wholesale traders or distributors of medicinal products. The code covers promotion and advertising which is directed towards state officers and officials working in the state healthcare administration or institutions or establishments in the healthcare sector.

"Company", as used in the present Code, is any company – member of ARPharM and any manufacturing company or marketing authorization holder which has undertaken the responsibility to observe the present Code.

Promotion and advertising of prescription-only medicinal products directed to general public constitutes a violation of the Bulgarian legislation and of the present code with the exception of the cases admissible by the Bulgarian legislation.

The ARPharM Code covers all methods of promotion and advertising including, but not limited to, oral and written promotional activity and communications in periodicals, direct e-mail advertising, the activity of medical sales representatives, internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage

services and the like, as well as provision of samples, items of medical utility, information and education materials and hospitality.

The Code also covers interactions between Companies and healthcare professionals including, but not limited to, those in the context of research activities, contractual arrangements, for example participation in clinical trials, non-interventional studies, consultancy and advisory board arrangements).

Interactions between Companies and patient organisations are covered by the Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations in Bulgaria. The ARPharM Code is not intended to restrain or regulate the provision of medical, scientific and factual information, which is not characterized as promotional; neither is it intended to restrain or regulate activities directed towards the general public which are related solely to non-prescription medicinal products.

The following are not considered to be promotion or advertisement, as used herein:

- labelling on the package and the accompanying leaflet or usage guidelines, approved during the procedure of granting marketing authorization.
- correspondence, accompanied by a material of non-promotional nature, prepared in response to a specific question related to a particular medicinal product;
- informative announcements and instructions referring to modifications of package, adverse-reactions warnings as part of the general precaution measures, commercial catalogues and price lists, provided that they do not include information of promotional nature with respect to the medicinal product;
- statements, relating to human health or human diseases, provided they do not directly or indirectly mention administration of medicinal products;
- activities related solely to non-prescription medicinal products;
- non-promotional, general information about the companies (such as information directed towards investors or current/prospective employees), including financial data, descriptions of research and development programs and discussions of regulatory drafts affecting the company and its products.

PROVISIONS

ARTICLE 1
Responsibility

1.1. The companies conducting promotion and advertising or interaction with healthcare professionals bear the responsibility for their actions and for the content of the promotional and advertising materials which is expected to be accurate, objective and complied with the SPC, as well as with the published scientific information. The company bears the responsibility for the activity of its employees and third parties conducting promotion and advertising of its medicinal products or interaction with healthcare professionals. The activity of the employees and the third parties, representing the companies on promotion and advertising of their medicinal products or on the interaction with healthcare professionals, shall not breach the provisions of this Code.

1.2. This responsibility is not limited only to the medicinal product subject of promotional activity, but also to the information provided or to the statements made with respect to other medicinal products that should also be in line with the SPC, regardless of the information/statement source.

ARTICLE 2

MARKETING AUTHORIZATION

2.1 It is prohibited to promote or advertise a medicinal product or a therapeutic indication of a particular medicinal product prior to the grant of the marketing authorization. This prohibition is not intended to impair the right of the scientific community and of the general public to be comprehensively informed about the progress of science and medicine. It is not intended to restrain the full and accurate exchange of scientific information with respect to a particular medicinal product, including disclosure of appropriate scientific facts in specialized or general communications media and at scientific conferences. It also should not limit reporting to shareholders and others about information related to a specific medicinal product in compliance with requirements or recommendations of the law, the rules or regulations.

ARTICLE 3

Obligatory information

3.1. Each promotional and advertising material, including advertisements in specialized medical issues, must be accompanied by the SPC or by information consistent with the data available in the SPC, specifying the date of its latest approval by BDA/EMA.

3.2. When the purpose of the advertisement is only to remind about a well-known medicinal product, the requirement stipulated in p. 3.1 above need not be complied with, provided that the advertisement includes no more that the trade name of the medicinal product, the international non-proprietary name of the active substance, the name of the company or a picture of the package. The advertisement serving as a reminder must not contain any promotional claims.

ARTICLE 4

STANDARDS OF PROMOTIONAL AND ADVERTISING ACTIVITIES

4.1. Promotion and advertising must be accurate, balanced, fair, objective and sufficiently complete in order to give opportunity for the recipient to form his/her own opinion about the therapeutic value of the medicinal product concerned.

4.2. The information in promotional and advertising materials must be based on up-to-date analyses of data, substantiated by scientifically valid evidence, and must not mislead or create wrong impression.

4.3. The additional information and scientific evidence confirming the statements laid out in the promotion or advertisement must be provided by the Company on request of healthcare professionals. The data, quoted in promotional materials or advertisements, including publications in specialized issues, must be provided to the persons that have required it within a month as of the receipt of this request.

4.4. Promotion and advertisement must encourage reasonable use of the medicinal product by presenting it objectively and without exaggeration of its properties. The statements should not suggest that a given medicinal product or active substance have any special merits, qualities or characteristics, unless this could be substantiated.

4.5. When promotion and advertisement refer to any published studies[1], they must be clearly indicated with the respective cross-reference.

4.6. The word "safe" shall never be used without proper qualification in order to describe a medicinal product.

4.7. The word "new" should not be used to describe any medicinal product, presentation or a therapeutic indication that have been available in the Bulgarian pharmaceutical market for more than one year from the date of placing it on the market.

4.8. Promotion and advertisements should not contain claims that the product has no adverse effects, toxic hazards or risk of addiction or dependency.

4.9. Promotion and advertisements should be directed only to those healthcare professionals for whom it could be reasonably assumed that the information contained is of interest to them.

4.10. Promotion and advertisements should not resemble messages or designs used by other manufacturers in a manner which might lead to misleading or confusion.

[1] Publications in specialized reviewed medical journals; abstracts of accredited congresses/ scientific conferences involving medical specialists" (Ordinance No. 1, Article 10, (4) (updated and amended on 16.04.2019, effect from 01.01.2020)

ARTICLE 5

USE OF QUOTATIONS, READY MATERIALS AND PARTS OF THEM

5.1. The quotations taken from medical or scientific literature must be faithfully reproduced (for the exception when adaptation or modification is required for the purposes of consistency with the applicable code(s), in which case it must be clearly specified that the quotes have been adapted and/or modified) and the sources must be identified.

ARTICLE 6

Misleading promotion and advertising

6.1. Any promotion and advertising, which contains misleading claims, contradicts the provisions of this code.

6.2. Advertisements and promotion are misleading if:

6.2.1 Promotion and advertisement attribute to a medicinal product a therapeutic effect or efficiency which the product does not have.

6.2.2 Promotion and advertisements contain claims that the treatment with this particular product will be surely successful.

6.2.3 Promotion and advertisements contain claims that no damage would occur if the medicinal product is administered according to the instructions, or if the medicinal product is applied over a long period of time.

ARTICLE 7

Comparative advertising

7.1. Any promotion and advertising, which points out directly or indirectly to a company competitor or to a product of a competitor, is a comparative promotion and advertising.

7.2 The information and statements contained in comparative advertising and promotion must be complied with article 4 of the present code, must correspond to factuality and be proved through reference to the respective source. For cases in which comparative advertising refers to studies that were not designed to compare directly the properties and characteristics of the advertised medicinal products and medicinal products used for comparison, this must be explicitly stated in the advertisements. *(Amended on 27.09.2011, in force since 01.01.2012)*

7.3. Comparative advertising and promotion contradicts the provisions of the present code if:

7.3.1 specifies medicinal products that have different therapeutic indications in comparison with the medicinal product, subject of the promotion or advertising;

7.3.2 does not objectively clarify one or several of the main, relevant properties and peculiarities of the medicinal products concerned;

7.3.3 creates confusion in respect to the company conducting the promotion and advertising and its competitors, or with respect to the medicinal products subject of this promotion and advertising, as well as to the medicinal products used to serve as a comparison, or regarding the trademarks of the medicinal products specified.

7.3.4 contains statements defining the medicinal products used for comparison as "imitation or copy" of the medicinal product, which is subject of the promotion or advertising;

7.3.5 contains disparaging or disgraceful statements concerning the products, activity, personal or business standing of a company competitor or its employees;

7.3.6 contains the trade name of the competitive medicinal product or the name of the company competitor.

ARTICLE 8

Disguised promotion and advertising

8.1. Promotion and advertising must not be disguised. They must be presented in a manner allowing identifying them as advertising and promotion by their recipients.

8.2. Clinical assessments, post-authorization surveillance, programs concerning experience and studies (including the retrospective ones, if any), non-interventional studies performed after the grant of marketing authorization must not be a disguised promotion and advertising. Such assessments, programs and studies should be conducted primarily with a scientific and educational purpose.

8.3. When a company pays for or otherwise provides for or organizes publication of a promotional material in specialized medical journals, such promotional material must not resemble an independent editorial.

8.4. Material which concerns medicinal products and their use, regardless whether promotional or not, which is otherwise financed or secured by a company, must clearly specify the sponsor company.

8.5. Independent materials reflecting organization of symposia/events shall not be considered sponsored materials, as used in p. 8.4.

ARTICLE 9

EVENTS AND HOSPITALITY

9.1. All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each of them called an "event") organised or sponsored by or on

behalf of a company must be held at an appropriate venue, which is conductive to the main purpose of the event and could only offer hospitality when such hospitality is appropriate and corresponds to the provisions of this Code. Hospitality, in which the participants in the event are accommodated in extravagant and luxurious hotels, which are associated mainly with entertainment activities is considered inappropriate. *(updated and amended on 16.04.2019, effect from 01.01.2020)*

9.1.1 Extravagant and luxurious hotels for the purposes of this Code are all 5 star hotels, located in year-round[2] resort destinations, as well as all hotels, regardless of the class, located in seasonal[3] resort destinations during the summer or winter tourist season respectively; wine tourism complexes, regardless of their class and location. *(updated and amended on 16.04.2019, effect from 01.01.2020)*

9.1.2. Hotels not considered extravagant and luxurious are other than those listed in Article 9.1.1.that have the necessary conditions for hosting scientific events, i.e. the required number of rooms, audio-visual equipment etc. *(updated and amended on 16.04.2019, effect from 01.01.2020)*

9.1.3. The sponsorship fact must be clearly announced in advance on behalf of the company, at the event and in all activities. *(updated and amended on 27.09.2011, effect from 01.01.2012)*

9.2. In cases of sponsorship of an event organized by a third party (company or organization which is not a member of the association and has not undertaken the obligation to observe the Code) the members of the association may not lay down conditions to those third parties organizing the event that other companies' sponsorship should not be accepted.

9.3. No company may organize or sponsor an event held outside Bulgaria ("**international event**") unless:

9.3.1 Most of the invitees come from other countries and, due to logistical considerations, it would be better to hold the event in another country;

9.3.2 In view of the location of the respective source or expertise, which is the subject matter of the event, it would be logistically justified to hold the event in another country.

9.3a An international event can be used for presenting and handing out to the participants promotional information on medicines, drugs or therapeutic indications, which are not authorized for use in the country, where the international event takes place, or these are registered under other conditions provided that (a) any such promotional materials specifically state that a medicinal product, formula or therapeutic indication is not authorized for use in the country and with explicit indication of the countries where the medicinal product, formula or therapeutic indication is permitted to use and (b) any such promotional material, which contains

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[2] *For year round resort destinations on the territory of the Republic of Bulgaria in view of Art. 9 of the Code, are considered Sandanski, Velingrad and Hissarya (in force from 01.01.2013)*

[3] For seasonal resort destinations in Bulgaria with a view to implementing Article 9 of the Code shall be considered:

- For the summer season (from 15 June to 15 September) - located at the seaside with the exception of Varna and Burgas (effective 01.07.2012); (updated and amended on 16.04.2019, effect from 01.01.2020)
- For the winter ski season (from 15 December to 30 March) - Bansko, Borovets and Pamporovo (effective 01.07.2012); (updated and amended on 16.04.2019, effect from 01.01.2020)

(amended on 16.04.2019)

information on prescriptions (indications, warnings, etc.), authorized in countries where the product is registered for use should include an explicit statement that authorization conditions vary across countries. *(amended on 27.09.2011, in force since 01.01.2012)*

9.4. Hospitality offered in connection with promotional, professional or other scientific events, shall be limited to travel, meal, accommodation and registration fees. The cost of a single offering of food and beverages to a healthcare professional cannot exceed the equivalent of 100 Levs including VAT. Outside the territory of Bulgaria, the monetary threshold set in the country where the event takes place (i.e. the "host country") shall prevail. *(updated and amended on 22.10.2014, effect from 22.10.2014)*

9.5. Hospitality may be extended only to healthcare professionals qualified as participants in their own right, for participation in an event concerning the domain in which the respective healthcare professional is in practice. No hospitality shall be offered or extended to accompanying persons.

9.6. All forms of hospitality extended to healthcare professionals must be reasonable and be strictly limited to the main purpose of the event. "Reasonable level" of hospitality provided as a rule means that it must not exceed what healthcare professional recipients would normally be prepared to pay for themselves. The hospitality provided must not cover a stay exceeding the officially declared duration of the event, unless the arrival on the previous day or the departure on the next is necessary for the effective planning of the trip. If the participant/participants wish to arrive earlier or to leave later, all expenses connected with their extra stay, may not be paid or reimbursed by the sponsoring company. *(updated and amended on 27.09.2011, effect from 01.01.2012) (updated and amended on 16.04.2019, effect from 01.01.2020)*

9.7. Hospitality shall not include sponsoring or organising entertainment (e.g., sporting or leisure) events in free from research/work programme time.

9.8. Organisation and sponsorship of an event by a company: *(updated and amended on 16.04.2019, effect from 01.01.2020)*

9.8.1 Companies organise and sponsor events for healthcare professionals in compliance with the provisions of this code. (updated and amended on 16.04.2019, effect from 01.01.2020)

9.8.2 Events, on the territory of the Republic of Bulgaria, organised or sponsored by a company, should not have duration of above three twenty-four hour periods. No less than 6 hours of each full day of the event shall be arranged for effective[4] working/scientific program. No less than 3 hours of each half-day[5] of the event shall be effectively committed to the working/scientific program, when the remainder of the day facilitates the arrival or departure of participants. (updated and amended on 16.04.2019, effect from 01.01.2020)

9.8.3 International events organised or sponsored by a company should not continue more than five twenty-four hour periods. No less than 6 hours of each full day of the

[4] The effective working/scientific program does not include the time set for registrations, coffee breaks, lunches, dinners and other events that have no scientific or educational purpose. (updated and amended on 16.04.2019, effect from 01.01.2020)

[5] Half-day is each day of the programme in which registration begins before 6 p.m. or the check-in is after 10 a.m. (updated and amended on 16.04.2019, effect from 01.01.2020)

event shall be arranged for the working/scientific program. This provision shall not be applied to events organized by the main office of the company. (updated and amended on 16.04.2019, effect from 01.01.2020)

9.9. The expenses of healthcare professionals related to the event sponsored or organized by the company shall be covered by bank transfers, by checks or postal order, on the grounds of primary supporting documents of the expenses made. If the participants are given daily allowances, this shall be arranged in accordance with the Bulgarian legislation. Daily allowances as defined by Bulgarian legislation cannot be provided. When organizing international events in which expenses are covered or healthcare professionals are otherwise sponsored to participate in the event, the Code of Ethics is applied to the expense coverage/sponsorship along with the jurisdiction in place where the healthcare professional conducts his/her medical practice and not the regulations valid for the country hosting the international event. *(updated and amended on 27.09.2011, effect from 01.01.2012)*

9.10. The maximum permissible limits for hospitality are:

9.10.1 Flight tickets (to Bulgaria and international) – economy class. Business class is allowed only with the exception of non-stop flight with over 6 hours duration.

9.10.2 Stay in a hotel – hospitality is limited to the value of an accommodation and breakfast package. All additional expenses are on the account of the participant.

9.11. (Deleted as of 01.01.2014)

9.12. Hospitality may not lay down conditions for obligation on behalf of the healthcare professional to prescribe or to encourage prescription of a specific medicinal product.

9.13. The amount of presentation/lecturer fees, leading/ moderating meetings and events, conducting courses/ trainings (for Bulgarian residents) is determined in correspondence with significance of the event (of regional or national character), the academic status of the lecturer and the form and duration of the presentation. The fees shall not be higher than 1.5 times of the average salary for professionals employed in the sphere of healthcare and social services with a full-time employment contract, determined by the National Statistics Institute[6], for non-academic persons, and 2 times the average salary amount for professionals employed in the sphere of healthcare and social services with an employment contract, for academic persons. (updated and amended on 16.04.2019, effect from 01.01.2020)

9.14. The provisions of this section shall be applied to cases when the event is organized by a third party but completely or partially financed by a company.

9.15. Member companies of ARPharM, when in the process of deciding whether to sponsor a national event, to participate in this event or to sponsor healthcare professionals to participate in the event, should consult the database for a preliminarily estimate of such an event, with the database available on the website of ARPharM. The database of national events under Art. 9.1 above, based on the system for preliminary assessment and monitoring of events in respect of

[6] The limits of the fees are calculated accordingly to the amount of the average salary of the people employed in the public and private human healthcare and social sector, determinate by the National Statistics Institute for the previous year, corrected with the inflation for the current year, which inflation is accumulated as per the moment of signing of the service agreement. (updated and amended on 16.04.2019, effect from 01.01.2020)

the Ethics Code, is designed and procedures established by the Managing Board of the Association. *(Amended on 27.09.2011, in force since 01.01.2012)*

9.16. Member companies of ARPharM, in the process of deciding whether to sponsor an international event, to participate in this event or to sponsor healthcare professionals to participate in the event, should consult the database for a preliminary estimate of such an event, the database being available on the website www.efpia-e4ethics.eu. *Amended on 27.09.2011, in force since 01.01.2012)*

9.17. A preliminary estimate of a national or international event can not be used to assess the quality or content of the scientific program or the quality of speakers. Each company autonomously decides whether to sponsor or participate in an event or to sponsor the participation of healthcare professionals in this event. Member Companies of ARPharM should consider the rules and regulations of this Code of Ethics when deciding whether to participate or sponsor the event, and whether to sponsor the participation of healthcare professionals in this event. *(Amended on 27.09.2011, in force since 01.01.2012)*

ARTICLE 10

INFORMATION AND EDUCATIONAL MATERIALS. ITEMS OF MEDICAL UTILITY

10.1. (Amended on 26.11.2013, in force since 01.01.2014) Information and educational materials can be provided to a healthcare professional if:

10.1.1. They are not high in value.
10.1.2. They are directly relevant to medical practice or pharmacy.
10.1.3. Providing them will improve patient care.
10.1.4. Their provision is not an incentive for the healthcare professional to recommend, prescribe, supply, sell or administer a specific medicinal product.

10.2. If they are not high in value; information and educational materials with value not higher than 40 Levs including VAT (amended on 27.09.2011, in force since 01.01.2012, amended on 26.11.2013, in force since 01.01.2014)

10.3. Items of medical utility only, aimed at educating healthcare professionals or providing patient care which are not high in value and cost up to 100 Levs including VAT. These items may be supplied with a view to support healthcare professionals' activity and to overcome the consequences of the insufficient public funding for healthcare in Bulgaria. The items provided must not be part of the necessary/mandatory equipment for the medical practice and may include medical and scientific literature. (amended on 26.11.2013, in force since 01.01.2014).

ARTICLE 11

GRANTS IN SUPPORT OF HEALTH CARE AND SCIENTIFIC RESEARCH

(amended on 26.11.2013, in force since 01.01.2014)

11.1 Grants, pecuniary or in kind, for health care organisations and medical societies who carry out healthcare and/or scientific research and have not been provided for in this Code or by the

Code of ARPharM for interaction with patient organisations, may be provided by a Company only if:

11.1.1. They are in support of healthcare and scientific research

11.1.2. They are documented and the documents are stored by the Donor and could be disclosed upon request by the Executive Director of the Association, by another Company or by the Committee.

11.1.3. They are not an incentive to purchase, supply, dispense or administer medicinal products.

11.2 Under this Article 11, grants to Healthcare professionals – physical persons, are not allowed.

11.3 Donations in the form of repair work, technical equipment and furniture may be provided only to hospitals for inpatient care, outpatient and diagnostic consultative centres.

11.4 Donations of medicines may be provided only to hospitals for inpatient care.

11.5 Sponsorship of healthcare professionals for participating in events is provided for under Article 9.

ARTICLE 12

Payment for services

12.1 Contracts between companies and healthcare organizations or medical societies for providing healthcare services are only allowed if the services in question are provided by the organization to the Company to enhance healthcare or scientific research; and do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

ARTICLE 12a
(amended on 26.11.2013, in force since 01.01.2014)

Sponsorship of healthcare professionals

12a.1. Companies comply with the applicable codes in the selection and sponsorship of healthcare professionals to participate in training and events. Healthcare professionals cannot be provided compensation only for participating in events. In the case of sponsorship of healthcare professionals to participate in an international event, the provisions of the national code of the country where the healthcare professional practices/exercises activities apply.

ARTICLE13

The Use of Consultants

13.1 It is permitted to use healthcare professionals, on individual or in group practice, as consultants and advisors, whether in groups or individually, for services such as involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research. The consultants can receive an appropriate

remuneration for their services as well as a compensation for the expenses made during the execution of the contract obligations. (updated and amended on 16.04.2019, effect from 01.01.2020)

13.2 The consultancy services must fulfil all the following criteria:

13.2.1 a written contract, which specifies the nature of the services to be provided and, the basis for payment of those services;

13.2.2 a legitimate need for the services has been clearly identified (according to the SOP of the company) by the Company in advance of requesting the services and entering into arrangements with the prospective consultants;

13.2.3 the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the qualification necessary to evaluate whether the particular healthcare professionals meet those criteria;

13.2.4 the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;

13.2.5 the contracting company maintains records concerning (according to the SOP of the company), and makes appropriate use of, the services provided by consultants;

13.3. The hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;

13.4. The written contracts between the consultants and the companies should include:

13.4.1 provisions regarding the obligation of the consultant to declare that he/she is a consultant to the Company in any public appearance about a matter that is the subject of the agreement or any other issue relating to that company.

13.4.2 provisions regarding the obligation of the healthcare professionals that are still practicing their profession, being employed by the company, to declare his/her employment arrangement with the company in any public appearance about a matter that is the subject of the employment or any other issue relating to that company.

13.5 Article 13 is not applicable in cases of healthcare professional answering questionnaires for market research (such as one-off phone interviews or mail/e-mail/internet questionnaires); provided that the healthcare professional is not consulted in a recurring manner and that the remuneration is up to 60 BGN, VAT inclusive.

13.6 If a healthcare professional attends an event in a consultant or advisory capacity the relevant provisions of Article 9 shall apply.

ARTICLE 14

Non-interventional Studies

14.1 A non-interventional study with medicines authorized for use in Bulgaria is conducted to obtain additional information about the product prescribed in the usual manner in accordance with the conditions specified in the authorization permit. Regarding the regulation of non-interventional studies, the Bulgarian law must be respected; (*updated and amended on 27.09.2011, effect from 01.01.2012)*

14.2 The inclusion of a patient in a specific therapeutic strategy is not determined in advance by a trial protocol but falls within the established practice whereof the prescription of the drug to the patient is clearly separated from the decision for that patient to be included in the study. With regard to patients any additional procedures for diagnosis or monitoring shall not apply. Epidemiological methods shall be used for the analysis of data collected. *(updated and amended on 27.09.2011, effect from 01.01.2012)*

14.3 Any non-interventional study should meet the following conditions cumulatively:

14.3.1. The study shall be conducted for scientific purposes;

14.3.2. There shall be in place: (a) a written plan or protocol of the study and (b) written agreements between the healthcare professionals and / or institutions in which the study will be conducted on one hand and on the other – the Company sponsoring the study, identifying the nature of the services to be provided and the remuneration for these services in compliance with art. 14.3.3. below. (*amended on 27.09.2011, in force since 01.01.2012)*

14.3.3. Any remuneration provided by the Companies for the healthcare professionals, taking part in the non-interventional studies is reasonable and reflects the fair market value of the work performed;

14.3.4. The participation of the healthcare professional in non-interventional studies is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;

14.3.5. The study protocol has been approved by the research unit within the company and the study is conducted under the supervision of the scientific units of the company as per the provisions of Article 15.12. *(amended on 27.09.2011, in force since 01.01.2012)*

14.4. The results of studies, held in Bulgaria only, must be analysed by or on behalf of the Company and made available to the company's scientific service (as described in Article 15.12) within 180 days of finalising the study, , which service shall maintain records of such reports for at least 5 years. The Company should send a summary of the results to all healthcare professionals that participated in the study and should make the summary available to the Ethics Commission upon motivated request. If the study shows results that are relevant to the assessment of the benefit – risk ratio, the results summary should be immediately sent to the competent authority. *(amended on 27.09.2011, in force since 01.01.2012)*

14.5 Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion and advertising of any medicinal product/products.

14.6 It is obligatory for the companies to comply with all the provisions listed above for all other types of studies, including epidemiological studies and registries and other studies that are

retrospective in nature. In any case, when healthcare professionals are involved, such studies are subject to Article 12.

14.7 Upon a well-grounded request by the Ethics Commission, the Company shall submit documents related to the conducted non-interventional study. Failure to provide information by the Company regarding that non-interventional study or obstructing the Ethics Commission in examining that study shall constitute a violation of the Code of Ethics. *(amended on 27.09.2011, in force since 01.01.2012)*

ARTICLE15

Medical sales representatives

15.1 Companies in cooperation with ARPharM are obliged to continuously provide training and education to the medical sales representatives.

15.2 Medical sales representatives may use only promotional or advertising materials prepared in compliance with the provisions of this code.

15.3 Oral statements of medical sales representatives should not violate the provisions herein.

15.4 Medical sales representatives must be acquainted with the provisions of this code, with the provisions of the current Bulgarian legislation with regard to the advertising and promotion of medicinal products, to be adequately trained and to be well versed as to enable them to provide the healthcare professionals with correct and complete information on the medicinal products which they promote.

15.5 The frequency, duration and the time of interviews arranged at the healthcare professional, as well as the manner of conducting them, should not cause inconvenience to the healthcare professional.

15.6 During each visit, Medical Sales Representatives must give the healthcare professionals visited, or have available for them, a summary of the product characteristics for each medicinal product they advertise/present.

15.7 The wishes of the distinct healthcare professional and the internal rules of the respective medical establishment should be observed by the medical sales representatives.

15.8 Medical sales representatives may not pay charges or promise or provide any other material goods to arrange an interview with a healthcare professional. When arranging or carrying out an interview, Medical Sales Representatives must not mislead as to their identity or that of the company they represent.

15.9 The provisions of art. 15 shall also apply to persons employed by third parties that perform the functions of medical sales representatives, as well as to all company staff, who are not medical representatives, but promote and/or advertise medicinal products to healthcare professionals.

15.10 Each company signed the Code of Ethics must have available at least one trained employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the Code are met.

15.11 All company staff, and any personnel retained by way of contract with third parties, who are concerned with the preparation or approval of promotional material or activities must be fully conversant with the requirements of the Codes of ARPharM, EFPIA, IFPMA and relevant Bulgarian laws and regulations.

15.12 Every company must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non- interventional studies.

15.12.1 the scientific service must include a medical doctor or a pharmacist who will be responsible for approving any promotional material before release. Such person must certify in an appropriate manner (by putting a signature and name under) that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the Applicable Codes and the applicable Bulgarian laws and regulations, is consistent with the SPC and is a fair and truthful presentation of the facts about the promoted medicinal products.

15.12.2 the scientific service must include a medical doctor or a pharmacist, who will be responsible for the oversight of any non-interventional study (including the review of any responsibilities assumed by Medical Sales Representatives and other company/third parties contracted employees relating to such studies). Such person must certify (by putting a signature and name under) that he or she has examined the protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the Applicable Codes and the applicable Bulgarian laws and regulations.

ATICLE 16

Materials used by the Medical Sales Representatives

16.1 One of the main principles of the present code is that any promotional or advertising claim should be accompanied by the SPC or by information consistent with the data contained in the SPC, at the same time specifying the date of its latest approval by BDA/EMA. When the intention is to provide for several forms of promotional materials, the SPC or the information consistent with the data contained in the SPC must be included at least once.

16.2 Audio-visual materials must be accompanied by a document containing the information under article 16.1.

16.3 Advertising and promotion materials on prescription-only medicinal products may be supplied only to healthcare professionals, with the exception of the cases, acceptable according to the Bulgarian legislation. Distribution of such materials at places accessible to the general public, such as pharmacies, waiting-rooms and corridors in healthcare facilities and etc., is prohibited.

ARTICLE 16a

(new, adopted on 27th of September 2011)

Samples

16a.1 Samples of medicinal products can by exception be given to a healthcare professional who is authorized to prescribe the medicinal product in his/her practice, in order to acquaint the healthcare professional with the medicinal product and subject to the provisions of this Code. Only samples from new products are provided. Under this article of the Ethics Code a "new product is such for which new authorization for use is granted or an authorization to use the product for a new therapeutic indication. When there is change in the authorization for use due to differences in the dosage or packaging of the medicine, but not in any of the therapeutic indications, the product is not considered "new" for the purposes of this article of the Ethics Code.

16a.2 A healthcare professional can not be provided samples of the medicinal product as an incentive to recommend, prescribe, sell or use this product in his/her practice.

16a.3 Samples of medicinal products containing psychotropic or narcotic substances subject to control under the Law for Control of Narcotic Substances and Precursors, shall not be provided.

16a.4 The total number of samples of a medicinal product that any healthcare professional can receive shall be no more than 2 packs of the same formula of the medicinal product per year for a period of 4 years after the date the healthcare professional asked for the first sample of the new product.

16a.5 Samples of medicinal products shall be given only in response to a written request by the healthcare professional who is authorized to prescribe this medicine. The written request must be signed and dated and completed by the healthcare professional requesting the sample.

16a.6 Companies must have in place systems for adequate control and accountability of the samples they give away. The systems should allow for clear reporting of at least the following: healthcare professional requesting, respectively receiving a sample, as well as type, quantity and time in providing those samples of a medicinal product, subject to the conditions of Art. 16a.4. above. The company is obligated to keep at least five years information about the samples given and be able to submit it at the request of the Ethics Commission.

16a.7 Samples of the product shall be no larger than the smallest presentation of that particular medicine in Bulgaria and shall be given to healthcare professionals together with the Summary of the product characteristics.

16a.8 Each sample should be labelled "Free sample - not for sale" or words to that effect.

16a.9 Notwithstanding the above, samples of medicinal products are given to senior medical schools and medical colleges in the quantities needed for training purposes and subject to the provisions of Art. 16a.6 above.

Article 16b
(adopted 26.11.2013, in force since 01.01.2014)

Ban on gifts

16b.1. Healthcare professionals can not be provided or offered gifts or other material benefits in cash or in kind.

Article 17

Ethics Commission

17.1 Ethics commission consists of 9 members and a legal advisor. The legal advisor shall give advice and is not entitled to vote.

17.2 The Chairperson and the Deputy Chairperson of Ethics Commission are appointed after commission establishment by its members through simple majority. The Deputy Chairperson of Ethics Commission shall perform the functions of the Chairperson on his/her unavailability. In case both heads of the Commission are not available, the Commission shall appoint ad hoc a chairperson for the respective action or period.

17.3 Seven members of Ethics Commission are members of the Association and are elected by the General Assembly of the Association.

17.4 Two members of Ethics Commission are not members of the Association and are nominated by the Managing board of the association by proposals by the association members.

17.5 The mandate of Ethics commission members is for the duration of two years and may not coincide with the Managing board mandate. In time of change of the Ethics commission members, all the unclosed cases are being reconsidered from the new members of the Commission.

17.6 Ethics commission shall be in session in its regular or extended composition. The regular composition includes the members of Ethics Commission under art. 17.3. The extended composition includes the members of Ethics commission under art. 17.3 and under art. 17.4.

17.7 For the Ethics Commission sessions all its members must be properly informed in writing at least 7 days before the respective session is held throughout stating the agenda and enclosure of all the materials. The Commission has quorum and shall hold a session if at least 5 of its members under art.17.3 are present, when sitting in regular composition, and at lest 6 of its members, one of which is under art. 17.4., are present, when sitting in extended composition. In the cases for objective reasons the regular composition of the Ethics Commission cannot gather quorum for two sessions in succession, it is admissible a member under art. 17.4 to take part in the session.

17.8 Every member of the Commission is obliged to ask for non-joinder for the cases in which the company he/she represents is complainant or respondent or there are any circumstances which could raise well-founded doubts for his/her objectivity. In case the person who might be interested does not ask for non-joinder, the Commission officio or by the request of one of the parties, shall state a definition as in its voting the person in question does not take part.

17.9 The Commission issues Decisions when is ruling substantive litigations and Definitions when is reviewing procedure issues. The Chairperson is in its power to render disposals in the cases provided in this Code.

17.10 Each member of Ethics Commission is entitled to one vote. The Ethics commission shall take decisions by majority of the members present at the session.

Procedure of lodging and processing complaints

1. Any legal entity, natural person or trade representative office may submit a complaint in line with the present Code, hereinafter called for the purposes of this procedure – COMPLAINANT[7].
2. The company against which the complaint has been submitted shall be hereinafter called for the purposes of this procedure – RESPONDENT.
3. Each complaint should be lodged in written form in Bulgarian and should contain the following:
    - 3.1 Complainant – name and registered address in compliance with the court registration or the registration at the BCIC when the complainant is a legal entity or a representation office. Name and address of residence when the complainant is a natural person.
    - 3.2 Respondent – name and registered address in compliance with the court registration or the registration at the BCIC when the respondent is a legal entity or a representative office.
    - 3.3 The complaint must contain the name of the medicinal product/products and a description of actions and circumstances considered to constitute a violation of the present code.
    - 3.4 The complaint must be accompanied by materials supporting the claims for violation of the present code[8].
    - 3.5 The date on which the claimed violation has been determined by the complainant.
    - 3.6 The date on which the claimed violation has been performed.
    - 3.7 Date of lodgement of complaint.
    - 3.8 The specific provisions of this code considered by the complainant to be violated – article, paragraph.
    - 3.9 Receipt for payment of inclusive charge, when is applicable.
    - 3.10 Signature of the Complainant.

3a. Special cases:

3a.1. The Ethics Commission may on its own initiative commence proceedings against a company for violations of the Code, if the Ethics Commission has received enough data about an occurred breach of Art. 9, 10, 11, 12a and 16b of this Code. In this case, the Ethics Commission may conduct its own investigation to establish if there are sufficient facts and circumstances proving the existence of a violation of this Code; the investigation will be conducted by a person hired for the occasion. After the investigation, the hired person shall prepare a written report[9] of his/her findings and submit it to the Ethics Commission and the Company, suspected of committing an offense. In the event that, according to the report there are reasons to allow the complaint, the Ethics Commission shall initiate proceedings and Art. 6.5 and the subsequent provisions of the procedure for placing and reviewing of complaints shall apply accordingly. *(updated and amended on 27.09.2011, effect from 01.01.2012)*

[7] The complaint should not contain names or other personal information of particular medical professionals. In cases where these details attend they will be deleted in the adoption of the complaint in the records of the Association.
[8] The materials should not contain names or other personal information of particular medical professionals. In cases where these details attend they will be deleted in the adoption of the complaint in the records of the Association.
[9] The report should not contain names or other personal information of particular medical professionals

3a.2. For cases where the Claimant sets out the allegations of violation of Art. 9, 10 and 11 of this Code, the complaint may not contain materials in support of the Claimant's statements, but shall contain evidence that such materials can be collected. In such cases, during the proceedings to review the complaint, the Ethics Commission may (a) decide on its own initiative or at the request of a party in the proceedings, that the procedure for collection of evidence is applied pursuant to Art. 6.9.2. below and / or (b) assign the collection of evidence to a specially hired person *(updated and amended on 27.09.2011, effect from 01.01.2012)*

4. Each complaint and the documents attached to it should be lodged at the following address: To the attention of ARPharM Ethics Commission

1113 Sofia, Iztok,
19, F. J. Curie Str., Bl. 1, fl. 14, app. 26

5. The Complainant pays an inclusive charge to the amount of 900 BGN for the reviewing of every complaint. In the Commissions judgment when the complainant is a patient, a patient organization, healthcare professional, as well as in other cases, it may be redeemed by the payment of an inclusive charge.

6. Processing of complaints:
   6.1. Acceptability of complaint – the Chairman of Ethics Commission checks the complaint for availability of the obligatory requisites specified under art. 3 above, within 7 working days. Should the complaint lack one or more of the requisites, the complaint is returned to the complainant to be completed with the disposal of the Chairperson of the Ethics Commission.
   6.2. The Complainant fills in the missing in the complaint requisites within 7 working days from the receiving of the disposal under art. 6.1 above, by which the time for setting down a date for a session under art. 6.8 below, stops . If the Complainant does not fill in the missing requisites in the stated term, the complaint gets no access.

   6.3. The complaints are unacceptable if:
      6.3.1. complaints lodged in more than one month as of the date, on which the violation has been determined by the complainant, or in more than three months of the date, on which this violation has been made, are inadmissible and are not processed by Ethics Commission.
      6.3.2. are based on facts and/or activities which are beyond the scope of the Code of Ethics.
      6.3.3. are in pursuit only of the corporate interests of the Complainant.

   6.4. Should the Chairperson determinate evident reasons for the complaint to be unacceptable he/she leaves it with no access and brings it back to the Complainant with motivated Disposal, which Disposal could be appealed within 14 calendar days from its receipt by the Complainant in front of the regular composition of the Ethics Commission. The regular composition of the Ethics Commission passes a Definition on the acceptability of the complaint, which Definition is final.
   6.5. If the complaint is considered acceptable through a Disposal or a Definition, the Chairperson sends copies of the complaint, together with all the enclosed papers, to the respondent within 7 days from the Disposal/Definition decree.

6.6. The respondent may submit a written position within 15 calendar days as of the receipt of the copy of the complaint[10]. The Chairperson sends, with no delay, a copy of the position of the respondent to the complainant.

6.7. The Chairperson of Ethics commission shall appoint a person reporting on the matters concerning the complaint, at the same time with the appointment of the date of the Ethics Commission first session, which shall acquaint with the materials available and shall report at the first session of Ethics Commission[11].

6.8. The Chairperson of Ethics Commission shall appoint a session for consideration of the admissible complaints within 30 calendar days as of the date of their lodgement or the date of correcting the omissions in the complaints. Both parties are summoned by the Chairperson of Ethics commission at least 7 calendar days prior to the date they are expected to be held in written form.

6.9. In the first session on the complaint, after hearing the parties, the Commission expresses an opinion on the submitted evidence by both sides.

6.9.1. In this session both the complainant and the respondent may make new claims for collecting of evidence with a view to the position in writing of the respondent under art. 6.6.

6.9.2. If the claim is based on statements or materials provided by or related to a healthcare professional, whose identity must not be disclosed to the parties in the proceedings, including the members of the Ethics Commission, the designated Rapporteur for the proceedings should be allowed by the party which would benefit from such materials or statements, to meet with the healthcare professional and examine materials in their entirety. The results of the meeting with the healthcare professional shall be announced to the parties and to the other staff members of the Ethics Commission at the next session of the claim, without revealing the identity of the healthcare professional. Documents prepared by the Ethics Commission in connection with the hearing of the claim, which was held under such proceedings / orders, rulings and decisions shall not contain data identifying the healthcare professional. *(updated and amended on 27.09.2011, effect from 01.01.2012)*

6.9.3. Should there are no claims for collecting additional evidence or the Commission does not take into consideration such claims made, end of the evidence collecting procedure is called and the session proceeds substantive, where both parties state their arguments and accordingly have the right of replication and duplication.

6.10. Both parties should be equal in rights in the proceedings. This principal includes as well the right of equal time for pleading.

6.11. The Commission members can ask questions both parties, any time, as to clarify the disputable facts and positions.

6.12. The Commission reviews the complaint on the grounds of the claimed violations of the Code of Ethics mentioned in it only. The Commission cannot extend officio the subject or the parties of the complaint.

6.13. Ethics commission shall notify both parties about its decision/definition within 14 days from the date of its rendering and shall enclose a copy of it[12]. In the decision/definition

[10] The written statement of the defendant should not contain names or other personal information of particular medical professionals.

[11] The report should not contain names or other personal information of particular medical professionals.

[12] Decision / definition of the Ethical Commission should not contain names or other personal information of particular medical professionals

is explicitly stated the body in front of which the act is to be appealed as well as the terms for it.

6.14. Within 7 days as of the receipt of Ethics commission's decision which determines violation of the present code, the respondent is expected to submit a list of particular measures for termination of activities proved to be violating the present code, made in writing, signed by the person representing the company and a declaration stating intolerable attitude towards similar actions in the future.

7. Should the respondent confess, in writing, the claimed violation within 15 days as of the receipt of the copy of the complaint, he/she must inform Ethics Commission about the measures undertaken to eliminate harmful consequences / to restore the condition as existed prior to the violation, before the fist session has been held. In these cases, Ethics commission may cease the proceedings.
8. Should the respondent express objection against the claimed violation, he/she must indicate definite reasons for his/her objection, and if applicable, submit reasoning (for example scientific publications) supporting the objection before the Ethics commission.

Procedures for appeal of decisions taken by the Ethics Commission in its regular composition.

1. The respondent and the complainant may appeal the decision of the Ethics commission in its regular composition before the extended composition of Ethics commission within 15 days as of the decision receipt.
2. With regard to the submission and the consideration of the complaint against the decision of the Regular composition of the Ethics Commission, apply the provisions listed above, when are applicable.
3. The Chairperson of Ethics Commission appoints a session of Ethics commission in extended composition within 30 days as of the lodgement of complaint under p. 1. Both parties shall be summoned, in written, by the Chairperson of Ethics Commission at least 7 calendar days prior to the sessions being held.
4. The decision taken by Ethics commission in its extended composition shall be considered conclusive and shall not be subject to appeal[13].

<u>Sanctions</u>

1. When a violation of this code has been determined, the Commission imposes a monetary sanction of BGN 2000 to BGN 7000 depending on the nature and seriousness of the offense. *(updated and amended on 27.09.2011, effect from 01.01.2012)*

a. In cases of relapse (two or more offenses within 12 months), the Commission imposes penalty of twice the maximum penalty.

b. Monetary penalty is due within 30 days of receipt of the Commission's decision by the Respondent.

c. Imposed monetary sanctions are payable to the Association pursuant to Section 37 of the Articles of Association as an additional voluntary contribution.

[13] The decision of the extended composition of the Ethical Commission should not contain names or other personal information of particular medical professionals

2. When a breach of the Code of Ethics is established, the decision of Ethics commission shall be announced to the remaining companies that have signed the present code Depending on the nature and seriousness of the offense, the Commission may decide to announce the decision to the parent company *(updated and amended on 27.09.2011, effect from 01.01.2012)*

3. In cases of repetitive violation, the decision of Ethics commission may be announced to the competent authorities and professional organizations including international ones.
4. The Ethics commission may prescribe mandatory corrective actions for overcoming the harmful consequences. In this case, the Commission approves and monitors the implementation of the corrective actions taken. *(updated and amended on 27.09.2011, effect from 01.01.2012)*

5. In cases when the Ethics commission consider necessary, it may suggest exclusion from the association of the respective member-company. The exclusion is performed in compliance with the procedure provided in the Articles of Association.

General provisions

1. Ethics commission shall perform monitoring on observance of this code and shall issue annual reports which summarize its implementation, and which shall be sent to EFPIA.
2. The annual reports shall be sent to all member-companies and the Ethics Commission may recommend to the Managing Board of the association that the report be published in an appropriate manner.
3. The contents of annual report:
   - 3.1 Respondents to complaints in respect of which decisions have been taken stating violations of this code.
   - 3.2 Promotional and advertising activities and materials violating the provisions of this code.
   - 3.3 Provisions of the code that have been breached.
   - 3.4 Sanctions imposed.
   - 3.5 Number of complaints lodged and processed.
   - 3.6 Total number of violations of the code.
   - 3.7 Short summary in English in cases of precedent and subject of an international interest (taking into consideration that both results – determination violation or declaring no violation may be precedents/subject of an interest)
   - 3.8 In case of insignificant violations or in case no violation is determined, publishing of details on the case can exclude the name/names of the company/ies.
4. Ethics commission may use external experts in its working process.
5. Ethics commission administrative expenses related to the procedure, as well as payment of inclusive charge on complaints processing, including costs for the hired person pursuant to Art. 3a.1, respectively. 3a.2. of the Procedure for filing and hearing complaints, as well as for hearing the Complaint are *(updated and amended on 27.09.2011, effect from 01.01.2012):*
   - 5.1. Chargeable to the respondent – when a violation of this code is ascertained, and in the cases when the respondent acknowledges the claimed violation.
   - 5.2. Chargeable to the complainant, – when Ethics commission cannot find any violation of this code or the complaint is unacceptable.
   - 5.3. Chargeable to association's budget – when Ethics commission cannot find any violation of this code and the complainant is a person, different from a company, as used in the code.

Transitional and conclusive provisions

1. The present code was adopted by the members of ARPharM on 20th of April 2006 and came into effect as of 15th of June 2006, and is applied to violations performed after its coming into effect.

2. The actualisations of the Code are adopted as follows: on 10th of July 2008 and came into effect as of 31st of July 2008; on 27th of September 2011 and come into force on 1st of January 2012; on 26th of November 2013 and come into force on 1st of January 2014.

3. Non-member companies may adopt the present code and for them the code comes into effect as of the date on which it has been signed by the respective company, and shall be applied for violations performed after that date.

4. This Code and related procedures, inclusively penalties under points 2,3 and 4 of the respective chapter, shall be applicable to pharmaceutical manufacturing companies or MAH members of EFPIA, operating in Republic of Bulgaria through their subsidiaries companies, representatives, or other form under Bulgarian law, even if they are not full or associate members of ARPharM. *(updated and amended on* 27.09.2011 and come into effect on 01.01.2012*)*

5. ARPharM shall not bear any responsibility for damages that have occurred as a result of Ethics commission decisions concerning the implementation and interpretation of the provisions of this code.

ARPharM Code of Ethics was adopted by:

Abbvie ……

Alcon S.A. ……

Amgen Bulgaria EOOD ……

Angelini Pharma Bulgaria ……

Astellas Pharma Europe B.V. ……

AstraZeneca UK Ltd. ……

Bayer Healthcare Bulgaria ……

Berlin-Chemie (Menarini Group) ……

Boehringer Ingelheim Pharma ……

Chiesi Bulgaria .....

Eli Lilly ……

Genesis Pharma Bulgaria Ltd. .....

GlaxoSmithKline ……

Johnson & Johnson Bulgaria ……

Lundbeck ……

Merck Bulgaria EAD ……

MSD ……

Novartis Pharma Services Inc. ……

Novo Nordisk A/S ……

Pfizer ……

Roche Bulgaria ……

Sanofi ……

Servier Medical ……

Takeda GmbH ……

UCB ……