ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ

AMENDMENT

OF CODE OF ETHICS

ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINAL PRODUCTS

&

DISCLOSURE OF TRANSFERS OF VALUE BY PHARMACEUTICAL COMPANIES TO HEALTHCARE

PROFESSIONALS AND HEALTHCARE ORGANISATIONS

SUMMARY OF MODIFICATIONS

ANALYSIS OF MODIFICATIONS

1st MODIFICATION ARTICLE 8 DISGUISED PROMOTION		
ARTICLE 8		
CODE OF ETHICS	**SUGGESTED MODIFICATIONS**	**COMMENTS/REASON TO MODIFY**
(BEFORE): **Article 8.1. page 12** **8.1.** Promotional material and activities must not be disguised.	**AFTER:** **Article 8.1. page 12** **8.1.** Promotional material and activities must not be disguised. Patients' awareness and public awareness campaigns/events may constitute disguised promotion, especially if the conditions set out under Article 6 of this present Code are met.	Addition

2nd MODIFICATION

ARTICLE 16

DONATIONS/GRANTS TO INSTITUTIONS, ORGANISATIONS AND SCIENTIFIC SOCIETIES

CODE OF ETHICS	SUGGESTED MODIFICATIONS	COMMENTS/REASON TO MODIFY
(BEFORE): **Article 16.3., page 17** **16.3.** Donations, where allowed, may be in kind or in money. A donation in money must serve a specific purpose. e.g. to finance a research programme, educate HCPs, patients and patient caregivers or facilitate the recipient to purchase medical equipment or part of it. Donations in kind may involve medical equipment (instruments, devices), consumables and reagents. For donations of computers and peripherals, detailed description and documentation shall be required. Donations for the construction/renovation of building facilities are not permitted. Donations in money cannot be aimed to serve the recipient's purposes "in general". As of 1 January 2014 this category includes various medical or diagnostic instruments, scientific textbooks, electronic aids (mainly electronic connections to databases, supportive software and computers, books) exceeding€ 15 in value.	**AFTER:** **Article 16.3., page 17** **16.3.** Donations, where allowed, may be in kind or in money. A donation in money must serve a specific purpose. e.g. to finance a research programme, educate HCPs, patients and patient caregivers or facilitate the recipient to purchase medical equipment or part of it. Donations in kind may involve medical equipment (instruments, devices), consumables and reagents but it may not involve establishments that create a relationship of dependency (i.e. a contractual relationship for the supply of goods or services from the Donor to the Donee). For donations of computers and peripherals, detailed description and documentation shall be required. Donations for the construction/renovation of building facilities are not permitted. Donations in money cannot be aimed to serve the recipient's purposes "in general". As of 1 January 2014 this category includes various medical or diagnostic instruments, scientific textbooks, electronic aids (mainly electronic connections to databases, supportive software and computers, books) exceeding€ 15 in value.	Addition

3rd MODIFICATION

ARTICLE 18

PROVISIONS ON THE ORGANISATION OF TYPE A SCIENTIFIC EVENTS

CODE OF ETHICS	SUGGESTED MODIFICATIONS	COMMENTS/REASON TO MODIFY
(BEFORE): **Article 17.3. page18** **Conferences of scientific content** Conferences of scientific content are conferences, seminars and similar continuing education events held by state entities, including universities and public hospitals (clinics, laboratories, government agencies and so-cial security organisations and health units), non-profit scientific associations, as well as non-profit scientific institutions, public or private law legal entities, asso-ciations of health scientists, and scientific unions, ir-respective of legal form. These can be held in Greece or abroad and their entire programme is exclusively of scientific content (medical / dental / pharmaceutical / nursing / public health / health services). Included in this category are all respective events which are held in Greece or abroad by foreign agencies and which are sponsored by companies with registered office in Greece. ……	**AFTER:** **Article 17.3, page 18** **Conferences of scientific content** a) Conferences of scientific content are conferences, seminars and similar continuing education events held by state entities, including universities and public hospitals (clinics, laboratories, government agencies and so-cial security organisations and health units), non-profit scientific associations, as well as non-profit scientific institutions, public or private law legal entities, asso-ciations of health scientists, and scientific unions, ir-respective of legal form. These can be held in Greece or abroad and their entire programme is exclusively of scientific content (medical / dental / pharmaceutical / nursing / public health / health services). Included in this category are all respective events which are held in Greece or abroad by foreign agencies and which are sponsored by companies with registered office in Greece. b) Scientific Events are divided in the following categories: **i) Local/One day events:** **Organized** within the District of the registered seat of the HCO and addressed, mainly HCPs practicing within the same	Addition of Definitions

	District, or a District of the same Administrative Region, according to the definitions laid down in L. 3852/2010, as in force. Exceptionally, local events are also repetitive one-day events that take place throughout Greece and are addressed to HCPs of one District and the greater Region of this District, provided that the element of Local information prevails. [The Districts of Greece are 51, according to art. 1 of L. 3852/2010] □ For Local events accommodation costs are not, in principle, justified. Exceptionally, accommodation costs may be justified when there is a confirmed need of more than three (3) hours transport and the duration of the Program is, at least, four (4) hours. □ The maximum financing amount per pharmaceutical company with registered office in Greece and per event may not exceed the amount of five thousand (5,000) Euros. **ii) Regional:** □ **Organized** within the Region of the registered seat of the HCO and addressed το HCPs practicing within the same Administrative Region, according to the definitions laid down in L. 3852/2010, as in force. Exceptionally. Regional scientific events may also be considered the scientific events that are organized by HCOs of Panhellenic range and are addressed to HCPs of the grater Administrative Region, with maximum limit of three (3) events per year. □ For Regional events accommodation costs are not, in principle, justified. Exceptionally, accommodation costs may be justified when there is a confirmed need of more than three (3) hours transport and the duration of the Program is, at least, sixteen (16) hours. □ The maximum financing amount per pharmaceutical company with registered office in Greece and per event may not exceed the amount of ten thousand (15,000) Euros. [The Administrative Regions of Greece are thirteen (13), they are independent public entities and constitute the second	

	degree of Local Authorities: 1) Region of Eastern Macedonia-Thrace, 2) Region of Central Macedonia, 3) Region of Western Macedonia, 4) Region of Epirus, 5) Region of Thessalia, 6) Region of the Ionian Islands, 7) Region of Western Greece, 8) Region of Continental Greece, 9) Region of Attika, 10) Region of Peloponnese, 11) Region of the Northen Agean Sea, 12) Region of the Southern Aegean Sea and 13) Region of Crete (art. 3, L. 3852/2010) and **iii) Panhellenic:** **Organized** by an HCO of PanHellenic rang, i.e. an HCO that the majority of its members comes from any District or Region of Greece, without a more specific local bond of its registered seat. PanHellenic scientific events shall have a Program of, at least, twenty four (24) hours duration. The maximum financing amount per pharmaceutical company with registered office in Greece and per event may not exceed the amount of ten thousand (30,000) Euros. [As far as the PanHellenic scientific events are concerned, SfEE Member companies are strongly advised to consult with EOF's Circular in force regulating Scientific Events.] c) There are two main categories of Scientific Events: ……..	
(BEFORE): **Article 17.3. page18** **Chapter E.** **E. Conferences on Health / Medicinal Issues organized by advertising or other services supply**	**AFTER:** **Article 17.3. page18** **Chapter E.** **E. Conferences on Health / Medicinal Issues organized by advertising or other services supply companies.**	Addition

companies. Conferences organized in Greece by advertising or other services' supply companies, which undertake the whole cost of the organization, without promotional purposes, aiming through the participation of different stakehold-ers (i.e. HCPs, patients, members' of pharmaceutical companies, public officers), to the general information of the public and exchange of views about topical health and medicinal issues. The organization of such conferences presupposes the EOF approval procedure in line with the current circular in force regulating scientific conferences. The pecuniary level of the grants should be proportion-ate to the duration of the conference, according to the thresholds of type A conferences (N.B. article 19.1.).	Conferences organized in Greece by advertising or other services' supply companies, which undertake the whole cost of the organization, without promotional purposes, aiming through the participation of different stakeholders (i.e. HCPs, patients, members' of pharmaceutical companies, public officers), to the general information of the public and exchange of views about topical health and medicinal issues. Scientific Events of this type, since they are not organized by HCOs, do not fall under the scope of evaluation of SFEE's Evaluating Committee. Since the events of this Type are addressed to the wide public, pharma companies may participate only by means of a business sponsorship. Product promotion or speech is not allowed. The financing of the participation of HCPs by pharma companies, is also not allowed, according to art. 14 of this present Code and the relevant legislation in force. SfEE Member companies are advised to carefully examine the Program and the character of such events and to calculate the amount of their sponsorship taking under consideration the fair market value, according to the thresholds of type A conferences (article 19.2.7.) and the duration of the event.	
(BEFORE): **Did not exist**	**AFTER:** **Chapter F.** **F. Patients Awareness Events**	Addition

	a) Organised by Pharma Companies Patients Awareness Events organized by Pharma Companies are not allowed under the Greek legislation. **b) Organised by Patients Associations** The financing of Patients and in general Public Awareness Events on prevention organized by Patients Associations, are not subject to the approval of EOF. **c) Organised by HCOs** The financing of Patients and in general Public Awareness Events on prevention organized by HCOs are considered Type A scientific events and are subject to EOF's approval.	

4rth MODIFICATION

ARTICLE 18

PROVISIONS ON THE ORGANISATION OF

TYPE A SCIENTIFIC EVENTS		
CODE OF ETHICS	**SUGGESTED MODIFICATIONS**	**COMMENTS/REASON TO MODIFY**
(BEFORE): **Article 18.3., page 20** **18.3.** Domestic type A conferences are assessed by the SFEE committee for the evaluation of conferences and the results are posted on SFEE's e-platform (scientific.events.sfee.gr). The committee shall be set up by decision of the Board of Directors of SFEE and shall comprise the Compliance Officers of member companies and the Legal Advisor of SFEE, who will participate without the right to vote. The committee and its decisions shall be supervised by the Board of Directors of SFEE. Member companies are recommended to take into account the SFEE committee's evaluation for each conference before they decide to participate in any manner and consult the files posted on the platform (program, sponsorships, etc.).	**AFTER:** **Article 18.3., page 20** **18.3.** Domestic type A conferences are assessed by the SFEE committee for the evaluation of conferences and the results are posted on SFEE's e-platform (scientific.events.sfee.gr). The committee shall be set up by decision of the Board of Directors of SFEE and shall comprise the Compliance Officers of member companies and is supported, when needed, by SFEE's Lawyer, who will participate without the right to, vote. The committee and its decisions shall be supervised by the Board of Directors of SFEE. Member companies are recommended to take into account the SFEE committee's evaluation for each conference before they decide to participate in any manner and consult the files posted on the platform (program, sponsorships, etc.).	Addition because of conflict deriving from the participation of SfEE's Legal Advisor to the First Instance Committee for Code Compliance.
(BEFORE): **Article 18.3.1., page 20** **18.3.1.** Scientific events are uploaded to SFEE's platform for evaluation, at least **45 days** before the date of the event, to enable the timely commitment of companies with the organizing entities. .	**AFTER:** **Article 18.3.1., page 20** **18.3.1.** Scientific events are uploaded to SFEE's platform for evaluation, at least **45 days** before the date of the event, to enable the timely commitment of companies with the organizing entities. The following data/information shall be uploaded in SFEE's e-platform:	Addition for facilitation of the works of the Committee.

	A) EOF's approval to the Organising entity. B) The Program of the Event. C) The Sponsorship Package(s). D) Registration fees and accommodation costs, if applicable. E) The total amount of registrations in the respective event of previous year(s). F) their Statutes (once per year) Further to the above, HCOs and/or PCOs shall fill up the following declaration: "*I hereby declare that all data/information submitted to be evaluated are accurate, true, in accordance to SfEE's Code of Ethics provisions and addressed to SfEE's Member-companies."* Note: Any alteration of data/information submitted (e.g. reduction of the duration of the Program, entertaining events, change of the date, financial offer for the participation of accompanying members etc.) that takes place following the opinion of SfEE's Evaluating Committee, shall be construed as violations of this present Code. In case such alterations take place following the approval of a scientific event by SfEE's Evaluating Committee and prior to the date of the event, the Evaluating Committee shall immediately indicate such event with White color. ***Further to s*** ***such indication re-evaluation shall be possible only when the changes were due to sudden and unforeseeable situations and following a relevant decision by the Board of Directors.***	

5rth MODIFICATION

ARTICLE 19

GENERAL PRINCIPLES FOR ORGANISING CONFERENCES AND SCIENTIFIC EVENTS IN GREECE AND ABROAD

CODE OF ETHICS	SUGGESTED MODIFICATIONS	COMMENTS/REASON TO MODIFY
(BEFORE): **Article 19.1.1. page 22** **19.1.1.** SFEE supports and encourages the participation of increasingly more resident physicians in all categories of training and scientific events sponsored by its members, ensuring that the continuing education it already provides can be an effective investment for the future.	**AFTER:** **Article 19.1.1. page 22** **19.1.1.** SFEE supports and encourages the participation of increasingly more physicians and resident physicians in all categories of training and scientific events sponsored by its members, ensuring that the continuing education it already provides can be an effective investment for the future. However, SFEE advises its Member companies to undertake transfer of values to HCPs and HCOs under the terms and conditions of the Law and more specifically of art. 16 of LD 96/1976, of art. 126,127 of CMD 32221/2013, of the Medical Code of Ethics (L. 3418/2005) and in general any of any type of restrictive provision. According to the abovementioned legislation, any transfer of value, offer or promise of gifts, monetary benefit of benefits in kind to persons entitled to prescribe or provide medicinal products closely associated with daily HCP practice is not allowed, unless if such transfer of value, offer or promise of gift, monetary benefit of benefit in kind is of insignificant value, (i.e. up to EUR15 per item, VAT included, according to art. 14.1. of this present Code).	Modification

(BEFORE): **Article 19.1.2. page 22** **19.1.2.** Failure to comply with the following rules entails the imposition of sanctions in accordance with the SFEE Code enforcement procedure (see Chapter C). .	**AFTER:** **Article 19.1.2. page 22** **19.1.2.** Failure to comply with the following rules entails the imposition of disciplinary sanctions in accordance with the SFEE Code enforcement procedure (see Chapter C).	Modification
(BEFORE): **Article 19.1.10. page 22** **19.1.10.** It is not allowed to use venues that are renowned for their entertainment facilities or are extravagant (e.g. spas, resorts, casinos, etc.).	**AFTER:** **Article 19.1.10. page 22** **19.1.10.** It is not allowed to use venues that are renowned for their entertainment facilities or are extravagant (e.g. spas, resorts, casinos, places of religious observance etc.). Museums are allowed only if there is a separate appropriate room. The choice of the places in above raises a presumption of the prevalence of the entertaining events and alienates the educational/professional purposes and character of the event.	Modification
(BEFORE): **Article 19.2.3. b., page 23** **19.2.3. b.** all 4-star hotels which fulfil the cost requirement under the Code and have a conference hall, subject to the provisions on seasonality.	**AFTER:** **Article 19.2.3. b., page 23** **19.2.3. b.** all 4-star hotels with rooms and cost relevant to the market value, which fulfil the cost requirement under the Code (up to 150 Euros including breakfast and VAT) and have a conference hall, subject to the provisions on seasonality.	Modification
(BEFORE):	**AFTER:** **Article 19.2.7. page 23** The maximum financing amount per pharmaceutical	Modification

Article 19.2.7. page 23

The maximum financing amount per pharmaceutical company with registered office in Greece and per event may not exceed the following limits:

Type of conference Type held in Greece	**Maximum limit (including VAT)**
Worldwide/International*	Up to 30.000 €
PanHellenic Conferences (One per acknowledged specialty of the Central Health Council with a two days program).	Up to 30.000 €
Regional Conferences (two days/ 8h program for each day)-three per year.	Up to 20.000 €
One-day Scientific Events (scientific program of at least 4 hours)	Up to 5.000 €
Scientific events held by Hospitals, University Clinics, NHS clinics, Scientific events held by Hospitals, University Clinics, laboratories, NHS clinics, private hospitals and clinics (a program of at least 4 hours per day)	Up to 2.500 € (including. VAT) per company, with a maximum limit of €10,000 (VAT included) in total for all companies

***** International/ Worldwide scientific events that take place in Greece organized by a foreign scientific institution/ association or co-organized with a Greek scientific institution/ association (not when the organizer is a Greek scientific institution/ association acting under the auspices of a foreign institution/association acting under the auspices of a foreign institution).

company with registered office in Greece and per event may not exceed the following limits:

Type of conference Type held in Greece	**Maximum limit (including VAT)**
Worldwide/International*	Up to 30.000 €
PanHellenic Conferences	Up to 30.000 €
Regional Conferences	Up to 15.000 €
Local/One-day Scientific Events	Up to 5.000 €
Scientific events held by Hospitals, University Clinics, NHS clinics, Scientific events held by Hospitals, University Clinics, laboratories, NHS clinics, private hospitals and clinics (a program of at least 4 hours per day)	Up to 2.500 € (including. VAT) per company, with a maximum limit of €10,000 (VAT included) in total for all companies

***** International/ Worldwide scientific events that take place in Greece organized by a foreign scientific institution/ association or co-organized with a Greek scientific institution/ association (not when the organizer is a Greek scientific institution/ association acting under the auspices of a foreign institution/association acting under the auspices of a foreign institution).

the organizer is a Greek scientific institution/ association acting under the auspices of a foreign institution/association acting under the auspices of a foreign institution).		
(BEFORE): **Article 19.4.3., page 24** **19.4.3.** Satellite conferences sponsored by pharmaceutical companies do not entail credits. Sponsorship of HCP participation and domestic conferences in general are permitted, provided that the event has been approved by EOF, the venue is appropriate for business purposes, has a conference hall for the event and is in line with the seasonality criterion, the daily accommodation cost does not exceed EUR 140 and the Conferences Committee of SFEE has issued a positive opinion on the conference……	**AFTER:** **Article 19.4.3., page 24** **19.4.3.** Satellite conferences sponsored by pharmaceutical companies do not entail credits. Sponsorship of HCP participation and domestic conferences in general are permitted, provided that the event has been approved by EOF, the venue is appropriate for business purposes, has a conference hall for the event and is in line with the seasonality criterion, the daily accommodation cost does not exceed EUR **150** and the Conferences Committee of SFEE has issued a positive opinion on the conference……..	Typo Correction
(BEFORE): **Article 19.6.5., page 25** **19.6.5.** Hospitality for participants should not include purely entertainment events. Venues should be selected carefully and based on their conference facilities rather than recreation or entertainment facilities.	**AFTER:** **Article 19.6.5., page 25** **19.6.5.** Hospitality for participants should not include purely entertainment events. Venues should be selected carefully and based on their conference facilities rather than recreation or entertainment facilities. The criteria applying for the choice of the venue of the event on Type A events are also applicable for the choice of venue on Type B events. The venue of the event shall be accessible to the majority of the participants and of reasonable cost.	Addition

6rth MODIFICATION **ARTICLE 24** **MARKET RESEARCH**		
CODE OF ETHICS	**SUGGESTED MODIFICATIONS**	**REASON TO MODIFY**
(BEFORE):	**AFTER:**	Modification

Article 24.1., page 29 **24.1.** Market research refers to any organised effort to collect information about the market and consumers of products or services.	**Article 24.1., page 29** **24.1.** Market research refers to any systematic data collection and analysis of opinions or positions of persons or organisations with the application of the methods of the applied social sciences aiming to support people or bodies to take a decision.	
(BEFORE): **Article 24.2., page 29** **24.2.** Market research is a valid method for recording the data and characteristics of the pharmaceutical market.	**AFTER:** **Article 24.2., page 29** **24.2.** Market research is a valid method for recording the data and characteristics of the pharmaceutical market. Market Research is different from the non-interventional studies (see Annex II, Schedule 5), have a commercial purpose and intendent to internal use.	Modification
(BEFORE): **Article 24.3., page 29** **24.3.** Market research can be conducted: i. either through questionnaires to which subjective answers are given by a sample that is representative of the reference population, i.e. the HCPs; ii. or through questionnaires given to groups comprising a representative sample of the population under examination (focus groups - qualitative market research), i.e. the HCPs, in order to obtain a synthesis of answers.	**AFTER:** **Article 24.3., page 29** **24.3.** Market research can be conducted: i. either through questionnaires to which subjective answers are given by a sample that is representative of the reference population, i.e. the HCPs (quantitative research); ii. or through a discussion guide (focus groups or in-depth interviews) to groups or personal interviews constituted by a representative sample of the population under examination, in order to obtain a synthesis of opinions.	Modification
(BEFORE):	**AFTER:** **Article 24.4., page 29**	Modification

Article 24.4., page 29 **24.4.** Market research must be unbiased, must not be focused on promoting sales, and must not aim at influencing the opinion of the participating HCPs.	**24.4.** Market research must be unbiased, must not be focused on promoting sales, and must not aim at influencing the opinion of the participating HCPs and is conducted for exclusively commercial purposes	
(BEFORE): **Article 24.5., page 29** **24.5.** In each market research, care must be taken to ensure the random and representative selection of the participating HCPs.	**AFTER:** **Article 24.5., page 29** **24.5.** Each Market Research shall be conducted through certified "Market Research" companies, which must abide by the principles of ESOMAR/ EphMRA (http://www.esomar.org, http://www.ephmra.org) as well as by the relevant provisions of the personal data protection legislation and of the pharmaceutical legislation in general and especially the provisions regarding pharmacovigilance. In each Market Research care should be taken to ensure the random but representative choice of the participants to the same.	Modification
(BEFORE): **Article 24.6., page 29** **24.6.** The data collected from HCPs and referring to patients must be in aggregate form. No personal patient data must be collected during market research, since this is regarded as a non-interventional/pharmaco-epidemiological study, governed by the rules described in Article 26 of the present Chapter of the Code.	**AFTER:** **Article 24.6., page 29** **24.6.** The data from HCPs referring to patients shall be collected and delivered fully anonymized and in aggregate form.	Modification
(BEFORE):	**AFTER:**	Modification

Article 24.7., page 29 **24.7.** Market research does not include any patient enrolment and/or randomisation.	**Article 24.7., page 29** **24.7.** Market research does not include any patient enrolment and/or randomisation.	
(BEFORE): **Article 24.8., page 29** **24.8.** Market research cannot be retrospective/prospective; it is a snapshot.	**AFTER:** **Article 24.8., page 29** **24.8.** Market Research shall be a snapshot, even if it refers to the past or future intentions, always to random/representative sample of population.	Modification
(BEFORE): **Article 24.9., page 29** **24.9.** Information and statistical results of market research may be used for promotional purposes, provided that the identity of the research (who, when, where, which sample) is clearly stated. In any case, the collection and the use of research data must be clearly distinct processes.	**AFTER:** **Article 24.9., page 29** **24.9.** Information and statistical results of market research may be used for commercial purposes, provided that the identity of the research (who, when, where, which sample) is clearly stated. In any case, the collection and the use of research data must be clearly distinct processes.	Modification
(BEFORE): **Article 24.10., page 29** **24.10.** Market research must be conducted in a manner that does not affect the credibility and reputation of the	**AFTER:** **Article 24.10., page 29** **24.10.** Market research must be conducted in a manner that does not affect the credibility and reputation of the pharmaceutical industry.	Modification

pharmaceutical industry.		
(BEFORE): **Article 24.11., page 29** **24.11.** Market research is usually conducted by certified market research companies, which must abide by the principles of ESOMAR/ EphMRA (European Society of Market Research, http://www.ephmra.org).	**AFTER:** **Deleted.**	Modification
(BEFORE): **Article 24.12., page 29** **24.12.** When the collection of data in the context of market research is conducted by a pharmaceutical company, the principles of ESOMAR/EphMRA should be followed. In this case, no fee is provided for HCPs participating in the research.	**AFTER:** **Article 24.12., page 29** **24.11.** When the collection of data in the context of market research is conducted by a pharmaceutical company, without the involvement of a Market Research company, the principles of ESOMAR/EphMRA should be followed. In this case, no fee is provided for HCPs participating in the research.	Modification
(BEFORE): **Article 24.13., page 29** **24.13.** Medical sales representatives may not be involved in the conduct of market research.	**AFTER:** **Article 24.12., page 29** **24.12.** Medical sales representatives may not be involved in the conduct of market research.	Modification
(BEFORE): **Article 24.14., page 29**	**AFTER:** **Article 24.14., page 29**	Modification

24.14. When pharmaceutical companies enter into contracts with market research companies, they may grant to Healthcare Professionals a reasonable compensation with regard to the time spent, which may not in any case exceed two hours.	**24.13.** When pharmaceutical companies enter into contracts with market research companies, they may agree for a reasonable compensation to be given to Healthcare Professionals, taking under consideration the working time spent by the HCP, which may not in any case exceed two hours.	

7th MODIFICATION

CHAPTER B

Article 4

CODE OF ETHICS	SUGGESTED MODIFICATIONS	COMMENTS/REASON TO MODIFY
(BEFORE): **Article 4.2., page 35-36**	**AFTER:)** **Article 4.2., page 35-36**	

4.2. *Sanctions.* The First-Instance Committee of Article 1, Chapter C (Compliance Monitoring Process) of the present Code, if, after examining an allegation/complaint received by it, rules that there is a violation of Articles 1, 2 and 3 of this Chapter B of the Code, may impose to the non-compliant SFEE member company the following sanctions, which shall be enforced after the period for referring the case to the Second-Instance Committee has elapsed without effect or after the issuance of the decision of the Second-Instance Committee, unless the respondent accepts the violation or part thereof: (a) Prompt publication of the text of the decision on SFEE's website. (b) A financial penalty of up to EUR 25,000. This amount shall be deposited by the pharmaceutical company to a dedicated bank account held by SFEE. The Second Instance Committee of Article 1, Chapter C of the present Code may impose to a SFEE member company that does not comply with the decision of the First Instance Committee a financial penalty of up to EUR 50,000, further to the sanctions mentioned above. These amounts shall be deposited by the pharmaceutical company to a dedicated bank account held by SFEE, not later than 30 business days of the date of issuance of the decision. In the event that the SFEE member company has not complied, or has not properly complied, with the sanction imposed on it by the Second Instance Committee, the Second Instance Committee shall meet upon request of the complainantand shall decide on further sanctions, which may amount up to three times the initially imposed sanction. In the event that the SFEE member company still fails to comply with the decision of the Second Instance Committee, the latter shall refers the issue to the Disciplinary Board of SFEE, which may decide the expulsion of the member.	**4.2.** *Sanctions.* a) The First-Instance Committee of Article 1, Chapter C (Compliance Monitoring Process) of the present Code, if, after examining an allegation/complaint received by it, rules that there is a violation of Articles 1, 2 and 3 of this Chapter B of the Code, may impose to the non-compliant SFEE member company a financial penalty of up to EUR 25,000. Such penalty shall be enforced after the period for referring the case to the Second-Instance Committee has elapsed without effect or after the issuance of the decision of the Second Instance Committee, unless the respondent accepts the violation or part thereof. This amount shall be deposited by the pharmaceutical company to a dedicated bank account held by SFEE. b) The Second Instance Committee of Article 1, Chapter C of the present Code may impose to a SFEE member company that does not comply with the decision of the First Instance Committee a financial penalty of up to EUR 50,000, further to the sanctions mentioned above. These amounts shall be deposited by the pharmaceutical company to a dedicated bank account held by SFEE, not later than 30 business days of the date of issuance of the decision. Any final decision imposing any of the sanctions in above shall be promptly publicized on SFEE's locked website for a three (3) month period. In the event that the SFEE member company has not complied, or has not properly complied, with the sanction imposed on it by the Second Instance Committee, the Second Instance Committee shall meet upon request of the complainantand shall decide on further sanctions, which may amount up to three times the initially imposed sanction. In the event that the SFEE member company still fails to comply with the decision of the Second Instance Committee, the latter shall refers the issue to the Disciplinary Board of SFEE, which may decide the	

	expulsion of the member.	
8th MODIFICATION **CHAPTER C** **Article 4**		
CODE OF ETHICS	**SUGGESTED MODIFICATIONS**	**COMMENTS/REASON TO MODIFY**
(BEFORE): **Article 4.1., page 42** **4.1.** The First Instance Committee, if, after examining the allegation/complaint, judges that there is a violation of any articles of the Code and taking into account the type of the violation, the number of violations, the gravity and the relapse, may impose to a member, company that fails to comply with the provisions of Chapter A of the Code the following sanctions, which shall be enforced after the deadline for filing an appeal has elapsed without any action or after the decision on the appeal, unless the respondent has accepted the violation or part thereof: a) A financial penalty of up to EUR 25,000. b) Correction of the non-compliant promotional material and obligation of the pharmaceutical company concerned to send the corrected material to its addressees, accompanied by a letter stating the amendments; c) Prompt publication of the decision on SFEE's website; Following the issuance of the First Instance Committee decision, the disputing parties reserve the right, within 30 business days of the date when the decision is communicated to them by SFEE's Secretariat, to file an application for	**(AFTER:)** **Article 4.1., page 42** **4.1.** The First Instance Committee, if, after examining the allegation/complaint, judges that there is a violation of any articles of the Code and taking into account the type of the violation, the number of violations, the gravity and the relapse, may impose to a member, company that fails to comply with the provisions of Chapter A of the Code the following sanctions, which shall be enforced after the deadline for filing an appeal has elapsed without any action or after the decision on the appeal, unless the respondent has accepted the violation or part thereof: a) A financial penalty of up to EUR 25,000. b) Correction of the non-compliant promotional material and obligation of the pharmaceutical company concerned to send the corrected material to its addressees, accompanied by a letter stating the amendments; Any final decision imposing any of the sanctions in	Modification

referring the case to the Second Instance Committee (see Article 2.15) of the Code Compliance Monitoring Procedure. The above sanctions shall be enforced if the deadline provided for in Article 2.15 of the SFEE Code Compliance Monitoring Procedure for referring an allegation/complaint to the Second Instance Committee elapses without any action.	above shall be promptly publicized on SFEE's locked website for a three (3) month period. Following the issuance of the First Instance Committee decision, the disputing parties reserve the right, within 30 business days of the date when the decision is communicated to them by SFEE's Secretariat, to file an application for referring the case to the Second Instance Committee (see Article 2.15) of the Code Compliance Monitoring Procedure. The above sanctions shall be enforced if the deadline provided for in Article 2.15 of the SFEE Code Compliance Monitoring Procedure for referring an allegation/complaint to the Second Instance Committee elapses without any action	
(BEFORE): **Article 8., page 43** In case of conflict of Laws between the provisions of this present Code and the Greek Laws, the stricter rule applies.	**(AFTER:)** **Article 8., page 42** In case of conflict of Laws between the provisions of this present Code and the relevant Circular of EOF, the stricter rule applies. Acts deemed as formally lawful, due to EOF's or other competent Authority's tacit approval may be challenged in terms of Ethical Compliance of their content under the provisions of this present Code.	Modification
8th MODIFICATION **ANNEXES** **ANNEX I**		

(BEFORE):

ANNEXES

I) Table of indicative calculation of HCP fees for services provided to pharmaceutical companies

II) Registry of non-interventional studies

ANNEX I

1. Indicative calculation of HCP fees calculation for services provided to pharmaceutical companies, depending on status/rank:

Status/Rank	Indicative fee per me (gross/assumed duration of vi minutes)
A. Academics	
Professors	Euro 72
Associate Professors	Euro 60
Assistant Professors	Euro 48
Lecturers	Euro 36
B. NHS-affiliated Specialists(Consultants)	
Coordinating Directors	Euro 64
Directors (Heads of Department/Clinics)	Euro 60
Attending physician - rank I	Euro 48
Attending physician – rank II	Euro 36
Attending physician – rank III	Euro 24
C. Nursing and paramedical professions	Euro 36

The above rates have been determined in accordance with Ministerial Decision oik.72944 (Gov. Gazette 1958/B/12.8.2013) for HCPs, excluding nursing and paramedical professions, for which the fees are determined at half the fees of Professors.

(AFTER:)

ANNEXES

I) Table of indicative calculation of HCP fees for services provided to pharmaceutical companies

II) Registry of non-interventional studies

ANNEX I

The following shall apply to agreements signed between pharmaceutical companies and HCPs as of 1 Septembre 2017.

For the purposes of the Directive 2005/36/EC, “Health-Care Professional (HCP)” is a doctor, a nurse responsible of general care, a dentist, a midwife, a pharmacist or other person considered as HCP under the legislation of the Member State where treatment is received. According to Law no. 4238 / Government Gazette A 38/ 17.02.2014, article 4, family physician and physicians of other specialties, dentists and other health professionals such as midwives, health visitors (or medical representatives), nurses, social workers, physiotherapists, dieticians - nutritionists, psychologists, the occupational therapists, medical laboratory technologists, medical assistants and of biological laboratories, medical equipment operators are considered as Healthcare Professional (PH). However, it is also noted that definition of HCP, according to the Code of Ethics of SFEE is narrower and pursuant to the provisions of the CMD ΔΥΓ3α Γ.Π. 32221/2013 and includes those of the above professionals have a legal right to prescribe.

Indicative calculation table of HCP fees for services provided to pharmaceutical companies

The following categories are used to rank all HCP (NHS, Academics, private physicians) and take into account the experience of HCP which also establishes (documents) the participation and remuneration in such services. The evaluation sheet is included in the file of this cooperation

2. Indicative calculation of HCP fees for services provided to pharmaceutical companies, depending on time of involvement (in hours) per service:

	Attendance	Preparation	Travel	Total
Speaker in a conference	**3.5**	**3**	**1.5**	**8**
Presentation / training	**4**	**3**		
Participation in an Advisory Board	**8**	**2**		
Article writing	**10**			
Protocol writing	**40**			

- According to the internal procedures applied for deriving reasonable remuneration levels, by market standards, hourly remuneration rates are based on the fee received by HCPs for examining a patient in the outpatient Hospital clinics.
- Finally, the HCP's fee for out-of-job engagements may not exceed his/her regular hourly pay in his/her permanent/main job.

1. Experience at international level: (to meet at least three of the following criteria)

 President of scientific events in international conferences which are held the last 3 years

 Speaker in international conferences which are held the last 3 years

 Participation in international clinical trials as a member of the steering committee of the study and / or principal investigator (PI in the center of) the last five years

 Active member of the editorial board or author of at least 5 publications in international peer-reviewed journals over the last five years

 Author of international guidelines on the last 5 years

 President or member of the International Scientific Board of Directors over the last three years

2. Experience at national level: (to meet at least three of the following criteria)

 President of scientific events in national conferences (specified in the applicable circular of EOF), which conducted the last 3 years (except satellite conferences)

 Speaker at national conferences (specified in the applicable circular of EOF), which are conducted the last 3 years (except satellite conferences)

 Participate in interventional clinical trials over the last five years as principal Investigator (PI)

 Author of at least 5 publications in Greek or foreign peer-reviewed journals over the last five years

 Author of national guidelines in the last 5 years

 Active president or board member of national scientific societies (specified in the applicable circular of EOF / as defined by the relevant circular of EOF)

3. Experienced and other specialists: (to meet at least three of the following criteria

 Speaker in local conferences that have been held the last 3 years

 Participation in clinical trials* the last five years

 Author of publications in Greek peer-reviewed journals

	over the last five years □ Clinical experience 5 years after the specialty **4. HCP: This category includes indicatively: nurses, pharmacists, dentists, no specialty physicians, physicians and physicians who are not included in the above categories.** In case of non-interventional clinical trials they should be uploaded in the electronic registry of non-interventional clinical trials at SFEE's platform. **Hourly Compensation** The hourly compensation is determined as follows: **Experience at international level:** up to 190€ * (maximum possible fee: 1520€ *), **Experience at national level:** up to 170€ * (maximum possible fee: 1360€ *), **Experienced and other experts:** up to 130€ * (maximum possible fee: 1040€ *), **Scientists / HCP** up to 100€ * respectively (maximum possible fee: 800€ *). * Fee includes travel expenses. Special Account for University Research (ELKE)/ Special Account for Research and Development (ELKEA) taxes & VAT are excluded. HCPs remuneration with experience at international level has been determined taking into account European standards. HCPs remuneration for the remaining categories is adjusted accordingly, taking also into account MD oik. 72944 (Government Gazette 1958/B/12.8.2013), of art. 36 of Law. 4272/2014, the provisions of Law.4009/2011 as applicable, and the decisions of the Senateof the National and Kapodistrian University of Athens (Government Gazette 826/B/1996 and Government Gazette 2163/B/2012). □ **The services provided by HCPs include:** - Lectures at scientific events, conferences, symposia - Consulting services, participation at the Advisory Board - Training of personnel seminars

	- Configuration of educational materials and / or presentations for educational purposes - Services such as protocol writing, bibliography review, other services that require considerable time of involvement and / or preparation, if supported, are calculated taking into account experience and hourly rate of compensation as described in this Directive while excluded from the restriction of preparation hours (see below) and the total time of involvement (see hourly rate). - HCP services related to legal cases are exempted by this method of calculation of HCP fees, since they are not covered by the Code of Ethics of SFEE. • The time of engagement (preparation and coordination) of an event, speech, personnel training or consulting services are defined by the content, scope and duration of the service and should not exceed four hours. In case of a presentation the content of which, partly or entirely, has occurred in the past, the preparation time is configured accordingly and should not exceed two hours. • The involvement time is defined by the scientific program of the event, while taking into account the time of presence in the session/event and not only the time of speaker in a conference so as there is enough time until the end of the event for the speaker to comment and give relevant clarifications. • The total annual (calendar year) plafond (cap) may not exceed EUR 5,000, excluding VAT and further deductions (see art. 22.6. (i)). • The aforementioned is indicative and constitutes a common perception of all SFEE members for fairness and reasonableness of the maximum possible compensation for HCP services as defined herein.