## SUMMARY OF MODIFICATIONS

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| **Article 5.1.a.** | **p. 9** | |
| **16.3.** | **p.16** | **Numerical correction of the amount in €** |
| **17.3. G.** | **p.18** | **NEW** |
| **18.3.2.** | **p. 19** | **NEW** |
| **18.8** | **p. 19** | **Lines 25-30** |
| **19.2.3.** | **p. 21** | **Lines 17-20** |
| **19.2.7.** | **p. 21** | **NEW (below the table with an *)** |
| **19.7.** | **p. 23** | **NEW** |
| **22.3.a. – 22.3.b** | **p. 24** | **22.3.b. NEW** |
| **23** | **p. 25-26** | **NEW** |
| **CHAPTER B 1.1.** | **p. 34** | **+2.4. page. 34 / A/ and harmonization of the whole article 2** |
| **C.1.** | **p. 33** | |
| **C.7.** | **p. 34** | |
| **CHAPTER C_4.1.(a,b,c)** | **p. 34** | |
| **8.** | **p. 39** | **NEW** |
| **Article 7** | **p. 39** | **PATIENTS' CODE** |

| CODE OF ETHICS | SUGGESTED MODIFICATIONS | REASON TO MODIFY |
|---|---|---|
| **1ST AMENDMENT** | **ADVERTISEMENTS ON PRINTED MATERIALS OF POSITIVELY EVALUATED (BY SFEE) CONFERENCES** | **EXPLANATORY NOTE** |
| **BEFORE:**<br><br>**Article 5, page 9**<br>Article 5. Advertisements<br><br>Advertisements may only appear in professional publications, namely publications sent or delivered exclusively to health scientists and nursing personnel. Scientific journals and publications of the health sector, printed material of conferences, medical/ pharmaceutical books etc, fall under this category. A loose insert in such a publication (for instance, separate leaflets distributed through the medical | **AFTER:**<br><br>**Article 5, page 9**<br>Article 5. Advertisements<br><br>Advertisements may only appear in professional publications, namely publications sent or delivered exclusively to health scientists and nursing personnel. Scientific journals and publications of the health sector, printed material of **POSITIVELY EVALUATED** conferences, medical/ pharmaceutical books, etc, fall under this category. A loose insert in such a publication | The insertion of the phrase **«POSITIVELY EVALUATED»** is suggested, so that it is clarified that the advertisements in conferences' printed materials should take place in materials of **positively evaluated** conferences by the SFEE evaluation committee. Otherwise, it is no worthy rejecting a positive evaluation due to infringement of code provisions, yet allowing the written advertisement. |

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| press) is not considered abbreviated advertisement. | (for instance, separate leaflets distributed through the medical press) is not considered abbreviated advertisement. | |
| **2nd AMENDMENT** | **ANY OFFER OF MEDICAL, DIAGNOSTIC INSTRUMENT, SCIENTIFIC TEXTBOOK, ELECTRONIC CONNECTION ETC. OVER 15€ IS CONSIDERED TO BE A DONNATION – Completion of the gap in the existing threshold between article 14 and 16.** | **EXPLANATORY NOTE** |
| **BEFORE:**<br><br>**Article 16.3. page 16**<br>As of 1st 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 € 100 in value. | **AFTER:**<br><br>**Article 16.3. page 16**As of 1st 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 (including VAT). | Correction of the amount in € because nowhere in the Code is there a provision stipulating that transfers of value up to a 100 € are allowed- the provision of article 16.2. – in its previous version- was contradictory to the provision of article 14.2. |

| 3rd AMENDMENT | DEFINITION OF SCIENTIFIC EVENTS ABOUT TOPICAL HEALTH AND MEDICINAL ISSUES ORGANISED BY ADVERTISING OR OTHER COMPANIES – MANDATORY EOF APPROVAL – THRESHOLDS TO GRANTS LIKE THE TYPE "A" CONFERENCES | EXPLANATORY NOTE |
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| **BEFORE:**<br><br>**No provision.**<br><br>**INSERTION:**<br><br>**NEW ARTICLE (insertion of paragraph "G" in ARTICLE 17.3. page 18.)** | **AFTER:**<br><br>**ARTICLE 17. 3. G., Page 18**<br><br>**G. Conferences on Health / Medicinal Issues organized by advertising or other services' supply companies.**<br><br>Conferences organized in Greece by advertising or other services' supply companies, which undertake the whole cost of the | **Harmonization with EOF circular**<br><br>"Pursuant to article 31 par. 3 of the L. 1316/83 *"organization or granting of conferences or seminars or any other relevant means of information referring to issues of EOF's competence by pharmaceutical industries or companies* ***or through any advertising or any other services' supply companies****, could be allowed solely prior to EOF approval".* |

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| | 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.<br><br>The organization of such conferences presupposes the EOF approval procedure in line with the current circular in force regulating scientific conferences.<br><br>The pecuniary level of the grants should be proportionate to the duration of the conference, according to the thresholds of type A conferences<br><br>(N.B. article 19.1.). | |

| 4th AMENDMENT | CONFERENCES' EVALUATION BY COLOURS | EXPLANATORY NOTE |
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| **BEFORE:**<br><br>**No provision.**<br><br>**INSERTION:**<br><br>**INSERTION AT THE END OF THE INTRODUCTION OF ARTICLE 18**<br><br>**As 18.3.2.** | **AFTER:**<br><br>**The SFEE Evaluation Committee evaluates the conferences and having first applied the criteria of the Code, distinguishes the conferences by the following color distinction:**<br><br>**BLUE: MISSING ELEMENTS, CANNOT BE EVALUATED.**<br><br>**GREEN: IN FULL HARMONISATION WITH THE CODE PROVISIONS**<br><br>**WHITE: INFRINGES ONE OR MORE OF THE CODE PROVISIONS, THE** | **NEW PROVISION**<br><br>**Filling in of the relevant gap.** |

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| | **COMPANY MAY PARTICIPATE AT THEIR OWN RESPONSIBILITY**<br>**PURPLE: EXCLUSIVELY FOR INTERNATIONAL CONFERENCES, AT THE DISCRETION OF ANY PHARMACEUTICAL COMPANY** | |
| **5th AMENDMENT** | **INVOICING BY THE PCO ONLY IN SPECIAL CIRCUMSTANCES WHERE THE SCIENTIFIC INSTITUTION/ ASSOCIATION IS NOT BY ITS LEGAL NATURE ENTITLED**<br>**TO ISSUE AN INVOICE** | **EXPLANATORY NOTE** |
| **BEFORE:**<br>**ARTICLE 18.5 page 25**<br>**INSERTION** | **AFTER:**<br>**ARTICLE 18.8 page 19 (end of paragraph, lines 25-30):**<br>**If the scientific organizing** | **Clarification- Insertion** |

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| If the scientific organizing entity is not competent or in view of its may not due to the nature of its legal form issue such receipts, it is entitled – under a valid contract signed with the Professional Conference Organizer, that should be explicitly mentioned in the EOF approval – to assign to the Professional Conference Organizer the entire financial management of the conference. | **entity is competent or it is by nature of its legal form able to issue receipts and invoices, the invoicing of the full range of services of the conference to the pharmaceutical company shall be done solely by the scientific organizing entity.**<br><br>If the scientific organizing entity is not competent or in view of its may not due to the nature of its legal form issue such receipts, it is entitled – under a valid contract signed with the Professional Conference Organizer, that should be explicitly mentioned in the EOF approval – to assign to the Professional Conference Organizer the entire financial management of the conference. | |

| 6th AMENDMENT | SAME LIMITS ON HOSPITALITY LEVEL (MEALS & OVERNIGHT STAY) APPLICABLE TO FOREIGNERS PARTICIPATING IN CONFERENCES IN GREECE *(HOST COUNTRY PRINCIPLE)* | EXPLANATORY NOTE |
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| **BEFORE:**<br><br>**Article 19, page 27**<br>**Scientific Events held in Greece**<br>The cost of meals per participant should not exceed EUR 70 (incl. VAT) per day in Greece. Accommodation costs must not exceed EUR 140 (incl. VAT) in Greece. In this price (EUR140) breakfast is included. | **AFTER:**<br><br>**Article 19.2.3., page 21, Lines 17-20**<br>**Scientific Events held in Greece**<br>The cost of meals per participant should not exceed EUR 70 (incl. VAT) per day in Greece. Accommodation costs must not exceed EUR 140 (incl. VAT) in Greece. In this price | **Harmonization with the EFPIA code provision.** |

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| **Scientific Events held abroad**<br><br>The cost of meals in scientific events held abroad should not exceed EUR 70 (excluding VAT) per day and the accommodation cost EUR 250 (excluding VAT) per day in 4-star hotels. | (EUR140) breakfast is included.<br><br>**The above mentioned meals' and accommodation limits apply also for foreign HCPs who participate in scientific events held in Greece**.<br><br>**Scientific Events held abroad**<br>The hospitality cost (meals and accommodation) of scientific events held abroad, should be in line with the thresholds of the country where the event takes place, if and in case the meals' cost does not exceed EUR 70 (excluding VAT) per day and the accommodation cost does not exceed EUR 250 (excluding VAT) per day in 4-star hotels. | |

| 7th AMENDMENT | CLARIFICATION OF THE DEFINITION OF INTERNATIONAL CONFERENCES – organization by a foreign scientific institution a mandatory pre-requisite | EXPLANATORY NOTE |
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| **BEFORE:**<br><br>**Table of page 28:**<br><br>**Completion of the definition of International Conferences**<br><br>*The organizer is a foreign scientific institution/ association or the foreign scientific institution/ association is a co-organizer with a Greek scientific institution/ association, as mentioned on the EOF approval. | **AFTER, Table of page 22 (new definition below the table):**<br><br>*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).** | **Clarification.** |

| 8th AMENDMENT | SFEE AUSPICES | EXPLANATORY NOTE |
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| **BEFORE:**<br>**No provision.** | **AFTER:**<br>**Article 19 7. SFEE Auspices [New***]**<br>SFEE may offer their auspices to any scientific event of whatever nature, as long as it fulfils the code harmonization requirement and the specific scientific event generally promotes the interests of the pharmaceutical sector. In cases of doubt, the SFEE BOD will issue the final judgement. | ***NEW ARTICLE***<br>***to fill in the relevant gap.*** |

| 9th AMENDMENT | 1. HONORARIA THROUGH ELKE/ELKEA OR NOT, pursuant to the currently existing Law provisions-<br>2. NEW PARAGRAPH TO ARTICLE 22: ADVISORY BOARDS, INVESTIGATORS MEETINGS & CONSULTANT MEETINGS WITHOUT EOF APPROVAL. | EXPLANATORY NOTE |
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| **BEFORE:**<br><br>**Article 22.** *Provision of Consulting Services or similar collaborations between HCPs and the Pharmaceutical Industry.* | **AFTER:**<br>**Article 22:**<br>**22.3. a.** Any honorary fee shall be deposited to the entities foreseen by the legislation in force, which shall transfer it to | 1. **Harmonization with the Law currently in effect (issuance of services' invoice).**<br><br>2. **INSERTION OF A NEW PARAGRAPH –b- to article 22.3.** |

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| **22.3. a.** Any honorary fee shall be deposited to the entities foreseen by the legislation in force, which shall transfer it to the beneficiary after the appropriate deductions and, at the end of the year, issue a relevant income certificate for tax purposes. In any case HCP fees must be paid as described above and not through third parties (e.g. scientific societies). | the beneficiary after the appropriate deductions and, at the end of the year, issue a relevant income certificate for tax purposes**, or (the honorary fee) could be directly deposited to the beneficiaries' (HCP) account as long as the latter is entitled by the law, as currently in effect, to invoice directly.** In any case HCP fees must be paid as described above and not through third parties (e.g. scientific societies).<br><br>**22.3. b. The meetings held with a small number of participants in order that the participants advise on scientific issues (advisory boards), get informed about new facts concerning clinical trials to which they participate as investigators** | |

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| | **(investigator meetings) or contribute with their acknowledged experience on scientific issues, elaborate epidemiological facts, that is diseases and therapeutic accesses etc (consultant meetings) and which are organized by the Medical Affairs' department of a company, do not need the EOF approval to the extent that the scientific element supersedes the sociable element.** | |
| **10th AMENDMENT** | **MODIFICATION OF ARTICLE 23: PATIENTS EDUCATION & TRAINING PROGRAMS** | **EXPLANATORY NOTE** |
| **BEFORE:**<br>**Article 23 Patient Education and Support Programs**<br>The key requirements that must be met are: | **AFTER:**<br>**Article 23. Patient Education and Support Programs**<br>**a. Definition- Purpose-** | ***[Provision prepared by the Committee of Medical Affairs Managers]***<br>**Definition, Clarifications, Prerequisites, Methodology.** |

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| i. Observance of the Pharmacovigilance obligations<br>ii. Observance of the law on sensitive personal data.<br>iii. The purpose and description of the program must be consistent with the SPC, and the program must not be promotional<br>iv. The use of printed instructions to the HCPs participating and the patients must comply with the applicable laws and the circulars of EOF on medical information and advertisement.<br>v. The Medical affairs departments of the companies must be responsible for the approval and/or supervision of programs<br>Programs may be implemented by means of outsourcing to third-party providers, authorized by the Data Protection Authority. | **Framework**<br><br>The patient education programs do not constitute Clinical Trials – they have clearly educative/ non-interventional character – and there is no patient personal data collection, further to the necessary information for the compliance with the legislative framework on pharmacovigilance.<br><br>These programs aim at enhancing the compliance of a potential patient to his/hers prescribed therapy and the amelioration of their quality of life and they are applicable mainly to special medicines which entail the need for specific handling either during the setting title procedure or instructions at the manual use.<br><br>The provision of education and support of nursery care by | |

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| | third parties is dictated by a social need and contributes, in parallel, to the right and safe therapy of the patients.<br><br>The performance of medical/ nursery actions, including the medicines' allowance at home, does not fall within the scope of this present provision.<br><br>Any direct or indirect communication between a patient and his familiars and the pharmaceutical company dealing with the trade/ allocation/ promotion of a drug, is forbidden within the framework of these education programs – as described above, apart from cases of reporting side effects in line with the relevant provisions of the law.<br><br>The patients' programs, as defined above, are not allowed to be applied by companies | |

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| | dealing with the trade/ allocation/ promotion of drugs for human use. Nevertheless, these companies may solely finance these programs.<br><br><u>The execution of these programs is assigned exclusively to HCPs, HCOs or Health Services' Companies in order to safeguard the independent and right provision of education and support services.</u><br><br>Programs entailing medical technology products are explicitly excluded from this present.<br><br>**b. <u>Conditions-Methodology</u>**<br><br>The education programs have as their object the familiarization of the patients and may include:<br>● Education of the patients/ or those nursing them to the use | |

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| | of the drug within the framework of the SPC and the product information leaflet (PIL) and supervision at home concerning the drug allowance.<br>● Education on the typical instructions in relation to the management of the disease.<br>● Provision of materials and services within the framework of compliance with the therapy, as for instance, leaflets and or reminder programs for the uptake of the drug.<br>● Anything relevant to the replacement of the drug either reminder or facilitation to its delivery at home.<br>● Centers for patients' information.<br>● Medicines that their allowance must be observed by a specialist doctor or / and at a hospital environment are explicitly excluded.<br>● All the above must be advised by the therapist doctor.<br>● The written consent of the patient or his attorney at law is mandatory.<br>Goods and Services of medical | |

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| | and educative character delivered to the patient must bear the company name of the grantor pharmaceutical company.<br>The intervention of a pharmaceutical company in these activities must become known to those interested HCPs and/ or to the administrative personnel participating in these services.<br>Moreover the patients should be as well fully informed – through their written consent- about the support of the pharmaceutical company to the services provided to them. The consent is collected by the provider company during the first visit. The consent forms and the patients' data are kept by the provider in a way compliant with the provisions of the law concerning sensitive personal data.<br><br>The consent form may be retired at any given time and | |

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| | unconditionally, by the patient's initiative.<br><br>The contract between the provider and the pharmaceutical company should contain the provisions of the laws about the protection of sensitive personal data and pharmacovigilance. The pharmaceutical company and their employees should not have access to personal data and files which may lead to the reveal of the identity of specific patients or be associated with specific patients, apart from the case of reporting side effects. The curating doctors who advise the participation of the patient to such a program do not receive any fee or any other indirect grant. The rest of the HCPs (i.e. nurses, dieticians, pharmacists etc) acting by the grant of a pharmaceutical company are | |

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| | not allowed to be involved in the promotion of specific products. The HCPs and the HCOs and in particular providers of support/ education and training should safeguard that all the information referring to patients must be at all times kept confidential and in compliance with the legislation of personal data. All the printed materials drafted to be used for education purposes should not be used for promotional reasons. It is not acceptable that these materials promote prescription, sales or allocation of the drugs of the grantor company. Nor is it as well acceptable that these materials make critical judgements about competitive products, as this might be deemed as a promotional activity. All the relevant materials addressed to the public should be approved by the Supervisory Committee | |

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| | of Medicinal Information and Advertisement Printed Materials distributed by pharmaceutical companies, along with the provisions of the existing legal framework.<br><br>**<u>Competences:</u>**<br><br>HCPs acting on behalf of an institution/ or health services' provider company, that could be granted by a pharmaceutical company are competent to substantiate these programs. The education programs are advised by the curating doctor to his/her patient. They cannot be substituted by financial remuneration or other reward in kind. The participation to these programs is not obligatory for the patients and it is not a prerequisite for the patients' social security | |

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| | coverage nor relevant to the level of the coverage care and the drugs for the confrontation of the disease.<br><br>These programs, as well as any other supportive documentation of these programs, are subject to the approval of the division of pharmacovigilance of EOF, in case they consist part of the distribution license of the drug and they are included in the risk management program of the product. In no other circumstances are they subject to EOF approval.<br><br>The HCO providing these services according to their articles of association, the organization of their personnel, their education and their quality control procedures should have a license issued by the competent authority or | |

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| | collection, elaboration, use and retain of sensitive personal data as well as any other form of accreditation (i.e. ISO 9001). Moreover, their personnel should be consisted by Health Practitioners or individuals with relative to the program specialties (nurses, dietitians, psychologists e.t.c.) Before the setting off of any of such programs, the grantor company must keep a file containing the following documents:<br><br>1. In depth description of the program with the relevant scientific documentation, either from the SPC or from the disease and bibliography, or by the technical need.<br><br>2. Cooperation contract with the company providing the program services. The contact will include an analytical description of each party | |

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| | obligations.<br><br>3. Compliance with the legislation about protection of personal data of those participating in the program.<br><br>4. All the supportive documents that will be used during the application of the program. | |
| **11th AMENDMENT** | **NO OBLIGATION TO CONSENT** | **EXPLANATORY NOTE** |
| **CHAPTER B DISCLOSURE CODE**<br><br>**BEFORE:**<br><br>**Article 1 par. 1.01., page 34**<br><br>A condition for the disclosure is the written consent of the Recipient. If the recipient does not consent to the disclosure of the transfer of value, the pharmaceutical company shall | **CHAPTER B DISCLOSURE CODE**<br>**AFTER:**<br>**Article 1 par. 1.1., page 34**<br><br>According to the above stipulated, any Pharmaceutical Company should disclose on their website and on the EOF website platform, within six months' by the end of each | **Harmonization with the Disclosure Law (4316/2014). The consent is not mandatory. The supervision falls within EOF competence.**<br><br>**+2.4. page. 34 / A/ and harmonization of the whole article 2** |

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| make an aggregate disclosure. The recipient may on serious grounds revoke in writing his/her consent once given. | calendar year at the latest, individually by name every transfer of value granted to third parties.<br>The supervision of the above obligation falls within the competence of EOF. | |
| **12th AMENDMENT** | **DISCONNECTION OF DONNATIONS**<br>**FROM PROMOTION** | **EXPLANATORY NOTE** |
| **BEFORE:**<br>**CHAPTER B**<br>**ARTICLE C.1.**<br>**Definitions used in Chapter B for the disclosure of Fees of HCPs and HCOs by pharmaceutical companies.**<br>**C.1. Donations and Grants** | **AFTER:**<br>**CHAPTER B**<br>**ARTICLE C.1.**<br>**Definitions used in Chapter B for the disclosure of Fees of HCPs and HCOs by pharmaceutical companies.**<br>**C.1. Donations and Grants**<br>Collectively, means donations, | |

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| Collectively, means donations and grants (either cash or benefits in kind), for the promotion of prescription and non-prescription medicinal products. | **under the meaning of article 16 of this present Code,** and grants (either cash or benefits in kind), for the promotion of prescription and non-prescription medicinal products. | |
| **13th AMENDMENT** | **Correction to the Definition of**<br><br>**Service & Consultancy** | **EXPLANATORY NOTE** |
| **BEFORE:**<br><br>**CHAPTER B**<br>**Article C.7.:**<br>**SERVICE AND CONSULTANCY**<br><br>**Service and Consultancy:** Education/ training (in house for company employees or externally to other HCPs), advisory boards (non-medical: commercial advisory boards or pharmaco-economics expert panels), | **BEFORE:**<br><br>**CHAPTER B**<br>**Article C.7.:**<br>**SERVICE AND CONSULTANCY**<br><br>**Service and Consultancy:** Education/ training (in house for company employees or externally to other HCPs), advisory boards/**Committees** (~~non-medical: commercial~~ **any** | **Deletions.** |

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| speeches/lectures, general consultancy (regarding medical information brochures, preparation of programs for informing HCPs and /or the public on diseases). The above term includes: education, market research, article authoring, translation, planning/ co-organization of scientific events. | **type of** advisory boards or pharmaco-economics expert panels), speeches/lectures, general consultancy (**i.e.** regarding medical information brochures, preparation of programs for informing HCPs and /or the public on diseases). The above term includes: education, market research, article authoring, translation, ~~planning/ co-organization of scientific events~~. | |
| **14th AMENDMENT** | **INSERTION OF CLARIFICATION-**<br><br>**DELETION OF subparagraph C.** | **EXPLANATORY NOTE** |
| **BEFORE:**<br>**CHAPTER C, ARTICLE 4, PARAGRAPH A**<br>***4.Sanctions***<br>A. The First Instance Committee, if, after examining the allegation/ | **AFTER:**<br><br>**4.Sanctions**<br>A. The First Instance Committee, if, after examining the allegation/ complaint, | **Insertion of aggravating criteria for penalties. Removal of –d- to –a-. Deletion of –c-.** |

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| complaint, judges that there is a violation of any of the articles of the Code, may impose to a member company that fails to comply with the provisions of the 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:<br><br>a) Prompt publication of the decision on SFEE's website.<br><br>b) Correction of the non-compliant promotional material and obligation of the pharmaceutical company concerned to send the corrected material to its addresses, accompanied by a letter stating the amendments;<br><br>c) Publication of the decision text, depending on its subject, in relevant scientific journals that are | judges that there is a violation of any of the 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 the 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:<br><br>a) A financial penalty of up to EUR 25,000.<br><br>b) Correction of the non-compliant promotional material and obligation of the pharmaceutical company concerned to send the corrected material to its | |

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| addressed to HCPs;<br>d) A financial penalty of up to EUR 25,000. | addresses, accompanied by a letter stating the amendments;<br>c) Prompt publication of the decision on SFEE's website.<br>~~c) Publication of the decision text, depending on its subject, in relevant scientific journals that are addressed to HCPs;~~<br>~~d) A financial penalty of up to EUR 25,000.~~ | |
| **15th AMENDMENT** | **GENERAL RULE: STRICTER RULE APPLIES** | **EXPLANATORY NOTE** |
| **CHAPTER C, page 41**<br>**No provision.** | **Article 8 (*NEW), Page 39**<br>**General Provision: In case of conflict of Laws between the provisions of this present Code and the Greek laws, the stricter rule applies.** | **We introduce an interpretation tool to facilitate the application of the rules each time in effect.** |

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## PATIENTS' ASSOCIATIONS CODE

| 1st AMENDMENT | AMENDMENT OF ARTICLE 7 | EXPLANATORY NOTE |
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| **BEFORE:**<br>"A pharmaceutical company cannot be the sole grantor of a program organized by a patients' association, except from the cases of diseases that there is no other alternative (i.e. a unique medicine available for the disease) as well as in the cases of rare diseases". | **AFTER:**<br>**"A pharmaceutical company cannot be the sole grantor of a Patients' Association and all the actions that this association may organize on an annual basis, except from the diseases that there is no other available funding. Patients' Associations active in rare diseases are explicitly excluded".** | **Several protestations by patients' associations.** |