SECTION 1: PRINCIPLES AND RULES

PART 1: INTRODUCTION

ARTICLE 1. SCOPE

This bylaw regulates the standards to be abided in the relation establishment methods between the members of the Producers of Medical Equipment and Their Representatives (SADER) and persons (including but not limited to doctors, nurses, technicians and research coordinators whether connected to the medical services providers or not) or legal entities (such as: hospitals or group purchase units; all together referred to as "Health Occupation Members") that, directly or indirectly purchases, hires, suggests and/or subscribes, uses or causes to purchase or hire or subscribe the medical equipment of the members.

This bylaw does not intend to remove or be a replacement to the domestic or foreign laws or regulations or professional bylaws (including company regulations) which puts forth mandatory obligations to the members or Health Occupation Members that are involved in certain activities.

If a conflict arises between this text and domestic laws, the domestics laws shall prevail and again, if the domestic laws have heavier sanctions than the sanctions herein or if the domestic laws set forth harsher conducts and rules, the domestic laws shall prevail and taken into consideration primarily.

All the members should be able to independently prove that their interactions with the Health Occupation Members are in accordance with all the domestic and foreign laws, regulations and professional bylaws.

ARTICLE 2. AIM and DEFINITIONS

The aim is to establish the social responsibility understanding whilst paying attention to the highest benefit of the patients during their interactions with the health occupation members and all other parties of the sector under health technologies and industry and to create policies in order to make the ethical work applications become standards of the work life, and to enable these policies with all parties.

SADER members are aware that commitment to ethical standards and complying with the applicable laws are of critical importance for the continuation of cooperation between the Health Occupation Members and the medical technology/equipment industry.

The legal interactions between SADER members and the Health Occupation Members, have a patient care-improving and medical science-developing results including the below-mentioned issues.

The advancement of medical technology: Cooperation between the members and Health Occupation Members is necessary for the development of innovative medical devices and the improvement of the existing products. The development and evolution of medical devices are based on innovation and creativity; this, mostly, comes from outside of the medical device company facilities.

Safe and Effective Use of Medical Technology: For safe and effective use of medical technology, the members should provide the Health Occupation Members with the necessary instructions, education, training, service and technical support. In addition, regulators may require this kind of education as a condition of product approval.

Research and Education: The support provided by the members to the well-intentioned medical research, education and the increase of the professional skills contributes to patient safety and to extend the access to new technologies as well as many other things.

Members, in accordance with these aims, should promote the industry's behaviour within the framework of social responsibility, ethical business practices, the conduct in accordance with the principles and rules determined by law and this bylaw and the prevention of unfair competition, on matter of interacting with the health occupation members.

Members are obliged to continue respecting the obligations of the Health Occupation Members for ensuring independent treatment decisions.

The definitions hereunder refers to as follows;

Definitions:

-Member; Refers to SADER members.

-Health Occupation Members; Refers to the persons (including but not limited to doctors, nurses, technicians and research coordinators whether connected to the medical services providers or not) or legal entities (such as: hospitals or group purchase units; all together referred to as "Health Occupation Members") that, directly or indirectly purchases, hires, suggests and/or subscribes, uses or causes to purchase or hire or subscribe the medical equipment.

-Ethical Code; Refers to this text which the SADER members sign and agree to abide.

-Laws; Refers to laws and secondary regulations of the Turkish Republic.

-Scientific Meeting; Refers to the domestic or foreign congresses, symposiums, workshops, seminars, courses and meetings organized by the Ministry, national and international expertise institutions, health institutions and organizations, universities, doctor/dentist/pharmacist professional society or medical equipment sales centres with the aim of giving information to the health occupation members and technical personnel working in the medical equipment area in the health institutions and organizations on a scientific matter.

-Education Activity; Refers to the education and information sharing meetings that may include medical equipment display and which are organized/supported by medical equipment sales centres.

-Simulation Centre; Refers to the domestic centres of the Ministry, national and international expertise institutions, health institutions and organizations, universities, doctor/dentist/ pharmacist professional society or medical equipment sales centres that give medical simulation training with the help of computer supported simulators.

-Simulation Training; Refers to the medical education given in the simulation centres.

-Cadaver Education; Refers to the education given in the cadaver centres.

ARTICLE 3-GENERAL PRINCIPLES:

Bylaw is based on the following principles and no article of the bylaw can be interpreted as in violation with the basic principles.

3.1. Principle of Differentiation: Mutual relationship between the Industrial and Health Occupation members should not be used for the purpose of obtaining irregular or improper benefit or in a way that will influence the sales decisions, or the aforesaid interaction, in any sense, should not be tied to the use or proposal of the member products or the sales process.

3.2. Principle of Transparency: The interaction between the industry and Health Occupation Members should be transparent and should be in full compliance with the Constitution, the provisions of existing laws, secondary legislation and the profession ethics. In this context, the members, by providing a prior written notice to the supervisor of the Health care worker or the office authorized by the relevant legislation, should ensure the required transparency to explain the objective and scope of the aforesaid interaction.

3.3. Principle of Equivalence : If any the Health Occupation members is included to a process by a member for the purpose of providing services on its behalf or for any member, the wages paid by the member should be proportionate to the services provided by the Health workers and should correspond to the fair value in the market.

3.4. Certification Policy: There should be a written agreement that regulates the purpose of the interaction, services to be provided between the member and the Health Occupation member, the remedy method for the losses and the fee to be paid by the member; especially, at all times, in the interactions between a member and a Health Occupant member, for example, in interactions that arise similar to a Health occupant member in performing the services to or on behalf of the member. The activities determined in the agreement should be supported by the activity report or similar documents, and documented. Reports, invoices etc. documents relating to the agreement and the provision of service should be kept ready by the member in order to both support the need and necessity of the service and to show the fairness of the paid fee.

The members shall request and procure compliance with standards that are equivalent to this bylaw from the third party mediators or third party representatives, including but not limited to consultants, distributors, sales representatives, marketing representatives, brokers, commercial agents that receive commission and independent sales representatives that interact with the Health occupation members for either their products, promotions or other activities. In this sense, it is suggested that the relevant contract documents should include the obligation of compliance with the present or equivalent bylaw with regards to the third person in case of inclusion to such agreements.

PART II:

SCIENTIFIC AND EDUCATIONAL ACTIVITIES OCCURED WITH THE MEMBER SPONSORSHIP

ARTICLE-4 :

4.1. The binding general principles about scientific and educational activities occurred with the member sponsorship:

As long as Laws, regulations and the profession practice rules permit, the members, to ensure safe and effective use of the medical technology, may provide the product, training and education for the Health occupation members. On no occasion may the scientific and educational activities of the medical equipment be used for purposes other than transferring the current information and/or presenting new information. In case there rises any claim or complaint about the members stating that they behave outside this purpose, the member should be able to explain the compliance of the actions and procedures with the principles and rules of the code of ethics. Under the condition of fully complying with the general principles set below, the members may support the Health occupation members, that will provide services, for their participation to the domestic and foreign scientific meetings congress, symposium such as congress, symposium:

4.2.a) Meeting, should be relevant to the expertise/duty field of the personnel.

4.2.b) The support should not be directly to the individual but to the organization or organizations that hold the meeting.

4.2.c) Such education and training programs or meetings should be carried out at proper places by taking the suitability of the health occupation members, participants and the quality of practice into account. Except for the international meetings that are held at different countries every time, in the season between 15 may- 15 October at seaside holiday destinations and in the season between 15 November- 30 April at ski resorts, no meeting organizations shall be organized or supported by the manufacturer, importer and/or sales centre. In the event that a new arrangement is brought about by the administration, this regulation shall be interpreted and implemented in accordance with these administrative arrangements.

4.2.d) All other restrictions brought to the legislation, notification rules and other liabilities should be observed carefully.

4.2.e) Programs, activities or meetings should be conducted at, clinic, laboratory, educational, conference or other appropriate places including the members' own facilities or commercially viable conference centres, that are suitable for effective information transmission and suitable for any "practical" training necessities. The training team should have the expertise to execute the training.

4.2.f) Members may provide dining for the participants in return to reasonable prices during the program. It may be proper to provide accommodation for the educational programs requiring overnight stay. Members may cover the reasonable accommodation and travel expenses of the Health Occupation members as long as it is not against any legislation and reserving the obligations foreseen by the legislation. However, the timeframe engulfed in the accommodation

and transportation expenses should be covered within the schedule of events suitable for the scientific purpose.

4.2.g) A personnel may only benefit from this support for a total of four times within the same year; two of these four supports may be provided by the same sales centre and the other two may only be used for abroad meetings. Meetings that the Health occupation member and the technical personnel working in the area of medical equipment within a health institution and organization attend as a researcher providing written or verbal announcement. The number limit determined by this paragraph shall not applied to the participants to the scientific meetings organized or supported by the Ministry.

4.3. Conditions regarding the scientific meetings:

The notices to our Institution and the activities executed about the scientific meetings organized/supported by the member medical equipment sales centres shall be done under the conditions set below.

4.3.a) The members may cover the registration, accommodation and travel expenses of the health occupation members and the technical personnel working in the area of medical equipment within a health institution and organization that will attend the meeting under the conditions set forth in article 21 of the Regulation.

4.3.b) The maximum number of supports that a personnel can have for attending the scientific meetings have been determined as four per year by the Regulation. Two of these four supports may be provided by the same sales centre and the other two may only be used for abroad meetings.

4.3.c) No number limit shall be applied to the meetings that the Health occupation member and the technical personnel working in the area of medical equipment within a health institution and organization attend as speaker, panellist, educator, chair, announcer researcher with the support of the members.

4.3.d) Only one of the researchers may be supported for announcing the manifest in the meetings where the written or verbal presentation of the scientific works with multiple researchers are done. Written/verbal poster hanging/presenting shall be deemed as manifest.

4.3.e) No number limit shall be applied to the participants to the scientific meetings organized or supported by the Ministry.

4.4. Conditions regarding the educational meetings:

Educational meetings organized/supported by the member medical equipment sales centres shall be done under the conditions set below.

4.4.a) Educational activities are organized for at most a day. The Health occupation member and the technical personnel working in the area of medical equipment within a health institution and organization working in surrounding cities may also participate to the educational activity.

4.4.b) The registration, accommodation and travel fees of the participants to the educational activities organized/supported by the members shall under no condition be covered.

4.4.c) No participation limit is applied to the educational activity meetings.

4.4.d) Only educational meetings, that the Health occupation member and the technical personnel working in the area of medical equipment within a health institution and organization, which are active in the area, maybe held at the holiday locations and ski resorts during the period when no scientific meeting and education activity may be organized/supported.

4.5. Simulation and cadaver centres:

4.5.a) The education activities held at the simulation and cadaver centres are not considered as scientific meeting or educational activity and no participation limit shall be applied to the participation of the supported ones in activities held in these facilities.

4.5.b) The simulation and cadaver centres are in the country, thus, the abroad educations shall be considered as scientific meetings.

PART III:SUPPORTING EDUCATION CONFERENCES TO BE HELD BY THIRD PARTIES

ARTICLE 5- General Principles:

Truly independent, educational, scientific or policymaking conferences enhance the scientific knowledge, medical advancement and helps to provide effective health services. For these purposes, the members may support these kinds of activities under the condition that the content of the conference is arranged in accordance with the other legislation and regulations published about the rules and procedures of such meetings by professional associations and organizations and that the content of the educational conference support the scientific advancement, effective health service and educational conference.

On no occasion may the scientific and educational activities of the medical equipment be used for purposes other than transferring the current information and/or presenting new information.

SADER members may support these kinds of activities through procuring the financial, scientific, technical, organizational and/or logistic assistance as set below.

ARTICLE 6- Health Workers Sponsorship:

In case that the laws, the other relevant legislation and the professional practice rules permit, the members may procure financial support for the purpose of covering the individual participation expense of the Health Occupation members.

The aforesaid financial support shall remain limited to the conference registration fee, reasonable travel, accommodation, dining expenses for participating in the activity. The

timeframe of the covered accommodation and transportation expenses should remain limited to the activity calendar suitable to the scientific purpose.

Member should fully comply with the rules determined by the legislation in disclosing and approval requirements regarding the aforesaid sponsorship; Even if such requirements are not determined, the members should ensure the necessary clarity to, for instance, the hospital management of the sponsor, the supervisor of the Health professional and the appointed local authority by a prior written notification.

ARTICLE 7-Advertisements and promotions:

Under the conditions brought by the law and by fully complying with the rules brought by law, members may purchase advertising and rent booth area for the purpose of company presentation.

ARTICLE 8-Conference Support:

The members may, in order to reduce the total attendance cost to the conferences, may directly financially aid the conference organizer and may, if possible by law and if reasonable, cover the service fee, travel, meal and accommodation fees of the Health occupation members dutied in the conference.

Conference organizer should make a written request to the member and all kinds of sponsorship fee should be paid directly to the conference organizer or the institution or organization that organizes the conference.

In this kind of sponsorship, the conference organizer is solely responsible from the content of the program and the selection of the academic staff. On no account should members be involved in content determination process of the conference except for, if it is requested, suggesting a speaker or commenting on the program.

ARTICLE 9- Satellite Symposiums:

Members may be a sponsor to the satellite symposiums of third parties' conferences. Members may make presentation about the subjects regarding the general content of third parties' conferences only if all of the information presented is fair, balanced and scientifically certain. Members may determine the content of these activities and be responsible for the selection of the academic staff. However, this implementation should be determined by a written contract

and the support of the member should be disclosed in all of the documents relating the satellite activity.

ARTICLE 10- Scholarships:

The members may, by procuring financial support for the university scholarship or similar scholarships, provide assistance to the education institutions, professional associations or medical institutions for medical education programs by providing financial support for university scholarships or similar scholarships under the condition that they fully comply with all the rules brought by law.

Even in the cases where no adjustments are done to the law;

Selection of the person being awarded scholarship shall be subject to the permit of the institution to which they are registered or the institution which they are to receive education from. Except for a prior written request by the Institution, the assistance shall be given, not to the individual members, but to the professional or academic institutions.

In no way should financial provision be related to the institution's purchase of the company's products, or for aiding the purpose of an institution in prior or future use of the products or services of the company.

PART IV:

SALES AND PROMOTION MEETINGS, CONSULTANCY AGREEMENTS.

ARTICLE 11-Sales and Promotional Meetings:

Even in meetings between the members and the Health Occupation members for discussing of the product characteristics, conducting the contract negotiations or discussing sales conditions are legitimate, the rules introduced by the legislation regarding the meeting should be complied with and no meeting should be held at seaside holiday locations and ski resorts within the active season periods determined by the Ministry.

Even where there is no regulation in law;

Members may provide support for the Health Occupation Members in the scientific meetings, scientific congress, education meetings and similar meetings, may become a host to the extent that the law permits. The hospitality and acceptance activities aimed at promotion should not push aside the purpose of the meeting. Such meetings shall be held in a proper place, style and level. Members may cover the reasonable dining expenses of the Health Occupation members regarding the meeting in an appropriate information exchange environment. But the hospitality should be deemed second in importance and in a reasonable way and should not seem exaggerated compared to the environment. The time allocated to hospitality should not exceed the time allocated to the scientific activity.

The aforesaid meetings should be held in the workplace of the Health Occupation members or in a place not far away from their workplace

If promotion for the immovable equipment and the facility trips are necessary, members may cover the Health professional's reasonable accommodation and travel expenses. However, members are not allowed to cover or support the costs of accommodation, travel and other expenses of the Health Occupation Members' spouse, guests or any other well-intentioned person with no professional relevance to the information shared at the meeting.

ARTICLE 12- Proportionate Acting Obligation:

The hosting expenses of the activities hereunder, which may be supported by the firms under the condition of full compliance with the law; shall be limited to the scientific part of the meeting's unadorned registration expenses, reasonable accommodation and transportation expenses and dining expenses. Attention shall be paid to the reasonableness of the support and expenses; the support and expenses should not be at a level that the public and the participants may find high. As a general rule, the hosting expenses should not exceed the amount that the invited persons can afford. Hosting should be modest in terms of value and should meet the main purpose of the meeting in terms of time and focusing.

ARTICLE 13-Consultancy Agreements:

Members may receive consultancy service from the Health Occupation Members provided that the Health Occupation members are assigned as consultants, that the legislation regarding all of the disclosures and approvals requirements are complied, that research, participation in the consulting council, education and third party education conferences under the sponsorship of the member, and provided that sensible and realist services are provided in terms of the content.

The members shall ensure the necessary clarity by a prior written notification that will disclose the purpose and the scope of the consultancy agreement to the hospital management, the supervisor of the Health Occupation member and the appointed local authority.

ARTICLE 14-Conditions in Determining Consultancy Wage:

A reasonable wage is appropriate to the Health occupation embers that perform these services. The payment should not be a quantity that would directly influence the decisions of the consultants regarding the medical devices they may use in their own duties.

The consultancy agreements to be made with the Health Occupation members shall be in writing and be signed by the parties and the provided services should be stated clearly. The written agreement should specify all of the expenses that the consultant may demand regarding the provision of the service. These agreements should be in accordance with the law to which the Health Occupation Members are subject to, and the other relevant law.

The wage to be paid to the Health Occupation Members should be equivalent to the fair market value of the provided services and the wages written in the agreement should be determined as tax included. The wages of the Health Occupation Members shall be paid as foreseen by the circulating capital unit, ita supervisor or, if exists, the decision making office, and the applied law.

The agreements that have been made and all of the payment should be conformed to the tax and other legal requirements.

Even if the Health Occupation member doesn't want to be paid in return for the consultancy and/or the agreement covers an activity of a single day, all of the consultancy agreements made with the Health Occupation Members should be documented in writing. It is recommended that, the consultancy agreements be made with a wage in accordance with the fair market value and, the wage to be paid to the respective person.

The place and conditions of the meetings to be held with the consultants should be appropriate to the subject of the consultation. The meetings should be conducted in conference halls suitable for education such as places like hotel, clinic and other convenient meeting places, which allow the exchange of information. The general principles and the obligation to act proportionate determined by this bylaw shall be complied with in accommodation, hosting, transportation expense, meeting season and other issues.

ARTICLE 15-The Issues to Take into Consideration in Consultancy Agreements:

If the following issues are complied, there can be a legit, real, legal and valid consultancy agreement between the members and the Health Occupation Members.

The consultancy agreements may only be made where a legit purpose is expressed in advance. The need for the relevant service and consultancy of the member should be evidently spotted before getting into touch with the consultant, demanding the service and starting to negotiate with the potential consultants.

In case that the person with whom consultancy agreement is made is a decision making body with regards to the member in any subject, there should be the disclosure liability of the consultant in the agreement to be made between the members and the Health Occupation Members.

The features of the provided services, the criteria of the payments to be made in return for these services and to be determined in accordance with the following articles should be included in the contract or agreement in writing before receiving the services.

The selection of the consultants should be based on the quality and craftsmanship/expertise aimed at the determined purpose and should not take into consideration the work capacity or assessment brought by the consultant. The criteria used in the selection of the consultant should meet the determined requirements. The persons appointed to select the consultant should be of good quality, knowledge and skill to be able to evaluate whether the relevant Health Occupation Members comply with these criteria. The number of the Health Occupation Members hired as the consultant should not surpass the required number to reach the determined requirement and purpose.

The company demanding the consultancy should keep the records that show the services offered by the consultants and used in the direction of the requirement.

The payments in cash or in-kind payments to be made to the Health Occupation Members for the service requested by the company should not pursue a goal of any kind of product proposal, prescription, purchase, provision for purchase or applications of the Health Occupation member.

The payment made in return for the consultancy should be at a reasonable level, the wages should be decided including taxes, and the payment should reflect the market value of the service. No written contracts should be arranged to justify other payments to be made to the Health Occupation Members

When a member makes a contract with the Health Occupation member as a consultant for the research services, he/she shall refer to a written business plan or research protocol compatible with the aforesaid conditions, and all necessary approvals and permissions should be taken.

ARTICLE 16- Intellectual Property:

If a member makes a contract with a Health Occupation member for developing intellectual property, a written agreement that provides a wage, compatible with the fair market value, should be available. In addition, any kind of additional material benefit regarding the medical devices, which covers the medical devices including the original intellectual property, that has been or will be proposed should not be provided for the Health professional. All of the necessary permissions and approvals should be taken through the hospital management or the officer of the Healthcare Worker (or designated local authority) before the agreement.

PART V:PROMOTIONAL REMINDERS

ARTICLE 17-Scope of Promotion:

17.1 Promotional activities cover the informing of the health service providers regarding the issues like instruction books and implementation of the devices and the promotion of medical devices within the context permitted by law to the health service providers.

17.2 “Technical Services" and "Clinical Support Activities" are not considered within the context of promotional activities

17.3 Promotion towards health care providers are done:

17.3.1. With the publications which are distributed/sold to the Health care providers or the publications which are involved in the scientific and medical professional magazines,

17.3.2. With arranging or supporting scientific meetings,

17.3.3. With arranging visits to the health care providers by the workers of the member which grasps the full extent of the general principles herein; these visits are done by giving information about the equipment, its application and instructions.

3.4. The promotion of the qualified devices specified in the legislation should not be made, directly or indirectly, on every public broadcasting media or communication media including the internet via movie, TV series, and news or through the similar ways. The newspaper/magazine advertisements with the permission of the Ministry announcing that the product is marketed to the Health care providers are beyond the scope of this provision.

ARTICLE 18-Basic Principles:

18.1 Within the scope of the relevant law, the promotion activities of the devices not bearing CE marking should not be made. But, unless the devices not bearing CE marking bear a plain marking that shows that they should not be marketed or be taken into the service, their presentation cannot be prohibited in the trade fairs or exhibitions.

18.2 The medical device promotion should not be made except for the Health care providers. This provision is not required for the exceptional medical equipment (protector and personal care products etc.) as foreseen by law.

18.3 In the promotional activities, the names of the public institutions and organizations, and the names of the institutions, organizations or the persons participating in the medical device research should not be used without permission.

18.4 No promotion that may harm the patient, user and environmental health and that may threaten its safety shall be made.

18.5. No promotion that would discredit the rival firm and their products, and that is violent shall be mae.

18.6 No promotion of the devices through lottery, chance games etc. should be made.

18.7 No promotion that can lead unfair competition or deception should be made. As a result of the following issues, the deceptive promotion occurs;

18.7.a In the event that the features that the product doesn't have is shown as if they exist or any kind of misinformation is given relating to the device,

18.7.b In case of the creation of that the success will definitely be achieved,

18.7.c In case an unsuitable statement is included that any hazardous effect will not be formed in the use,

18.7.d In case the misinformation is given about the success or competence of the persons who manufacture, import, develop or market a product,

18.7.e In case the disuse of the medical device and the feeling is awakened regarding that the person's overall well-being is to be decreased in contrary to the truth

18.7.f In case the devices apart from the personal test devices are given an impression of suitable for self-diagnosis.

18.7.g In the Promotion of the medical device, by means of giving unproven, exaggerated deceptive information that leads to the unexpected risky situations or encourage the use of the device unnecessarily or in case of the use of the attractive and unrelated images.

ARTICLE 19-Principle and Procedures:

(1) Promotion of the medical devices includes the following information;

a) The information regarding that the promotion clearly belongs to the medical device,

b) The compatible device name and information and the device name and information which is situated in the documents (Declaration of Conformity, EC certificates, technical documentation, etc.),

c) The information compatible with the intended use which is situated in the user’s manual and medical device tag,

d) The scientific reports and certificates being the subject of the promotion, the date of issue and the contact information of the preparing person or institution,

e) If the device has a remedial effect, the information that proves this remedial effect.

(2) If the promotion is to be made with quotations from the magazines in the field of medical or biomedical or other scientific studies and is used with the charts and other visual materials,

these materials should be used by means of remaining faithful the authenticity and denoting the resources literally.

(3) Promotion includes the evidence-based and informative regarding the product's feature medical information that will help the Health Occupation Members create their own opinions about the therapeutic value of the product.

(4) The images, devices, visuals, electronics and all of the ways of access to the professional information about the medical device by means of notifying should be restricted only with the Health care providers.

(5) The promotions to the Health care providers should not be conflicted with the informational brochure made for the Health care providers and the package that prepared for the users.

(6) The results and evaluations of the medical devices not bearing CE marking should not be used in the promotions before they have been completed and published in the scientific literature.

ARTICLE 20-Reminders-Visiting Materials:

Members, without the purpose of affecting the decisions of the Health Occupation Members; such reminder visiting materials as pen, pencil, notepad and calendar that shall not exceed the %2,5 of the gross minimum wage can be given as promotional material

Reminder visiting materials should be connected with the application of the Health Occupation Members, should provide help for the patients and should have an educational and specific function. Reminder visiting materials should not be given in the form of cash or equivalent of cash.

The annual turnover of which the free samples that has been distributed in a way that doesn't exceed the previous year's sales of the relevant device, which has been determined in accordance with the legislation, should not be accepted as reminder visiting material.

In case a different regulation shall be made in relation to the restrictions introduced by this article, this instruction shall be interpreted and implemented in accordance with the administrative regulations.

SECTION VI:PHILANTHROPIC DONATIONS AND EDUCATIONAL GRANTS

ARTICLE 21- Philanthropic Donations:

Members;

a) To get permission in advance from the institution or organizations that they will make donations

b) Not to lead an unethical practice that can be connected with the device sale

c) To bear one of the purposes of the research, education, health and patient care

d) To be oriented not for the use of an individual but for the common use of an institution or organization.

e) To keep the records of the donation that has been made.

f) To be able to make donations to the non-profit making or public organizations and institutions as long as the medical device donation to be used for the clinical trial is made directly to the responsible researcher and is in accordance with the other legislation.

On the condition that the rules introduces by the legislation is abode by; members can make donations towards philanthropic donations. Donations can be made to the philanthropic institutions or other non-profit making legal entities which are entitled to receive these kinds of donations in accordance with the legislation. Donations can be made to support towards the general activities of well-intentioned organizations or the funding activity which an organization has undergone.

Philanthropic donations should in no sense be connected with the past, existing or the possible use in the future of the member service or product.

The donations made to a charity or non-profit organization should be documented as required. For example, a written statement explaining the activities and purpose of the foundation of the charity organization in detail should be requested by the member.

Members should not have a right of requesting an inspection or feedback of the ultimate use of the provided funds.

The payment should be made in the name of and to charity directly. The philanthropic donations to be made to a well-intentioned organization, if the Health professional is not an employer or officer and does not present the request on behalf of the organization, should not be made in return for the requests of the Health Occupation Members. In return for the request of a health professional, a member that supports a charity which have, may have or will able to have any kind of relationship between the member and the health professional is interpreted as the violation of this instruction.

ARTICLE 22-Educational Donations:

Members can receive funds for the sake of supporting the education of the society or patient, development of the education or medical science and specific independent medical researches. In addition, a price concession of the aforesaid member program or activities, awards to the privileged customers are important not to be seen an encouragement for sale, proposal or prescription of the members' service or products. For this reason, members should make a commitment that they hold all of the necessary documents regarding the education donations that have been made.

In no sense should education donations be connected with the past, existing and the possible use in the future of the members’ service and products.

Education donations can only be made to the legal entities or organizations that are entitled to receive aid as per the national and local laws or legislations, not to individual or Health Occupation Members. (For the information how the members can support the activities of the Health Occupation Members' education, see also, Support of Third Party Education Conferences)

ARTICLE 23-Education Programs:

(1) The proper education program samples and the relevant notes are giving below:

Scholarship: The places in which the Health Occupation Members receive education: hospitals, professional organizations, and universities that are available for granting scholarship. (See also, the subject of how members can support the scholarship and similar facilities, Support of Third Party Education Conferences)

Advancement of Health Education: Members, by making donations to the institutions and organizations for the health education, can support the education of the Health Occupation Members. (See also, the subject of how members can support the scholarship and similar facilities, Section III, Support of Third Party Education Conferences)

Research: The member may be allowed to assist the research aids bearing the purpose of support for the works under the customer initiative for the programs involving the clinical or non-clinical researches in the fields of member's legitimate interest. Member, as long as the national and local laws, legislation and professional statutes permits, may assist the well-intentioned research activities, identified as required, of the Health Occupation Members for the documented expenses and in kind services by making donations or providing the products free of charge. All research assistance requests should be made in writing and should state the characteristics of the research. No assistance should be made until the both parts have made an agreement and the agreement in question should also include the report of the antagonistic activities where appropriate. The assistance should be disclosed to the Hospital administration and the supervisor of the Health Occupation Members or other designated local authority and an aid receipt should be requested for recording the member's support for the activity in verbal or writing declaration of the member.

Public Promotion: Members can make donations for supporting the education about public health issues or patients. This provision cannot be interpreted in a way that lead the violation of the promotion rules.

SECTION VII: ACCOUNTINGSTANDARDS ANDINVOICING

ARTICLE 24-Payment of Costs and Other Economic Information:

Members are liable for invoicing to the authorities and other payers in accurate content and in accordance with the accounting standards.

In this way, that the third parties and the Health Occupation Members that make payments regarding the members products are provided with the payment information and economic efficiency. The payments to be made to the Health Occupation Members of public official position should be actualized through the circulating capital of the institution with which they are affiliated.

PART II: COMPLAINTSANDDISPUTE RESOLUTIONPROCEDURES

SECTION I: ELIGIBILITYANDAPPLICATION PROCESS

ARTICLE 1-Application Eligibility:

When the notification and complaints reaches SADER from the Health Occupation Members, patient associations or non-governmental organizations, the process shall be initiated ex officio by Secretary-General of SADER. To initiate a process regarding the incoming e-mails or the issues appeared in the media is at Secretary-General discretion. Parts shall be informed of the result of the application satisfactorily at reasonable intervals.

Only may Members duly complain as per this instruction.

ARTICLE 2-Obligation to Notify in Writing Prior to Complaint:

The complaints among SADER members should be strived to be solved through correspondence (by way of registered letter/fax/e-signature) between the companies in care of General Managers.

Unless a satisfactory result has been obtained within ten workdays at the latest, an application can be made to SADER

In case the complaint is made by a non-member o SADER, the use of the described method is recommended as well.

ARTICLE 3-Exception:

If complaint subject has been an issue in the correspondence and intercourses between two companies and/or has not been a complaint matter for the solution has been generated, however it is used again despite this (if it is an event, and is repeated despite the promises) or if a breach decision has been taken ECAC (Ethical Codes Assessment Committee) in consequence of the complaint and activity/material has been decided to stop, the event is still repeated despite this; or the aforesaid event that is considered to breach the principles will be made after a while later and the time is limited to stop it, the complaint company can apply to SADER directly.

ARTICLE 4-Application Method Terms:

(1) The complaints coming from SADER members should include at least the following information and be addressed to SADER Secretary-General and have signature of General Manager:

Name of Complainee Company; if it is not a member of SADER, contact address;

Date of complaint;

Grievance material(s) or event(s): In every case, what the grievance event, the print material and the other evidence are has to be stated clearly, if possible, an example and evidence or the coloured copy should be annexed to the complaint application;

Summary of complaint: In every case, in the grievance the breached articles of the principles should be summarized. If there are errors in the quotations taken from the medical publications, the mentioned publications and the incorrectly interpreted places should be clearly stated. If the quotation is taken from an article, the whole article, if the quotations is taken from a book, the sufficient reference and the copy of the relevant section should be added to the complaint.

Use Period of Grievance material: if it is an event, dates and places of event;

If the above mentioned in the article ( ) solution steps have been taken, the documents (the examples of the correspondence outgoing to the complainee company and incoming from it, the verbal intercourse dates and short summaries);

(2) Every complaint file should be sent by reproducing. Complaint files should be sent in electronic media as well.

SECTION II: PRE-ASSESSMENT

ARTICLE 5-Pre-Assessment Criteria:

(1) When the complaint stating that the principles have been breached reached SADER, the following issues shall be determined as effective in the first place:

That the subject is included in the principles:

As stated in Article 4, for the complaint can be assessed for process, that the sufficient information is included in the application letter,

One complaint letter may include more than one breach cases; SADER, by taking the severity and the situation of the repeating breaches into consideration and converting the grievance event or materials into a single case or different cases, may file them as different cases. This subject is at the Secretary-General's discretion.

If the complaint is about the arguments claims, information on the promotion material related to the product or a breach of any article in the ethical code, the complainant shall be responsible for presenting the documents to prove the claim. The complainee company shall be responsible for providing the technical reports and/or scientific publications, documents and resources on which its defence is.

The terms in the Article (4) shall be taken into account for each case.

ARTICLE 6-Conclusion of the Pre-Assessment Phase:

If the complaint file is found to be deficient, the complainant is asked to complete the file; the file shall not pun in the process until I has been completed.

If the incoming complaint does not present convincing evidence related to the breach or doesn not show the breach of the Ethical Code, the file is closed and the situation is explained to the complainant in writing.

When the complaints whose purpose is literally to defame the commercial credit of a company or to form an opinion of being made as a service for the commercial interests or similar ill-intentioned complaints are encountered, the file is closed and the written statement is sent to both parts.

If the complaint related to the promotion material or events, or other ethical code breaches is made before that the use or application of the material is done more than twenty four monts ago, the complaint shall not be assessed.

As per this article, the decisions taken by Secretary-General shall be submitted to the information of the committee in the first meeting of ECAC.

SECTION III: RIGHT OF DEFENCE AND REVIEW OF REPORTERS

ARTICLE 7-Right of Defence:

Although the breach of principles have been seen clearly, the complaint cannot be concluded directly by SADER.

The example of the complaint file is to be sent to the complainee company with a preliminary writing and the written response is to be requested. When necessary, the information or document can be requested by means of telephone or face to face interviews.

The complainee company should respond to SADER within ten days at the latest. If the response has not been received, the process shall be put into practice without further delay. However, the company may be given additional time upon a reasonably justified request.

ARTICLE 8-MADDE 8 Review of Reporters:

The file containing the complaint and response shall be taken into preliminary examination by ECAC reporter. When considering it proper, the reporter shall interview with the parts, visit the event place and gather information from the witnesses or parties, want additional documents and opinions from the parties; prepare the report by examining the findings.

If the subject of the complaint is related to a similar subject about which has been taken a decision, the complaint may be examined through referring to the relevant decision. If the recurrence of the material or case is not a subject to be discussed, the case file can be examined without calling parties. The parties shall be let to know the decisions which was taken before. A new breach decision shall not be taken, the file shall be closed, however; the case shall be recorded.

If the complaint is related to a subject about which a decision has been taken previously, the reporter shall state in his or her report.

When the similar material or event is complained by more than one companies at the same time and together, the files shall be joined together; if the complaints have not been made from different views, one reporter's report shall be written.

The file case and the reporter's report shall be sent to the Ethical Code Assessment Committee within 20 workdays. When considered necessary, the additional time may be requested form ECAC.

SECTION IV: ETHICAL CODE ASSESSMENT COMMITTEE (ACEC)

ARTICLE 9-Putting Complaint into Agenda:

The complaint files which has been undergone preliminary examination shall be put into the agenda in the incoming order by denoting the complaint subject. In emergency circumstances.

The Chairman may propose a change in the agenda order or make an emergency meeting call. If there are more than one complaint about the same subject, all of the complaints can be dealt with in single session.

The agenda and reports shall be distributed to the members two workdays before the meeting in normal circumstances. The reporter's report shall be sent to the parties.

ECAC shall examine the complaints through the files.

ARTICLE 10-Option of Verbal Defence:

When it is considered necessary by ECAC members and the Chairman, the parties may be summoned to the meeting to make verbal presentation and reply to the questions. Both parties may participate in the session together in a way that is approved by the Chairman or may be accepted to the hall separately. First, the representative of the complainant company, and then the representative of the complainee company shall make presentations within the given time.

Interviews are conducted held in accordance with generally accepted meeting manners.

If there is the complaint made by more than one company about an event or material, the complaints may be combined. All parts may be listened at the same time by being summoned to the same hall.

ACAC Members may ask both parts' representatives and demand additional documents. If ECAC wants to decide after seeing the documents or taking a decision for an additional investigation, the interview; the interview shall be conducted through files.

ARTICLE 11-Assessment Process:

The company representatives shall be taken out from the hall after the presentations and questions. In case of no opposite decision of the Chairman, the representatives from both sides, if they are the permanent or reserve members of ECAC and present in the meeting, are invited to leave the hall.

After the files and the other subjects on which the interviews are made at the committee, every topic shall be voted separately and the decision will be taken on the basis of the majority. The vote is held in secret. Which decision is taken by whom shall not be stated in the Committee

decisions. If the decision is taken on the basis of majority, the vote numbers shall be stated. All Committee decisions are taken as justified. The justification of the opposite votes shall be stated in the decision without disclosing the names of the members having held opposite votes.

The results of the assessment by ECAC shall be recorded and a case report will be prepared for each case.

If the complaint subject, as well as submitting to SADER, has been taken to the Ministry of Health or the Competition Committee, the file shall be suspended by ECAC until a verdict has been reached by the Ministry of Health or the Competition Committee. In the same way, if it has been taken to court or complained to the Ministry and the cases which has been understood as concluded is in question, ECAC can close the file.

The decision of court or the Competition Committee or the Ministry of Health is against the member complainee company, The Secretary-General shall submit the subject to the information of the Board.

ARTICLE 12-Verdict:

The assessment and the last report, whether any sanction has been imposed or not, shall be sent with a preliminary letter having the signature of Secretary-General to the parties.

If a verdict concludes with the breach of ECAC Principles, both parties shall be informed in writing of the sanction and the decision; if the company on which the sanction is imposed is requested to end the breach and the additional sanctions are to be discussed, these shall be requested to be done.

If there comes a verdict concluding with that a breach is not existing, both the complainant and the complainee parties shall be informed in writing of the decisions and reasons.

The complainee company shall send a commitment and declaration letter to the Secretary-General including that the requested corrective measures for not recurring the breach by explaining the corrective measures that have been taken.

SECTION V: OBJECTION AND APPEAL

ARTICLE 13-Objection Process:

The complainant and the complainee companies may object to the decisions within ten workdays by explaining the opposition reasons clearly. The verdict to which an objection has been raised within ten workdays shall become.

When an objection has been raised, the file shall be re-examined by ECAC.When considered necessary, ECAC shall re-examine the objection file and make a decision after having listened to the companies' representatives. The new verdicts shall be announced to the parties as mentioned above.

ARTICLE 14-Ethical Code Committee of Appeal (ECCA):

Stating their justifications, the parties may raise objection again to the ECAC verdicts given upon objection. In this case the objection shall be taken to Ethical Code Committee of Appeal (ECCA). Committee of Appeal's verdict is definite.

The verdicts and methods of Committee of Appeal are similar to the ones of ECAC.

PART III: SANCTIONS

ARTICLE 1-Issues to be Paid Attention When Imposing Sanctions:

The sanctions that are in proportion with the severity of the breach shall be taken into consideration.

For the fact that the sanctions have a preventive influence and in case of that a company repeats its breaches as a common attitude for a certain product and also continue the breaches on account of its indifference attitudes, the necessary measures should be taken to provide the effective prevention.

Throughout that ECAC and ECCA assesses the complainee company's behaviours in relation to the principles and a certain case, in case of ill-intention and/or recurrence of rule breaches despite the warnings, if considered proper, the decision to impose more severe sanctions on that company may be made.

ARTICLE 2-Types of Sanctions:

(1) In all cases, ECAC and ECCA, SADER Board of Director, when necessary, and General Assembly shall impose the following sanctions:

Warning Letter,
Attracting Attention,
Caveat,
Reprimand,
Severe Reprimand,
Temporary Suspension of Association Membership

Discharge from Association.

(2) The following additional sanctions may also be imposed:

To bring a stop the use of the material or the recurrence of the event;

To request the collection of the material;

To publish the decision details in proportion to the error that has been done regarding the company,

To demand the inspection or, if need be, the development of the company's processes with respect to the principles that have been breached;

To demand an inspection by which the person or persons or institutions to be determined by SADER is made and in a way that the expense shall be covered by the company to be inspected,

To demand that the company publish corrective ads, publish corrective statement in the publications towards physicians, dentists, pharmacists,

To make a written statement to the headquarters of the multinational companies,

To make a written statement to other international institutions of which the company is a member,

To inform The Ministry of Health or the Competition Committee or both of that the company has breached the Ethical Code and the company's incompatibility with the principles.

In the direction of preventing the recurring and prevailing behaviours, SADER Board of Directors are authorized to arrange sanctions in proportion to thwart these errors.

PART IV-CASE REPORTS:

ARTICLE 1-Publication of Case Reports:

When reached a decision within the scope of the principles, the compliant and the complainee shall be informed of the result verbally and then and the General Manager of both parties shall be informed in writing by adding the case result report.

The complainee company, the summary of the complaint and the decision taken in the meeting shall be included in the report. If there is any material error in the reporter's report, it is corrected and re-distributed.

All of the case report's summaries shall sent to SADER Board of Directors for information.

At the end of each year, SADER Secretary-General shall publish the severity of each case, orientations, insisting behaviour and all case reports that has been dealt with and concluded in a proper detail by taking the recurrence of them into account; recommends to SADER General Assembly the Ethical Principles amendments that will develop further the ethical rules, the transparency and openness between the members and the medical device sector. The summary report shall be sent to the EFPIA Ethical Code Committee and IFPMA.

ARTICLE 2-Criteria to be Paid Attention When Writing Reports:

The case detail and the name of the company shall be included in the severe and recurring breaches.

If a breach is not in question, or in a breach of low level, the company name and the details signifying the company may not be included in the case report..

SADER shares its good promotional practice experience with EFPIA Code Committee and IFPMA Code Compliance Network (CCN) and other drug sector associations and benefit from their experience.

SADER publish the summary of its case reports in English on the web site that attract attention in the national or international arena in order to contribute the exchange of information.

PART V: RECONCILIATION and COMMENT RULES

Upon reaching an agreement on the subjects of dispute in relation to the promotion, for reaching an agreement, the companies needing a mediator may apply to Ethical Study Commission (ESC) Representatives, ECAC members or SADER Secretary-General in order to ask for advice and support.

The SADER member companies may ask for advice with respect to the interpretation of the Ethical Code Principles by conveying their questions and problems to ECAC or ESC.

PART VI: COMMISSION AND COMMITTEES

SECTION I: ETHICAL STUDY COMMISSION (ESC)

SADER Ethical Study Commission (ESC) is responsible for developing and managing the Ethical Code including the advice in relation to the principles, guidance and provision of education.

ESC is comprised of two representative, each of whom has been offered by the companies in writing. ESC member names shall be offered to SADER Secretary-General by the General Managers. There is no limitation for participation in ESC meetings. However, in case of voting, each company has single vote.

ESC chooses a Chairman and A Vice-Chairman among the members having right to vote in the first meeting of the year and submit to Secretary-General.

ESC determine the study method and frequency itself. The minutes of the meeting shall be kept and submit to SADER Board of Director and ECAC members.

ESC, any subject in relation to the ethical studies, the principles or practices of the principles, may do exchange of opinions with ECAC, ECCA and SADER Board of Directors.

The application decisions taken by ESC shall be a part of Ethical Code Rules after approval of SADER General Assembly.

The behaviours opposite to the application decision approved by SADER Board of Directors is included by the responsibility of ECAC.

The behaviours opposite to these decisions about which Ethical Code Assessment Committee shall make a decision as per the provisions in this instruction upon application or their own account.

SECTION II: ETHICAL CODE ASSESSMENT COMMITTEE (ECAC)

ECAC members shall serve for a period of two years and shall be elected by the Board. Company representative membership shall be renewable e once.

7 permanent and 5 reserve member, including the Chairman, constitute the quorum of the meeting and the decisions shall be taken on the basis of the majority of the members having right to vote.

The reserve and 5 permanent member shall be selected by means of drawing of lots from the persons who have served at least five years in management position. According to nature of breach forming the agenda of the meeting, 2 independent expert shall be selected as permanent members. ECAC or the Board may decide that an independent expert serve permanently.

The company representative reserve members shall be summoned to each meeting for providing the majority and shall contribute as made by permanent members. At the beginning of each meeting, the vacant membership shall be filled up by the reserve members by means of drawing of lots.

ECAC shall hold meetings four times a year or when necessary for evaluating the complaints within the scope of the principles.

The permanent member who fails to attend the meetings three consecutive times without submitting a justifiable excuse shall fall from the membership and the reserve member who has got the most votes shall replace him or her. In case of separation of a member, the same process shall be implemented.

The Chairman can have an outside consultant support in any field. The consultants, in case of the Chairman's invitation, may attend the General Assembly buy these persons does not have the right of vote.

ECAC, if need be, shall appoint one or more than one reporters to examine the incoming cases and make a brief investigation.

SADER Secretary-General shall provide the necessary administrative support for ECAC.

ESC Chairman or member, when invited by the SADER Secretary-General, may attend the meeting without right of vote.

SECTION III: ETHICAL CODE COMMITTEE OF APPEAL (ECCA)

ECCA members shall be selected by SADER Board of Directors.

Unresolved or appealed at the level of ECCA, the cases shall be made a decision about by ECCA. ECCA decisions shall be definite.

SADER Committee of Appeal shall gather to evaluate any subject in relation to the principles and the objections within the scope of the principles.

SADER ETHICAL CODE COMMITTEE OF APPEAL (ECCA) constitutes 7 members: two members to be selected from the own members of SADER Administrative and/or Assessment Committee, 2 representative from Branch association; 1 independent member to be determined by the Board.

The meeting shall be started to be held with Chairman and five members having right of vote. And the decisions will be taken on the basis of majority.

If a Board Member is in the position of the complainant or complainee party in a case, another Board member shall be selected instead.

Committee of Appeal Chairman can have a consultant support in any field. The consultants does not have right of vote.

When a complaint is evaluated, the complainant and the complainee shall be summoned to the session. The complainant and the complainee parties may make verbal presentation.

ECCA decisions shall be definite.