

European Chamber of Commerce in Vietnam
Medical Devices & Diagnostics Sector Committee
Code of Ethical Conduct for Interaction with HCPs

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Contents

A. Preamble	2
B. Applicability of the Code	2
C. Definition	2
D. Ethical Principles	3
1. Collaborative interactions to preserve independent decision- making and public confidence ...	3
2. Interactions with Healthcare Professionals	3
2.1 Cultural Gifts, Give-aways, Event Stationeries Items of Medical Utility and Medical Literature	3
2.2 Meals Associated with HCP Business Interactions	5
2.3 Evaluation/ Sample/ Demonstration Products	5
2.4 Honoraria and Agreements for HCP’s Scientific or Educational Services	6
2.5. Member Support of Third Party Educational Events	6
2.6 Member Organized or/and Supported Medical Technology Training and Education	7
2.7. Research and Educational Grant	8
2.8 Charitable Donations.....	8
2.9 Market research.....	9
2.10 Product information	9
3. Product quality commitment	9
4. Trade promotion	10
5. Fair competition in doing business	10
6. Trainings	10
7. Monitoring & Controlling	10
7.1 General principles	10
7.2 Controlling mechanism.....	10
8. Management of the Code	11

A. Preamble

The Medical Devices & Diagnostics Sector Committee (MDDSC) members represent the diversity of the Medical Devices and Diagnostics industry, with companies operating in fields like (without limitation to) wound care solutions and artificial joints, endoscopes and catheters, in vitro diagnostics and high volume disposable devices, and large imaging equipment such as CT's and MRI's.

Member companies are foreign owned Medical Devices and Diagnostics manufacturers or foreign owned distribution companies representing such manufacturers in Vietnam. The MDD SC is open to all such international companies, no matter if their headquarters are based in Europe or on other continents, as the aim of the group is to unify the voices of all international industry players in Vietnam, which face similar challenges and opportunities and share the same aim to support the development of healthcare in the country.

Our group operates under the management of an Executive Board with six members and has three Working Groups all working towards achieving the above.

B. Applicability of the Code

This Code of Ethical Conduct ("Code") is effective as of the 2nd of October, 2019.

The MDDSC Code of Conduct promotes ethical interactions between the medical devices and diagnostics technology industry and health care professionals to advance the MDDSC Mission. The purpose of this Code is to promote ethical interactions between MDDSC's corporate members that develop, manufacture, sell, market, or distribute medical devices and diagnostics technologies in Vietnam ("Members") and those individuals and entities that use, recommend, purchase, or prescribe medical devices and diagnostics technologies in Vietnam.

Members commit to adhere to this standard by adopting and abiding by the ethical principles outlined in this Code. This Code is subject to the laws of Vietnam. If a provision in law or another code of conduct applicable to a Member is more restrictive than the corresponding provision in this Code, the Member shall adhere to the more restrictive provision in the law or other code of conduct. Likewise, if a provision in this Code is more restrictive than the corresponding provision in law or another code of conduct applicable to a Member, the Member shall adhere to the more restrictive provision in this Code as it relates to the Member's business operations in or concerning Vietnam.

It is required that a Member ensures that its third-party intermediaries (including consultants, distributors, sales agents, and brokers) appointed by the Member who may interact with HCPs in connection with the Member's medical devices and/or diagnostics technologies agree to conduct their interactions in accordance with applicable laws and ethical principles at least as restrictive as those contained in this Code.

C. Definition

Healthcare Professional ("HCP") means any individual or entity (with a clinical or non-clinical role - whether a government official, or employee or representative of a government agency or other public or private sector organisation - including, but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators, or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure, or determine the purchase or lease of, or who may prescribe medical and diagnostics technologies or related services.

Professional Association is a regional, national, or specialty clinical or other professional body representing HCPs.

Healthcare Organisation (“HCO”) means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical, or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale, or lease of medical and diagnostics technologies or related services such as a hospital or group purchasing organization, clinic, laboratory, pharmacy, research institution, foundation, university, or other teaching institution or learned or professional society (except for patient organisations); or through which one or more HCPs provide services.

Member means a full corporate member (“**Member Company**”) of MDDSC.

Third Party Educational Event is a conference or meeting that is of a medical, scientific, and/or educational nature, intended to promote scientific knowledge, medical advancement, and/or the delivery of effective health care, and organized by a Professional Association, Healthcare Organisation, or by a bona fide medical or other professional education provider.

D. Ethical Principles

1. Collaborative interactions to preserve independent decision-making and public confidence

The MDDSC recognizes that collaborative interactions between Members and HCPs are essential to advancing medical devices and diagnostics technology and ensuring the safe and effective use of Members’ products and services. Ultimately, such interactions are to the benefit of patients.

The MDDSC is committed to ensuring that these interactions meet the highest ethical standards, preserve HCPs’ independent decision-making, and reinforce public confidence in the integrity of patient care, treatment, and product and service selection.

All interactions with HCPs must be:

- (a) conducted in compliance with applicable laws and codes of conduct;
- (b) based on the best interests of the patient; and
- (c) appropriately documented.

In promoting or advertising their products and services to HCPs, Members must ensure that they comply with applicable laws and codes of conduct. No off-label use for a product to be promoted until the requisite approval has been given by the Ministry of Health. All statements must be true, accurate, and substantiated.

2. Interactions with Healthcare Professionals

2.1 Cultural Gifts, Give-aways, Event Stationeries Items of Medical Utility and Medical Literature

2.1.1 Cultural Gifts

On no occasion may gifts ever be given to a HCP, directly or indirectly. Members shall not provide, nor arrange, entertainment or recreation to, or for, HCPs. Entertainment or recreation includes, for example, theatre, sporting events, golf, skiing, hunting, and leisure or vacation trips.

2.1.2 Event Stationery

Primarily during Member's organized events, Members may provide stationery to help participants take notes, review material, or to take away the materials/hand-outs/related scientific materials from the event. It can be applied to third party events where Members have satellite activities such as satellite symposia/workshops. It cannot be considered as a door gift.

The total value of stationery items (including pen, notepad, document holder, USB, etc.) must not exceed VND 200,000 (excluding VAT) per HCP per event.

2.1.3 Give-aways

Members must ensure that sales of products and services are never made on the basis of a HCP receiving anything of value from a Member. Members may occasionally provide HCPs branded or non-branded items of minimal value not exceeding VND 200,000 per item. These items must serve a genuine educational function relating to the HCP's practice or otherwise benefit the patients. The giving of such items must be infrequent.

2.1.4 Medical utility, educational and informational support items

Items of medical utility may be offered or provided to HCPs if such items are of modest value, do not offset routine business practices, and are directly beneficial to enhancing the provision of medical services or for patient care, and in line with Vietnamese laws. Items of medical utility can include the company name but must not be branded product, unless the product's name is essential for the correct use of the item by the patient, and in line with Vietnamese laws.

- Examples of permissible medical utility items include inhalation devices (without an active ingredient) or devices intended to assist patients learn how to self-inject, and software or mobile apps (e.g. BMI calculator).
- Examples of medical utility items that are not permissible include stethoscopes, surgical gloves, blood pressure monitors, and needles. These are examples of items that should be covered as part of an HCP's/HCO's routine business expenses, and they are expected to be supplied by the HCPs themselves or their employers.

Informational and educational support items that enhance Patient Care provided to HCPs for their education or for the education of patients on disease and its treatments may be acceptable provided that the items are primarily for educational purposes and do not have independent value. These informational and educational items can include the company name but must not be branded product, unless the product's name is essential for the correct use of the item by the patient.

- Examples of permissible educational or informational items include memory sticks pre-loaded with educational or informational data (if storage capacity is commensurate with materials provided), medical/scientific books/magazines, etc.
- Examples of educational or informational items that are not permissible include tablet computers and other such items which have an independent value to an HCP/HCO, notwithstanding that they could be used to deliver education to patients

The total value for items of medical utility, informational, and educational items that enhance patient care that a Member may give to an HCP must be less than VND 8,000,000 per HCP per year and must be less than VND 2,000,000 per HCP per occasion. The Member must notify the HCP of their obligation to report items received over VND 500,000 in accordance with Vietnamese laws.

Items of medical utility, and informational and educational items that enhance patient care, must never be given to HCPs/HCOs, or medical institutions, organizations, or associations for the personal benefit

of the HCP or to influence recommendation, prescription, purchase, or usage of medicines or medical devices and must never be formative of a quid pro quo arrangement.

Diagnostics reagents and/or diagnostics consumables are excluded from Medical Utility.

2.2 Meals Associated with HCP Business Interactions

Meals and refreshments provided to HCPs must be modest in value and subordinate in time and focus to the business part of the meeting/ legitimate business discussion.

The location and venue of any meeting with an HCP must be suitable for and conducive to the exchange of business or scientific information.

Members must not provide recreation or entertainment in conjunction with a consulting relationship or other interactions with an HCP.

Members must not invite or meet the expenses of anyone accompanying an HCP to an event unless that individual has a separate and legitimate need to attend the meeting or business discussion.

2.3 Evaluation/ Sample/ Demonstration Products

A Member may provide its medical devices and diagnostics technology products to HCPs without any charge or any commercial commitment for evaluation and demonstration purposes, subject to the following principles:

- They must not be provided as a means of inappropriate inducement to purchase product or as a rebate based on the volume or value of the business generated by the recipient HCP;
- They are appropriately documented and accounted for by the Member, including to minimize any risk of the HCP being able to financially benefit from the products;
- Only reasonable quantities of evaluation products are supplied to HCPs to familiarize them with the products and enable them to gain experience with the products in their practice. Company products provided for this purpose are typically expected to be used in patient care without any patient charge, include single use products (e.g., consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). The number of single use products provided free of charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances. For example, no more than 2 diagnostics reagent kits of the same kind per laboratory or HCO may be provided per year. Multiple use products may only be provided for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Members should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the HCP’s location at the conclusion of the evaluation period unless the HCP purchases or leases the products.
- The demonstration products are normally used for the HCP and patient awareness, education, and training. Hence, demonstration products typically are not intended to be used in patient care. If not meant for such patient care or human use or diagnostics purposes, the products must be marked “Not for human use”, “Sample” or “Not for diagnostic purposes” or with similar language to indicate that the products are solely for demonstration purposes and that they cannot be sold or used for human clinical studies or routine patient management.

2.4 Honoraria and Agreements for HCP's Scientific or Educational Services

Members or Member's employees or any third-party intermediary representing the Member's interest or on the Member's behalf may engage or contract with HCPs, HCOs, institutions, organizations or associations of HCPs (hereinafter referred to as "professional consultant") for professional, valuable, bona fide services (hereinafter referred to as "service" or "services") to the Member itself or on its behalf if supported by the following elements:

- It is directly in relation to clinical research; scientific development; development and/or research in areas relating to the Member's products and/or its business; participation on advisory boards; sharing experience, training, and education of other HCPs on the safe and effective use of the Member's products and services or associated procedures; presentations at scientific events; professional translation; and/or other legitimate services.
- The agreement or contract or engagement must be in writing specifying in detail the services to be provide. The agreement or contract must be signed by both parties in advance of service execution and must not be in breach of any laws or regulation or both parties respective policies.
- The selection of the professional consultant should be based on the professional consultant's legitimate "license to operate", consultant qualifications, and expertise in dealing with the defined service engaged. The professional consultant shall not be selected in any event based on the volume or value of the business generated by that professional consultant.
- The honorarium paid to the professional consultant must be fair market value and not a means of inappropriate inducement. In no event shall an honorarium be paid by cash on hand, but must be by cash in bank via bank transfer. If the professional consultant is an entity or organization, the honorarium must be transferred to the bank account of the entity or organization, not to the personal bank account of an employee of the entity or organization.
- In addition to the above, the Member should design its own control process to ensure that the service is engaged and executed in compliance with the signed agreement or contract and that the services were provided in accordance with the agreement or contract.

2.5. Member Support of Third Party Educational Events

2.5.1 Member support of a Third Party Educational Event shall at all times preserve the independence of medical and scientific education. A Third Party Educational Event must primarily be dedicated to promoting medical, scientific, and educational activities and discourse, and must be initiated by the Third Party Educational Event organizer.

2.5.2 Any Member's decision to support a Third Party Educational Event must be based on sufficient information to enable the Member to evaluate the medical, scientific, and educational merit of the Third Party Educational Event, as well as the appropriateness of the venue and agenda. Members should not seek to inappropriately influence the program content, selection of faculty, educational methods, or materials at the Third Party Educational Event.

2.5.3 Under no circumstances shall a Member's support of a Third Party Educational Event be to induce an HCP to use, recommend, purchase, or prescribe the Member's products and/or services. The nature of and the conditions attaching to a Member's support of a Third Party Educational Event must be properly documented in writing.

2.5.4 In accordance with Section 2.7 (Research and Educational Grants), Members may only support attendance of HCPs at Third Party Educational Events through provision of Educational Grants to:

- (a) the organizer of the Third Party Educational Event to defray the costs of running the Third Party Educational Event and/or to support attendance of HCPs at the Third Party Educational Event;
- (b) a Professional Association or Health Care Institution to support attendance of HCPs at the Third Party Educational Event; provided that the recipient of the Grant makes an independent decision on selection of the attending HCPs.

2.5.5 Without limiting Section 2.5.4, Member support of Third Party Educational Events shall be limited to funding:

- (a) the purchase of advertising and leasing of booth space for displays and promotional activities at the Third Party Educational Event;
- (b) the holding of satellite symposia at the Third Party Educational Event;
- c) registration fees to the Third Party Educational Event;
- (d) reasonable travel to, and modest accommodation at, the Third Party Educational Event where out-of-town travel is required;
- (e) incidental meals and refreshments, provided the meals and refreshments are modest in value and are subordinate in time and focus to the educational purpose of the Third Party Educational Event.

2.5.6 Members shall neither:

- (a) arrange, pay for, offer to pay for, or otherwise reimburse the expenses of any individual HCP to attend or speak at a Third Party Educational Event; nor
- (b) select, or influence the selection of, any HCP to attend a Third Party Educational Event, whether as a delegate or as faculty.

2.6 Member Organized or/and Supported Medical Technology Training and Education

2.6.1 Members may provide or support training and education to HCPs on product-specific technology deployment, use, and application to facilitate the safe and effective use of medical devices and diagnostics technologies. Members may also provide or support education to HCPs on topics concerning or associated with the use of their medical devices and diagnostics technologies, in accordance with their registered scope of business in Vietnam.

Training and education shall be conducted by qualified personnel, which may include Member personnel with appropriate technical expertise or personnel of an independent, reputable, professional third party.

2.6.2 Training and education programs shall be conducted in appropriate venues that are conducive to the transmission of education and training and are selected based on their suitability for the proposed program and for the convenience of attendees. Appropriate venues may include the HCP's premises, the Member's premises, or other clinical, laboratory, educational, or conference training facilities (including hotel conference rooms), depending on the nature of the program. The venue must not be selected because of its entertainment, leisure, or recreational facilities.

2.6.3 To assist HCPs attending Member's organized training and education programs, Members may fund the costs of individual HCPs' reasonable travel, modest accommodation, and incidental, modest meals, and refreshments. Members shall not provide, pay for, or arrange for recreation or entertainment for participating HCPs, nor shall Members provide, pay for, or arrange for travel, accommodation, meals, or refreshments of spouses or other guests of participating HCPs.

2.7. Research and Educational Grant

A Member may provide research and educational grants provided that the Member:

- Adopts objective criteria for providing the grants;
- Implements appropriate procedures to ensure that grants are not conditional on the use, recommendation, purchase, or prescription of the Member's products and services; and
- Ensures that the recipient of the grant makes an independent decision on application of the grant and/or selection of any beneficiary of the grant.

Research grants may only be used to support independent medical research with scientific merit or health care policy development, provided that such activities have well-defined objectives and milestones.

Educational grants may only be made to advance patient care, for medical education of medical students, fellows participating in fellowship programs, or other medical personnel, or for educating the public on health care issues.

In reference to section 2.5 – Member Support of Third Party Educational Events, a member may provide an educational grant to:

- (1) The organizer of the Third Party Educational Event to defray the costs of running the Third Party Educational Event and/or to support attendance of HCPs at the Third Party Educational Event.
- (2) A Healthcare Institution to support attendance of HCPs at the Third Party Educational Events; and/or
- (3) A Professional Association to support attendance of HCPs at the Third Party Educational Events.

in which, the following controls shall be maintained:

- i. All request must come officially in written from a recognized Event Organizer, HCO, Healthcare Institution, or Professional Association, and not from any individual.
- ii. A Member shall not issue any invitation to a Hospital/Healthcare Institution to attend such events
- iii. A Member shall ensure that the grant provided is legitimate and at fair market value.
- iv. A Member may provide a suggested list of the key professional Medical education/events organized by a 3rd party while ensuring no influence on the selection of any specific HCP occurs.
- v. A Member may not assist in any arrangement of logistics for such requests.
- vi. Educational grants provided shall be documented in a legal agreement between the Member and the Event organizer/Healthcare Institution, which reserves to the Member audit rights and requires the recipient to provide the actual spending/usage of the fund to the Member upon request.
- vii. Educational grants shall be made by bank transfer to the bank account of the Event organizer/Healthcare Institution/Professional Association based on their request.

2.8 Charitable Donations

Members may make donations of money, products, or services for charitable or other philanthropic purposes, or sponsor events where the proceeds are intended for charitable purposes, unless the donations are prohibited under applicable laws and/or codes of conduct.

Charitable donations are not to be used as a marketing tool, and must not be targeted to HCPs, nor shall they be used as an encouragement or as a reward for a HCP/HCO using, recommending, purchasing, or prescribing a Member's products or services.

Charitable donations shall only be made for charitable purposes to bona fide non-profit entities and charitable organizations as determined by Vietnamese laws, and shall not be made based on the recommendation of any HCP and/or Government Official. Charitable Donations are prohibited to be given directly to individuals.

All charitable donations shall be appropriately documented.

2.9 Market research

Research is initiated and intended to answer legitimate scientific questions about the efficacy, safety, efficiency or utilization of products, or otherwise to advance the science in members therapy areas. Research is not conducted as a means to promote products and/or therapies, or to reward individuals or organizations for past, present, or future business.

All scientific research must be conducted consistent with applicable regulations in Vietnam

2.10 Product information

Product information and claims must be presented with a high ethical standard, in compliance with the latest product information approved by the Ministry of Health (Vietnam Medical Device and Medical Construction Department), and in such a way as not to be misleading or ambiguous.

2.10.1 Product information to HCP in medical journals

The contents of the product information and/or product advertising provided to HCP must satisfy the requirements of the Medical Device information and advertisement regulations issued by the Ministry of Health (Vietnam Medical Device and Medical Construction Department), and shall only be issued in respect of Medical Devices that have received a 5 year Medical Device License and/or Import License.

2.10.2 Contents of product information

The contents of the product information provided to an HCP must satisfy the requirements of the Medical Device information (Decree 43 of Labeling and Decree 36 for Medical Device) and the advertisement regulation issued by the Ministry of Health

Printed material must be presented in a legible manner. Information and claims for pharmaceutical products must be true, accurate, clear, and objective, as substantiated by scientific evidence. Information and claims must also be presented with a high ethical standard, in compliance with the Ministry of Health authorized product information, and in such a way that is not misleading or ambiguous.

3. Product quality commitment

The reputation and sustainable development of Members are based or shall be based on the highest quality of their products as well as integrated services, to enable HCPs to provide their patients with the best possible results from the use of such products.

Hence, all members commit to compliance with the quality and safety standards prescribed by the relevant laws and regulations.

Members must take action immediately to withdraw non-qualified products and must try their best with mitigating actions as well as corrective actions whenever identifying problems caused through non-qualified products or integrated services.

4. Trade promotion

This Code does not restrain or regulate commercial trade terms and/or trade promotion activities in accordance with Vietnamese law for the supply of medical devices and diagnostics. The Members encourage healthy competition among companies. Trade promotion must be in line with applicable laws and must not be misused as a means of improper inducement.

5. Fair competition in doing business

Members are entitled to freedom of competition in accordance with the laws of Vietnam.

Competition must be implemented on the principles of honesty, fairness, and non-infringement upon legitimate rights and interests of other companies and consumers.

6. Trainings

Members are responsible for

- Oversight of the Members' compliance with this Code.
- Effective communication of the Code to its employees, contractors and third party intermediaries on ethical conduct for interactions with HCPs.

7. Monitoring & Controlling

7.1 General principles

Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable laws and to review and monitor all of their activities and materials in that regard.

To promote compliance with the MDDSC Code of Ethics, the Member companies will proactively monitor the practices of other companies regarding compliance with the Code. Any complaints should be submitted to the MDDSC Secretariat and handled by the EuroCham appointed Board member and/or a law firm/audit firm as an independent and competent 3rd party with consultancy from the Business Ethics Working Group.

7.2 Controlling mechanism

In case of a complaint, Member companies should file an official complaint in writing stating the identity of the company, reference material, along with copies of all necessary documents and evidence and submit the same to the EuroCham MDDSC Secretariat. EuroCham MDDSC Secretariat shall submit the complaint to EuroCham appointed Board member. EuroCham appointed Board member and the Business Ethics Working Group shall review and consider documents from EuroCham MDDSC Secretariat, determine whether a breach of the Code has occurred. Depending on severity of the breach, a law firm/audit firm could be involved if necessary.

EuroCham appointed Board member and Business Ethics WG could ask for official information back from the company compliance representative and its General Manager. With these information, and advices from the Business Ethics Working Group, EuroCham appointed Board member and the MDDSC Chair/ MDDSC authorised Board member will have final decision on the complaint, including the types of sanctions to be applied. Conflicts of interest shall be considered in the process of review and decision making.

Based on the severity, circumstance and frequency of the breach, actions that may be taken by the MDDSC Board as sanctions against Member in breach, such as the following:

- (i) Request the Member in breach to issue a written undertaking that the practice complained of will be discontinued on or before a date to be determined by the MDDSC Board.
- (ii) Suspend the membership of the Member in breach for no more than 3 years.

8. Management of the Code

The MDDSC General Assembly will review the operation and effectiveness of the Code at regular intervals of not more than five (5) calendar years. The review of the Code will be conducted under the direction of the MDDSC Board and Business Ethics Working Group.

This Code may be amended by vote of at least two-thirds of MDDSC Members presenting and entitled to vote at a Meeting, properly convened and held, or via written confirmation.