

Code of Ethical Conduct for Interaction with Healthcare Professionals Information and Training session

Time: 9.00-11.00, Tuesday, October 29th, 2019

Venue: Sofitel Saigon Plaza

Code of Ethical Conduct for Interaction with Healthcare Professionals Information and Training session

Opening speech

**Presented: Lead of Business Ethics Working Group, EuroCham
MDDSC: Mr. Hoang Thanh Viet**

Agenda

- Statement of Anti-trust and Healthy competition
- Introduction on EuroCham MDDSC
- Code of Ethical Conduct Sharing
 - Introduction on the Code
 - Key principles
- Q&A
- Conclusion
- Participants collect Certificate of attendance

Statement of Anti-trust and Healthy competition

Mrs. Le Bich Lien
General Counsel, B.Braun Vietnam
Member of EuroCham MDDSC Business Ethics Working Group

Statement of Anti-trust and Healthy competition

Medical Devices and Diagnostics Sector Committee Members **must not** engage in any illegal activity or engage in EuroCham Sector Committees' activities with the purpose to circumvent certain international laws, in particular with regards to Vietnamese and international competition- and/or antitrust laws.

EuroCham MDDSC Members may meet and discuss matters concerning their industry at meetings, provided they do so **without a specific and continuing purpose, understanding or agreement** to pursue actions tending to unreasonably restrict commerce or violate any laws, rules or regulations.

Local distributors of EuroCham MDDSC Members who may interact with healthcare professionals in connection with the Member's medical devices and/or diagnostics technologies, agree to comply with applicable laws and ethical principles, in particular with regards to Vietnamese and international competition- and/or antitrust laws.

Code of Ethical Conduct for Interaction with Healthcare Professionals Information and Training session

Introduction on EuroCham MDDSC

**Presented: Business Ethics Working Group, EuroCham MDDSC
Mr. Hoang Thanh Viet; Mrs. Nguyen Huu Uyen Hanh; Mrs. Le
Bich Lien; Mrs. Dang Thi Tuyet Nhung**

Introduction on EuroCham MDDSC

Medical Devices and Diagnostics Sector Committee (MDDSC): 1 of 16 Sector Committees of EuroCham

Established in April 2016. Members represent the vast diversity of the industry.

Mission: engage with governments, regulators, payers, healthcare providers, etc. to:

- ❖ advocate good practices
- ❖ promote high industry standards
- ❖ help develop policies
- Shape the future of healthcare in Vietnam

Vision: enable timely access to sustainable, innovative and high quality healthcare for all citizens of Vietnam

Management:

- ❖ Executive Board
- ❖ By Law was adopted on September 27th, 2018

List of 23 MDDSC Members

Abbott	GE Vietnam
Alcon Pharmaceuticals	Johnson & Johnson
B.Braun	KarlStorz
Baxter Healthcare	Medtronic Vietnam
Bayer Vietnam	Olympus Medical Systems Vietnam
Becton Dickinson	Philips
Boston Scientific	Roche Diagnostics
Carl Zeiss	Siemens Healthineers
DKSH	Terumo Vietnam Medical Equipment
Draeger	Urgo
Fresenius Medical Care Vietnam	Zuellig Pharma
Fujirebio	

Introduction on MDDSC Business Ethics Working Group

MDDSC has 3 Working Groups working towards achieving the MDDSC's missions and visions:
Regulatory Working Group; Market Access Working Group; Business Ethics Working Group

Business Ethics Working Group: kick-off in July 2017

Objectives:

- ❖ Promote the ethical and compliant business
- ❖ Foster awareness, capacity building and the implementation of best practice mechanism in order to enhance the quality of compliance
- ❖ Represent MDDSC, advise and advocate on compliance related matters
- ❖ Create a common policies to enhance the quality of compliance

Members of Business Ethics Working Group:

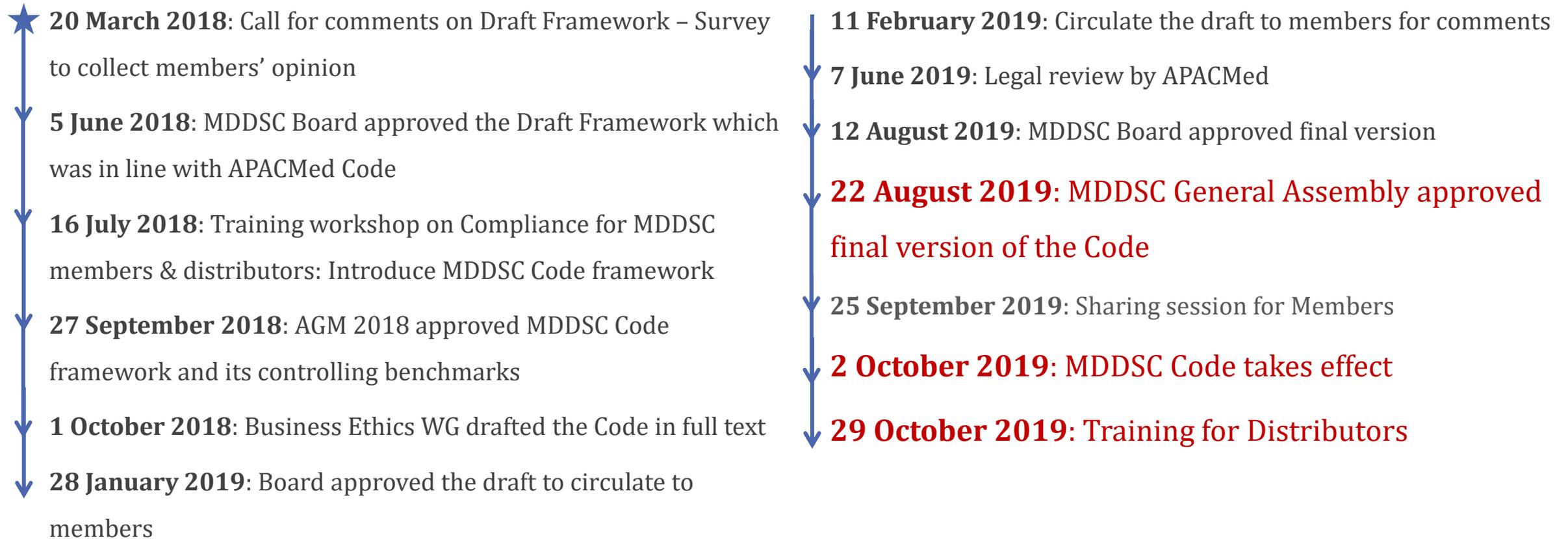
- ❖ Compliance/internal audit/legal representatives of MDDSC Members
- ❖ Nominated by the General Manager of MDDSC Members

Code of Ethical Conduct for Interaction with Healthcare Professionals Information and Training session

Code of Ethical Conduct Sharing

**Presented: Business Ethics Working Group, EuroCham MDDSC
Mr. Hoang Thanh Viet; Mrs. Nguyen Huu Uyen Hanh; Mrs. Le
Bich Lien; Mrs. Dang Thi Tuyet Nhung**

Introduction: Timeline



Introduction: Contributors

MDDSC Board

- Provide strategic oversight, direction to the Code
- Approve final version of the Code

MDDSC Business Ethics Working Group

- Active role in drafting, developing the Code
- Clarify members' questions

MDDSC General Assembly: 23 members

- Feedback during the drafting process
- Provide inputs to the Code's revision
- Vote for adoption of final version of the Code

APACMed

- Legal review for final version of the Code
- Key framework for the Code

MDDSC Secretariat

- Coordinate activities of the Code

Introduction: Objectives

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.

This Code is subject to the laws of Vietnam, Members shall adhere to the more restrictive provision in the law or other codes of conduct.

This Code is applicable to all MDDSC's members and its Third-party Intermediaries (including consultants, distributors, sales agents, and brokers).

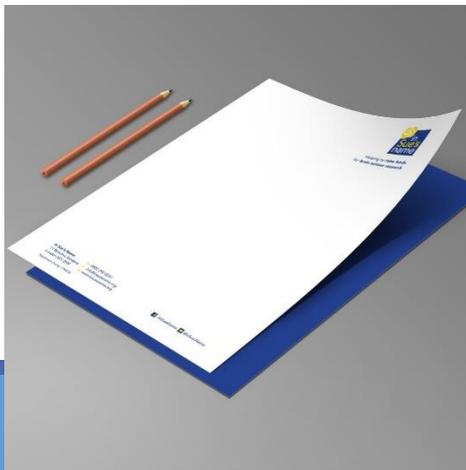
Key principles:

Ref.	Contents	Controlling principle
Section 2.1.1	Cultural Gifts	<ul style="list-style-type: none">• No gift directly or indirectly to a HCP (e.g. no gift for Tet, Mid-Autumn, Xmas ...)• No entertainment or recreation is allowed (e.g. theatre, sporting event, golf, skiing, hunting, leisure or vacation trips ...)



Key principles:

Ref.	Contents	Controlling principle
Section 2.1.2	Event stationery	<p>Allowed with total value must not exceed VND 200,000 per HCP per event.</p> <p>Stationery (pen, notepad, document holder, USB, etc.) to help participants take notes, review material, or to take away the materials/hand-outs/related scientific materials form the event.</p>



Key principles:

Ref.	Contents	Controlling principle
Section 2.1.3	Give-aways (branded or non-branded items)	<p>May occasionally provide HCPs branded or non-branded items of minimum value not exceeding VND 200,000 per item. These items must serve a <u>genuine educational function relating to the HCP's practice or otherwise benefit the patients.</u></p> <p>E.g. Branded pens, small notebooks, medical gloves, safety glasses, medical face masks, etc.</p>



Key principles:

Ref.	Contents	Controlling principle	Examples
Secti on 2.1.4	Medical Utility/ Informational Item/ Educational support items	<p>Medical Utility allowed if such items are at modest value, not offset routine business practice, are directly beneficial to enhancing the provision of medical service and in line with Vietnamese law.</p> <p>Informational item and Educational support item allowed if such items are for educational purposes and do not have independent value</p> <p>Total value (all of these items) less than VND 8,000,000 per HCP per year and less than VND 2,000,000 per HCP per occasion. The Member must notify the HCP of their obligation to report items received.</p>	<p>E.g. Medical utility items:</p> <ul style="list-style-type: none"> ➤ not permissible: stethoscopes, surgical gloves, blood pressure monitors, and needles. ➤ permissible: 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). <p>E.g.: Educational or informational items :</p> <ul style="list-style-type: none"> ➤ not permissible: tablet computers ➤ permissible: memory sticks pre-loaded with educational or informational data (if storage capacity is commensurate with materials provided), medical/scientific books/magazines, etc.

Key principles:

Ref.	Contents	Controlling principle
Section 2.2	Meals associated with HCP Business Interaction	Allowed, provided that the meals are <ul style="list-style-type: none">- Modest value- Legitimate business discussion/purpose- Appropriate location and venue- Not provide recreation/entertainment- Not invite or pay for anyone accompanying an HCP to an event

Key principles:

Ref.	Contents	Controlling principle	
Section 2.3	Evaluation/ Sample/Demonstration products	<p>* Evaluation products are 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”). For example, no more than 2 diagnostics reagent kits of the same kind per laboratory or HCO may be provided per year.</p> <p>* Sample/Demonstration products are solely for demonstration purposes and that they cannot be sold or used for human clinical studies or routine patient management.</p>	<p>Allowed, provided that:</p> <ul style="list-style-type: none"> - For evaluation and demonstration purposes - Not a mean of inappropriate inducement to purchase product - Appropriately documented and accounted - Reasonable quantities - Demonstration products should be marked “not for human use”, “sample”, or “Not for diagnostic purposes”

Key principles:

Ref.	Contents	Controlling principle
Section 2.4	Honoraria and Agreement for HCP's Scientific or Educational Services	<p>Allowed, provided that:</p> <ul style="list-style-type: none"> - It is directly in relation to legitimate services - The selection based on consultant's legitimate license, qualification, and expertise. - The honorarium must be fair market value - Payment by bank transfer to consultant's bank account. No cash payment - The agreement/contract must be in writing specifying in detail the service and signed by both parties before the service provided. - Service provided in accordance to the signed agreement/contract. <p>Member should design its own control process.</p>

Key principles:

Ref.	Contents	Controlling principle
Section 2.5	<p>Member support of Third-party Educational events</p>	<p>Allowed, provided that:</p> <ul style="list-style-type: none"> - The third party educational event primary be dedicated to promoting <u>medical, scientific and educational activities</u>. - Decision to support must be based on sufficient information – evaluate the medical, scientific and education purpose as well as the appropriateness of the venue & agenda. - Members should not seek to inappropriate influence the program content, selection of the faculty, educational methods or material at the third party event. - Not use as a mean to induce HCPs to use, recommend, purchase, or prescribe Members’ products and services <p>Members may support the attendance of HCPs at Third Party Educational Events through provision of as Educational Grants (ref. section 2.7 of the Code) to:</p> <ul style="list-style-type: none"> - The organizer of the Third party Educational event to defray the costs of running the event and/or to support attendance of HCPs at the event. - A Professional Association or Healthcare Institution to support attendance of HCPs at the third party educational event (decision on selection of HCP will be independently made by the recipient of the grant)

Key principles:

Ref.	Contents	Controlling principle
Sect ion 2.5	Member support of Third-party Educational events	<p>Members may support of third party educational event by providing funding to the above parties for the following purposes:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Advertising and leasing of booth space to display and promotional activities at Third Party Educational Event <input type="checkbox"/> Holding of satellite symposia at the Third party Educational Event <input type="checkbox"/> Registration fees to the Third party Educational Event <input type="checkbox"/> Reasonable travel to, and modest accommodation at, the Third party Educational Event where out-of-town travel is required <input type="checkbox"/> Incidental meals and refreshment at modest value and are subordinate in time and focus to the educational purpose of the Third Party Educational Event. <p>Members shall neither:</p> <ul style="list-style-type: none"> <input type="checkbox"/> 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 <input type="checkbox"/> Select, or influence the selection of, any HCP to attend a Third party Educational Event, whether as a delegate or faculty.

Key principles:

Ref.	Contents	Controlling principle	
Section 2.6	<p>Member Organized or/and Supported Medical Technology Training and Education</p>	<p>Allowed, provided that:</p> <ul style="list-style-type: none"> - Training and education organized by member with qualified resource to HCPs on member's product-specific technology deployment, use, and application to facilitate the safe and effective use of medical devices and diagnostics technologies (ref. member registered scope of business in Vietnam) - Training and education programs shall be conducted in appropriate venues - Reasonable cost of travel, accommodation, meals, and refreshment for HCPs attending 	<p>Who can be a qualified resource for training? It may include member's personnel with appropriate technical expertise or personnel of an independent, reputable, professional third party.</p> <p>Example of appropriate venues 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</p> <p>The following are considered as inappropriate venues in general: Resorts, gaming locations (casinos); leisure facilities, amusement park</p>

Key principles:

Ref.	Contents	Controlling principle
Section 2.7	<p>Research and Educational Grant</p> <ul style="list-style-type: none"> <i>Note: new point comparing to other codes: No individual HCPs sponsorship;</i> 	<p>Member may provide Research and Educational Grants provided that member:</p> <ul style="list-style-type: none"> ✓ Adopts objective criteria for providing the grant ✓ Implement appropriate procedures to ensure that grants are not conditional on the use, recommendation, purchase, or prescription of the member's products and services; and ✓ Ensure that the recipient of the grant makes an independent decision on application of the grant and/or selection of any beneficiary of the grant. <p>Research grant only be provided to support independent medical research with scientific merit or healthcare policy development, provided that such activities have well-defined objectives and milestones.</p> <p>Educational Grant only be provided to advance patient care, for medical education of medical student, fellows participating in fellowship program, or other medical personnel , or for educating the public on healthcare issues.</p>

Key principles:

Ref.	Contents	Controlling principle
Secti on 2.7	<p>Research and Educational Grant</p> <ul style="list-style-type: none"> <i>Note: new point comparing to other codes: No individual HCPs sponsorship;</i> 	<p>Reference to section 2.5, Member may support Third Party Educational Events by providing Educational Grants to:</p> <ul style="list-style-type: none"> - The organizer of the Third party Educational event to defray the costs of running the event and/or to support attendance of HCPs at the event. - A Professional Association or Healthcare Institution to support attendance of HCPs at the third party educational event <p>With conditions:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Official written request from a recognized Event organizer, HCO, professional association, not from any individual. <input type="checkbox"/> Member shall not issue any invitation <input type="checkbox"/> Member shall ensure that the grant provided is legitimate and at fair market value <input type="checkbox"/> Member ensure no influence, the decision on the selection of HCP will be independently made by the recipient of the grant. <input type="checkbox"/> Member may not assist in any logistic arrangement for such request <input type="checkbox"/> Grants shall be documented in a legal agreement between the member and the event organizer/Healthcare Institution/Professional Association <input type="checkbox"/> Educational grant shall be made by bank transfer to the bank account of Event Organizer/Healthcare Institution/Professional Association

Key principles:

Ref.	Contents	Controlling principle
Section 2.8	Charitable Donation	<p>Allowed, provided that the donation is:</p> <ul style="list-style-type: none"> - Made for charitable purposes only to bona fide non-profit entities and charitable organization as determined by Vietnamese law. - Not to be used as a marketing tool - Not made based on the recommendation of any HCP and/or Government officials. - Not given directly to individual - Shall be appropriately documented <p>* Bona fide non-profit entities: <i>“Non-profit organisations are legal entities or organisations with main operation being mobilisation or distribution of funds for charitable, religious, cultural, educational and social purposes or similar purposes, but not for profits, include: foreign non-governmental organisations, social funds, charity funds established and operate in accordance with Vietnamese laws.”</i></p>

Key principles:

Ref.	Contents	Controlling principle
Section 2.9	Market research	<p>Market Research</p> <ul style="list-style-type: none"> • Can be 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. • Must not use as a means to promote products/therapies, or to reward individuals or organization. • Must be conducted consistent with applicable regulations in Vietnam
Section 2.10	Product information	Must be presented in high ethical standard, in compliance with latest approved product information and Vietnamese laws and regulations.

Key principles:

Ref.	Contents	Controlling principle
Section 3	Product Quality Commitment	Compliance with the quality and safety standards prescribed by the relevant applicable Vietnamese laws and regulations
Section 4	Trade Promotion	Member to ensure the trade promotion to be in line with applicable laws and must not be misused as a means of improper inducement.
Section 5	Fair Competition in doing business	Competition must be implemented in the principles of compliance with Vietnam law, honesty, fairness and non-infringement upon legitimate rights and interest of other companies and consumers
Section 6	Trainings	Members are responsible for <ul style="list-style-type: none"> - Oversight of the members' compliance with this Code - Effective communication of the Code to its employees, contractors and third party intermediaries

Handling complaints procedure:

Complaint submission: Member companies file an official complaint in writing to EuroCham MDDSC Secretariat, who submit the complaint to EuroCham appointed Board member



Complaint processing: EuroCham appointed Board member and the Business Ethics Working Group review, consider, determine whether a breach of the Code has occurred

Conflicts of interest to be considered

Law firm/audit firm be involved if necessary

Ask for official information back from the company compliance representative and its General Manager



Complaint handling decision: EuroCham appointed Board member and the MDDSC Chair/ MDDSC authorized Board member make final decision, including the types of sanctions



Actions taken against Member in breach by MDDSC Board, such as:

- Request the Member to issue a written undertaking to discontinue the practice complained
 - Suspend the membership of the Member for no more than 3 years

Code of Ethical Conduct for Interaction with Healthcare Professionals Information and Training session

Q&A
**Discussion between Business Ethics Working Group
and Participants**

Common Q&A

1. Is this Code aligned with the Vietnamese laws/APACMed Code?

- ❖ This Code is subject to the laws of Vietnam. If a provision in law is more restrictive than the corresponding provision in this Code, the Member shall adhere to the more restrictive provision in the law.
- ❖ This Code is in line with APACMed Code, legal reviewed by APACMed

Common Q&A

2. Governing scope:

(i) Is this Code applied for companies' business activities outside of EuroCham and/or all Eurocham members?

❖ This Code is applied for all EuroCham MDDSC Members' business activities in Vietnam including members' third party intermediaries (including consultants, distributors, sales agents, and brokers).

(ii) If Member applies the company's own policies which have duplicate/differences between this Code and the company's policies, does this affects somehow to their positions within MDDSC?

❖ According to Section B of the Code, the more stringent rules shall be applied.

Common Q&A

3. Cultural gifts:

(i) Is it also applied for giving gift in some major festive events of Vietnam which are considered as Vietnam official cultural events such as Tet Holiday, New Year's Eve, Christmas and Mid-Autumn?

❖ According to provision 2.1.1. under Section D of the Code, no cultural gift is allowed for any occasion. No more of such above cultural gifts is considered for HCPs. No exception to be granted.

(ii) What if another company violates this provision, can any action be taken?

❖ According to provision 7.2. under Section D of the Code, Member companies could file an official complaint in writing stating the identity of the company, reference material against Member in breach to the MDDSC Secretariat. Following the complaint handling process and decision, EuroCham appointed Board member and MDDSC Board can take actions against the Member in breach.

Common Q&A

3. Cultural gifts:

(iii) Could Members send wreath of flowers to funeral of HCPs or flowers to opening ceremony of hospital?

- ❖ Decree 59/2019 on guiding the Anti-corruption Law regulates that servants must not by all means receive gifts from organisations and individuals involved in their work. Flowers as an item therefore is not allowed.
- ❖ Decree 105/2012 on funerals of civil and public servants regulates that guests don't bring wreath of flowers but only a black ribbon to attach to the wreath of flowers that the organiser prepares.

Common Q&A

4. Charitable Donations

(i) Can Health Care Organization and Professional Association/Society receive the Charitable Donation?

- ❖ According to provision 2.8. under Section D of the Code, Charitable Donations can be made for charitable purposes to bona fide non-profit entities and charitable organizations as determined by Vietnamese laws.

(ii) Can Health Care Organization and Professional Association/Society send to Member the request Letter to ask for a Charitable Donation?

- ❖ All charitable donations shall be appropriately documented. Charitable Donations can be made based on the written request of Bona fide non-profit entities and charitable organizations.

Common Q&A

5. What is the definition of the appropriate venue which is mentioned as a condition in all interactions with HCPs i.e. in business meals with HCPs, in supporting third party education event, in Members' product training event, etc.

The venue is considered as appropriate for members' business meals, members' organized or third parties' organized the scientific/educational meeting / training shall meet the followings:

- ✓ Be modest - reasonable & not extravagant
- ✓ Be appropriate and conducive to the exchange of scientific information - appropriate for training and education purposes with adequate facilities, including security and sanitary conditions
- ✓ Accessibility - Location should be easily accessible, taking into account the residential locations and/or countries of origin of HCPs

Examples of inappropriate venue: resort, gaming (casino), leisure location (e.g. golf club, karaoke, bar, beer restaurants)

Q&A

6. Local distributors

In situation where local distributors takes the main role to execute all activities including interactions with HCPs and/or GO on behalf of members in Vietnam (e.g. local distributor organize event and engage HCP for speaker service, or local distributor provide educational grant to hospital....)

(i) Is it required local distributor to adhere to MDD Code of Ethical Conducts?

- ❖ The MDD Code of Ethical Conducts is applicable to all members and its third party intermediates including distributors, it's the must that the local distributor adhere to the MDD Code Of Ethical Conduct in the all interactions with HCPs and/or GOs on behalf of members.

(ii) In case if local distributors of members have query, who should they contact ?

- ❖ In case local distributors of members have any query, they should proactive contact members for guidance. Further, according to the Code section 6, members are responsibilities for: (i) Oversight of the members' compliance with this Code and (ii) Effective communication of the Code to its employees, contractors and third party intermediaries.

Q&A

7. Are Members allowed to invite speakers and pay expenses (travel, accommodation, meal and honoraria) for speakers to speak at the Member's satellite symposium at third party educational events?

- ❖ Members' satellite symposium is allowed following principles in Section 2.6 on activities organized by the Member.
- ❖ The Member may pay honoraria to the speakers who provide bona fide services at the Member's satellite symposia, in accordance with Section 2.4.
- ❖ The Member can only fund the costs for the speaker to speak at their satellite symposium, but not fund the costs for the speaker to attend the third party educational event.
- ❖ If the speaker is already benefiting from an educational grant covering his/her attendance to the Third party Educational Event, cost for speaking at the Member's satellite symposium is not covered.
- ❖ The Member must maintain the independence of agenda of the satellite symposium, and ensure it is not affected by agenda of the third party education event.

Q&A

8. When a Member provides a grant for a hospital/organization to attend a research and educational event, could the Member know identity of the individuals who benefit from the grant to verify that the provided grant is used for the right purpose?

- ❖ The Member is not allowed to have any influence on the selection of any specific individual who benefit from the grant, and must ensure the independence of the hospital/organization in selecting the beneficiary.
- ❖ Best practice sharing: The valid contract between the Member and the hospital/organization should include a provision that the selected beneficiary meet requirements mentioned in the request letter, and usage of the grant is in accordance with signed agreement between the two sides. After signing the agreement, the hospital/organization should have a written document confirming the actual spending/usage of the fund along with copy of valid invoices of all expenses, but must not include name of the beneficiary (no specific HCP name is mentioned).

Q&A

9. Under Decree 59/2019 on guiding the Anti-corruption Law, any item giving to HCPs need to have approval from Healthcare organisations (e.g. hospital, clinic, laboratory, pharmacy, research institution, foundation, university). Regarding medical and educational items that MDDSC Members can provide to HCPs, do they need approval from HCOs?

- ❖ Yes, following regulations under Decree 59, Members need approval from HCOs to provide medical and educational items to HCPs.
- ❖ Best practice sharing: For transparency in providing medical and educational utilities to HCPs regulated under Section 2.1.4 of the MDDSC Code, Members should provide via an educational grant to HCOs, given that the Member receives an official written request from HCOs and the HCOs are independent in deciding on application of the grant and/or selection of any beneficiary of the grant.

Code of Ethical Conduct for Interaction with Healthcare Professionals Information and Training session

Other Q&A

Code of Ethical Conduct for Interaction with Healthcare Professionals Information and Training session

Conclusion

**Presented: Lead of Business Ethics Working Group, EuroCham
MDDSC: Mr. Hoang Thanh Viet**

Conclusion

1. Contact of MDDSC Secretariat

Email: mddsc@eurochamvn.org

Phone: **(84-28) 3827 2715 Ext 117**

2. Next Information and Training session: in Hanoi

- ❖ Time: **14.30-16.30pm, Tuesday, 12 November 2019**
- ❖ Location: **Metropole Hanoi**
- ❖ Language: Vietnamese; handout and slides will be provided both Vietnamese and English
- ❖ MDDSC Secretariat will send Invitation to Members → Members support circulating to distributors

Code of Ethical Conduct for Interaction with Healthcare Professionals Information and Training session

Thank you!

**Participants collect Certificate of Attendance at
the Receptionist/Registration table**