Partner workshop: Business Code of Ethics and Compliance
Hội thảo đối tác: Bộ Quy tắc đạo đức trong kinh doanh và Tuân thủ

16 July, 2018 – Sofitel Plaza – Ho Chi Minh city

Opening Address

Ms. Zohra Anwari, Legal Counsel, AdvaMed - Introduction

Mr. Marc Clapera, General Manager, URGO & Vice-Chair, EuroCham Vietnam Medical Device & Diagnostic Sector Committee (MDDSC)

Mr. Do Duc Chi, Deputy Chief of Office, Vietnam Medical Equipment Association (VIMEDAS)

Anti-Competition Statement

Ms. Nguyen Lan Huong
Senior Legal Director – DKSH Vietnam
MDDSC Legal Working Group

Partner Workshop

Medical Device Sector

16 July 2018 | Ho Chi Minh, Vietnam

The Importance of Compliance for Business Growth and Sustainability

Marc Clapera
Business Unit Manager, URGO
Vice-Chair MDDSC

Partner Training

Medical Device Sector

16 July 2018 | Ho Chi Minh, Vietnam

What comes to our mind when talking about ethics and compliance?

What ethics and compliance really mean?

GROWTH

Patient Oriented

Education

Sales

Social Contribution

PROFIT

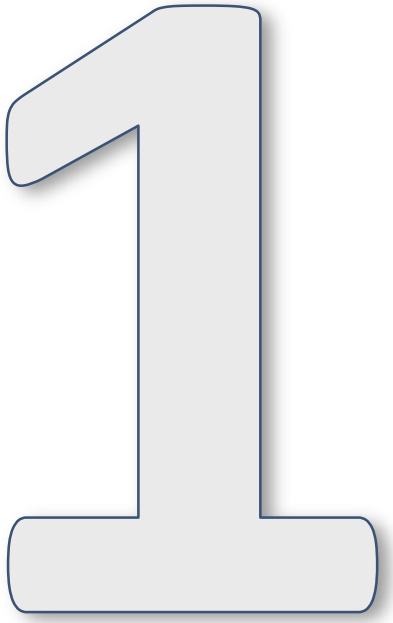
INTEGRITY

Why is it so important for Medical Device Industry?

- Collaboration with health care professionals are:
  - Essential to medical product innovation and development
  - Critical to training for safe and effective use of medical devices

- Ethical arrangements are needed to:
  - Ensure products selected are in best interest of patients
  - Protect public trust in health care delivery
  - Promote Innovation

Why is Compliance Important?



Meets Regulatory Expectations

- Meets Regulatory Expectations

  - Foreign Corrupt Practices Act
  - Bribery Act
  - Country Specific Anti-Corruption Laws
  - Local Industry Codes of Conduct

Why is Compliance Important?

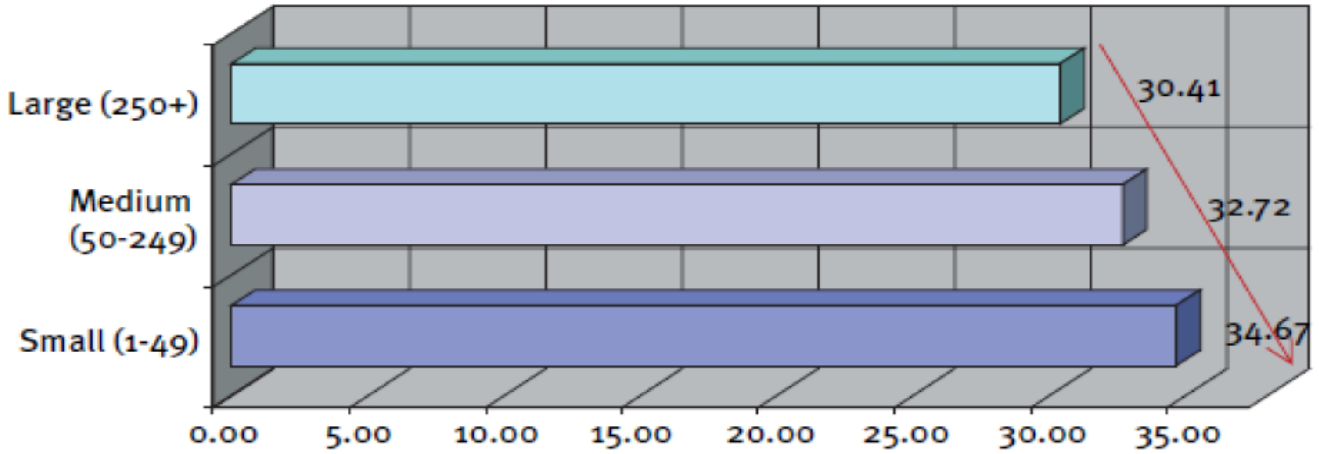
Protects Company from Legal & Financial Harm


Legal
Cost to Defend & Investigate
Dealing with Regulatory Bodies
Managing Public Relations
Significant Regulatory Fines
Distraction of Management & Internal Resources


Financial
Criminal Prosecution
Exclusion
Loss of Profits
Compliance Monitor, Corporate Integrity Agreement
Share Values Decrease

According to the World Bank Institute, more than **$1 trillion dollars** (U.S.$ 1,000 billion) are paid in bribes every year, the cost of corrupt activities is equal to a full **3%** of the world's GDP.

Corruption perceived as a major business obstacle by SMEs and large companies (in per cent)



- According to the Business Environment and Enterprise Performance Survey (BEEPS):
  - More than 70 per cent of SMEs in transition economies perceive corruption as an impediment to their business.
  - Almost 35 per cent of Small companies perceived corruption as a major business obstacle.

Why is Compliance Important?

Creates Productive Corporate Culture

- Creates Productive Corporate Culture
  - Enhances employee morale, productivity and retention
  - Competitive advantage in branding and recruitment

Why is Compliance Important?

Creates Foundation for Long Term Corporate Sustainability

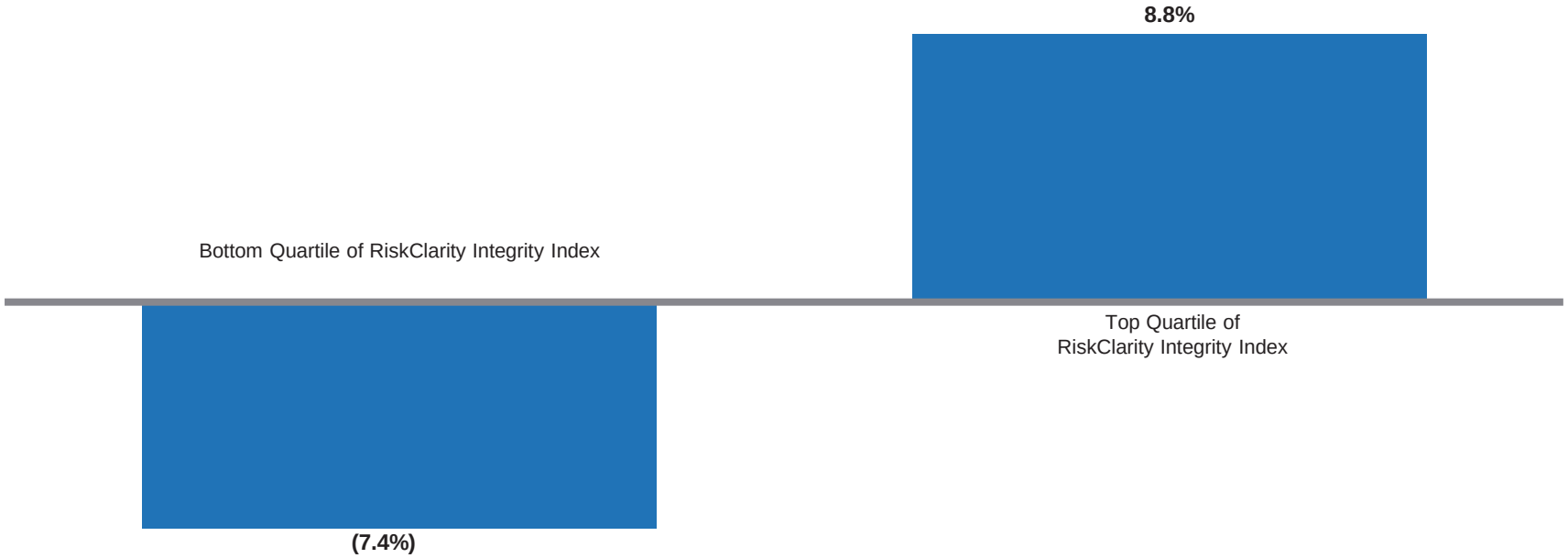
- Creates Foundation for Long Term Corporate Sustainability
  - Reduces cost of capital
  - Increases shareholder value
  - Attracts customers & institutional investors

Higher Integrity, Stronger Long-Term Total Shareholder Returns

Companies with a higher culture of integrity have 10-year total shareholder returns that are 16% points higher than companies with lower integrity scores.

HIGHER INTEGRITY, STRONGER LONG-TERM TOTAL SHAREHOLDER RETURNS

Average 10-Year Total Shareholder Return for Bottom and Top Quartile of 48 Companies



Correlation (r) = 0.58
Significance level of Correlation: P-value < 0.01

n = 48.

From the CORPORATE INTEGRITY PRACTICE
www.executiveboard.com

Why is Compliance Important?

Protects Company's Reputation

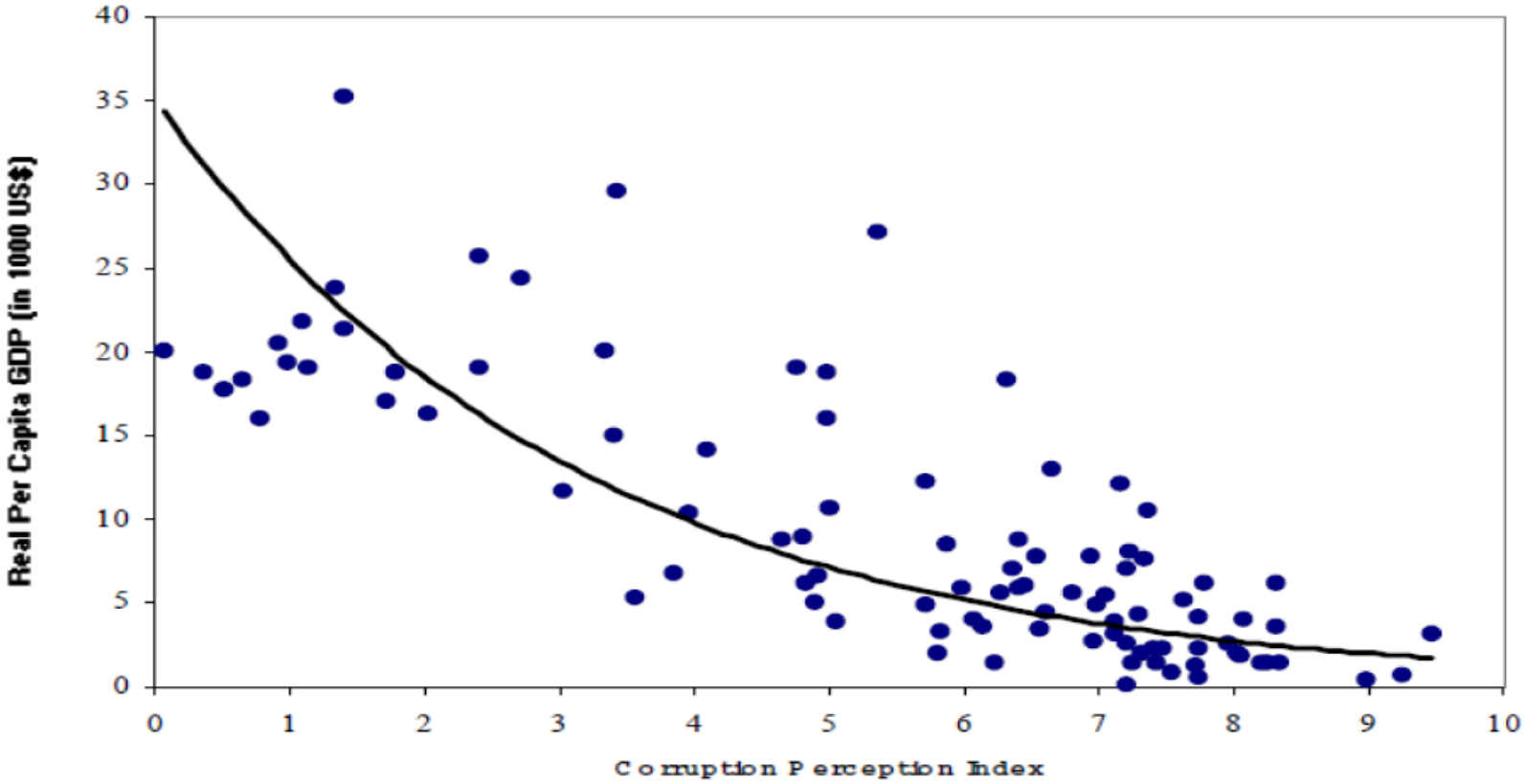
- **We are the International Partner for Speciality Care and Selfcare.**
  Nous sommes le partenaire de santé international pour le traitement des plaies et pour la médication familiale.
- **We have Ethical Behaviour in our Group and we require the same for our partners.**
  Nous avons une démarche éthique dans notre Groupe et dans nos engagements avec nos partenaires.
- **We encourage Team Spirit.**
  Nous encourageons l'esprit d'équipe.
- **We promote Creativity and Innovation.**
  Nous favorisons la créativité et l'innovation.
- **We are Responsive, Efficient and Compliant.**
  Nous sommes réactifs, performants et conformes aux réglementations en vigueur.
- **We are Customer Oriented.**
  Nous sommes à l'écoute de nos clients (patients, soignants, ...).

Why is Compliance Important?

Attracts Foreign Investment

Relationship between Corruption and Development

(in 97 countries)



Countries with higher perceived corruption tend to have lower real per capita GDP.

Thanks for your attention

Working With a Code of Ethics: Key Areas for Distributors

Introduction – Mr. Hoang Thanh Viet, MDDSC Business Ethics Working Group, Eurocharm.

AdvaMed Code of Ethics – Ms. Zohra Anwari – Legal Counsel, AdvaMed

Vimedas Code of Ethics - Mr. Do Duc Chi – Deputy Chief of Office, VIMEDAS

INTRODUCTION:

MDDSC Business Ethics Working Group, EUROCHAM

By: HOANG THANH VIET

- The European Chamber of Commerce in Vietnam was established in 1998 to help develop Vietnam into an attractive investment destination and trading partner for European business.
- EuroCham is licensed by the Vietnamese government as a business association solely operating for and on behalf of its members and independent of any government and/or governmental organization.
- EuroCham is an apolitical, independent and not-for-profit organization.
- EuroCham Vietnam is now amongst the 5 largest European Chambers world-wide and the winner of the ICCA Large Chamber Award in Asia-Pacific in 2017.

EuroCham's Sector Committees

- Medical Devices and Diagnostics
- Pharma Group
- International Quality Generics
- Human Resources and Training
- Information & Communication Technology
- Legal
- Wine and Spirits
- Nutritional Foods Group
- …

Sector Committees are not legal entities, but internal working groups of EuroCham, and are as such subject to Sector Committee rules and regulations; and the provisions of the EuroCham Statutes as well as the Laws of Vietnam.

Business Ethics Working Group of Medical Devices and Diagnostics Sector Committee

Purpose

- To create a trusted environment for MDD SC members to discuss their experience on how to promote the ethical and compliant business
- To foster awareness, capacity building and the implementation of best practice mechanism in order to enhance the quality of compliance among the MDD SC members as well as other key industry players in the local MDD industry
- To represent MDD SC within the Healthcare community as well as advise and advocate on compliance related matters authorities and other representatives groups of the Healthcare industry

This Working Group is only open to In-house counsels, Compliance officers and senior internal auditors/internal control from industry players.

Abbott, Alcon, Baxter, Fresenius Medical Care, GE imagination at work Vietnam, Boston Scientific, ZEISS, OLYMPUS, Dräger, URGO, Siemens Healthineers, DKSH, Medtronic, STORZ Karl Storz – Endoskope, Zuellig Pharma, Reckitt Benckiser, Santen, Terumo, Roche, Philips, stryker, B Braun Sharing Expertise, Bayer

Code of Ethics of Medical Devices and Diagnostics Sector Committee

- Terms and standards: Approved by MDDSC Boards.
- Code of Ethics outline: Done
- Working together to come up with the final version.
- Code of Ethics completion expectation: End of 2018

Thank you!

Introduction to the AdvaMed Code of Ethics

AdvaMed
Advanced Medical Technology Association

- **Who is AdvaMed?**
- **The AdvaMed Code as a Tool to Manage Conflicts**
- **AdvaMed Distributor Guidance**

Who is AdvaMed?

Advanced Medical Technology Association (AdvaMed)

- World's largest medical technology association
- Nearly 300 members with a global presence in countries including China, Europe, India, Brazil and Japan
- Advocate on a global basis for the highest ethical standards, timely patient access to safe and effective products and economic policies that reward value recreation
- Act as the common voice for companies producing medical devices, diagnostic products and health information systems

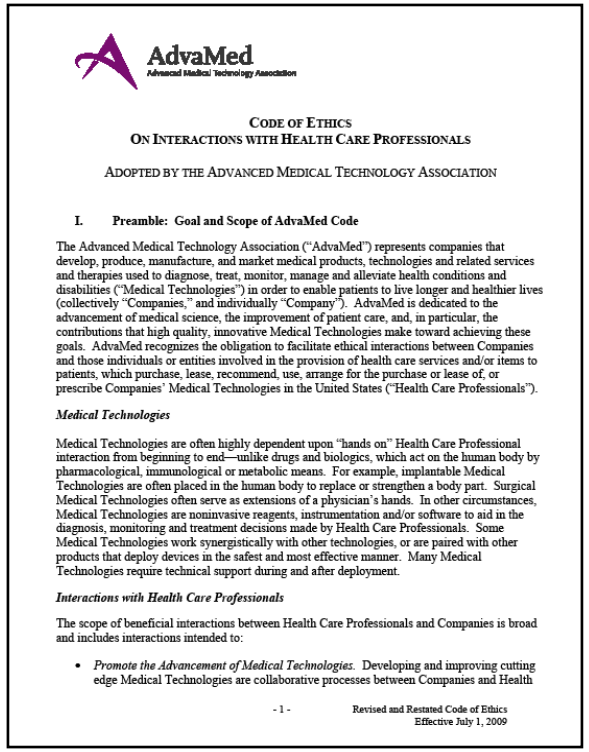
AdvaMed
Advanced Medical Technology Association

The AdvaMed Code as a Tool to Manage Conflicts

Sections of the AdvaMed Code

I. Preamble: Goal and Scope of the AdvaMed Code
II. Code of Ethics Compliance
III. Company-Conducted Product Training and Education
IV. Supporting Third-Party Educational Conferences
V. Sales, Promotional, and Other Business Meetings
VI. Consulting Arrangements with Health Care Professionals (HCPs)
VII. Prohibition on Entertainment and Recreation
VIII. Modest Meals Associated with HCP Business Interactions
IX. Educational Items; Prohibition on Gifts
X. Provision of Coverage, Reimbursement & Health Economics Info
XI. Research and Educational; Grants and Charitable Donations
XII. Evaluation and Demonstration Products

The AdvaMed Code as a Tool to Manage Conflicts



AdvaMed
Advanced Medical Technology Association

Code of Ethics
On Interactions with Health Care Professionals

Adopted by the Advanced Medical Technology Association

I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association ("AdvaMed") represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities ("Medical Technologies") in order to enable patients to live longer and healthier lives (collectively "Companies," and individually "Company"). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States ("Health Care Professionals").

Medical Technologies

Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician's hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health

- 1 - Revised and Restated Code of Ethics
Effective July 1, 2009

AdvaMed Code www.advamed.org/CodeOfEthics

- Guides medtech companies on their interactions with Health Care Professionals (HCPs)
- Facilitates ethical interactions to ensure that medical decisions are based on the best interests of the patient
- HCP is broadly defined to include providers and those who arrange for the purchase or lease of medical technologies, such as individuals within GPOs

CODE OF ETHICS AdvaMed SUPPORTER

AdvaMed
Advanced Medical Technology Association

The AdvaMed Code as a Tool to Manage Conflicts

AdvaMed Code

www.advamed.org/CodeOfEthics

- Based in part on HHS OIG Guidance on the elements of an effective compliance program

Main elements

- Prohibiting Gifts & Entertainment
- Delineating areas of appropriate interactions with HCPs, and when doing so requiring:
  - Legitimate business justification for the interactions; and
  - A Fair Market Value limit to the exchange

Advamed Distributor Guidance

AdvaMed
Advanced Medical Technology Association

Thank you!

Working With a Code of Ethics: Key Areas for Partners

The Code of Ethics of VIMEDAS

Mr Do Duc Chi - VIMEDAS

Partner Workshop

Medical Device Sector

16 July 2018 | Ho Chi Minh, Vietnam

Content

1. Introduction to the Vietnam Medical Equipment Association.
2. The development of the Code of Conduct on Practice of Medical Device.
3. Content of Code of Conduct on Practice of Medical Device.
4. Implementation of the Code of Conduct on Practice of Medical Device and commitments of stakeholders.
5. Implementation after signing commitment.

1. Introduction to the Vietnam Medical Equipment Association

- Established in 2002
- 15 years of operation and development.
- 1,380 members, 02 affiliated units, i.e. Ho Chi Minh City Medical Equipment Association and Da Nang Medical Equipment Association; 70 inter-chapters and chapters.

1. Introduction to the Vietnam Medical Equipment Association

Include organizations and individuals in medical equipment industry, detailed as: scientific and technical research, management, production, business, maintenance, repair and technical services of medical equipment, distributed as follows:

- 36% : medical equipment research, management, production and trading units.
- 32%: provincial and central hospitals.
- 22%: training institutions such as universities, colleges.

1. Introduction to the Vietnam Medical Equipment Association

- Units under the Vietnam Medical Equipment Association:
  + VIMEDAS Office.
  + Institute for Medical Equipment Technology Research, Manufacturing and Transfer.
  + Institute of Health Technology.
  + Institute Laser Surgery.
  + Center of Medical Equipment Tech Service.

2. The development of the Code of Conduct on Practice of Medical Device

- In the General Meeting for the term of 2015 - 2020, the Association has agreed to include the Code of Conduct development in the Resolution.
- The compilation team developed a draft Code of Conduct on practice of Medical Device Industry, reported to the Editorial Board. After five consultations of the Editorial Board, the team has completed the draft to submit to the Standing Committee of Vietnam Medical Equipment Association.

2. The development of the Code of Conduct on Practice of Medical Device

- The Editorial Board sent the draft to 125 delegates for comments and received about 97 answers. In general, the draft has been agreed and supported.
- The Editorial Board revised the draft, submitted to the Ministry of Health, the Ministry of Home Affairs, the Vietnam Union of Science and Technology Associations and received favourable comments.
- On 20/10/2016, the Chairman of Vietnam Medical Equipment Association signed Decision No. 50/QD-TWH promulgating the Code of Conduct.

3. Content of Code of Conduct on Practice of Medical Device

3.1. To put interest of patient and health of people first.

3.2. To strictly follow laws, and professional regulations relating to each field of practice.

3.3. To only provide the market with medical device which fully meets quality requirements defined by competent authorities. To provide customers completed document on Certificate of Origin (C/O), Certificate of Quality (C/Q), year of manufacture together with operational manual, and procedure for maintenance.

3. Content of Code of Conduct on Practice of Medical Device

3.4. To strictly implement current regulations, to respect and cooperate with state management agencies. To ensure the publicity, transparency, and integrity, to strongly fight against wrongdoing in practice.

3.5. To have responsibility for providing sufficient information to management agencies and customers when: equipment faces break-down due to system errors from manufacturers as well as changes such as: dissolution, merger, bankruptcy of related manufacturers and distributors.

3. Content of Code of Conduct on Practice of Medical Device

3.6. For medical device technical service activities, it is required to ensure that: equipment used for service performance, and equipment put into operation shall be precise, stable, safe and efficient. Medical device technical consultancy activities shall be honest, objective and scientific.

3.7. Personnel training of medical device technical sector shall ensure the basis, update and close connection with reality.

3.8 Research, manufacturing and production of medical device should be directed toward modern, efficiency, safety, stability, aesthetics, pain and uncomfortable reduction for patients, and eco-friendly.

3. Content of Code of Conduct on Practice of Medical Device

3.9. Be honest, righteous, solidarity and respect to colleagues, be ready to cooperate and support each other in practicing the profession.

3.10. To Continuously study, improve professional qualification and experience for increasing service quality to contribute to the cause of people's health care and protection.

4. Implementation of the Code of Conduct on Practice of Medical Device and commitments of stakeholders:

January 13, 2017: Issued the Code of Conduct and the signing of implementation commitments.

To date, the Vietnam Medical Equipment Association has received written commitments from 33 units representing our members.

5. Implementation after signing implementation commitment

- About the development of the Association:

  Have 9 more chapters and hundreds members
- Continue carrying out Code of Conduct in the spirit of common engagement in APEC Hanoi
- Organize annual national workshop 2018 (14^{th}) on July 27-28 with the topic of Capacity building in administration, sciences and technology updates of Medical devices.

About Training:

- Training and counselling on Medical devices technology via 3-months course with national practice certificate.
- Training course provides trainee with standard objective, consultancy on purchasing Medical devices which are suitable with technology capacity for fully efficiency and to avoid wasting.
- Developing standard mechanism for Medical devices procurement aiming for transparency in bidding.

Ensure the transparency and fair competition to avoid group interest in Medical Devices bidding and procurement.

Regular training to improve the capacity for Medical Device technical consultants:

- Establish editor committee to work on Medical devices publishers:

+ Medical devices terminology handbook.

+ Develop a list of qualified medical equipment compiled into medical equipment dictionaries.

+ Develop list, quota, arrangement for medical devices in health facilities in order to be transparent in procurement plans.

Social feedback

- ✓Active participation to amendment of Decree 36 about Medical Devices Administration.
- ✓Invite Medical devices enterprises, manufacterersto provide comments –23 comments in total.
- ✓Attend workshops on Decree amendment to advocate on: reducing administration procedure, sub-licenses, business conditions which are hassles to enterprises, enhancing enterprises independence in doing business.

Monitoring the implementation of Medical examination code:

Participate in the monitor of the implementation of Medical examination code in public and private health facilities.

Upcoming activities:

+ Implementation of Code of Conducts and commitment at HN APEC 2017

+ Management of Medical devices in health facilities, maintenance and operation to improve the absolute effectiveness and avoid any mistakes.

Improvement of training curriculums to adapt the development of science and technology

Regular trainings

Medical devices handbook and dictionary

These above activities will be well-implemented in cooperation with other associations and chambers, especially EuroCham.

Thank you!

Networking Break

Getting Started: Key Elements of an Effective Compliance Program

Ms. Zohra Anwari – Legal Counsel, AdvaMed

Key Components of a Compliance Program

What is a compliance program?

A compliance program is an internal system employed by a business to:

- Identify and reduce the risks for the business
- Remedy any breach that may occur
- Create a culture of compliance within the business

Key Components of a Compliance Program

1. Written Policies and Procedures
2. A Designated Corporate Compliance Officer or Compliance Committee
3. Effective Training and Education
4. Open Lines of Communication
5. Enforcement Through Clear Disciplinary Guidelines
6. Auditing and Monitoring
7. Corrective Action Plans
8. COMPLIANCE COMMITMENT THROUGHOUT THE COMPANY

Benefits of an effective compliance program

- Meet manufacturer's expectations
  - Enhanced focus by enforcement authorities on distributor and sub-distributor compliance
  - Manufacturers increasingly selecting distributors based on existence of effective compliance controls
- Protect distributor from unwanted problems under local laws
  - Anti-corruption laws
  - Labor laws
  - Tax laws
- Clarity and consistency throughout the organization
- Internal oversight to detect, respond to and resolve issues

Common Questions to Distributors

- What type of compliance program do you have in place?
- How do you detect and/or avoid improper interactions with HCPs and Government Officials?
- How do you manage the following activities:
  - Donations?
  - Grants?
  - Sponsorships?
  - Fee-for-service arrangements with HCPs as speakers, etc.?
  - Customs clearance?
  - Other government interactions
- Do you have written policies and procedures on the above activities?
- Do you train your employees on these issues?
- Do you keep careful and accurate records?

Pre-Contract Due Diligence

- Medical Device manufacturers typically perform some level of due diligence on potential distribution partners and other third parties, before entering into distribution agreements or other contracts
  - Questionnaire seeking information about distributor's ownership, background, business model, any history of compliance problems, government enforcement activity, etc.
  - Search newspapers, Internet, government records
  - Report from due diligence service
  - Any "red flags" identified during the process must be addressed before the contract can be signed
  - Refusal to participate in due diligence review will usually end the relationship

Compliance-Related Contract Provisions

- Common compliance-related provisions in distribution agreement or similar agreement
  - Compliance with laws
  - Anti-corruption compliance
  - Compliance program and training
  - Monitoring/documentation
  - Reporting issues
  - Audit rights

Best practices for a successful audit

Manufacturer

- Give sufficient notice to third party
- Explain the reasons for the audit
- Be transparent in methodology and what the third party can expect
- Explain how the audit can be beneficial for the distributor
- Be flexible (timing)
- Understand your business position (i.e., leverage) with the third party
- Minimize disruption to business
- Provide sufficient communication to third party throughout the audit process

Distributor

- Allow full access to documentation and people
- Be responsive to inquiries; if deadlines will not be met, communicate early and discuss with manufacturer and auditor
- Organize documentation and provide explanation of documentation as necessary
- Consider the audit a priority
- Be transparent, honest and avoid surprises

Common Challenges

Manufacturer

- Compliance expectations not included in the contract and/or clearly communicated to the distributor
- Lacking or ineffective delivery of training
- Lacking or ineffective monitoring
- Lacking or ineffective communication/reporting from the distributor
- Lack of controls to mitigate sub-distributor risks
- Not providing the distributor's employees access to the Hotline

Distributor

- Insufficient documentation
- Incomplete books and records
- Payments in cash
- Lack of compliance awareness
- Lacking or unorganized compliance program
- Lacking or insufficient compliance training, and documentation of training
- Lacking or insufficient sub-distributor oversight
- Questionnaire responses are incorrect
- Lack of compliance with local laws
- Overall internal control weaknesses

Thank you!

Promoting/Supporting Distributor Compliance Today

Ms. Nguyen Huu Uyen Hanh, Compliance Officer, JNJ Vietnam

Mr. Ta Minh Cuong, Head of MDD Business Line, DKSH Vietnam

Mr. Hoang Thanh Viet, Head of Country Compliance Management, DKSH Vietnam,

Promoting/Supporting Distributor Compliance Today

Partner Workshop

Medical Device Sector

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Disclaimer

The following presentation and the respective point of views are that of the presenter's and do not reflect the view or opinion or position of Johnson & Johnson.

Promoting/Supporting Distributor Compliance Today

Topic	Pharma/Medical Device Company	Distributor
Perform Due Diligence: • Background check • Third Party Questionnaire	• Improve knowledge of its partner • Identify shareholders and key stakeholders • Identify potential risks and/or red flags	• Gains trust and improves business relations by being transparent
Written contracts and addendum(s)	• Minimum required clauses and provisions (ABAC, Right-to Audit, Termination, Training, Books and Records) • Clarity on service rendered and location for which the services are to be provided • Clarity on sub distributors / distribution channel	• Sets best practice standards with which the distributor can perform reliably • Understand all the ABAC requirement of the contract • Include own ABAC requirement (i.e., support, etc.) • Clarity and delimitation of the responsibilities of each party
Policies, Procedures, and Programs	• Code of Conduct • ABAC policies • SOPs (i.e., T&E, Sponsorship, Donations, Tender, Pricing) • Resources (i.e., Compliance Toolkit)	• Sets examples to improve current policies, procedures and programs • Additional control and standardization of business activities and procedures • Advantage over competitors when engaging with local and multinational suppliers

Promoting/Supporting Distributor Compliance Today

Topic	Pharma/Medical Device Company	Distributor
Training	• Mitigate non-compliance risks • Improve awareness and understanding of ABAC requirements (i.e. scenario based) • Partnering to increase compliance awareness • Formalize activities, efficient processes	• Increases employee knowledge and best practices • Ensures compliance with current regulatory requirements • Improves reputation and marketability • Ensure employee understanding of materials presented in trainings
Healthcare Compliance Officer (HCCO)	• Ensure processes and activities are in compliance with regulatory standards	• Report compliance issues to the HCCO, receive and implement remedial recommendations • Standardize and select the most conservative approach to remain compliant with all supplier requirements
Monitoring	• Proactive verification that distributor is in compliance with regulation, contract terms and conditions, and company policies.	• Identify gaps and improve opportunity over established controls • Strengthen distributor or sub distributors controls and procedures

Promoting/Supporting Distributor Compliance Today

Topic	Pharma/Medical Device Company	Distributor
Auditing	• Proactive verification that distributor and in compliance with regulation and company policy	• Free audit • Assessment of whether control activities adequately address the more significant compliance risks • Identifies opportunities to improve risk management
Hotline	• Direct access to third party / Market representative in case of issue • Manage, track, evaluate, escalate and investigate incidents that arise	• Direct access to your Vendor's top compliance team • Reports issues anonymously (competitor misbehavior / market issues / inappropriate pressure by the business)
Books and records	• Comply with regulation • Improve data accuracy • Improve monitoring efficiency	• Improve business process efficiency based on data management

Thank you!

Case Study Analysis and Discussion: How Would You Approach This Scenario?

Moderators:

Mr. Pete Viksnins and Mr. Marcus, PwC Kuala Lumpur Sentral

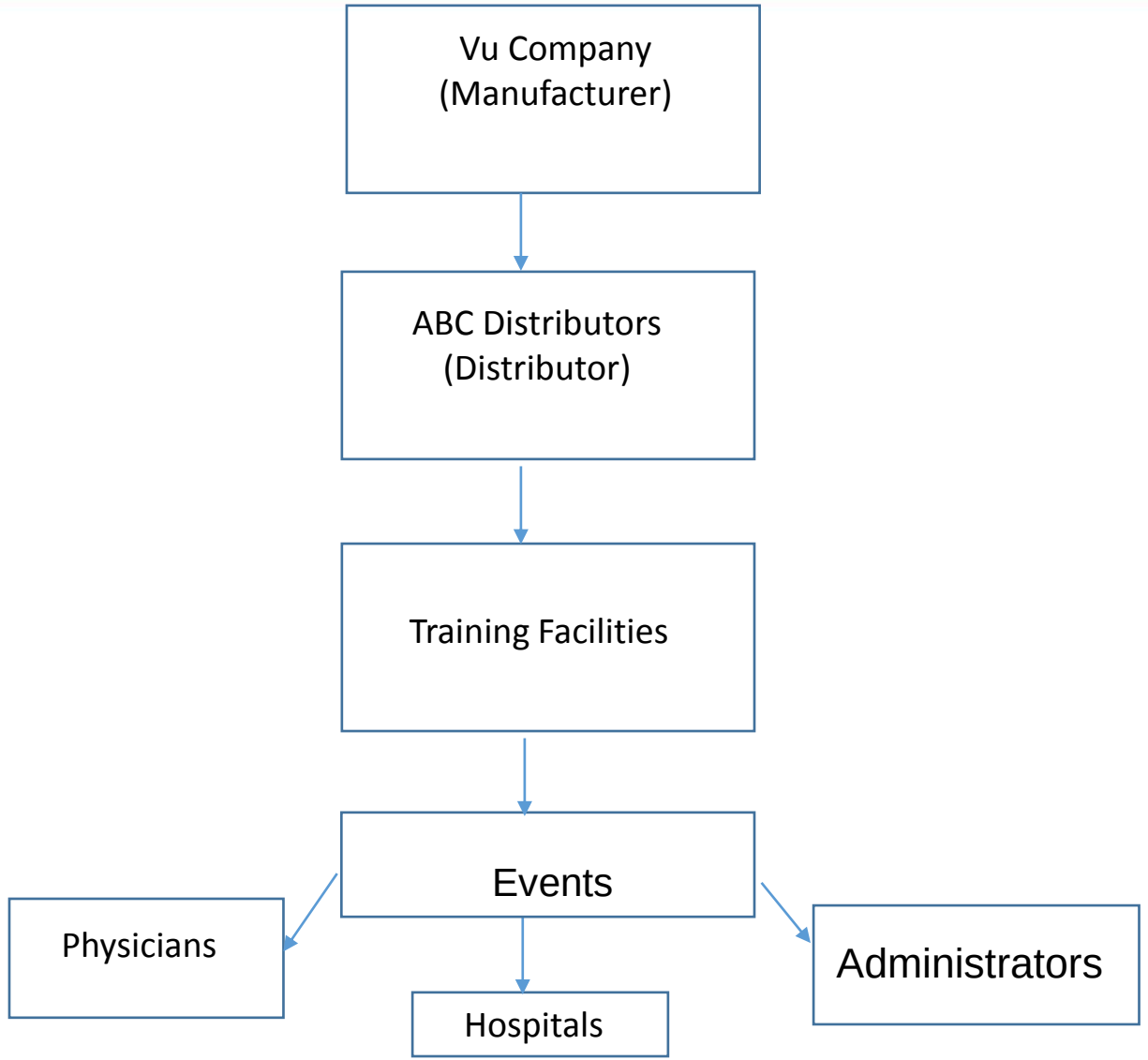
Ms Dao Diem Quyen, Senior Manager, Risk Management of DKSH VN

Case Study #1

ABC Distributors is the primary distribution company in Vietnam for Vu Company, and sales of Vu's medical devices comprises the majority of ABC's sales. As part of the distribution agreement with Vu, ABC receives a certain percentage of its sales to assist with marketing-related events. ABC typically develops a marketing plan (with Vu's approval), interacts with event coordinators and other third parties to implement the marketing plan, and is reimbursed for said costs up to the marketing allowance.

In the current year, Vu Company proposed a new program to promote its products and improve brand recognition. The program involves providing funds and equipment for educational events hosted by select training facilities. According to Vu, certain training facilities, to be selected by ABC, will offer educational events, varying from one day to one week, in major cities. Physicians and administrators from key hospitals will be invited to the events. In addition, Vu is offering limited educational grants to certain hospitals through the new program.

As ABC has historically managed the marketing activities and interacted with the service providers to carry out the marketing plan, Vu has asked ABC to serve a similar role related to the new training program. To fund this new initiative, Vu is offering a significant additional allowance and asked that ABC oversee payments for the training events and grants, as well as distribution of product samples to the training centers.


Vu Company
(Manufacturer)
ABC Distributors
(Distributor)
Training Facilities
Events
Physicians
Hospitals
Administrators

Discussion Items- Case Study #1

Questions

1) What risks / concerns should ABC be aware of when considering such a request from the manufacturer?

2) Is this a compliance risk to ABC?
   a) Why or why not?
   b) Should ABC agree to the manufacturer's request:
      1) To oversee payments related to the training events?
      2) To oversee provision of free goods / samples?
      3) If yes, what should ABC be aware of / concerned with?

3) What could go wrong with this scenario?

4) Could ABC do something to help minimize the risk (if necessary)?
   a) If so, what processes or controls should ABC put in place to do so?
   b) What documentation should ABC retain to support their case?

Case Study #2

Vu Company is a well-established manufacturer and distributes its products in Vietnam through an exclusive contract with ABC Distributors. Vu is currently working with ABC to bid on a new contract with XYZ Hospital, a large, public hospital in Vietnam. Rho recently modified one of its key offerings to incorporate new, cutting edge technology that is not offered by any of its competitors. Given the high-quality product offering at a competitive price, ABC and Vu expect to win the tender as Rho has recently introduced a new and innovative device.

Given the recent modifications in Vu's product, the companies have been working together over the past several months to update the required registrations and permits. Unfortunately, the process has been delayed several times, resulting in a halt of imports for the product and significant declines in sales. Vu and ABC are concerned that the registrations will not be resolved in time to meet the first round of delivery deadlines listed in the tender.

Given the delays, Vu has identified a local agent to help obtain the appropriate registrations and permits with Vietnam authorities,. Rho has asked that ABC enter into a contract with the agent to help resolve the registration delays. Vu requested that ABC oversee the agent, and Vu will reimburse ABC for any of the agent's fees. ABC contacted the agent at Vu's request, at which time the agent indicated they had already come to a flat – fee arrangement with Vu. The agent also offered to interact with the hospital to postpone the bid (if possible) for a moderate success fee.

Vu Company
(Manufacturer)
ABC Distributors
(Distributor)
Agent
Vietnam
Government

Discussion Items - Case Study #2

Questions

1. What risks / concerns should ABC be aware of when contracting and overseeing the agent at the request of the manufacturer?

2. Is this a compliance risk to ABC?
   a) Why or why not?
   b) If so, what are the potential ramifications of non-compliance to ABC?

3. Should ABC agree to Vu's request?

4. What a could go wrong with this scenario?

5. Could ABC do something to help minimize the risk (if necessary)?
   a) If so, what processes or controls should ABC put in place to do so?
   b) What documentation should ABC retain to support their case?

Thank you!