Asia-Pacific
Economic Cooperation

2018 APEC Business Ethics for SMEs Forum

18–20 July 2018 • Tokyo, Japan

PLANNING SESSION ON IMPLEMENTATION OF APEC THIRD PARTY GUIDANCE (18 JULY) MEDICAL DEVICE SECTOR

Introductory Remarks

Ms. Tricia Van Orden, Project Overseer
Business Ethics for APEC SMEs Initiative
U.S. Department of Commerce

PLANNING SESSION ON IMPLEMENTATION OF APEC THIRD PARTY GUIDANCE (18 JULY) MEDICAL DEVICE SECTOR

Participant Introductions

NAME | POSITION | ORGANIZATION | ECONOMY

PLANNING SESSION ON IMPLEMENTATION OF APEC THIRD PARTY GUIDANCE (18 JULY) MEDICAL DEVICE SECTOR

Scene Setting Presentation

Ms. Faye Sumner
MTANZ (New Zealand)

Defining Third Party Sales and Marketing Intermediaries

Large, medium, and small-sized enterprises that contract with medical device researchers and manufacturers ("medical device companies") in support of their business activities.

Third party intermediaries can include: distributors, wholesalers, distribution or sales agents, marketing agents or consultants, brokers, commission agents, and independent sales representatives.

Any enterprise that is paid by medical device companies in support of their business activities can be a third party intermediary. Especially if the enterprise is being paid by the company and interacting with external entities (governments, HCPs, hospitals, etc.)

Examples of Third Party Intermediary Risks in the APEC Region

- The absence of a medical device company having an anti-bribery policy in place and/or the third party intermediary engaging in an act of bribery to advance their business mission with the company.
- Incomplete / outdated collection and retention policies on financial transactions as well as external engagements.
- Low threshold by the company as well as the third party on what is an acceptable activity when engaging with external entities.
- Unusual arrangements or the absence of a written / routinely reviewed contract with a clear anti-corruption focus.

Industry's Early Response

- **This is an ethics issue that extends to every industry and economy**
- Large, Multi-National Companies
- Early Industry Association Focus
  - MTAA & MTANZ
  - AdavMed
  - MedTech Euorpe
- Role of the U.S. FCPA and U.K. Anti-Bribery Act

Building International Industry Association Collaboration

In 2014, the medical device industry achieved a milestone that no other sector has done: jointly shared, multi-national guidance on high-standard ethical business practices for third parties:

Australia (MTAA)

Canada (MEDEC)

European Union (MedTech Europe)

New Zealand (MTANZ)

United States (AdvaMed)

Breakthrough of the APEC Guidance / Expert Working Group

- Building on the joint industry association guidance by four APEC economies, the opportunity for APEC guidance was raised at the 2016 APEC Business Ethics for SMEs Forum in Lima.
- It was recommended by the plenary in Lima for the overseer to form an Expert Working Group to prepare draft APEC Guidance. This was completed virtually, on a multi-economy and multi-stakeholder, with the draft Guidance prepared for the 2017 APEC Business Ethics for SMEs Forum in Hanoi.
- The Guidance was reviewed and updated by the plenary in Hanoi, recommended to the overseer for submission to the APEC SME Working Group and 2017 APEC SME Ministerial.

2017 APEC SME Ministerial Statement

Ho Chi Minh City, Viet Nam (15 September 2017)

We welcome the APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector and encouraged its implementation. This Guidance serves as a concrete tool to support thousands of SMEs who play a critical role in the medical device sector, such as distributors, wholesalers and sales agents.

What the Guidance Says, In Short…

- First inter-governmental, international guidance to encourage ethical third party relationships in the medical device sector.
- Guidance applies equally to companies and third parties.
- Embraces APEC Kuala Lumpur Principles implementation
- Seven key sections: Written Anti-Bribery Policy / Procedure, Risk Assessment, Diligence Program, Written Contract, Training and Education, Monitor/Audit, Appropriate Corrective Action.
- Implementation Provisions (Foundation to Tokyo Statement)

What the Guidance Says, In Short…

- **Implementation Provisions (Foundation to Tokyo Statement)**
  - Multi-Stakeholder cooperation is a necessity
  - Implementation of consistent codes of ethics
  - Development and implementation of high-standard, aligned policies
  - Encourage regulators and enforcement authorities to acknowledge and support the success of this guidance
  - Economies to advance ethical collaborations through regular communication, joint policies and capacity-building

Our Four Morning Tasks:

1. Patricia Wu to overview APEC virtual capacity-building planning and developments since the Guidance was launched
2. Mexico, Japan, and Brazil perspective on local ethics trainings programs to-date for third party intermediaries
3. Outcomes from APEC Guidance pilot webinar in New Zealand and Canada by Chrisoula Nikidis (Polaris)
4. **Inputs from delegates on the Tokyo Statement**

TAKING STOCK: OVERVIEW OF IMPLEMENTATION RESOURCES

Ms. Patricia Wu
Managing Director
C&M International (Technical Secretariat)

http://klprinciples.apec.org/view.asp?ccid=471

CAPACITY BUILDING EXAMPLES: DISTRIBUTOR ETHICS TRAININGS

Recent Association Approaches

Ms. Tamara Olmos
AMID (Mexico)

WHO WE ARE?

amid®
Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos.

Is conformed by 32 multinational companies, all manufacturers

TIMETABLE

2013 Code of Interaction w/ HCP´s

2016 Review of Code of Interaction w/ HCP´s

2017 Review alignment w/ Bogota Principles

2017 New Code was published.

Is also mandatory for distributors by contract

2018 January prohibition

- Direct sponsorship

-E & R places

2018 January Sanctions procedure

HOW DID WE IMPLEMENTED OUR CODE?

Step 1
- Release a Code of Interactions with HCPs signed by all affiliates

Step 2
- Train all affiliates

Step 3
- Train distributors and all commercial channels of the associates

Step 4
- Make all the information available online

Step 5
- CAPACITY-BUILDING SUPPORT in process: we will draft a template for a code of conduct accessible to distributors and commercial channels

TRAININGS DONE & OUR EXPERIENCE

Companies want to change but they do not want to be behind, Associations and alliances are a great tool

Tone from the top is a basic

People do not like changes but they adapt

Every time is easier

AMID´s Code of Conduct Trainings

- April 6th, 2017
- May 17th, 2017
- June 11th, 2017
- Dec. 6th, 2017
- Jan. 23rd, 2018
- March 20th, 2018

Upcoming trainings:

- July 18th, 2018
- Aug. 21st, 2018

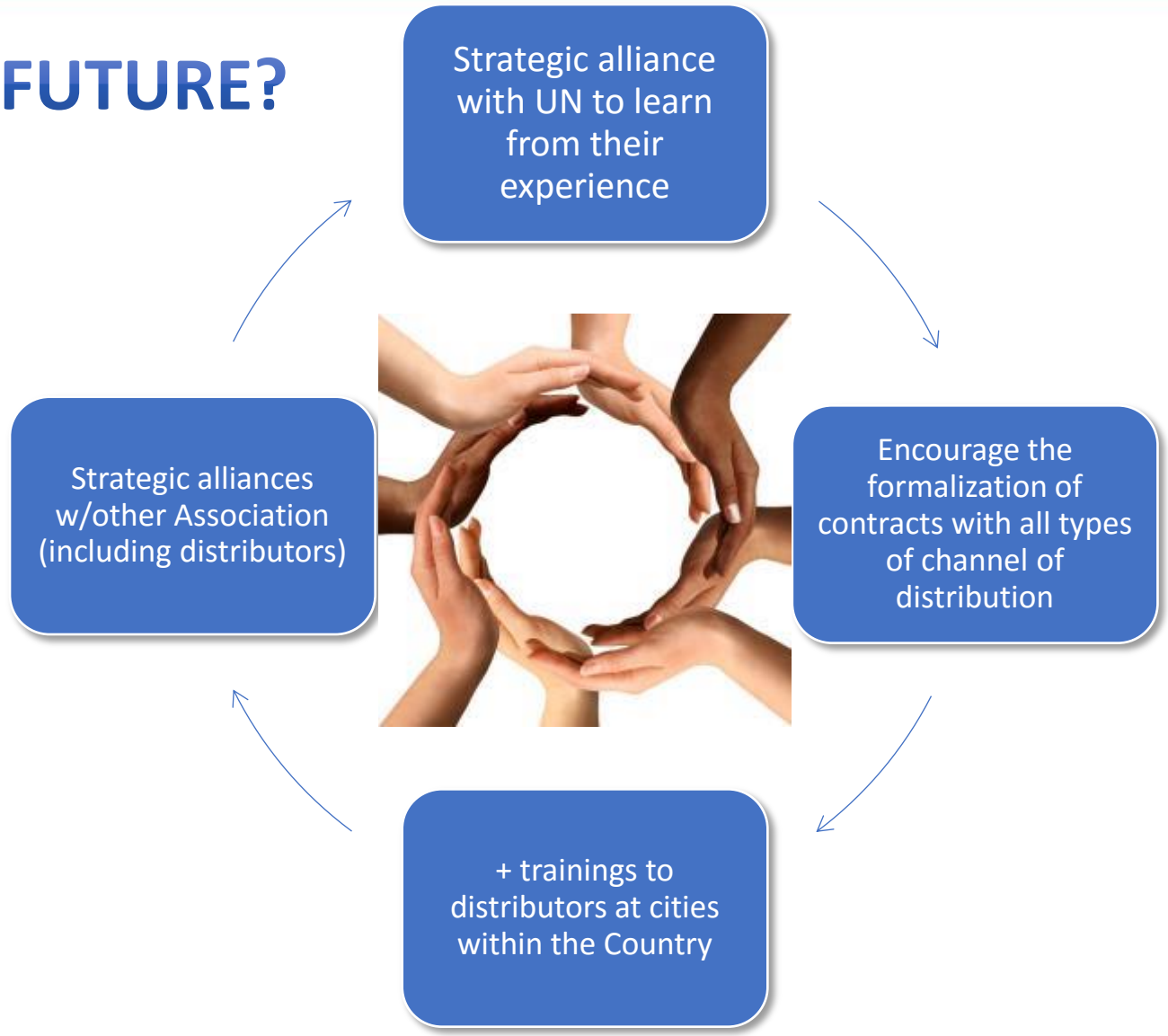
LESSONS LEARNED / RECOMMENDATIONS

Affiliates/distributors may say:	What to do:
They do not know the AMID´s Code	Main tool: train affiliates first & distributors to make them aware of the Code´s provisions
They have commitments prior the effectiveness of the Code	Provide a time-period for implementation of New Code
Is how business is done in the Country	Sensitize all affiliates on the importance of the Tone from the Top with distributors to set an example
Codes and/or rules only apply for direct Affiliates	During the training distributors sign Compliance Certification
They lost, forgot, or did not understand the information given	Facilitate Marketing in social media

CHALLENGES

- Distributors are not part of AMID therefore we cannot force them directly to comply
- In Mexico we have many family owned companies that do not have the size/budget to have a Compliance officer
- High index of corruption in the country

WHAT IS IN THE FUTURE?



CAPACITY BUILDING EXAMPLES: DISTRIBUTOR ETHICS TRAININGS

Recent Association Approaches

Koichiro Miyata
AMDD (Japan)

- Capacity-Building Examples on Distributors Ethics Trainings -

AMDD-organized Anti-corruption training to dealers

- Efforts to help delivering the training efficiently and effectively

July 18, 2018
Koichiro Miyata
Legal & Compliance Committee
AMDD

AMDD

- Date of Establishment: April 1, 2009
- # of Member Companies: 63 (as of Feb 2018)
- # of Employees: 26,000
- Total Sales of member Cos. : 1.8 trillion yen (67％ of Japanese Market)

<Mission Statement>

Enabling a healthier Japan

Providing valuable medical technology and information to your loved ones today, so that they may live in good health.

Org Structure

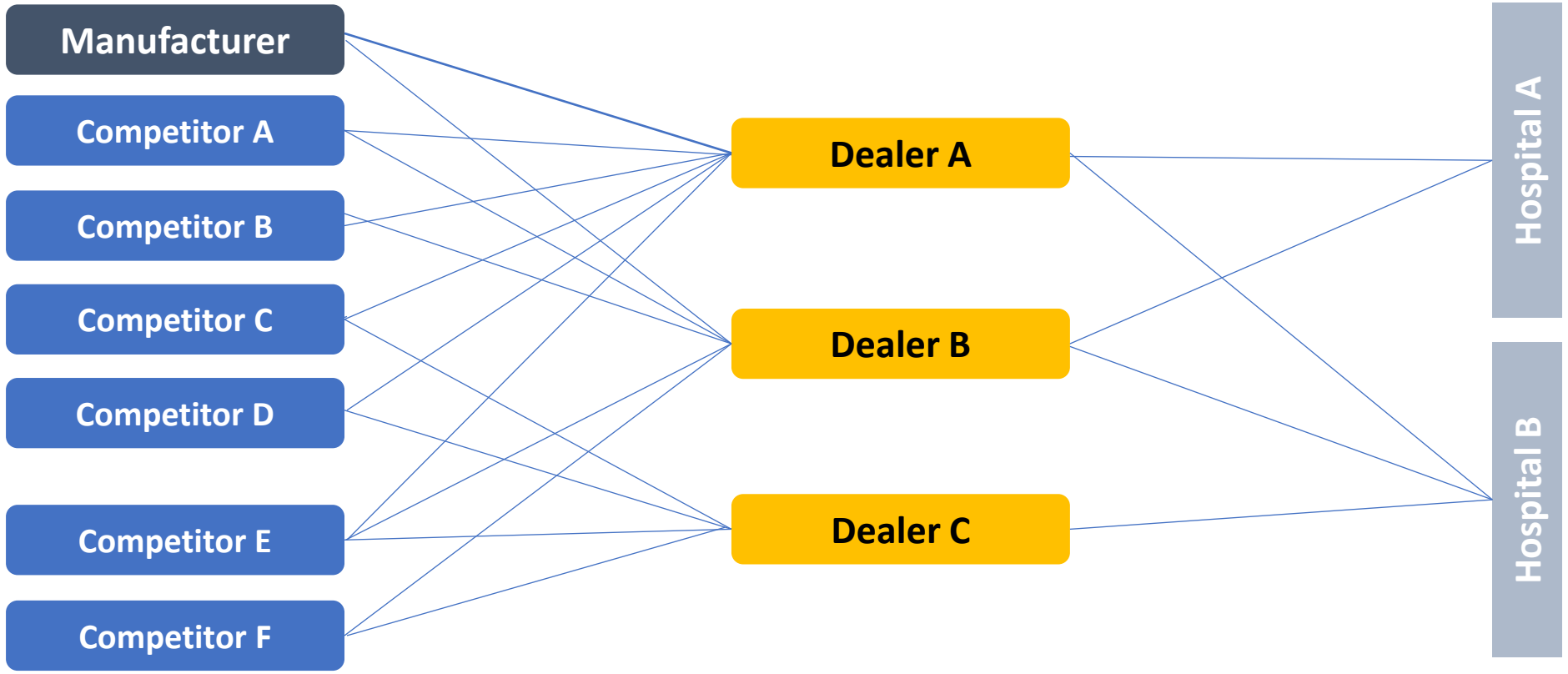
Started as a WG in 2012 and became a Committee in 2013

Anti-corruption training to dealers organized by AMDD

- Overview
  - Program scheme:
    - AMDD organizes and delivers trainings
    - Sponsoring member companies endorse AMDD training as their own training and certify dealers who took the training
  - Program Launch: 2012
  - Frequency: Once a year (every November)
  - Venue: 7 major cities across Japan
  - Length of training: 2 hrs.
  - Speaker: Licensed lawyer (*Bengoshi*) from an outside law firm
  - # of sponsoring/endorsing AMDD members: 26 (2017)

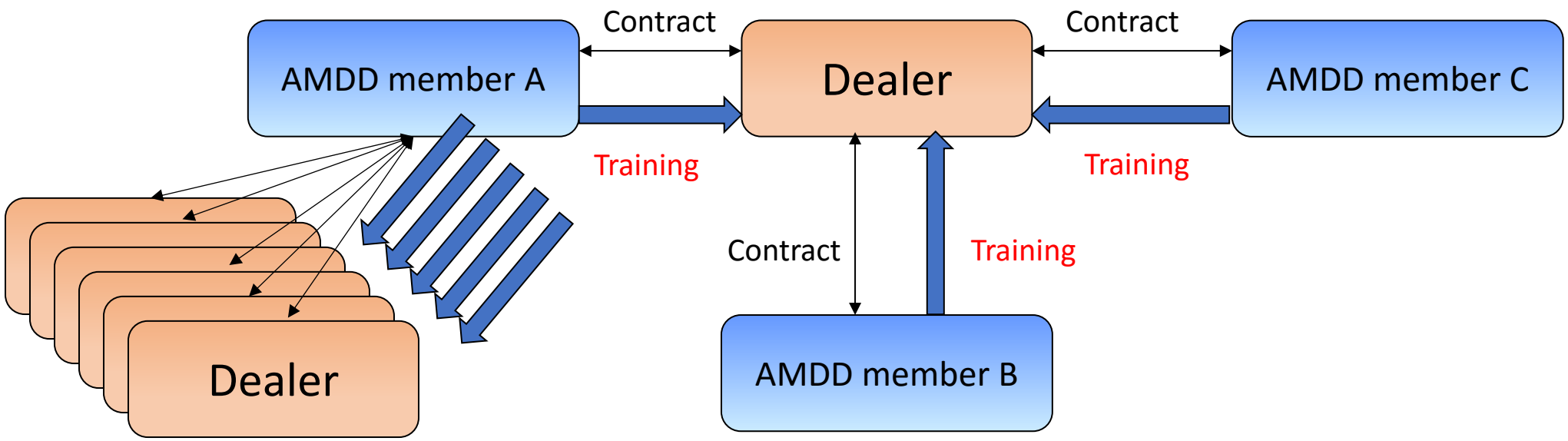
Anti-corruption training to dealers organized by AMDD

- Why we started it -- Distribution systems and practices in Japan



Anti-corruption training to dealers organized by AMDD

- As a result…

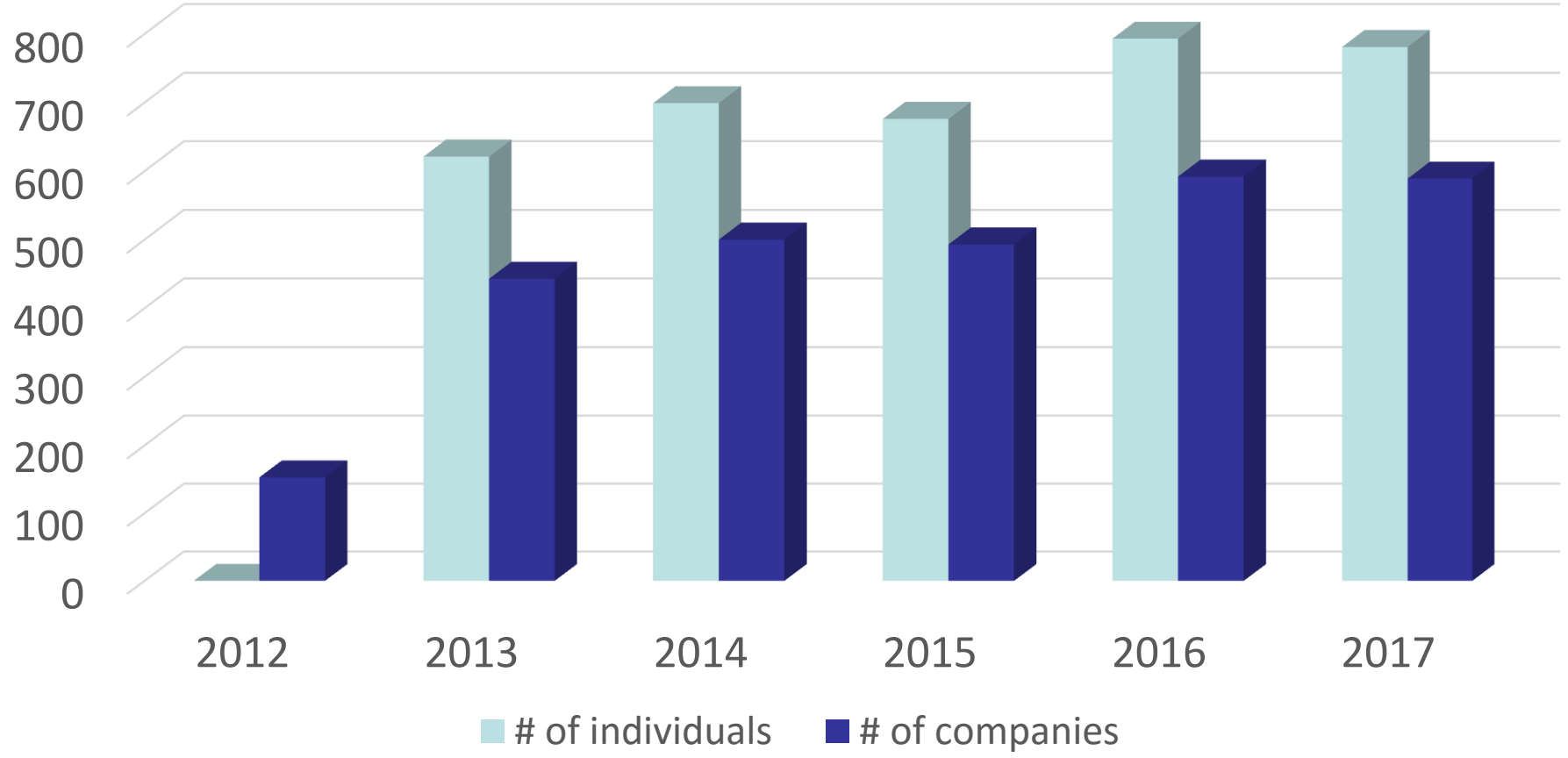


Anti-corruption training to dealers organized by AMDD

- Content
  - Outline of anti-corruption laws (FCPA, UK bribery act, Japan unfair competition prevention law, National public service ethics act and other local laws and regulations)
  - Case studies
    - Real case examples
    - Discussion on hypothetical cases
  - Compliance topics
    - Effective compliance program recommended under the FCPA guidelines and model company compliance policy based thereon (2014)
    - How to keep compliance program effective (management's commitment, monitoring and employee training, etc. (2015)
    - How to provide effective compliance training and practical preventive measures for corruption (2016)
    - Self-assessment for company compliance structure (2017)

Anti-corruption training to dealers organized by AMDD

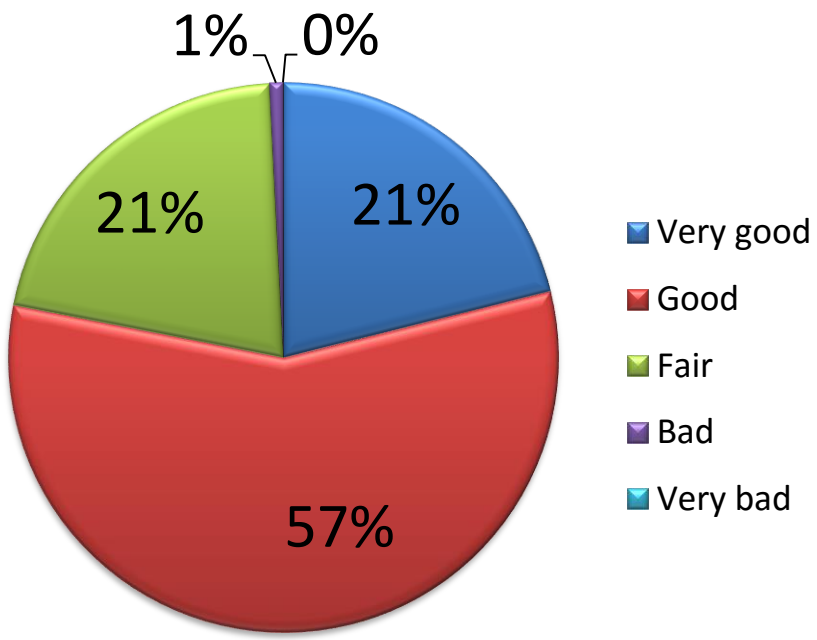
- Attendees



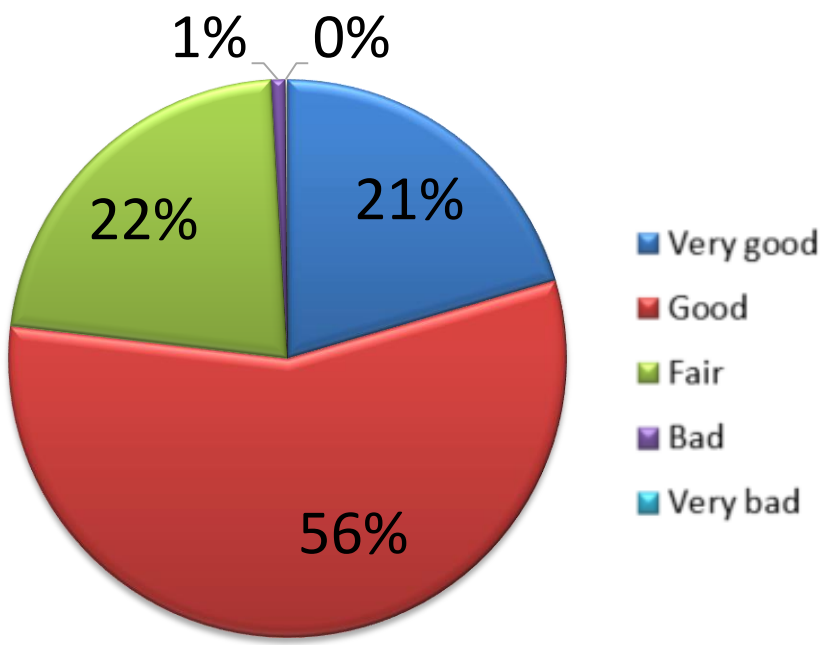
Anti-corruption training to dealers organized by AMDD

- VOC

2016



2017



Anti-corruption training to dealers organized by AMDD

- Learnings and challenges – key to keep the program effective and efficient
  - Program generally well accepted by dealers
  - Increase the number of sponsoring companies
  - Keep the contents fresh while covering all the key points

CAPACITY BUILDING EXAMPLES: DISTRIBUTOR ETHICS TRAININGS

Recent Association Approaches

Carlos Gouvea
ABIIS (Brazil)

ETHICS AND INTEGRITY:

SUSTAINABLE HEALTHCARE THAT CREATES VALUE


Jornal do Comércio
O Jornal de economia e negócios do RS
84 anos
Esquema de corrupção na saúde tem âmbito nacional, segundo a polícia
Valor.com.br
Valor
Lucro das operadoras de saúde sobe 70,6% em 2016, a
FOLHA DE S.PAULO
Remédios não entregu do RJ perdem val
FANTÁSTICO
EXAME
Para 89% dos brasileiros, saúde é considerada péssima, ruim ou regular
Avaliação é compartilhada por 94% dos que possuem plano de saúde e por 87% dos que dependem do SUS
PRUDENTE E REGIÃO
Presidente Prudente e Região
Grande Minas
Pela web
Todo mês, 100 sorteios de R$ 1 MIL e 1 sorteio de R$ 30 MIL.
Shawn Mendes considera Rock in Rio o momento mais incrível da vida dele

Why IES Ethics Health?

Why IES - Ethics Health?

- ✓ Environment without maturity in “transparent and ethical relationship ”. Relationship was “hostile - lack of trust among the parties”
- ✓ Companies, doctors and HCPs, hospitals and HMOs/Insurance Plans were acting without clear pre-defined rules.
- ✓ Unreal consumption of Medical Devices, overindication of procedures (just as example – there was a decrease in volume of over 35% after dissemination of news in the media).
- ✓ Lack of credit with the Market and with the public opinion.
- ✓ The whole cost of a ”surgery" was built into the "cost of the product" (medical fees, training, hospital fees, renewal of instruments in the hospitals, surgical technicians, etc).

Why IES - Ethics Health?

- ✓ Conflicts with HMOs / Health Insurances:
  - ✓ Lack of payment
  - ✓ Postponement of the invoicing authorization
  - ✓ Financial payment denials
  - ✓ Policy of "dictating" the purchase price
  - ✓ Flattening medical fees
  - ✓ Flattening hospital fees x health plans

"ROCK BOTTOM"

It was mandatory to re-structure the whole healthcare chain or we would face the colapse of the "system"!

Who we are

INSTITUTO ÉTICA SAÚDE

Who we are

Mechanism of self-regulation of the conduct of health actors through:

Governance
Regulations and Statutes/Bylaws
Prevention and Control

- ✓ **Prevention:** Education and Integrity Program
- ✓ **Control:** Reporting Channel

Mission

To promote the best practices in the relationships, by means of self-regulatory mechanisms for the healthcare sector.

Purposes

- ✓ To disseminate and to consolidate a culture of honesty and transparency in the healthcare sector
- ✓ Fair and healthy competition
- ✓ Access to the best technologies
- ✓ The best cost/benefit for the healthcare systems
- ✓ Appropriate availability of medical technology
- ✓ And last, but not least,

The main purpose is to **assure the safety and respect to the patient!**

Values

Ethic
Integrity
Awareness and Education
Transparency
Legality

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Advisory Board

abraidi · Instituto Ethos · ABIIS Aliança Brasileira da Indústria Inovadora em Saúde · abimed 20 anos · ABIMO · AMB Associação Médica Brasileira · anahp · AUDIF · cbdl Diagnóstico para a Vida

Colégio Brasileiro de Cirurgia e Traumatologia Buco-Maxilo-Facial · fehosp Federação das Santas Casas e Hospitais Beneficentes do Estado de São Paulo · Sociedade Brasileira de Cardiologia SBC · sbhci Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista · SBOT Sociedade Brasileira de Ortopedia e Traumatologia · SBPC/ML Sociedade Brasileira de Patologia Clínica Medicina Laboratorial · SOBECC Nacional · Sociedade Brasileira De Cirurgia Cardiovascular

Members - Manufacturers

Arthrex · BIOTRONIK excellence for life · B|BRAUN Sharing Expertise · BRAILE BIOMÉDICA · LDR a passion for innovation · medartis® · NuVasive · smith&nephew · SCITECH Innovation for Life · Taimin · WRIGHT Focused Excellence · ZIMMER BIOMET Your progress. Our promise.

Members - Distributors and Importers
220 companies

Members - Hospitals

Albert Einstein Hospital Israelita · FSFX Fundação São Francisco Xavier · INDSH Instituto Nacional de Desenvolvimento Social e Humano · Hospital Moinhos de Vento Affiliated with Johns Hopkins International

Agreements signed up to now

ANVISA · AMPASA · CNMP Conselho Nacional do Ministério Público · TCU Tribunal de Contas da União · CADE Conselho Administrativo de Defesa Econômica

Scopes of Performance

- Awareness and Education
- Monitoring of Compliance
- Institutional and Government Relations

Reporting Channel

Indicators

588 Cases Reported

1446 People/Institutions Reported

Until may 2018

Cases Reported - Main Issues

249 Concession of personal incentives, commissions for promoting the prescription of products or use of material.

56 Unfair practices to competition in public or private environment.

52 Payment to the hospital of fee or commission related to the use of materials.

42 Physician / patient relationship.

39 Practice of donating equipment or instruments in order to obtain undue advantage.

139 Members
1307 Non Members

Total: **1446**

652	Medical Doctors
461	Distributors
183	Hospitals
81	Importers
39	HMO / Health Plans
21	Manufacturers
6	Institutes
3	Public Offices

Main Actions

Our main actions

Institutional and Government Relations

- ✓ **To amplify scope of action**
  - Cooperation Agreements
  - Advisory Board
  - Hospitals
  - Manufacturers

- ✓ **New members**
  - HMOs / Health Insurance Companies
  - Other segments of Medical Devices and IVDs

- ✓ **InterAmerican Coalition of Ethics in the Medical Device Sector**

  Member of the Interamerican Coalition that gets together associations of Medical Technologies of Brazil, United States, Canada, Mexico, Argentina, Chile, Colombia, Peru, Ecuador and Venezuela.

Compliance Monitoring

- ✓ Working Groups:
  - Supply Chain
  - Hospitals
    - Risk Mapping

- ✓ Assessment of the Compliance Systems of Members (2nd Questionnaire - In 02)

- ✓ IES Certificate

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Compliance Monitoring

Qualification Program IES - QualIES

To enable the implementation and qualification of Compliance programs

- ✓ Audit
- ✓ Consultancy

(Ernst & Young, Deloitte, PWC, KPMG, Grant Thornton)

Benefits

- ✓ Protection of the Ethics Health members in hiring audit companies;
- ✓ Guarantee of compliance to a minimum common check-list of requirements for the Medical Technology Market, promoting the most effective prevention against deviation of conduct;
- ✓ Saving time and resources;
- ✓ Education and awareness.

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Awareness and Education

- ✓ Annual Forum Ética Saúde
- ✓ Closed Events (CADE, ANVISA, TCU, etc.)
- ✓ Campaign

Ethics is not Fashion. Ethics are manners *("Ética não é moda. Ética são modos")*.

- ✓ Partnerships with Universities
- ✓ Online Courses (in cooperation with other entities) FEHOSP - EducaSUS
- ✓ Presential Trainings
- ✓ Training recognized by Industries Compliance Systems
- ✓ Training focused on the Value Channel (Distributors) = Pilot with ABRAIDI

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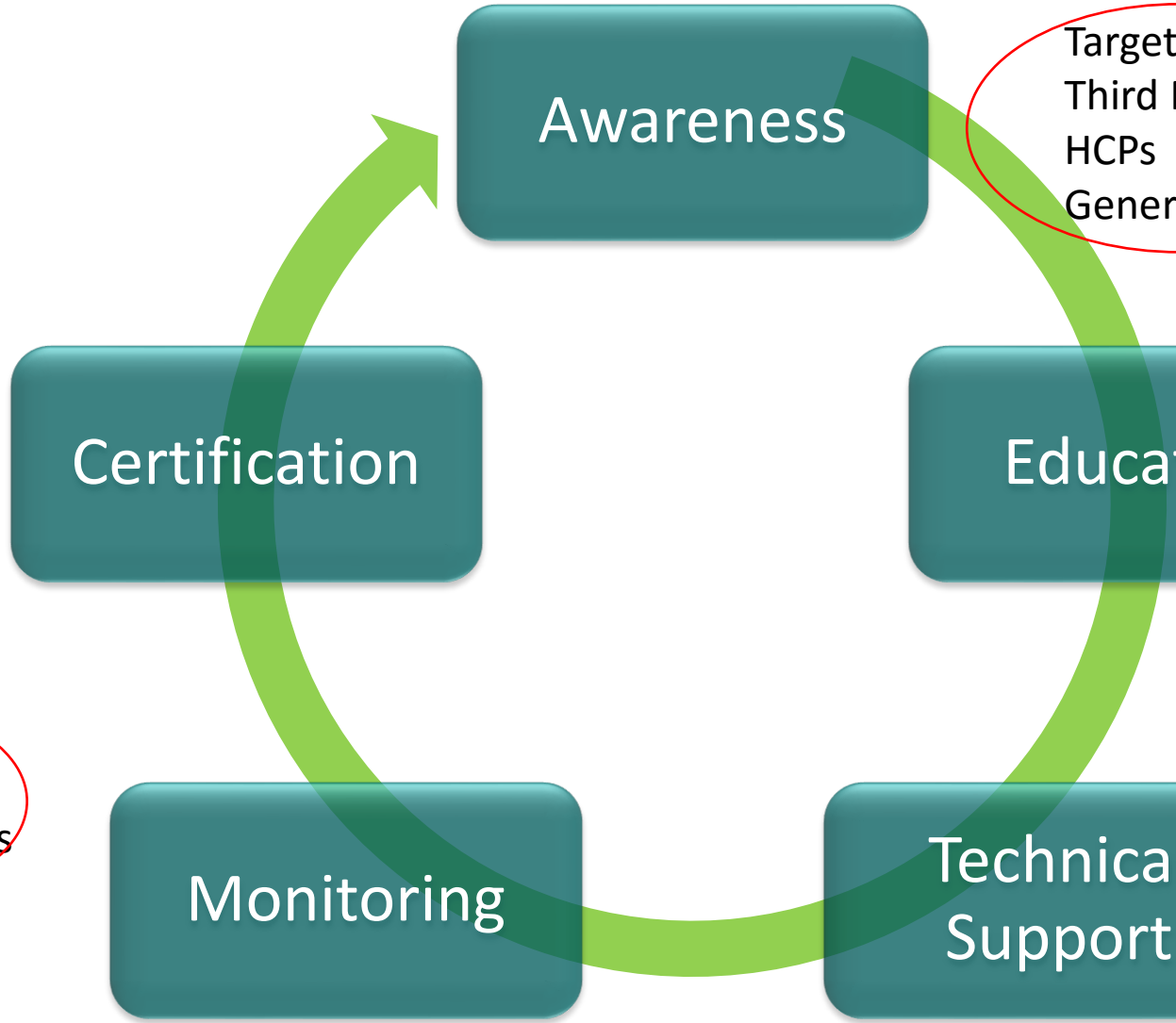
Education
Pilot Project



Target:
Third Party SMIs
HCPs
General Public

Target:
Third Party SMIs
(Compliance Officers)

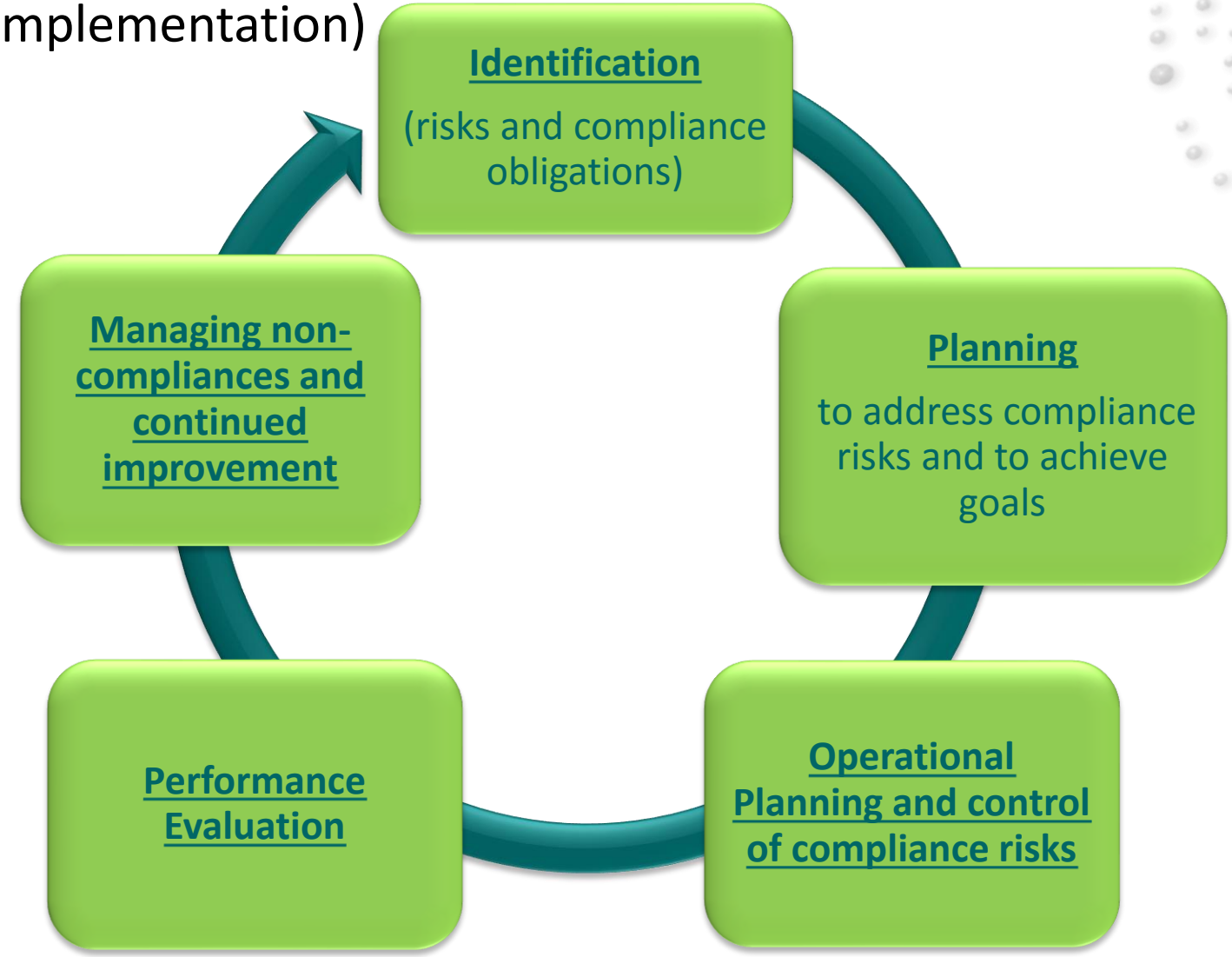
Target:
Third Party SMIs

Target:
Third Party SMIs

Target:
Third Party SMIs
(Compliance Officers)

abraidi
Associação Brasileira de Importadores e Distribuidores de Produtos para Saúde

Technical Support (CMS - Implementation)



INSTITUTO ÉTICA SAÚDE

Thank you!

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Higienópolis – São Paulo - SP

CAPACITY BUILDING EXAMPLES: DISTRIBUTOR ETHICS TRAININGS

Pilot Webinars on the APEC Guidance

Ms. Chrisoula Nikidis
Polaris (Canada)

SME Webinar on APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

Asia-Pacific Economic Cooperation

Business Ethics for APEC SMEs
Medical Device Sector

This webinar has been prepared for the *Business Ethics for APEC SMEs Initiative* as a contribution by: IQVIA™

Develop an interactive, engaging eLearning module in partnership with Polaris/IQVIA based on the Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

Asia-Pacific Economic Cooperation

Business Ethics for APEC SMEs
Medical Device Sector

Map out strategy

- Map out eLearning module
  - Develop a story board
  - Determine the flow and pace of the eLearning presentation/module
  - Determine most appropriate format
  - Determine method of delivery

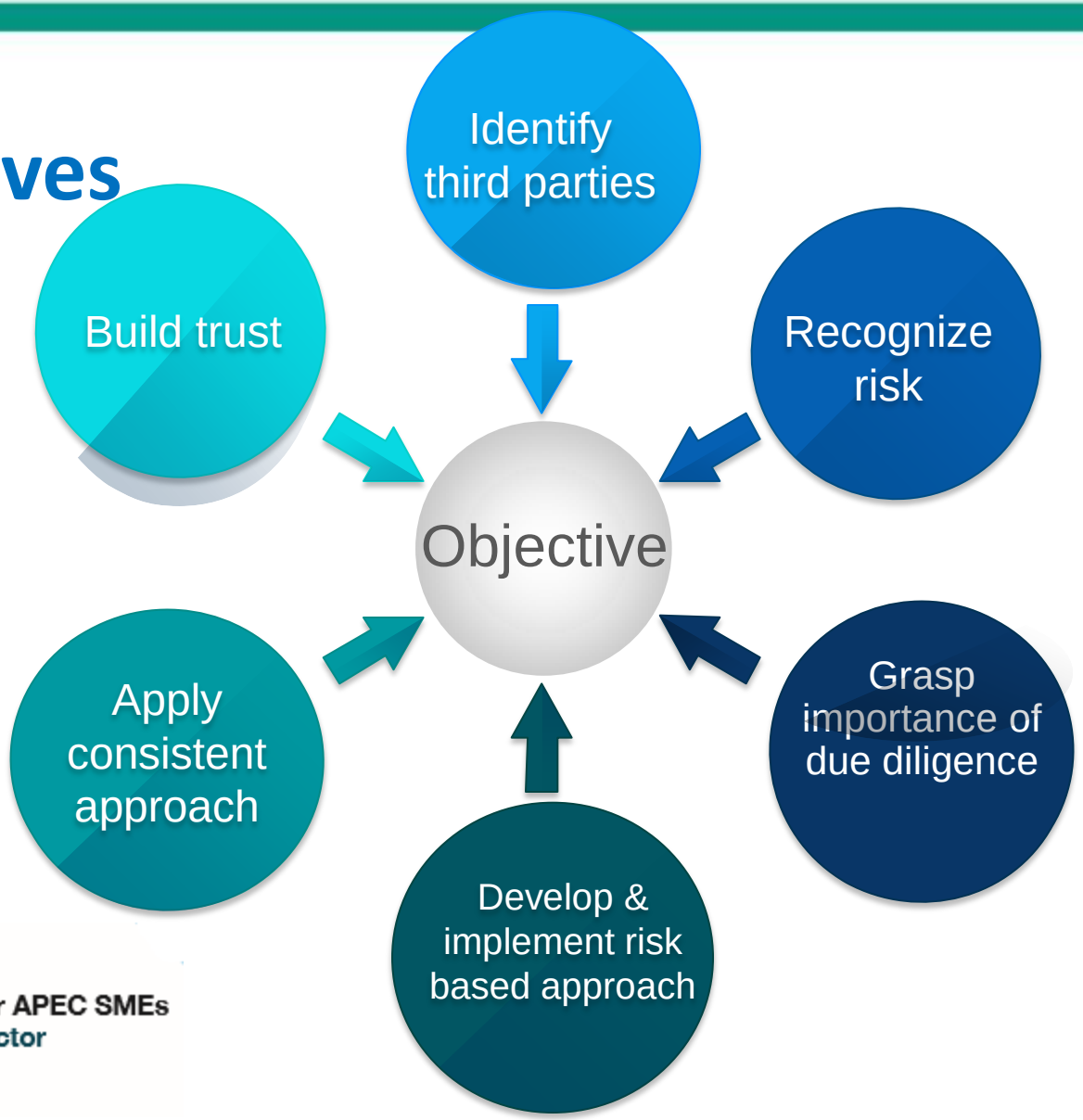
Develop Learning Objectives/Learning Outcomes

- Who are the learners completing this course?
- What do you want them to be able to do after completing the course?
- What do they need to know to do this, and
- What must the learner understand to be able to do it?

Develop Content

- **Develop Content based on the** Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector
- Pilot with APEC economies
- Provide voice over

Learning Objectives



Content

Introduction

- **Remind learner of:**
- The APEC initiative and the context in which the Guidelines were developed;
- The context of "why" 3rd Party Due Diligence is important in todays environment.

Understanding the Guidelines

- **Principles and Standards summary**:
- **Outline the principles-** Summarize each principle into one to two slides using both text and visuals followed by 1 to 2 slides that provide examples and best practices, reinforcing the understanding of the principle.

Conclusion

- Recap of material reinforcing the key points

Resources/References/Documents

- Embed links to references and resources
- Including links to articles, reference sites, and other web resources.

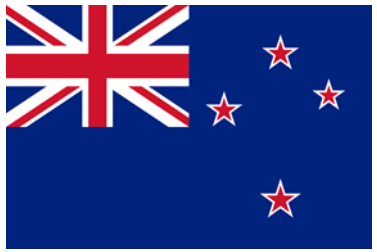
Contact Information

Pilot Webinars

PILOT PROJECT

In early July piloted the third party due diligence Webinar was piloted with two APEC Economies:

New Zealand

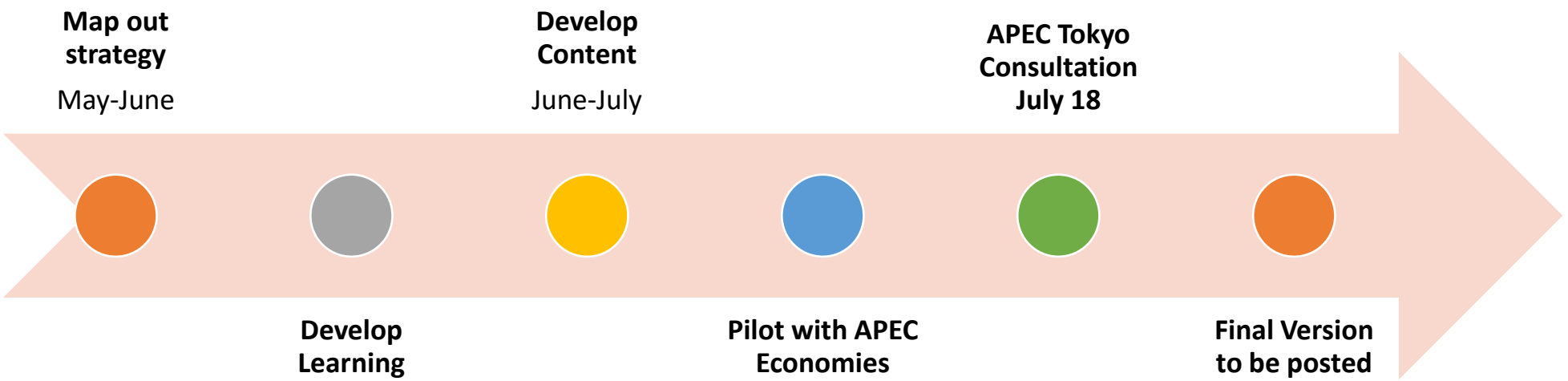


Canada

Recommendations for the Final version of the Webinar

- Underscore the importance and the resources that local Associations can offer;
- Stress the importance of third party due diligence and the cost of non-compliance;
- Highlight why this "Guidance applies to me" and use it as an opportunity to level the playing field;
- Provide examples of where to embed ethical third party due diligence in the current due diligence process;
- Distill principles into a template check list and action plan;
- Develop an extensive resource guide with links to global legislation, regulations, questionnaires etc.; and
- Provide contact information for embassies and trade commissions

Timelines and Roll out



CONSIDERING A "TOKYO STATEMENT" ON IMPLEMENTING THE APEC GUIDANCE FOR ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS IN THE MEDICAL DEVICE SECTOR

Facilitator:

Ms. Faye Sumner, MTANZ (New Zealand)

PLANNING SESSION ON IMPLEMENTATION OF APEC THIRD PARTY GUIDANCE (18 JULY) MEDICAL DEVICE SECTOR

Closing Observations

Ms. Tricia Van Orden, Project Overseer
Business Ethics for APEC SMEs Initiative
U.S. Department of Commerce

NETWORKING LUNCH
(13:00 – 14:00)

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HALF DAY SME COMPLIANCE WORKSHOP (18 JULY)
MEDICAL DEVICE SECTOR

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Business Ethics for APEC SMEs Initiative
U.S. Department of Commerce

HALF DAY SME COMPLIANCE WORKSHOP (18 JULY)
MEDICAL DEVICE SECTOR

Emcee:

Ms. Zohra Anwari, Legal Counsel
The Advanced Medical Technology Association

HALF DAY SME COMPLIANCE WORKSHOP (18 JULY)
MEDICAL DEVICE SECTOR

Participant Introductions

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HALF DAY SME COMPLIANCE WORKSHOP (18 JULY)
MEDICAL DEVICE SECTOR

Panel: Spotting Global Compliance Trends for SMEs and Understanding Risks

MODERATOR:

Ms. Zohra Anwari
AdvaMed

Ms. Angela Main
Zimmer Biomet

Ms. Caroline West
Olympus Corporation

Ms. Joyce Wong
Polaris

SHORT PRESENTATIONS ON ORGANIZING YOUR COMPLIANCE PROGRAM TO SUPPORT YOUR COMPANY'S GROWTH

Structuring your Compliance Program

Ms. Tamara Olmos
AMID (Mexico)

amid®
Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos.

WHO WE ARE?

amid®
Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos.

Arthrex · BARD · Baxter · BD · ZIMMER BIOMET
BIO-RAD · B BRAUN SHARING EXPERTISE · Boston Scientific · ConvaTec
BIOMÉRIEUX · Dräger · Edwards · GE · Johnson & Johnson · Medtronic
NIPRO · PHILIPS · Roche · SIEMENS · smith&nephew
ST. JUDE MEDICAL · stryker · Teleflex · IL Werfen · QIAGEN
ZEISS · Alcon A Novartis Division · OLYMPUS · 3M

To promote progress of health services in Mexico through the access to medical advances, improving the quality of people's life.

SMALL & MEDIUM COMPANIES: OUR REALITY

10% subsidiaries from multinational companies

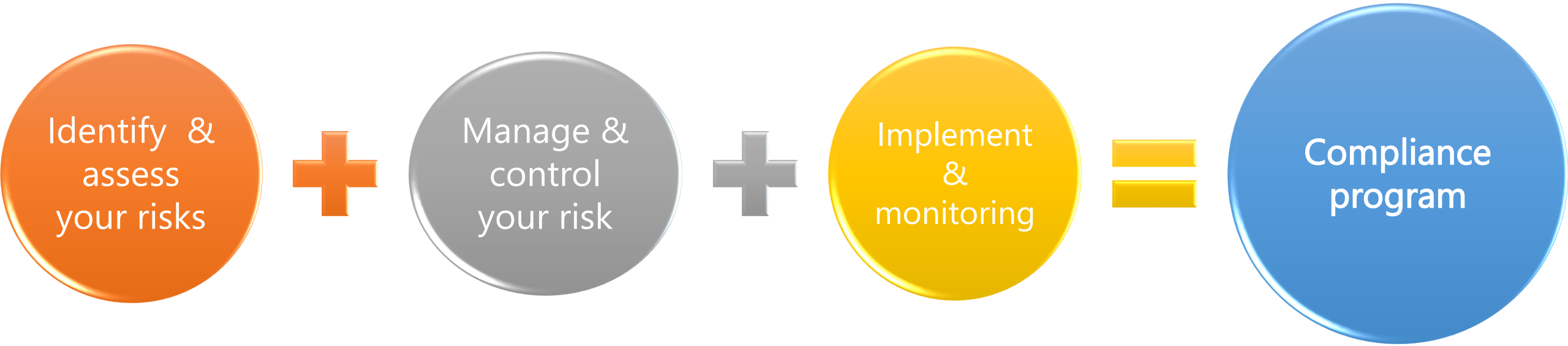
= HAVE

90% family run business (local)

≠ Don´t Have

All companies Must have a compliance program

STRUCTURING YOUR COMPLIANCE PROGRAM



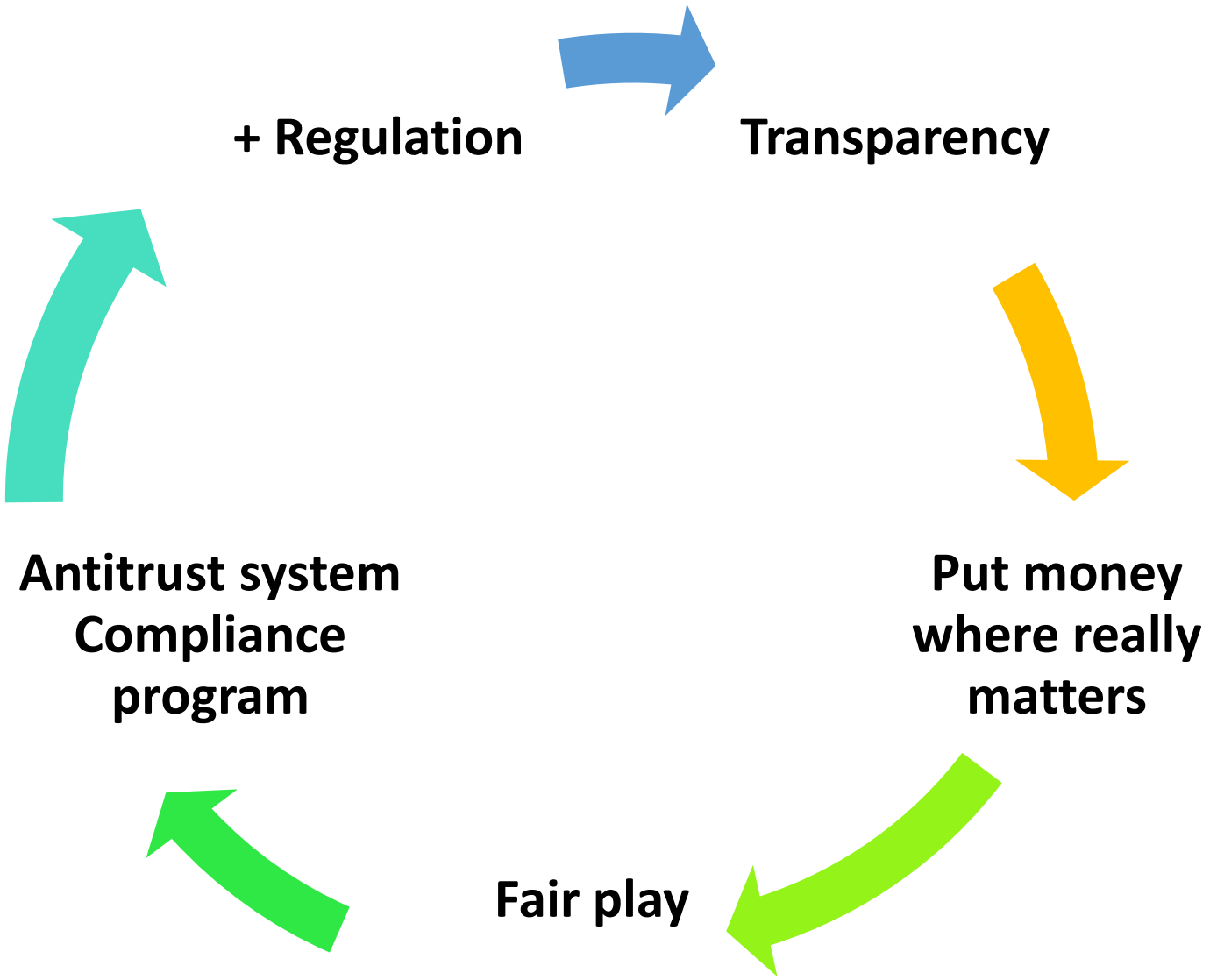
ACTIONS TAKEN

- Trainings
- Co-responsibility of distributors by contract
- Monitoring and auditing

GETTING CLOSER TO YOUR DISTRIBUTORS THROUGH YOUR ASSOCIATION

- ✓ Code of Interaction w/ HCP´s
- ✓ End of direct sponsorships notice
- ✓ Q & A
- ✓ 3 minutes video (FB, LinkedIn, Twitter, Website)

HOW A COMPLIANCE PROGRAM MAKES YOUR COMPANY GROW



"Compliance is not a waste of money, it´s a necessary investment if you want your Company to succeed".

amid®
Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos.

SHORT PRESENTATIONS ON ORGANIZING YOUR COMPLIANCE PROGRAM TO SUPPORT YOUR COMPANY'S GROWTH

Training, Metrics, Auditing & Monitoring

Mr. Wes Porter
Wright Medical (The United States)

Mr. Emmanuel Vicencio
Wright Medical (The United States)

Agenda

- Developing an Audit, Monitoring, and Training Program
  - Risk Assessment
  - Project Plan – Audit & Monitoring
  - Training Program
- Final Thoughts

Developing an Audit, Monitoring, and Training Program

- Risk Assessment
  - Priority
  - Metrics
  - Change Management
- Project Plan
  - Audit Projects
  - Monitoring Activities
- Training Program
  - Policies/Procedures
  - Applicable Laws/Risks

Risk Assessment

- Identify risk areas.
  - Interviews with Company Leaders
  - Use of Metrics/Financial Data

- Results utilized to develop the Compliance Project Plan.

Audit

- Projects designed to review a specific activity or risk areas.

- Audit projects may include:
  - Global Anti-Bribery/Anti-Corruption Reviews
  - Third Party Intermediary Reviews
  - Process Reviews
  - Special Projects

Monitoring

- Activities/tasks that are continuous and measured.

- Monitoring may include:
  - Metrics/Analytics
  - Change Management/ Environment

Training

- Avenue to communicate policies and any applicable laws.
  - Delivered electronically or in person.
    - New hires globally
    - Company representatives
  - Consider Audit & Monitoring results.

Final Thoughts

- The Risk Assessment is the starting point for developing a Project Plan.
- The Audit Plan addresses risks and includes an effective monitoring of activities to identify on-going potential risks.
- A Compliance Training program includes major risks or control weaknesses.

SHORT PRESENTATIONS ON ORGANIZING YOUR COMPLIANCE PROGRAM TO SUPPORT YOUR COMPANY'S GROWTH

Association Tools & Resources/Benefits of Association Codes

Ms. Michelle Wagner
MTAA (Australia)

Association Tools & Resources / Benefits of Association Codes

Michelle Wagner
Member, MTAA Code Authority

Health Care Compliance Sector Lead, Medical Devices Asia Pacific
Johnson & Johnson Health Care Compliance & Privacy

Johnson & Johnson Medical

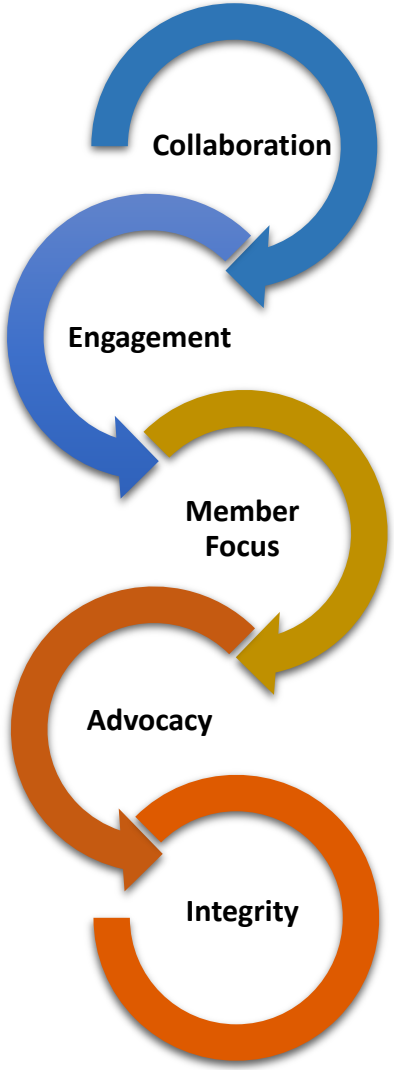
About MTAA

The Medical Technology Association of Australia (MTAA) is the peak association representing over 100 medical technology industry members from across the country.

MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

Strategic areas of activities

The MTAA Strategic Plan 2017-2020 prioritises work in five strategic areas




Medical Technology Industry
Code of Practice
(Administered by the Medical Technology Association of Australia)
9th Edition – 2015
MTAA
Medical Technology
ASSOCIATION OF AUSTRALIA

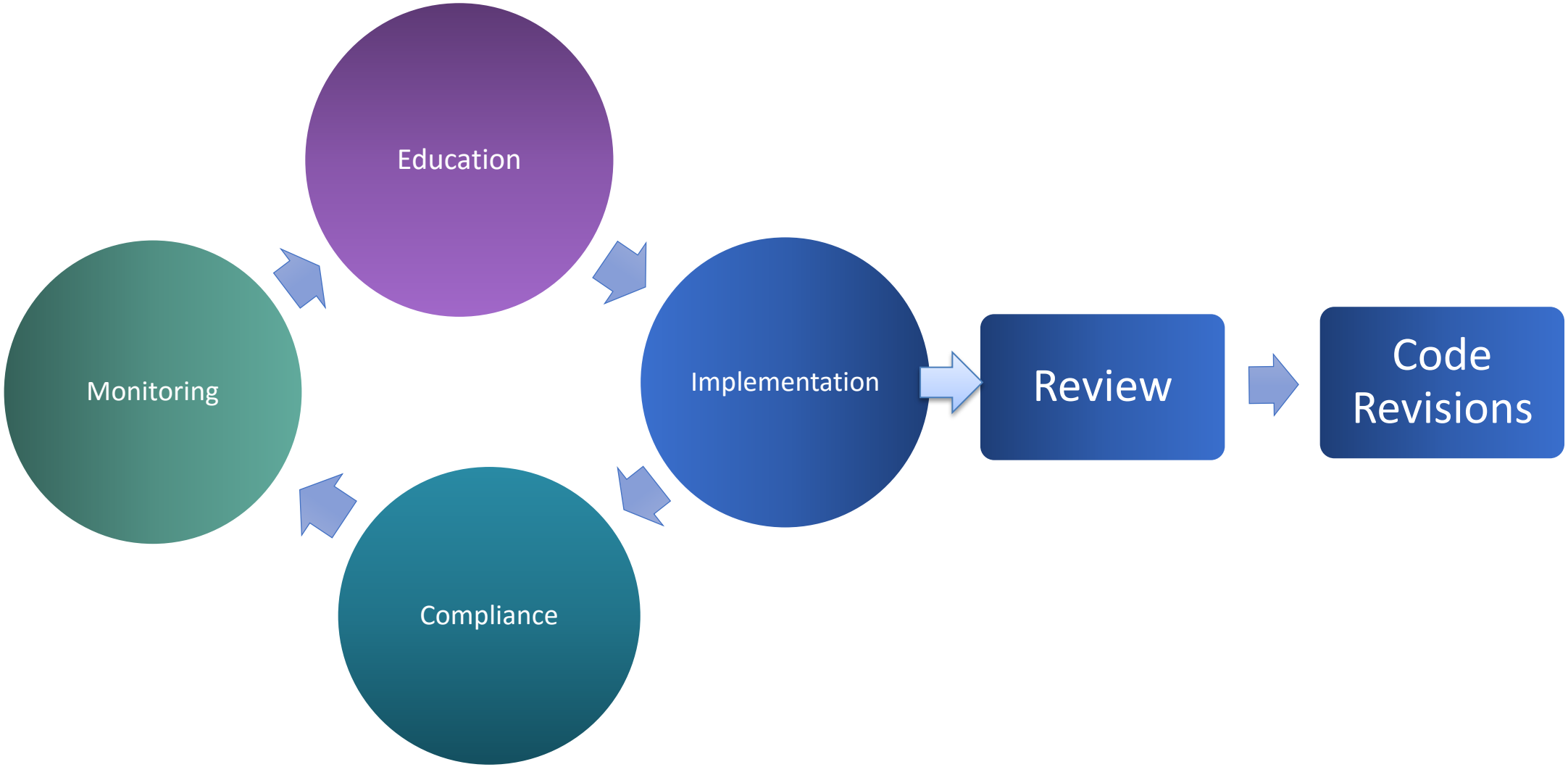
Code Review

- The Code of Practice 9th Edition 2015 - current
- The Code is reviewed every 3 years
- An administrative review of the Code of Practice is currently underway
- Principle changes and Edition 10 of the Code is expected end of 2018/early 2019

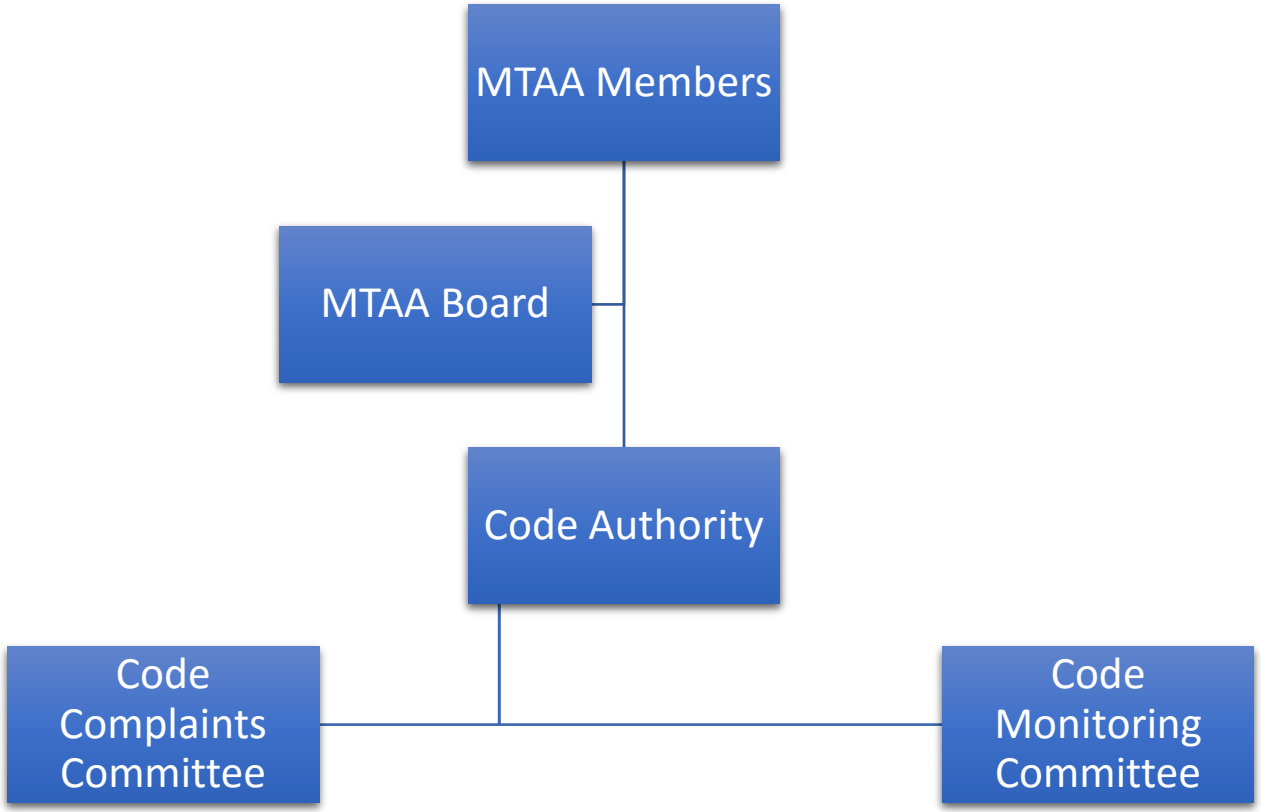
Benefits of an Association Code

- The MTI Code demonstrates members' proactive commitment to high standards of ethical behaviour - as an industry and as individual companies
  - ➢ *Ethical Leadership*
- Self regulatory
- Robust processes that include independent experts, consumer representatives and HCPs
- Industry maintains input into the Code and the administrative processes - provides flexibility to update/improve as necessary

Benefits of an Association Code



Governance of the MTI Code



Code Monitoring - Committee Structure

MTTAA has two Code Committee Structures:

- Code Authority Committee - oversight and effective administration of the Code
- Code Monitoring Committee - reviews monitoring reports from member companies
- To provide consistency, The Chair is the same for both Committees

Monitoring - Reporting Topics & Administration

- Member companies are asked to report on how they ensure internal compliance and to provide distributed comparative advertisements and competitions held within the reporting period
- The monitoring process is conducted as set out on the next slide

Monitoring Process

Collection

- MTAA collects monitoring reports from each member once per annum
- MTAA checks reports have been filled correctly and follow up if necessary prior to meeting
- MTAA sends monitoring reports to CMC 2 weeks prior to review meeting

Review Meeting

- For each report reviewed, the CMC agrees on the appropriate decision of either compliant, a follow-up is required or a potential breach of the Code
- For each follow up or potential breach the CMC agrees on the content of and questions to be raised with the company

Post Meeting

- A report of the meeting is drafted for publishing to committee members
- MTAA carries out actions with each member in accordance with CMC decisions
- Additional information is provided back to CMC to determine compliance

Reporting

- Chair to provide updates to the Code Authority
- MTAA records statistics each year for annual reporting
- Quarterly report is published to committee members on monitoring activities.

MTAA Education and Training

- The Code of Practice is the overarching governance that ensures MTAA Members adhere to strong ethical practices and ensure compliance through the provisions of the Code
- This is achieved through ongoing education and training, monitoring of compliance and dedicated Committee meetings and forums
- Non-member Medical Device companies are also strongly encouraged to comply with the Code

MTAA Education and Training

- The online Code of Practice training is free for all employees of our members
- For non-members, the Code of Practice training is $99
- Currently, 2484 employees predominately from member companies have completed the online Code of Practice E9 training since the revision of the Code in 2015
- The online training includes hypothetical scenarios for members to complete based on the context of each clause in the Code
- MTAA are currently revising the face to face training offered to members

Ongoing Advice and Information for Members

- The MTAA website includes a FAQs section, the content within this section is derived from queries received from members
- Enquiries received from members include the interpretation and clarification of the clauses and provisions of the Code
- Common enquiries received from members include questions and clarification surrounding advertising, branding and gifts

THE POSITIVE OUTCOMES OF AN ETHICAL CULTURE: WHY THIS MATTERS TO INVESTORS AND ENTERPRISE SUCCESS

Ms. Diane Biagianti
Vice President, Chief Responsibility Officer
Edwards Lifesciences

NETWORKING TEA (16:30-16:45)

Asia-Pacific
Economic Cooperation

2018 APEC Business Ethics for SMEs Forum

18–20 July 2018 • Tokyo, Japan

ISSUE SPECIFIC CASE STUDIES

VIA 45 MINUTE ROTATING BREAKOUT SESSIONS

FACILITATOR:
Ms. Patricia Wu,
Managing Director,
C&M International
(Technical Secretariat)

SPONSORSHIPS
Mr. Campbell Clark,
Medtronic, Singapore

CONFERENCE VENUES
Mr. Kei Matsumoto,
JFMDA, Japan

VALUE-ADDS/TENDERS/ CONFLICTS OF INTEREST AND PROCUREMENT
Mr. Rhoel Laderas,
PAMDRAP, Philippines

CASE STUDY TWO:
CONFERENCE VENUE

CASE OVERVIEW:

- JPMed Corp (JPM) is a Japanese company, a member of an industry association, and is planning promotional events for healthcare professionals.
- JPM is considering an island resort hotel as the conference venue.
- JPM is planning a dinner cruise for the healthcare professionals coming to the island and marine activities for them after the conference.
- JPM's industry association has a code of ethics, which mentions "no excessive offers to healthcare professionals" but does not provide venue guidelines.
- JPM has order the conference leaflet.

Time Table

	Day 1 18 Jul.	Day 2 19 Jul.	Day 3 20 Jul.
9:00-12:00	Introduction / Key note speech	Hands-On 2	Excursion at the beach with lunch buffet
12:00-13:00	Lunch	Lunch	
13:00-17:00	Hands-On 1	Discussion / Wrap up	Go to airport
18:00-	Reception Dinner	Cruise Dinner	

Case Study # 3: Financial Transparency

Financial transparency is of paramount importance when Healthcare Companies deal with Healthcare Professionals. Companies should always be on the look out for potential conflicts of interests and or “red flags’ when conducting business relations with key decision makers who can also be the company’s contracted resource. Efforts must also be made to prove/show that scientific engagements with HCPs are focused on professional learning and not a means to broaden business opportunities within the HCPs scope of influence.

Scenario:

Apex Hospital is a family owned corporation managed by Dr. Phil, a practicing Cardiologist. Dr. Phil co-owns the hospital with his siblings and has a 20% stake in the company. He is concurrently the Head of the hospital's Cardiology Department.

In July 2017, he was invited a Clinical Research Organization (CRO) ClinMax to be the principal investigator for a major clinical study for an improved artificial heart valve manufactured by ValveX. The study will be conducted in Apex hospital and was pre selected by its clinical study sponsor, ValveX as one of 3 clinical study sites in the country.

While negotiations were ongoing for the clinical study, a ValveX Sales Manager Mike A approaches the purchasing department to offer their Artificial Pacemaker to the hospital. The ValveX pacemaker offers some distinct advantage over the currently used device in the hospital. He conducts product presentations and trainings to hospital staff for product appreciation. Per internal purchasing process, final approval any department related purchase orders is the Department Head.

Two months after the Clinical Trial contracts were signed and approved by the hospital, Mike A was able to close a supply agreement with Apex Hospital covering a period of 3 years.

Analysis/Questions:

- What do you think are the red flags in this scenario?
- How can Dr. Phil better manage his role as a consultant and a customer?
- How can ValveX avoid the perception that utilizing the scientific relationship with Dr. Phil was a means to expand business opportunities within Apex Hospital?

CONCLUDING SESSION AND PREVIEW OF TOMORROW

Ms. Zohra Anwari, Legal Counsel
The Advanced Medical Technology Association

Asia-Pacific
Economic Cooperation

2018 APEC Business Ethics for SMEs Forum

18–20 July 2018 • Tokyo, Japan

MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY)
MEDICAL DEVICE SECTOR

Introductory Remarks

Ms. Tricia Van Orden, Project Overseer
Business Ethics for APEC SMEs Initiative
U.S. Department of Commerce

MULTI-STAKEHOLDER TRAINING WORKSHOP (19 JULY)
MEDICAL DEVICE SECTOR

Participant Introductions

NAME | POSITION | ORGANIZATION | ECONOMY

Asia-Pacific
Economic Cooperation

2018 APEC Business Ethics for SMEs Forum

18–20 July 2018 • Tokyo, Japan

LEVERAGING TECHNOLOGY AND OTHER RESOURCES TO SCALE CODE OF ETHICS IMPLEMENTATION FOR SMES

PRESENTERS

Ms. Stephanie Chew
AdvaMed China

Ms. Minah Cho
KMDIA Korea

Ms. Fara Zalina Mohamed
SME Corp Malaysia

Asia-Pacific
Economic Cooperation

2018 APEC Business Ethics for SMEs Forum

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"Leveraging Technologies and Other Resources to Scale Code of Ethics Implementation for SMEs"
A Public Sector Perspective

19 July 2018

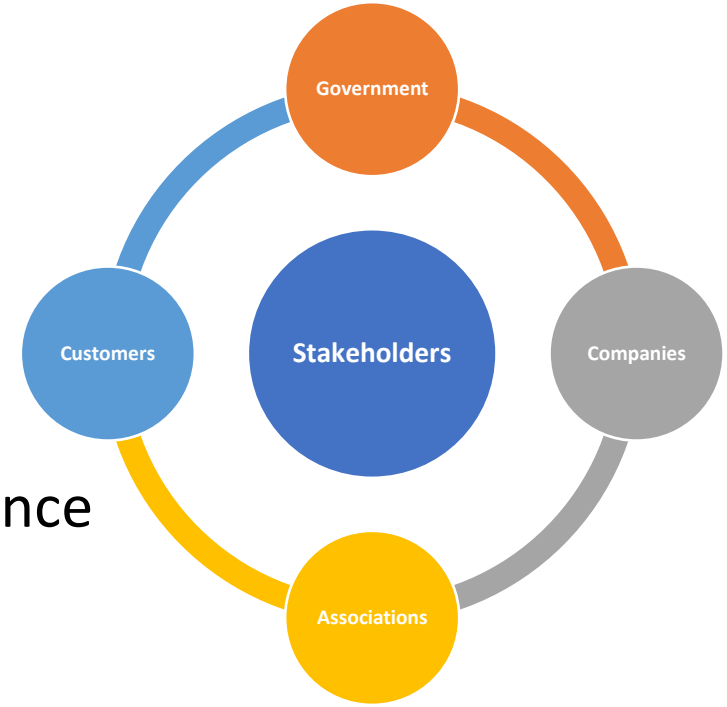
Barriers (AdvaMed China)

- Lack of resources such as funding for human resources and technologies
- Hard to attract members (HCPs, Distributors or local manufacturers)
- Government or other healthcare institution policies may not be of the same high standards
- Lack of consequences for not adopting or breaching the code
- Uneven level playing field

Heighten prioritization of code implementation from large company perspective

Internally

- Build a culture of ethics and compliance – Do the Right Thing!
- Lead by requiring TPI engaged comply with ethical code
- Sponsor, support and participate in industry ethics initiatives (certify the adoption of the code).



Externally

- Lobby with government (through association) to provide preference treatment for companies who have under taken higher ethics & integrity standards. (e.g. enforcement or procurement)
- Encourage government to “punish” the demand side
- Influence HCPs to comply with the law and code of ethics

How Korea Medical Device Associations to leverage ***Technologies*** for companies to implement Code of Conduct or Government requirement ?

Code of Conduct Reporting System

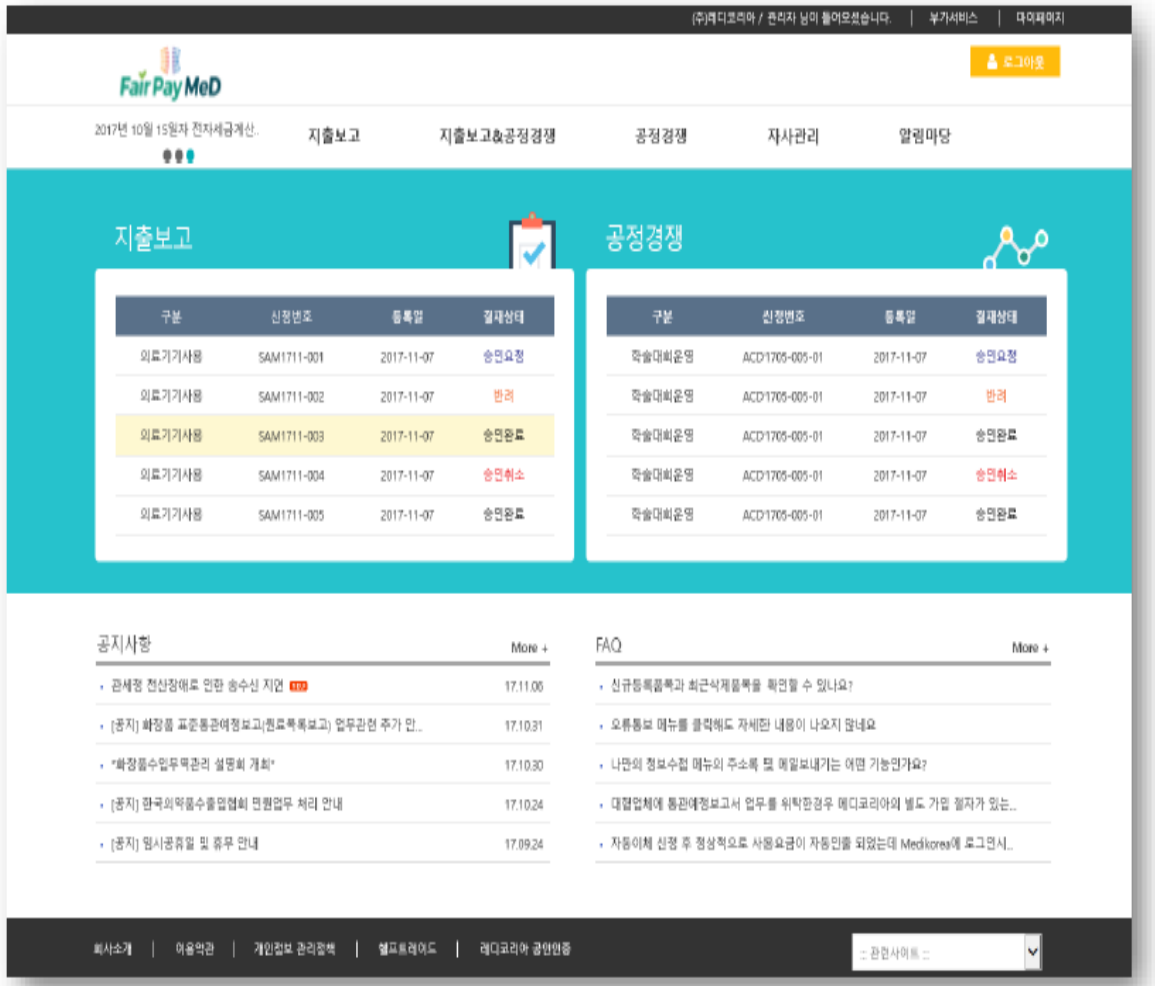
- Set up the ***Code of Conduct Reporting System*** for companies easy access from 2013 for Pre- Post Reporting Requirement based on CoC
  - ✓ Sponsoring Overseas symposium , Sponsoring 3rd party event, Product Presentation with Multi hospital , Speaker & Consultation engagement, Market research , Exhibition , Advertisement , Donation and Product Training

- In 2017 More than 7, 000 were submitted

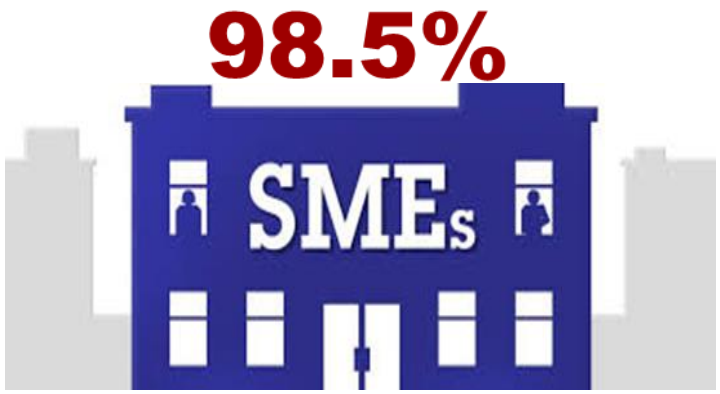
Expense Reporting System

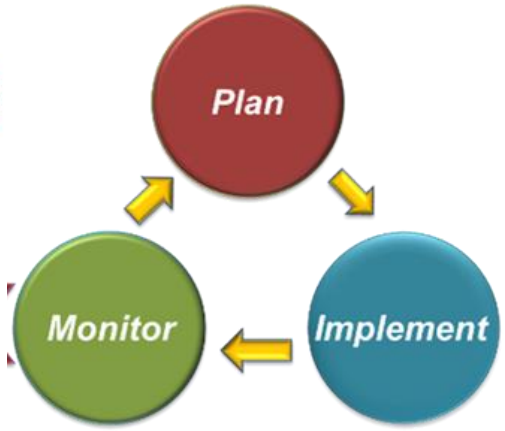
- KMDIA codeveloped system for SMEs
- Medical device companies are required to establish and maintain an expense reporting system to collect and report on economic benefits provided to HCPs based on transparency ACT from 2018 Jan.1
  - ✓ samples , clinical trials, post market surveillance , product presentations, academic conference, prices discount based on payment conditoins and demo evaluation

시스템 메인 화면



Malaysian Perspective





MACRO | PROGRAMME | FIRM

MONITORING LEVEL

- **Digital Future & IR4.0**: SMEs that seize the opportunities stand to gain significantly — M1
- **Globalisation**: Faster growth and favourable demographics in Asia & rapid-growth markets — M2
- **Community living**: Empower communities with the power of ICT and broadband enabling creation — M3
- **Rising of Entrepreneurship**: The drivers of entrepreneurial activity moving from Necessity to Opportunity — M4

Good Business Perspective

Customers → Employees → Stake-holders → Environ-ment → Sustainable SMEs

Scale Up

Better Geographical Reach Out
Fast processing | Global | Transparent

Better Business Image
Communication | Agile | Efficient

Better Operations Management
Less Error | Optimized SOP | Maximised Cost

Superficial Interaction

Less Human Touch

Analysis & Data Collection

Automated Process

Security

Privacy

Ethics Implementation

Lead By Example

- Declare wealth
- Refuse gifts

Anti-Corruption Commission

- Independent Body for Enforcement
- Anti-Corruption Movement

Cultural Shift

- Find an acceptable balance
- Willingness to change

Awareness Activities

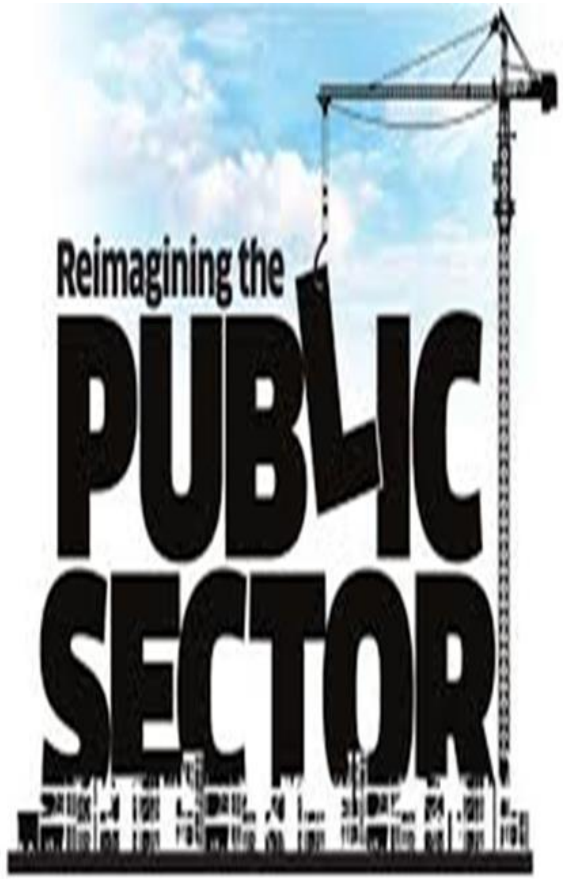
- Clear vision & mission
- Transparent & Upfront
- Sharing of Best Practices

Code of Conduct / Code of Ethics

- Reference point
- Guideline
- Pledges

Ethics Awareness

Efforts to promote the importance of Business Ethics

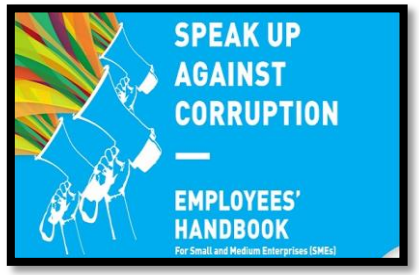


Training

- Sectoral Guidance
- Samples

Partners

- Private Sector
- Associations
- NGOs



Publications

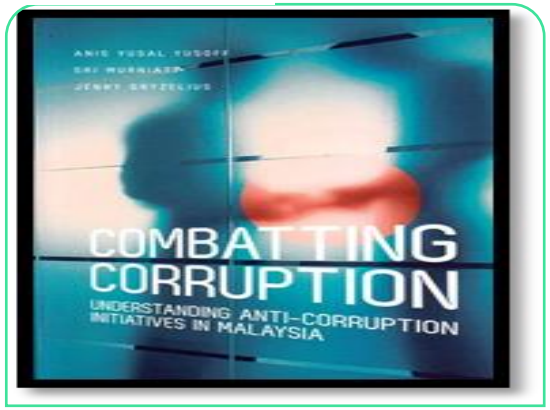
- Articles
- Books
- Journals

SME Corp. Malaysia

SME CORP MALAYSIA

SME Pledge

Anti-Corruption Clauses



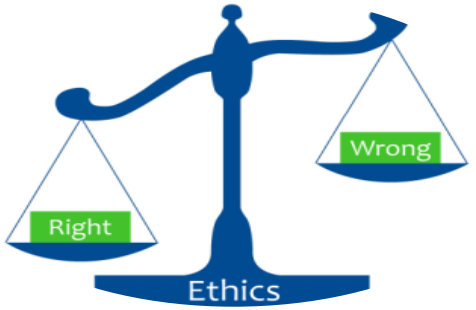
Publications

Regulations

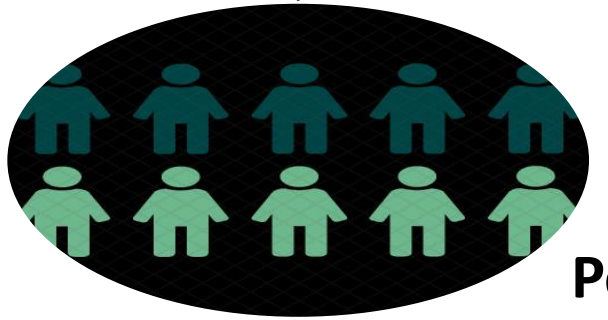
How can APEC economies and governments create "enablers" for high-standard ethical *business* practices?

Leadership

Policies & Procedures



Ethical Climate



People

Asia-Pacific Economic Cooperation

EXERCISE ON STRATEGIES TO SCALE CODE OF ETHICS IMPLEMENTATION FOR SMES

Facilitators

Mr. Thomas Hsu
Edwards Lifesciences

Ms. Tamara Tubin
Wright Medical

MEDICAL DEVICE SECTOR
MULTI-STAKEHOLDER TRAINING WORKSHOP (19th July 2018)
Leveraging Technologies to Scale Code of Ethics Implementation for SME's

Manhattan Room Three, Tokyo American Club, 2-1-2 Azabudai, Minato-ku, 106-8649 Tokyo, Japan

11:00 – 12:00 Exercise on Strategies to Scale Code of Ethics Implementation for SMEs

Facilitators: Mr. Thomas Hsu, Edwards Lifesciences, Ms. Tamara Tubin, Wright Medical

Objective: This exercise will focus on strategies that SMEs may develop for the scaling of Code of Ethics implementation.

This exercise shall help
i) identifying possible challenges and
ii) how to remove barriers in order to be successful and effective.

Proposed Timeline

11:00 – 11:05 Brief Introduction of Facilitators.

11:05 – 11:10 Objective & Introduction of the Workshop.

11:10 – 11:40

- Groups to be created for the workshop.
- Quick individual introduction around the tables.
- Appointment of a leader to present during the outcome session.
- Start exercise.
- Facilitators to facilitate.

11:40 – 11:55 Each group's leader to present

11:55 - 12:00 Conclusion and Closing

NETWORKING LUNCH (12:00-13:00)

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STRATEGIES FOR SUCCESS ON IMPLEMENTING THE APEC GUIDANCE FOR ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS

FACILITATORS

Ms. Faye Sumner
MTANZ
New Zealand

Ms. Stephanie Chew
Medtronic
China

Mr. Ronald Goon
Johnson & Johnson
Singapore

Guidance for Ethical Third Party Intermediary Relationships

A. Written Anti-Bribery Policy/Procedure
B. Risk Assessment
    I. Companies
    II. Third Party SMIs
C. Diligence Program
D. Written Contract
E. Training and Education
F. Monitor/Audit
G. Appropriate Corrective Action

Implementation

- Stakeholders: Industry associations, Company employees, Third Party SMIs (Distributors, Marketing Agents, etc.), HCPs, Government authorities
- Implementing codes of ethics consistent with the principles set out above and additional steps to encourage the adoption of this guidance among their respective members and/or employees;
- Encouraging the development and implementation of high-standard, aligned policies and practices consistent with this guidance;
- Undertaking joint communication and training on this guidance and other relevant policies;
- Encouraging medical device sector regulators and enforcement authorities to acknowledge and support the guidance , and to support steps by stakeholders to implement effective guidance for ethical Third Party SMI relationships; and
- Encouraging APEC economies to advance ethical collaborations consistent with this guidance, through regular communication, joint policies, joint capacity building, and other forms of collaboration.

Exercise

- Group 1 – Written Anti-Bribery Policy/Procedure & Written Contract
- Group 2 – Risk Assessment
- Group 3 – Diligence Program
- Group 4 – Training and Education
- Group 5 – Monitor/Audit & Appropriate Corrective Action

✓**Assign a table lead (who do not rotate and will report out)**

✓**Team members to rotate to another table after 20 min discussion**

✓**Report Out (5 min per group)**

Discussion questions

- What are the 3 keys priorities to implement or execute the elements?
- What are the resources needed?
- What are the potential challenges and propose potential solutions?

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INTERACTIVE, MULTI-STAKEHOLDER CASE STUDIES

14:30-16:45

LEAD FACILITATOR

Mr. Adrian Cosenza, Chief Executive Officer
Australian Orthopaedic Association

MENTOR TEAM INTRODUCTIONS

Ms. Michelle Wagner
Compliance Lead Medical Devices, Johnson & Johnson
Medical Technology Association of Australia

Ms. Ana Garcia Bello
Vice President – Law, Medical Devices Group, Asia-Pacific
Johnson & Johnson

MENTOR TEAM INTRODUCTIONS

Ms. Charlotte Tan
Sr. Director, Group Compliance Officer, Asia-Pacific
Stryker Corporation

Mr. Kei Matsumoto
General Manager, Compliance Dept.
Olympus Corporation
The Japan Federation of Medical Device Association

INTERACTIVE, MULTI-STAKEHOLDER CASE STUDIES
14:30-16:45

Session One 14:30-15:30

Case Study One: Consulting arrangements with HCP's

Networking Tea Coffee Break 15:30-15:45

Session Two 15:45-16:45

Case Study Two: Sponsorships

Case Study Three: Research

The Kuala Lumpur Principles
Medical Device Sector Code of Ethics

- **Integrity** means dealing honestly, truthfully and fairly with all parties
- **Independence** means that HCP interactions with companies should not skew the HCP's medical decision making from the best interests of the patient
- **Appropriateness** means that arrangements conform to proper commercial standards, and are accurate and free from corrupt purposes
- **Transparency** means that companies and HCP's are open regarding significant financial relationships between the parties
- **Advancement** means that relationships are intended to advance medical technology innovation and patient care

Strengthening Ethical Interactions

Industry Associations

Medical Device Companies

Healthcare Professionals

Healthcare Professional Associations

Patients

Hospitals

Regulators

CASE STUDY ONE:
CONSULTING RELATIONSHIPS WITH HCPS

Key Players - Role Play

Industry Association – Head of Legal & Compliance Committee - **Ana**

Medical Device Company – RTS Eye Health Pty Ltd- Marketing Director - **Charlotte**

Healthcare Professional - Dr Flowers Opthalmologist - **Michelle**

Healthcare Professional Association – College of Opthalmologists

Patient - **Adrian**

KEY QUESTIONS:

- Discuss each of the services planned for Dr Flowers and determine if they would meet the requirements of the Code.

- Would each of these interactions appear ethical to patients in Japan and the US and why or why not?

- If you are Dr Flowers what considerations would you give to this proposal and could you commit to this contract with RTS?

- If you are the Compliance Officer at RTS, what advice would you give RTS about the planned activities and consultancy arrangement?

NETWORKING TEA (15:30-15:45)

CASE STUDIES TWO & THREE: SPONSORSHIPS and RESEARCH

The Kuala Lumpur Principles
Medical Device Sector Code of Ethics

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Strengthening Ethical Interactions

Industry Associations

Medical Device Companies

Healthcare Professional Leaders

Healthcare Professional Associations

Patients

Professional Conference Organisers

CASE STUDY TWO : SPONSORSHIPS

- Dr. Jones, an experienced and generally well known medical professional from the United Kingdom would like to attend a third party educational congress in Thailand, Thai Hip and Knee Society Annual Meeting (THKS).
- Dr. Jones is a strong supporter of your company and currently has a consulting agreement with your company to teach other surgeons in the use of your products.
- The THKS event will be held at a beach resort commonly used for large meetings. The scientific and educational value of the event has been assessed to be adequate. Your company has decided to have a booth at the event.

CASE STUDY TWO : SPONSORSHIPS

- Your sales representative suggested the following:
  - Organize a company training event 1-2 days before the congress in Thailand and invite Dr. Jones as the faculty speaker/trainer. This will enable your company to sponsor his travel costs from the United Kingdom to Thailand.
  - Provide a grant to the Thai Hip and Knee Society and informally advise that the grant is for Dr. Jones' registration and accommodation at the congress.
  - Thai Hip and Knee Society provides Dr. Jones with accommodation during the THKS as part of his faculty arrangement.

KEY QUESTIONS:

- Are there any challenges with the proposal by the sales representative?

- Assuming the local industry code prohibits direct HCP sponsorship, what controls can be implemented to detect attempts to circumvent the prohibition of providing direct sponsorship?

CASE STUDY THREE : RESEARCH

A large university hospital in Tokyo and is seeking funding for its research. The university has requested ABC Limited (a medical device company) to support a number of its research projects as follows:

- Scholarship fund 10,000,000 JPY – The prospectus reads that the funding will be used for any and all research related to surgery. No details on each research is provided. The University have asked ABC Limited, as a market leader, to support 70%.
- The university is celebrating their 90th anniversary and they have requested funding for their memorial project. The project includes renovation of the research facilities and the department of medicine's building, construction of a new clinic, and installation of a garden in their affiliated hospital. Funding breakdown is 30% for university and 70% for clinic/hospital.

CASE STUDY THREE : RESEARCH

The University have advised ABC Limited that if the support is not provided, their products will be “subject for reconsideration on its continuous usage” at their affiliated hospitals in Japan.

The Industry Association Code requires that the research needs to be on specific theme in order to avoid funds to be utilised for operational /management cost. In addition, research funding requires a report at the end from the requester to explain the summary of the research and usage of fund. Grants cannot be supported if:

- The research does not contain highly professional and sophisticated subjects on medicine and medical devices beyond the normal medical practice
- The support is excessive compared to other companies
- The support is allocated and forced
- Used to induce or maintain sales

KEY QUESTION

You are the Compliance Officer for ABC Limited. Consider the above scenario and provide your advice to ABC management as to whether it complies with the Code, whether the support would be considered ethical to the public and your reasons. If the company proceeds with the support, what would you recommend they require for documentation.

The Kuala Lumpur Principles
Medical Device Sector Code of Ethics

- **Integrity** means dealing honestly, truthfully and fairly with all parties
- **Independence** means that HCP interactions with companies should not skew the HCP's medical decision making from the best interests of the patient
- **Appropriateness** means that arrangements conform to proper commercial standards, and are accurate and free from corrupt purposes
- **Transparency** means that companies and HCP's are open regarding significant financial relationships between the parties
- **Advancement** means that relationships are intended to advance medical technology innovation and patient care

GUIDANCE FOR PLENARY (20 JULY)

Ms. Patricia Wu
Managing Director
C&M International