



2017 APEC Business Ethics for SMEs Forum

Hà Nội, Việt Nam | 7-8 September 2017



ADVANCED BREAKOUT SESSIONS (COURSE B)
CODE OF ETHICS IMPLEMENTATION

10:30-12:30

SCHEDULE OF MODULES

1. *Adapting to a Changing Environment*
led by Thomas, Stephanie, and Benjamin
2. *Code of Ethics Accessibility* *led by Bronwen and David*
3. *Time Permitting: Individual / Small Group Mentor Sessions*

MODULE ONE: ADAPTING TO A CHANGING ENVIRONMENT

MENTOR TEAM INTRODUCTIONS



*Mr. Thomas Hsu
Head of Ethics & Compliance, APAC and Japan
Edwards Lifesciences*



*Ms. Stephanie Chew
Head of Ethics & Compliance Officer, Greater China
Medtronic*

MODULE ONE: ADAPTING TO A CHANGING ENVIRONMENT

MENTOR TEAM INTRODUCTIONS



*Mr. Benjamin Kwak
Vice President, Compliance Officer,
& Senior Legal Counsel
Zimmer Biomet*

Overview

- Demand for healthcare services will continue to grow in Asia-Pacific (APAC) due to demographic and epidemiological transitions impacting the entire region.
- This will require a transformation in the way healthcare is delivered in APAC and will impact key stakeholders, including:
 - Manufacturer
 - Sales channel - Sales Reps, Indirect Channels
 - Compliance Officers
 - Global companies and local company representatives
 - Medical device industry association
 - Health Care Professionals and related associations
 - Providers e.g. hospitals / clinics
 - Payers e.g. insurers
 - Regulators
- In order for regional industry association Codes of Ethics to continue to be relevant they need to adapt to this changing environment.

Objectives and Desirable Outcome

Objectives: Brainstorm the major trends, elements and activities required to adapt to a changing environment

Tools: Use a fish bone diagram methodology to facilitate this brainstorming / discussion session

Desirable outcome: A list of elements and activities to support us to navigate how Codes of Ethics can successful adapt through this changing environment.

Fish Bone Diagram Illustration

The fishbone diagram identifies many possible causes for an effect or problem.

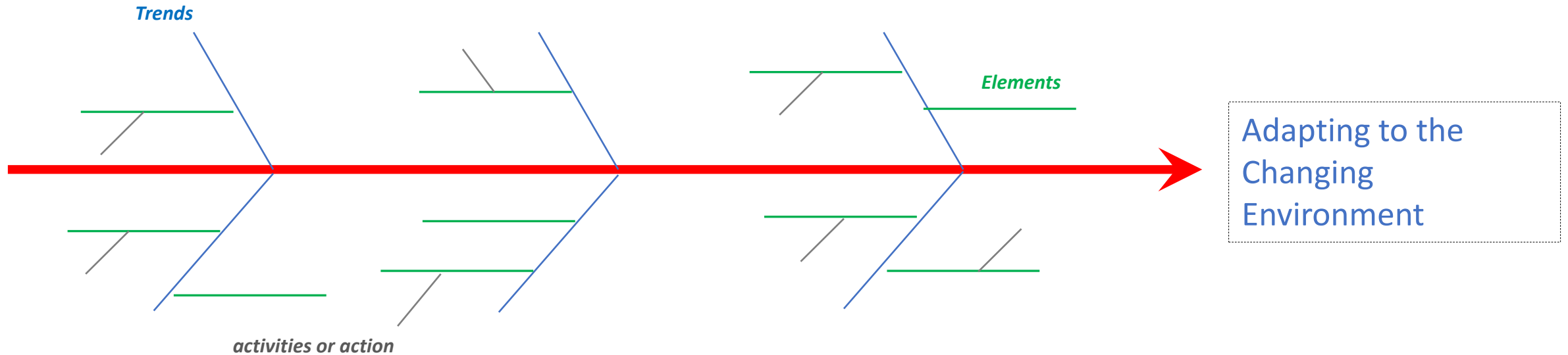
Fishbone diagrams are typically worked right to left, with each large "bone" of the fish branching out to include smaller bones containing more detail.



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Question: **What are the major Trends and its Elements required to stay relevant in this ever changing environment - compliant and competitive?**



Question: **What are the Activities or Action needed to support these Elements?**

Elements to consider in group discussion

Identify what are the changing environment Trends relevant to Asia Pacific? For example:

- **Transparency** - Governments wants pharmaceutical and device companies to disclose how and why they pay HCPs who prescribe their products to reveal potential bias and help build trust.
- **Technology and Data** - Technology trends are spreading through “technology extenders,” such as mobile telemedicine, and real-time collaborative tools and electronic monitoring systems such as a “virtual bedside” with the capacity to transmit secure data from such devices to smartphones and tablets; and through more widespread use of interoperable electronic health record (EHR) systems.
- **New Care Delivery Models** – Examples include: Virtual clinics and virtual doctors or one-stop destination for medical and tourism needs, move from inpatient to outpatient services, etc.
- **Changing in Payers influence** - Incentives are not aligned between payers and providers. Patients will become first and foremost consumers, with the freedom that come with making more decisions on their health through a rise in financial affluence.
- **Changing Regulatory Environment** – Example include: Anti-trust, Cybersecurity, Data Protection, Registration and etc.
- **Any Others?**

Elements to consider in group discussion

- Based on the changing Trends affecting the region, identify major Elements required for Codes to stay relevant. Consider Elements like:
 - Role of Leadership
 - Use of Technology
 - Agility and Speed of Response
 - Strategic Focus
 - Culture Alignment and Changing Habit
- Then consider what are the Activities or Actions needed to support these Elements. These Activities can be approached through:
 - Planning,
 - Communication,
 - Empowerment, and
 - Patience.

Process (45 mins)

10 mins - Introduction

20 mins - Each team brainstorms their ideas on the Fish Bone
- Nominate a team member to be the spokesperson to share team ideas with the total audience

15 mins - Debrief 5 minutes / team
- Each team shares the team ideas with the larger group

MODULE TWO: CODE OF ETHICS ACCESSIBILITY

MENTOR TEAM INTRODUCTIONS



Ms. Bronwen Taylor

*Vice President, Compliance & Risk Management
Stryker*



Mr. David Rosenzweig

*Ethics & Compliance Officer - Asia Pacific
Abbott*

Background

- **APEC**
 - 21 member economies, >13,000 firms with nearly 11,000 being small to medium enterprises in the medical device sector
- **Voluntary codes that embrace the APEC Kuala Lumpur Principles**
 - **Integrity** - dealing honestly, truthfully, and fairly with all parties
 - **Independence** - interactions should not skew medical decision making from the best interest of the patient
 - **Appropriateness** - arrangements conform to proper commercial standards, accurate and free from corrupt purposes
 - **Transparency** - open regarding financial relationships between parties
 - **Advancement** - relationships are intended to advance medical technology, innovation and patient care
- **2014 Nanjing Declaration's 2020 commitment - regional industry association code alignment with the APEC Principles**

Overview

- In order to promote an ethical commercial environment, cooperation among stakeholders is essential
- Adoption and active involvement is key to code implementation and ongoing refinement
- Complexity of adoption arises due to multiple
 - Stakeholders and perspectives
 - Local, regional and global business practices
 - Languages and cultural practices
 - Regulations
- Access to codes and related materials can enhance ongoing adoption
 - Simple, relevant, realistic



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Tools and Resources

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Business Ethics for APEC SMEs Initiative: Digital Collection

The screenshot shows the website for the 2017 APEC Business Ethics for SMEs Forum, Biopharmaceutical Sector. The header includes the APEC logo (Asia-Pacific Economic Cooperation) and navigation links for CONTACT US, SITEMAP, and HOME. A search bar with a Submit button is also present. The main navigation menu lists ABOUT US, EVENTS, RESOURCES, WHAT'S NEW, PHOTO GALLERY, APEC CODES OF ETHICS, and MEDIA ROOM. The main content area features a banner for the 2017 APEC Business Ethics for SMEs Forum in Hanoi, Viet Nam, held on 7-8 September 2017, with a focus on PARTICIPANT INFORMATION. Below the banner, four key documents are highlighted with icons and brief descriptions:

- MEXICO CITY PRINCIPLES**: The APEC Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector. [Learn more >>](#)
- NANJING DECLARATION**: Nanjing Declaration to Promote Ethical Business Practices in the Medical Device and Biopharmaceutical Sectors. [Learn more >>](#)
- MULTI-STAKEHOLDER ETHICAL COLLABORATIONS**: Industry, Healthcare Professionals, Patients and Civil Society Organizations, and Governments. [Learn more >>](#)
- APEC LEADERS AND MINISTERIAL ENDORSEMENTS**: Endorsements from APEC Economic Leaders (Heads of State), APEC Ministers (Foreign and Trade), APEC SME Ministers and APEC Ministers Responsible for Trade. [See here >>](#)

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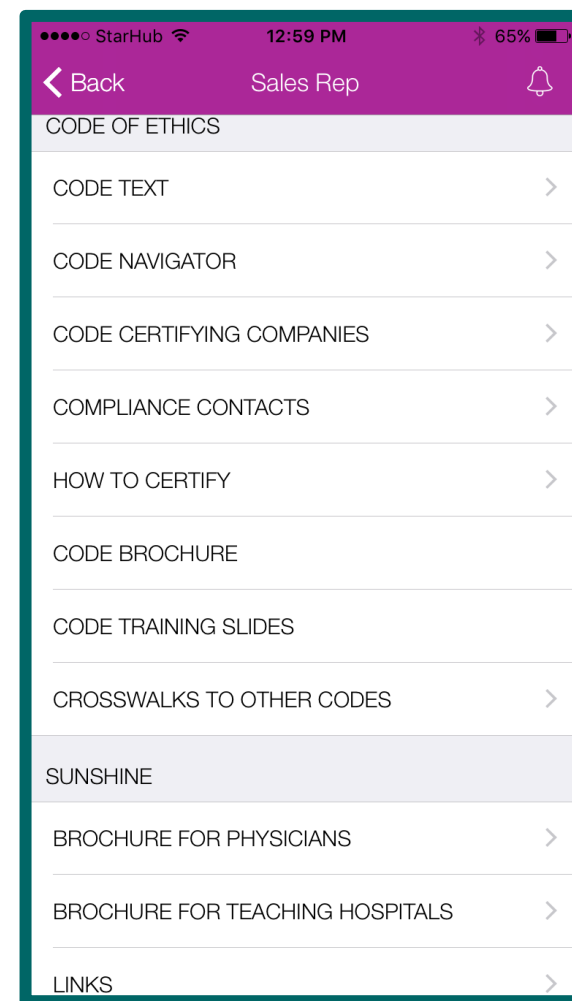
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AdvaMed Member Website

The screenshot shows the AdvaMed website interface. At the top, there is a navigation menu with links for ABOUT, ISSUES, ADVOCACY, EVENTS, RESEARCH, NEWSROOM, JOIN, and MEMBERS. A search bar is located in the top right corner. The main content area features a large header for 'JOINT GUIDANCE ON RELATIONSHIPS WITH DISTRIBUTORS' with a background image of a gavel. Below the header, there are several sections: 'DISTRIBUTOR GUIDANCE', 'BACKGROUND', 'GUIDANCE ON ETHICAL RELATIONSHIPS WITH 3RD PARTY DISTRIBUTORS', and 'DISTRIBUTOR TRAINING SLIDES'. A 'QUICK LINKS' sidebar on the right includes links to 'MedTech Compliance 101: Boot Camp', 'MedTech Compliance 201: A Deeper Dive Into The Compliance Landscape', and 'RELATED LINKS' such as 'AdvaMed Code of Ethics' and 'MedTech Europe Code of Business Practice'. The footer contains a 'TRANSPARENCY INTERNATIONAL UK HANDBOOK' link.

This collage features several informational cards. The top-left card, titled 'Where Can I Find More Information?', lists various guidance documents and codes of ethics, including the National Industry Code of Conduct, AdvaMed Code of Ethics, and the EDMA Code of Ethics. The top-right card, 'Industry Codes of Conduct', discusses national medical technology trade associations and their codes of conduct. The middle-right card, 'ETHICAL INTERACTIONS WITH HEALTH CARE PROFESSIONALS and GOVERNMENT OFFICIALS', emphasizes the industry's commitment to ethical interactions. The bottom-left card, 'Why is Avoiding Bribery Important?', explains that bribery is illegal and unethical, and provides examples of bribery. The bottom-right card, 'What Laws Prohibit Bribery?', lists laws such as the U.S. Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act of 2010. The AdvaMed and MedTech Europe logos are prominently displayed in the center of the collage.

AdvaMed Compliance App

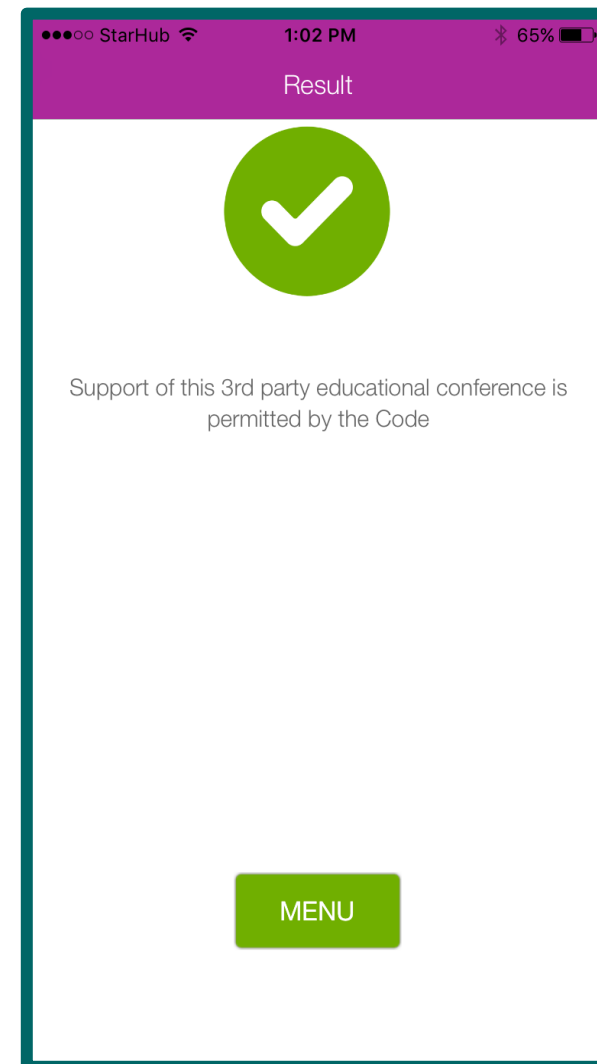
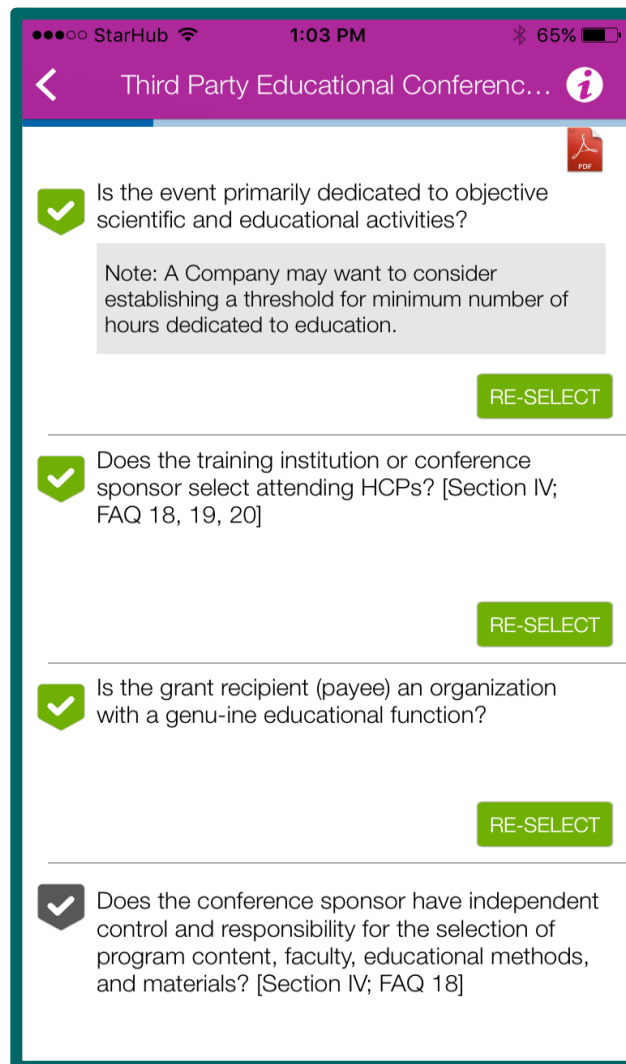




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AdvaMed Compliance App



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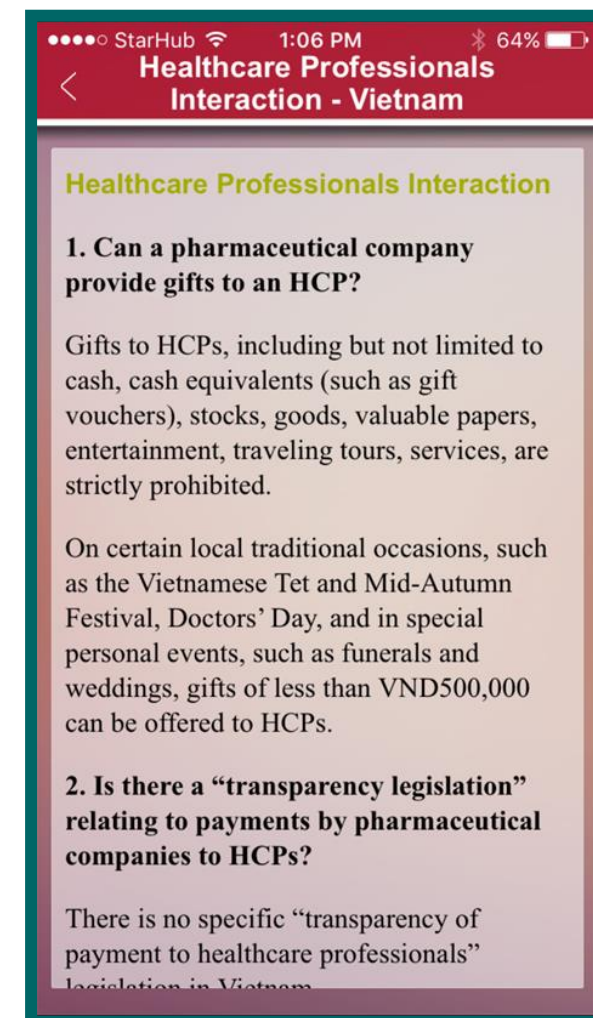
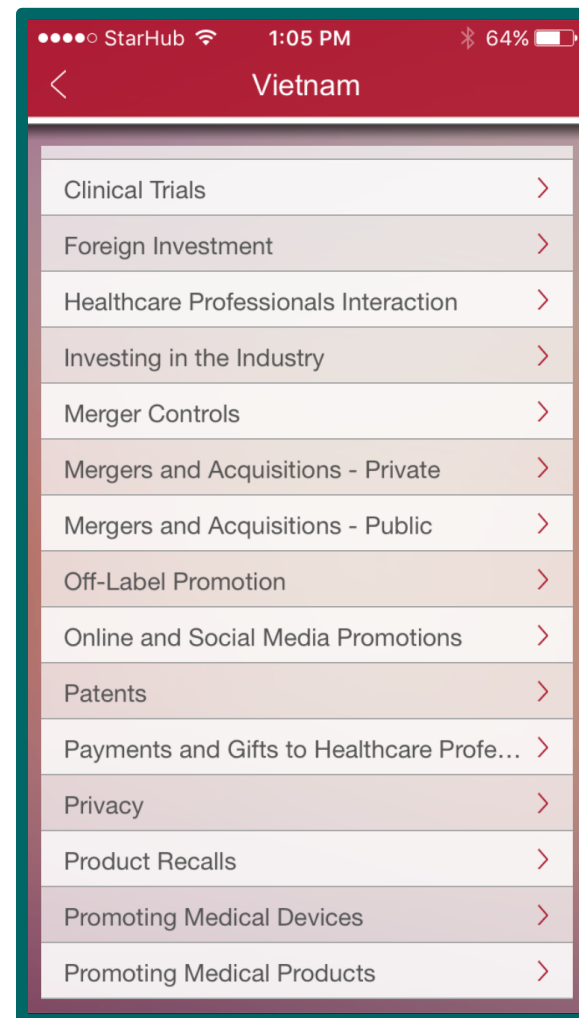
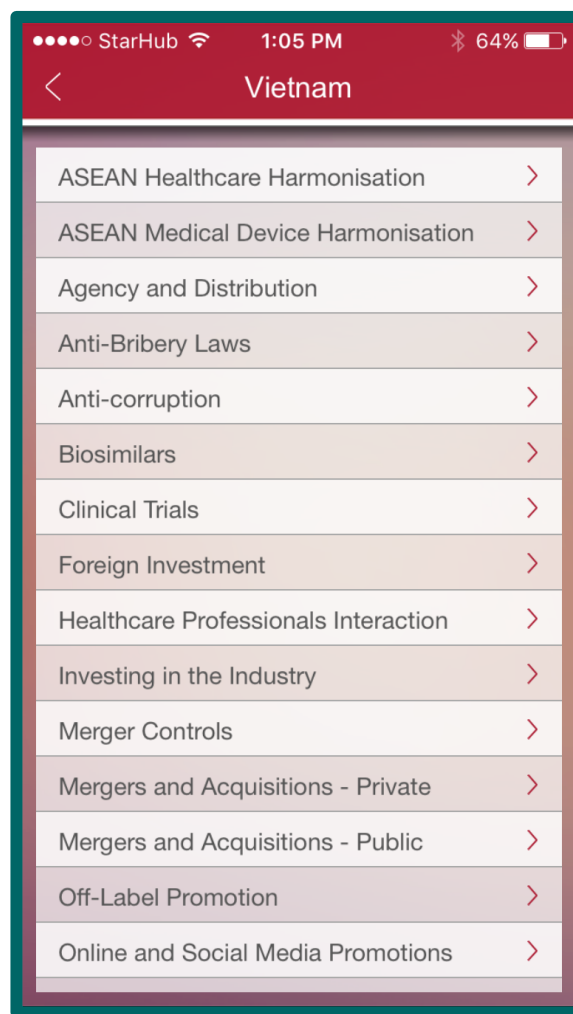
Baker & McKenzie App



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Baker & McKenzie App



Group Discussion

- 1. List activities, actions, tools to enable access and availability of industry codes of ethics to your assigned stakeholder group?**
- 2. What barriers would prevent access and availability of industry codes of ethics to your assigned stakeholder group?**

Elements to consider in group discussion

- Maturity of local / regional codes - from none to fully evolved
- Maturity of local associations - from new to well established
 - Consider members / non-members of stakeholder group
- Lean to rich communication methods and styles
- Messages, sequencing and frequency
- Implementation complexity
 - Easy to hard
 - Simple to complex
 - Short to long term
 - Inexpensive to expensive
 - Technology novices to geeks

Groups

1. Manufacturer
 - a. Sales channel - Sales Reps, Indirect Channels
 - b. Compliance Officers
 - c. Global companies and local company representatives
2. Medical device industry association
3. Health Care Professionals and related associations
4. Providers e.g. hospitals / clinics
5. Payers e.g. insurers
6. Regulators

Process

15 mins

- Each team brainstorms their ideas on the flip chart
- Nominate a team member to be the spokesperson to share team ideas with the total audience

20 mins

- Debrief 5 minutes / team
- Each team shares their ideas with the larger group