2018 APEC Business Ethics for SMEs Forum
18–20 July 2018 • Tokyo, Japan
PLENARY SESSION (20 JULY)
MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

WELCOME REMARKS

Ms. Tricia Van Orden, Project Overseer
Business Ethics for APEC SMEs Initiative
U.S. Department of Commerce
PLENARY SESSION (20 JULY)
MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

WELCOME REMARKS

Ms. Diane Farrell, U.S. Deputy Assistant Secretary of Commerce for Asia
U.S. Department of Commerce
日本における倫理的連携のためのコンセンサス・フレームワーク

JAPANESE CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION
JAPAN CONSENSUS FRAMEWORK
KEYNOTE REMARKS & SIGNING CEREMONY

Ms. Yukiko Mori
President
Japan Patients Association

Mr. Shinsuke Amano
President
Japan Federation of Cancer Patient Groups

Ms. Rieko Kawamoto
Executive Officer
Japanese Nursing Association

Mr. Toshihiko Miyajima
Director General
The Federation of Pharmaceutical Manufacturers’ Association of Japan

Mr. Kenichi Matsumoto
Vice Chairman
Japan Federation of Medical Device Associations

Mr. Nobuo Yamamoto
President
Japan Pharmaceutical Association

Dr. Yosihtake Yokokura
President
Japan Medical Association

Mr. Toshihiko Takeda
Director –General of Health Policy Bureau
Ministry of Health, Labor, and Welfare, Japan
AUSTRALIAN CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION IN THE HEALTHCARE SECTOR

A CONSENSUS STATEMENT OF SHARED VALUES AND ETHICAL PRINCIPLES FOR COLLABORATION AND INTERACTION AMONGST ORGANISATIONS IN THE HEALTHCARE SECTOR
AUSTRALIAN CONSENSUS FRAMEWORK
AGENDA

• INTRODUCTIONS

• WELCOME FROM THE THE HON GREG HUNT FEDERAL MINISTER OF HEALTH, AUSTRALIA

• THE AUSTRALIAN CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION

• PANEL DISCUSSION

• SIGNING CEREMONY
INTRODUCTIONS

- The Honourable Greg Hunt, Federal Minister of Health
- Bassim Blazey, Deputy Head of Mission, Australian Embassy in Japan
- Jane Fitzpatrick, Australasian College of Sport and Exercise Physicians (ACSEP)
- Alison Verhoeven, Australian Healthcare and Hospitals Association (AHHA)
- Peter Subramaniam, Australian and New Zealand Society for Vascular Surgery (ANZSVS)
- Andreas Loefler, Australian Orthopaedic Association
- Sophie Hibburd, Medicines Australia
- Michelle Wagner, Medical Technology Association of Australia (MTAA)
- Jo Watson, Consumers Health Forum
- Tracey Duffy, Therapeutic Goods Administration (Federal Department of Health)
AGENDA

• INTRODUCTIONS

• WELCOME FROM THE THE HON GREG HUNT FEDERAL MINISTER OF HEALTH, AUSTRALIA

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• PANEL DISCUSSION

• SIGNING CEREMONY
A MESSAGE FROM THE
HONOURABLE GREG HUNT
FEDERAL MINISTER OF HEALTH

Video
AGENDA

- INTRODUCTIONS
- WELCOME FROM THE THE HON GREG HUNT FEDERAL MINISTER OF HEALTH, AUSTRALIA
- THE AUSTRALIAN CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION
- PANEL DISCUSSION
- SIGNING CEREMONY
BACKGROUND

- A small group of Australian organisations have participated at APEC Business Ethics for SME Forum over past six years:
  
  - Medicines Australia
  - Medical Technology Association of Australia
  - Australian Healthcare and Hospitals Association
  - Royal College of Physicians
  - Australian Orthopaedic Association
COMMON ETHICAL DILEMMAS...

• Advocated for wider involvement and participation;
• More purposefully include clinicians in particular;
• And embrace all participants in the Health system;
• Message resonated strongly amongst small group and by APEC leadership;
THE CHALLENGE...

- At Hanoi meeting APEC promoting national consensus frameworks amongst all 21 member countries;
- Canada, Peru and Vietnam...in place;
- APEC leaders challenged the small Australian contingent to lead the development of the Australian Consensus Framework; and
- And to demonstrate world class capability in health by demonstrating best practice in developing a statement for others to follow;
THE JOURNEY

- Group of 5 meet in Hanoi and commit
- Invitation to participate sent to Federal Minister for Health

September 2017

October 2017

- Met with Federal Minister for Health
- Provided commendation and support, as well as secretariat support

November 2017

- Letter of invitation co-signed by the Chief Executive Officers of the group of five sent to 60 participants

- Sound project management principles
- Scheduled five meetings in lead up to 18-20 July 2018 APEC meeting
RAPID GROWTH IN PARTICIPATION

December 2017: 17 Participants

February 2018: 30 Participants

April 2018: 40 Participants

May 2018: 50 Participants

June 2018: 60 Participants
THE KEY PRINCIPLES

• Completely voluntary
• Widely embracing
• No deadlines
• No prescriptions
• Collaborative, cooperative process
• High mutual respect
• Humble leadership
THE RESULT

• IN SEVEN MONTHS 52 PARTICIPANTS JOINED AS SIGNATORIES;

• A FURTHER 13 CONTINUE AS PARTICIPANTS AND CONTRIBUTORS;

• ALL STATE AND TERRITORY JURISDICTION SUPPORT;
Does Trust Matter?

- Trust is society’s most fragile asset;
- Trustworthiness is made up of: competence; reliability; integrity and benevolence;
- As distributed trust gains momentum there’s a chance to build systems that put people first in ways that are more transparent, inclusive and accountable;
- Institutional trust is eroding at an alarming rate; and
Does Trust Matter?

TRUST ACROSS FOUR SECTORS

Edelman Trust Barometer 2014-2017

<table>
<thead>
<tr>
<th>Year</th>
<th>Government</th>
<th>Media</th>
<th>NGOs</th>
<th>Business</th>
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<tr>
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<td>2016</td>
<td>63</td>
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<tr>
<td>2017</td>
<td>52</td>
<td>52</td>
<td>52</td>
<td>48</td>
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</table>
THE STATEMENT

• SUBSTANTIVE PRINCIPLES
• PROCEDURAL PRINCIPLES
• IMPLEMENTATION
SUBSTANTIVE PRINCIPLES

• BENEFIT AND WELFARE:
  ➢ Acting in ways that advance the health, wellbeing and interests of patients, consumers, communities, populations, healthcare systems and the healthcare sector, and that avoid or minimise harm.

• JUSTICE:
  ➢ Fair distribution of access, opportunities, and privileges, and reduction of socio-political and economic inequity. Justice also refers to fairness in the processes that allocate resources and resolve disputes.
SUBSTANTIVE PRINCIPLES

• RESPECT
  ➢ for patients, consumers, communities, students, educators, colleagues and organisations: All interactions and activities are respectful of the dignity, worth, rights, beliefs, values, preferences, customs and cultural heritage of all involved.

• SOLIDARITY:
  ➢ A collective commitment to equitably sharing costs and benefits for the good of a group, community, nation or global population.
SUBSTANTIVE PRINCIPLES

- EFFECTIVENESS

  - efficiency, safety, sustainability: Continuous commitment to improving outcomes in healthcare through promotion of responsible innovation, generation and utilisation of evidence, economic cooperation, reduction of waste, and productive utilisation of limited resources.
PROCEDURAL PRINCIPLES

- **HONESTY:**
  - Those engaged in collaborations are truthful in all their interactions.

- **INTEGRITY:**
  - Those engaged in collaborations are alert to competing and conflicting personal, professional and organisational interests and to the management of bias.

- **REFLEXIVITY:**
  - There is ongoing critical reflection on the values, principles and evidence underpinning collaborative judgments and actions.

- **TRANSPARENCY:**
  - The processes of collaboration, and the values, principles and evidence upon which decisions are made, are open to scrutiny.
PROCEDURAL PRINCIPLES

• INCLUSIVENESS AND SHARED UNDERSTANDING:
  ➢ All relevant stakeholders should participate in collaborations in order to learn from one another and work together respectfully to generate mutually agreed outcomes.

• RESPONSIBILITY AND ACCOUNTIBILITY:
  ➢ Those involved in collaborative processes take responsibility for, are able to explain, and are accountable for, their actions and decisions.

• REASONABLENESS:
  ➢ Those involved in collaborations act, and make decisions, on the basis of rationales that are widely accepted as relevant and fair.
PROCEDURAL PRINCIPLES

• TESTABILITY:
  - The judgments and decisions made by those engaging in collaboration are open to independent verification and revision.

• REVISABILITY:
  - There are procedures in place for appeals and for revising collaborative judgments and decisions in the light of challenges to them.

• OVERSIGHT:
  - There are mechanisms in place to ensure that the principles described above are given due consideration.
IMPLEMENTATION

• Align own policies and procedures with the consensus principles

• Signatories commit to principles being the basis for collaboration and interaction
GOVERNMENT ENDORSEMENT

Jurisdictions Supporting

- Federal Member for Flinders, Minister for Health, Minister for Sport - The Honourable Gregory Hunt MP,
- NSW – The Honourable Brad Hazzard MP Minister for Health and the Minister for Medical Research
- NT – The Honourable Natasha Fyles MLA Minister for Health
- VIC – The Honourable Jill Hennessy MP Minister for Health Minister for Ambulance Services
- TAS – The Honourable Michael Ferguson MP Minister for Health
- WA – The Honourable Roger Cook MLA Minister for Health
- QLD – The Honourable Dr Steven Miles MP Minister for Health and Minister for Ambulance Services
- SA – The Honourable Stephen Wade MLC Minister for Health and Wellbeing
THE CONTRIBUTORS AND PARTICIPANTS

• Australasian College for Emergency Medicine
• Australasian Society of Immunology
• Australian and New Zealand Society of Cardiac and Thoracic Surgeons
• Australian College of Nursing
• Australian College of Rural and Remote Medicine
• Australian Dental Industry Association
• Australian Medical Association
• Australian Private Hospitals Association
• Chiropractors' Association of Australia
• Health Consumers Council of WA
• In Vitro Diagnostics Australia
• Pharmacy Guild of Australia
• Urological Society of Australia and New Zealand
NEXT STEPS

- FULL DAY WORKSHOP SEPTEMBER 2018 INVOLVING ALL TOGETHER TO PLAN:
  - Measures of success
  - Infrastructure support
  - Branding and logo
  - Core secretariat
  - Process of review
  - Consequences
  - Practical application
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AUSTRALIAN CONSENSUS FRAMEWORK
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PLENARY DIALOGUE (20 JULY)
MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

PRESENTATION

2018 APEC BUSINESS ETHICS FOR SMES
LIGHTHOUSE AWARD
2018 APEC Business Ethics for SMEs Forum
18–20 July 2018 • Tokyo, Japan
PLENARY SESSION (20 JULY)
MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

SME LUMINARIES SPOTLIGHT:
BUSINESS ETHICS AND OUR HEALTHTECH FUTURE

Dr. Ben Hwang
Chairman and Chief Executive Officer
Profusa (The United States)
HOW IS OUR ENVIRONMENT CHANGING? HOW SHOULD THE APEC BUSINESS ETHICS FOR SMES INITIATIVE ACCOUNT FOR THESE CHANGES IN CONSIDERING POST-2020 NANJING DECLARATION GOALS?

Ms. Caroline West
Global Chief Compliance Officer
Olympus Corporation (The United States)
BRIEF REPORTS TO PROJECT OVERSEER

Ms. Faye Sumner
Tokyo Statement on Implementation of APEC Guidance for Ethical Third Party Intermediary Relationships

Dr. Kenneth Hartigan-Go
Healthcare Professional Session Recommendations

Mr. Russell Williams
Patient Organization Session Recommendations
**2011**

- **Kuala Lumpur, Malaysia**

- The Kuala Lumpur Principles
  - **Medical Device Sector Codes of Ethics**

**2014**

- **Nanjing, China**

- Nanjing Declaration on Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors Through 2020

**2017**

- **Hanoi, Viet Nam**

- Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

**2018**

- **Tokyo, Japan**

- Tokyo Declaration on Third Party Ethical Relationships
  - Portal and two voluntary certification pilots (to 2017 APEC Guidance for 3rd Parties) by 2021

**Companies**

- Double codes by 2020
- Universal adoption/implementation of KL Principles by 2020

**HCPs**

**Associations**

- Implement association codes at company level by 2017
- Codes aligned with principles in 2017

**Third Parties**

- **Govts**
  - Incentives (e.g., procurement) by 2021
- Expectations of behavior aligned with KL Principles by 2021

- **HCPs**
  - Incentives (e.g., logos) by 2020

- **Associations**
  - Inform members about portal by 2019
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.)
BRIEF REPORTS TO PROJECT OVERSEER

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PLENARY DIALOGUE (20 JULY)
MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

NETWORKING LUNCH
(12:30-13:30)
2018 YEAR IN REVIEW
A Presentation on Code Implementation and Strategic Assessment Updates

13:30 – 13:45

Mr. Andrew Blasi
Director
C&M International
2018 APEC Business Ethics for SMEs Forum
18-20 July 2018 • Tokyo, Japan

BIOPHARMACEUTICAL SURVEY
2018: SUCCESSES

- adoption of the code
- government recognition
- workshops
- government respect
- approved the code
- better practices endorsed the code
- updated the code
- self-regulated system
- transparency
- increased industrial awareness
- improved relationships
- good governance
- developed rules
- expanded the scope of code
- broad adoption
- improved relationships
- collaborated
- increased industrial awareness
- supporting members
- consensus framework
- declining complaints
- signed new framework
- created new framework
- support
2018 APEC Business Ethics for SMEs Forum
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BIOPHARMACEUTICAL SURVEY
2015-2017: SUCCESSES

- promotion
- compliance
- improvement
- Memorandum of Understanding
- transparency
- leadership
- adoption of the code
- government recognition
- member support
- cooperation
- education
- industrial awareness
- awareness
- online training
- declaration of compliance
- online learning program
- support
- turnover
- transparency guidelines
- increasing awareness
- serve as a model
- good governance
- self-regulating
- signing an agreement
- effective review procedure
- stakeholder recognition
- public-sector support
- consensus framework
- acceptance
- compliance
- active dialogue
- promotion of the code
- collaboration agreement signed
- member adherence
- new transparency model
- implementation of the code
- practical implementation
- updated the code
- communication to stakeholders
Biopharmaceutical Survey 2018: challenges

- Support
- Revision of the code
- Government support
- Lack of enforceable code
- Utilization of complaint process
- Keeping code relevant
- Buy-in
- Standardization
- Weak compliance system
- Speed of acceptance
- Improving the code
- Company support
- Uneven playing field
- Coordination

- Promotion
- Lack of resources
- Financial resources
- Differing protocols
- Resistance
- Awareness
- Stakeholder readiness
BIOPHARMACEUTICAL SURVEY
2014-2017: CHALLENGES

uneven playing field

training
resistance
awareness

resources

limited tool kits
gray zone

alignment
adoption

monitoring
multiple regulatory environments

enforcement mechanism

cost of compliance

reluctance to accept new rules

compliance

weak enforcement
no positive reinforcement

government recognition
multiple interpretations
industry support

limited guidance
consensus

limited tool kits
gray zone

education
organizational development

non-member adoption

reputation
education

non-member unethical business practice
competition with non-members
weak compliance system

government support
compliance monitoring
MEDICAL DEVICES SURVEY
2018: SUCCESSES

- signed framework
- full board endorsement
- support members' implementation
- development of consensus framework
- raising the standard of compliance
- acceptance
- recognition
- training
- increased industrial awareness
- government alignment
- attracting companies
- harmonized criteria
- member participation
- good commercial practices
- strong commitment
- support of local associations
MEDICAL DEVICES SURVEY
2015-2017: SUCCESSES

- increased member awareness
- alignment
- implementation
- sharing of best practices
- greater involvement
- investigation system
- increased industrial awareness
- recognition as 'gold standard'
- public recognition
- acceptance
- acceptance
- creation of mandatory code
- value
- establishment of transparency guidelines
- support
- credibility
- member support
- government alignment
- improved compliance
- member engagement
- member participation
- government acknowledgment
- standardization
- guidance
- adherence to industry code
- full member adoption
- update of code
- national support
- greater participation
- signing the code
- buy-in

reduction in corruption
training
lack of resources
uneven playing field
improving codes
communication
inadequate multi-stakeholder involvement
harmonization
full-implementation
weak compliance system
no incentives
stakeholder awareness
ensuring non-member adherence
geographical locations
full adoption by all members
managing expectations
prioritizing
no enforcement mechanisms
government support
complaint procedures
limited tool kits
SME awareness
local resistance
regulatory challenges
1. Code Adoption by Medical Device and Biopharmaceutical Industry Associations
2. 2018 Implementation Takeaways: Governance
3. 2018 Implementation Takeaways: Alignment with APEC Principles
4. 2018 Implementation Takeaways: Member Enterprise Adherence
5. 2018 Implementation Takeaways: External Stakeholder Engagement
6. Other 2018 Monitoring & Evaluation Program Takeaways
7. APEC – Industry Association Pilot Surveys with Member Enterprises
Medical Device Industry Association Code Adoption (2012-18)
Biopharmaceutical Industry Association Code Adoption (2012-18)
Remaining Industry Associations *without* a known Code of Ethics

<table>
<thead>
<tr>
<th>MEDICAL DEVICE SECTOR</th>
<th>BIOPHARMACEUTICAL SECTOR</th>
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<tbody>
<tr>
<td>CHILE (1) – <em>IN PROCESS</em></td>
<td>CHILE (1) &amp; MEXICO (1) + ALIFAR (1)</td>
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<td>CHINA (1)</td>
<td>HONG KONG, CHINA (2)</td>
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<td>CHINESE TAIPEI (1)</td>
<td>KOREA (1) &amp; SINGAPORE (1)</td>
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<td>MEXICO (1)</td>
<td>CHINESE TAIPEI (8)</td>
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<tr>
<td>SINGAPORE (1)</td>
<td>RUSSIA (1)</td>
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<tr>
<td><strong>TOTAL: 5 of 34 (15%)</strong></td>
<td><strong>TOTAL: 16 of 71 (22%)</strong></td>
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</table>
“BIG FOUR” IN CODE IMPLEMENTATION EVALUATION

1. **Code Governance** – is it legitimate and alive…
2. **Code Alignment** – is it a quality code of ethics…
3. **Member Implementation** – is it being adhered to by enterprises in daily business practice…
4. **External Engagement** – is the code understood and embraced by other stakeholders in the health system…
## 2018 IMPLEMENTATION TAKEAWAYS: GOVERNANCE

### MEDICAL DEVICE SECTOR
- Many governance indicators are well reported, but could be improved
- Decline in sufficient code resources and one-on-one assistance
- Corresponding increase in designated staff member indicates an opportunity

### BIOPHARMACEUTICAL SECTOR
- Most governance indicators remain strong, but also under-reported
- More associations are providing members with one-on-one assistance
- Routine code of ethics trainings remain too low (68%)
2018 IMPLEMENTATION TAKEAWAYS: ALIGNMENT

MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

• Continues to move in a positive direction for both sectors
• Voluntary audit program may prove best next step to ensure alignment
## 2018 IMPLEMENTATION TAKEAWAYS: MEMBER ADHERENCE

### MEDICAL DEVICE SECTOR
- Of the 29 associations with a code, at least 35% report majority adherence
  - Associations are lowering their majority adherence rates (many sit below 50%)
- 55% require members to certify code compliance, 63% of these do so annually
- Non-Member Dilemma remains a problem

### BIOPHARMACEUTICAL SECTOR
- Of the 55 associations with a code, at least 69% report majority adherence
- 97% report interest in APEC virtual capacity-building, 90% would disseminate
- Non-Member Dilemma remains a problem
<table>
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<th>2018 IMPLEMENTATION TAKEAWAYS: EXTERNAL ENGAGEMENT</th>
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<tbody>
<tr>
<td><strong>MEDICAL DEVICE SECTOR</strong></td>
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<tr>
<td>• 47% of industry associations with a code distribute to non-members</td>
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<td>• 79% of industry associations have an interest to heighten external engagement</td>
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<td>• Only 33% of associations are building awareness through consensus frameworks</td>
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<tr>
<td><strong>BIOPHARMACEUTICAL SECTOR</strong></td>
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<tr>
<td>• 74% of industry associations coordinate with governments on ethics, 60% with HCPs, 44% with third parties, and 40% with patient groups and non-members</td>
</tr>
<tr>
<td>• 71% of industry associations have an interest to heighten external engagement</td>
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<tr>
<td>• When coordination is happening, it is likely from consensus frameworks</td>
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PLENARY DIALOGUE (20 JULY)
MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

CONSENSUS FRAMEWORK IMPLEMENTATION STRATEGIES

SESSION CHAIR
Mr. Thomas Cueni
Director General
International Federation of the Pharmaceutical Manufacturers and Associations (IFPMA)
PLENARY DIALOGUE (20 JULY)
MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

NETWORKING BREAK
(15:00 – 15:15)
<table>
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<tr>
<th>Time</th>
<th>Session A Location/Content</th>
<th>Session B Location/Content</th>
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<tr>
<td>Breakout Session A: Chinese Consensus Framework and Collaboration</td>
<td>Breakout Session B: Expanding Collaboration in the Americas</td>
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PLENARY DIALOGUE (20 JULY)
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CLOSING SUMMATION

ANNOUNCEMENT OF
2019 APEC BUSINESS ETHICS FOR SMES FORUM

SANTIAGO DE CHILE