



Asia-Pacific
Economic Cooperation

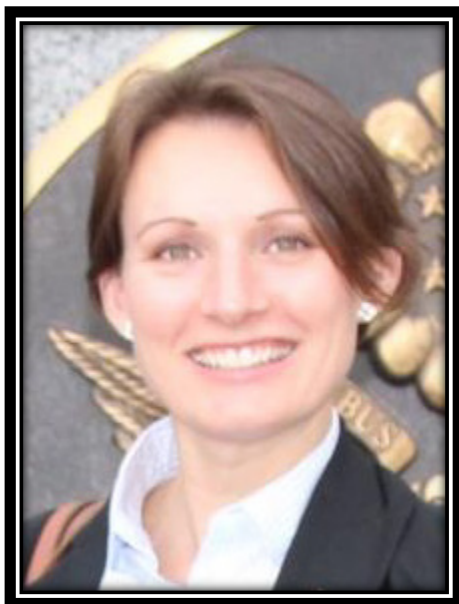
2018 APEC Business Ethics for SMEs Forum

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. Kenichi Matsumoto
Vice Chairman
Japan Federation of Medical Device
Associations



Mr. Shinsuke Amano
President
Japan Federation of Cancer Patient Groups



Mr. Nobuo Yamamoto
President
Japan Pharmaceutical Association



Ms. Rieko Kawamoto
Executive Officer
Japanese Nursing Association



Dr. Yoshtake Yokokura
President
Japan Medical Association



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



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



Dr. Jane Fitzpatrick
Australasian College of
Sport and Exercise
Physicians



Ms. Alison Verhoeven
Australian Healthcare and
Hospitals Association



Dr. Peter Subramaniam
Australian and New
Zealand Society for
Vascular Surgery



Mr. Bassim Blazey
Australian Embassy to Japan



Mr. Adrian Cosenza
Australian Orthopaedic
Association



Dr. Andreas Loeffler
Australian Orthopaedic
Association



Ms. Sophie Hibbard
Medicines Australia



Ms. Michelle Wagner
Medical Technology
Association of Australia



Ms. Jo Watson
Consumers Health Forum of
Australia



Ms. Tracey Duffy
Therapeutic Goods
Administration



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 Loeffler, 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)

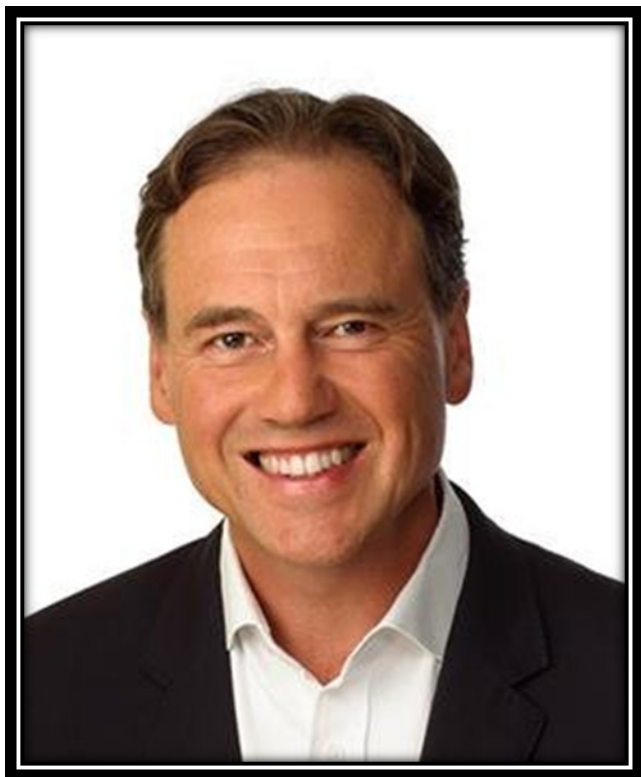




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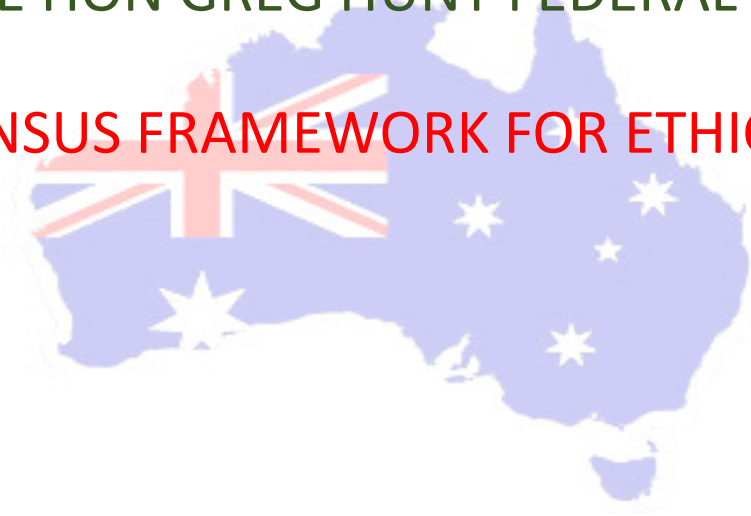
**A MESSAGE FROM THE
HONOURABLE GREG HUNT
FEDERAL MINISTER OF HEALTH**

[Video](#)



AGENDA

- INTRODUCTIONS
- WELCOME FROM THE THE HON GREG HUNT FEDERAL MINISTER OF HEALTH, AUSTRALIA
- **THE AUSTRALIAN CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION**
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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

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

October 2017

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

November
2017

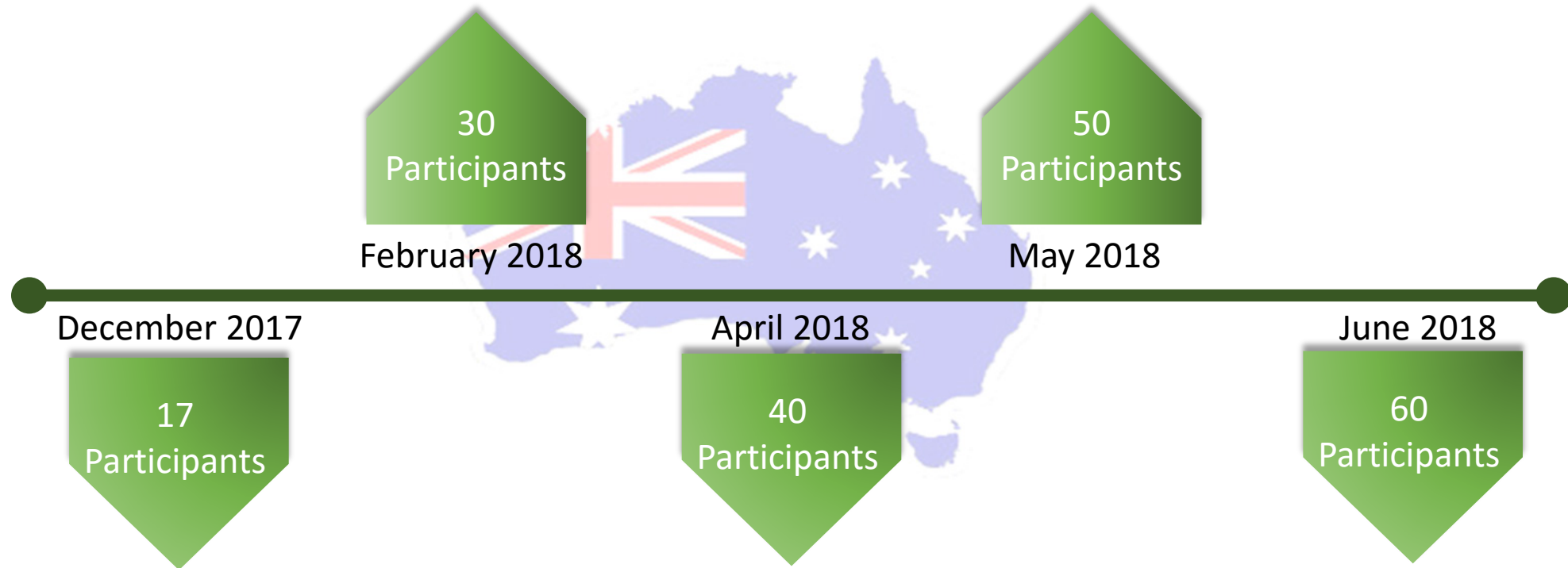
- **Sound project management principles**
- **Scheduled five meetings in lead up to 18-20 July 2018 APEC meeting**



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RAPID GROWTH IN PARTICIPATION





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



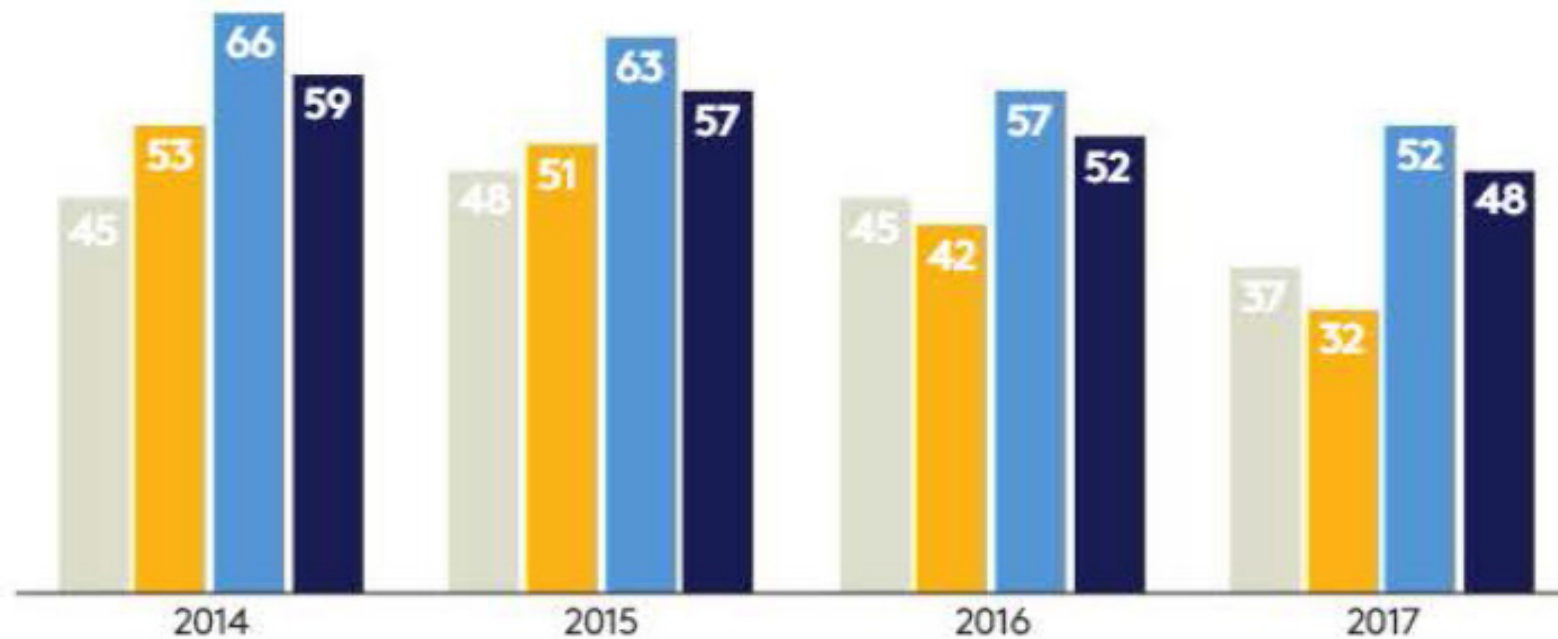


Does Trust Matter?

TRUST ACROSS FOUR SECTORS

Edelman Trust Barometer 2014-2017

Government Media NGOs Business





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
- ACT – The Honourable Meegan Fitzharris MLA Minister for Health and Wellbeing, Transport and City Services and Higher Education, Training and 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





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THE SIGNATORIES



THE AUSTRALASIAN COLLEGE OF PHEBOLOGY



AUSTRALIAN ORTHOPAEDIC ASSOCIATION



THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS



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THE SIGNATORIES



ROYAL AUSTRALASIAN COLLEGE OF SURGEONS





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**



Asia-Pacific
Economic Cooperation

2018 APEC Business Ethics for SMEs Forum

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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



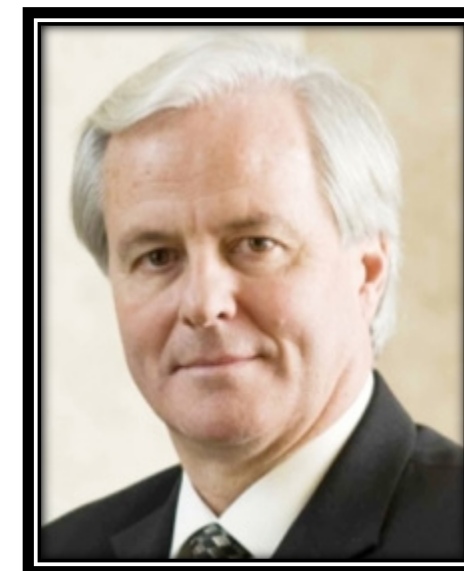
Ms. Faye Sumner

*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*



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2011

2014

2017

2018

Kuala Lumpur,
Malaysia

Nanjing,
China

Hanoi,
Viet Nam

Tokyo,
Japan

The Kuala Lumpur Principles

Medical Device Sector Codes of Ethics

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

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

Tokyo Declaration on Third Party Ethical Relationships

Companies

HCPs

Associations

Companies

Companies

Third Parties

Govts

HCPs

Associations

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

- Implement association codes at company level by 2017

- Portal and two voluntary certification pilots (to 2017 APEC Guidance for 3rd Parties) by 2021

- Incentives (e.g., procurement) by 2021
- Expectations of behavior aligned with KL Principles by 2021
- Inform members about portal by 2019
- Incentives (e.g., logos) by 2020
- Codes aligned with principles in 2017 APEC Guidance for 3rd Parties by 2021



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



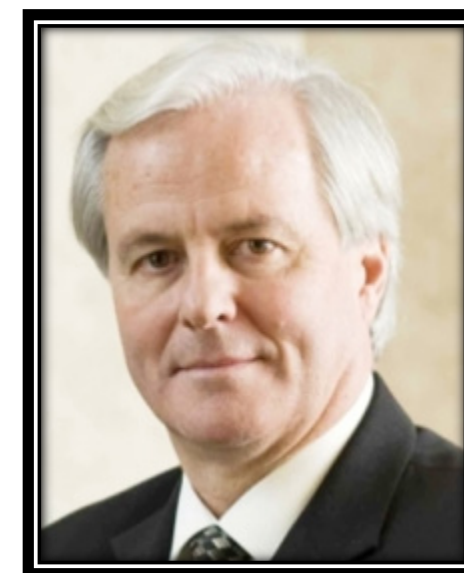
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PLENARY DIALOGUE (20 JULY)
MEDICAL DEVICE & BIOPHARMACEUTICAL SECTORS

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



BIOPHARMACEUTICAL SURVEY
2018: SUCCESSES





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BIOPHARMACEUTICAL SURVEY 2015-2017: SUCCESSES





BIOPHARMACEUTICAL SURVEY

2018: CHALLENGES





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BIOPHARMACEUTICAL SURVEY 2014-2017: CHALLENGES





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MEDICAL DEVICES SURVEY

2018: SUCCESSES





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MEDICAL DEVICES SURVEY 2015-2017: SUCCESSES

increased member awareness





MEDICAL DEVICES SURVEY
2018: CHALLENGES





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MEDICAL DEVICES SURVEY 2014-2017: CHALLENGES





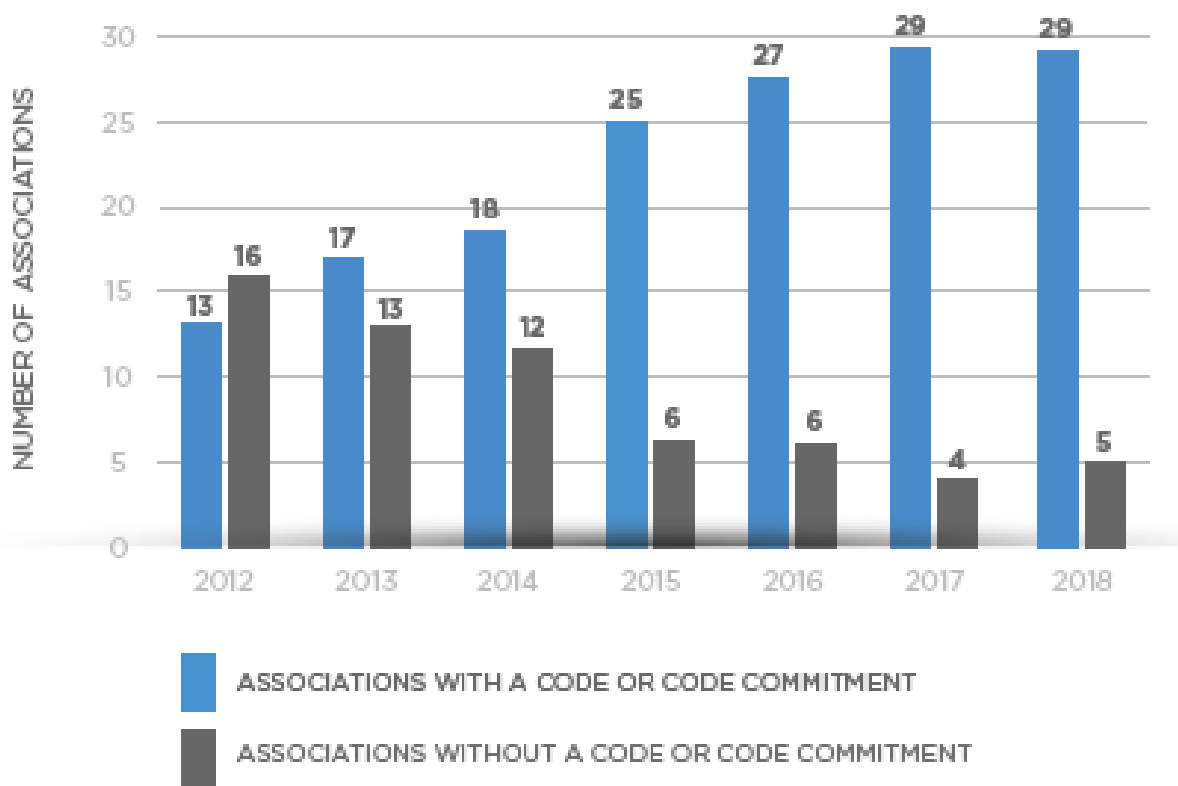
PRESENTATION OVERVIEW

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

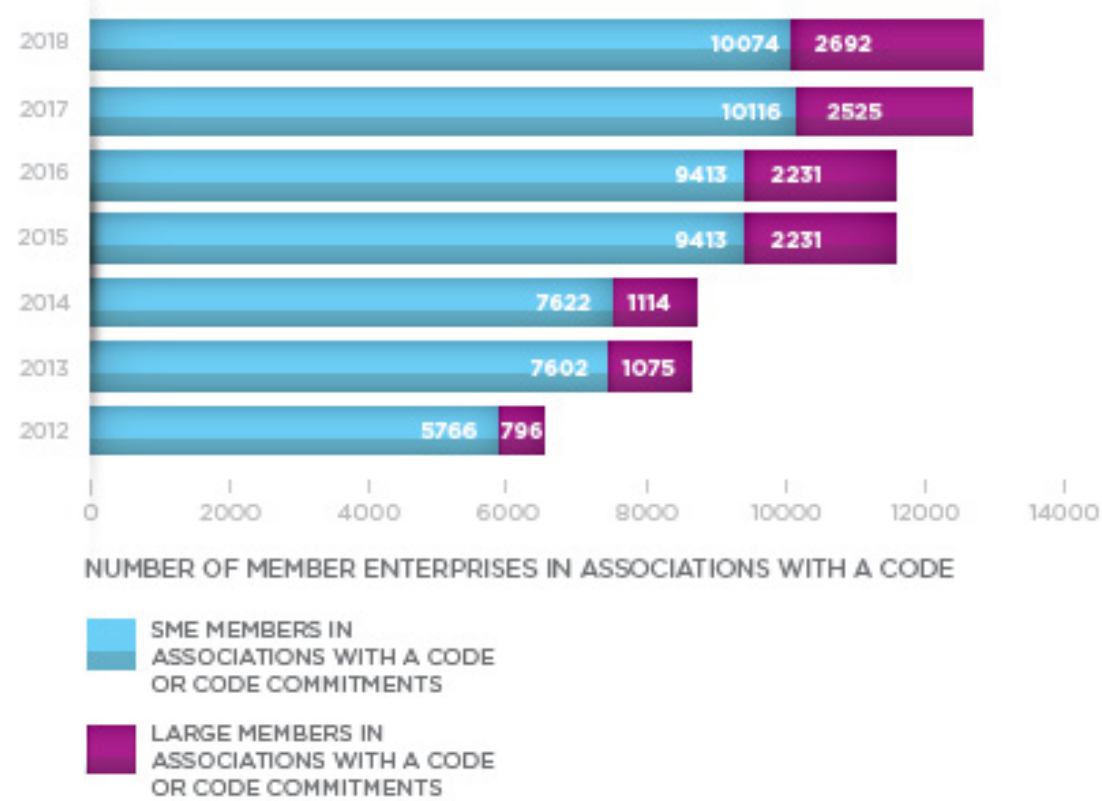


Medical Device Industry Association Code Adoption (2012-18)

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT



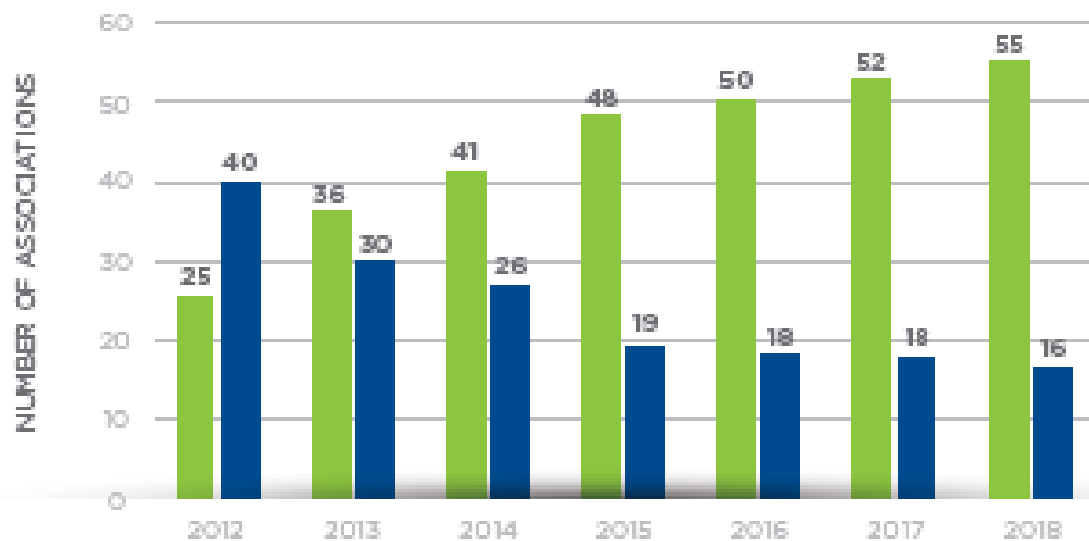
ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENT





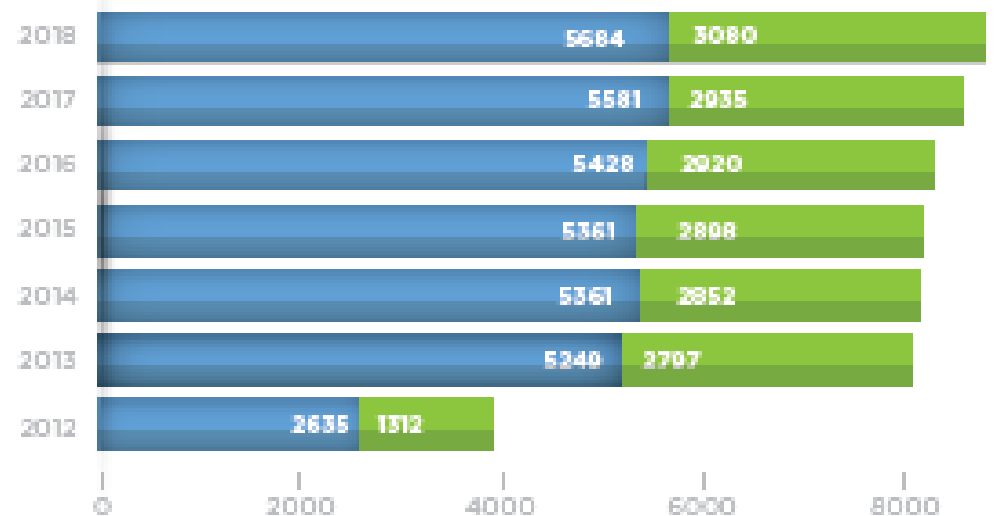
Biopharmaceutical Industry Association Code Adoption (2012-18)

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT



■ ASSOCIATIONS WITH A CODE OR CODE COMMITMENT
■ ASSOCIATIONS WITHOUT A CODE OR CODE COMMITMENT

ENTERPRISE MEMBERSHIP OF ASSOCIATIONS WHO HAVE ADOPTED A CODE OR CODE COMMITMENTS



NUMBER OF MEMBER ENTERPRISES IN ASSOCIATIONS WITH A CODE
■ SME MEMBERS IN ASSOCIATIONS WITH A CODE OR CODE COMMITMENTS
■ LARGE MEMBERS IN ASSOCIATIONS WITH A CODE OR CODE COMMITMENTS



Remaining Industry Associations *without* a known Code of Ethics

MEDICAL DEVICE SECTOR	BIOPHARMACEUTICAL SECTOR
CHILE (1) – <i>IN PROCESS</i>	CHILE (1) & MEXICO (1) + ALIFAR (1)
CHINA (1)	HONG KONG, CHINA (2)
CHINESE TAIPEI (1)	KOREA (1) & SINGAPORE (1)
MEXICO (1)	CHINESE TAIPEI (8)
SINGAPORE (1)	RUSSIA (1)
TOTAL: 5 of 34 (15%)	TOTAL: 16 of 71 (22%)



“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

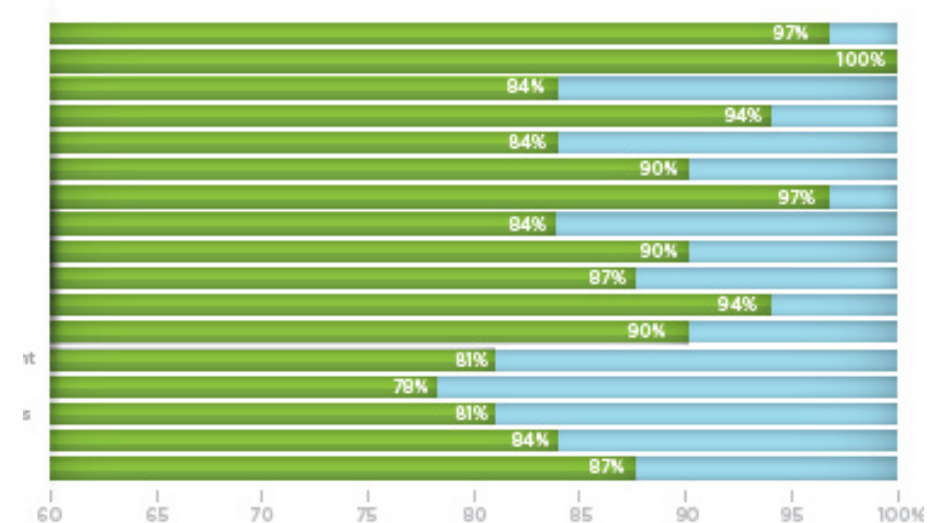
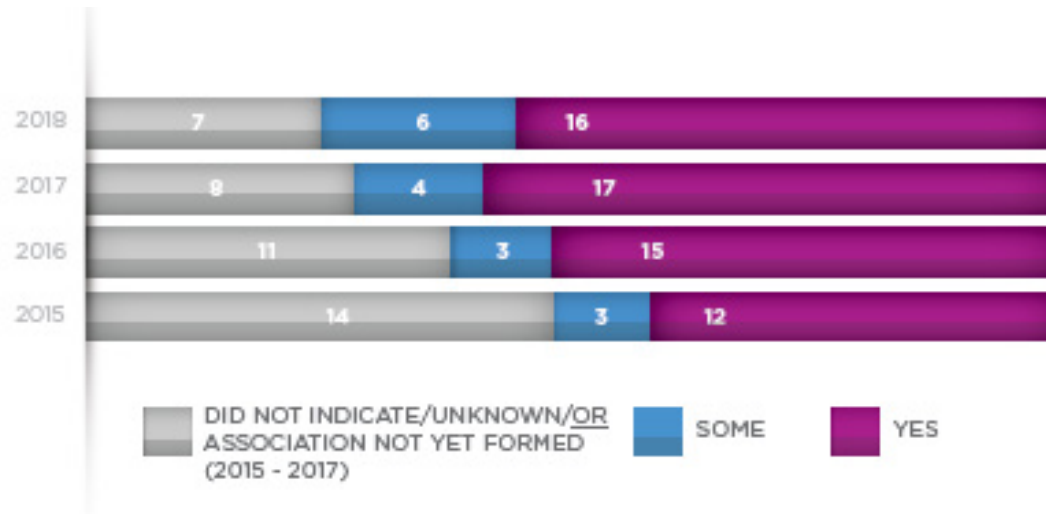
- Most governance indicators remain strong, but also under-reported
- More associations are providing members with one-on-one assistance
- Routine code of ethics trainings remain too low (68%)



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



2018 IMPLEMENTATION TAKEAWAYS: EXTERNAL ENGAGEMENT

MEDICAL DEVICE SECTOR

- 47% of industry associations with a code distribute to non-members
- 79% of industry associations have an interest to heighten external engagement
- Only 33% of associations are building awareness through consensus frameworks

BIOPHARMACEUTICAL SECTOR

- 74% of industry associations coordinate with governments on ethics, 60% with HCPs, 44% with third parties, and 40% with patient groups and non-members
- 71% of industry associations have an interest to heighten external engagement
- When coordination is happening, it is likely from consensus frameworks



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)



BREAKOUT SESSIONS (15:15-16:45)

15:15-16:00	Breakout Session A (New York Ballroom) China Consensus Framework & Collaboration	Breakout Session B (Brooklyn Suite 3) Expanding Collaboration in the Americas
16:00-16:45	Breakout Session C (New York Ballroom) Australia Consensus Framework & Collaboration Philippines Consensus Framework & Collaboration	Breakout Session D (Brooklyn Suite 3) Priorities for the 2019 APEC Business Ethics for SMEs Forum in Santiago, Chile



BREAKOUT FACILITATOR SUMMARIES (3 MINUTES)

***Breakout Session A: Chinese
Consensus Framework and
Collaboration***

***Breakout Session B
Expanding Collaboration in
the Americas***

***Breakout Session C: Australia
Consensus Framework &
Collaboration Philippines
Consensus Framework and
Collaboration***

***Breakout Session D: Priorities
for the 2019 APEC Business
Ethics for SMEs Forum in
Santiago, Chile***



PLENARY DIALOGUE (20 JULY)
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CLOSING SUMMATION

ANNOUNCEMENT OF
2019 APEC BUSINESS ETHICS FOR SMES FORUM

SANTIAGO DE CHILE