

APEC Business Ethics for SMEs Forum

*Promoting Ethical Business Environments in the
Medical Device and Biopharmaceutical Sectors*

1-3 September 2014 | Nanjing, China



**Asia-Pacific
Economic Cooperation**



**APEC
CHINA 2014**

Opening session

Mr. Zhen Xin

**Director General, Ministry of Industry
and Information Technology**

People's Republic of China



**Asia-Pacific
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**APEC
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**The Honorable
Zenaida Cuison-Maglaya
Under Secretary for Regional Operations
Group, Department of Trade and Industry**

The Philippines



**Asia-Pacific
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Ms. Lynn Costa

Project Overseer, Business Ethics for APEC SMEs Initiative

**Senior Policy Advisor for Global Markets
U.S. Department of Commerce**

The United States



**Asia-Pacific
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**APEC
CHINA 2014**

Overview:

“Business Ethics for APEC SMEs” initiative

- Small & Medium Enterprises (SMEs) are the engine of economic growth and will continue to serve as a key driver in the APEC region’s economic expansion **as long as they are able to operate, trade, and innovate in ethical business environments.**
- As a result, the *Business Ethics for APEC SMEs* initiative was launched under the APEC SME Working Group in 2010.
- The initiative is led by the United States with active support and participation from **all 21 APEC economies**. Since 2010, initiative programs have been hosted by **China, Malaysia, Indonesia, Philippines, Chinese Taipei, Brunei Darussalam, Mexico, Vietnam, and Japan**. The initiative is also strongly supported by the APEC Business Advisory Council (ABAC).

What have we achieved?

APEC Principles for codes of business ethics in three sectors, **setting the highest ethical standards for the region**, each developed by experts from government, industry and academia from all 21 APEC economies.

The cover of the Kuala Lumpur Principles document features the APEC USA 2011 logo in the top right corner. The title 'The Kuala Lumpur Principles' is in a dark blue box, with the subtitle 'Medical Device Sector Codes of Ethics' below it. The background is white with a light blue gradient at the top.

Text on the right side of the cover includes:

- between
- professionals'
- medical
- professionals also
- bring to
- business
- companies,
- of the
- integrity,
- HCP's
- and
- financial
- technology,
- corporate,
- dependent
- care,
- or arrange
- business

Text at the bottom of the cover:

Individuals who make product or service decisions on behalf of their organizations should be guided by these Principles. These Principles are intended to complement and reinforce other codes of ethics and standards of practice that may apply to individuals in the medical device sector. These Principles are intended to complement and reinforce other codes of ethics and standards of practice that may apply to individuals in the medical device sector.

The cover of the Mexico City Principles document features the APEC USA 2011 logo in the top right corner. The title 'The Mexico City Principles' is in a green box, with the subtitle 'For Voluntary Codes of Business Ethics in the Biopharmaceutical Sector' below it. The background is white with a light blue gradient at the top.

Text on the right side of the cover includes:

- interests of
- to meet
- aided by
- es, free
- ms with
- pecting
- ation,
- and other
- ing and
- highest
- encourage
- panies to
- essional
- These
- patients
- relationship

Text at the bottom of the cover:

Individuals who develop, manufacture, market, or distribute pharmaceutical and/or biological products. Such products are also referred to in these Principles as "medicines."

The cover of the Hanoi Principles document features the APEC USA 2011 logo in the top right corner. The title 'The Hanoi Principles' is in a dark red box, with the subtitle 'For Voluntary Codes of Business Ethics in the Construction and Engineering Sector' below it. The background is white with a light blue gradient at the top.

Text on the right side of the cover includes:

- the best
- its and
- ut. In
- station
- time,
- business
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- itation
- ies of
- APEC
- ethical
- business
- panies,
- ument
- ective
- ing with
- jective
- ential
- factors
- n, the
- s. The
- meet

Text at the bottom of the cover:

The company shall be transparent in its business dealings, such as by declaring any conflicts of interest or related party transactions. The company shall respect and

Endorsement by APEC Ministers (Foreign and Trade Ministers) in the U.S. APEC Host Year



“We applaud the decision of the APEC SME Ministers at Big Sky, Montana in May 2011 to endorse the Kuala Lumpur Principles for Medical Device Sector Codes of Business Ethics. This set of principles for the region’s medical devices industry is the first of its kind, and will improve the quality of patient care, encourage innovation, and promote the growth of SMEs that produce medical devices.”



Support by APEC Leaders (Heads of State) in the Russia APEC Host Year



Corruption is "...a tremendous barrier to economic growth, the safety of citizens, and to the strengthening of economic and investment cooperation among APEC...We will also support the efforts of respective member economies to build capacity to combat corruption...by encouraging the implementation of high standard codes of ethics."

-- November 2012, Vladivostok

Capacity building from 2012 – 2013 to implement the principles

Formation of a network of over 100 ethics trainers, spanning all three sectors and 21 economies!

April 22-24, 2012

Brunei Darussalam

APEC workshop to assist industry associations to draft codes aligned with The KL Principles



July 10-11, 2012

Taipei, Chinese Taipei

APEC workshop to assist industry associations to draft codes aligned with The Mexico City Principles



August 26 – 30, 2013

KL, Malaysia

APEC Train-the-Trainer Workshop hosted by Malaysian Anti-Corruption Academy



Jan/Feb
2012

Mar/Apr
2012

May/
June
2012

July/
Aug
2012

Sep/
Oct
2012

Nov/
Dec
2012

Jan/
Feb
2013

March/
April
2013

May/
June
2013

July/
Aug
2013

Sept/
Oct
2013

April 2012 – today

Monitoring programs and mentor teams in all three sectors are progressing implementation of codes of ethics in preparation.

Making Tools Available to Facilitate Code Adoption & Best Practices

Outreach & Educational Resources

Helpful sample materials. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Fusce dignissim tincidunt libero, eu scelerisque nisi pulvinar ut. Morbi dignissim, est eget pellentesque feugiat, libero orci tempus ac congue orci arcu ut diam. Nulla ac ligula at ligula gravida venenatis quis eu libero.

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- Sunshine Brochure for Physicians** - Brochure for physicians detailing the Physician Payments Sunshine Act. [PDF](#)
- Sunshine Brochure for Teaching Hospitals** - Brochure for teaching hospitals detailing the Physician Payments Sunshine Act. [PDF](#)
- AdvaMed Code of Ethics Brochure** - Brochure to help explain the AdvaMed Code of Ethics on Interactions with Healthcare Professionals. [PDF](#)
- AdvaMed Code Training Slides** - Overview of the revised AdvaMed Code of Ethics on Interactions with Health Care Professionals. [PDF](#)
- MTAA Code License Brochure** - A brochure of the Medical Technology Industry Code of Practice license. [PDF](#)
- MTAA Code Postcard** - A postcard that summarizes the Medical Technology Industry Code of Practice. [PDF](#)
- MTAA Company Training Slide Deck Template** - A templated slide deck for MTAA member companies to conduct introductory training on the Code of Practice. [PDF](#)

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APEC Train-The-Trainer Workshop | **Codes of Ethics** | **Outreach & Educational Resources**

Kuala Lumpur, Malaysia: 26-30 August 2013

Apec Train-the-Trainer Workshop for Voluntary Codes of Business Ethics in the Medical Device, Biopharmaceutical, and Construction & Engineering Sectors.

The Malaysia Anti-Corruption Academy (MACA) & Malaysian Institute of Integrity (IIM) 26-30 August 2013 | Kuala Lumpur, Malaysia

- Program Agenda** - Program Agenda for the Medical Device Sector Workshop. [DOC](#)
- Participant List** - List of participants attending the Medical Device Sector Workshop. [DOC](#)
- Shuttle Schedule** - Schedule of police escorted shuttle service for conference attendees. [DOC](#)

Key Documents

- The Kuala Lumpur Principles (The KL Principles)** - The Kuala Lumpur (KL) Principles for Medical Device Sector Codes of Business Ethics. [PDF](#)
- Sample Code of the KL Principles (Template Code)** - Sample code of Ethical Conduct based on the KL Principles. [DOC](#)
- Comparison of Gift Provisions of APEC Economies** - Comparison document of the gift provisions within the various code of ethics of various countries/associations. [DOC](#)
- Compendium for Ethical Codes of APEC Medical Device Associations** - Compendium spreadsheet that compares the APEC Medical Device Associations Code of Ethics. [XLS](#)

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APEC Train-The-Trainer Workshop | **Codes of Ethics** | **Outreach & Educational Resources**

Medical Device Codes of Ethics (by Country & Association)

Approved and finalized codes of ethics for the medical device sector by country and association.

| | |
|---------------------------------------|---|
| Australia (MTAA) | MTAA Medical Technology Industry Code of Practice; Published December 2012 (8th Edition). PDF |
| Canada (MEDEC) | MEDEC Code of Conduct on Interactions with Healthcare Professionals; Published October 2012. PDF |
| Hong Kong, China (HKMHDA) | HKMHDA Medical Device marketing Practice Guideline; Published November 2011. PDF |
| Indonesia (Gakeslab Indonesia) | Gakeslab Indonesia Medical and Laboratory Appliance Business Activities Indonesia Code of Ethics; Published May 2013. DOC |
| Japan (JFMDA) | JFMDA Promotion Code of the Medical Devices Industry; Published March 2005. HTML |
| Korea (KMDIA) | KMDIA Fair Competition Code of Transactions of Medical Devices; Published December 2011. PDF |
| Malaysia (AMMI) | AMMI Codes of Ethics; Published June 2013 (Version 1). PDF |
| Mexico (AMID) | AMID Code of Interactions with Healthcare Professionals; Published February 2013. PDF |
| New Zealand (MTANZ) | MTANZ Code of Practice; Published July 2013 (6th Edition). PDF |

New APEC Business Ethics Websites



Highlight

Welcome to the Business Ethics for APEC SMEs Initiative

The Business Ethics for APEC SMEs Initiative welcomes you to its new online portal to support the implementation of codes of ethics aligned with APEC Principles endorsed by APEC Ministers and Leaders. From here you may access general information and three additional websites for each sector covered under this initiative...

News

06/26/2014 at 10:42 PM

APEC Bulletin: Enhancing SME Business Ethics in the Healthcare Industry

26 June 2014 -- The relationship between healthcare companies and physicians is complex, presenting potential conflicts of interest that require oversight. Biopharmaceutical and medical device companies operate in a highly competitive market. As a result, some companies may seek an advantage by extending gifts or other inappropriate inducements to healthcare...

05/19/2014 at 12:00 AM

APEC Ministers Responsible for Trade encourage wider adoption of codes of ethics

APEC Ministers Responsible for Trade met in Qingdao, China on 17-18 May 2014. Their annual statement calls for wider adoption of codes of ethics in accordance with APEC principles. Excerpt: "We will continue to undertake actions to address the barriers that Small and Medium-Sized Enterprises (SMEs) face in trading in..."



View

- News
- Medical
- Biopharmaceutical

View

- http://k
- http://m
- http://h



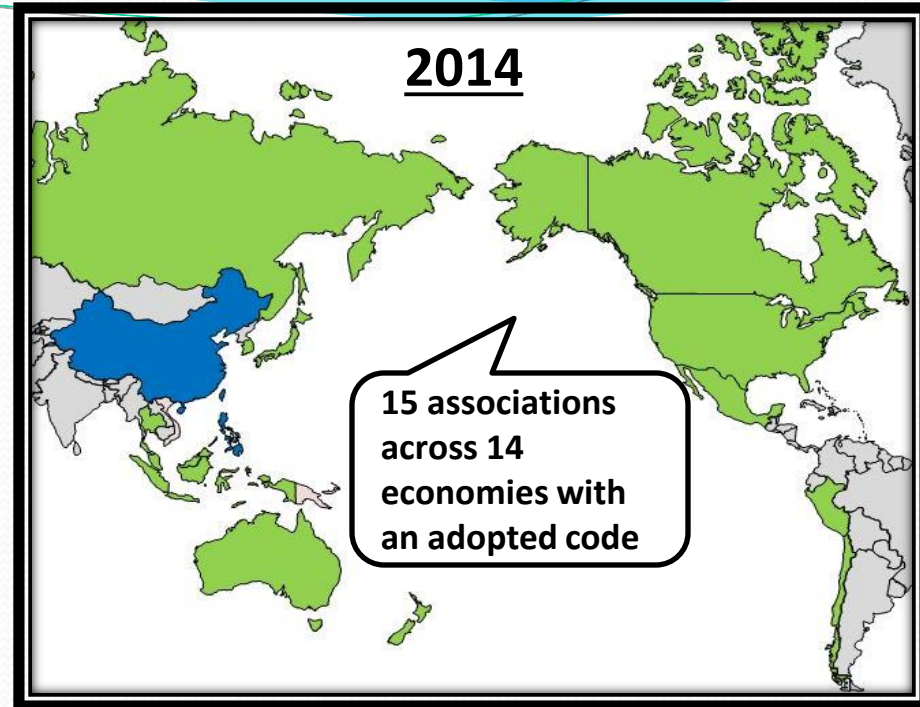
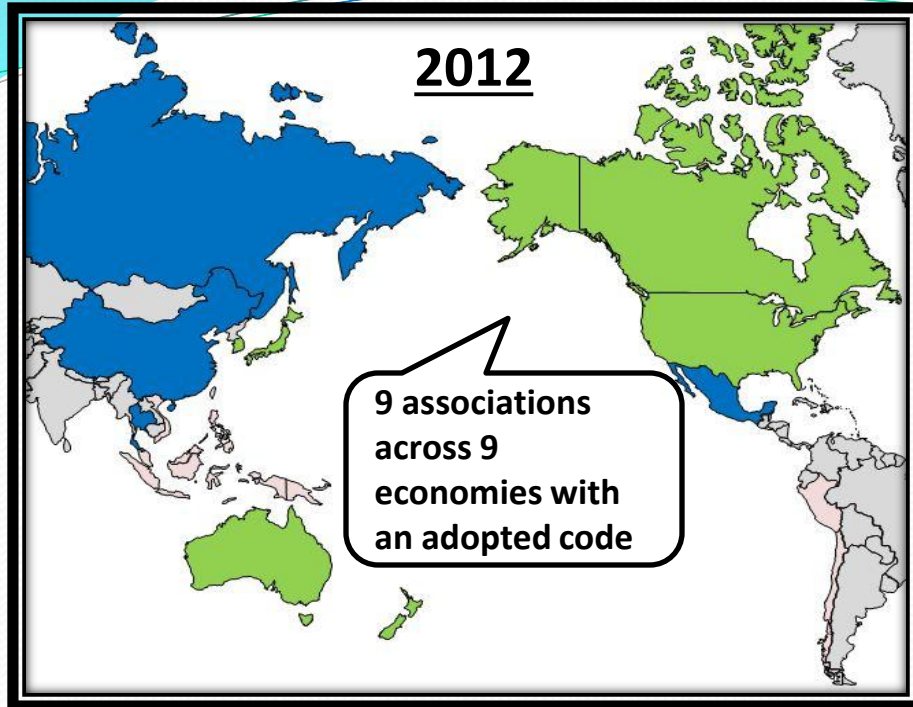
<http://businessethics.apec.org>

<http://mcprinciples.apec.org>



**Results since we first started
monitoring progress in 2012...**

Medical Device Sector: 2012 vs 2014



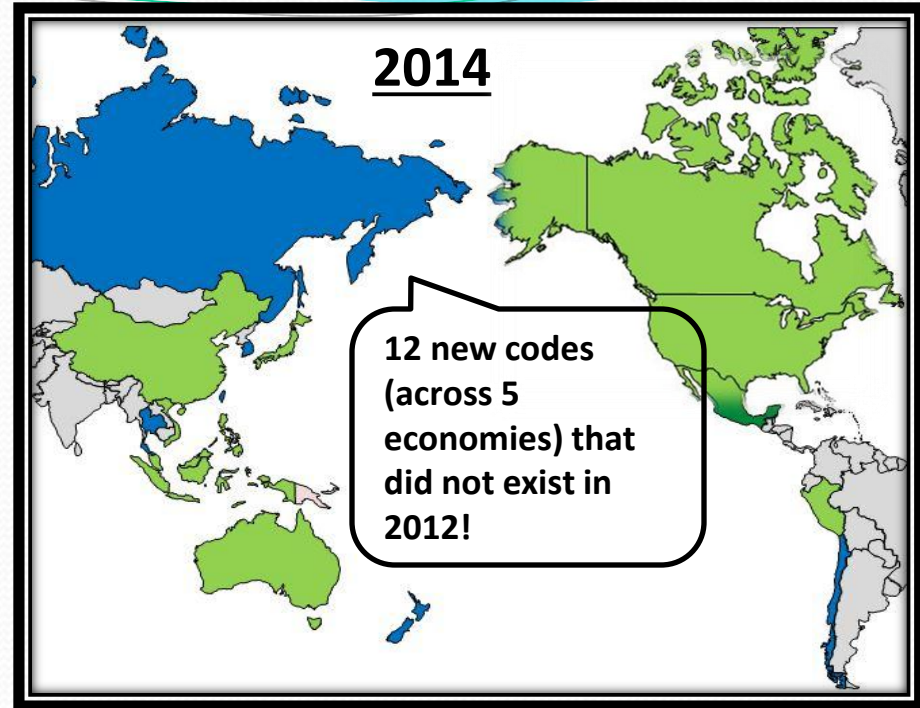
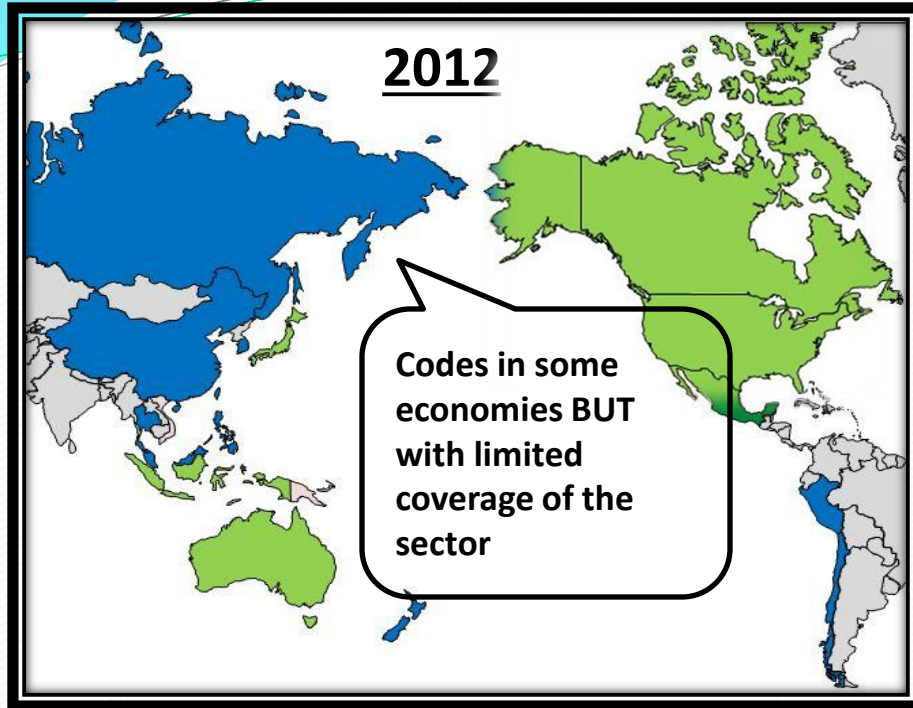
Code adopted



Code under development / alignment

| | | |
|---------------------------------|-------------|------------------|
| Industry Associations Monitored | 24 | |
| Member Companies | 10,542+ | |
| SME Member Companies | 6,010+ | |
| STATUS REPORT | 2012 | 2014 |
| Associations with Code | 9 | 15 (↑6) |
| Member Companies | 5,720+ | 6,773+ (↑1,053+) |
| SME Member Companies | 4,027+ | 4,740+ (↑713+) |

Biopharmaceutical Sector: 2012 vs 2014



Codes with broad coverage of the sector

Codes but with limited coverage of the sector

| | | |
|---------------------------------|-------------|------------------|
| Industry Associations Monitored | 53 | |
| Member Companies | 7,724+ | |
| SME Member Companies | 3,746+ | |
| STATUS REPORT | 2012 | 2014 |
| Associations with Code | 24 | 36 (↑12) |
| Member Companies | 3,699+ | 6,870+ (↑3,171+) |
| SME Member Companies | 2,536+ | 3,308+ (↑772+) |

In summary, in two years we have supported the development of **18 new industry codes** across **9 economies** where they previously did not exist, expanding high standard APEC principles to nearly **14,000 companies** (of which over **8,000 are SMEs**)

Business Ethics for SMEs Forum

1-3 September 2014 -- Nanjing, China

- Over **200 participants** representing more than **80 different organizations** – bringing together stakeholders critical to ethical business practices in the healthcare sector (senior representatives from ministries of health, hospital and physician associations, patient organizations, industry, and APEC SME Working Group delegates).
- Co-hosted by China and the United States to facilitate regional cooperation, build capacity and provide strategic vision and recommendations for this initiative through 2020 (Nanjing Declaration to be discussed this afternoon)

THANK YOU...

- China Ministry of Industry & Information Technology
- RDPAC
- Previous APEC member economy hosts: Malaysia, Indonesia, Philippines, Chinese Taipei, Brunei Darussalam, Mexico, Vietnam, and Japan
- APEC SME Working Group and Delegates
- Mentors and trainers from companies and associations
- The Philippines



Official Photo



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Part I:

The Importance of Ethical Environments to Sustainable Business and Trade



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Session One: The view from industry leaders operating in the APEC region

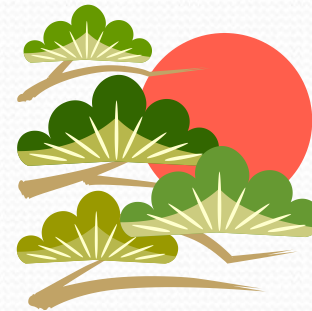
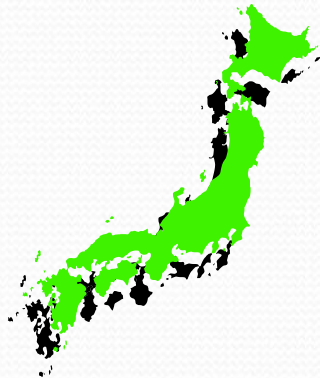
Moderator: Mr. Stephen Dibert, Advisor, International Affairs, MEDEC (Canada)

Discussants (5 minutes each / 20 minutes Q&A and Discussion):

1. **Ms. Roberta Lipson**, CEO, Chindex International & Board Chair, United Family Healthcare (China)
2. **Mr. Jesse Wu**, Chairman, Johnson & Johnson China & Board of Directors, U.S.-China Business Council
3. **Mr. Mario Mongilardi**, General Manager, Laboratories Americanos S.A., President, COMSALUD (Peru)
4. **Mr. Katsumi Takahashi**, President, Omnico Co & Vice Chairman, Japan Dental Trade Association (JDTA)
5. **Mr. Leonard Ariff Abdul Shatar**, CEO, CCM Duopharma Biotech Berhad & Immediate Past President, Malaysian Organization of Pharmaceutical Industries (MOPI)



Ethical Environment for Medical Devices Business **in Japan**



September 2, 2014
JFMDA & JFTC

4 Ethics Rules & 5 Guidelines in Japan

4 Ethics Rules
(JFMDA/JFTC)



5 Guidelines
(JFMDA)

1. The Code of Ethics (JFMDA)

2. The Charter of Business Behavior (JFMDA)

3. The Promotion Code of the Medical Devices Industry in Japan (JFMDA)

4. The Fair Competition Code of the Medical Devices Industry in Japan (JFTC)

1. Transparency Guidelines

2. Guideline for Medical Devices' Advertisement

3. Guideline for Medical Devices Exhibition Under Application for Approval

4. Guideline for Personal Information Management

5. Guideline for Donation to Medical Society

Positioning of 4 Ethics Rules for Medical Devices for Establishment of Fair Business Practice in Japan

1. The Code of Ethics (JFMDA)

**2. The Charter of Business
Behavior (JFMDA)**

**3. The Promotion Code of the
Medical Devices Industry in Japan
(JFMDA)**

**4. The Fair Competition Code
of the Medical Devices
Industry in Japan (JFTC)**

Outline of The Japan Federation of Medical Devices Associations

Since 1984, Only One Federation for Medical Devices

- The Japan Federation of Medical Devices Associations (JFMDA) was founded in February 1984 by medical device associations consisting of manufacturers and suppliers of medical and health-care devices, equipment, instruments and materials.
- Since then, JFMDA has been addressing various national and international issues related to all its member associations.
- By taking appropriate actions on these issues, and through the support of innovation and sustainable supply of medical devices and technologies to the world, JFMDA has contributed to the growth of the industries it represents and to the improvement of welfare and health care in Japan.
- JFMDA became a legal entity as of January 6th,2014.

19 Associations and Approx. 4,900 Companies

- At present, membership has increased to 19 associations (representing approx. 4,900 companies), while associate member organizations and about 130 individual companies are registered as supporting members approved sponsoring JFMDA's Activities.

Member List of JFMDA -19 Associations

(12 Associations in "Red" are the member of JFTC, too)

1. The Japan Home-health Apparatus Industrial Association
2. Japan Association of Health Industry Distributors
3. Japan Analytical Instruments Manufacturers' Association
4. Japan Association of Medical Devices Industries
5. Japanese Association of Surgical Sutures
6. Japan Condoms Industrial Association
7. Japan Contact Lens Association
8. Japan Dental Trade Association
9. Japan Electronics and Information Technology Industries Association
10. Japan Home Health Care Association
11. Japan Hearing Instruments Dispensers Association
12. Japan Hearing Instruments Manufacturers Association
13. Japan Hygiene Products Industry Association
14. Japan Industries Association of Physical Therapy Devices
15. Japan Medical Imaging and Radiological Systems Industries Association
16. Japan Medical Industry Association
17. Japan Medical-Optical Equipment Industrial Association
18. Japan Ophthalmic Instruments Association
19. Medical Technology Association of Japan

(Note: random order)



The Japan Fair Trade Council of the Medical Device Industry (JFTC)

- JFTC is established for administration of “The Fair Competition Code of the Medical Devices Industry in Japan (FCC)”.
- FCC , as voluntary ethics rule, focuses on “Restriction on Premium Offers in the Medical Devices Industry” and was established in 1998.
- Also JFTC is authorized by the Consumer Affairs Agency and the Japan Fair Trade Commission (Japanese Government)
- So “The Fair Competition Code of the Medical Devices Industry in Japan” has regal grounds. This is the difference from other JFMDA’s voluntary ethics rules/guidelines.
- At present, 12 medical devices related associations are the member of JFTC. (Those 12 associations are the member of JFMDA, too.)
- JFTC has the following 3 committees to administrate FCC.
 - ◆ Planning & Public Relations Committee
 - ◆ Guidance & Examination Committee
 - ◆ Regulations & Standard Committee





Outline of The Fair Competition Code of the Medical Devices Industry (FCC)

- FCC is authorized under the Fair Trade Commission on November 16, 1998 Notification No.19.
- FCC was enforced in April 1999 as “Voluntary Ethics Rule for Restrictions on Premium Offer in the Medical Devices Industry”.
- FCC aims to prevent unfair inducement of customers through restrictions on unjustifiable premium offers in the medical devices manufacturing and distributing industry. And to ensure fair competition and order within the industry.
- FCC restricts the following activities as unjustifiable premium offers.

**Cash & Cash
equivalent**

NG !

**Free-of-Charge
Medical Devices**

NG !

**Free-of-charge
benefit & Labor**

NG !

Key Points to Consider

- JFMDA has promoted high compliance & ethics standards for 30 years !
- This helped improve our reputation and trust with doctors, patients, media and other stakeholders !

Thank you !!



Session One: The view from industry leaders operating in the APEC region

Moderator: Mr. Stephen Dibert, Advisor, International Affairs, MEDEC (Canada)

Discussants (5 minutes each / 20 minutes for Q&A and Discussion):

1. **Ms. Roberta Lipson**, CEO, Chindex International & Board Chair, United Family Healthcare (China)
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3. **Mr. Mario Mongilardi**, General Manager, Laboratories Americanos S.A., President, COMSALUD (Peru)
4. **Mr. Katsumi Takahashi**, President, Omnico Co & Vice Chairman, Japan Dental Trade Association (JDTA)
5. **Mr. Leonard Ariff Abdul Shatar**, CEO, CCM Duopharma Biotech Berhad & Immediate Past President, Malaysian Organization of Pharmaceutical Industries (MOPI)



Part II:

A Multi-Stakeholder Response to Strengthen Ethical Business Practices



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Session Two: The Role of Industry & Implementing Voluntary Industry Codes

Moderator: Mr. Iván Ornelas Díaz, Director of International Relations, Ministry of Economy (Mexico) & Co-Chair, Expert Working Group, The Mexico City Principles

Discussants (5 minutes each / 30 minutes for Q&A and Discussion):

1. **Dr. Lee Kyeong-Ho**, Chairman, Korea Pharmaceutical Manufacturers Association
2. **Ms. Wang Tongyan**, Vice President, China Pharmaceutical Industry Association
3. **Ms. Faye Sumner**, CEO, Medical Technology Association of New Zealand (MTANZ)
4. **Dr. Yio-Wha Shau**, Chairman, Taiwan Biotech Association (Chinese Taipei)
5. **Dr. Masami Ishii**, Executive Board Member, Japan Medical Association
6. **Ms. Elise Owen**, Associate Vice President, The Advanced Medical Technology Association (United States)



推行医药伦理准则 营造健康产业环境

Implementing Pharmaceutical Ethics Guidelines
Creating Healthy Industrial Environment

王彤焱 副会长 - 中国化学制药工业协会
Wang Tongyan Vice President - CPIA

APEC Business Ethics for SMEs Forum
Biopharmaceutical Sector
1-3 September 2014 | Nanjing, China



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内容提要

Content

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- 《医药企业伦理准则》实施意义
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- CPIA工作及成果
CPIA Key achievements
- CPIA的其他活动和推进
CPIA other initiatives in China



CPIA协会介绍

Introduction of CPIA

中国化学制药工业协会（简称CPIA）是1988年9月经民政部批准正式注册的全国性4A级行业协会

China Pharmaceutical Industry Association (CPIA) was approved as national 4A level industry association by Ministry of Civil Affairs in September 1988

- 拥有313家会员单位
313 members
- 制药企业主营业务收入占化学制药全行业的65%以上
Main business incomes of pharmaceutical companies account for more than 65% of the whole pharmaceutical industry
- 利润占60%左右
Profits account for about 60%



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CPIA推行《医药企业伦理准则》原因

Meaning for implementing "Pharmaceutical Industry Principles of Ethics"

- 中国医药市场和制药企业快速发展
Fast development of healthcare market and pharmaceutical industry
- 建立完善的市场法制环境
To establish a perfect legal market environment
- 建立规范的市场经营行为
To regulate market business behavior
- 实现行业可持续发展
To realize the sustainable development of the industry



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CPIA的工作及取得成果

CPIA Key Achievements

参加APEC组织推行《墨西哥城原则》的培训

Participating the "Mexico City Principles" training by APEX

- 2012-7 CPIA参加“关于生物制药业志愿实施企业伦理准则草案研讨会”
CPIA attended the "Draft seminar about the biopharmaceutical industry voluntarily implementing corporate ethics guidelines"
- 2013-8 CPIA参加“生物制药行业、医疗器械行业、建筑工程行业商业道德自愿行动准则培训班”
CPIA attended the "Training course for the bio-pharmaceutical industry, Medical device and pharmaceutical industry, and construction industry voluntarily implementing operative norm of business ethics"



CPIA的工作及取得成果

CPIA Key Achievements

积极将《墨西哥城原则》引进中国

Actively engaged in introducing "Mexico City Principles" into China

- 2013-8 CPIA将《墨西哥城原则》引进中国
CPIA introduced "Mexico City Principles" into China
- 2013-11 CPIA推出《医药企业伦理准则（草案）》
CPIA introduced the "pharmaceutical Industry principle of Ethics (draft)"
- CPIA发布《伦理准则》并推进实施
CPIA issued the "Principle of Ethics" and drive the implementation



CPIA成功召开两次全国专题会议

CPIA Successfully Held Two National Conferences

- 2013-10-29 “中国医药企业伦理准则发布大会”
"China Pharmaceutical Industry Principle of Ethics Launch Conference"
- 2014-05-27 “医药企业伦理准则中国论坛”
"China Forum of Pharmaceutical Industry Principles of Ethics"



CPIA开展信用评价和交流互动

Credit Rating Evaluation and more cooperation

《伦理准则》的推进实施与行业信用等级评价相结合
Combining the implementation of the "Principles of Ethics" with the credit rating evaluation in industry

- 2007 CPIA 获得行业企业信用评价资质
CPIP was approved to work for Credit Rating Evaluation
- 2008 启动信用评价工作
CPIA started pharmaceutical industry Credit Rating Evaluation
- 2013 80余家医药企业 获得A级以上信用等级
Over 80 pharmaceutical industry enterprises obtained A level
- 国际交流与合
International Communication and Cooperation



Code of Practice

Faye Sumner

Chief Executive Officer

Medical Technology Association of NZ

APEC Business Ethics for SMEs Forum

Medical Device Sector

1-3 September 2014 | Nanjing, China



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Certificate of Adoption

Required:

- Written Policies & Procedures
- Compliance Officer /Committee
- Training & Education
- Lines of Communication
- Auditing & Monitoring
- Corrective Action



Certificate of Adoption

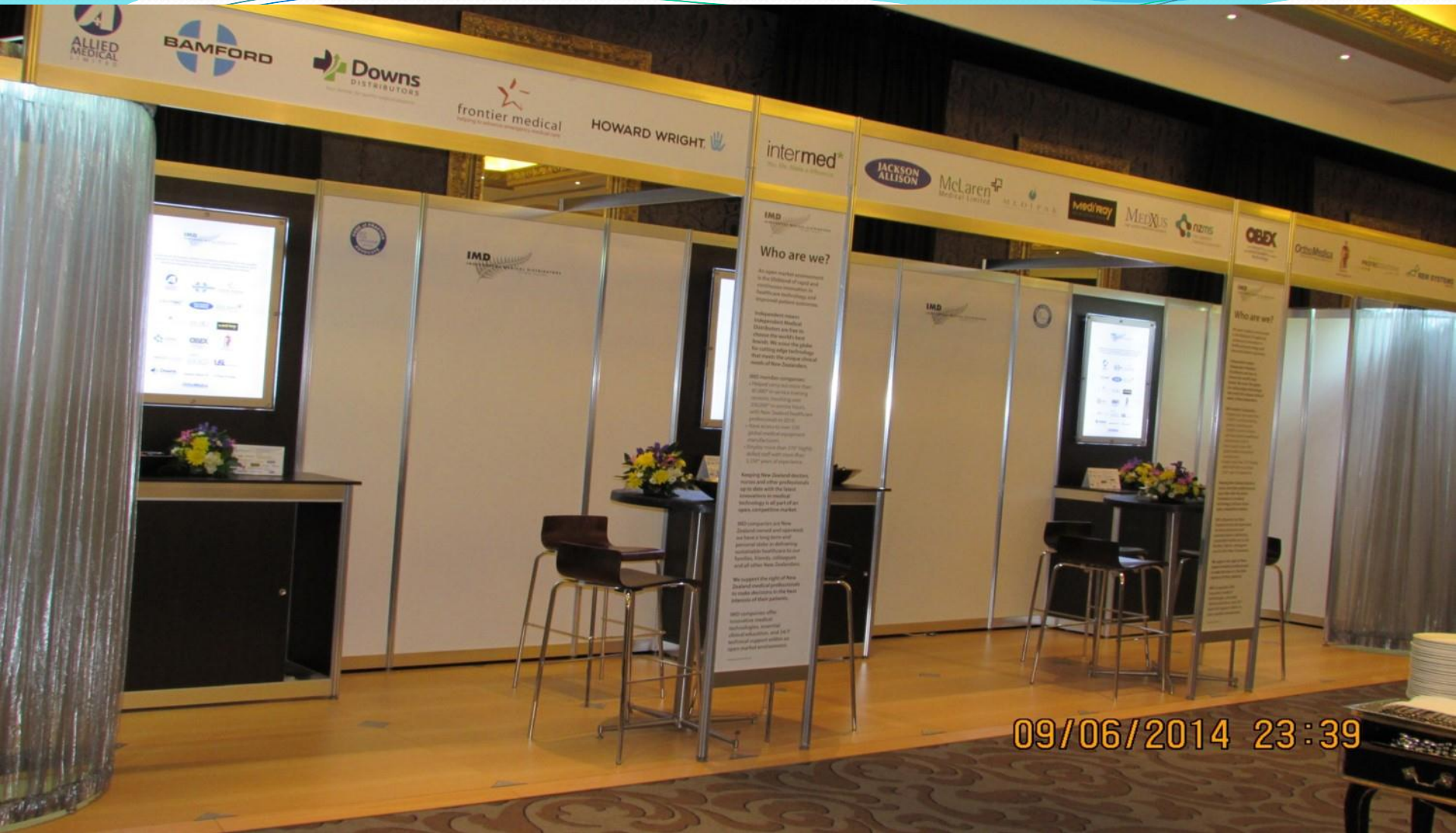
Suggested Use:

- Marketing materials
- Business cards
- Displays at meetings / conferences
- Company stationery



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Asia-Pacific
Economic Cooperation



APEC
CHINA 2014



JOHNSON & JOHNSON



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Session Three: The Role of Healthcare Providers and Professional Organizations and Best Practices in Ethical Collaboration with Industry

Moderator: Mr. Russell Williams, President, Rx&D – Canada’s Research-Based Pharmaceutical Companies; Chair of the IFPMA Code Compliance Network (CCN); and Co-Chair, Expert Working Group, The Mexico City Principles

Discussants (5 minutes each / 40 minutes for Q&A and Discussion):

1. **Kin-ping Tsang**, Chairman, International Alliance of Patient Organizations (Hong Kong, China)
2. **Sabrina Chan**, Executive Director, The Hong Kong Association of the Pharmaceutical Industry
3. **Dr. Wonchat Subhachaturas**, Immediate Past President, The Medical Association of Thailand
4. **Dr. Andreas Loeffler**, Second Vice President, Australian Orthopaedic Association



The Global Patients Movement: The value of patient engagement and the need for collaboration

King-Pin Tsang

IAPO Chair

APEC Business Ethics for SMEs Forum

Biopharmaceutical Sector

1-3 September 2014 | Nanjing, China



**Asia-Pacific
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IAPO's Mission

Our mission is to help build patient-centred healthcare in every country by:

1. Realizing active partnerships with patients' organizations, maximizing their impact through capacity building
2. Advocating internationally with a strong patients' voice on relevant aspects of healthcare policy, with the aim of influencing international, regional and national health agendas and policies
3. Building cross-sector alliances and working collaboratively with like-minded medical and health professionals, policy makers, academics, researchers and industry representatives



What is patient-centred healthcare?


The essence of patient-centred healthcare is that the healthcare system is designed and delivered so that it can answer the needs of patients

1. Patient-Centred Healthcare Principles
2. Respect and support for the individual patient, their wants, preferences, values, needs and rights
3. Choice and empowerment
4. Patient engagement in health policy
5. Access and support
6. Information that is accurate, relevant and comprehensive



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*Principles defined in IAPO's Declaration on Patient-Centred Healthcare: www.patientsorganizations.org/declaration



International Alliance of
Patients' Organizations
A global voice for patients

Declaration on Patient-Centred Healthcare

Patient-centred healthcare is the way to a fair and cost-effective healthcare system

Health systems in all world regions are under pressure and cannot cope if they continue to focus on diseases rather than patients; they require the involvement of individual patients who adhere to their treatments, make behavioural changes and self-manage. Patient-centred healthcare may be the most cost-effective way to improve health outcomes for patients.

To us, the International Alliance of Patients' Organizations, the essence of patient-centred healthcare is that the healthcare system is designed and delivered to address the healthcare needs and preferences of patients so that healthcare is appropriate and cost-effective. By promoting greater patient responsibility and optimal usage, patient-centred healthcare leads to improved health outcomes, quality of life and optimal value for healthcare investment.

Patients', families' and carers' priorities are different in every country and in every disease area, but from this diversity we have some common priorities. To achieve patient-centred healthcare we believe that healthcare must be based on the following Five Principles:

- 1. Respect**
Patients and carers have a fundamental right to patient-centred healthcare that respects their unique needs, preferences and values, as well as their autonomy and independence.
- 2. Choice and empowerment**
Patients have a right and responsibility to participate, to their level of ability and preference, as a partner in making healthcare decisions that affect their lives. This requires a responsive health service which provides suitable choices in treatment and management options that fit in with patients' needs, and encouragement and support for patients and carers that direct and manage care to achieve the best possible quality of life. Patients' organizations must be empowered to play meaningful leadership roles in supporting patients and their families to exercise their right to make informed healthcare choices.
- 3. Patient involvement in health policy**
Patients and patients' organizations deserve to share the responsibility of healthcare policy-making through meaningful and supported engagement in all levels and at all points of decision-making, to ensure that they are designed with the patient at the centre. This should not be restricted to healthcare policy but include, for example, social policy that will ultimately impact on patients' lives. See IAPO's Policy Statement at: www.patientsorganizations.org/involvement
- 4. Access and support**
Patients must have access to the healthcare services warranted by their condition. This includes access to safe, quality and appropriate services, treatments, preventive care and health promotion activities. Provision should be made to ensure that all patients can access necessary services, regardless of their condition or socio-economic status. For patients to achieve the best possible quality of life, healthcare must support patients' emotional requirements, and consider non-health factors such as education, employment and family issues which impact on their approach to healthcare choices and management.
- 5. Information**
Accurate, relevant and comprehensive information is essential to enable patients and carers to make informed decisions about healthcare treatment and living with their condition. Information must be presented in an appropriate format according to health literacy principles considering the individual's condition, language, age, understanding, abilities and culture. See IAPO's Policy Statement at: www.patientsorganizations.org/healthliteracy

To achieve patient-centred healthcare at every level in every community, the International Alliance of Patients' Organizations is calling for the support and collaboration of policy-makers, health professionals, service providers and health-related industries to endorse the Five Principles and to make them the centre of their policies and practice. We call upon all stakeholders to provide the necessary structures, resources and training to ensure that the Principles outlined in this Declaration are upheld by all.

© 2016 IAPO. All rights reserved. This policy was adopted in February 2016 by IAPO following member consultation and agreement by the Governing Board. Further information about Patient-Centred Healthcare including evidence for its impact and lessons to be learned in the IAPO position What A Patient-Centred Healthcare? A Note of Definition and Principle (IAPO, 2016) at: www.patientsorganizations.org/what-a-patient-centred-healthcare. Contact IAPO at: info@patientsorganizations.org

Globalization and Healthcare

- Public health issues are global
- The health industry is increasingly multinational
- Healthcare policies are debated and developed internationally
- Progress in science, medicine and technology is international
- Other important stakeholders in healthcare are organized and influential internationally



Global Issues for Patients' Organizations: IAPO's Policy Priorities

1. The massive issues of access to treatment and care
2. Lack of meaningful patient involvement in health policy decision-making
3. The need for an international concerted effort to address patient safety
4. The need for quality health information and communication



Patient Group – Industry Collaborations

Benefits

- ✓ Skills/expertise sharing
- ✓ Greater understanding of respective needs
- ✓ Access to information & data
- ✓ Funding, resources & in-kind support

Challenges (and in some cases risks)

- ✓ Potential loss of independence (on both sides!)
- ✓ Differing expectations and aims
- ✓ Perceived threat to public image and credibility

Benefits and challenges are not exclusive to patient group-industry collaborations



Consensus Framework for Ethical Collaboration

- putting patients first;
- supporting ethical research and innovation;
- ensuring independence and ethical conduct; and
- promoting transparency and accountability.



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Session Four: The Role of Government and Proactive Support to Encourage Ethical Business Practices in the Medical Device and Biopharmaceutical Sectors

Moderator: Dato' Hafsa Hashim, Chief Executive Officer, SME Corporation Malaysia & Co-Chair, Expert Working Group, The Kuala Lumpur Principles

Discussants (5 minutes each / 30 minutes for Q&A and Discussion):

1. **Dr. Kenneth Hartigan-Go**, Acting Director-General, The Food & Drug Administration (Philippines)
2. **Ms. Julie Mu**, Director of Community Relations, Independent Commission Against Corruption (Hong Kong, China)
3. **Ms. Kathleen Hamann**, Partner, White & Case (United States)
4. **Ms. Andrea Perez Figueroa**, Head of Ethics Committee, Mexican Association of Innovative Medical Devices
5. **Ms. Jessie Yap**, Chief Compliance Counsel, Asia Pacific & General Counsel, Australia and New Zealand, Covidien (Australia)



Lunch: “The Kitchen” (by lobby)

**PLEASE RETURN AND READY TO
RESUME BY 14:00**



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Session Four: Views from China

Moderator: Dr. Xu Ming, Vice President, China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE) & Expert Working Group, The Mexico City Principles

Discussants (5 minutes each / 40 minutes for Q&A and Discussion):

1. **Ms. Zheng Hong**, Executive Chairman, China Pharmaceutical Industry Association
2. **Mr. Joseph Cho**, President, R&D-based Pharmaceutical Association Committee
3. **Mr. Zhao Yisu**, General Secretary, China Association for Medical Devices Industry



推行《医药企业伦理准则》 建议坚持的原则

Principles for the implementation of “Principles of Ethics”

郑 鸿 执行会长 - 中国化学制药工业协会
Zheng Hong President - CPIA

APEC Business Ethics for SMEs Forum
Biopharmaceutical Sector
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中国《医药企业伦理准则》

" Pharmaceutical Industry Principles of Ethics" - China

- 《墨西哥城原则》是积极推动市场法制化、合规化的具有可操作性的重要文件
"Mexico City Principles" is the operational important documents that actively promote market legal system and market compliance
- 中国医药行业九家协会共同推出了《医药企业伦理准则》
The nine associations worked together to issue the "pharmaceutical industry principles of ethics" in China



推行《医药企业伦理准则》需要坚持的原则

Principles for the implementation of “Principles of Ethics”

- 坚持患者至上，确保患者能够获得安全有效的使用品
Adhere to the patient first, and ensure the patients could have access to safe and effective drugs
- 各利益相关方在相互合作、交流的基础上，围绕《医药企业伦理准则》的各条规定，致力于在自己的行业范围内推行实践，共同营造健康、道德、合规的市场环境
Different stakeholders, on the basis of cooperation and communication, execute the “Principles of Ethics” in their own industry within the scope of their practice, to create a healthy, ethical, compliant market environment
- 科学界定医药代表的职责，规范其行为
Scientifically define the responsibilities of the medical representatives and regulate their behaviors



坚持患者利益至上

Adhere to the patient first

- 药企责任
Corporate responsibility
- 医疗人员责任
Medical staff responsibility
- 政府相关部门责任
Relevant government departments responsibility



执行与监督认同一致统一原则

The consensus of execution and supervision identity

- 利益相关方沟通，取得认同
Stakeholders obtained consensus based on communication
- 政府有关部门与利益相关方沟通取得认同
Relevant government departments communicate with different stakeholders to obtain consensus
- 执行和监督认同一致统一原则
The consensus of execution and supervision identity



科学界定认同医药代表责任 与职责规范其行为

Scientifically define the responsibilities of the medical representatives, and regulate their behaviors



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中国医疗器械行业协会
China Association for Medical Devices Industry

中国医疗器械行业 诚信体系建设工作介绍

中国医疗器械行业协会

2014年9月 南京

目录

第一部分 中国医疗器械行业发展现状

第二部分 协会所做的工作

第三部分 问题及建议



第一部分

中国医疗器械行业发展现状

行业发展现状

国际现状

- 2012年全球医疗器械市场产值超过4000亿美元，占医药市场42%，发达国家药械产值比达1:1
- 近年成为发达国家提升生物医药产业和高端装备制造业的重要抓手，受到高度重视

行业发展现状

2013年全国医疗器械产值

➤ 工信部统计规模以上企业：

| 行业 | 主营业务收入(亿元) | 同比(%) |
|-------------|------------|-------|
| 医疗仪器设备及器械制造 | 1888.6 | 17.2 |
| 卫生材料及医药用品制造 | 1398.2 | 21.8 |

● 卫生材料按医疗器械纳入监管，因此样本医疗器械企业产值合计应达到2500亿元

行业协会推算全行业产值：超过4000亿元

行业发展现状

生产、经营企业情况

2013年

➤ 生产企业15961家

I类4587家，II类8649家，III类2725家

➤ 经营企业16万家。

数据来源：国家药监局

行业发展现状

我国三大医疗器械生产区

- 珠江三角洲——广东、深圳
- 长江三角洲——江苏、浙江、上海
- 京津环渤海湾——京、津、鲁、冀、辽



行业发展现状

我国医疗器械产业发展的特点

- 区域发展态势良好
- 贸易呈顺差，但进口增速明显强于出口
- 研发投入加大
- 产业总体水平在国际上处于中等偏下水平
- 外资品牌、合资品牌在高端市场上占有优势



第二部分

协会所做的工作

国际活动

2010年9月，与美国先进医疗技术协会（AdvaMed）共同签订《关于推进中国医疗器械市场道德准则行为的谅解备忘录》。

关于推进中国医疗器械市场道德准则行为的谅解备忘录
2010年9月

中国医疗器械行业协会(CAMDI)和美国先进医疗技术协会(AdvaMed)是代表中美医疗器械企业和先进医疗技术的行业协会。一直以来，双方致力于共同合作，探讨双边利益问题，并不断推进对双方成员共同重大意义问题的协作。

随着保健和医疗技术创新逐渐跨越了国家和文化的界限。对于推动国际统一文化、实现医疗器械公司与医护人员之间道德互动的需求越来越强。美国先进医疗技术协会制订了道德准则，指导其成员与医护人员之间的互动；中国医疗器械行业协会制定的行业公约中也包含了行业道德的内容，倡导其会员单位遵守行业规范和准则。双方均在道德框架下有着相似的目标：推动行业遵守良好道德原则和公平业务运营规范。

为了确保中美双方持续发展先进的医疗技术，安全和有效地使用医疗技术，并对医护人员进行教育和培训，中美双方协会通过本谅解备忘录对以下事宜达成一致。

- 一、协商制定《中国医疗器械行业道德准则》（“中国道德准则”），并与美国先进医疗技术协会准则中提出的道德标准一致。
- 二、中美协会通过双边对话以及亚太经合组织(APEC)渠道进行，与其他亚太经合组织成员共同制定《亚太经合组织成员医疗器械行业职业道德原则》。
- 三、通过新的中国医疗器械行业道德准则为中国医疗器械行业的公司与医护人员在以下方面的互动提供职业道德行为指导：涉及研究与开发、医疗技术教育培训及慈善事业相关赞助等。
- 四、双方在2011年5月之前为中国医疗技术行业的道德准则提出最终的一系列建议，并鼓励中国医疗器械行业的公司遵守和执行中国道德准则。

Memorandum of Understanding
To Develop an Ethical Code for the Chinese Medical Device Market
September 2010

The China Association for Medical Devices Industry (CAMDI) and the Advanced (AdvaMed) are industry associations representing medical technology in China and U.S.A.. CAMDI and AdvaMed are cooperating to discuss issues of mutual interest to improve their collaboration on issues of

innovation increasingly extends beyond national boundaries. The need to promote internationally harmonized standards among medical device and diagnostics companies has developed a Code of Ethics to guide its members and professionals. Similarly, CAMDI includes a code of ethics to guide its member companies. Both associations have similar goals in their ethical frameworks, promoting and fair business operations.

development of advanced medical technologies, safe and effective use of medical technologies, and training, education for medical professionals. AdvaMed and CAMDI agree the following:

standards for China's medical device industry that are in harmony with ethical standards set out in the United States and through APEC channels, where the United States and other APEC members to develop joint Principles of Ethics for the Medical Device Industry.

国际活动

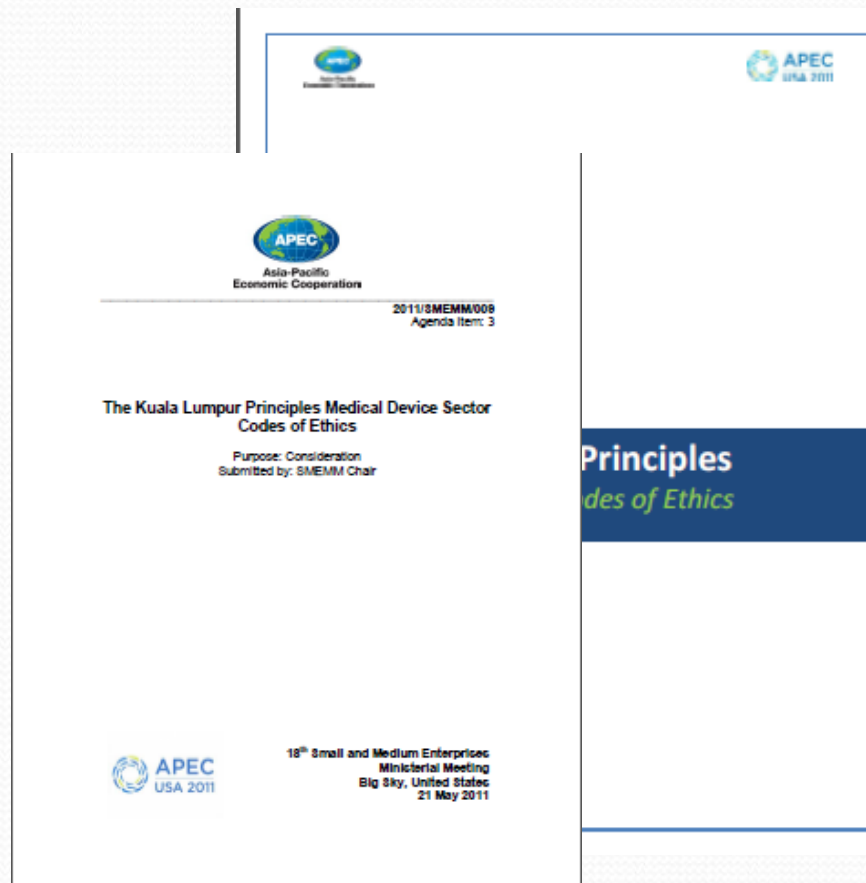
2010年9月，协会参加了在日本举行的“亚太经济体医疗器械行业职业道德原则”研讨会。

国际活动

2011年，协会与美国先进医疗技术协会（AdvaMed）共同起草了《中国医疗器械行业协会专业医务人士道德行为准则》。

国际活动

2011年4月，创新联盟理事长、协会副会长姜峰博士参加了APEC医疗器械行业会议，与10余个APEC成员国代表共同讨论了《医疗器械行业道德准则吉隆坡原则》



国际活动

2013年8月26-30日，协会受邀参加“2013亚太经合组织医药产业伦理准则会议”，会议推进了各成员国医药产业伦理准则的制定与实施

政府相关工作

2008年3月，协会成为第二批行业信用评价试点单位之一。



政府相关工作

- ▶ 2011年8月、2012年5月，参加商务部市场秩序司和国资委行业办组织召开的2011年行业信用建设工作会议，推动企业诚信体系建设。

协会工作

- 2011年9月，协会邀请专家对《吉隆坡原则》的背景、内容及要求向重点会员企业进行了解读。


协会工作

协会在2013年3月17日召开的五届三次理事会上审议通过了信用体系评价工作方案。



协会工作

- 2013年3月18-19日，协会在会员年会同期举办了中国医疗器械行业诚信体系建设论坛
- 2013年4月，由协会作为发起单位之一在第69届CMEF开幕式上发起诚信体系建设倡议启动仪式



第三部分

问题及建议

问题及建议

- ▶ 政府方面
- ▶ 协会方面
- ▶ 企业方面
- ▶ 社会环境方面

Part III:

The Nanjing Declaration



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Awarding of the APEC Business Ethics for SMEs Lighthouse Award:

Recognition of an individual or organization that has served as a bright and steady light to strengthen the ethical business environment for SMEs in the APEC region.



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