



## Asia Pac Compliance Code and APEC Principles and Nanjing Declaration Updates - Healthier China Through Innovation

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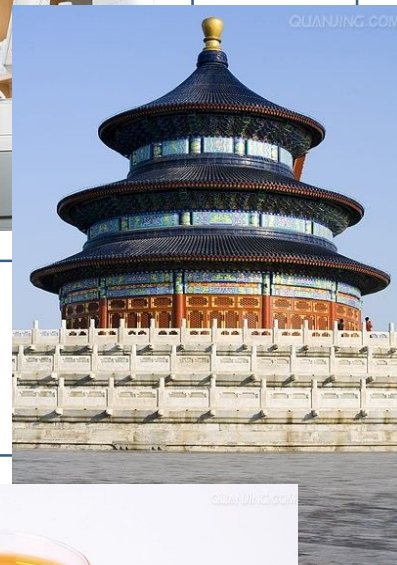
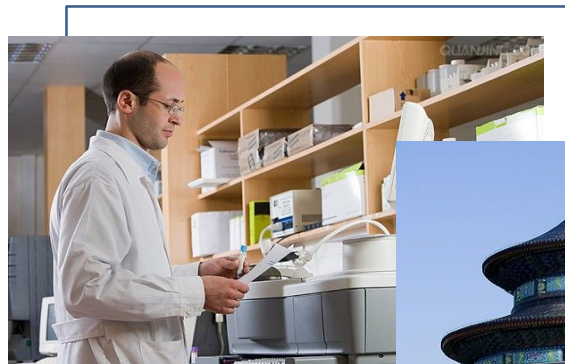
# About **RDPAC**: R&D based Pharmaceutical Association Committee

## The conditions for membership are:

- the company is a R&D-based pharmaceutical company;
- the company has substantial business operations in China;
- the company has agreed to the RDPAC Code of Practice.

## Milestones

- 1995 – the R&D based pharmaceutical association was organized;
- 1999 – Beijing Rep Office was established;
- 2005 – RDPAC was formally incorporated.



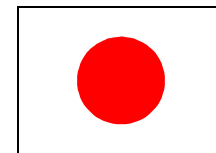
# 38 Member Companies



| Abbott               |
|----------------------|
| AbbVie               |
| Allergan             |
| Amgen                |
| Baxter               |
| Bristol Myers Squibb |
| Celgene              |
| Eli Lilly            |
| GE Healthcare        |
| MSD                  |
| Pfizer               |
| Xian-Janssen         |



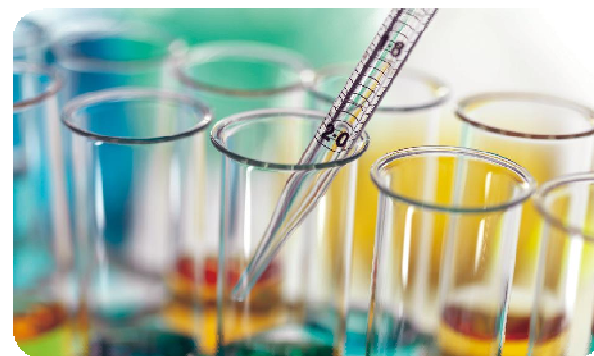
| AstraZeneca         |
|---------------------|
| Bayer HealthCare    |
| Boehringer          |
| Ingelheim           |
| Chiesi              |
| Fresenius Kabi      |
| Gedeon Richter Plc. |
| Helsinn             |
| Ipsen               |
| LEO Pharma          |
| Lundbeck            |
| Menarini            |
| Merck Serono        |
| Mundipharma         |
| Novartis            |
| Novo Nordisk        |
| Roche               |
| Sanofi Aventis      |
| Servier             |
| UCB                 |
| Zambon              |



| Astellas    |
|-------------|
| Chugai      |
| Eisai       |
| Kyowa Kirin |
| Sumitomo    |
| Takeda      |

# RDPAC in China

**38** member companies , **49** plants , **31** R&D centers. In the last five years, RDPAC members have introduced at least **67** innovative drugs for the benefit of Chinese patients, representing over **80%** of all innovative drugs introduced to China during this period.



# Worldwide Federation of RDPAC

|   |  |                                       |
|---|--|---------------------------------------|
| 1 | <b>International Federation of Pharmaceutical Manufacturers &amp; Associations (IFPMA)</b> | <b>国际制药企业协会联盟<br/>(RDPAC系IFPMA会员)</b> |
| 2 | <b>European Federation of Pharmaceutical Industries and Associations (EFPIA)</b>           | <b>欧洲制药企业协会联盟</b>                     |
| 3 | <b>Pharmaceutical Research and Manufacturers of America (PhRMA)</b>                        | <b>美国药品研发与制造企业协会</b>                  |
| 4 | <b>Japan Pharmaceutical Manufacturers Association (JPMA)</b>                               | <b>日本制药企业协会</b>                       |

# RDPAC rigorously promotes ethical business practice

- ◆ RDPAC Code of Practice
- ◆ Medical Rep Certification (MRC) Program



# RDPAC Code of Practice 2012 and 2015



# RDPAC keeps on devoting itself to ensure promotional behaviors match high ethical standards

- Sponsorship to an overseas meeting must fulfill the new principle of IFPMA;
- Prohibit to sponsor individual HCPs;
- Prohibit payment in cash (transfer through company bank account);
- Prohibit collecting patient's case or prescription data via HCPs;
- More control on speaker fee to HCPs (contract; to monitor "high risk" speakers, etc.)
- Prohibit cultural gift.

- Enlarge the applicable scope of the Code;
- Added several provisions on transparency;
- Further emphasize and explicit the prohibition of any form of entertainment.

2<sup>nd</sup> edition of Code of Practice

**2016**

*In the process of updating RDPAC Code of Practice 2015*

**2015**

**2012**

5<sup>th</sup> edition of RDPAC Code  
• Enlarge the scope to the interaction activities between Pharmaceutical enterprises and HCPs, HCOs and patient orgs.

**2010**

3<sup>rd</sup> version RDPAC Code follow IFPMA Code  
• Minimum level of criterion and principle of global industry;  
• Specify the scope and enumerate non applicable situation;  
• Explicit the basic principle of promotion behavior;  
• Roll out the Medical Reps training.

**2006**

**2002**

**1999**

1<sup>st</sup> edition of Code of Practice





## RDPAC's MRC Program

- There are an estimated 70,000 Medical Reps in RDPAC member companies.
- There are 2,000,000 Medical Reps in China, according to estimation by the magazine “Economist”

# In 2015 MR officially listed in China's "Occupation Encyclopedia"

## ■ Occupation name:

Medical Representatives)

## ■ Occupation definition:

Professionals representing pharmaceutical enterprises in delivering, communicating and providing feedbacks on information of medicines.

***Very much in line with international standard!***



# RDPAC's MRC Program

- 2003: Training materials preparation
- 2005: Pilot trials in Beijing – 9 members, 226 MRs
- 2007: Roll-out to all members companies
- 2007: in January first batch of MR Certificates were issued
- 2012: MRC Renewal System was launched
- 2014: Improved MRC system's capability
- 2016: plan on expanding MRC to other local pharmaceutical associations

# MRC Training Manual

-- the Code of practice part is the most important one

## Volume 1. medical basics

- Chapter 1 Human Body
- Chapter 2 Pathology and immunity
- Chapter 3 Nervous System
- Chapter 4 Circulation system
- Chapter 5 Respiratory system
- Chapter 6 Muscle-Skeletal System
- Chapter 7 Digestive System
- Chapter 8 Urological system
- Chapter 9 Endocrine System
- Chapter 10 Genitor System
- Chapter 11 Dermatological
- Chapter 12 Sensory Organs

Developed the on-line  
course ware on e-learning  
platform:

[http://e-  
training.rdpacmrc.org](http://e-training.rdpacmrc.org)



## Volume 2. pharmaceutical basics

- Chapter 1 Pharmacology
- Chapter 2 Clinical pharmacology
- Chapter 3 Pharmacy
- Chapter 4 Monitoring of Adverse Drug Reaction

## Volume 3. Code of Pharmaceutical Marketing Practices

- Chapter 1 Code of  
Pharmaceutical Marketing  
Practices and value of  
Medical Reps. (2015)

## Volume 4. Industry overview

- Chapter 1 Healthcare  
overview in China
- Chapter 2 Current  
organization and  
operation of healthcare  
players in China
- Chapter 3 Drug market  
worldwide

## Attachments

- Examination Syllabus
- Test questions answers
- Laws related to Medicine  
industry
- Mexico City Principles

**RDPAC collaborated closely with domestic and international partners on promotion of ethical business practice**



# Industry Alignment – 2015 China Forum of Pharma Enterprises on Ethical Business Practice

## 17 associations:

- CPIA
- CCCMHPIE
- Sino-PHIRDA
- RDPAC
- CATCM
- CAPC
- CNMA
- CPEP
- CRAECC

9 Initiators

- CMP
- CAMDI
- CNPPA
- CMEA
- CPEA
- CPAPE
- CMBA
- CQAP

8 newly joined



### 中国医药企业伦理准则实施 倡议书

(2015年6月29日)

各会员单位及医药工商企业：

为确保患者在医疗活动中的利益最大化，亚太经合组织（APEC）于2011年9月在墨西哥推出了生物医药领域的商业道德准则（即《墨西哥城原则》），号召经济体备成员所有生物医药行业利益相关者拥护共同的道德标准，其中包括公司、行业协会、专业组织以及管理单位和反腐败单位。《墨西哥城原则》的中文译本定名为《医药企业伦理准则》。

作为APEC成员，我国推行《医药企业伦理准则》对于加强药品安全监管工作，打击商业贿赂，改善利益相关方之间的商业道德行为具有重要意义。

为切实保障人民群众的生命健康，促进中国医药行业的健康发展，今向业界全体同仁发出倡议：

遵循《医药企业伦理准则》以医疗保健和患者为中心、诚信、独立、合法、透明和责任的原则，完善企业规章制度，自觉遵守《医药企业伦理准则》各项条款。

#### （一）遵守法律法规，恪守职业道德

自觉遵守和执行国家法律、法规，严格执行药品管理法和药品生产、经营质量管理规范的各项规定。恪守职业道德操守，积极履行社会责任，发展产业，贡献国家，服务民生。

#### （二）强化安全标准，确保药品质量

企业应遵守有关药品研发、生产、销售、物流、商业化和安全方面的标准，严把质量关，按照道德规范从事药品推广流通，向消费者提供更安全、更有效的药品，确保人民群众的生命健康权益。

#### （三）加强行业自律，坚持诚信经营

强化自律意识，完善诚信体系。提供真实、准确的信息，规范市场行为。维护消费者的合法权益，维护社会公共利益，使诚信经营理念落实到企业生产经营的全过程。自觉接受消费者、政府监管部门和新闻媒体的监督及企业之间、行业之间的相互监督。

我们同时强烈呼吁政府继续深化医药卫生体制改革，进一步完善药品集中采购制度，推进药品价格、医保支付制度和医院用药管理制度改革。政府有关部门应当严格执法，依法行政，保障遵守商业道德准则企业的合法权益和正当利益；从制度、体制、机制上净化我国医药市场，建立有利于医药产业健康发展的良好的市场环境。

#### 倡导单位：

中华全国工商业联合会医药业商会

中国医疗器械行业协会

中国医药包装协会

中国医药教育协会

中国医药企业管理协会

中国医药设备工程协会

中国医药生物技术协会

中国医药质量管理协会

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## Effort aiming at developing a national MRC system in China

- Forum on EBP of Pharma Enterprises on June 28, 2016 in Beijing



- ❑ Signed a MOU among four key pharmaceutical associations in China - CPIA (China Pharmaceutical Industry Association), CATCM (China Association of Traditional Chinese Medicine) and CPEP (China Pharmaceutical Enterprises Promotion)
- ❑ Aim at, among others, deepening the alignment by these associations in China on MR occupation management and promotion in China and EBP of MRs.



Thanks

