Ethical Business Practice and Declaration for Pharmaceutical Innovation

A Presentation by Mike Dethick, Managing Director, RDPAC 2017.
## RDPAC 40 Members – Landscape

<table>
<thead>
<tr>
<th>Beijing (14)</th>
<th>Shanghai (26)</th>
<th>Shanghai (26)</th>
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<tbody>
<tr>
<td>Astellas</td>
<td>Abbott</td>
<td>Gedeon Richter Plc.</td>
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<tr>
<td>Bayer HealthCare</td>
<td>AbbVie</td>
<td>Gilead</td>
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<tr>
<td>Chugai</td>
<td>Allergan</td>
<td>Kyowa Kirin</td>
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<tr>
<td>Fresenius Kabi</td>
<td>Amgen</td>
<td>LEO Pharma</td>
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<td>Helsinn</td>
<td>AstraZeneca</td>
<td>Menarini</td>
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<td>Ipsen</td>
<td>Baxter</td>
<td>MSD</td>
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<td>Lundbeck</td>
<td>Bristol Myers Squibb</td>
<td>Novartis</td>
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<td>Merck Serono</td>
<td>Boehringer Ingelheim</td>
<td>Roche</td>
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<td>Mundipharma</td>
<td>Celgene</td>
<td>Shire</td>
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<td>Novo Nordisk</td>
<td>Chiesi</td>
<td>Sanofi</td>
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<td>Eisai</td>
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<td>Servier</td>
<td>Eli Lilly</td>
<td>UCB</td>
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<td>Takeda</td>
<td>Ethypharm</td>
<td>Zambon</td>
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<td>Xian-Janssen</td>
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RDPAC Members 30 R&D Centre's

<table>
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<tr>
<th>City</th>
<th># of R&amp;D Centers</th>
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<tr>
<td>Suzhou</td>
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<td>Wuhan</td>
<td>2</td>
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<tr>
<td>Wuxi</td>
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<td>Changsha</td>
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RDPAC Members 49 Plants

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<tr>
<td>Guangzhou</td>
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<td>Wuxi</td>
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<td>Nanchang</td>
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<tr>
<td>Jiaxing</td>
<td>1</td>
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<tr>
<td>Shenyang</td>
<td>1</td>
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<tr>
<td>Taizhou</td>
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<tr>
<td>Chengdu</td>
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<td>Fuyang</td>
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<td>Tangshan</td>
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<td>Shenzhen</td>
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<td>Zuhai</td>
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<td>Xian</td>
<td>1</td>
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<tr>
<td>Haikou</td>
<td>1</td>
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<td>Nanjing</td>
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RDPAC’s Vision is to be a valued partner in delivering the “Healthy China” goal to improve the health and quality of life of the people in China.
RDPAC members launch about 80% of all Innovative Medicines in China.

RDPAC members are growing their local capabilities with significant investment throughout the provinces.

Overall, 8 billion RMB is being plowed into Research & Development in China every year.

That translates into the potential for good jobs, growing technology excellence, and the potential for cures for China’s patients.
The Three Guiding Principles for Ethical Business Practice
1. Integrity

Fundamentally, there must always be confidence that prescription decisions are made on an ethical and patient-focused basis.

----IFPMA
2. Self-Discipline

1. Supports government enforcement and anti-corruption efforts

2. Provides companies with clarity and harmonization in rules and practices

3. Allows companies to compete across the region at a reduced cost

4. Facilitates ongoing innovation

5. Ethical collaborations fuel advances and promote access to life-saving medicines

6. Ethical collaborations ensure that decisions are made in the best interest of patients
3. Consensus

1. Put Patients First
2. Support for Ethical Research and Innovation
3. Ensure Independence and Ethical Conduct
4. Promote Transparency and Accountability
Fostering a Sustainable Ecosystem for Drug Innovation in China
China’s Healthcare Ecosystem is shaped by the government’s three fundamental healthcare priorities.

- **Build an economically viable healthcare system**
- **Improve access to quality care for patients**
- **Foster a sustainable innovation ecosystem**
China’s goal of drug innovation outlined in the 13th five-year-plan

### Three phases for “Major New Drug Development Project”

**11th five-year plan (“Spread”)**
- Establish innovative R&D system/platform
- Invest in infrastructure
- Build capability

**12th five-year plan (“Streamline”)**
- Capability
- Identify and focus on key products, key medical needs and key R&D issues

**13th five-year plan (Breakthrough)**
- Resources concentrated on limited key projects
  - Plan to develop **30 new drugs**¹ including 8~10 breakthrough drugs
  - Develop and drive globalization of 20~30 chemical drugs, 3~5 new TCMs and 3~5 new biologics
- Achieve **breakthrough** in a few leading areas

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¹ Including 10 chemical drugs, 10 biologics and 10 TCMs

Source: Literature search; MoST MNDDP project review
China contributes to 3-4% of global drug innovation today, and is a 3rd-tier country in drug innovation.

Methodology

- **Pipeline**: number of pipeline compounds in pre-clinical, phase I-III and NDA review phase by companies with HQ in a given country at the end of 2015
- **New drugs Launched**: number of NMEs in “first launch” countries during 2007-2015

Contributions to global pharma innovation

1. **Pipeline**
   - 48.7%
   - 7.0%
   - 8.0%
   - 5.2%
   - 6.5%
   - 5.6%
   - 4.1%
   - 3.8%
   - 4.4%
   - 1.7%
   - 2.2%
   - 2.1%

2. **New drugs launched**
   - 56.3%
   - 12.6%
   - 7.7%
   - 6.5%
   - 0.9%
   - 3.1%
   - 2.5%
   - 1.8%
   - 0.3%
   - 1.5%
   - 0.9%
   - 0%

Only listed countries are included in the analysis, total=100%

1 Ration of contribution of active compounds in each country in 2015
2 2007-2015 first launch percentages, only NMEs are included

Observations

• **Innovation** is central to China’s reform agenda. It serves as a reflection of the core competency of a nation.

• **Globalization** and China’s role in the world economy is becoming a central theme of President Xi’s focus. The messages from Davos and OBOR have resonated with industry and people are increasingly looking towards China.

• **ICH** membership is a significant step forward.

• **Healthy China 2030** is one of the most important overarching policies for our industry.

• **The Chinese Patient**, their ‘wellbeing’ and their access to quality, innovative medicines will drive the reforms.
Environment

• Healthcare Speeches - People/Patient
• Anti-corruption drive (heavy punishments)
• A System that is Right for China
• Decision Hierarchy
• International Harmonization & Standards
• Compliance & transparency will become central to the reforms
• Global Big Industry
On June 22nd, CFDA Minister Bi commissioned by the State Council reported to the Standing Committee of the National People’s Congress on China’s current drug management status update.

In his speech, he stressed that in order to strengthen China’s overall drug supervision process; (“Four Stricts”) were needed:

• Strictest Standards,
• Strictest Supervision,
• Strictest Punishments and
• Strictest Accountability Mechanisms.
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<tbody>
<tr>
<td><strong>1</strong></td>
<td>Recognition of the Chinese government’s stance on anticorruption.</td>
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<tr>
<td><strong>2</strong></td>
<td>Joint action by the Chinese Pharmaceutical Industry Associations.</td>
</tr>
<tr>
<td><strong>3</strong></td>
<td>Support from and cooperation with international Pharmaceutical Associations.</td>
</tr>
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Addressing Ethical Practices in China

4 Ethical business practices and Codes add value in regulating the behavior of the pharmaceutical industry.

5 Drug safety and scientific promotion of medicines, necessitates the implementation of ethical practices.

6 Ethical practice will improve the international image of the Chinese pharmaceutical industry.
Transforming Words into Action

Oct 29, 2013
The Mexico City Principles

May 27, 2014
Industry alignment
9 industry associations
CFDA, National Bureau of Corruption Prevention of China, State Administration of Traditional Chinese Medicine

China’s Pharmaceutical Enterprises Ethical Business Practice Launch Event

China forum on Ethical Business Practices for Pharmaceutical Industry

APEC Business Ethics for SMEs Forum

Nanjing Declaration
Double the number of medical device and biopharmaceutical industry associations with codes of ethics between 2012 and 2015, working toward universal adoption and implementation of the APEC Principles by 2020.

June 29, 2015
Implementation of Nanjing Declaration
17 industry associations signed the Pharmaceutical Enterprise Ethical Business Practice
Further engaged key HCP associations

International initiative
For Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

Improve awareness among medical group
9 industry associations
4 key HCP associations

China forum on Ethical Business Practices for Pharmaceutical Industry
Industry Associations signed the Pharmaceutical Enterprise Ethical Business Practice

**17 Associations:**
- CPIA
- CCMHPIE
- Sino-PHIRDA
- RDPAC
- CATCM
- CAPC
- CNMA
- CPEP
- CRAECC
- CMP
- CAMDI
- CNPPA
- CMEA
- CPEA
- CPAPE
- CMBA
- CQAP

9 Initiators

8 newly joined
The definition of “医药代表” in the “China Occupation Category Encyclopedia” (《中华人民共和国职业分类大典》):
“professionals on behalf of pharmaceutical manufacturing enterprises engaging in delivering, communicating and giving feedback on scientific drug information.”
Industry Self-Regulation

RDPAC MRC Test
As of end of August, 2017, total of 81,362 MRs have passed the test, the average pass rate of 78.4%. Totally 12,858 MRs have finished the MRC continue-education.

Four Associations Signed Memorandum of Understanding to Promote the Professionalization and Formal Management of Medical Representatives
Continuous Assessment & Improvements for RDPAC Members

1999
FRPIA 1st edition of Code

2002
FRPIA 2nd edition of Code

2006
Start follow IFPMA Code

2010
The 4th revision

2012
The 5th revision

2015
The 6th revision

2017
The 7th revision
The International Pharmaceutical Innovation Forum (IPIF) March 2017 -
10 Leading International & Domestic Associations Signed A Joint
Declaration for Pharmaceutical Innovation

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Other Influencers & Areas of Related Activity
RDPAC, as a National Association member of IFPMA, is working with CFDA and CDE to facilitate expert representation on ICH working committees.
Patient & Educational Platforms - PSM China

1. China Non Prescription Medicines Association (CNMA)
2. China Pharmaceutical Association (CPA)
3. China Pharmaceutical Industry Association (CPIA)
4. China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee (RDPAC)
5. Chinese Medical Association (CMA)
6. China Association of Traditional Chinese Medicine (CATCM)
7. China Association of Pharmaceutical Commerce (CAPC)
8. China Licensed Pharmacist Association (CLPA)
9. Chinese Pharmaceutical Enterprises Association (CPEA)
10. Southern Medical Economics Research Institute (SMERI)
11. China Pharmaceutical Newspapers and Periodicals Association (CPNPA)
12. Beijing Pharmaceutical Industry Association (BPIA)

12 Initiators:

Founded on November 28th 2012

24 National and local organizations

1. China Medical Biologics Association (CMBA)
2. China Hospital Association (CHA)
3. China Pharmaceutical Packaging Association (CPPA)
4. China Medical Equipment Engineering Association (CPAPE)
5. National Pharmaceutical Technology Marketing Association Excipients (CROU)
6. China Association of Traditional Chinese Medicine (CATCM)
7. Shandong Pharmaceutical Industry Association
8. Chongqing Pharmaceutical Industry Association
9. China Medicinal Biotechnology Magazine
10. China Health Information Standard Technology Committee; (CHISTC)
11. China Society of Toxicology (CSOT)
12. Beijing PSM Foundation
Safe Medicines - Track and Trace in China

- Government leading
- Enterprise Self-responsibility
- Public Service / Security

Past → Present → Future
Identification of Pharmaceuticals...After 2019

- Green = country requires global standards
- Red = country requires national ID #
- White = no input available
New Technology Needs to Reinforce EBP

Ethical business practice

The fragmentation of time lead to fragmentation of learning and communication

Communicate with HCPs in a cost-effective way

Demand for customized information and knowledge
Ethical business practice and innovation depends primarily upon:

- An understanding of the **Principles & Voluntary Compliance**;
- **Reinforcement** by **Peers & Public Opinion**; and
- When necessary... **Enforcement through Disciplinary Proceedings**
The true innovation of a nation is always demonstrated through its transparency, compliance and business ethics.
There is no one single stakeholder – it is a multiple
Thank you for your attention