The Role of Industry in Working with NRA to Implement ICH/Experience of Experts

LU Xiaoti
Deputy Secretary-General of PhIRDA
Oct. 2022
In November, 2016, the IFPMA Council Meeting held in Washington DC approved PhIRDA as an association member.

In June 2017, China former CFDA officially joined the ICH.

In June 2017, ICH Assembly approved Standing Observers has a seat to be filled on each of the EWGs.

In June 2018, China NMPA was elected as the member of ICH Management Committee.

In June 2021, China NMPA was re-elected as the member of ICH Management Committee.

Up to May 2022, NMPA announced that 59/63 ICH guidelines was timelined, and 55/63 guidelines was fully implemented.

Conversion Rate 93%

- Deepen communication and introduce new concept, method, tool and standards
- Participate in global Multi-regional R&D and registration
- Facilitate the drug review and approval system in line with international standard
- Promote the system construction of drug technical guideline in China
IFPMA’s Role

IFPMA Plays a Pivotal Role in Industry Participation in ICH

Industry experts from non-represented ICH regions have not had the possibility to participate at the EWG level. IFPMA as a Standing Observer could:

• Attend the Meetings of the Assembly and the Management Committee
• Appoint 1 expert to Working Groups

IFPMA collaborate closely with other Industry Founding Members (EFPIA, JPMA and PhRMA):

• Actively participates in ICH meetings
• Supports the ICH Training Strategy
• Contributes to ICH technical Working Groups

Methodology:

• Assembly and Management Committee Participation
• Industry Executive Council* (IEC) Participation
• ICH Training Subcommittee
• Information Sharing
• Expert Working Groups

Works above can ultimately facilitate the implementation of ICH guidelines at the national level.
As of September 2022, PhIRDA recommended **43 experts** (including 14 leads and 9 alternate leads), accounting for **53%** of all TF experts in IFPMA.
PhIRDA

Principle and Members

Principle: Innovation, Industrialization, Internationalization

Outstanding National Pharmaceutical Enterprises
Qilu, Hengrui, Fosun, Simcere, Tasley, Luye, SPH, Chia Tai Tanqing, Betta, Kanghong, 3S Bio

Clinical Medical Institutions
Peking Union Medical College Hospital, Beijing Tiantan Hospital

Innovative R&D Service Institutions
WuXi AppTec, Tigermed, dMed, ClinChoice, Jiuzhou, AmoyDx, Gentalker, Qlife, Highthink

Innovative R&D Enterprises

Research Institutes/Colleges and Universities
Shanghai Institute of Materia Medica of CAS, Institute of Materia Medica of CAMS, Westlake University

Financial/Investment Institutions
Ping An Bank, Hillhouse Capital, Qiming Ventures, Warburg Pincus, Yuanming Capital, Eli Lilly Asia, China Life Private Equity, Huagai...
Deeply Participate in International Cooperation

**PhIRDA**

### IFPMA
- RSC Meetings
- TF Kick-off Meetings
- Meetings on Codes of Ethics
- Regulatory Frameworks Meetings
- Preparatory and ATM of ICH Assembly

### APAC
- Meetings of SC Organizing Committee
- DA-EWG Meetings
- RA-EWG Meetings
- E-Labeling Meetings
- VBH EWG Meetings
- APAC Annual Conference

### Cooperation Conferences of Regional Organizations
- Hosted the “Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference”
- Participated in the ASEAN Market Expansion Conference of Chinese Biopharmaceutical Enterprises
- Participated in the “Belt and Road” Forum on Health Cooperation
- The 8th China Healthcare Summit and other international conferences on pharmaceutical innovation, investment and regulation
Actively Participate in the Reform of Drug Review and Approval in China

2016.02
The State Council issued the Opinions on the Reform of the Review & Approval System for Drugs and Medical Devices
Clarity aim of the reform, change the concept, point out the direction.

2017.06
China CFDA joined the ICH as a member
Integrate with global standard
Speed up review and approval
Promote drug R&D innovation

2019.06
Adoption of Vaccine Administration Law and the Drug Administration Law of the People’s Republic of China
Strengthen vaccine management guarantee the quality

2020.10
Patent Law of the People’s Republic of China
Clarify early resolution mechanism for drug patent term restoration

2021.6
China NMPA was re-elected as Member of the ICH Management Committee
Participate in drafting international rules, accelerate regulation globalization

2015.05
The State Council issued Made in China 2025
Biopharmaceutical industry becomes a pillar industry

2017.10
General Office issued the Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Drugs and Medical Devices Innovation
Deepen the reform of review and approval
Encourage innovation to promote industrial Restructuring and technical innovation

2018.06
General Office issued the Opinions on Deepening the Reform of the Medical Insurance System
Define direction for medical insurance reform
Make preparation for re-construction

2021.5
The General Office of the State Council issued the Implementation Opinions on Comprehensively Strengthening the Construction of Drug Regulatory Capacity
Learn from international rules, deepening the reform of review and approve

2021.12
The NRDL were released
Improve NDRL dynamic adjustment mechanism

2015.08
The State Council issued the Opinions on the Reform of the Review & Approval System for Drugs and Medical Devices
Clarify aim of the reform, change the concept, point out the direction.

More than 50 feedbacks and suggestions, submitted on:
• Deepening drug regulatory reform;
• Drug Review and Approval, clinical inspection, intellectual property protection, drug reimbursement policies, etc.
PhIRDA Building the Platform between Industry and Government Promoting the Localization and Implementation of ICH in China

As an association focusing on innovation, PhIRDA actively participated in the relevant work of Center for Drug Evaluation, NMPA, including:

Collect Comments & Propose Suggestions
• Provide comments and suggestions on guidelines translation, revisions and implementation opinions
• Covers 59 guidelines;

Organize Trainings & Seminars
• Organize/Participate 20+ ICH trainings and seminars in China

Conduct Feasibility Study
• Establish PhIRDA ICH working group, organize 92 representatives and draft ICH three-tiered guidelines implementation report

Participate Industry Internal Test
• Organize representatives from industry to participate in trial operation of eCTD
Professional Experts Committees

14 Special Committees

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<th>Drug R&amp;D</th>
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- Experts from various areas, covering the whole pharmaceutical innovation industry chain
- Gathered a large number of top leading experts in clinical, academic, industrial and investment fields
- Experts pay more attention and gave full support to PhIRDA's work
### Selection of Candidates - Clear requirements

- More than 10 years' working experience
- Specific to a certain field
- Participated in ICH guidelines drafting before
- Fluent in English
- Oversea drug regulatory experience is preferred

### Rich Expert Tank

- PhIRDA members are all top leading companies in China
- Experts in Special Committees covering whole industry chain
- ICH Working Group Communication System
- Targeted invitation and recommendation
Requirements of Candidates

Establish Normalized Expert Communication Mechanism

- Keep close contact with experts, track TF working progress
- Establish Experts’ WeChat group to share information in time
- Regularly organize ICH expert sharing seminar
- Follow international and latest regulatory trends and policies
- Organize seminar for members

Build communication platform, expand industrial influences

- Share information with members, raise awareness
- Liaise with NMPA, CDE on expert participation and policies
Seasoned Experts and Efficient Management Systems

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**Rich Expert Resources**
- Top clinical experts from special committees;
- Experts having experiences in advanced regulatory agencies;
- Experts from world famous MNCs

**Good Professional Moral and Dedication**
- Bilingual competence and innovative ideas in line with international standards;
- Devotion and all-out efforts & extra time;
- Faith to promote high-quality development of pharmaceutical industry, creating favorable innovation ecosystem

- According to previous experience, PhIRDA drafted an efficient and rigorous system for ICH expert recommendation and supplementation to selected the best candidate and minimize the impact of expert adjustment;
- Conduct Pre-employment training. Invite seasoned expert to share experience to newly recruited experts to start faster and more efficient
China’s Contribution to Pharmaceutical Innovation R&D Has Stepped into the Second Tier in Global Market

China’s Pharmaceutical Innovation Ranks Top in the 2nd Tier in Global Market in Terms of Numbers of Products in R&D Pipelines and Listed New Drugs

Data source: Pharmapros
Industry Development

The Proportion of MRCT has Gradually Increased Greatly Narrowing the “Time Difference” with Advanced Countries

Number of MRCT Added in 2015-2019

Number and Proportion of MRCT Initiated by Domestic Companies in 2015-2021

Data source: Frost & Sullivan, Tigermed's prospectus, and Pharmacodia
The Number and Proportion of New Drugs on the Market Broke Records

Number of new drugs on the market and proportion of domestic new drugs in 2017-2021

In the 1st Half of 2022, 6 Domestic Class 1 innovative drugs were launched.

Data sources: CDE’s review reports in recent years, Official website of NMPA, and data summarized by PhiRDA
China’s Innovative Capability Received International Recognition, Achieving more license-outs

In the past 7 years, number of license-in and license-out by pharmaceutical companies in China is increasing, involving more in global pharmaceutical trades.

Deeply Participate in ICH-related work in the Future

- Actively recommend high-quality and seasoned experts
- Actively participate in the international rulemaking, further promote implementation and transformation of ICH guidelines in China
- Strengthen international organization cooperation, organize ICH training and seminars
- To host the ICH Assembly in China, PhIRDA is volunteer to serve as organizer
- Share China's pharmaceutical regulatory and industrial achievements to the world
Thank you

Xiaoti Lu
luxt@phirda.com