



药促会微信公众号

**创新·产业化·国际化**

Innovation · Industrialization · Internationalization

## 中国医药创新促进会

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PhIRDA  
中国药促会

2021—2022

ASSOCIATION JOURNAL

协  
会  
会  
刊

# 中国医药 创新促进会

China Pharmaceutical Innovation and Research  
Development Association

◎搭建政府和产业沟通的桥梁

Build A Bridge Between  
Government & Industry

◎维护会员单位的合法权益

Safeguard Members'  
Legitimate Rights & Interests

◎提升中国医药产业国际竞争力

Enhance International Competitiveness  
of China's Pharmaceutical Industry





创新·产业化·国际化

Innovation · Industrialization · Internationalization



## 做有温度的创新，以科技驱动未来

2021年是中国医药产业加速转型升级、市场格局重构的一年，我国持续鼓励以临床需求为导向的药物创新，引领中国医药产业迎来最活跃、最快速发展的创新时代。与此同时，国外创新药大批涌入，国内生物科技公司如雨后春笋般不断涌现，市场竞争持续白热化、立体化。创新药高投入、高风险、长周期，不创新是死，创新慢了也是死。在当前的市场环境中，医药企业真正立稳脚跟、赢得先机、脱颖而出，以临床需求为导向的价值创造是重中之重，这也是时代的呼唤、历史的选择。

未来五年，中国加速由医药制造大国向医药创新强国迈进。中国医药创新真正驶入从“跟跑”向“并跑”“领跑”转变的快车道，需要国家持续强化基础研究投入，药品监管体系不断科学化、法治化、国际化，需要医药产业群体群策群力、合力高质量发展。

医药创新是医药企业的主体责任。药者慧心、药者匠心，我们以患者为亲人的同理心，研发更多优质、安全、高效的药品，帮助患者驱散病痛、服务健康，让患者的生活更有质量、更有尊严，因此医药创新一定是有温度、温暖的。

医药产业的发展也离不开与资本的良性互动、相互成就。中国医药创新促进会以“创新、产业化、国际化”为宗旨，“政产学研用资”紧密结合，不断扩大创新“朋友圈”，为患者谋健康，为产业谋发展。

非常高兴作为药促会年度会长，与大家一道共同探讨与资本良性互动的，更加高效、务实、扎实、前沿的中国医药创新研发之路。独行快、众行远，面向全球科技前沿、面向人民生命健康，让我们持续推动中国医药产业行稳致远、跨越发展，推动更多高品质药物上市，让有温度的科技创新驱动人类更加美好的未来！



## Innovate with Heart and Soul, Drive the Future with Science and Technology

The Year of 2021 witnessed the accelerated transformation and upgrading of the Chinese pharmaceutical industry as well as the remodeling of market structure, while clinical needs-oriented pharmaceutical innovation constantly boosted by the National Drug Regulatory System led to an innovation era which may be the most dynamic and rapidly developing to date. Meanwhile, with notable number of foreign novel drugs poured into the domestic market and domestic biotech companies spring up continuously, market competition has been constantly heating up and dimensionalized. Heavy investment, high risk and long development cycle of innovative drugs indicate a dead end would await if one refuses to innovate, or innovate with hesitation. In current market environment, it is the value creation guided by clinical needs that is of top priority of the pharmaceutical enterprises, which requires the enterprises to stand firmly, exceed competitors and finally standout in the market, this is not only the call of the times, but also the choice of history.

While the next 5 years would witness accelerated transformation of China from a major pharmaceutical manufacturing country to a leading pharmaceutical innovative force, as a country used to follow with advanced foreign counterparts, Chinese innovative pharmaceutical industry would be speeding up and catching up by gradually paralleling with the foreign industry and eventually be the leader in the global innovation system, which requires constant and intensified investment in fundamental research by the National Government, constant scientification, legalization and international of the drug regulatory system, as well as high quality development united, planned, organized and led by the pharmaceutical industry as a whole.

Pharmaceutical innovation is the primary responsibility of pharmaceutical enterprises, while such innovation has to be heart-warming and full of compassion, and to be achieved by developing more high quality, safe and efficient drug products and offering patients with more therapies to cure diseases and servicing public health, eventually making lives with better quality and more dignity possible for patients.

Development of the pharmaceutical industry is also inseparable from constructive interactions and mutual accomplishment with capital. With “Innovation, Industrialization and Internationalization” as its mission, PhIRDA integrates resources from government, industry, academia, research and capital together closely, so as to constantly build new connections and scout new opportunities for innovation, to eventually guard patients’ health and to boost industrial development.

As the annual president of PhIRDA, I am glad to explore a more efficient, pragmatic, solid yet advanced pathway for Chinese innovative pharmaceutical development together with you. As an old saying goes, if one wants to go fast, walk alone, if one wants to go far, walk together with others, with purposes of being on top of the global scientific peak and guarding the people’s health, let’s keep promoting sustainable growth and leaping development of the Chinese Pharmaceutical Industry by delivering more high quality drugs to the market, and driving better future for the human being through science and technology with heart and soul!

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## 中国医药创新促进会简介

中国医药创新促进会(原名“中国医药工业科研开发促进会”,简称“中国药促会”),英文名称:China Pharmaceutical Innovation and Research Development Association (PhIRDA),成立于1988年,是经国家民政部登记注册的非营利性全国性4A级社会组织。

中国药促会秉承“创新、产业化、国际化”的宗旨,以临床需求为导向,长期致力于“产学研用资”紧密结合,促进医药行业创新发展,已经成为集医药创新研发型企业、科研机构、临床研究机构、创新服务机构和医药投资机构所组成的医药创新产业化促进平台,目前有会员单位167家。中国药促会已成立了药物研发、药物临床试验研究、医药政策、医药创新投资、创新研发服务、心血管药物临床研究、国际创新药物监管、抗肿瘤药物临床研究、脑神经药物临床研究、医药企业合规、糖尿病与代谢性疾病药物临床研究专业委员会,形成了以创新为核心,以促进创新为目的的涵盖药物研发、生产、使用以及投融资的全链条组织架构,并作为国际药品制造商协会联合会(IFPMA)的成员继续拓展国际交流渠道。

中国药促会工作内容主要包括:一是,开展医药政策研究,为我国医改事业、完善药物政策和医药产业发展建言献策;二是,通过举办各种论坛、发布会、大型会议等活动,促进会员单位乃至整个医药产业的相互交流、创新发展;三是,通过与国内外医药行业协会、企业、科研机构和外国驻华使馆合作,推动国际医药产业的多方位、多维度合作交流,为会员单位搭建国际交流平台;四是,践行国家创新驱动发展战略指导精神,为会员单位拓宽医药创新投融资渠道、搭建合作平台,推动社会资本加大对初创及研发型企业自主创新项目的投入,营造更有吸引力的医药创新投资环境;五是,为会员单位提供医药信息搜集、整理、评价服务,包括编辑每日《医药信息简报》、每周《国际医药产业发展动态与研发信息简报》等内部电子刊物以及中国药促会官方网站、微信公众号等服务平台。

中国药促会将围绕办会宗旨,不断拓展服务内涵和外延,做好政府与会员企业的桥梁和纽带,维护会员合法权益,加强行业自律,推动我国医药产业的创新和可持续发展,为加快我国经济社会发展、保障人民群众健康不断做出贡献!



## Brief Introduction of PhIRDA

Founded in 1988, China Pharmaceutical Innovation and Research Development Association (PhIRDA), formerly named China Pharmaceutical Industry Research and Development Association, is registered as a non-profit 4A social organization by the Ministry of Civil Affairs of China at national level.

PhIRDA has been exerting great effort on “academia-industry-investment collaboration”, which centers on the principle of “innovation, industrialization, internationalization”, and persists in innovation to achieve unmet clinical requirements. As a platform facilitating the industrialization of pharmaceutical innovation, PhIRDA currently has 167 members mainly consists of pharmaceutical R&D enterprises, research institutions, clinical institutions, R&D Services companies and investment institutions focusing on pharmaceutical innovation. Moreover, PhIRDA has established the following Specialty Committees: Drug R&D, Clinical Trial Research, Medicinal Policy, Pharmaceutical Innovation Investment and Innovation R&D Services, Clinical Research on Cardiovascular Drugs, International Regulatory Science, Clinical Research on Oncology Drugs, Clinical Research on Cranial Nerve Drugs, Ethics and Business Compliance, Clinical Research on Diabetes and Metabolic Diseases, forming a fully functional organization structure focusing on innovation, aiming to promote the development of innovation, covering the whole industrial chain, including drug R&D, manufacturing, using, investment and capital market. PhIRDA is also a member of International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) to continuously broaden channels of international collaboration.

Major work of PhIRDA includes: first, to conduct policy researches, propose valuable suggestions on healthcare reform and the development of pharmaceutical industry; second, to promote communication and innovative development of our members and even the whole pharmaceutical industry through forums, press-conferences, summits, etc.; third, to make efforts to establish an international exchange platform for our members through cooperation with foreign embassies and foreign associations to stimulate comprehensive communication between China and foreign countries in pharmaceutical field; fourth, to practice the guiding spirits of national innovation-driven development strategy, to broaden the investment and financing channels of pharmaceutical innovation, to build the cooperation platform for our members, and to promote social capitals to pay more attention on investment in innovative projects of start-up and R&D enterprises to create a more attractive environment of pharmaceutical innovation and investment; fifth, to improve the website and WeChat official account of PhIRDA and provide collecting, arranging, revising service of pharmaceutical information, which includes the following internal e-magazines such as the daily *Pharmaceutical Information Brief*, the weekly *International Pharmaceutical Development Tendency and Research Information Brief*.

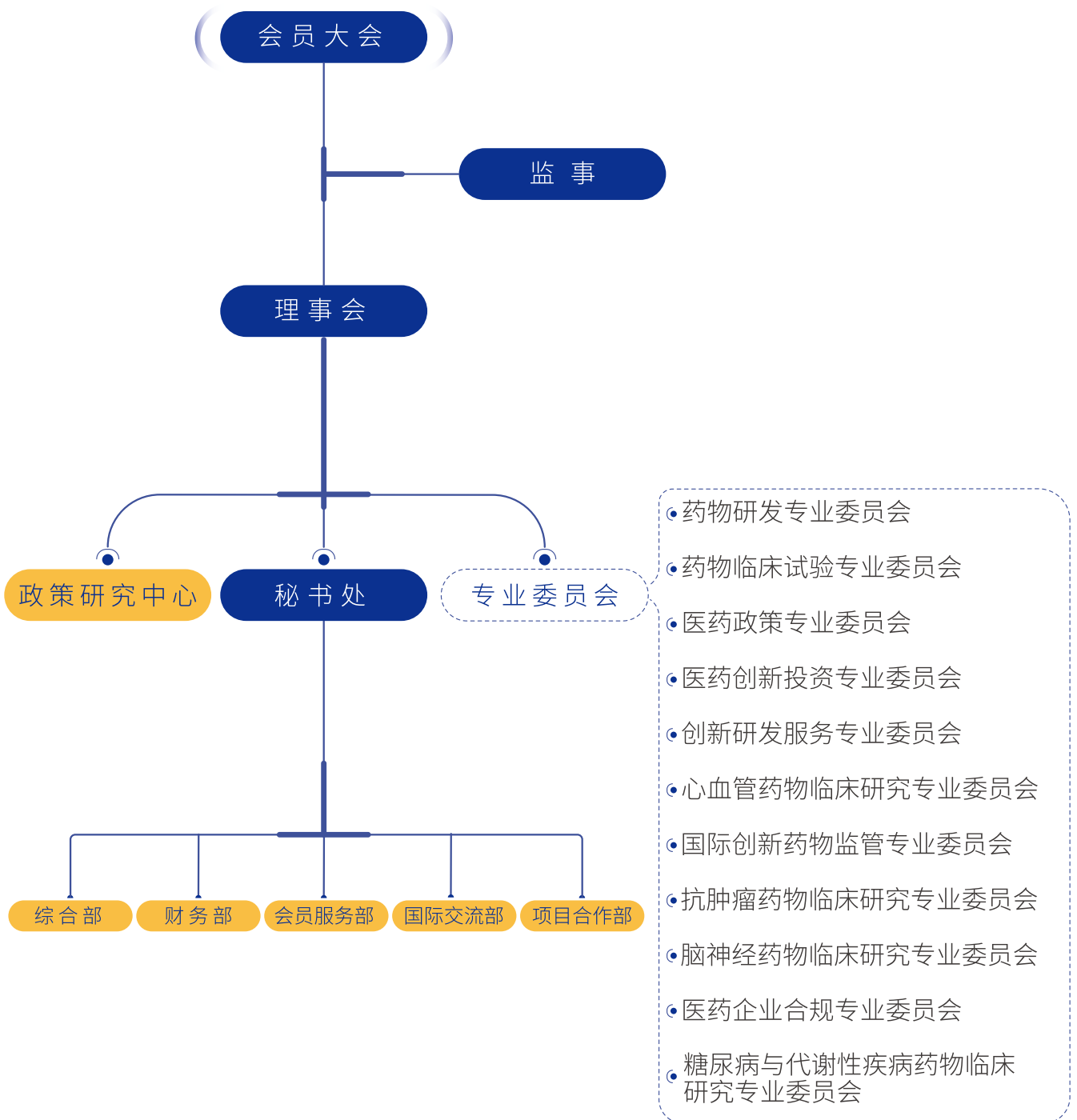
PhIRDA will center on our principle, continuously expand services, build a bridge between the government and our members, maintain legitimate rights and interests of members, strengthen self-discipline, promote healthy development of Chinese pharmaceutical industry, making constant contributions to the greater economic development of the country and public health.



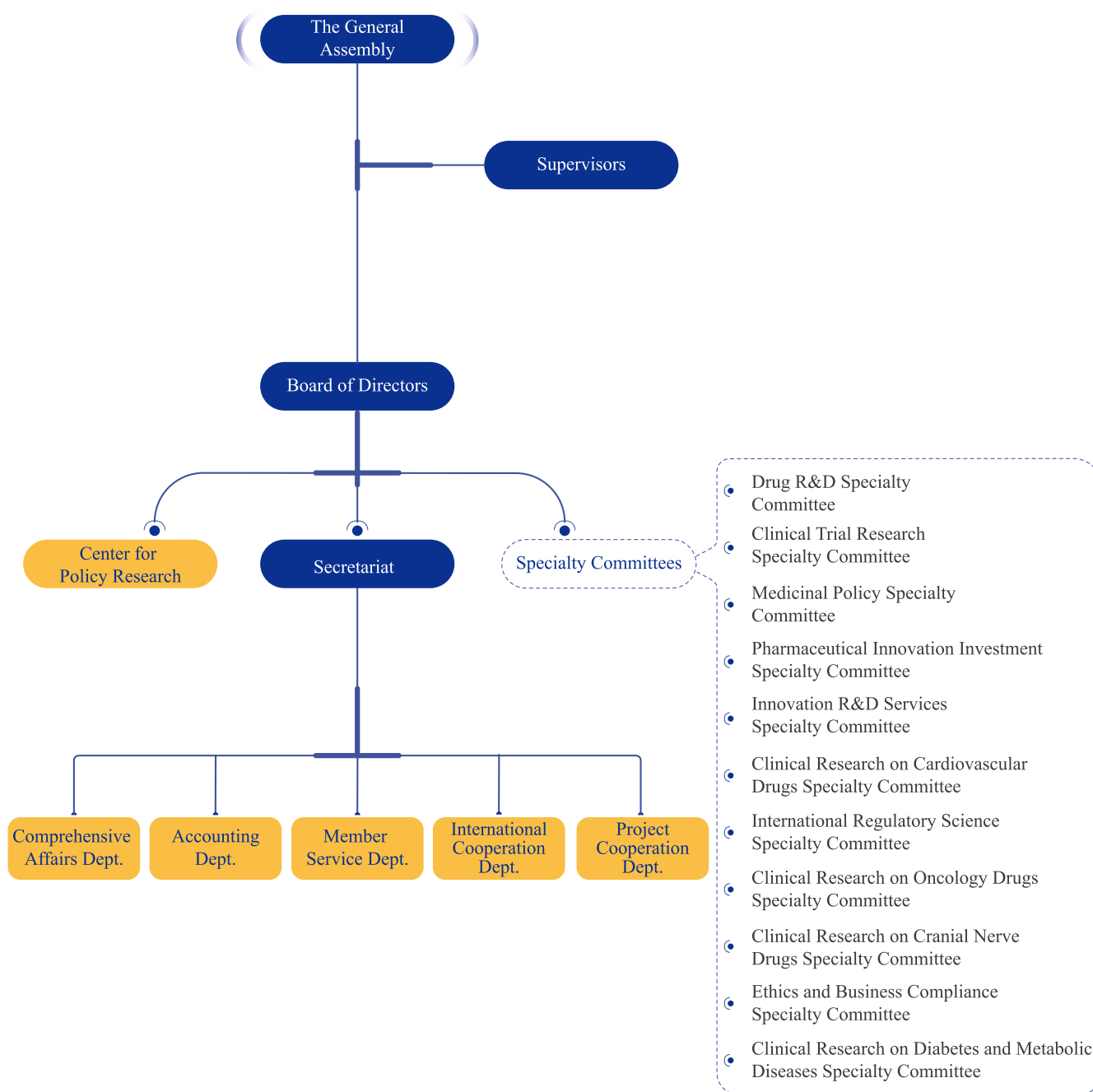




## 机构设置



## Organizational Structure of PhIRDA



## 中国医药创新促进会医药创新科学委员会专家名单

### Expert List of PhIRDA Pharmaceutical Innovation Scientific Committee



**桑国卫 荣誉主任**  
中国工程院院士

Honorary Chairman, Sang Guowei  
Academician of Chinese Academy of Engineering



**陈凯先 主任**  
中国科学院院士

Chairman, Chen Kaixian  
Academician of Chinese Academy of Sciences



**曹雪涛 委员**  
中国工程院院士

Member, Cao Xuetao  
Academician of Chinese Academy of Engineering



**蒋华良 委员**  
中国科学院院士

Member, Jiang Hualiang  
Academician of Chinese Academy of Sciences



**丁 健 委员**  
中国工程院院士  
发展中国家科学院院士

Member, Ding Jian  
Academician of Chinese Academy of Engineering,  
Academician of The World Academy of Sciences



**王广基 委员**  
中国工程院院士

Member, Wang Guangji  
Academician of Chinese Academy of Engineering



**葛均波 委员**  
中国科学院院士

Member, Ge Junbo  
Academician of Chinese Academy of  
Sciences



**魏于全 委员**  
中国科学院院士

Member, Wei Yuquan  
Academician of Chinese Academy  
of Sciences



**裴 钢 委员**  
中国科学院院士  
发展中国家科学院院士

Member, Pei Gang  
Academician of Chinese Academy of  
Sciences  
Academician of The World Academy  
of Sciences



**程 京 委员**  
中国工程院院士

Member, Cheng Jing  
Academician of Chinese Academy of  
Engineering



**王晓东 委员**  
中国科学院外籍院士

Member, Wang Xiaodong  
Foreign Academician of  
Chinese Academy of Sciences



**王松灵 委员**  
中国科学院院士

Member, Wang Songling  
Academician of Chinese Academy  
of Sciences





**丁文江 委员**  
中国工程院院士

Member, Ding Wenjiang  
Academician of Chinese Academy of  
Engineering



**岳建民 委员**  
中国科学院院士

Member, Yue Jianmin  
Academician of Chinese  
Academy of Sciences



**樊 嘉 委员**  
中国科学院院士

Member, Fan Jia  
Academician of Chinese Academy  
of Sciences



**王 锐 委员**  
中国工程院院士

Member, Wang Rui  
Academician of Chinese  
Academy of Engineering



**李校堃 委员**  
中国工程院院士

Member, Li Xiaokun  
Academician of Chinese Academy of  
Engineering

# 领导介绍

>> Introduction  
of Leadership



## 会领导介绍

### Introduction of PhIRDA Leadership

#### 第九届会员大会以来历任会长

#### Chairman of PhIRDA Since the 9<sup>th</sup> General Assembly



##### 桑国卫

中国药促会会长（2009-2012）  
中国药促会荣誉会长（2012-2014）  
十一届全国人大常委会副委员长  
中国工程院院士

##### Sang Guowei

Chairman of PhIRDA (2009-2012) Honorary Chairman of PhIRDA (2012-2014)  
Vice Chairman of the Standing Committee of Eleventh National People's Congress  
Academician of Chinese Academy of Engineering



##### 陈启宇

2012-2013年度会长  
复星国际执行董事兼联席首席执行官  
复星医药董事

##### Chen Qiyu

Annual Chairman 2012-2013  
Executive Director & Co-CEO  
of Fosun International  
Director of Fosun Pharma



##### 闫希军

2013-2014年度会长  
天士力创始人  
天士力控股集团董事局终身荣誉主席  
天士力大健康产业投资集团董事长

##### Yan Xijun

Annual Chairman 2013-2014  
Founder of Tasly, Permanent Honorary  
Chairman of Tasly Holding Group  
Chairman of Tasly Great Health  
Industrial Investment Group



##### 孙飘扬

2014-2015年度会长  
江苏恒瑞医药股份有限公司董事长

##### Sun Piaoyang

Annual Chairman 2014-2015  
Chairman of the Board, Jiangsu  
Hengrui Medicine Co., Ltd.



##### 蒋华良

2015-2016年度会长  
中国科学院院士  
中国科学院上海药物研究所研究员

##### Jiang Hualiang

Annual Chairman 2015-2016  
Academician, Chinese Academy of  
Sciences  
Researcher, Shanghai Institute of  
Materia Medica, Chinese Academy of  
Sciences



**丁列明**

2016-2017年度会长  
贝达药业股份有限公司  
董事长兼CEO

**Ding Lieming**

Annual Chairman 2016-2017  
Chairman of the Board & CEO, Betta  
Pharmaceutical Co., Ltd.



**蒋建东**

2017-2018年度会长  
中国工程院院士  
中国医学科学院药物研究院院长

**Jiang Jiandong**

Annual Chairman 2017-2018  
Academician, Chinese Academy of  
Engineering  
Director, Institute of Pharmaceutical  
Science, Chinese Academy of Medical  
Sciences



**刘殿波**

2018-2019年度会长  
绿叶生命科学集团董事局主席

**Liu Dianbo**

Annual Chairman 2018-2019  
Chairman of the Board, Luye Life  
Sciences Group



**宋瑞霖**

2019-2020年度会长  
中国医药创新促进会

**Song Ruilin**

Annual Chairman 2019-2020  
China Pharmaceutical Innovation and  
Research Development Association



**任晋生**

2020-2021年度会长  
先声药业有限公司董事长

**Ren Jinsheng**

Annual Chairman 2020-2021  
Chairman of the Board, Sincere  
Pharmaceutical Group



## 现任会领导 Current Leadership of PhIRDA



### 李 燕 会长

齐鲁制药集团有限公司总裁

Li Yan, Chairman  
President, Qilu Pharmaceutical Group  
Co., Ltd.



### 宋瑞霖 执行会长

中国医药创新促进会

Song Ruilin, Executive President  
China Pharmaceutical Innovation and  
Research Development Association



### 李 佳 副会长

中国科学院上海药物研究所所长

Li Jia, Vice President  
Director, Shanghai Institute of  
Materia Medica, Chinese Academy of  
Sciences



### 陈启宇 副会长

复星国际执行董事兼联席首席执行官  
复星医药董事

Chen Qiyu, Vice President  
Executive Director & Co-CEO  
Fosun International  
Director of Fosun Pharma



### 孙飘扬 副会长

江苏恒瑞医药股份有限公司董事长

Sun Piaoyang, Vice President  
Chairman of the Board, Jiangsu  
Hengrui Medicine Co., Ltd.



### 丁列明 副会长

贝达药业股份有限公司  
董事长兼CEO

Ding Lieming, Vice President  
Chairman of the Board & CEO, Beta  
Pharmaceutical Co., Ltd.



### 蒋建东 副会长

中国工程院院士  
中国医学科学院药物研究院院长

Jiang Jiandong, Vice President  
Academician of Chinese Academy of  
Engineering  
Director of Institute of Pharmaceutical  
Science, Chinese Academy of  
Medical Sciences



### 刘殿波 副会长

绿叶生命科学集团董事局主席

Liu Dianbo, Vice President  
Chairman of the Board, Luye Life  
Sciences Group



**任晋生 副会长**  
先声药业有限公司董事长  
  
Ren Jinsheng, Vice President  
Chairman of the Board, Simcere  
Pharmaceutical Group



**柯尊洪 副会长**  
成都康弘药业集团股份有限公司  
董事长  
  
Ke Zunhong, Vice President  
Chairman of the Board, Chengdu  
Kanghong Pharmaceutical Group  
Co., Ltd.



**闫凯境 副会长**  
天士力医药集团股份有限公司  
董事长  
  
Yan Kaijing, Vice President  
Chairman of the Board, Tasly  
Pharmaceutical Group Co., Ltd.



**赵 勇 副会长**  
上海医药党委副书记、副总裁  
  
Zhao Yong, Vice President  
Deputy Secretary of the Party Committee  
& Vice President, SPH



**张抒扬 副会长**  
北京协和医院院长  
中国医学科学院北京协和医学院  
副院校长  
  
Zhang Shuyang, Vice President  
President, Peking Union Medical  
College Hospital  
Vice President of Chinese Academy  
of Medical Sciences & Peking Union  
Medical College



**吴晓滨 副会长**  
百济神州总裁  
  
Wu Xiaobin, Vice President  
President, BeiGene Ltd.



**冯 岚 秘书长**  
中国医药创新促进会  
  
Feng Lan, Secretary-General  
China Pharmaceutical Innovation and  
Research Development Association

## 专业委员会介绍

根据工作需要,经中国医药创新促进会会员大会或理事会审议通过,批准成立药物研发、药物临床试验、医药政策、医药创新投资、创新研发服务、国际创新药物监管、医药企业合规、心血管药物临床研究、脑神经药物临床研究、抗肿瘤药物临床研究、糖尿病与代谢性疾病药物临床研究专业委员会。

药物研发专业委员会旨在通过强化药物研发交流,促进会员单位创新研发能力的提升;参与ICH及国内外相关技术指南修订,为促进行业药物研发规范性及与国际接轨提出意见和建议。

心血管药物、脑神经药物、抗肿瘤药物、药物临床试验以及糖尿病与代谢性疾病药物临床研究专业委员会旨在通过推动创新药物研发及临床研究,促进我国相关领域研究能力与水平提升。

医药政策专业委员会旨在研究国内外医药政策领域理论与实践问题,为政府相关部门提供决策参考。

医药创新投资专业委员会旨在促进创新主体与投资界的密切合作,提升医药创新的效率和效益,营造包容开放的医药创新投资环境。

创新研发服务专业委员会旨在通过为国内外企业提供符合国际标准的新药研发服务,形成具有国际竞争力的新药研发核心服务商集群,助力创新成果转化。

国际创新药物监管专业委员会旨在协助政府有关部门进一步完善我国药品监管体系,进一步提高我国医药企业的国际竞争力,推动我国医药产业整体转型升级和创新发展。

医药企业合规专业委员会旨在推动我国医药企业合规体系建设,强化企业风险与合规意识,促进我国医药行业健康发展。

各专业委员会允许吸纳相关专家以个人身份加入,在政策、技术创新、临床研究、投融资及研发服务等方面提供指导与咨询,为会员单位开展创新活动提供切实服务。



## Introduction of Specialty Committees

According to PhIRDA General Assembly and Council Meetings, China Pharmaceutical Innovation and Research Development Association (PhIRDA) approved the establishment of the following Specialty Committees: Drug R&D, Clinical Trial Research, Medicinal Policy, Pharmaceutical Innovation Investment and Innovation R&D Services, Clinical Research on Cardiovascular Drugs, International Regulatory Science, Clinical Research on Oncology Drugs, Clinical Research on Cranial Nerve Drugs, Ethics and Business Compliance, Clinical Research on Diabetes and Metabolic Diseases.

Drug R&D Specialty Committee aims to promote the innovation and research ability of PhIRDA member through strengthening the communication of drug R&D; participate in the revision of domestic and foreign ICH guidelines and related technical documents, and put forward suggestions for further standardizing drug R&D and harmonization.

Clinical Research on Cardiovascular Drugs, Cranial Nerve Drugs, Oncology Drugs, Diabetes and Metabolic Diseases Specialty Committees, and Clinical Trial Research Specialty Committee, aim to promote the relevant abilities by enhancing the research on innovative drug R&D and clinical trial.

Medicinal Policy Specialty Committee aims to research on domestic and foreign medical and pharmaceutical policies theoretically and practical, aims to provide guidance and suggestions to government ministries and departments for their decision making.

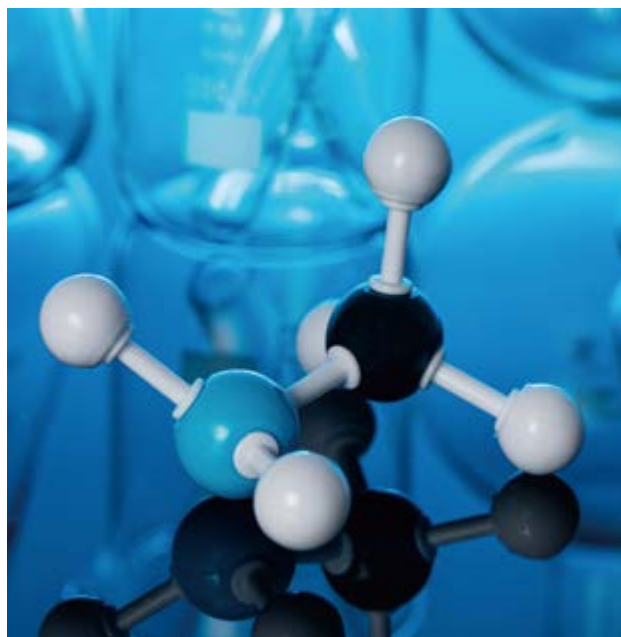
Pharmaceutical Innovation Investment Specialty Committee aims to stimulate the close cooperation between investment institutions and innovators, enhance the efficiency and effectiveness of innovation, and build an open environment for medical and pharmaceutical investment.

Innovation R&D Services Specialty Committee aims to providing service for innovative drug R&D with international standardization, to create an international competitive new drug R&D service group, to enhance the transfer of innovation achievements.

International Regulatory Science Specialty Committee aims to assist government departments to further improve China's drug administration system, level up the international competitiveness of Chinese pharmaceutical enterprises, and promote the overall transformation, upgrading and innovative development of pharmaceutical industry in China.

Ethics and Business Compliance Specialty Committee aims to promote compliance system of China's pharmaceutical enterprises, raise the awareness of risk management and compliance, and promote the healthy ecosystem of Chinese pharmaceutical industry.

All specialty committees allow related experts to join personally and provide guidance and consultation on policies, technological innovation, clinical research, investment and financing, and R&D service to provide practical services to PhIRDA members.



## 第三届药物研发专业委员会 The 3<sup>rd</sup> Drug R&D Specialty Committee



**杨大俊 主任委员**

亚盛医药董事长兼CEO

**Chairman, Yang Dajun**  
Chairman of the Board & CEO of  
Ascentage Pharma Group Corp., Ltd.



**鲁先平 副主任委员**

深圳微芯生物科技股份有限公司  
董事长、总裁

**Vice-Chairman, Lu Xianping**  
Chairman of the Board & President  
of Shenzhen Chipscreen Biosciences  
Co., Ltd.



**俞德超 副主任委员**

信达生物制药（苏州）有限公司  
董事长兼总裁

**Vice-Chairman, Yu Dechao**  
Chairman of the Board & President of  
Innovent Biologics (Suzhou) Co., Ltd.



**王印祥 副主任委员**

北京加科思新药研发有限公司  
董事长兼CEO

**Vice-Chairman, Wang Yinxiang**  
Chairman of the Board & CEO  
of Beijing Jacobio Pharma Co.,  
Ltd.



**房健民 副主任委员**

荣昌生物制药（烟台）有限公司  
总经理兼首席科学官

**Vice-Chairman, Fang Jianmin**  
General Manager & Chief Scientist  
Officer of RemeGen, Ltd.



**陈 力 副主任委员**

华领医药技术（上海）有限公司  
创始人、董事长、首席执行官

**Vice-Chairman, Chen Li**  
Founder, Chairman of the Board &  
CEO of Hua Medicine (Shanghai) Ltd.





**张 丹 副主任委员**

昆翎医药联合创始人  
兼首席战略官

**Vice-Chairman, Zhang Dan**  
Co-founder and Chief Strategy  
Officer of ClinChoice Inc.



**王晓良 副主任委员**

中国医学科学院药物研究院副院长

**Vice-Chairman, Wang Xiaoliang**  
Associate Director of Pharmaceutical  
Institute, Chinese Academy of  
Medical Sciences



**薛 群 副主任委员**

北海康成制药有限公司  
董事长及首席执行官

**Vice-Chairman, Xue Qun**  
Chairman & CEO of CANbridge  
Pharmaceuticals Inc.



**阎水忠 副主任委员**

再鼎医药（上海）有限公司  
首席运营官，研究及开发

**Vice-Chairman, Yan Shuizhong**  
COO, R&D of Zai Lab



**任 进 副主任委员**

中国科学院上海药物研究所药物  
安全评价研究中心主任、研究员

**Vice-Chairman, Ren Jin**  
Professor & Director of Center for  
Drug Safety Evaluation and Research,  
Shanghai Institute of Materia Medica,  
Chinese Academy of Sciences



**彭少平 秘书长**

先声药业南京研究院副院长

**Secretary-General, Peng Shaoping**  
Vice President of Sincere R&D  
Center in NanJing





## 第三届药物临床试验专业委员会

### The 3<sup>rd</sup> Clinical Trial Research Specialty Committee



#### 崔一民 主任委员

北京大学临床药理研究所所长

Chairman, Cui Yimin

Director of Institute of Clinical Pharmacology, Peking University



#### 王兴河 副主任委员

首都医科大学附属北京世纪坛医院  
药物I期临床试验研究室主任

Vice-Chairman, Wang Xinghe

Director of Phase I Clinical Trial Center, Beijing Shijitan Hospital, Capital Medical University



#### 李海燕 副主任委员

北京大学第三医院  
药物临床试验机构主任

Vice-Chairman, Li Haiyan

Director of Clinical Research Center, Peking University Third Hospital



#### 李可欣 副主任委员

原北京医院临床试验研究中心主任

Vice-Chairman, Li Kexin

Former Director of Clinical Trial Center, Beijing Hospital



#### 胡 蓓 副主任委员

北京协和医院创新药临床药代药效  
研究北京市重点实验室主任

Vice-Chairman, Hu Bei

Director of Beijing Key Laboratory of Clinical Pharmacokinetics and Pharmacodynamics of Innovative Drugs, Peking Union Medical College Hospital



#### 郭 彤 副主任委员

零氮科技（北京）有限公司  
执行副总裁

Vice-Chairman, Guo Tong

Executive Vice President, LinkDoc Technology (Beijing) Co., Ltd.



#### 阳国平 秘书长

中南大学湘雅三医院  
临床药理中心主任

Secretary-General, Yang Guoping

Director of Center of Clinical Pharmacology, Third Xiangya Hospital of Central South University

## 第三届医药政策专业委员会 The 3<sup>rd</sup> Medicinal Policy Specialty Committee



### 胡善联 名誉主任委员

复旦大学公共卫生学院  
卫生经济学教授

Honorary Chairman, Hu Shanlian  
Professor of Health Economics,  
School of Public Health, Fudan  
University



### 胡 欣 主任委员

北京医院药学部主任药师  
首席专家

Chairman, Hu Xin  
Chief pharmacist & Chief Expert of  
Beijing Hospital



### 刘军帅 副主任委员

国家罕见病诊疗与保障专家  
委员会委员

Vice-Chairman, Liu Junshuai  
Committee Member of National  
Expert Consultation Committee of  
Diagnosis and Treatment of Rare  
Disease



### 邵 蓉 副主任委员

中国药科大学教授  
国家药物政策与医药产业  
经济研究中心执行副主任

Vice-Chairman, Shao Rong  
Professor & Vice Executive  
Director of the Research Center of  
National Drug Policy & Ecosystem  
of China Pharmaceutical University



### 宣建伟 副主任委员

中山大学医药经济研究所所长

Vice-Chairman, Xuan Jianwei  
Director of Institute of Medicine and  
Economics, Sun Yat-Sen University



### 武志昂 副主任委员

沈阳药科大学亦弘商学院院长

Vice-Chairman, Wu Zhi'ang  
Dean of Yechong Business School ,  
Shenyang Pharmaceutical University



### 赵 琨 副主任委员

国家卫生健康委药物与卫生  
技术评估中心副主任

Vice-Chairman, Zhao Kun  
Deputy Director of Division of Health  
Policy Evaluation and Technology  
Assessment of the National Health  
Development Research Center



### 王晓玲 副主任委员

首都医科大学附属北京儿童医院  
药学部主任

Vice-Chairman, Wang Xiaoling  
Director of Department of Pharmacy,  
Beijing Children's Hospital, Capital  
Medical University



**梅 丹 副主任委员**

中国医学科学院北京协和医院  
主任药师

**Vice-Chairman, Mei Dan**

Chief Pharmacist of  
Pharmacy, Peking Union Medical  
College Hospital



**冯婉玉 副主任委员**

北京大学人民医院原药剂科主任

**Vice-Chairman, Feng Wanyu**

Former Director of Department  
of Pharmacy, Peking University  
People's Hospital



**赵志刚 副主任委员**

首都医科大学附属北京天坛医院  
药学部主任

**Vice-Chairman, Zhao Zhigang**

Director of Department of  
Pharmacy, Beijing Tian Tan Hospital,  
Capital Medical University



**冯 毅 副主任委员**

四川科伦药业股份有限公司  
研发副总裁兼首席战略官

**Vice-Chairman, Feng Yi**

Vice President of R&D & Chief  
Strategy Officer of Sichuan Kelun  
Pharmaceutical Co., Ltd.



**王 峰 秘书长**

先声药业有限公司  
党委书记兼副总裁

**Secretary-General, Wang Feng**

Secretary of Party Committee & Vice  
President of Sincere Pharmaceutical  
Group

### 第三届医药创新投资专业委员会

#### The 3<sup>rd</sup> Pharmaceutical Innovation Investment Specialty Committee



**蔡达建 主任委员**

高特佳投资集团  
创始人、原董事长

Chairman, Cai Dajian  
Founder & Former Chairman,  
GTJA Investment Group



**田 源 副主任委员**

元明资本创始合伙人

Vice-Chairman, Tian Yuan  
Founding Partner of Yuanming  
Capital



**杜 莹 副主任委员**

再鼎医药董事长兼首席执行官

Vice-Chairman, Du Ying  
Chairman of the Board & CEO, Zai  
Lab



**李凯军 副主任委员**

醴泽资本管理合伙人

Vice-Chairman, Li Kaijun  
Managing Partner of LYZZ Capital



**朱晋桥 副主任委员**

倚锋资本董事长

Vice-Chairman, Zhu Jinqiao  
Chairman of EFung Capital



**陈鹏辉 副主任委员**

博远资本创始合伙人

Vice-Chairman, Chen Penghui  
Founding Partner of Biotrack Capital



**梁颖宇 副主任委员**

启明创投主管合伙人

Vice-Chairman, Liang Yingyu  
Managing Partner of Qiming Venture  
Partners



**易诺青 副主任委员**

高瓴资本联席首席投资官、合伙人

Vice-Chairman, Yi Nuoqing  
Co-CIO and Partner, Hillhouse Capital



**储慧斌 副主任委员**

海捷投资控股集团首席合伙人

Vice-Chairman, Chu Huibin  
Chief Partner of Hiyield Capital  
Holding Group



**陆潇波 副主任委员**

红杉资本中国基金医疗合伙人

Vice-Chairman, Lu Xiaobo  
Partner of Sequoia Capital China



**余世新 副主任委员**

招商局健康产业控股有限公司  
总经理

Vice-Chairman, Yu Shixin  
General Manager, China Merchants  
Health Care Holdings Co., Ltd.



**王晓滨 副主任委员**

宝石花医疗健康投资控股集团  
有限公司副董事长

Vice-Chairman, Wang Xiaobin  
Vice Chairman of Gem Flower  
Healthcare Investment Holding  
Group Co., Ltd.



**方 敏 副主任委员**

华平投资合伙人  
中国医疗健康投资负责人

Vice-Chairman, Fang Min  
Managing Director & Head of  
Healthcare Investment, Warburg  
Pincus



**胡雪峰 秘书长**

南京和润资本董事长

Secretary-General, Hu Xuefeng  
Chairman, Nanjing Herun Capital



## 第二届创新研发服务专业委员会

### The 2<sup>nd</sup> Innovation R&D Services Specialty Committee



**闻丹忆 主任委员**

上海立迪生物技术股份有限公司  
董事长兼执行总裁

Chairman, Wen Danyi  
Chairman of the Board & CEO,  
Shanghai LIDE Biotech Co., Ltd.



**甄 岭 副主任委员**

昆翎医药全球董事长兼首席执行官

Vice-Chairman, Zhen Ling  
Global Chairman & CEO of  
ClinChoice Inc.



**宋青春 副主任委员**

北京春天医药科技发展有限公司  
创始人兼总经理

Vice-Chairman, Song Qingchun  
Founder & General  
Manager of Proswell Medical Co.,  
Ltd.



**王 斌 副主任委员**

浙江九洲药业股份有限公司  
高级副总裁

Vice-Chairman, Wang Bin  
Senior Vice President of Zhejiang  
Jiuzhou Pharmaceutical Co., Ltd.



**李 明 副主任委员**

滬港中科国际生物科技有限公司  
首席执行官

Vice-Chairman, Li Ming  
CEO of ZSHK Laboratories Co., Ltd.



**马 健 副主任委员**

深圳晶泰科技有限公司首席执行官

Vice-Chairman, Ma Jian  
CEO of XtalPi Inc.



**刘 熠 秘书长**

缔脉生物高级副总裁  
首席医学官

Secretary-General, Liu Yi  
Senior Vice President & CMO, dMed  
Biopharmaceutical Co., Ltd.

## 第一届心血管药物临床研究专业委员会

### The 1<sup>st</sup> Clinical Research on Cardiovascular Drugs Specialty Committee



#### 葛均波 名誉主任委员

中国科学院院士  
上海复旦大学附属中山医院  
心内科主任

Honorary Chairman, Ge Junbo  
Academician of Chinese Academy of Sciences  
Director of Cardiology Department,  
Zhongshan Hospital Fudan University



#### 霍勇 主任委员

北京大学第一医院心内科教授

Chairman, Huo Yong  
Professor of Cardiology Department,  
Peking University First Hospital



#### 袁祖贻 副主任委员

西安交通大学第一附属医院  
心血管病医院院长

Vice-Chairman, Yuan Zuyi  
Director of Institute of Cardiology,  
the First Affiliated Hospital of Xi'an  
Jiaotong University



#### 陈纪言 副主任委员

广东省人民医院心内科主任

Vice-Chairman, Chen Jiyan  
Director of Cardiology Department,  
Guangdong Provincial People's  
Hospital



#### 周玉杰 副主任委员

首都医科大学附属北京安贞医院常  
务副院长, 北京心肺血管疾病研究  
所常务副所长

Vice-Chairman, Zhou Yujie  
Executive President of Beijing  
Anzhen Hospital, Capital Medical  
University; Executive President,  
Beijing Institute of Heart, Lung,  
Blood Vessel Disease



#### 荆志成 副主任委员

北京协和医院心内科主任

Vice-Chairman, Jing Zhicheng  
Director of Cardiology Department,  
Peking Union Medical College Hospital



#### 耿美玉 副主任委员

中国科学院上海药物研究所  
学术所长、研究员

Vice-Chairman, Geng Meiyu  
Principal Investigator & Academic  
Director General of Shanghai Institute  
of Materia Medica, Chinese Academy  
of Sciences



#### 傅向华 副主任委员

河北医科大学第二医院  
心血管内科首席专家

Vice-Chairman, Fu Xianghua  
Chief Expert of Cardiology  
Department, the Second Hospital of  
HeBei Medical University



#### 周达新 副主任委员

上海复旦大学附属中山医院  
心内科副主任

Vice-Chairman, Zhou Daxin  
Deputy Director of Cardiology  
Department, Zhongshan Hospital  
Fudan University



#### 高晓丽 秘书长

华北石油管理局总医院  
心血管内科主任

Secretary-General, Gao Xiaoli  
Director of Cardiology Department,  
Huabei Petroleum Administration  
Bureau General Hospital

## 第一届国际创新药物监管专业委员会

### The 1<sup>st</sup> International Regulatory Science Specialty Committee



#### 何如意 主任委员

荣昌生物首席医学官、国投创新医疗健康首席科学家、前国家食品药品监督管理局药品审评中心首席科学家

**Chairman, He Ruyi**  
CMO of RemeGen  
CMO of SDIC  
Former Chief Scientist of Center for Drug Evaluation, CFDA



#### 陈少羽 副主任委员

美国安诺波特律师事务所驻上海代表处管理合伙人

**Vice-Chairman, Chen Shaoyu**  
Managing Partner of Arnold & Porter LLP Shanghai Rep. Office



#### 杜涛 副主任委员

深圳埃格林医药有限公司董事长

**Vice-Chairman, Du Tao**  
Chairman of Shenzhen Evergreen Therapeutics Co., Ltd.



#### 杜新 副主任委员

深圳埃格林医药有限公司首席执行官

**Vice-Chairman, Du Xin**  
CEO of Shenzhen Evergreen Therapeutics Co., Ltd.



#### 李 宁 副主任委员

上海君实生物首席执行官

**Vice-Chairman, Li Ning**  
CEO of Shanghai Junshi Biosciences Co., Ltd.



#### 赵孝斌 副主任委员兼秘书长

浙江海昶生物医药有限公司总裁

**Vice-Chairman & Secretary-General, Zhao Xiaobin**  
President of Zhejiang Haichang Biotech Co., Ltd.

## 第一届抗肿瘤药物临床研究专业委员会

### The 1<sup>st</sup> Clinical Research on Oncology Drugs Specialty Committee



#### 管忠震 顾问

中山大学肿瘤医院肿瘤内科教授

Counselor, Guan Zhongzhen  
Professor of Department of Medical  
Oncology, Sun Yat-Sen University  
Cancer Center



#### 秦叔逵 顾问

解放军东部战区总医院全军  
肿瘤中心主任

Counselor, Qin Shukui  
Director of PLA Cancer Center



#### 孙飘扬 顾问

恒瑞医药董事和战略委员会  
主任委员

Counselor, Sun Piaoyang  
Chairman of the Board & Director  
of Strategy Committee, Hengrui  
Medicine Co., Ltd.



#### 孙 燕 顾问

中国工程院院士

Counselor, Sun Yan  
Academician of the Chinese  
Academy of Engineering



#### 吴一龙 顾问

广东省人民医院终身主任

Counselor, Wu Yilong  
Tenured Professor & Director of  
Guangdong General Hospital



#### 于金明 顾问

中国工程院院士

Counselor, Yu Jinming  
Academician of Chinese Academy of  
Engineering



#### 李 进 主任委员

同济大学附属东方医院  
肿瘤医学部主任

Chairman, Li Jin  
Director of Oncology Department,  
Tongji University Shanghai East  
Hospital



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### The 1<sup>st</sup> Clinical Research on Cranial Nerve Drugs Specialty Committee



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### The 1<sup>st</sup> Clinical Research on Diabetes and Metabolic Diseases Specialty Committee



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Co., Ltd.

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Easton Biopharmaceuticals Co., Ltd.

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赛生医药江苏有限公司  
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Manager, CF PharmTech, Inc.

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合肥天麦生物科技发展有限公司  
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Tianji Pharma Co., Ltd.



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Founder, Chairman of the Board  
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(Shanghai)Co., Ltd.

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Pharmaceutical (Shanghai) Co., Ltd.

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Biopharmaceuticals Co., Ltd.

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陈志行 Chen Zhixing	大钲资本合伙人 Partner, Centurium Capital
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韩 晔 Han Ye	北京科信必成医药科技发展 有限公司总经理 General Manager, CoSci Med- Tech Co., Ltd.
李 靖 Li Jing	药渡经纬信息科技(北京)有限 公司董事长 Chairman of the Board, Pharmacodia (Beijing) Co., Ltd.



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# 重要活动

>> Important Events



# 01 PhIRDA Party Organization Construction

## 中国药促会党组织建设

在中国共产党百年华诞之际，中国药促会党支部积极开展党史学习教育，根据总书记“学党史、悟思想、办实事、开新局”的讲话精神，明确方向，凝聚力量，制定详细方案，通过丰富的形式开展线下线上党课学习、实地参观和集中讨论，学习党的实践创造和历史经验以启迪智慧。

On the occasion of the centenary of the Communist Party of China, the party branch of PhIRDA actively carried out history learning and education of Communist Party. According to the spirit of President Xi's speech of "Learning party history, understanding ideology, doing practical things, and opening up a new situation", the party branch of PhIRDA clarified the direction, gathered strength, formulated detailed plans, and carried out activities through rich forms. Offline and online Party lessons, on-site visits and intensive discussions, and learning the party's practical creation and historical experience were conducted to enlighten wisdom.



党支部组织开展党史学习系列活动

The party branch organized a series of activities to study party history





红色教育——红旗渠参观学习  
Red Education -- Visit and study at the Red Flag Canal



支部党员在录音棚录制红歌  
The branch of Party members recorded  
Red Songs in the studio



红色教育——昌延联合县政府旧址参观学习  
Red Education -- Visit and study at the old government  
site of Changyan united county





# 02

## Important Meetings

# 重点工作会议



参会代表合影  
Photograph of Representatives

### ◆ 2021年会长会议扩大会议(2021年3月20日·海口)

2021 PhIRDA President Board Meeting (March 20, 2021·Haikou)

全国政协经济委员会副主任、中国国际经济交流中心常务副理事长毕井泉应邀出席会议并对中国药促会工作进行指导。

中国药促会会长、副会长、秘书长,部分专业委员会主任委员以及受邀会员代表共计60余位主要负责人出席会议。会议总结了十一届二次理事会以来的重点工作成果,并对2021年重点工作提出建议。

Bi Jingquan, Deputy Director of Economic Committee of CPPCC, Permanent Vice Chairman of China Center for International Economic Exchanges (CCIEE), was invited to participate in the meeting.

More than 60 participants attended the meeting, including PhIRDA's presidents, vice-presidents, secretary-general, Chairmen of PhIRDA Specialty Committees, and representatives from invited members. The meeting summarized the key work achievements since the 2<sup>nd</sup> Meeting of the 11<sup>th</sup> Board of Directors and put forward suggestions on the key work in 2021.



毕井泉副主任讲话  
Bi Jingquan gave a speech



参会代表合影  
Photograph of Representatives

◆ 第十一届理事会第三次会议(2021年9月24日·苏州)

The 3<sup>rd</sup> Meeting of the 11<sup>th</sup> Board of Directors(September 24, 2021·Suzhou)

中国药促会理事、监事以及会员单位代表共150余人出席会议。会议选举齐鲁制药集团总裁李燕为年度会长,选举中国科学院上海药物研究所所长李佳为候任会长。与会代表围绕中国药促会2021-2022年度重点工作展开讨论并达成共识。

More than 150 directors, supervisors and representatives of members of PhIRDA participated in the meeting. The meeting elected Li Yan, President of Qilu Pharmaceutical Group, as the Annual Chairman, and Li Jia, Director of Shanghai Institute of Materia Medica, Chinese Academy of Sciences, as the Chairman-elected. Participants discussed and reached consensus on the work priorities in 2021-2022.



2020-2021年度会长任晋生为新当选会长李燕颁发证书  
2020-2021 Annual Chairman Ren Jinsheng presented certificate  
to newly elected Annual Chairman Li Yan



# 03 Grand Activities, Fascinating and Wonderful 重磅活动, 精彩纷呈

## • 2020年中国罕见病大会 (2020年10月24日-25日·北京)

2020 China Conference on Rare Diseases (October 24-25, 2020·Beijing)

2020年10月24-25日,由国家卫生健康委、国家药监局指导,中国罕见病联盟与中国药促会共同主办的“2020年中国罕见病大会”在北京举行。国家卫生健康委主任马晓伟,国家工业和信息化部副部长王江平,中国罕见病联盟理事长、北京协和医院名誉院长赵玉沛院士,国家药监局副局长陈时飞出席大会并致辞。大会设开幕式、主论坛、九个分论坛和十个卫星会,吸引了来自行政部门和海内外科研究所、医药协/学会、医疗机构、高等院校等机构的知名专家学者与罕见病患者3000余人参会,受到社会各界广泛关注和强烈反响。



赵玉沛 Zhao Yubei

中国科学院院士、中国罕见病联盟理事长、北京协和医院名誉院长  
Academician of Chinese Academy of Sciences, President of CARD  
and Honorary President of Peking Union Medical College Hospital



马晓伟 Ma Xiaowei

国家卫生健康委主任  
Minister and Secretary of the Leading  
Party Members' Group of NHC

领导致辞  
Remarks



王江平 Wang Jiangping  
国家工业和信息化部副部长

Vice Minister of the Ministry of Industry and  
Information Technology of the People's Republic of China



陈时飞 Chen Shifei  
国家药监局副局长

Member of NMPA Leading Party Group,  
NMPA Deputy Commissioner

Under the guidance of NHC and NMPA and co-hosted by China Alliance for Rare Diseases (CARD) and PhIRDA, the 2020 China Conference on Rare Disease was held on October 24-25, 2020 in Beijing. Ma Xiaowei, Minister and Secretary of the Leading Party Members' Group of NHC, Wang Jiangping, Vice Minister of the Ministry of Industry and Information Technology of the People's Republic of China, Academician Zhao Yupei, President of CARD and Honorary President of Peking Union Medical College Hospital, and Chen Shifei, Member of NMPA Leading Party Group, NMPA Deputy Commissioner, participated in the conference and made remarks. The conference set opening ceremony, main forum, 9 sub-forums and 10 satellite meetings, attracting more than 3,000 well-known experts, scholars, and patients with rare diseases from administrative departments, scientific research institutes at home and abroad, medical associations, medical institutions, universities, and other institutions, receiving wide attention and strong response from all sectors of society.







◆ 2021中国医药创新政策论坛(2021年7月17日·南京)

2021 China Pharmaceutical Innovation Policy Forum (July 17, 2021·Nanjing)



胡善联 Hu Shanlian  
中国药促会医药政策专委会名誉主任委员、  
复旦大学公共卫生学院卫生经济学教授  
Honorary Chairman of PhIRAD Medicinal Policy  
Specialty Committee, Professor of Health Economics  
of School of Public Health, Fudan University



胡欣 Hu Xin  
中国医药创新促进会医药政策专委会主任委员、  
北京医院药学部主任药师  
Chairman of PhIRAD Medicinal Policy Specialty  
Committee, Chief Pharmacist of Department of  
Pharmacy, Beijing Hospital

中国药促会和艾美达医药咨询主办,中国医药创新促进会医药政策专委会协办的2021中国医药创新政策论坛在南京顺利召开。本届论坛以“监管科学推动中国医药创新”为主题,特邀20多位来自政府相关部门人员及医保、药学、药物经济学专家学者与产业界企业代表共聚一堂,围绕审评审批体系改革、医疗保障体系建设、创新药支付体系制度改革等议题进行多角度、多方位的报告分享及主题讨论,推动以更科学的监管理念保障中国医药创新的可持续性。



会议现场  
Plenary Meeting

2021 China Pharmaceutical Innovation Policy Forum, co-hosted by PhIRDA and iMeta Health Information Consulting Co., Ltd. (iMeta), organized by PhIRDA Medicinal Policy Specialty Committee, was held in Nanjing. Themed on “Scientific Administration Promotes Pharmaceutical Innovation in China”, the forum invited more than 20 experts and scholars from relevant government departments, medical insurance, pharmacy, pharmacoeconomics as well as representatives from the industry to gather together. Multi-angle and multi-directional sharing and discussion focusing on the reform of review and approval system, construction of medical insurance system, reform of new drug payment system and other issues were delivered to promote the sustainability of China pharmaceutical innovation with more scientific regulatory concepts.



◆ 2021中国国际服务贸易交易会健康卫生服务专题展(2021年9月3-7日·北京)

The 2021 China International Fair for Trade in Services (CIFTIS) Exhibition on Section of Healthcare Services (September 3-7, 2021·Beijing)

中国国际服务贸易交易会（服贸会）由商务部联合北京市人民政府共同举办，是专门为服务贸易搭建的国家级、国际性、综合型大规模展会和交易平台。本届服贸会首次将“健康卫生”纳入服贸会八大版块之一，中国药促会作为健康卫生版块的承办机构，在北京市卫生健康委员会的指导下负责专题展的策划、组织、招商招展等工作。服贸会期间，中国药促会主（承）办的11场专业论坛成功召开。



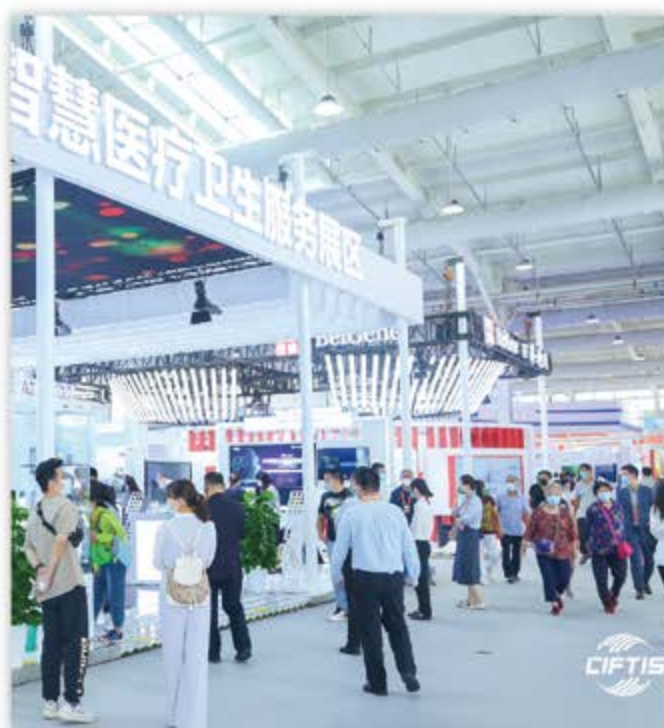
展区盛况  
Exhibition Area



北京市领导巡馆  
Leaders of the People's Government of Beijing Municipality visited the Exhibition on Section of Healthcare Services



签约区  
Signing Area



展区盛况  
Exhibition Area



互动区  
Interactive Area

The 2021 China International Fair for Trade in Services (CIFTIS), co-hosted by the Ministry of Commerce of the People's Republic of China and the People's Government of Beijing Municipality, was a national, international and comprehensive large-scale exhibition and trading platform specially built for trade in services. Exhibition on Section of Healthcare Services was included as one of its 8 sections for the first time this year. Under the guidance of Beijing Municipal Health Commission, PhIRDA, as the organizer of the Exhibition on Section of Healthcare Services, was responsible for the planning, organization, investment and exhibition recruitment. During CIFTIS, 11 forums were successfully hosted or organized by PhIRDA.



心血管疾病预防与创新论坛 (2021年9月3日·北京)  
 Forum on Cardiovascular Disease Prevention and Innovative Treatment (September 3, 2021·Beijing)



临床肿瘤学新进展暨抗肿瘤药物创新研发论坛 (2021年9月3日·北京)  
 Forum on Up-to-date Clinical Oncology Advance & Research of Innovative  
 Anti-cancer Drugs (September 3, 2021·Beijing)



国际卫生服务与医药创新合作论坛 (2021年9月3日·北京)  
 International Health Services and Pharmaceutical Innovation Cooperation Forum (September 3, 2021·Beijing)





脑科学与脑神经医药创新高峰论坛 (2021年9月4日·北京)  
Innovation Summit Forum on Brain Science and  
Neuromedicine (September 4, 2021·Beijing)



创新研发服务论坛 (2021年9月4日·北京)  
Summit Forum on Innovative R&D Services (September 4, 2021·Beijing)



医疗器械创新发展与科学监管论坛 (2021年9月6日·北京)  
Summit Forum on Medical Device Innovation  
Development and Scientific Supervision  
(September 6, 2021·Beijing)



糖尿病与代谢性疾病诊疗论坛 (2021年9月6日·北京)  
Forum on Diagnosis and Treatment of Diabetes and  
Metabolic Diseases (September 6, 2021·Beijing)



• **第六届中国医药创新与投资大会 (2021年9月25日-27日·苏州)**  
The 6<sup>th</sup> China BioMed Innovation and Investment Conference  
(September 25-27, 2021 · Suzhou)

由中国药促会、香港交易所、蓝迪国际智库、艾美达医药咨询共同主办，深圳证券交易所、上海证券交易所特别支持的第六届中国医药创新与投资大会在苏州工业园区召开。

大会设置20个主题专场/论坛，评审专家委员会遴选出115个具有临床优势并极具商业价值的优质项目进行路演。51场主题报告剖析医药行业热点问题及投融资现状，探讨行业发展动向。近50家媒体对大会全程跟踪报道，发表新闻近百篇次。大会注册用户共发出5711个会面请求，大会期间线上成功达成商务洽谈285场，现场达成商务洽谈614场。

大会将持续为行业领袖、专家、学者以及国内外医药创新企业和投资人，搭建专业、多维度的对话沟通与合作平台，共商医药政策新变化、新趋势、新挑战，探讨医药创新发展与资本融合的新未来。

Co-hosted by PhIRDA, Hong Kong Exchanges and Clearing Limited (HKEX), Research and Development International (RDI) and iMeta Health Information Consulting Co., Ltd. (iMeta), and supported by Shenzhen Stock Exchange (SZSE) and Shanghai Stock Exchange (SSE), the 6<sup>th</sup> China BioMed Innovation and Investment Conference (2021 CBIIC) was held in Suzhou Industrial Park.

2021 CBIIC set 20 thematic sessions/forums and 115 high-quality projects with clinical advantages and high commercial value selected by the expert review committee for roadshows. 51 keynote speeches analyzed hot topics and investment and financing status of pharmaceutical industry, and discussed the development trend of the industry. About 50 media followed 2021 CBIIC and published nearly 100 news articles. A total of 5711 meeting requests were made by registered participants; 285 virtual one-on-one business negotiations were successfully completed; and 614 on-site business negotiations were successfully achieved during the conference.

CBIIC will continue to build a professional and multi-dimensional dialogue and cooperation platform for industry leaders, experts, scholars, as well as domestic and foreign pharmaceutical innovation enterprises and investors to discuss new changes, new trends and new challenges in pharmaceutical policy, and probe into the future of the integrated pharmaceutical innovation and capital.



开幕式主持人

Chairs of the Opening Ceremony



开幕式致辞嘉宾  
KOLs of the Opening Ceremony



沙雁 深圳证券交易所  
党委副书记、总经理  
Sha Yan, Deputy Secretary of the  
Party Committee, President and CEO  
of Shenzhen Stock Exchange



许昆林 江苏省委常委、苏州市委书记  
Xu Kunlin, Member of the Standing  
Committee of the CPC Jiangsu Provincial  
Committee, Secretary of the CPC Suzhou  
Municipal Government



欧冠升 香港交易所集团行政总裁  
Nicolas Aguzin,  
Chief Executive Officer of HKEX



开幕式会场全景  
The Opening Ceremony



## 多位重量级嘉宾现身大会开幕式，并做精彩报告

Several KOLs participated in the Opening Ceremony and gave keynote speeches



**蒋华良**  
 中国科学院院士  
 中国药促会2015-2016年度会长  
 中国科学院上海药物研究所研究员  
 Jiang Hualiang  
 Academician of Chinese Academy of Sciences,  
 2015-2016 Annual Chairman of PhIRDA,  
 Professor of Shanghai Institute of Materia Medica,  
 Chinese Academy of Sciences



**宋瑞霖**  
 中国药促会执行会长  
 Song Ruilin  
 Executive President of PhIRDA



**周思源**  
 国家药品监督管理局药品审评中心副主任  
 Zhou Siyuan  
 Deputy Director of Center for Drug  
 Evaluation, National Medical Products  
 Administration



**张洪刚**  
 科技部重大专项司副司长  
 Zhang Honggang  
 Deputy Director-General of Department of  
 Major Science and Technology Project,  
 Ministry of Science and Technology of the  
 People's Republic of China



**张继强**  
 华泰证券研究所副所长、总量研究负责人、  
 固定收益首席分析师  
 Zhang Jiqiang  
 Managing Director and Chief Fixed Income  
 Analyst of Huatai Securities Research Institute



“医药创新产业发展”主题讨论  
Panel: Trends on Pharmaceutical Innovation Industry



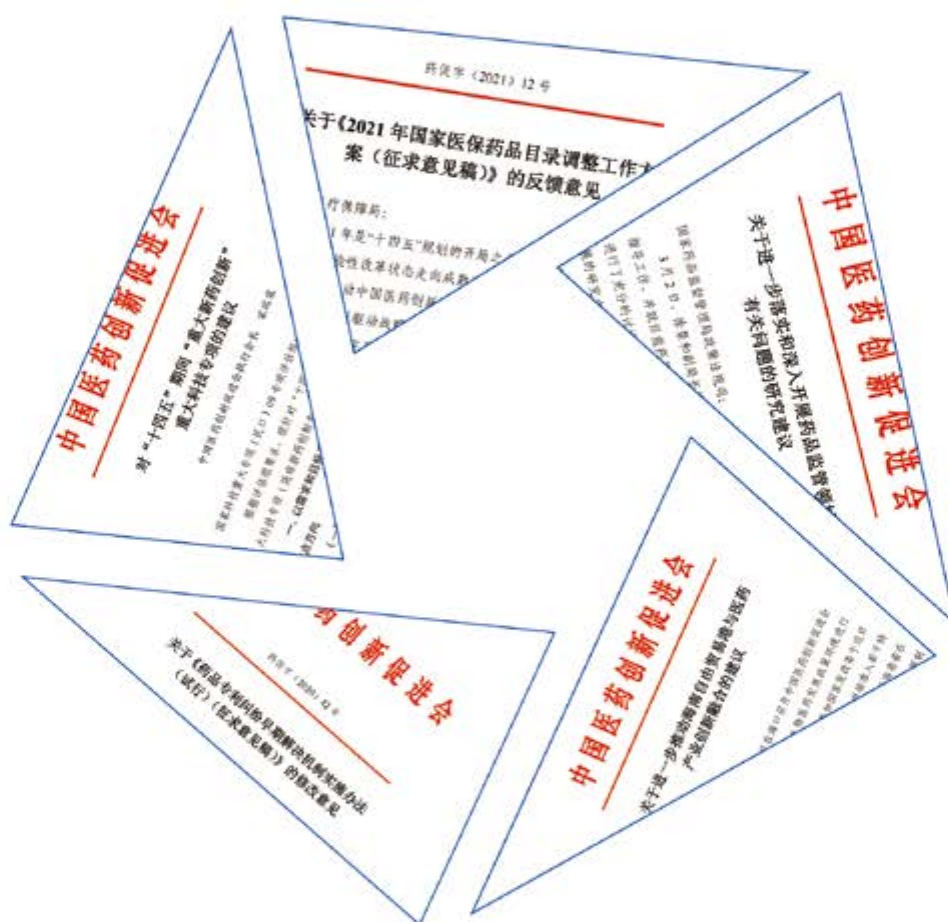
“投资与医药创新发展”主题讨论  
Panel: Investment and Pharmaceutical Innovation Development



# 04

Give Full Play to the Role of High-end  
Think Tank and Offer Advice and Suggestions

## 发挥高端智库作用， 积极建言献策



### ◆ 积极开展医药政策研究

Actively conduct researches on pharmaceutical policies

中国药促会坚持为我国医药产业创新谋篇布局，深入研究影响我国医药产业创新发展的核心问题，向国家和政府有关部门提出适合我国国情、符合行业发展需求的可操作性意见和建议，受到社会各界高度评价和认可。

PhIRDA has been making plans for China's pharmaceutical innovation industry, conducting in-depth studies on the core issues affecting the innovative development of China's pharmaceutical industry, and putting forward practical opinions and suggestions suitable for China's national conditions and in line with the development needs of the industry for the country and government departments, winning high praise and recognition from all sectors of society.

◆ 向政府相关部门建言献策

Offer advice and suggestions for relevant government departments

相关政府部门领导先后率团队赴中国药促会调研指导，就完善我国医药创新政策、优化审评审批程序和加强党风廉政建设等问题交流意见并达成诸多共识。

Leaders of relevant government departments have led teams to PhIRDA for investigation and guidance, exchanging views and reaching consensus on issues including improving China's pharmaceutical innovation policy, optimizing the review and approval process, and strengthening the construction of party conduct and clean government.



国家药品监督管理局副局长徐景和率工作团队莅临中国药促会指导工作 (2021年3月2日·北京)  
Xu Jinghe, Member of NMPA Leading Party Group, NMPA Deputy Commissioner, led his team visited PhIRDA. (March 2, 2021·Beijing)





国家药监局药品审评中心纪委书记李江宁率工作团到中国药促会调研 (2021年4月6日·北京)  
Li Jiangning, Secretary of Commission for Discipline Inspection of Center for Drug Evaluation,  
NMPA, led his team visited PhIRDA. (April 6, 2021·Beijing)



全国政协经济委员会副主任、中国国际经济交流中心常务副理事长毕井泉莅临中国药促会指导工作 (2021年8月26日·北京)  
Bi Jingquan, Deputy Director of Economic Committee of CPPCC, Permanent Vice  
Chairman of China Center for International Economic Exchanges (CCIEE), visited PhIRDA. (August 26, 2021·Beijing)



• 中国药促会联合RDPAC发布《构建中国医药创新生态系统》系列报告

PhIRDA and RDPAC jointly released *A Series of Reports on Building China's Pharmaceutical Innovation Ecosystem*



• 宋瑞霖会长受聘为上海交通大学客座研究员(2021年7月19日·上海)

PhIRDA Executive President Song Ruilin was appointed as Guest Research Professor of Shanghai Jiao Tong University. (July 19, 2021·Shanghai)



# 05 Brought Together All Forces to Promote Pharmaceutical Innovative Development

## 汇聚各方力量， 促进医药创新发展

### ◆ 中国药促会与深圳证券交易所签署战略合作协议(2020年12月30日·深圳)

PhIRDA signed a strategic cooperation agreement with Shenzhen Stock Exchange.  
(December 30, 2020·Shenzhen)

2020年末,中国药促会与深交所在已有合作基础上签署战略合作协议,未来双方将充分发挥各自资源优势,重点围绕举办专业会议、后备上市企业培育、已上市企业规范发展、行业信息交流、产融结合平台对接、产业研究等方面开展务实合作,建立全方位、多层次、长期稳定、合作互惠的战略合作关系,支持我国医药产业创新和可持续发展。

At the end of 2020, on the basis of existing cooperation, PhIRDA and Shenzhen Stock Exchange signed a strategic cooperation agreement. In the future, both sides will give full play to their respective resource advantages, focusing on holding professional conferences, fostering reserve listed companies, standardizing development of listed companies, exchanging industry information, industry-finance integration platform docking, industrial research and other aspects to carry out pragmatic cooperation and establish a comprehensive, multi-level, long-term and stable, and mutually beneficial strategic partnership to support the innovation and sustainable development of China's pharmaceutical industry.



与深交所会谈现场  
Meeting with Shenzhen Stock Exchange





◆ 中国药促会与海口市人民政府签署战略合作协议(2021年3月20日·海口)

PhIRDA signed a strategic cooperation agreement with Haikou Municipal Government. (March 20, 2021·Haikou)

2021年3月,中国药促会与海口市人民政府秉承优势互补、资源共享的理念签署共促医药创新发展战略合作协议。双方将充分发挥海南自由贸易港政策优势,结合海口医药产业发展实际,搭建“政产学研金服用”交流合作平台并共同举办海南自由贸易港国际医药创新发展论坛,进一步促进和提升海口市在医药领域中的国际交流合作与创新能力。

In March 2021, adhering to the concept of complementary advantages and resource sharing, PhIRDA and Haikou Municipal Government signed a strategic cooperation agreement on promoting pharmaceutical innovation and development. Both sides will give full play to the policy of Hainan Free Trade Port and combine Haikou's pharmaceutical industry development to build the "Government, Industry, Talent, Research, Fund, Service, and Transformation" exchanges and cooperation platform, and jointly hold the Hainan Free Trade Port International Pharmaceutical Innovation and Development Forum to further promote and enhance Haikou's competitiveness in international pharmaceutical exchanges, cooperation, and innovation.



签约合影  
Signing Ceremony



# 06

## International Events

## 国际交流活动

- 执行会长宋瑞霖会见新加坡驻华大使馆参赞彭银荃一行(2020年12月21日·北京)

PhIRDA Executive President Song Ruilin met with Jackson Phang, Counselor of the Embassy of the Republic of Singapore. (December 21, 2020·Beijing)



合影留念(左一彭银荃,右一蔡宗伦)

Photograph (Jackson Phang, Left; Cai Zonglun, Right)

- 执行会长宋瑞霖会见荷兰驻华大使馆参赞史明康一行(2021年1月5日·北京)

PhIRDA Executive President Song Ruilin met with Nico Schiettekatte, Counselor of Health, Welfare and Sports of the Embassy of the Kingdom of the Netherlands. (January 5, 2021·Beijing)



合影留念(左一史明康,右一Peter A. Bootsma)

Photograph (Nico Schiettekatte, Left; Peter A. Bootsma, Right)

- 执行会长宋瑞霖会见上海合作组织副秘书长张海舟一行(2021年3月17日·北京)

PhIRDA Executive President Song Ruilin met with Zhang Haizhou, Deputy Secretary-General of the Shanghai Cooperation Organization (SCO). (March 17, 2021·Beijing)



合影留念(右二张海舟,左一郑薇,右一刘建华)

Photograph (From left to right:Zheng Wei, Song Ruilin,Zhang Haizhou, Liu Jianhua)



◆ 执行会长宋瑞霖拜访白俄罗斯驻华大使先科·尤里 (2021年7月14日·北京)

PhIRDA Executive President Song Ruilin met with Yuri Senko, Belarusian Ambassador to China. (July 14, 2021·Beijing)



与白俄罗斯驻华大使会谈现场  
Meeting between PhIRDA  
and Belarusian Ambassador  
to China

◆ 执行会长宋瑞霖拜访乌兹别克斯坦驻华大使巴赫季约尔·赛义多夫 (2021年7月14日·北京)

PhIRDA Executive President Song Ruilin met with Bakhtiyor Saidov, Uzbek Ambassador to China. (July 14, 2021·Beijing)



与乌兹别克斯坦驻华大使会谈现场  
Meeting between PhIRDA and Uzbek Ambassador to China

◆ 执行会长宋瑞霖会见日本大使馆一等书记官伊藤秀俊一行 (2021年8月30日·北京)

PhIRDA Executive President Song Ruilin met with Hidetoshi Ito, First Secretary of Embassy of Japan in China. (August 30, 2021·Beijing)



会谈现场  
Meeting Between PhIRDA and Embassy of Japan



# 07

## Specialty Committee Events

# 专业委员会活动



- ◆ 中国医药创新促进会脑神经药物临床研究专业委员会  
PhIRDA Clinical Research on Cranial Nerve Drugs  
Specialty Committee

成立会议 (2020年11月8日·北京)  
Inaugurating Meeting of PhIRDA Clinical Research on  
Cranial Nerve Drugs Specialty Committee (November 8,  
2021·Beijing)



- ◆ 中国医药创新促进会医药企业合规专业委员会  
PhIRDA Ethics and Business Compliance Specialty  
Committee

成立会议 (2020年11月9日·线上)  
Inaugurating Meeting of PhIRDA Ethics and Business Compli-  
ance Specialty Committee (November 9, 2020·Virtual)



- ◆ 中国医药创新促进会药物临床试验专业委员会  
PhIRDA Clinical Trial Research Specialty Committee

第三届换届会议 (2020年11月24日·线上)  
General Election of the 3<sup>rd</sup> PhIRDA Clinical Trial Research  
Specialty Committee (November 24, 2020·Virtual)



- ◆ 中国医药创新促进会抗肿瘤药物临床研究专业委员会  
PhIRDA Clinical Research on Oncology Drugs  
Specialty Committee

发布《2020年度中国抗肿瘤新药临床研究评述》  
(2021年8月12日)  
Released the *2020 Review of Clinical Research on New  
Oncology Drugs in China*. (August 12, 2021)





◆ 药物研发创新模式与精准医疗论坛  
(2020年12月4日·杭州)

New Model of Drug R&D and Precision Medicine Forum  
(December 4, 2020·Hangzhou)



◆ 中国医药创新促进会药物研发专业委员会、  
中国医药创新促进会创新研发服务专业委员会

PhIRDA Drug R&D Specialty Committee, PhIRDA  
Innovation R&D Services Specialty Committee

药物研发(第三届第一次)及创新研发服务(第二届第一次)  
专业委员会工作会议(2020年12月4日·杭州)  
Drug R&D Specialty Committee (First Meeting of the 3<sup>rd</sup> Committee),  
Innovation R&D Services Specialty Committee (First Meeting of the  
2<sup>nd</sup> Committee) (December 4, 2020·Hangzhou)



◆ 中国医药创新促进会脑神经药物临床研究专业委员会  
PhIRDA Clinical Research on Cranial Nerve Drugs  
Specialty Committee

2021年胶质母细胞瘤(GBM)新药研发研讨会  
(2021年3月20日·北京)  
2021 Symposium on Glioblastoma (GBM) New  
Drug R&D (March 20, 2021·Beijing)



◆ 中国医药创新促进会糖尿病与代谢性疾病药物临  
床研究专业委员会

PhIRDA Clinical Research on Diabetes and Metabolic  
Diseases Specialty Committee

成立会议(2021年9月5日·北京)  
Inaugurating Meeting of PhIRDA Clinical Research on  
Diabetes and Metabolic Diseases Specialty Committee  
(September 5, 2021·Beijing)

◆ 中国医药创新促进会医药创新投资专业委员会

PhIRDA Pharmaceutical Innovation Investment Specialty Committee

明星企业走访系列活动——走进长沙(2020年11月26-27日·长沙)

A Series of Activities of Visiting Star Companies in Changsha (November 26-27, 2020·Changsha)



走进明星企业(人和未来)  
 Visiting the Star Company (Genetalks)



走进明星企业(圣湘生物)  
 Visiting the Star Company (Sansure Biotech)



走进明星企业(尔康制药)  
 Visiting the Star Company (Er-Kang Pharmaceutical)



# 大事记

»» Remarkable Events



## 大事记(2020年10月-2021年9月)

### 2020年

- 10月24日 由中国罕见病联盟和我会共同主办的2020中国罕见病大会在北京举行。
  - 10月31日 由我会主办、贝达药业承办的凯美纳上市九周年庆典暨贝美纳(恩沙替尼)上市发布会在上海召开。
  - 11月6日 我会和国家卫生健康委国际交流与合作中心共同主办的第三届虹桥国际健康科技创新论坛在上海举行。
  - 11月8日 中国医药创新促进会脑神经药物临床研究专业委员会在北京成立。北京天坛医院院长王拥军当选第一届名誉主任委员，北京市神经外科研究所名誉所长张亚卓当选第一届主任委员。
  - 11月9日 中国医药创新促进会医药企业合规专业委员会在北京成立。中国药科大学教授、国家药物政策与医药产业经济研究中心执行副主任邵蓉当选第一届主任委员。
  - 11月24日 中国医药创新促进会药物临床试验专业委员会第三届换届会议成功召开。北京大学临床药理研究所所长崔一民当选第三届主任委员。
  - 12月4日 中国医药创新促进会药物研发专业委员会在杭州召开换届会议。亚盛医药董事长杨大俊当选第三届主任委员。
- 中国医药创新促进会创新研发服务专业委员会在杭州召开换届会议。上海立迪生物技术股份有限公司董事长闻丹忆当选第二届主任委员。
- 中国医药创新促进会药物研发专业委员会和中国药促会创新研发服务专业委员会联合主办的药物研发创新模式与精准医疗论坛在杭州顺利召开。

- 12月21日 宋瑞霖执行会长会见新加坡驻华大使馆参赞彭银荃。
- 12月30日 我会与深圳证券交易所签署战略合作协议。

### 2021年

- 1月4日 上海艾力斯医药科技股份有限公司、上海盟科药业股份有限公司、鸿运华宁(杭州)生物医药有限公司、拜奥新管理(上海)有限公司、江苏亚虹医药科技股份有限公司、嘉和生物药业有限公司、浙江海昶生物医药技术有限公司、北京五和博澳药业股份有限公司加入我会。
  - 1月5日 宋瑞霖执行会长会见荷兰驻华大使馆参赞史明康。
  - 1月12-13日 中国医药创新投资论坛在线上成功召开，累计观看量超过10万人次。
  - 1月31日 我会与北京市希思科临床肿瘤学研究基金会共同主办的抗肿瘤创新药物临床研究高峰论坛在京召开。
  - 2月26日 我会主办的子宫内膜异位症药物研发进展研讨会在京召开。
  - 3月2日 国家药监局副局长徐景和一行莅临我会指导工作，并就深入开展医药创新政策研究达成一致意见。
- 我会联合RDPAC发布《构建中国医药创新生态系统系列报告第一篇：2015-2020年发展回顾及未来展望》。
- 3月12日 山西转型综合改革示范区领导带队到访我会。

- 3月17日** ● 宋瑞霖执行会长会见上海合作组织副秘书长张海舟一行。

**3月20日** ● 我会2021年会长会议扩大会议在海口召开。

海南生物医药发展座谈会在海口召开，我会与海口市人民政府签署战略合作协议。

中国医药创新促进会脑神经药物临床研究专业委员会主办的“2021年胶质母细胞瘤（GBM）新药研发研讨会”在京召开。

**4月6日** ● 国家药监局药品审评中心纪委书记李江宁率队到我会就合规体系建设进行调研。

**4月16日** ● 我会主办的糖尿病新机制药物研发进展研讨会在京召开。

**5月6日** ● 远大医药（中国）有限公司、亿一生物制药（北京）有限公司、来凯医药科技（上海）有限公司加入我会。

**5月27日** ● 我会召开“生物制品专利纠纷早期解决机制研究”课题结题会。

**5月24日-28日** ● 我会受邀参与《药品管理法实施条例》起草修订工作，重点参与“注册与研发”章节完成初稿起草和修订。

**6月3日** ● 我会受邀参加上海合作组织民间友好论坛卫生健康分论坛。

**6月11日** ● 我会主办的提升淋巴瘤患者用药可及研讨会在京召开。

我会联合RDPAC发布《构建中国医药创新生态系统——系列报告第二篇：推动基础研究，激活创新源头》。

**6月17日** ● 我会召开“制定真实世界数据研究有关规则”结题会。

**7月5日** ● 宋瑞霖执行会长会见香港贸易发展局华北、东北首席代表陈嘉贤。

宋瑞霖执行会长作为评估组专家成员，受邀参加“重大新药创制”国家重大专项“十一五”、“十二五”和“十三五”的总结评估启动会和系列调研座谈会，并向国家科技重大专项（民口）09专项评估组提出《对“十四五”期间“重大新药创新”重大科技专项的建议》。

**7月14日** ● 宋瑞霖执行会长会见白俄罗斯驻华大使先科·尤里。

宋瑞霖执行会长会见乌兹别克斯坦驻华大使巴赫季约尔·赛义多夫。

**7月17日** ● 我会主办的2021中国医药创新政策论坛在南京召开。

**7月19日** ● 宋瑞霖执行会长受聘为上海交通大学客座研究员。

**7月22日** ● 我会召开商保与医药融合创新高端闭门研讨会。

**7月23日** ● 我会与新加坡经济发展局（EDB）、艾社康共同主办的中国生物医药新加坡/东南亚拓展线上研讨会召开。

**7月28日-30日** ● 我会会同烟台市政府等机构主办的2021医药创新与发展国际会议在山东烟台召开。

**8月11日** ● 我会召开2021年度联络秘书工作会议。

**8月12日** ● 中国医药创新促进会抗肿瘤药物临床研究专业委员会发布《2020年度中国抗肿瘤新药临床研究评述》。



8月16日

我会联合RDPAC发布《构建中国医药创新生态系统——系列报告第三篇：多层次医疗保障体系助力人民健康和产业高质量发展》。

8月23日

上海琅钰健康科技(集团)有限公司、上海蔼睦医疗科技有限公司、派格生物医药(苏州)股份有限公司、瓴路药业(上海)有限责任公司、辉诺生物医药科技(杭州)有限公司、上海海和药物研究开发股份有限公司、四川三叶草生物制药有限公司、北京谷神生命健康科技有限公司、微智医疗器械有限公司、润东医药研发(上海)有限公司加入我会。

8月26日

中国国际经济交流中心常务副理事长毕井泉莅临我会指导工作。

8月30日

宋瑞霖执行会长会见日本大使馆一等书记官伊藤秀俊。

9月3-7日

我会承办的2021中国国际服务贸易交易会健康卫生服务专题展在京顺利召开。服贸会期间,我会主(承)办的11场专业论坛成功举办。

9月5日

中国医药创新促进会糖尿病与代谢性疾病药物临床研究专业委员会在北京成立。亚洲糖尿病学会副主席杨文英当选第一届名誉主任委员;北京大学人民医院内分泌科主任纪立农当选第一届主任委员。

9月6日

我会受邀参加由药品审评中心召开的儿童用药研发热点问题专家研讨会。

9月24日

我会第十一届理事会第三次会议在苏州召开。齐鲁制药集团总裁李燕当选2021-2022年度会长。

深圳君圣泰生物技术有限公司、上海礼邦医药科技有限公司加入我会。

9月25日

由我会联合香港交易所、蓝迪国际智库、艾美达医药咨询主办,深圳证券交易所、上海证券交易所特别支持的第六届中国医药创新与投资大会在苏州召开。



# Remarkable Events (October, 2020 - September, 2021)

## 2020

## 2021

- October 24** • 2020 China Conference on Rare Diseases, co-hosted by China Alliance for Rare Diseases (CARD) and PhIRDA, was held in Beijing.
- October 31** • The 9<sup>th</sup> Listing Anniversary of Conmana and the Launch of Ensacove (Ensartinib), hosted by PhIRDA and organized by Beta Pharmaceuticals, was held in Shanghai.
- November 6** • The 3<sup>rd</sup> Hongqiao International Health Technology Innovation Forum, co-hosted by PhIRDA and International Health Exchange and Cooperation Center NHC PRC (IHECC), was held in Shanghai.
- November 8** • PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee was established in Beijing. Wang Yongjun, President of Beijing Tiantan Hospital, was elected as the first Honorary Chairman, and Zhang Yazhuo, Honorary Director of Beijing Neurosurgical Institute, was elected as the first Chairman.
- November 9** • PhIRDA Ethics and Business Compliance Specialty Committee was established in Beijing. Shao Rong, Professor of China Pharmaceutical University, Vice Executive Director of the Research Center of National Drug Policy & Ecosystem, was elected as the Chairman.
- November 24** • General Election of the Third PhIRDA Clinical Trial Research Specialty Committee was successfully held. Cui Yimin, Director of Institute of Clinical Pharmacology, Peking University, was elected as the Chairman.
- December 4** • General Election meeting of PhIRDA Drug R&D Specialty Committee was held in Hangzhou. Yang Dajun, Chairman of the Board of Ascentage Pharma, was elected as the Chairman.  
  
General Election meeting of PhIRDA Innovation R&D Services Specialty Committee was held in Hangzhou. Wen Danyi, Chairman of the Board of Shanghai LIDE Biotech Co., Ltd., was elected as the Chairman.  
  
New Model of Drug R&D and Precision Medicine Forum, co-hosted by PhIRDA Drug R&D Specialty Committee and Innovation R&D Services Specialty Committee, was successfully held in Hangzhou.
- December 21** • PhIRDA Executive President Song Ruilin met with Jackson Phang, Counselor of the Embassy of the Republic of Singapore.
- December 30** • PhIRDA signed a strategic cooperation agreement with Shenzhen Stock Exchange.
- January 4** • Shanghai Allist Pharmaceuticals Co., Ltd., Shanghai MicuRx Pharmaceutical Co., Ltd., Gmax Biopharma LLC, BioShin (Shanghai) Consulting Services Co., Ltd., Jiangsu Asieris Pharmaceuticals Co., Ltd., Genor Biopharma Co., Ltd., Zhejiang Haichang Biotech Co., Ltd., and Beijing Wehand-Bio Pharmaceutical Co., Ltd. officially joined PhIRDA.
- January 5** • PhIRDA Executive President Song Ruilin met with Nico Schiettekatte, Counselor of Health, Welfare and Sports of the Embassy of the Kingdom of the Netherlands.
- January 12-13** • 2021 China BioMed Forum was successfully held virtually, attracting more than 100,000 participants.
- January 31** • The Summit Forum of Clinical Research on New Oncology Drugs, co-hosted by PhIRDA and CSCO, was held in Beijing.
- February 26** • PhIRDA hosted the Symposium of Development on Endometriosis Drug R&D in Beijing.
- March 2** • Xu Jinghe, Member of NMPA Leading Party Group, NMPA Deputy Commissioner, and his team visited PhIRDA. Both sides reached consensus on in-depth research on pharmaceutical innovation policy.  
  
PhIRDA and RDPAC jointly released *The First of a Series of Reports on Building China's Pharmaceutical Innovation Ecosystem: Review of Development and Future Prospects during 2015-2020*.
- March 12** • Delegation of Shanxi Transformation and Comprehensive Reform Demonstration Zone visited PhIRDA.
- March 17** • PhIRDA Executive President Song Ruilin met with Zhang Haizhou, Deputy Secretary-General of the Shanghai Cooperation Organization (SCO).
- March 20** • Expanded meeting of 2021 PhIRDA President Board was held in Haikou.  
  
The Hainan Biomedical Development Symposium was held in Haikou, and PhIRDA signed a strategic cooperation agreement with Haikou Municipal Government.  
  
2021 Symposium on Glioblastoma (GBM) New Drug R&D, hosted by PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee, was held in Beijing.



- April 6** Li Jiangning, Secretary of Commission for Discipline Inspection of Center for Drug Evaluation, NMPA, led his team to visit PhIRDA to investigate the construction of compliance system.
- April 16** PhIRDA hosted the Symposium on the Development of New Mechanism Drugs R&D for Diabetes in Beijing.
- May 6** Grand Pharma (China) Co., Ltd., Evive Biotechnology (Beijing) Co., Ltd., and Laekna Therapeutics Shanghai Co., Ltd. officially joined PhIRDA.
- May 27** PhIRDA held the project conclusion meeting on “Early Settlement of Disputes over Biologic Product Patents”.
- May 24-28** PhIRDA was invited to participate in the drafting and revision of the *Regulations for Implementation of the Drug Administration Law of the People's Republic of China*, focusing on the drafting and revision of the first draft of the chapter “Registration and R&D”.
- June 3** PhIRDA was invited to attend the Health Session of Shanghai Cooperation Organization Forum on People-to-People Friendship.
- June 11** PhIRDA hosted the Seminar on Improving the Access for Lymphoma Patients in Beijing.
- PhIRDA and RDPAC jointly released *The Second of a Series of Reports on Building China's Pharmaceutical Innovation Ecosystem: Promote Basic Research and Activate Innovation Sources*.
- June 17** PhIRDA hosted a project conclusion meeting “Making Rules for Real-world Data Research”.
- July 5** PhIRDA Executive President Song Ruilin met with Kevin Chan, Chief Representative of North and Northern China, Hong Kong Trade Development Council (HKTDC).
- PhIRDA Executive President Song Ruilin, as an expert member of the evaluation team, was invited to participate in the summary evaluation kick-off meeting and series of research seminars of National Science and Technology Major Project for Major New Drug during the 11<sup>th</sup> Five-Year Plan, the 12<sup>th</sup> Five-Year Plan and the 13<sup>th</sup> Five-Year Plan period, and submitted *Suggestions on National Science and Technology Major Project for Major New Drug during “the 14<sup>th</sup> Five-year Plan” Period* to National Science and Technology Major Project (Civilian) 09 special evaluation team.
- July 14** PhIRDA Executive President Song Ruilin met with Yuri Senko, Belarusian Ambassador to China.
- PhIRDA Executive President Song Ruilin met with Bakhtiyor Saidov, Uzbek Ambassador to China.
- July 17** PhIRDA successfully hosted the 2021 China Pharmaceutical Innovation Policy Forum in Nanjing.
- July 19** PhIRDA Executive President Song Ruilin was appointed as Visiting Professor of Shanghai Jiao Tong University.
- July 22** PhIRDA held the High-end Closed-door Seminar on Commercial Insurance and Pharmaceutical Integrated Innovation Seminar.
- July 23** China BioMed Singapore/Southeast Asia Expansion Online Seminar, co-hosted by PhIRDA, EDB and ASK Health, was successfully held.
- July 28-30** 2021 International Pharmaceutical Innovation and Development Conference, co-hosted by PhIRDA and the People's Government of Yantai, etc., was held in Yantai, Shandong.
- August 11** 2021 PhIRDA Annual Contact Representatives Meeting was held.
- August 12** Clinical Research on Oncology Drugs Specialty Committee released the *2020 Review of Clinical Research on New Oncology Drugs in China*.
- August 16** PhIRDA and RDPAC jointly released *The Third of a Series of Reports on Building China's Pharmaceutical Innovation Ecosystem: People Health and High-quality Industrial Development Promoted by Multi-tiered Medical Security System*.
- August 23** RareStone Group Co., Ltd., Shanghai AffaMed Therapeutics Co., Ltd., Pegbio. Co., Ltd., Overland Pharmaceutical (Shanghai) Co., Ltd., Phaeno Therapeutics Co., Ltd., Haihe Biopharma Co., Ltd., Clover Biopharmaceuticals, Inc., Beijing GuShen Life Health Science Technology Co., Ltd., IntelliMicro Medical Co., Ltd., and Rundo International Pharmaceuticals R&D Co., Ltd. official joined PhIRDA.
- August 26** Bi Jingquan, Permanent Vice Chairman of China Center for International Economic Exchanges (CCIEE), visited PhIRDA.

- August 30

PhIRDA Executive President Song Ruilin met with Hidetoshi Ito, First Secretary of Embassy of Japan in China.
- September 3-7

The 2021 China International Fair for Trade in Services (CIFTIS) Exhibition on Section of Healthcare Services, organized by PhIRDA, was successfully held in Beijing. During CIFTIS, 11 forums were hosted or organized by PhIRDA.
- September 5

PhIRDA Clinical Research on Diabetes and Metabolic Diseases Specialty Committee was established in Beijing. Yang Wenying, Vice-Chairman of Asian Association for the Study of Diabetes (AASD), was elected as the first Honorary Chairman; Ji Linong, Director of Endocrinology and Metabolism Department of Peking University People's Hospital, was elected as the first Chairman.
- September 6

PhIRDA was invited to attend the Expert Seminar on Hot Issues of Pediatric Drug R&D held by the Center for Drug Evaluation, NMPA.
- September 24

The third meeting of the 11<sup>th</sup> Board of Directors was held in Suzhou. Li Yan, President of Qilu Pharmaceutical Group, was elected as 2021-2022 PhIRDA Annual Chairman.

Shenzhen HighTide Biopharmaceutical Ltd. and Alebund Pharmaceuticals Ltd. official joined PhIRDA.
- September 25

The 6<sup>th</sup> China BioMed Innovation and Investment Conference (CBIIC), co-hosted by PhIRDA, Hong Kong Exchanges and Clearing Limited (HKEX), Research and Development International (RDI), and iMeta Health Information Consulting Co., Ltd., was held in Suzhou.



# 中国医药创新促进会章程

## 第一章 总则

**第一条** 中国医药创新促进会是由国内医药创新型生产企业、专注于医药创新的研发型企业、从事医药创新研发的高等院校和科研院所、在新药临床研究领域具有较高水平的药物临床研究机构 and 致力于医药创新投资的金融机构自愿结成的全国性、行业性社会团体，是非营利性社会组织。

本会会员分布和活动地域为全国。

**第二条** 本会的宗旨是：高举中国特色社会主义伟大旗帜，以邓小平理论、三个代表重要思想、科学发展观和习近平新时代中国特色社会主义思想为指导，贯彻国家有关方针、政策和改革精神，提高中国医药产业的科研创新能力，促进医药研发与创新成果的转化，提升中国医药产业的国际竞争力，维护会员单位的合法权益，搭建政府和产业沟通的桥梁，为医药创新和社会经济发展做出应有贡献。

本会遵守宪法、法律、法规和国家政策，践行社会主义核心价值观，弘扬爱国主义精神，遵守社会道德风尚，自觉加强诚信自律建设。

**第三条** 本会坚持中国共产党的全面领导，根据中国共产党章程的规定，设立中国共产党的组织，开展党的活动，为党组织的活动提供必要条件。

本会的登记管理机关是民政部，业务主管单位是国务院国有资产监督管理委员会。

本会接受登记管理机关、业务主管单位、有关行业管理部门的业务指导和监督管理。

**第四条** 本会负责人包括会长、副会长、秘书长。

**第五条** 本会的住所设在北京市。

本会的网址：[www.phirda.com](http://www.phirda.com)。

## 第二章 业务范围

**第六条** 本会的业务范围：

（一）认真贯彻执行党中央、国务院有关中国医药创新各项政策，深入研究新药研发政策和中国医药体系创新的相关问题，科学预测新药研发的走向，及时提出中国医药创新发展的政策建议，切实反映会员单位合理的愿望和诉求，协助会员单位解决实际问题；

（二）组织和参加有关医药行业发展的交流活动，增强中国医药行业的创新能力。组织和参加有关学术交流，推动医药行业产学研的结合，积极开展新药科研和技术协作及科技成果的推广，推动技术转让与协作，促进医药高科技的产业化、专业化；

（三）发挥自身优势、充分利用现代化手段，搜集、整理、研究、传递医药科技研发信息，聚焦医药行业重点问题，并开展咨询服务；

（四）推动中国医药行业的国际交流，组织开展各种形式的中外医药行业信息、技术、人员的交流与合作；

（五）践行国家创新驱动发展战略指导精神，为会员单位搭建医药创新合作平台，推动社会资本加大对医药创新项目的投入。

业务范围中属于法律法规规章规定须经批准的事项，依法经批准后开展。

## 第三章 会员

**第七条** 本会的会员为单位会员。

**第八条** 拥护本会章程，符合下列条件的，可以自

愿申请加入本会：

- (一) 有加入本会的意愿；
- (二) 在本会的业务领域内具有一定的影响；
- (三) 本会要求的其他条件。

**第九条** 会员入会的程序是：

- (一) 提交入会申请表(盖章)；
- (二) 提交其他相关材料, 包括：
  - 1、单位中文简介(盖章)；
  - 2、单位英文简介(盖章)；
  - 3、本会要求提供的其他材料。
- (三) 由理事会讨论通过；
- (四) 由本会颁发会员证, 并予以公告。

**第十条** 会员享有下列权利：

- (一) 选举权、被选举权和表决权；
- (二) 对本会工作的知情权、建议权和监督权；
- (三) 参加本会活动并获得本会服务的优先权；
- (四) 按规定获得本会发出的信息资料和刊物权；
- (五) 对本会提出保护合法权益不受侵害的权利；
- (六) 退会自由。

**第十一条** 会员履行下列义务：

- (一) 遵守本会的章程和各项规定；
- (二) 执行本会的决议；
- (三) 按规定交纳会费；
- (四) 维护本会的合法权益；
- (五) 向本会反映情况, 提供有关资料；
- (六) 完成本会交办的工作。

**第十二条** 会员如有违反法律法规和本章程的行为, 经理事会或理事会授权的机构表决通过, 给予下列处分：

- (一) 警告；
- (二) 通报批评；
- (三) 暂停行使会员权利；

(四) 除名。

**第十三条** 会员退会须书面通知本会并交回会员证。

**第十四条** 会员有下列情形之一的, 自动丧失会员资格：

- (一) 1年不按规定交纳会费；
- (二) 1年不按要求参加本会活动；
- (三) 不再符合会员条件。

**第十五条** 会员退会、自动丧失会员资格或者被除名后, 其在本会相应的职务、权利、义务自行终止。

**第十六条** 本会置备会员名册, 对会员情况进行记载。会员情况发生变动的, 应当及时修改会员名册, 并向会员公告。

## 第四章 组织机构

### 第一节 会员大会

**第十七条** 会员大会是本会的最高权力机构, 其职权是：

- (一) 制定和修改章程；
- (二) 决定本会的工作目标和发展规划；
- (三) 制定和修改理事、监事和负责人产生办法, 报业务主管单位备案；
- (四) 选举和罢免理事、监事；
- (五) 制定和修改会费标准；
- (六) 审议理事会的工作报告和财务报告；
- (七) 决定名誉职务的设立；
- (八) 审议监事的工作报告；
- (九) 决定名称变更事宜；
- (十) 决定终止事宜；
- (十一) 决定其他重大事宜。

**第十八条** 会员大会每5年至少召开1次。本会召开会员大会, 须提前15日将会议的议题通知会员。

会员大会应当采用现场表决方式。

**第十九条** 经理事会或者本会50%以上的会员提议,应当召开临时会员大会。

临时会员大会由会长主持。会长不主持或不能主持的,由提议的理事会或会员推举本会一名负责人主持。

**第二十条** 会员大会须有2/3以上的会员出席方能召开,决议事项符合下列条件方能生效:

(一)制定和修改章程,决定本会终止,须经到会会员2/3以上表决通过;

(二)选举理事,当选理事得票数不得低于到会会员的1/2;

(三)罢免理事,须经到会会员1/2以上投票通过;

(四)制定或修改会费标准,须经到会会员1/2以上无记名投票方式表决;

(五)其他决议,须经到会会员1/2以上表决通过。

## 第二节 理事会

**第二十一条** 理事会是会员大会的执行机构,在会员大会闭会期间领导本会开展工作,对会员大会负责。

理事人数最多不得超过48人,不能来自同一会员单位。

本会理事应当符合以下条件:

(一)拥护本会的章程;

(二)有担任本会理事的意愿,支持本会工作;

(三)在本会所从事的领域具有一定影响力。

**第二十二条** 理事的选举和罢免:

(一)第一届理事由发起人商申请成立时的会员共同提名,报业务主管单位同意后,会员大会选举产生;

(二)理事会换届,应当在会员大会召开前6个月,由理事会提名,成立由理事代表、监事代表、党组织代表和会员代表组成的换届工作领导小组(或专门选举委员会);

理事会不能召集的,由1/5以上理事、监事、本会

党组织或党建联络员向业务主管单位申请,由业务主管单位组织成立换届工作领导小组(或专门选举委员会),负责换届选举工作;

换届工作领导小组拟定换届方案,应在会员大会召开前2个月报业务主管单位审核;

经业务主管单位同意,召开会员大会,选举和罢免理事;

(三)根据会员大会的授权,理事会在届中可以增补、罢免部分理事,最高不超过原理事总数的1/5。

**第二十三条** 每个理事单位只能选派一名代表担任理事。单位调整理事代表,由其书面通知本会,报理事会备案。

**第二十四条** 理事的权利:

(一)理事会的选举权、被选举权和表决权;

(二)对本会工作情况、财务情况、重大事项的知情权、建议权和监督权;

(三)参与制定内部管理制度,提出意见建议;

(四)向会长或理事会提出召开临时会议的建议权。

**第二十五条** 理事应当遵守法律、法规和本章程的规定,忠实履行职责、维护本会利益,并履行以下义务:

(一)出席理事会会议,执行理事会决议;

(二)在职责范围内行使权利,不越权;

(三)不利用理事职权谋取不正当利益;

(四)不从事损害本会合法利益的活动;

(五)不得泄露在任职期间所获得的涉及本会的保密信息,但法律、法规另有规定的除外;

(六)谨慎、认真、勤勉、独立行使被合法赋予的职权;

(七)接受监事对其履行职责的合法监督和合理建议。

**第二十六条** 理事会的职权是:



- (一) 执行会员大会的决议；
- (二) 选举和罢免负责人；
- (三) 决定名誉职务人选；
- (四) 筹备召开会员大会，负责换届选举工作；
- (五) 向会员大会报告工作和财务状况；
- (六) 决定设立、变更和终止分支机构、代表机构、办事机构和其他所属机构；
- (七) 决定副秘书长、各所属机构主要负责人的  
人选；
- (八) 领导本会各所属机构开展工作；
- (九) 审议年度工作报告和工作计划；
- (十) 审议年度财务预算、决算；
- (十一) 制定分支机构管理办法等重要的管理制度；
- (十二) 决定本会负责人和工作人员的考核及薪酬管理办法；
- (十三) 决定其他重大事项。

**第二十七条** 理事会每届5年。因特殊情况需提前或者延期换届的，须由理事会表决通过，报业务主管单位审核同意后，报登记管理机关批准。延期换届最长不超过1年。

**第二十八条** 理事会会议须有2/3以上理事出席方能召开，其决议须经到会理事2/3以上表决通过方能生效。

理事两次不出席理事会会议，自动丧失理事资格。

**第二十九条** 负责人由理事会采取无记名投票方式从理事中选举产生。

罢免负责人，须经到会理事2/3以上投票通过。

**第三十条** 选举负责人，按得票数确定当选人员，但当选的得票数不得低于总票数的2/3。

**第三十一条** 理事会每年至少召开1次会议，情况

特殊的，可采用通讯形式召开。负责人调整不得以通讯会议方式进行决定。

**第三十二条** 经会长或者1/5的理事提议，应当召开临时理事会会议。

会长不能主持临时理事会会议，由提议召集人推举本会一名负责人主持会议。

### 第三节 会长会议

**第三十三条** 本会设立会长会议，由本会负责人组成。

**第三十四条** 会长会议由会长决定召开，须有2/3以上组成人员出席方能召开，其决议须经到会人员2/3以上表决通过方为有效。

经会长或1/3以上的负责人提议，应当召开临时会长会议。会长不能主持临时会长会议，由提议召集人推举本会1名负责人主持会议。

**第三十五条** 会长会议行使以下职权：

- (一) 贯彻会员大会和理事会决议；
- (二) 监督本会各项规章制度以及年度工作计划和年度预算的实施；
- (三) 向理事会提出建议议题。

### 第四节 负责人

**第三十六条** 本会负责人包括会长1名，副会长10-14名，秘书长1名。

本会实行年度轮值会长制度；会长从理事中经选举产生，任期1年。

本会负责人应当具备下列条件：

- (一) 坚持中国共产党领导，拥护中国特色社会主义，坚决执行党的路线、方针、政策，具备良好的政治素质；
- (二) 遵纪守法，勤勉尽职，个人信用记录良好；
- (三) 具备相应的专业知识、经验和能力，熟悉行

业情况,在本会业务领域有较大影响;

(四) 身体健康,能正常履责,年龄不超过70周岁,秘书长为专职;

(五) 具有完全民事行为能力;

(六) 能够忠实、勤勉履行职责,维护本会和会员的合法权益;

(七) 无法律法规、国家政策规定不得担任的其他情形。

会长、秘书长不得兼任其他社会团体的会长、秘书长,会长和秘书长不得由同一人兼任,并不得来自于同一会员单位。

**第三十七条** 本会负责人任期与理事会相同,连任不超过2届。

**第三十八条** 会长为本会法定代表人。

因特殊情况,经会长委托、理事会同意,报业务主管单位审核同意并经登记管理机关批准后,可以由副会长或秘书长担任法定代表人。聘任或向社会公开招聘的秘书长不得任本会法定代表人。

法定代表人代表本会签署有关重要文件。

本会法定代表人不兼任其他社团的法定代表人。

**第三十九条** 担任法定代表人的负责人被罢免或卸任后,不再履行本会法定代表人的职权。由本会在其被罢免或卸任后的20日内,报业务主管单位审核同意后,向登记管理机关办理变更登记。

原任法定代表人不予配合办理法定代表人变更登记,本会可根据理事会同意变更的决议,报业务主管单位审核同意后,向登记管理机关申请变更登记。

**第四十条** 会长履行下列职责:

- (一) 召集和主持理事会和会长会议;
- (二) 检查会员大会、理事会的落实情况;
- (三) 向会员大会、理事会报告工作。

会长应每年向理事会进行述职。不能履行职责时,由其委托或理事会推选一名副会长代为履行职责。

**第四十一条** 副会长、秘书长协助会长开展工作。

秘书长行使下列职责:

- (一) 协调各机构开展工作;
- (二) 主持办事机构开展日常工作;
- (三) 提名副秘书长及所属机构主要负责人,交理事会决定;
- (四) 决定专职工作人员的聘用;
- (五) 拟订年度工作报告和工作计划,报理事会审议;
- (六) 拟订年度财务预算、决算报告,报理事会审议;
- (七) 拟订内部管理制度,报理事会批准;
- (八) 处理其他日常事务。

**第四十二条** 会员大会、理事会会议应当制作会议纪要。形成决议的,应当制作书面决议,并由出席会议成员核签。会议纪要、会议决议应当以适当方式向会员通报或备查,并至少保存10年。

理事、负责人的选举结果须在20日内报业务主管单位审核,经同意,向登记管理机关备案并向会员通报或备查。

## 第五节 监事

**第四十三条** 本会设监事1-6名。监事任期与理事任期相同,期满可以连任。

本会接受并支持委派监事的监督指导。

**第四十四条** 监事的选举和罢免:

- (一) 由会员大会选举产生;
- (二) 监事的罢免依照其产生程序。

**第四十五条** 本会的负责人、理事和本会的财务管理人员不得兼任监事。

**第四十六条** 监事行使下列职权:

(一)列席理事会、会长会议,并对决议事项提出质询或建议;

(二)对理事、负责人执行本会职务的行为进行监督,对严重违反本会章程或者会员大会决议的人员提出罢免建议;

(三)检查本会的财务报告,向会员大会报告监事工作和提出提案;

(四)对负责人、理事、财务管理人员损害本会利益的行为,要求其及时予以纠正;

(五)向业务主管单位、行业管理部门、登记管理机关以及税务、会计主管部门反映本会工作中存在的问题;

(六)决定其他应由监事审议的事项。

**第四十七条** 监事应当遵守有关法律法规和本会章程,忠实、勤勉履行职责。

**第四十八条** 监事可以对本会开展活动情况进行调查;必要时,可以聘请会计师事务所等协助其工作。监事行使职权所必需的费用,由本会承担。

## 第六节 分支机构、代表机构

**第四十九条** 本会在本章程规定的宗旨和业务范围内,根据工作需要设立分支机构、代表机构。本会的分支机构、代表机构是本会的组成部分,不具有法人资格,不得另行制订章程,不得发放任何形式的登记证书,在本会授权的范围内开展活动、发展会员,法律责任由本会承担。

分支机构、代表机构开展活动,应当使用冠有本会名称的规范全称,并不得超出本会的业务范围。

**第五十条** 本会不设立地域性分支机构,不在分支机构、代表机构下再设立分支机构、代表机构。

**第五十一条** 本会的分支机构、代表机构名称不以各类法人组织的名称命名,不在名称中冠以“中国”、“中华”、“全国”、“国家”等字样,并以“分会”、“

专业委员会”、“工作委员会”、“专项基金管理委员会”、“代表处”、“办事处”等字样结束。

**第五十二条** 分支机构、代表机构的负责人,年龄不得超过70周岁,连任不超过2届。

**第五十三条** 分支机构、代表机构的财务必须纳入本会法定账户统一管理。

**第五十四条** 本会在年度工作报告中将分支机构、代表机构的有关情况报送登记管理机关。同时,将有关信息及时向社会公开,自觉接受社会监督。

## 第七节 内部管理制度和矛盾解决机制

**第五十五条** 本会建立各项内部管理制度,完善相关管理规程。建立《会员大会选举规程》、《理事会选举规程》、《会员管理办法》、《分支机构管理办法》等相关制度和文件。

**第五十六条** 本会建立健全证书、印章、档案、文件等内部管理制度,并将以上物品和资料妥善保管于本会场所,任何单位、个人不得非法侵占。管理人员调动工作或者离职时,必须与接管人员办清交接手续。

**第五十七条** 本会证书、印章遗失时,经理事会2/3以上理事表决通过,在公开发布的报刊上刊登遗失声明,可以向登记管理机关申请重新制发或刻制。如被个人非法侵占,应通过法律途径要求返还。

**第五十八条** 本会建立民主协商和内部矛盾解决机制。如发生内部矛盾不能经过协商解决的,可以通过调解、诉讼等途径依法解决。



## 第五章 资产管理、使用原则

**第五十九条** 本会收入来源：

- (一) 会费；
- (二) 捐赠；
- (三) 政府资助；
- (四) 在核准的业务范围内开展活动、提供服务的收入；
- (五) 利息；
- (六) 其他合法收入。

**第六十条** 本会按照国家有关规定收取会员会费。本会开展评比表彰等活动，不收取任何费用。

**第六十一条** 本会的收入除用于与本会有关的、合理的支出外，全部用于本章程规定的业务范围和非营利事业。

**第六十二条** 本会执行《民间非营利组织会计制度》，建立严格的财务管理制度，保证会计资料合法、真实、准确、完整。

**第六十三条** 本会配备具有专业资格的会计人员。会计不得兼任出纳。会计人员必须进行会计核算，实行会计监督。会计人员调动工作或者离职时，必须与接管人员办清交接手续。

**第六十四条** 本会的资产管理必须执行国家规定的财务管理制度，接受会员大会和有关部门的监督。资产来源属于国家拨款或者社会捐赠、资助的，必须接受审计机关的监督，并将有关情况以适当方式向社会公布。

**第六十五条** 本会重大资产配置、处置须经过会员大会或者理事会审议。

**第六十六条** 理事会决议违反法律、法规或章程

规定，致使社会团体遭受损失的，参与审议的理事应当承担责任。但经证明在表决时反对并记载于会议记录的，该理事可免除责任。

**第六十七条** 本会换届或者更换法定代表人之前必须进行财务审计。

法定代表人在任期间，本社团发生违反《社会团体登记管理条例》和本章程的行为，法定代表人应当承担相关责任。因法定代表人失职，导致社会团体发生违法行为或社会团体财产损失的，法定代表人应当承担个人责任。

**第六十八条** 本会的全部资产及其增值为本会所有，任何单位、个人不得侵占、私分和挪用，也不得在会员中分配。

## 第六章 信息公开与信用承诺

**第六十九条** 本会依据有关政策法规，履行信息公开义务，建立信息公开制度，及时向会员公开年度工作报告、第三方机构出具的报告、会费收支情况以及经理事会研究认为有必要公开的其他信息，及时向社会公开登记事项、章程、组织机构、接受捐赠、信用承诺、政府转移或委托事项、可提供服务事项及运行情况等信息。

本会建立新闻发言人制度，经理事会通过，任命或指定1名负责人作为新闻发言人，就本组织的重要活动、重大事件或热点问题，通过定期或不定期举行新闻发布会、吹风会、接受采访等形式主动回应社会关切。新闻发布内容应由本会法定代表人或主要负责人审定，确保正确的舆论导向。

**第七十条** 本会建立年度报告制度，年度报告内容及时向社会公开，接受公众监督。

**第七十一条** 本会重点围绕服务内容、服务方式、

服务对象和收费标准等建立信用承诺制度,并向社会公开信用承诺内容。

## 第七章 章程的修改程序

**第七十二条** 对本会章程的修改,由理事会表决通过,提交会员大会审议。

**第七十三条** 本会修改的章程,经会员大会到会会员2/3以上表决通过后,报业务主管单位审核,经同意,在30日内报登记管理机构核准。

## 第八章 终止程序及终止后的财产处理

**第七十四条** 本会终止动议由理事会提出,报会员大会表决通过。

**第七十五条** 本会终止前,应当依法成立清算组

织,清理债权债务,处理善后事宜。清算期间,不开展清算以外的活动。

**第七十六条** 本会经登记管理机构办理注销登记手续后即终止。

**第七十七条** 本会终止后的剩余财产,在业务主管单位和登记管理机构的监督下,按照国家有关规定,用于发展与本会宗旨相关的事业,或者捐赠给宗旨相近的社会组织。

## 第九章 附则

**第七十八条** 本章程经2019年9月20日第十一届会员大会表决通过。

**第七十九条** 本章程的解释权属本会的理事会。

**第八十条** 本章程自登记管理机构核准之日起生效。

# Constitution of PhIRDA

## Chapter I: General Principle

**Article 1.** China Pharmaceutical Innovation and Research Development Association (PhIRDA) is a nationwide industrial, non-government and non-profit organization, which consists of domestic pharmaceutical enterprises excelling at innovation, star-up and R&D enterprises focusing on independent innovation of pharmaceutical products, domestic first-class universities, colleges and research institutions conducting innovative pharmaceutical R&D, clinical institutions featuring high skills in applicable research on new drugs, and investment institutions committing to pharmaceutical innovation. The members' distribution and activity area of the Association is nationwide.

**Article 2.** The objectives of the Association: Upholding the banner of socialism with Chinese characteristics, taking Deng Xiaoping Theory, the Theory of Three Represents, the Scientific Outlook on Development and Xi Jinping thought on socialism with Chinese characteristics in a new era as our guide, PhIRDA will fully and faithfully apply relevant policies and the reform spirit of the government in our work, improve the scientific research and innovation capacity of China's pharmaceutical industry, promote the transformation of pharmaceutical R&D and innovation achievements, enhance the international competitiveness of China's pharmaceutical industry, protect the legitimate rights and interests of members, build a bridge to communication among the government and industry, and make due contributions to pharmaceutical innovation and social and economic development.

PhIRDA follows the China's related constitution, laws, regulations and policies, practices core socialist values, advocates the spirit of ethnic patriotism, observes social ethics, consciously promotes credibility building and raises awareness of self-discipline.

**Article 3.** PhIRDA upholds the unity Party leadership and sets up the Party organizations in accordance with the provisions of the Party Constitution to carry out Party activities and provide necessary service.

PhIRDA was registered in the Ministry of Civil Affairs of the People's Republic of China, and administrated by State-owned Assets Supervision and Administration Commission of the State Board of Directors.

PhIRDA receives administration by the registration authority, the administrative department and the relevant industry administrative departments.

**Article 4.** The leaders of PhIRDA include the Chairman, the Vice President and the Secretary-General.

**Article 5.** The residence of PhIRDA is in Beijing.  
The website of the PhIRDA: [www.phirda.com](http://www.phirda.com).

## Chapter II: Business Range

**Article 6.** Business range of PhIRDA:

(1) To carry out and implement relevant policies on Chinese pharmaceutical industry development made by the Central Committee of CPC and the State Council, perform in-depth research on new drug development and Chinese pharmaceutical innovation system, scientifically forecast the direction of new drug development, timely propose the suggestions for development of Chinese pharmaceutical industry, reflect members' reasonable suggestions and demands, and assist members to solve practical problems.

(2) To organize and participate in the events for exchanging and communication, promote China's pharmaceutical industry development. To organize and participate in the relevant academic exchanges, promote the pharmaceutical industry combination of scientific research and practices, advance the relevant research cooperation and academic-achieve transformation, and assist to industrialization and specification of the high



technology.

(3) To fully play PhIRDA's advantages and modern technologies in collecting, studying and releasing information on pharmaceutical science and technology, focus on the key issues of industry and provide consulting service.

(4) To promote the international communication of China's pharmaceutical industry, and organize diverse cooperation and exchanges on information, technologies and personnel.

(5) To implement National Innovation-driven Development Strategy, build a platform for cooperation in pharmaceutical innovation, and promote social capital into innovative drug R&D projects.

The matters within the business range requires approval and prescribed by laws, regulations and rules shall be carried out upon approval according to law.

## Chapter III: Members

**Article 7.** PhIRDA Members: Institutional members.

**Article 8.** Applicant members who uphold the constitution of the Association and meet the following conditions may voluntarily apply to join the Association:

- (1) Be willing to join the Association;
- (2) Possess certain influences in the PhIRDA's business range;
- (3) Meet other conditions required by the Association.

**Article 9.** Procedures of joining the Association:

- (1) Submitting application (with stamp);
- (2) Submitting other relevant materials, including:
  1. Introduction in Chinese (with stamp);
  2. Introduction in English (with stamp);
  3. Other materials required by the Association.
- (3) Being approved through discussion by the Board of Directors;
- (4) Membership will be issued by the Association and announced.

**Article 10.** Rights and duties of members:

- (1) The rights of election, being elected and vote;
- (2) The rights to be informed, advise and supervise the work of the Association;
- (3) The rights to participate in the Association activities and obtain services from Association;
- (4) The rights to have access to information and publications issued by the Association;
- (5) The right on protection of legitimate rights and interests;
- (6) The freedom of quitting the Association.

**Article 11.** Duties of the members:

- (1) Obey the Constitution and regulations of PhIRDA;
- (2) Implement the decision of the Association;
- (3) Pay membership dues on time as per the stipulation;
- (4) Protect the legal rights and interests of the Association;
- (5) Provide information requested by the Association;
- (6) Complete the work entrusted by the Association.

**Article 12.** Any member violating the laws, regulations and the Constitution shall be subject to the following punishment by vote of the Board of Directors or the institution authorized by the Board of Directors:

- (1) Warning;
- (2) Criticism in notice;
- (3) Suspension of membership rights;
- (4) Being removed from membership.

**Article 13.** The withdrawing member shall inform the Association in written statement and return membership certificate.

**Article 14.** The member will automatically lose its membership under any of the following circumstances:

- (1) Refuse to pay membership dues on time as per the stipulation for 1 year;
- (2) Refuse to participate the activities of the Association as per the stipulation for 1 year;
- (3) No longer meet the membership conditions.

**Article 15.** After withdrawing from the Association, automatically losing the membership or being removed with membership, the position, rights and obligations



of the member in the Association will be terminated automatically.

**Article 16.** The member will be recorded in the member list. For any change of the membership, the list shall be revised in a timely manner and announced to all members.

## Chapter IV: Organization Structure

### Section One: PhIRDA General Assembly

**Article 17.** The PhIRDA General Assembly is the highest powerful organization of the Association. Functions of the PhIRDA General Assembly include:

- (1) Composing and revising the Constitution of the Association;
- (2) Deciding on the objectives and development plan of the Association;
- (3) Formulating and revising the method of electing Directors, Supervisors and persons in charge, and reporting to the administrative department as record;
- (4) Electing and recalling Directors and Supervisors;
- (5) Establishing and modifying the membership fee standard;
- (6) Reviewing working report and financial report of the Board of Directors;
- (7) Deciding the establishment of honorary position;
- (8) Reviewing working report of Supervisors;
- (9) Deciding the name change of the Association;
- (10) Deciding termination of the Association;
- (11) Deciding other important issues.

**Article 18.** The PhIRDA General Assembly shall be held at least once every five years. PhIRDA members shall be notified of the issue of General Assembly 15 days in advance.

The PhIRDA General Assembly shall adopt the form of on-site voting.

**Article 19.** An Interim General Assembly shall be held upon the proposal of the Board of Directors or the members of the Association of more than 50%.

The Interim General Assembly shall be chaired by the

Chairman. If Chairman is not able to chair, a charge person proposed by the Board of Directors or members shall be elected.

**Article 20.** The PhIRDA General Assembly's holding requires a participation of more than two thirds of all members. Any decision shall not come into effect unless:

- (1) In composing and revising the Constitution of the association as well as deciding termination of the Association, it should be adopted by more than 2/3 of the members present;
- (2) The numbers of votes obtained by the elected members shall not be less than 1/2 of the members present in electing a Director;
- (3) The recall of a Director shall be approved by more than 1/2 of the members present;
- (4) The establishment or modification of the membership fee standard shall be subject to a secret ballot of not less than 1/2 of the members present;
- (5) Other decisions shall be approved by more than 1/2 of the members present.

### Section Two: Board of Directors

**Article 21.** The Board of Directors is the executive body of the PhIRDA General Assembly. During the period when the PhIRDA General Assembly is not in session, the Board of Directors shall carry out work and be responsible for the PhIRDA General Assembly.

The maximum number of Directors shall not exceed 48, and they shall not come from the same member unit.

The Directors of the Association shall meet the following requirements:

- (1) Upholding the Constitution of the Association;
- (2) Be willing to act as the Director of the Association and support the work of the Association;
- (3) Possessing certain influences in the business range of the Association.

**Article 22.** Election and recall of Directors

- (1) The first session of Directors shall be jointly nominated by the members upon the application of the sponsor and submitted to the administrative department

for approval, and then elected by the PhIRDA General Assembly;

(2) For the term change of the Board of Directors, the Board of Directors shall nominate a leading group (or special election committee) consisting of the representatives of the Directors, the Supervisors, the Party organizations and PhIRDA members six months prior to the convening of the PhIRDA General Assembly; If the Board of Directors is unable to be convened, more than 1/5 of the Directors, Supervisors, Party organizations or Party building liaison officers shall apply to the administrative department, and organize a leading group (or special election committee) to be responsible for the election of the new term;

The leading group for term change shall draft a term change plan, which shall be reported to the administrative department for review and approval 2 months prior to the holding of the PhIRDA General Assembly;

With the consent of the administrative department, the PhIRDA General Assembly shall be held to elect and recall the Directors;

(3) With the authorization of the PhIRDA General Assembly, the Board of Directors may add and recall some of the Directors in the session, no more than 1/5 of the total number of the original Directors.

**Article 23.** Each Director unit can only select one representative to serve as a Director. If the unit adjusts the representative, it shall notify the Association in writing and report to the Board of Directors for archival purposes.

**Article 24.** Rights of Directors:

- (1) The rights of election, being elected and vote;
- (2) The rights to know, advise and supervise the work, financial situation and major matters of the Association;
- (3) The rights to participate in the development of internal management system and provide comments and suggestions;
- (4) The rights to propose to the Chairman or the Board of Directors to hold an interim meeting.

**Article 25.** The Directors shall abide by the laws,

regulations and the Constitution of the Association, faithfully perform their duties, safeguard the interests of the Association and perform the following obligations:

- (1) To attend meetings of the Board of Directors and implement the resolutions of the Board of Directors;
- (2) To exercise rights within the scope of their duties and powers;
- (3) Not to use the authority of Directors for illegitimate interests;
- (4) Not to engage in activities damaging the legitimate interests of the Association;
- (5) Not to disclose confidential information related to the Association obtained during the term, except as otherwise provided by laws and regulations;
- (6) To exercise the functions and powers lawfully conferred with prudently, seriously, diligently and independently;
- (7) To accept the lawful supervision and reasonable suggestions of Supervisors on their performance of duties.

**Article 26.** Functions of the Board of Directors:

- (1) Implementing the decisions by PhIRDA General Assembly;
- (2) Electing and recalling the persons in charge;
- (3) Nominating honorary position;
- (4) Preparing for the holding of the PhIRDA General Assembly and taking charge of election at expiration of office terms;
- (5) Reporting work and financial situations to the PhIRDA General Assembly;
- (6) Making decision on the establishment, modification and termination of branches, representative offices, offices and other subordinate bodies;
- (7) Nominating the deputy secretary-general and the principal responsible persons of all subordinate institutions;
- (8) Leading the work of the institutions affiliated to the Association;
- (9) Deliberating annual work reports and work plans;
- (10) Deliberating annual financial budget and final settlement;
- (11) Formulating management measures for branch offices and other important management systems;
- (12) Deciding on the measures for the assessment and salary management of the person in charge and staff of

the Association;

(13) Deciding other important issues.

**Article 27.** Each term of the Board of Directors is 5 years. Where the term change needs to be made in advance or postponed due to special circumstances, it shall be adopted by the Board of Directors by voting, be reported to the administrative department for review and approval, and then be reported to the registration authority for approval. The term change shall not be postponed by one year in maximum.

**Article 28.** The Board of Directors Meeting shall be held only with over 2/3 of Directors are present, and its decisions will take effect only after being adopted by more than 2/3 Directors.

Any Director absent twice will be automatically disqualified.

**Article 29.** The person in charge shall be elected by the Board of Directors through secret ballot from the Directors.

The recall of the person in charge shall be approved by more than 2/3 of the Directors present.

**Article 30.** The person in charge shall be elected according to the number of votes obtained, but the number of votes elected shall not be less than 2/3 of the total number of votes.

**Article 31.** The Board of Directors shall meet at least once a year, and may convene in the form of online or telephone communication if the circumstances are special, but the way should not be applied in adjustment of the person in charge.

**Article 32.** An interim Board of Directors meeting shall be convened upon the proposal of the Chairman or 1/5 of the Directors.

The Chairman shall not preside over the interim Board of Directors meeting, and the convener shall elect a person in charge from the Association to preside over the meeting.

### **Section Three: Chairman Meeting**

**Article 33.** The Association shall establish a Chairman Meeting composed of the persons in charge of the Association.

**Article 34.** The Chairman Meeting shall be convened upon the decision of the Chairman with over 2/3 of the persons in charge, and the resolution shall come into effect only when passed by over 2/3 of the persons in charge.

An interim Chairman Meeting shall be convened upon the proposal of the Chairman or 1/3 of the persons in charge.

**Article 35.** Functions of the Chairman Meeting:

- (1) Implementing the decisions of the PhIRDA General Assembly and the Board of Directors;
- (2) Supervising the implementation of the rules and regulations of the Association as well as the annual work plan and annual budget;
- (3) Proposing topics to the Board of Directors.

### **Section Four: Association Leaders**

**Article 36.** The leaders of the Association include one Chairman, 10-14 Vice Presidents and one Secretary-General.

The Association applies system of annual Chairman rotation; the Chairman shall be elected from members, and the term is 1 year.

The leaders of the Association must meet the following requirements:

- (1) Adhering to the Party leadership, upholding socialism with Chinese characteristics, resolutely implementing political direction, guidelines and policies, and possessing good political qualities;
- (2) Complying with laws and disciplines, working with due diligence, and possessing good social credibility;
- (3) Mastering professional knowledge, experience and ability, being familiar with the industry situation, and possessing great influence in the business field of the Association;
- (4) Being in good health, able to perform normal duties, and aged no more than 70 years old, and the Secretary-



General should be in full-time position;  
(5) With ability of complete civil behavior;  
(6) Being able to perform duties faithfully and diligently, and protect the legitimate rights and interests of the Association and its members;  
(7) There is no other circumstance that laws, regulations and national policies prohibiting the holding of the post. The Chairman and the Secretary-General shall not concurrently hold the counterpart in other social organizations. The Chairman and the Secretary-General shall not be concurrently held by the same person and shall not come from the same member unit.

**Article 37.** The term of the leaders of the Association shall be the same as those of the Board of Directors, and the term shall not exceed 2 consecutive terms.

**Article 38.** The Chairman is the legal person of the Association.

Under special circumstances, upon the agreement of the Chairman and the Board of Directors, and upon the review and approval of the administrative department and the approval of the registration authority, the Vice President or the Secretary-General may act as the legal person. The Secretary-General employed or publicly recruited shall not be the legal person of the Association. The legal person will represent PhIRDA to sign the relevant documents.

The legal person is not allowed to hold a counterpart position in other associations.

**Article 39.** After the person in charge who serves as the legal person is recalled or leaves office, he/she will no longer perform the functions and powers of the legal person of the Association. Within 20 days after being recalled or retiring from office, the Association shall apply to the registration authority for registration of change after reporting to the administrative department for review and approval.

Where the former legal person fails to cooperate in the modification registration of the legal person, the Association may, according to the resolution of the Board of Directors on approving the modification, report to the

administrative department for review and approval, and then apply to the registration authority for registration modification.

**Article 40.** Function and powers executed by the Chairman:

- (1) Calling for and hosting the PhIRDA General Assembly;
- (2) Examining the implementation of decisions made by the PhIRDA General Assembly;
- (3) Report work to the PhIRDA General Assembly and the Board of Directors.

The Chairman shall report annually to the Board of Directors. A Vice President elected by the Board of Directors or appointed by the Chairman who cannot fulfill his or her duty.

**Article 41.** The Vice President and the Secretary-General shall assist the Chairman in carrying out the work, the functions executed by the Secretary-General include:

- (1) To coordinate the work of various administrative sectors;
- (2) To be in charge and organize administrative sectors to do routine work;
- (3) To nominate the Deputy Secretary-General and representatives of sub-branches for the PhIRDA General Assembly's approval.
- (4) To manage the employment of full-time working staffs for the Association;
- (5) To draft the annual work report and work plan, and submit them to the Board of Directors for deliberation;
- (6) To prepare the annual financial budget and final settlement report, and submit them to the Board of Directors for deliberation;
- (7) To draw up the internal management system and submit it to the Board of Directors for approval;
- (8) In charge of executing other routine affairs.

**Article 42.** Meeting summary shall be made for the PhIRDA General Assembly and Board of Directors meeting. Where a decision is made, a written report shall be made and verified and signed by the members present at the meeting. The Meeting summary and decisions of

the meeting shall be circulated to the members or kept for future reference in an appropriate manner for at least 10 years.

The election result of Directors or persons in charge shall be reported to the administrative department for review and approval within 20 days, and upon approval, be reported to the registration authority for archival filing and to the members for notification or future reference.

### Section Five: Supervisors

**Article 43.** The Association has 1-6 Supervisors. The term of a supervisor shall be the same as that of a Director, and the supervisor may be re-elected upon expiration.

The Association accepts and supports the supervision and guidance of the appointed supervisor.

**Article 44.** The election and recall of a supervisor:

- (1) The Supervisors are elected by the PhIRDA General Assembly;
- (2) The recall of Supervisors shall be subject to the procedures for their election.

**Article 45.** The leaders of the Association, the Directors and the financial management personnel of the Association shall not concurrently serve as Supervisors.

**Article 46.** The functions executed by the Supervisors include:

- (1) To attend the Board of Directors Meeting and Chairman Meeting, and make queries or suggestions on matters to be resolved;
- (2) To supervise the performance of the duties of the Association by the Directors and persons in charge, and put forward suggestions for the recall of the personnel who seriously violates the Constitution of the Association or the resolutions of the PhIRDA General Assembly;
- (3) To examine the financial report of the Association, report the work of Supervisors and present proposals to the PhIRDA General Assembly;
- (4) To rectify any acts damage the interests of the Association of the persons in charge, Directors or financial managers in a timely manner;
- (5) To report the problems existing in the work of the

Association to the administrative department, industry administrative department, registration authority and competent taxation and accounting departments;

- (6) To decide on other matters to be deliberated by the Supervisors.

**Article 47.** The Supervisors shall abide by the relevant laws and regulations and the Constitution of Association, and perform their duties fully and faithfully.

**Article 48.** Supervisors may investigate the activities carried out by the Association and, if necessary, hire an accounting firm to assist them in their work. The expenses necessary for the Supervisors to exercise their functions and powers shall be borne by the Association.

### Section Six: Branch and representative office

**Article 49.** The Association shall establish branches and representative offices within the business range and purpose required by the present Constitution of Association. The branches and representative offices of the Association is an integral part of the Association, not qualified to possess legal person status or additional constitution or registration certificate in any forms. The branches and representative offices will organize activities and include member under the scope authorized by the Association. The legal liabilities shall be assumed by the Association.

When carrying out activities, branches or representative offices shall use the standard full name of the Association, and shall not go beyond the business range of the Association.

**Article 50.** The Association will not establish regional branches or reestablish sub-branches or sub-representative offices.

**Article 51.** The names of the branches and representative offices of the Association shall not be named after the names of various legal person organizations, and shall not be prefixed with the words 'China', 'nation' and 'country' etc., and shall be ended with the words 'branch', 'specialty committee', 'working committee', 'special

fund management committee', 'representative office' and 'office' etc.

**Article 52.** The persons in charge of branches or representative offices shall not be more than 70 years old, the term shall not exceed 2 consecutive terms.

**Article 53.** The financial affairs of branches and representative offices shall be subject to the unified management of the statutory accounts of the Association.

**Article 54.** The Association shall, in its annual work report, report the relevant information on its branches and representative offices to the registration authority. At the same time, the Association shall disclose relevant information to the public in a timely manner, and accept social supervision consciously.

#### **Section Seven: Internal management system and conflict resolution mechanism**

**Article 55.** The Association shall establish various internal management systems and improve relevant management procedures. The Association shall formulate *Rules for the Election of Members of the PhIRDA General Assembly*, *Rules for the Election of the Members of the Board of Directors*, *Measures for Member Management*, *Measures for the Branch Management* and other relevant documents.

**Article 56.** The Association shall establish and improve the internal management rules for certificates, stamps, archives, documents, etc., and properly keep the aforesaid articles and materials in the place of the Association that shall not be legally possessed by any unit or individuals. If management leave or are transferred, they must go through handing-over procedures with the managing staff and shifting persons.

**Article 57.** If the certificate or stamp of the Association is lost, upon the approval of 2/3 or more of the Directors of the Board of Directors, and the loss statement is published in a publicly released newspaper or periodical, an application may be filed with the registration authority

for re-development or engraving. If they are illegally embezzled by an individual, it shall be required to return through legal means.

**Article 58.** The Association shall establish a mechanism for democratic consultation and resolution for internal conflicts. If any internal contradiction cannot be resolved through negotiation, it may be turned to mediation or litigation.

#### **Chapter V: Assets Management and Utilization**

**Article 59.** Source of revenue of the Association:

- (1) Member annual fee;
- (2) Donation;
- (3) Government subsidies;
- (4) Income from activities and service approved business range;
- (5) Interests;
- (6) Other income from legitimate sources.

**Article 60.** The Association shall collect membership fees in accordance with the relevant regulations of the State. No fees will be charged for the rating and honoring.

**Article 61.** The income of the Association shall be used for the business range and non-profit undertakings stipulated in this Constitution, except for the reasonable expenses related to the Association.

**Article 62.** The Association implements the Accounting System for Non-governmental Non-profit Organizations, sets up strict financial management rules and regulations, in order to ensure that the accounting data is legitimate, true, accurate and complete.

**Article 63.** The Association employs professional and certified accounting staff.. The accountant cannot additionally serve as the cashier. Accountants must perform accounting and accounting supervision. If accountants leave or are transferred, they must go through handing-over procedures with the managing staff and shifting persons.

**Article 64.** Management of assets of the Association shall be executed according to the financial regulations stipulated by the state, and shall accept supervision of the General Assembly and the financial department. The assets that come from the government subsidies and social contribution shall be subjected to supervision by the audit institution, and shall be also promulgated to the public by the proper means.

**Article 65.** The allocation and disposal of major assets of the Association shall be deliberated by the PhIRDA General Assembly or the Board of Directors.

**Article 66.** Where a resolution of the Board of Directors violates any law, regulation or articles of association, thereby causing losses to a social group, the Board of Directors member participating in the deliberation shall be liable, who may be exempted from liability if he/she proves that he/she objects at the time of voting and is recorded in the minutes of the meeting.

**Article 67.** Prior to any replacement or the expiration of the legal person of the Association, he/she must be subjected to the financial audit.

During the term of the legal person, the legal person shall bear the relevant liabilities for the violation of the *Regulation on Registration and Administration of Social Organizations* and the Constitution of Association. Where any illegal act or property loss of a social organization is caused due to the legal person's dereliction of duty, the legal person shall bear individual liabilities.

**Article 68.** All the assets and their added value of the Association shall be owned by the Association, and no entity or individual could embezzle, illegally divide or misappropriate, or distribute them among its members.

## Chapter VI: Information Disclosure and Credit Commitment

**Article 69.** In accordance with the relevant policies and regulations, the Association shall perform the obligation of information disclosure, establish an information

disclosure system, timely provide members with annual work reports, reports issued by third-party institutions, income and expenditure of membership fees, and other information that should be released considered by the Board of Directors, and timely release the information to the public including registered items, Constitution of Association, organizational institutions, donations accepted, credibility, commitments, items transferred or entrusted by the government, services provided, and the state quo.

The Association shall establish a spokesperson system. The spokesperson, appointed or designated by the Board of Directors will respond to social concerns in the form of regular or irregular press conferences, briefings, interviews, etc. on major events or hot issues of the Association. The contents of news release shall be examined and approved by the legal representative or the chief person in charge of the Association, so as to ensure the correct guidance of public opinions.

**Article 70.** The Association shall establish an annual report system, which shall be timely disclosed to the public and subject to public supervision.

**Article 71.** The Association shall establish a credit commitment system focusing on service contents, service modes, service objects and charging standards, and disclose the contents of credit commitments to the public.

## Chapter VII: Revision Procedure of the Constitution

**Article 72.** Any amendment to the Constitution of Association shall be adopted by the Board of Directors through voting and submitted to the PhIRDA General Assembly for deliberation.

**Article 73.** The Constitution of Association amended by the Association shall be submitted to the administrative department for review and approval after being adopted by more than 2/3 of the members of the PhIRDA General Assembly present and, upon approval, be submitted to the registration authority for approval within 30 days.



## Chapter VIII: Termination Procedure and Post-dissolution Assets Management

**Article 74.** The termination of the Association shall be proposed by the Board of Directors and be submitted to the PhIRDA General Assembly for vote.

**Article 75.** Prior to the termination of the Association, a liquidation organization shall be established according to law to clear up the creditor's rights and debts and deal with the aftermath. During the liquidation period, no activities other than liquidation shall be conducted.

**Article 76.** The registration shall be terminated after the registration authority has gone through the formalities for cancellation of registration.

**Article 77.** The remaining property after the termination of the Association shall be used for the development of undertaking related to the purpose of the Association or donated to social organizations with similar purposes under the supervision of the administrative department and registration administrative authorities in accordance with the relevant provisions of the State.

## Chapter IX: Appendix

**Article 78.** This Constitution was approved by the 11<sup>th</sup> PhIRDA General Assembly on September 20th, 2019.

**Article 79.** The right of interpreting this Constitution belongs to PhIRDA General Assembly.

**Article 80.** The Constitution comes into force on the date when it is approved by the authority of registration & administration.

## 2020~2021年度工作报告 暨2021~2022年度工作建议

----2021年9月24日第11届理事会第3次会议

(中国医药创新促进会秘书长 冯岚)

各位理事：

受会长会议委托，我向理事会报告我会2020~2021年度主要工作，并对2021~2022年度重点工作提出建议，请各位审议。

近年来，我会积极组建贯穿医药产业创新发展全链条的新型社团架构，始终将推动中国医药产业创新发展作为自身肩负的使命，努力营造开放包容、富有活力的医药创新生态环境，为医药产业各创新主体搭建跨界、跨境交流合作平台探索新思路、开拓新路径、提供新方法，以解决影响我国医药产业创新和可持续发展的全局性、长期性问题。

2021年是“十四五”规划的开局之年，面对复杂多变的国际形势，特别是在当前以美国为首的西方国家对我正当合理的技术交流合作及投资行为进行限制和打压，遏制中国发展的形势下，我会及各会员单位重点围绕药品及医疗器械监管体制改革、医保制度改革、专利纠纷及补偿机制、优化药物研发及临床试验资源配置、疫情防控政策体系建设、药物及疫苗研发和资本市场上市服务等事关我国医药创新生态环境建设的多个领域开展专项研究，为统筹推进我国疫情防控、经济社会和医药产业创新发展做出了重大贡献。此外，我会还不断加强秘书处及分支机构建设，为各项重点工作提供有力保障。我会2020~2021年度重点工作完成情况如下：

### 第一部分 2020~2021年度主要工作回顾

自2020年9月26日第11届理事会第2次会议召开以来，我会始终坚持党的领导，围绕“创新、产业化、国际化”的办会宗旨，依托涵盖医药创新产业全链条的会员单位组织架构及专业委员会资源优势，深度聚焦我国医药领域“卡脖子”问题，深入研究医药产业政策、全球医药科技创新趋势及投融资动向，不断深化为政府有关部门决策建言献策的角色定位，在服务会员、服务产业、服务国家，创办品牌特色活动及推动我国医药产业国际化等领域不断迈上新的台阶，已成为行业监管部门认可、在医药创新领域具有重大影响力的社会团体。

#### 一、以习近平新时代中国特色社会主义思想为统领，积极开展党史学习教育，进一步促进支部党建与我会日常工作深度结合

我会党支部在国资委党委和中国工经联党委的坚强领导下，以学习贯彻落实习近平新时代中国特色社会主义思想为统领，持续有序开展党的组织生活和党员教育学习工作。在我党百年诞辰之际，我会党支部积极开展党史学习教育，根据总书记“学党史、悟思想、办实事、开新局”的讲话精神，明确方向，凝聚力量，制定详细方案，通过丰富的形式开展线上线下党课学习、实地参观和集中讨论，学习党的实践创造和

历史经验以启迪智慧。党员同志进一步提高了党性，在党的理论指导下，支部党建工作与我会业务工作进一步深度结合，从行业协会视角推动了我党事业全面发展。

## 二、发挥高端智库作用，积极为政府有关部门建言献策，促进中国医药创新事业蓬勃发展

一直以来，我会坚持为我国医药产业创新谋篇布局，深入研究影响我国医药产业创新发展的核心问题，向国家和政府有关部门提出适合我国国情、符合行业发展需求的可操作性意见和建议，为我国鼓励医药产业创新发展的纲领性文件、政策和法律法规出台落地做出了重要贡献，受到社会各界高度评价和认可。全国政协经济委员会副主任、中国国际交流中心常务副理事长毕井泉、国家药品监督管理局（以下简称国家药监局）副局长徐景和、国家药监局药品审评中心纪委书记李江宁等领导先后率团队赴我会调研指导，就完善我国医药创新政策、优化审评审批程序和加强党风廉政建设等问题交流意见并达成诸多共识。

### （一）就海南自由贸易港建设与医药创新发展深度融合向海南省委领导建言献策

为了协助海南省进一步引进和培育优质企业、吸引高阶人才落户、打造市场准入政策高地等内容，以实现医药创新与海南自由贸易港的建设深度融合、协同发展，我会深度参与《关于支持海南自由贸易港建设放宽市场准入若干特别措施的意见》起草工作，并向海南省委沈晓明书记提出《关于进一步推动海南自由贸易港与医药产业创新融合的建议》，得到高度评价。

### （二）受邀参与《药品管理法实施条例》起草修订工作

受国家药监局邀请，我会作为新版《药品管理法实施条例》（以下简称《条例》）工作小组重要成员，全程参与《条例》修订草案的基本框架和内容讨论工作，并重点参与“注册与研发”章节初稿起草和修订工作。

### （三）向国家科技重大专项（民口）09专项评估组提出《对“十四五”期间“重大新药创新”重大科技专项的建议》

我会受邀参加中国工程院受国务院委托开展的“重大新药创制”专项总结评估，宋瑞霖执行会长作为评估组专家成员参与现场调研和座谈会，提出“政府拨付专项经费放在产业化前端，重点支持源头创新、基础研发等有望产生中国原始性、突破性成果的领域和关键阶段”和“尽快出台与激发药物创新活力生态环境相配套的支持政策与法规”等进一步完善创新市场准入体系，切实满足人民健康需求和患者用药可及性的意见和建议。

### （四）我会领导受聘为农工党中央参政议政咨询专家，提出推动中国医药创新与国际深度融合的建议

2020年12月，宋瑞霖执行会长受聘成为农工党中央参政议政咨询专家，向农工党中央提出《推动中国医药创新与国际深度融合的建议》，推动国家药品监督管理局启动“一带一路”沿线国家药品监管和注册互认制度，帮助中国医药创新产品走出国门走向世界。相关建议在《关于全面加强药品监管能力建设的实施意见》（国办发〔2021〕16号）中体现。

### （五）进一步提升本土医药创新的国际竞争力，改革和完善我国创新药医保报销机制

我国现有医保支付体系中按固定比例支付药品费用是以仿制药为基础设计的定价方式，与我国医药产业创新发展大环境不相匹配。我会领导面见国家医保局主要负责同志，并提出我会建议：应建立更加灵活的医保支付比例机制，以临床价值为基础确定创新

药价格,以医保实际支付能力为依托确定医保支付标准,建立不同于仿制药的定价谈判机制,由“谈判定价”调整为“谈判确定报销比例”。

### 三、深入研究行业热点和痛点问题,积极开展课题研究,为完善和推动医药创新相关政策落地奠定基础

#### (一) 研究构建真实世界数据研究体系,加快推动真实世界证据用于注册和监管决策

我会受国家药监局和海南乐城医疗管理局委托开展《药品医疗器械真实世界数据有关规则研究》,课题组通过国际经验比对和专家调研访谈,在明确适用产品范围、临床研究机构资质、伦理审查和遗传审批、数据管理等方面,形成了真实世界证据用于药品注册和监管注册的相关规则,并指导乐城国际医疗旅游先行区作为应用试点。

#### (二) 基于化学药与生物药的本质区别,深入开展适用于生物制品专利纠纷早期解决机制

为切实保护药品专利权人合法权益,我会在借鉴国际经验的基础上,结合我国国情、产业实际现状和未来发展趋势,围绕明确生物制品专利纠纷早期解决机制的内涵和实施主体、原研药专利信息登记和公示制度、专利纠纷早期解决程序、知识产权保护等领域开展研究,并形成政策建议。

### 四、组建中国—上合组织医药创新合作工作组,切实推动中国与上合组织及“一带一路”国家医药产业务实合作,构建国内国际双循环的新发展格局

为推动我国医药创新产品“走出去”,加强中国与各国的医药领域合作交流、推动建立平衡高效的国际药品监管体系互认机制,我会成立了中国-上合组织

医药创新合作工作组(以下简称工作组)。成立以来,工作组积极通过多种渠道推进《医药产品走向“一带一路”沿线国家市场策略研究》相关工作,依托上海合作组织(以下简称上合组织)、上合组织睦邻友好合作委员会、国家药监局国际合作司,充分发挥自身产业优势,积极参加民间友好论坛卫生健康分论坛、中国-东盟博览会药品合作发展高峰等高层会议,推动中国与上合组织及一带一路国家间医药产业合作交流,建立医药研发合作机制,实现多边或双边药品监管互认,为提升更多国家的人民健康福祉做出积极贡献。

### 五、高度关注制约医药创新发展的薄弱环节,发布《构建中国医药创新生态系统》系列报告,为营造有利于医药创新和国际化的良好生态环境提出系统性规划建议

《构建中国医药创新生态系统》是由我会联合中国外商投资企业协会药品研制和开发行业委员会(RDPAC)发起的,重点围绕“创新产业竞争力”、“创新药物可及”和“创新医药产业可持续”三条主线对我国医药创新生态系统长期发展提出多维度建设性意见的系列报告。自今年3月起,已陆续发布《2015-2020年发展回顾及未来展望》、《推动基础研究,激活源头创新》、《多层次医疗保障体系助力人民健康和产业高质量发展》和《推进创新药同步研发、注册与审评》4篇子报告,在业界引起热烈反响,受到了“两会”代表委员、相关领导及社会各界的高度肯定。《构建中国医药创新生态系统》报告将在中国医药创新与投资大会正式发布。

### 六、不断丰富和完善专业委员会设置,创新活动方式,探索搭建主题化、常态化、品牌化的特色活动平台,为推动中国医疗健康产业创新和可持续发展贡献新的力量



自2020年9月26日11届2次理事会闭幕以来,我会国际创新药物监管(9月27日在苏州成立)、医药政策(9月29日在苏州换届)、抗肿瘤药物临床研究(10月18日在上海成立)、脑神经药物临床研究(11月8日在北京成立)、医药企业合规(11月9日在北京成立)、药物临床试验(11月24日在北京换届)、药物研发(12月4日在杭州换届)、创新研发服务(12月4日在杭州换届)、糖尿病与代谢性疾病药物临床研究(2021年9月5日在北京成立)共9个专业委员会圆满完成换届或成立任务。我会现有11个专业委员会,依托专委会专家及委员资源优势,在药物研发、临床研究、行业监管、政策研究、投融资和合规等6大方面开展了大量卓有成效的工作,受到社会各界广泛关注和好评。

### (一) 发布研究报告,服务我国医药创新

我会抗肿瘤药物临床研究专业委员会对目前热门靶点及其药物的作用机制、国内研发现状进行了全面梳理,发布了《2020年度中国抗肿瘤新药临床研究评述》,引导药物研发理性、有序发展。

### (二) 创新活动方式,多领域推动我国药物研发和临床研究

我会抗肿瘤药物临床研究、脑神经药物临床研究、心血管药物临床研究、糖尿病与代谢性疾病药物临床研究、药物临床试验、创新研发服务专委会在2021中国国际服务贸易交易会期间分别主办了“临床肿瘤学新进展暨抗肿瘤药物创新研发论坛”、“脑科学与脑神经高峰论坛”、“心血管疾病预防与创新”、“糖尿病与代谢性疾病诊疗论坛”和“创新研发服务论坛”等学术活动;医药创新投资等专业委员会举办了“‘产融携手,创新发展’明星企业走访第一站--走进长沙”系列活动、2020年抗肿瘤新药研究及肿瘤治疗年终大盘点论坛等形式多样,丰富多彩的专业活动。

## 七、继往开来,举办丰富多彩、形式多样的线下会议,为医药产业各创新主体提供更

## 多价值服务

### (一) 2021中国国际服务贸易交易会

2021年9月2日~7日,经党中央、国务院批准,由商务部、北京市人民政府主办,以“数字开启未来,服务促进发展”为主题的2021中国国际服务贸易交易会(以下简称服贸会)在北京召开。服贸会作为专门为服务贸易搭建的国家级、国际性、综合型三大展会交易平台之一,首次将健康卫生服务纳入八大主题,增设以“数字健康,创新融合”为主题的健康卫生服务专题展及相关论坛,受到全球高度关注。我会受大会组委会委托承办服贸会健康卫生服务专题展,组织多家地方政府、医疗机构、国内外知名医药和医疗器械企业、保险和养老机构通过展览展示、专业论坛等形式,向世界展示我国生物医药产业综合实力和水平,积极推动我国生物医药产品和服务在国际领域务实合作,共同为守护全人类生命与健康做出新的贡献。

健康卫生服务专题展区总面积6600m<sup>2</sup>,涵盖政策、医疗、器械、投资、科研、服务等多个领域,累计吸引百余家医疗健康领域相关机构和万余人次线上线下参展参会,全面实现了“云展示”和“云对接”。其中线下参展500强及行业龙头企业45家,占比51%;外资企业13家,国际化率15%;在我会专业委员会的支持下举办的14场专业论坛,邀请国内外卫生健康管理部门领导、院士、知名专家学者、世界500强企业高管等百余位行业大咖,围绕公共卫生、国际卫生服务与医药创新合作、心血管疾病预防与创新、临床肿瘤学新进展、创新研发服务等议题展开深入交流;健康卫生服务板块举办签约活动40场,签约金额约10亿人民币。我会24家会员单位在服贸会线上线下进行展示。

服贸会期间,由北京协和医院、北京天坛医院等8家公立三甲医院和北京市疾控中心组成的“智慧医疗卫生服务”集团展集中展示了5G移动卒中单元、机器人手术、新生儿疾病筛查系统等多项尖端医疗技术,成为本届服贸会一大亮点。

## （二）第五届中国医药创新与投资大会

第五届中国医药创新与投资大会（以下简称投资大会）于2020年9月27~29日在苏州成功举办。第五届投资大会在往届基础上新设创业板、医药创新城市发展、创新药准入政策分享等主题论坛，齐聚我国三大证券交易所——港交所、上交所和深交所，共同谱写我国资本市场多元化改革助力生物医药产业创新发展的崭新篇章，热议全球融资平台对医药产业支持政策和未来发展趋势。第五届投资大会累计吸引国内外105个优秀企业（项目）现场或云端路演，医药企业、投资机构等代表近3000人参会，为参会者提供830桌次一对一邀约洽谈服务，受到业界广泛好评。

第六届投资大会将新设医药数字化及创新疗法论坛和创新药基础研究与成果转化路演专场，同期举办深交所创业板专题座谈会和国际云路演专场为投资大会赋能，为国内外参会者提供更多价值服务。

## （三）2021中国医药创新政策论坛

2021年7月17日，由医药政策专委会主导、我会与艾美达医药咨询共同主办的中国医药创新政策论坛于在南京召开。政府有关部门、医疗机构、药学、药物经济学专家学者和产业界300余位代表共聚一堂，从患者的需求出发，围绕我国审评审批体系和医疗保障体系建设、创新药支付体系制度改革等议题进行多角度、多方位的解读和讨论，深入研究医药创新全链条各环节政策，推动我国医药创新可持续发展。

## （四）2020年中国罕见病大会

2020年10月24日~25日，由国家卫生健康委和国家药监局指导，中国罕见病联盟与我会联合主办的2020年中国罕见病大会在北京举行。大会围绕罕见病防治与保障、大数据平台建设、药物创新与患者可及、国际协作和以患者为中心的健康生态圈建设等主题展开深入交流，受到了社会各界的广泛关注。

## （五）从实验室到IPO：医药企业高峰论坛

2021年5月12日，由我会支持，艾美达医药咨询主办的从实验室到IPO：医药企业高峰论坛在上海举行。200余位国内外医药和投资界领袖、专家、学者齐聚论坛，深入探讨在新形势下如何以专业经验服务于医药企业的现实需求，推动医药产业跨越式发展。

## 八、与深交所签署战略合作协议，共同为 我国医药产业高质量发展提供源动力

2020年末，我会与深交所在已有合作基础上签署战略合作协议，未来双方将充分发挥各自资源优势，深入贯彻国家关于促进医药健康产业创新发展的决策部署，充分发挥资本市场引领医药产业创新发展的优势作用，重点围绕举办专业会议、后备上市企业培育、已上市企业规范发展、行业信息交流、产融结合平台对接、产业研究等方面开展务实合作，建立全方位、多层次、长期稳定、合作互惠的战略合作关系，支持我国医药产业创新和可持续发展。我会将持续推动高质量发展的医药研发型企业赴资本市场上市融资，拓展多元融资渠道、深度服务中国医药产业改革、创新、发展大局。

## 九、深入开展国际医药交流，推动全球医药产业交流与合作

（一）积极参与国际规则制定，组织专家开展与国际接轨药品监管标准、政策等研究与制定工作，推动ICH指导原则转化实施

作为国际药品制造商协会联合会（IFPMA）成员，我会自2017年起已向IFPMA 19个ICH工作组推荐38名专家（包括14名组长，7名候补组长），推荐的专家在IFPMA全球专家总人数中占比过半。

受国家药品监督管理局ICH工作办公室委托，我会已对59个ICH指导原则征求会员单位意见，及时反

馈行业意见,推动ICH指导原则在我国的顺利转化实施。此外,受药审中心委托,我会积极开展ICH指导原则专家工作组的招募工作,目前已有36位我会推荐的专家被纳入19个CDE ICH专家工作组中,其他工作组名单还在进一步遴选中。

## (二) 与外国驻华大使馆、国外医药行业协会和国际组织展开交流,发出我国医药创新行业声音、贡献中国力量,推动全球医药产业相互交流与合作

在全球抗疫的大背景下,我会积极拓展国际事务新领域,与荷兰、白俄罗斯、乌兹别克斯坦、新加坡驻华大使馆、上合组织等各国驻华使领馆及国际组织建立紧密联系,共同推动全球医药产业相互交流与合作。

此外,我会领导还受邀参加J.P.摩根健康产业大会、中国生物医药企业东盟市场拓展闭门会、亚洲制药组织合作会议(APAC)、第七届中国医疗峰会、APEC中小企业伦理合规论坛等创新、投资、监管类主题国际会议,通过主旨报告和参与圆桌讨论的形式向世界展示我国药品监管改革和医药创新发展成果,并向其它国家和地区学习先进监管经验。

## 十、不断提高医药信息服务能力

### (一) 搜集整理医药行业最新动态消息

我会坚持每日搜集整理全球医药政策、药物研发成果、医药行业热点新闻等医药行业最新动态消息,编辑《医药信息简报》,发送至会员单位以及业内专家、政府部门、合作机构。2020年共发送《医药信息简报》238篇,累计受众59万人次。

### (二) 运用微信自媒体便捷沟通,传递信息

我会通过微信公众号、投资大会服务号以及协会官网等公开宣传渠道向社会各界发布我会重点工作、医药行业最新热点新闻,并通过微信自媒体平台,广泛宣传我会对医药政策研究意见建议,筛选并推送深

度分析文章,受到业界广泛关注。截至2021年9月,我会订阅号关注人数18817人;投资大会服务号关注人数9804人。

各位代表,在全体药促会同仁的不懈努力奋斗下,我会已经成为国家有关部门推动医药创新生态环境建设和各地方政府布局医药健康产业倚重并信赖的社会组织;我会会员单位医药研发、投资等活动日益活跃,国际地位和影响力显著提升,形成了一批高质量发展的医药上市公司群体,描绘出医药创新蓬勃发展的生动局面,已经成为世界医药创新格局中不可或缺的中坚力量。在此,向全体会员单位及分支机构的大力支持和帮助表示衷心感谢!

## 第二部分 2021~2022年度重点工作建议

《国民经济和社会发展第十四个五年规划和2035年远景目标纲要》中指出:要坚持创新在我国现代化建设全局中的核心地位,强化企业创新主体地位,注重原始创新,推进产学研深度融合;鼓励发展天使投资、创业投资,更好发挥创业投资引导基金和私募股权基金引导作用,多渠道投入医药基础研究,推动医药及医疗设备等产业创新发展;提高金融服务实体经济能力,完善金融支持创新体系,畅通科技型企业国内上市融资渠道,推动生物技术和信息技术融合创新,构建实体经济、科技创新、现代金融协同发展的现代化生物医药产业体系。新的一年,我会将以“十四五”规划为指导方向,以推动我国医药产业创新和国际化为己任,整合并合理配置各方医药创新要素力量,持续改善我国医药产业生态环境,着重围绕以下几个方面开展相关工作:

## 一、进一步加强党组织建设,结合我会工作实际开创党建工作新局面

未来一年,我会将继续以习近平新时代中国特色社会主义思想为指引,在国资委党委和中国工经联党委的全面、坚强领导下,进一步加强党的基本组织、基本队伍和基本制度建设,将党的政治领导与监督和协会治理相融合,坚决保障协会发展的政治方向不偏不移。我会全体员工将进一步深刻领悟学习贯彻习近平总书记“七一”重要讲话精神,将党史教育学习活动常态化,真正把学史明理、学史增信、学史崇德、学史力行的成果转化为实际行动。我会党组织将落实全面从严治党主体责任,切实加强党风廉政建设,坚持党建和业务两手抓,以党建统领业务发展。

## 二、继续发挥行业智库作用,深入开展重大医药政策研究,积极为政府有关部门建言献策,促进中国医药创新健康可持续发展

(一)深化与药品监管各部委联系,通过主动或接受委托的形式,对影响行业发展的重大政策开展研究,向中央有关部门呈报产业发展和研究报告,充分发挥行业组织为政府决策服务、协调和监督职能

(二)认真开展深化药品监管改革配套措施和相关指导原则的实施工作,尤其是《药品管理法实施条例》的修订;继续推进药品知识产权保护相关政策的落地,保证我国药品监管改革政策顺利推进,真正实现创仿平衡

(三)继续推进完善医疗保障制度与促进医药创新的平衡,引导创新药形成合理、可行的医保支付价和实时动态准入机制,促进医保支付品种落地使用

(四)积极开展《中华人民共和国人类遗传资源

管理条例》实施细则修订工作,聚焦管理条例实践过程中面临的实际问题,包括但不限于备案审批流程、出入境管理、数据采集以及中外方单位的认定等监管要求,以期管理条例实施细则的编写和修订提供建议参考

(五)持续推动“一带一路”课题研究相关工作,保持与上合组织及上合组织睦委会的紧密合作,以重点国家和地区为突破,推动建立国际药品监管互认,加速推动我国医药创新产品实现国际化,为我国医药产业形成宽领域、深层次、高水平、全方位的对外贸易合作新格局贡献新的力量

## 三、积极拓展与国外相关机构交流合作,稳步提升中国医药创新力量的国际地位和国际话语权

我会将继续拓展与各国驻华使领馆、行业协会及社会组织间的合作与交流,一方面按照IFPMA秘书处和国家药监局ICH工作办公室要求,推荐业内权威专家参与ICH指导原则的制修订工作,推动中国专家参与国际标准和规则制定并在国际舞台发声;另一方面,配合国家药监局做好ICH相关指导原则在中国转化实施工作,稳步推进中国制药行业标准与国际接轨。

此外,我会还将整合并合理配置我会资源,进一步提高我国医药企业的国际竞争力,帮助会员单位寻求更多新药研发趋势、医药卫生领域海外合作机会,促进我国医药产业界在贸易、投资和技术等领域与国际社会深入融合。

四、构建医药创新投资生态闭环,持续推动高质量医药研发型企业赴港、沪、深、京上市,携手谱写新时代资本市场助力生物医药产业高质量发展的崭新篇章



自2015年以来,我会认真贯彻落实习近平总书记关于资本市场的一系列重要指示批示精神,积极探索行业协会跨界参与全面深化资本市场改革的新路径,深度参与我国资本市场多元化改革,针对影响医药产业创新和可持续发展的堵点,重点围绕加强资本市场基础制度建设和增强包容性等方面问题先后与港交所、上交所和深交所建立紧密联系,达成诸多共识,为打通医药研发型企业上市融资的“每一公里路”贡献应有力量。我会多名医药创新科学委员会成员、理事、监事和分支机构负责人先后受聘成为联交所、上交所和深交所医药领域相关专家库成员。我会多家医药创新研发型会员单位先后赴港交所和科创板上市融资,实现了一个又一个里程碑。未来,我会还将继续推动并深化与我国三大交易所及即将设立的北京证券交易所的务实合作,携手谱写新时代资本市场助力生物医药产业高质量发展的崭新篇章。

## 五、不断丰富和完善专业委员会设置,汇聚不同专业领域专家力量,为促进整个医药产业跨界交流探索新思路、开拓新路径、提供新方法

经理事会表决通过,我会决定设立高端医疗器械专业委员会(以下简称器械专委会),并于本次理事会表决设立医药数字化及创新疗法专业委员会(以下简称数字化专委会)。

### (一) 高端医疗器械专业委员会

伴随着全球人口老龄化进程不断加速,人类对生命健康和美好生活的需求日益强烈,高端医疗器械市场需求和潜力激增,经济和社会价值进一步显现。为了响应“十四五”规划中“培育先进制造业集群,推动医药及医疗设备产业创新发展”的号召,在国家药监局领导的关怀下,我会决定将医疗器械领域政策研究和工作推动纳入我会重点工作,设立器械专委会,拟通过政策研究、合作交流和学术培训等方式,充分发

挥产业界和政府之间沟通桥梁的作用,一方面协助政府有关部门研究推动先进医疗器械监管政策,为打造并符合我国国情的科学、高效、系统、全面的医疗器械全周期监管体系提供理论和智力支持;另一方面,全面提升我国高端医疗器械产业研发能力,重点关注体外诊断、影像设备、治疗设备、植入介入产品、医用机器人、智慧医疗等“卡脖子”领域,为我国医疗器械企业全球化策略和布局尽早打破进口产品垄断实现国产替代,推动我国高端医疗器械产业赶超国际先进水平做出应有贡献。

### (二) 医药数字化及创新疗法专业委员会

伴随着大数据、人工智能等新一代信息技术的发展和运用,全球经济发展已经进入到数字化时代,医疗行业进入了数字化转型的历史节点,从新药研发、生产至健康预防、疾病诊断治疗等全产业链正迸发出越来越多的数字化创新之新机遇,且以数据驱动和数字治理为核心的数字监管、社会治理科学化的建设已成为全球创新的核心议题。为了做好应对未来创新形势的准备,我会已成立医药创新数字化推进工作办公室,牵头设立数字化专委会。数字化专委会旨在开展全球医药数字化政策研究,围绕AI新药创制、新型医工结合、数字疗法等新兴医药创新领域,从医药数字化的宏观产业分析、监管政策建议、代表企业创新推广、投融资平台搭建等多方面开展工作,搭建医药数字化企业与科研机构、医疗机构、国际组织、监管机构和投资机构之间的沟通平台,共同助力数据驱动的基础设施现代化建设工作,推动中国医疗数字化创新产业蓬勃发展,为数字化创新赋能医药创新做出新的贡献。

未来,我会将继续依托各分支机构专家资源优势,深耕药品及医疗器械监管、医药投资、药物研发和医药数字化等领域,继续为我国各医药创新主体跨界合作提供全方位价值服务。

## 六、与盖伦基金会共同举办“盖伦奖”，助力中国品牌在全球的传扬和发展，增强我国医药创新国际竞争力

盖伦奖成立于1970年，旨在褒奖医疗创新在改善人类状况方面取得的卓越成就，已在法国、美国、德国、英国、意大利、加拿大等15个国家设立奖项，被公认为“生物制药界和医疗技术研究行业的诺贝尔奖”。

为激励中国自主创新，引导中国医药创新向原创创新、颠覆性技术创新转变，我会与盖伦基金会将共同举办盖伦奖，对促进中国医药科技创新做出突出贡献的个人以及在中国研发上市的创新产品予以奖励。为了配合盖伦奖落地，我会特邀国内、外知名专家组建盖伦奖评审委员会，在苏州牵头设立苏州工业园区鼎新医药创新研究中心，并完成了公安部境外非政府组织的活动备案。盖伦奖奖项评选相关工作预计今年12月前正式启动，颁奖典礼拟于2022年6月在苏州举行。

## 七、继续办好“中国医药创新与投资大会”等各类论坛及学术交流活动，服务医药创新关键环节

我会将继续与国内外各相关机构鼎力合作，办好一年一度的中国国际服务贸易交易会、中国医药创新与投资大会、中国医药创新政策论坛和中国罕见病大会等活动，并以各专业委员会工作重点为切入点，结合学术研究方向，继续深入开展各专业领域活动，服务医药创新关键环节，推动我国生物医药发展和医学技术进步。

当前，全球追求医药产业高质量发展已成共识，中国医药创新正在为推进人类健康共同体的伟大愿景贡献中国智慧和力量。我会诚邀您一道，继续汇聚

并整合各方资源力量，聚焦影响我国医药产业创新和可持续发展的痛点和堵点问题，做好产业与政府的桥梁，让医药产业全链条携手赋能医药创新，为我国医药产业各创新主体提供新的便利，促进我国医药创新生态环境不断完善，推动医药产业创新和可持续发展，为实现全面建成医药强国和让更多中国制造创新药早日惠及全球百姓的伟大目标而不懈奋斗！

## 2020-2021 Annual Work Report & 2021-2022 Work Proposal

----The Third Meeting of 11<sup>th</sup> Board of Directors, September 24, 2021  
(Feng Lan, Secretary-General of PhIRDA)

### Dear All Directors:

Entrusted by the Chairman, I hereby report to the Board of Directors on 2020-2021 main work and 2021-2022 work proposal of China Pharmaceutical Innovation and Research Development Association (hereinafter referred to as "PhIRDA").

Shouldering the mission of promoting innovative development of China's pharmaceutical industry, PhIRDA has striven to establish a new community architecture covering the entire chain of innovative development of the pharmaceutical industry, spared every effort to create an open, inclusive, and dynamic ecological environment for pharmaceutical innovation, built an international exchange and cooperation platform for various innovation entities in the pharmaceutical industry, explored new ideas, developed new paths, provided new methods, and tried to solve the overall and long-term problems that may affect the innovative and sustainable development of China's pharmaceutical industry.

2021 is the first year of the 14<sup>th</sup> Five-Year Plan. Facing the complex, volatile international situation, particularly the current situation that Western countries led by the United States spare no effort to restrict, suppress and curb China's legitimate and reasonable technical exchanges, cooperation and investments, PhIRDA and its members have carried out special researches on various fields related to the creation of an ecological environment for pharmaceutical innovation in China, mainly including the reform of the regulatory system for medical devices and drugs, the reform of the medical insurance system, the mechanism for drug patent dispute resolution and patent term restoration, the optimization of resource allocation for pharmaceutical R&D and clinical trials, the improvement in the pandemic prevention and control

policy system, the R&D of drugs and vaccines, and the listing on capital markets. Meanwhile, PhIRDA and its members have made significant contributions to the overall pandemic prevention and control, economic and social development, and innovative development of the pharmaceutical industry in China. In addition, PhIRDA has continued to promote the institutional improvement of the secretariat and branches to strongly support various focuses of work. The main work completed by PhIRDA in 2020-2021 is reported as follows:

### Part I. Review of Major Work in 2020-2021

Since the Second Meeting of 11th Board of Directors on September 26, 2019, PhIRDA has always adhered to the Party's leadership, and always followed the tenet of "innovation, industrialization and internationalization". Relying on our competitive organizational structure with PhIRDA members covering the entire industry chain of pharmaceutical innovation and resource advantages of specialty committees, PhIRDA has focused on solving the tricky problems in the pharmaceutical field, made in-depth researches on pharmaceutical industry policies, global trends of pharmaceutical technology innovations, investment and financing, given full play to the role of offering advice and suggestions for government decision-making, constantly stepped up to a new level in terms of serving PhIRDA members, the industry and the country, creating brand-specific activities, and promoting China's pharmaceutical industry to go international, and become a social organization recognized by the industry regulatory authority and having a significant influence in the field of pharmaceutical innovation.

**I. Under the command of Xi Jinping Thought on Socialism with Chinese Characteristics in a New Era, actively organize the Party history learning and education, and promote the deep integration**

## of the Party building work of the Party branch with the routine work of PhIRDA

Under the strong leadership of the Party committee of China Federation of Industrial Economics, and of the Party committee of the State-owned Assets Supervision and Administration Commission (SASAC), and the command of Xi Jinping Thought on Socialism with Chinese Characteristics in a New Era, the Party branch of PhIRDA continued to organize Party members to accept education, learn and participate in the Party's regular activities. On the occasion of the Party's centennial birthday, the Party branch of PhIRDA actively organized the Party members to study the Party's history in response to General Secretary Xi Jinping's call to study the Party's history, understand its theories, do practical work and make new advances. With clear direction and joint forces, the Party branch made a detailed plan for organizing the offline and online learning of the Party's history, and organized field visits and concentrated discussions about the Party's practices and experience in various forms, to enlighten Party members. Under the theoretical guidance of the Party, the Party branch further improved the Party spirit of Party members, continuously promoted the in-depth integration of its Party building work with the business work of PhIRDA, and boosted the overall development of the Party's cause.

## II. Give full play to the role as a high-end think tank, and actively offer advice and suggestions to relevant government departments, to promote the booming development of China's pharmaceutical innovation undertaking

Always planning for the innovative development of China's pharmaceutical industry, and carrying out in-depth researches on the core issues affecting the innovative development thereof, PhIRDA has put forward many feasible opinions and suggestions in line with China's national conditions and pharmaceutical industry development needs for the State and relevant government departments, and made significant contributions to the promulgation and implementation of programmatic

documents, policies, laws and regulations favorable to the innovative development of the pharmaceutical industry in China, thus winning high praises and recognition from all sectors of society. Mr. Bi Jingquan, Deputy Director of the Committee on Economic Affairs of the Chinese People's Political Consultative Conference (CPPCC), and Executive Vice President of China Center for International Economic Exchanges (CCIEE), Mr. Xu Jinghe, Deputy Commissioner of National Medical Products Administration (hereinafter referred to as "NMPA"), Mr. Li Jiangning, Secretary of Discipline Inspection Committee of Center for Drug Evaluation, NMPA, and other leaders, together with their teams, successively visited and guided PhIRDA, exchanged opinions and reached a consensus on many aspects such as improving the policy for innovative development of China's pharmaceutical industry, optimizing the review and approval procedures, and deepening the work of improving Party conduct and upholding integrity.

### (I) Offer advice and suggestions to the leaders of the Hainan Provincial Committee of the CPC on the deep integration of the construction of Hainan Free Trade Port with the innovative development of the pharmaceutical industry

In order to help Hainan Province further introduce and cultivate high-quality enterprises, attract high-level talents, build a highland of market access policy, and ultimately realize the deep and coordinated integration of innovative development of the pharmaceutical industry with the construction of Hainan Free Trade Port, PhIRDA deeply participated in the drafting of *Opinions on Several Special Measures for Relaxing Market Access to Support the Construction of Hainan Free Trade Port*, and proposed the *Suggestions on Further Promoting the Integration of the Construction of Hainan Free Trade Port with the Innovative Development of the Pharmaceutical Industry* to Mr. Shen Xiaoming, Secretary of the Hainan Provincial Committee of the CPC, winning high praises.

### (II) Participate in the drafting and revision of the *Provisions for the Implementation of the Drug*



*Administration Law upon invitation*

Upon invitation from NMPA, PhIRDA as an important member of the working group for drafting the new version of the *Provisions for the Implementation of the Drug Administration Law* (hereinafter referred to as the "Provisions"), fully participated in the discussion of the basic framework and content thereof, focusing on the drafting and revision of "Registration and R&D" chapter.

*(III) Propose the Suggestions on National Science and Technology Major Project for Major New Drug Research and Development During the 14th Five-Year Plan to the Assessment Team of National Science and Technology Major Projects (Civilian, 09)*

Upon invitation, PhIRDA participated in the special conclusive evaluation of National Science and Technology Major Project for Major New Drug Research and Development organized by Chinese Academy of Engineering (CAE) upon entrustment by the State Council. Mr. Song Ruilin, Executive President of PhIRDA, in the capacity of an assessment team member, took part in the field survey and symposium, proposing the following opinions and suggestions to further improve the innovation market access system and meet the people's needs for health and medical treatment: "Special funds allocated by the government should be used in the forefront areas of industrialization, particularly in the fields and key stages of source innovation and basic R&D where original and ground-breaking achievements are most likely to be made"; and "it is necessary to unveil the policies, laws and regulations that support the creation of an ecological environment favorable to simulating the pharmaceutical innovation as soon as possible".

*(IV) As a consultant expert of the Central Committee of Chinese Peasants and Workers Democratic Party (CPWDP) and responsible for participating in the administration and discussion of state affairs, put forward suggestions on deep integration of China's pharmaceutical industry with the global pharmaceutical industry in innovation*

In December 2020, Executive President Song Ruilin was appointed as a consultant expert of the Central Committee of CPWDP who is responsible for participating in the administration and discussion of state affairs. He proposed the *Suggestions on Deep Integration of China's Pharmaceutical Industry with the Global Pharmaceutical Industry in Innovation* for CPWDP. In addition, President Song promoted the NMPA to establish the system of mutual recognition in drug administration and registration covering the countries along the Belt and Road Initiative (BRI), to help China's innovative pharmaceutical products go global. For details of relevant suggestions, please refer to the Implementation Opinions on Comprehensively Strengthening the Capacity Building of Drug Administration (GBF [2021] No. 16).

*(V) Further enhance the international competitiveness of China's pharmaceutical innovations, reform and improve China's medical reimbursement mechanism for innovative pharmaceutical products*

Currently in China, drug expenses are paid at a fixed proportion according to the prices of generic drugs under the existing medical insurance payment system, which is unfavorable to the overall innovative development of China's pharmaceutical industry. When meeting with the main responsible persons of National Healthcare Security Administration (NHSA), PhIRDA put forward valuable suggestions: establish a ratio mechanism of more flexible medical insurance payment, calculate the prices of innovative drugs according to their clinical value, establish the medical insurance payment standard based on the actual medical insurance payment capacity, establish a pricing negotiation mechanism different from that for generic drugs, and change from "negotiation-based pricing" to "determining the reimbursement ratio through negotiation".

**III. Deeply study industry hotspots and pain points, and actively conduct researches on related topics to better advance the implementation of pharmaceutical innovation-related policies**

(I) Study and establish a real-world data research system, and speed up the application of real-world evidences for registration and regulatory decision-making

Upon entrustment by NMPA and Boao Lecheng International Medical Tourism Pilot Zone Administration (“Pilot Zone” for short), PhIRDA carried out the Research on Relevant Rules for Real World Data of Drugs and Medical Devices. After referring to international experience and conducting expert surveys and interviews, the research team established relevant rules for use of real-world evidences for pharmaceutical and regulatory registration on the basis of clarifying the qualifications of clinical research institutions, and the scope of applicable products, ethical review, genetic approval, data management, etc. PhIRDA guided the Pilot Zone to carry out the pilot work.

(II) Conduct in-depth studies on the early settlement mechanism of patent disputes for biological products according to the essential difference between chemical drugs and biological drugs

In order to safeguard the legitimate rights and interests of drug patent holders, PhIRDA, on the basis of drawing on international experiences and combining with China’s national conditions, actual industrial status and future development trends, conducted researches mainly on the connotation and implementation subjects of the early settlement mechanism of patent disputes for biological products, the patent information registration and publication system for innovator drugs of biological products, and the early settlement procedures for patent disputes of biological products, and intellectual property protection, etc. PhIRDA put forward relevant policy suggestions.

**IV. Establish the Working Group for China-SCO Cooperation in Pharmaceutical Innovation to promote the pragmatic pharmaceutical cooperation between China and the SCO members & the countries along the BRI, and form a new development pattern of dual circulation (taking domestic development as the mainstay,**

**with domestic and international development reinforcing each other)**

In order to help China's pharmaceutical innovative products go global, strengthen the cooperation and exchange between China and other countries in the pharmaceutical field, and establish a balanced, efficient mechanism for mutual recognition of international drug regulatory systems, PhIRDA established the Working Group for China-SCO Cooperation in Pharmaceutical Innovation (hereinafter referred to as “the Working Group”). Since its establishment, the Working Group has actively carried out relevant work of the Research on Market Strategies for Pharmaceutical Products into Countries along the Belt and Road through diverse channels. Relying on the resources of Shanghai Cooperation Organization (SCO), Good-Neighborly Friendship and Cooperation Committee of SCO, and Department of Science, Technology and International Cooperation, and giving full play to its own industrial advantages, the Working Group has actively attended many high-level meetings such as the SCO Forum on People-to-People Friendship Health Session, and China-ASEAN Summit for Drug Development and Cooperation, promoted the pharmaceutical cooperation and exchange between China and the SCO members & the countries along the BRI, established a cooperation mechanism for pharmaceutical research and development, realized the multilateral or bilateral mutual recognition in drug administration, and made positive contributions to improving the health and well-being of people from more countries.

**V. Attach great importance to the weak links that restrict the innovative development of the pharmaceutical industry, release the series of reports on Establishing China's Pharmaceutical Innovation Ecosystem, and put forward systematic plans and suggestions for creating a good ecological environment conducive to pharmaceutical innovation and internationalization**

In the series of reports on *Establishing China's Pharmaceutical Innovation Ecosystem* prepared by PhIRDA and R&D-based Pharmaceutical Association Committee (RDPAC), constructive opinions were put forward mainly from multiple perspectives (namely "innovative industry competitiveness", "accessibility of innovative drugs" and "sustainability of innovative pharmaceutical industry" to promote the long-term development of China's pharmaceutical innovation ecosystem. Since March 2021, four sub-reports, namely *Review of Development in 2015-2020 and Future Prospects*, *Promoting Basic Research and Activating Source Innovation*, *Contributing to the People's Health and High-quality Industrial Development Through Multi-level Medical Security System*, and *Promoting the Simultaneous Research and Development, Registration and Review of Innovative Drugs*, have been successively released, which aroused enthusiastic responses and won the high praises from deputies to the "Two Sessions", relevant leaders and all sectors of society. The series of reports on Establishing China's Pharmaceutical Innovation Ecosystem will be officially released at the China BioMed Innovation and Investment Conference (hereinafter referred to as "CBIIC").

## **VI. Continuously enrich and improve PhIRDA Specialty Committees, make innovations in the modes of activities, explore and establish thematic, normalized, and brand-based special activity platforms, and contributed new forces to the promotion of the innovation and sustainable development of China's pharmaceutical and health industry**

After the closing of the Second Meeting of the 11<sup>th</sup> Board of Directors on September 26, 2020, nine specialty committees including the International Regulatory Science Specialty Committee (established in Suzhou on September 27, 2020), the Medicinal Policy Specialty Committee (renewed in Suzhou on September 29, 2020), Clinical Research on Oncology Drugs Specialty Committee (established in Shanghai on October 18, 2020), Clinical Research on Cranial Nerve Drugs

Specialty Committee (established in Beijing on November 8, 2020), Ethics and Business Compliance Specialty Committee (established in Beijing on November 9, 2020), Clinical Trial Research Specialty Committee (renewed in Beijing on November 24, 2020), Drug R&D Specialty Committee (renewed in Hangzhou on December 4, 2020), Innovation R&D Services Specialty Committee (renewed in Hangzhou on December 4, 2020), and Clinical Research on Diabetes and Metabolic Diseases Specialty Committee (established in Beijing on September 5, 2021) were successively established or renewed. Relying on the resource advantages of experts and members of totally 11 specialty committees, PhIRDA has done a lot of fruitful work in six major areas, including drug R&D, clinical research, industry supervision, policy research, investment and financing, and compliance, having won widespread attention and praises from all walks of life.

### **(I) Publish research reports to promote China's pharmaceutical innovation**

The Clinical Research on Oncology Drugs Specialty Committee of PhIRDA, on the basis of comprehensively analyzing the current popular targets, drug action mechanisms, and domestic R&D situation, released the *Review of Clinical Researches on New Anti-tumor Drugs of China in 2020* to guide the rational and orderly R&D of drugs.

### **(II) Make innovations in the modes of activities, and propel the drug R&D and clinical researches in multiple areas**

During 2021 China International Fair for Trade in Services, the Clinical Research on Oncology Drugs Specialty Committee, Clinical Research on Cranial Nerve Drugs Specialty Committee, Clinical Research on Cardiovascular Drugs Specialty Committee, Clinical Research on Diabetes and Metabolic Diseases Specialty Committee, Clinical Trial Research Specialty Committee, and Innovation R&D Services Specialty Committee of PhIRDA respectively hosted the academic

conferences such as Summit Forum on Up-to-date clinical oncology advance & research of innovative anticancer drug, Innovation Summit Forum on Brain Science and Neuromedicine, Forum on Cardiovascular Disease Prevention and Innovative Treatment, Forum on Diagnosis and Treatment of Diabetes and Metabolic Diseases, and Forum on Innovative R&D Services. Meanwhile, the Pharmaceutical Innovation Investment Specialty Committee and other specialty committees held various kinds of colorful professional activities including the series of activities of “Star Enterprises Visit the First Stop Changsha” themed by “Promoting Innovative Development Through Integration of Industry and Finance”, and 2020 Forum on Anti-tumor Drug Development and Review of Onco-therapy.

## **VII. Carry forward the past and forge ahead into the future, and hold colorful and diverse offline conferences to provide more value services for various innovative entities in the pharmaceutical industry**

### **(I) 2021 China International Fair for Trade in Services**

From September 2 to September 7, 2021, 2021 China International Fair for Trade in Services (hereinafter referred to as “CIFTIS”) themed by “toward digital future and service-driven development” was hosted by the Ministry of Commerce and the Beijing Municipal People's Government in Beijing upon approval by the CPC Central Committee and the State Council. As one of the three major national, international, and comprehensive platforms specially for trade in services trade, CIFTIS incorporated health into eight major themes for the first time. In addition, thematic exhibitions and related forums themed by “digital health, innovation and integration” and the like attracted widespread attention from the international community. Upon entrustment by the Organizing Committee of CIFTIS, PhIRDA hosted the exhibitions themed by health services, and organized local governments, medical institutions, well-known domestic and foreign pharmaceutical and medical device manufacturers, insurance companies and

institution offering services for the elderly to showcase the comprehensive strength and level of China's biopharmaceutical industry in the forms of exhibition, display, professional forum, etc. PhIRDA hoped to promote the practical cooperation between China and other countries in biopharmaceutical products and services, and make new contributions to safeguarding the life and health of all mankind.

The area of Special Exhibition on Healthcare Services of CIFTIS covered a total area of 6,600m<sup>2</sup>, involving multiple fields such as policy, medical treatment, medical devices, investment, scientific research, service, etc. Totally more than 100 biopharmaceutical and health institutions and more than 10,000 people participated in the health service exhibition online and offline, and “Cloud Show” and “Cloud Connection” were comprehensively realized. Offline exhibitors included 45 Fortune Global 500 and industry-leading enterprises (accounting for 51% of the total) and 13 foreign-funded enterprises (occupying 15% of the total). During the 14 professional forums hosted with the support of specialized committees of PhIRDA, more than one hundred invited industry leaders including domestic and foreign health management leaders, academicians, well-known experts and scholars, and executives of Fortune Global 500, had in-depth exchanges on the topics such as public health, international cooperation in health service and pharmaceutical innovation, cardiovascular disease prevention and innovation, new progress in clinical oncology, innovation R&D services, etc. A total of 40 signing ceremonies on health services were held, involving the contract amount of approximately RMB 1 billion. Meanwhile, 24 PhIRDA members attended CIFTIS online and offline.

During CIFTIS, the “Smart Medical and Health Services” group composed of Beijing Center for Disease Control and Prevention and eight public class-A hospitals including Peking Union Medical College Hospital and Beijing Tiantan Hospital, showcased a number of cutting-edge medical and pharmaceutical technologies such as 5G mobile stroke units, robotic surgery, and



neonatal disease screening system, which became a big highlight of CIFTIS.

## (II) 2020 China BioMed Innovation and Investment Conference

2020 China BioMed Innovation and Investment Conference (hereinafter referred to as "CBIIC") was successfully held in Suzhou from September 27 to September 29, 2020. 2020 CBIIC brought together China's three major stock exchanges- HKEX, SSE and Shenzhen Stock Exchange (SZSE), which jointly discussed how to promote the innovative development of the biopharmaceutical industry through the diversified reform and development of China's capital market. In addition to sub-forums such as SZSE ChiNext, Biomedical Innovation Cities Development Forum, and Access to New Drug Policy Sharing Forum, heated discussion was had around the financing support policies and future development trends of innovative financing platforms for pharmaceutical industry. 2020 CBIIC attracted a total of 105 outstanding domestic and foreign companies (projects) that conducted the on-site or virtual roadshows, and nearly 3,000 representatives from pharmaceutical companies and investment institutions present, delivering the services of one-on-one round-table negotiation upon invitation for 830 person-times. 2020 CBIIC was widely acclaimed by industry professionals. 2021 CBIIC will be enriched by the Digitalization in Pharma and Innovative Therapy Forum, and Fundamental Research & Transformation of New Drugs Roadshow. Meanwhile, Reform of the ChiNext Seminar and Virtual International Roadshows will be held to provide more valuable services for domestic and foreign participants.

## (III) 2021 Forum on China's Pharmaceutical Innovation Policies

On July 17, 2021, the Forum on China's Pharmaceutical Innovation Policies, sponsored by the Medicinal Policy Specialty Committee and co-hosted by PhIRDA and iMeta Health Information Consulting Co., Ltd. (iMeta), was held in Nanjing. More than 300 representatives including relevant government departments, medical and pharmaceutical institutions, experts and scholars

in pharmacy and pharmacoeconomics, and industry professionals gathered and jointly discussed many topics from multiple angles and perspectives including the improvement of China's review and approval system and healthcare security system, and the reform of the innovative drug payment system. Proceeding from the needs of patients, the Forum deeply studied the policies covering the entire chain of pharmaceutical innovation, to promote the sustainable, innovative development of China's pharmaceutical industry.

## (IV) 2020 China Conference on Rare Diseases

From October 24 to October 25, 2020, China Conference on Rare Diseases, co-hosted by China Alliance for Rare Diseases and PhIRDA, was successfully held in Beijing under the guidance of the National Health Commission and the NMPA. The in-depth exchanges were conducted mainly on such topics as rare disease prevention, treatment and healthcare, big data platform construction, drug innovation and patient access, international cooperation, and the establishment and improvement of a patient-centered health ecosystem, which received great attention from all walks of life.

## (V) Summit Forum for Pharmaceutical Companies themed by "From the Laboratory to the IPO"

On May 12, 2021, Summit Forum for Pharmaceutical Companies themed by "From the Laboratory to the IPO", supported by PhIRDA and hosted by iMeta, was held in Shanghai. More than 200 domestic and foreign leaders, experts, and scholars in the biopharmaceutical and investment areas gathered and deeply discuss how to meet the needs of pharmaceutical companies with professional experience in face of the new situation, and to promote the leap-forward development of the pharmaceutical industry in China.

## VIII. PhIRDA enter into a strategic cooperation agreement with the SSE to promote the high-quality development of China's pharmaceutical industry

At the end of 2020, PhIRDA entered into a strategic cooperation agreement with the SSE to deepen the existing cooperation. According to the agreement, both parties will give full play to their respective advantages in resources, thoroughly implement the national decisions and arrangements on promoting the innovative development of the pharmaceutical and health industry, fully play the role of the capital market in driving the innovative development of the pharmaceutical industry, and carry out pragmatic cooperation in many aspects mainly including holding of professional conferences, cultivation of candidates for listing, standardized development of listed companies, industry information exchange, integration of industry-finance platforms, industrial research, etc. Both parties aim to establish and maintain the comprehensive, multi-level, long-term, stable, mutually beneficial strategic partnership, so as to better support the innovative and sustainable development of China's pharmaceutical industry. PhIRDA will continue to facilitate the financing and listing for high-tech companies specialized in pharmaceutical R&D, diversify financing channels, and further serve the overall reform, innovation and development of China's pharmaceutical industry.

## **IX. Deeply carry out international pharmaceutical exchanges and promote mutual exchanges and cooperation in the global pharmaceutical industry**

(I) Actively participate in the formulation of international rules, organize experts to study and formulate drug regulatory standards and policies in line with international standards, and promote the transformation and implementation of ICH guidelines

As a member of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), PhIRDA has recommended 38 experts (including 14 Leaders and 7 Alternate Leaders) to 19 ICH Expert Working Groups (EWGs) of the IFPMA since 2017, accounting for more than half of the total number of IFPMA experts worldwide.

Entrusted by the ICH Office of the NMPA, PhIRDA

solicited opinions from PhIRDA members and timely fed back industry opinions on 59 ICH guidelines to promote the smooth implementation of ICH guidelines in China. Entrusted by the Center for Drug Evaluation, PhIRDA actively recruited experts for ICH EWGs. By far, 36 experts recommended by PhIRDA have been included in 19 CDE ICH EWGs, and the experts for other EWGs are under further selection.

(II) Communicate with foreign embassies in China, foreign pharmaceutical industry associations and international organizations, utter the voice of China's pharmaceutical innovation industry, contribute China's strength, and promote mutual exchanges and cooperation in the global pharmaceutical industry

In the context of fighting against COVID-19, PhIRDA makes positive exploration in new areas of international affairs, having established close ties with the embassies and consulates of Netherlands, Belarus, Uzbekistan, Singapore and other SCO members in China, and many international organizations, with an aim to jointly promoting mutual exchange and cooperation in the global pharmaceutical industry.

The leaders of PhIRDA were invited to participate in Annual J.P. Morgan Healthcare Conference, Closed-door Meeting on Business Expansion of Chinese Biomedical Companies in ASEAN Countries, Asia Partnership Conference of Pharmaceutical Associations (APAC), China Healthcare Summit 2020, APEC Business Ethics for SMEs Forum, and other international conferences themed with innovation, investment, and supervision. Through keynote speech and participation in panel discussions, PhIRDA showed the world the achievements of China's drug regulatory reform and pharmaceutical innovation and development, and learned advanced administration experience from other countries and regions.

## **X. Continuously improve the pharmaceutical information service capability**

## (I) Collect and sort out the latest news in the pharmaceutical industry

PhIRDA insisted on collecting and sorting out the latest news of the pharmaceutical industry on a daily basis, including global pharmaceutical policies, drug R&D results, and breaking news, edited *Daily Pharmaceutical Information Brief*, and sent it to PhIRDA members as well as industry experts, government departments, and cooperative agencies. In 2020, a total of 238 pieces of *Daily Pharmaceutical Information Brief* were issued for 590,000 readers.

## (II) Facilitate communication and transfer information through WeChat and official platforms

PhIRDA released its work focuses and latest breaking news of the pharmaceutical industry through public publicity channels such as its official WeChat and official website, and widely publicized its opinions and suggestions on medical and pharmaceutical policy research, and screened and pushed in-depth analysis articles through WeChat and official website platforms, which received widespread attention from the industry. As of September 2021, PhIRDA Subscription has been followed by 18,817 people and 9,804 for CBIIC WeChat. Distinguished delegates, thanks to the unremitting efforts of all members, PhIRDA has become a reliable social organization through which relevant government departments advance the creation of an ecological environment for pharmaceutical innovation, and local governments make arrangements for the development of the pharmaceutical and health industry. The member units of PhIRDA play an increasingly active role in Investment and other activities, and significantly improve their international status and influence. A number of high-quality listed pharmaceutical companies have been established, which have become an indispensable mainstay of global pharmaceutical innovation, significantly promoting the pharmaceutical innovation. I hereby would like to express my heartfelt thanks to all PhIRDA members and branches for their great support and help.

## Part II. Proposal for Key Work in 2021-2022

The 14<sup>th</sup> Five-year Plan for National Economic and Social Development and the Long-Range Objectives Through the Year 2035 propose to make innovation remain at the heart of China's modernization drive, boost the role of enterprises in innovation, pay attention to the original innovation, and deepen the industry-university-research cooperation; encourage the development of angel investment and venture capital, and give better play to the role of venture capital guide funds and private equity funds, invest in basic medical researches through multiple channels, and promote the innovation and development of industries such as medicine and medical equipment; improve the ability of financial services serving the real economy, improve the financial support system for innovation, provide smooth financing channels for domestic listing of technology-based enterprises, promote the integration and innovation of biotechnology and information technology, and strengthen institutional support for symbiotic interaction between the real economy, scientific and technological innovation, financial services, and talent development. In the new year, PhIRDA, shouldering the mission to promote the innovation and internationalization of China's pharmaceutical industry, will integrate and rationally allocate various factors and forces for pharmaceutical innovation under the guidance of the 14<sup>th</sup> Five-Year Plan, continue to improve the ecological environment for China's pharmaceutical industry, and focus on the following aspects of work.

### I. Further strengthen construction of the Party organization and create a new situation for Party building based on the actual work of PhIRDA

In the coming year, PhIRDA, under the guidance of Xi Jinping Thought on Socialism with Chinese Characteristics in a New Era, and under the comprehensive and strong leadership of the Party committee of China Federation of Industrial Economics, and of the Party committee of the State-owned Assets Supervision and Administration Commission (SASAC), will further

improve the Party's basic organization structure, basic teams and basic systems, integrate the Party's political leadership and supervision with its own governance, and resolutely maintain a politically proper development. All staff of PhIRDA will further learn and implement the content of an important speech delivered by General Secretary Xi Jinping on July 1, the CPC Founding Day, and receive the regular education and learning about the Party's history, to truly understand the truth, boost self-confidence, value morality, and practice diligently. The Party organization of PhIRDA will assume the leadership and oversight responsibilities for strict self-governance, earnestly deepen the work of improving Party conduct and upholding integrity, pay equal attention to Party building and business development, and drive the business development through Party building.

## **II. Continue to play the role as an industry think tank, deeply study major pharmaceutical policies, and actively offer advice and suggestions to relevant government departments to promote the healthy and sustainable pharmaceutical innovation in China**

(I) Deepen ties with various ministries and commissions of drug administration, study major policies affecting the development of the industry through proactive or commissioned forms, submit industry development and research reports to the relevant central government authorities, and give full play to the role of industry organizations to serve, coordinate and supervise the government

(II) Earnestly put supporting measures and related guiding principles for deepening the drug regulatory reform into effect, and focus on the revision of the Provisions for the Implementation of the Drug Administration Law; continue to promote the implementation of policies related to drug intellectual property protection, to ensure China's drug regulatory reform policies are smoothly promoted and the balance between innovator drugs and generic drugs is truly realized

(III) Continue to promote the balance between improving the healthcare insurance system and promoting pharmaceutical innovation, guide the formation of a reasonable and feasible medical insurance payment price and real-time dynamic access mechanism for innovative drugs, and promote the application of varieties included into the National Reimbursement Drug List (NRDL)

(IV) Actively carry out the work of revising the implementation rules of the *Regulations of the People's Republic of China on the Management of Human Genetic Resources*, and pay attention to the practical problems concerning the implementation of the *Regulations*, including but not limited to those concerning the filing and approval procedures, entry and exit management, data collection, identification of Chinese and foreign parties, and other regulatory requirements, to offer suggestions and references for the formulation and revision of the implementation rules of the Regulations

(V) Continue to carry out the work related to the research on the BRI, maintain close ties with the SCO and its Good-Neighborliness, Friendship and Cooperation Commission (GNFCC), promote the establishment of a mechanism for mutual recognition of international drug regulatory systems in key countries and regions, speed up the internationalization of Chinese innovative drugs, and make new contributions to the formation of a new pattern of wide-range, deep-level, high-level and all-round foreign trade cooperation in China's pharmaceutical industry

## **III. Actively expand cooperation with relevant institutions at home and abroad, and steadily enhance the international status and say of China's pharmaceutical innovation forces**

PhIRDA will continue to expand cooperation and exchange with foreign embassies and consulates in China, industry associations and social organizations, recommend authoritative experts in the industry to participate in the formulation and revision of ICH guidelines in accordance with the requirements of the



Secretariat of the IFPMA and the ICH Office of the NMPA, and urge Chinese experts to participate in the formulation of international standards and rules and speak out on the international stage; cooperate with relevant departments of the NMPA to complete the implementation of ICH-related guidelines in China, and steadily promote China's pharmaceutical industry standards to comply with international standards.

In addition, PhIRDA will integrate and rationally allocate resources to further help Chinese pharmaceutical companies improve their international competitiveness, help member units to acquire more opportunities of new drug R&D and overseas cooperation in the medical and health field, and promote the deep integration of China's pharmaceutical industry with the global pharmaceutical industry in the areas of trade, investment and technology, etc.

#### **IV. Form an ecological closed loop of investment for pharmaceutical innovation, and continue to promote the listing of high-quality companies specialized in pharmaceutical R&D in Hong Kong, Shanghai, Shenzhen, and Beijing, to jointly write a new chapter that capital markets boost the high-quality development of the biopharmaceutical industry in the new era**

Since 2015, PhIRDA has conscientiously implemented the series of important instructions on the capital market from General Secretary Xi Jinping, actively explored new paths through which industry associations engage in comprehensive deepening of capital market reforms, deeply participated in the diversified reforms of capital markets in China, successively established close ties with HKEX, SSE and SZSE and reached consensus mainly on strengthening the basic institutional improvement of capital markets and enhancing inclusiveness, to remove blocking points that affect the innovative and sustainable development of the pharmaceutical industry, and help the companies specialized in pharmaceutical R&D in term of ultimate listing and financing. Many members, directors, supervisors, and branch heads of PhIRDA Pharmaceutical

Innovation Scientific Committee successively were hired as the experts of HKEX, SSE and SZSE in the pharmaceutical field. A number of PhIRDA members of successively were listed on the HKEX and SSE STAR Market, achieving one milestone after another. In the future, PhIRDA will continue to promote and deepen the pragmatic cooperation with China's three major stock exchanges and the Beijing Stock Exchange to be established, to jointly write a new chapter that capital markets boost the high-quality development of the biopharmaceutical industry in the new era.

#### **V. Continuously enrich and improve PhIRDA Specialty Committees, gather together experts in different professional fields, and explore new ideas, develop new paths, and provide new methods for promoting cross-border exchanges in the pharmaceutical industry**

Upon approval by the Board of Directors, PhIRDA decided to establish the High-end Medical Device Specialty Committee and Digital Medicine and Innovative Therapy Specialty Committee.

##### **(I) High-end Medical Device Specialty Committee**

With the accelerated aging of global population, people have raised higher demands for health and better life, and high-end medical devices have increased sharply in the demand and potential, whose economic and social values have been further highlighted. In response to the call of "fostering advanced manufacturing clusters, and promoting the innovative development of the pharmaceutical and medical device industry" in the "14<sup>th</sup> Five-Year Plan" period, and under the leadership of NMPA, PhIRDA decided to focus on promoting the policy research and relevant work in the field of medical devices, and established the High-end Medical Device Specialty Committee, planning to fully play the role of bridging between the industry and the government through policy research, cooperation and exchange, academic training and the like. On the one hand, PhIRDA will assist relevant government departments in

researching and promoting the policies on supervision of advanced medical devices, and provide theoretical and intellectual support for establishing the system for scientific, efficient, systematic, and all-round full-cycle supervision of medical devices in line with China's national conditions; on the other hand, PhIRDA will try to comprehensively enhance the R&D capabilities of high-end medical devices, focus on in vitro diagnosis, imaging equipment, treatment equipment, implanted interventional products, medical robots, smart medical treatment, and other fields in urgent needs, and make due contributions to breaking the foreign monopoly in high-end medical devices and helping China's high-end medical devices reach the international advanced level as soon as possible.

## **(II) Digital Medicine and Innovative Therapy Specialty Committee**

Along with the development and application of big data, AI, and other new-generation information technologies, the world has entered an era of digitalization, and the medical and pharmaceutical industry has kicked off digital transformation in history. Meanwhile, the entire industry chain of new drug development and production, disease prevention and control, disease diagnosis and treatment, is embracing more and more new opportunities for digital innovation, and digital supervision and scientific social governance centered on data driving and digital governance have become the core topics of global innovation. In order to prepare well for the future innovations, PhIRDA has established the Office for Digitalization Promotion on Pharmaceutical Innovation, and took the lead in establishing the Digital Medicine and Innovative Therapy Specialty Committee. Studying the global pharmaceutical digitalization policies, the Specialty Committee actively carries out the work related to macro-industry analysis of pharmaceutical digitalization, regulatory policy suggestions, promotion of representative enterprises' innovations, construction of investment and financing platforms around new drug innovation and production based on AI, new medical-industry integration, digital therapy, and other emerging

pharmaceutical innovation fields. The Specialty Committee aims to build a platform for communication of digital pharmaceutical enterprises with scientific research institutions, medical and pharmaceutical institutions, international organizations, regulatory agencies, and investment institutions, advance the modern data-driven construction of infrastructures, and promote the digital innovation of medical and pharmaceutical industry in China, as well as pharmaceutical innovation through digital innovation.

In the future, PhIRDA will, relying on the advantageous expert resources of branches, continue to deepen the fields of drug and medical device administration, pharmaceutical investment, drug R&D, and pharmaceutical digitalization, and provide all-round value services for domestic pharmaceutical innovation subjects in cross-border cooperation.

## **VI. Establish "Prix Galien Awards" to help the spread and development of Chinese brands in the world, and enhance the international competitiveness of China's pharmaceutical innovation**

The Prix Galien Awards, initiated in France in 1970 to commend the outstanding achievements of medical innovation in improving the human conditions, is hailed as the "Nobel for the biopharmaceutical industry and medical technology research industry", and has been extended to 15 countries including France, the United States, Germany, the United Kingdom, Italy, and Canada etc.

In order to encourage China's independent innovation and drive the transformation of Chinese pharmaceutical innovation to original and disruptive technological innovation, PhIRDA and Galien Foundation will jointly hold the Prix Galien Awards issuing ceremony, to commend individuals and organizations that have made outstanding contributions to promoting China's pharmaceutical innovation as well as innovative products developed and marketed in China. In order to facilitate

the Prix Galien Awards issuing ceremony, PhIRDA established the review committee composed of some specially invited well-known domestic and foreign experts, and also Dingxin Pharmaceutical Innovation Research Center in Suzhou Industrial Park (SIP), completing the filing of activities of overseas NGOs of the Ministry of Public Security. It is estimated that the selection work of Prix Galien Awards will officially start before December 2021, and the award ceremony will be held in Suzhou in June 2022 as planned.

## **VII. Continue to hold various forums and academic exchange activities including CBIIC well to serve the key links of pharmaceutical innovation**

PhIRDA will continue to vigorously cooperate with relevant institutions at home and abroad, and hold the annual China International Fair for Trade in Services, CBIIC, Forum on China's Pharmaceutical Innovation Policies, China Conference on Rare Diseases, and other activities. Meanwhile, PhIRDA will continue to carry out in-depth activities in various professional fields according to the work focuses and academic research directions of specialty committees, serve the key links of medical and pharmaceutical innovation, and promote the development of China's biopharmaceutical industry, and the advances in medical and pharmaceutical technologies.

At present, the international community has reached a consensus on promoting the high-quality development of the pharmaceutical industry, and China, through pharmaceutical innovation, is contributing its wisdom and strength to achieving the great vision of building a community of common health for mankind. PhIRDA hereby invites you to work together to integrate various resources, focus on the pain points and blocking points that affect the innovative and sustainable development of China's pharmaceutical industry, play a role of bridging between the industry and the government, stimulate the pharmaceutical innovation along the entire chain of pharmaceutical industry, provide new conveniences for all innovative entities in China's pharmaceutical industry, further improve China's ecological environment for

pharmaceutical innovation, promote the innovative and sustainable development of the pharmaceutical industry, and make unremitting efforts to achieve the great goals of building a pharmaceutical power in all respects and making more innovative drugs of China available to all people in the world.