药促会官方微信
WeChat Official Account of PhIRDA

创投大会微信服务号
WeChat Official Account of the CBHC

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PhIRDA
中国药促会

创新·产业化·国际化
Innovation·Industrialization·Internationalization

中国医药创新促进会

China Pharmaceutical Innovation and Research Development Association

2020-2021 会刊
ASSOCIATION JOURNAL

为帮助患者而创新
Innovations Dedicated to Patients

会长寄语
Message from Chairman of PhIRDA

2020 是极不平凡的一年，中国生物医药行业面临诸多不确定性因素和一系列挑战，也承载着前所未有的重任。研发和生产更具临床价值的药物，帮助更多患者，是时代赋予我们的使命，更是我们共同的初心。

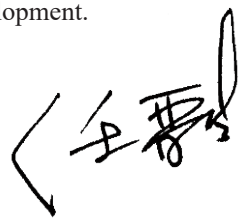
未来五年将是中国生物医药行业转型升级的关键机会期，因为患者不分种族、创新没有国界，中国医药创新与投资不应封闭起来，既要重视市场和资源要素的内循环，更要用好中国元素和中国优势，积极进取、大胆有为，更大力度推动对外交流合作，用开放和合作促进更高层次上的创新和投资。

中国医药创新促进会在全体会员单位的支持和努力下，在宋瑞霖执行会长及历任会长的用心耕耘下，取得了快速而持续的发展，呈现蓬勃兴盛之势。协会正成为汇聚行业力量，促进创新、投资与合作的平台。感谢朋友们的信任与支持，作为 2020-2021 年度会长，我倍感责任与压力，唯有与各位朋友精诚携手，实践我们共同的帮助患者的初心，为促进行业创新升级和开放发展贡献力量。

2020 is an unusual year. China's biopharmaceutical industry has been facing tremendous uncertainties and changes, as well as responsibilities greater than ever before. It is not only a mission given by the era but also a common aspiration for us to develop and produce pharmaceuticals with greater clinical value in efforts to benefit more patients.

The upcoming five years would be a key window for the transformation and upgrading of the country's biopharmaceutical industry. Patients have no races, while innovations have no nation boundaries. The pharmaceutical innovation and investment should by no means be restricted. We should not only focus on the internal circulation in terms of market and resources, but also better utilize the Chinese elements and advantages to boost external communication cooperation in a positive and bold manner. It is only by openness and cooperation can we achieve innovation and investment at a higher level.

Thanks to the support and joint efforts by its members and diligent endeavors by Executive Preseident Song Ruilin and all other annual chairmen, the China Pharmaceutical Innovation and Research Development Association (PhIRDA) has witnessed sustainable development and prosperous growth. PhIRDA is becoming an increasingly important momentum to gather all industry forces and develop a platform incorporating innovation, investment and cooperation. I would like to extend my gratitude to all my friends for your trust and support. As Annual Chairman, I become greatly aware of the huge responsibility and even pressure. I would like to make joint efforts with all my friends, to fulfill our mission to help patients and make dedicated contributions to boost the country's pharmaceutical innovation and open development.



创新·产业化·国际化

*I*nnovation · *I*ndustrialization · *I*nternationalization

目　录
CONTENTS

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 151 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、医药企业合规专业委员会，形成了以创新为核心，以促进创新为目标的涵盖药物研发、生产、使用以及投融资的全链条组织构架，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

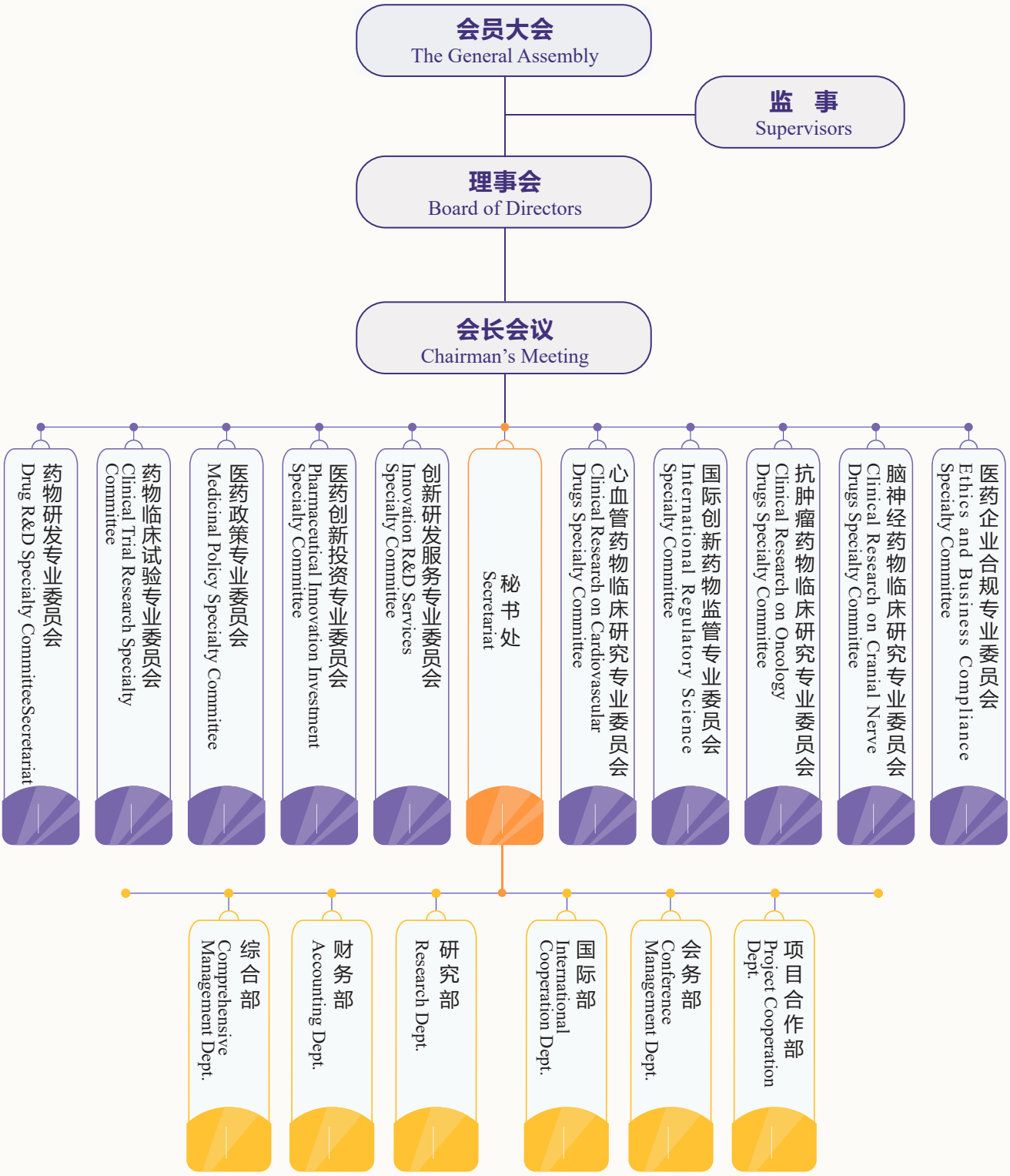
Founded in 1988, China Pharmaceutical Innovation and Research Development Association (PhIRDA), formerly named China Pharmaceutical Industry Research and Development Association, is registered as a non-profit 4A social organization by the Ministry of Civil Affairs of China at national level.

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 151 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, 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

荣誉主任 桑国卫

十一届全国人大副委员长、十四届农工党中央主席
重大新药创制国家科技重大专项技术总师、中国药学会名誉理事长

Honorary Chairman, Sang Guowei

Vice Chairman of Standing Committee of Eleventh National People's Congress,
Chairman of Fourteenth Central Committee of Chinese Peasants and Workers Democratic Party,
Chief Engineer of National Science and Technology Major Project for Major New Drug Research and Development,
Honorary President of Chinese Pharmaceutical Association

主任 陈凯先

中国科学院院士
中国科学院上海药物研究所研究员、学位委员会主任
上海中医药大学学术委员会主任

Chairman, Chen Kaixian

Academician of Chinese Academy of Sciences,
Researcher & Director of Academic Degree Committee of Shanghai Institute of Materia Medica, China Academy of Sciences,
Director of Academic Committee of Shanghai University of Traditional Chinese Medicine

委员 曹雪涛

中国工程院院士
南开大学党委委员、副书记、校长

Member, Cao Xuetao

Academician of Chinese Academy of Engineering,
Member of Party Committee,
Vice Chancellor & President of Nankai University

委员 蒋华良

中国科学院院士
中国科学院上海药物研究所研究员

Member, Jiang Hualiang

Academician of Chinese Academy of Sciences,
Researcher of Shanghai Institute of Materia Medica, China Academy of Sciences

委员 丁 健

中国工程院院士
发展中国家科学院院士
中国科学院大学药学院院长
中国科学院上海药物研究所学术委员会主任

Member, Jian Ding

Academician of Chinese Academy of Engineering,
Academician of The World Academy of Sciences,
Dean of School of Pharmacy at University of Chinese Academy of Sciences,
Director of Academic Committee of Shanghai Institute of Materia Medica, Chinese Academy of Sciences

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中国药科大学学术委员会主席、重点实验室主任

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Chairman of Academic Committee & Director of Key Laboratory, China Pharmaceutical University

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上海复旦大学附属中山医院心内科主任

Member, Ge Junbo

Academician of Chinese Academy of Sciences,
Dean of Institutes of Biomedicine at Fudan University,
Director of Cardiology Department of Zhongshan Hospital, Fudan University

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四川大学生物治疗国家重点实验室教授

Member, Wei Yuquan

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Professor of National Key Laboratory of Biotherapy, Sichuan University

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中国科学院院士
发展中国家科学院院士
同济大学前校长

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Academician of Chinese Academy of Sciences,
Academician of The World Academy of Sciences,
Former President of Tongji University

委员 程 京

中国工程院院士
清华大学医学院生物医学工程系教授

Member, Cheng Jing

Academician of Chinese Academy of Engineering,
Professor of Department of Biomedical Engineering, School of Medicine, Tsinghua University

委员 王晓东

中国科学院外籍院士
北京生命科学研究所所长
百济神州（北京）生物科技有限公司创始人

Member, Wang Xiaodong

Foreign Academician of Chinese Academy of Sciences,
Director of National Institute of Biological Sciences, Beijing,
Founder of BeiGene

委员 王松灵

中国科学院院士
首都医科大学教授、首都医科大学口腔转化医学研究所所长

Member, Wang Songling

Academician of Chinese Academy of Sciences,
Professor & Director of Institute of Oral Translational Medicine, Capital Medical University

委员 丁文江

中国工程院院士
轻合金精密成型国家工程研究中心主任
原上海交通大学副校长

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Academician of Chinese Academy of Engineering,
Director of Light Alloy Net Forming National Engineering Research Center,
Former President of Shanghai Jiao Tong University

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中国科学院院士
中国科学院上海药物研究所研究员

Member, Yue Jianmin

Academician of Chinese Academy of Sciences,
Researcher of Shanghai Institute of Materia Medica, Chinese Academy of Sciences

委员 樊 嘉

中国科学院院士
复旦大学附属中山医院院长

Member, Fan Jia

Academician of Chinese Academy of Sciences,
President of Zhongshan Hospital, Fudan University

委员 王 锐

中国工程院院士
兰州大学副校长、医学部主任

Member, Wang Rui

Academician of Chinese Academy of Engineering,
Vice President & Director of School of Medicine, Lanzhou University

委员 李校堃

中国工程院院士
温州医科大学校长

Member, Li Xiaokun

Academician of Chinese Academy of Engineering,
President of Wenzhou Medical University

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 9th 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
天士力控股集团董事局主席

Yan Xijun
Annual Chairman 2013-2014
Chairman of the Board, Tasly Holding Group

孙飘扬

2014-2015年度会长
江苏恒瑞医药集团有限公司董事长

Sun Piaoyang
Annual Chairman 2014-2015
Chairman of the Board, Jiangsu Hengrui Medicine Group 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
中国医学科学院药物研究所所长

Jiang Jiandong
Annual Chairman 2017-2018
Director, Institute of Materia Medica, Chinese Academy of Medical Sciences

刘殿波

2018-2019年度会长
绿叶制药集团有限公司董事长

Liu Dianbo
Annual Chairman 2018-2019
Chairman of the Board, Luye Pharma Group Co., Ltd.

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

现任会领导
Current Leadership of PhIRDA

会长 任晋生

先声药业有限公司董事长

Ren Jinsheng, Chairman
Chairman of the Board, Simcere Pharmaceutical Group

执行会长 宋瑞霖

中国医药创新促进会

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

副会长 李 燕

齐鲁制药集团有限公司总裁

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

副会长 陈启宇

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 of Fosun International, Director of Fosun Pharma

副会长 孙飘扬

江苏恒瑞医药集团有限公司董事长

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

副会长 丁列明

贝达药业股份有限公司
董事长兼CEO

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

副会长 蒋建东

中国医学科学院药物研究所所长

Jiang Jiandong, Vice President
Director, Institute of Materia Medica, Chinese Academy of Medical Sciences

副会长 刘殿波

绿叶制药集团有限公司董事长

Liu Dianbo, Vice President
Chairman of the Board, Luye Pharma Group Co., Ltd.

副会长 柯尊洪

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.

副会长 李　佳

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

副会长 闫凯境

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.

副会长 赵　勇

上海医药集团股份有限公司
党委副书记、副总裁

Zhao Yong, Vice President
Deputy Secretary of the Party Committee & Vice President, Shanghai Pharmaceuticals Holding Co., Ltd.

副会长 张抒扬

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

副会长 吴晓滨

百济神州中国区总经理兼公司总裁

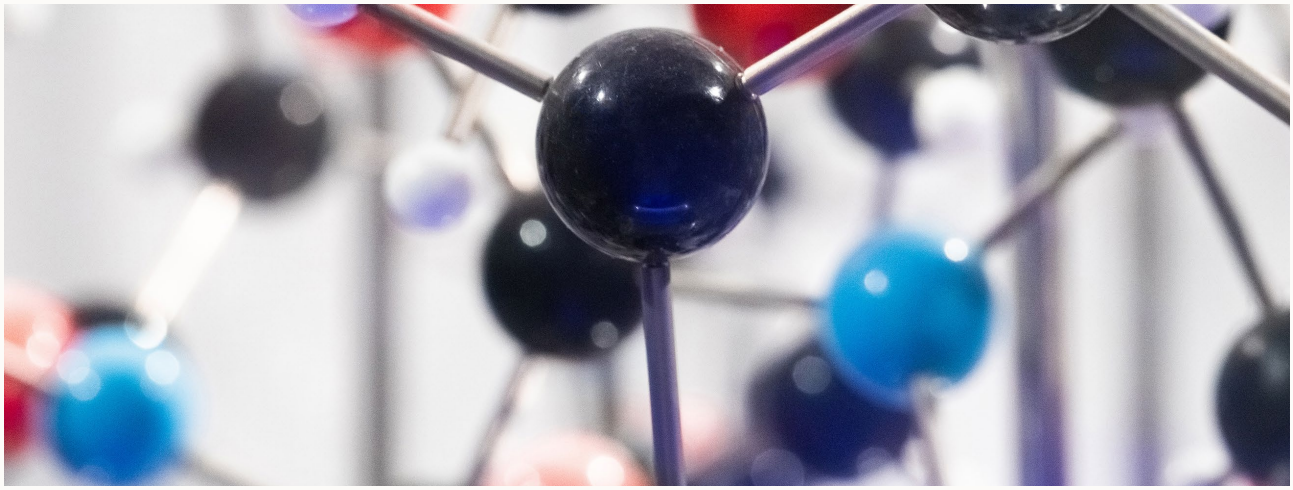
Wu Xiaobin, Vice President
General Manager of China & President, BeiGene Ltd.

秘书长 冯　岚

中国医药创新促进会

Feng Lan, Secretary-General
China Pharmaceutical Innovation and Research Development Association

专业委员会简介



根据工作需要，经中国医药创新促进会（以下简称“中国药促会”）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、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、抗肿瘤药物和药物临床试验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。

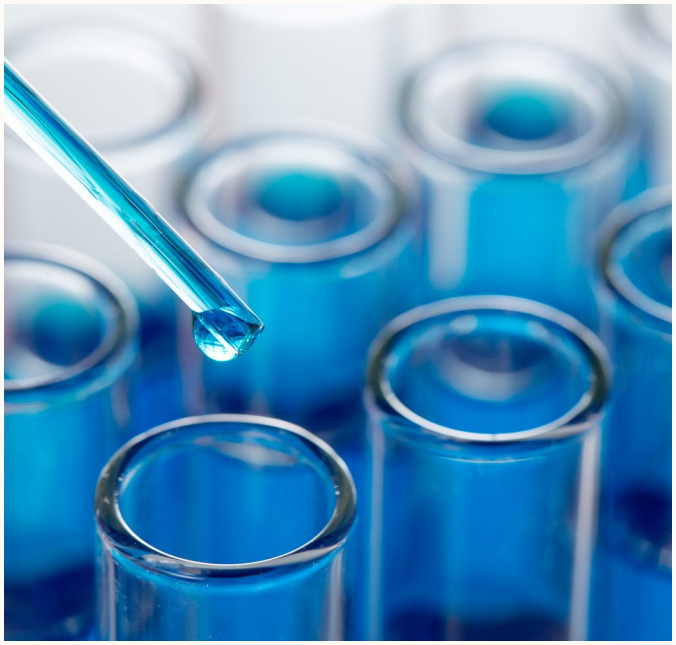
Introduction of Specialty Committees

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, 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.

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 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 3rd Drug R&D Specialty Committee

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

副主任委员 俞德超

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.

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北京加科思新药研发有限公司董事长兼CEO

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

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Founder, Chairman of the Board & CEO of Hua Medicine (Shanghai) Ltd.

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昆翎联合创始人兼首席战略官

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Co-Founder & Chief Strategy Officer of ClinChoice Inc.

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中国医学科学院药物研究院
副院长

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Associate Director of Pharmaceutical Institute, Chinese Academy of Medical Sciences

副主任委员 薛 群

北海康成制药有限公司
董事长及首席执行官

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Chairman & CEO of CANbridge Pharmaceuticals Inc.

副主任委员 阎水忠

再鼎医药（上海）有限公司
研究及开发首席运营官

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COO, R&D of Zai Lab

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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

秘书长 彭少平

先声药业南京研究院副院长

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

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The 3rd Clinical Trial Research Specialty Committee

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Director of Institute of Clinical Pharmacology, Peking University

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Vice-Chairman, Wang Xinghe
Director of Phase I Clinical Trial Center, Beijing Shijitan Hospital, Capital Medical University

副主任委员 李海燕

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

副主任委员 李可欣

北京医院临床试验研究中心主任

Vice-Chairman, Li Kexin
Director of Clinical Trial Center, Beijing Hospital

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北京协和医院临床药理中心教授、主任医师

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Professor & Chief Physician of Clinical Pharmacology Research Center, Peking Union Medical College Hospital

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宝石花医药科技有限公司总裁

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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
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卫生经济学教授

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Director of Department of Pharmacy,
Beijing Hospital

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国家罕见病诊疗与保障专家
委员会委员

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Committee Member of National
Expert Consultation Committee of
Diagnosis and Treatment of
Rare Disease

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国家药物政策与医药产业经济研
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Drug Policy & Ecosystem of China
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秘书长 王 峰

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Founder & Chairman of GTJA Investment Group

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元明资本创始合伙人

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Founding Partner of Yuanming Capital

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Chairman of the Board & CEO, Zai Lab

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第二届创新研发服务专业委员会
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首席执行官

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Proswell Medical Co., Ltd.

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高级副总裁

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Jiuzhou Pharmaceutical Co., Ltd.

秘书长 刘 熠

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医学事务副总裁

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Science & Medical Affairs, dMed
Biopharmaceutical Co., Ltd.

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Director of Cardiology Department, the First Affiliated Hospital of Xi'an Jiaotong University

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北京协和医院心内科主任

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中国科学院上海药物研究所学术所长、研究员

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Professor & Academic Director-General, Shanghai Institute of Materia Medica, Chinese Academy of Sciences

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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

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上海复旦大学附属中山医院
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秘书长 高晓丽

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心血管内科主任

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Director of Cardiology Department, Huabei Petroleum Administration Bureau General Hospital

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The 1st International Regulatory Science Specialty Committee

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国投创新医疗健康首席科学家
前国家食品药品监督管理总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

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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

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首席顾问、合伙人

Vice-Chairman, Du Tao
Chief Consultant & Partner of Humphries Pharmaceutical Consulting, LLC.

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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.

副主任委员 李 宁

上海君实生物首席执行官

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

副主任委员兼秘书长 赵孝斌

白橡树医药创始人
浙江海昶生物医药创始人

Vice-Chairman & Secretary-General, Zhao Xiaobin
Founder of WhiteOak Group Inc.
Founder of Zhejiang Haichang Biotech Co., Ltd.

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The 1st Clinical Research on Oncology Drugs Specialty Committee

顾问 管忠震

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

顾问 秦叔逵

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

顾问 孙飘扬

江苏恒瑞医药集团有限公司董事长

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Chairman of the Board, Jiangsu Hengrui Medicine Group Co., Ltd.

顾问 孙 燕

中国工程院院士

Counselor, Sun Yan
Academician of the Chinese Academy of Engineering

顾问 吴一龙

广东省人民医院终身主任

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

顾问 于金明

中国工程院院士

Counselor, Yu Jinming
Academician of Chinese Academy of Engineering

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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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Vice-Chairman, Hui Aimin
President of Global R&D Center, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.

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哈尔滨血液病肿瘤研究所所长

Vice-Chairman, Ma Jun
Director of Harbin Institute of Hematology & Oncology

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北京大学肿瘤医院副院长

Vice-Chairman, Shen Lin
Vice President of Beijing Cancer Hospital

副主任委员 俞德超

信达生物制药（苏州）有限公司董事长

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

副主任委员 张 力

中山大学附属肿瘤医院副主任

Vice-Chairman, Zhang Li
Deputy Director of Sun Yat-Sen University Cancer Center

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上海市肺科医院主任

Vice-Chairman, Zhou Caicun
Director of Shanghai Pulmonary Hospital

副主任委员 朱 军

北京大学肿瘤医院党委书记、主任

Vice-Chairman, Zhu Jun
Secretary of the Party Committee & Director, Beijing Cancer Hospital

秘书长 蔺 强

华北石油管理局总医院副院长

Secretary-General, Lin Qiang
Vice President of Huabei Petroleum Administration Bureau General Hospital

副秘书长 薛俊丽

同济大学附属东方医院副教授

Deputy Secretary-General, Xue Junli
Associate Professor of Tongji University Shanghai East Hospital

第一届脑神经药物临床研究专业委员会
The 1st Clinical Research on Cranial Nerve Drugs Specialty Committee

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首都医科大学附属
北京天坛医院院长

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Dean of Beijing Tian Tan Hospital, Capital Medical University

主任委员 张亚卓

北京神经外科研究所前任所长

Chairman, Zhang Yazhuo
Former Director of Beijing Neurosurgical Institute

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中国人民解放军空军总医院
神经内科主任

Vice-Chairman, Shi Jin
Director of Neurology Department, Air Force General Hospital, PLA

副主任委员 马文斌

北京协和医院神经外科主任

Vice-Chairman, Ma Wenbin
Director of Neurosurgery Department, Peking Union Medical College Hospital

副主任委员 吴安华

中国医科大学附属第一医院
神经外科主任

Vice-Chairman, Wu Anhua
Director of Neurosurgery Department, the First Hospital of China Medical University

副主任委员 尤永平

江苏省人民医院神经外科主任

Vice-Chairman, You Yongping
Director of Neurosurgery Department, Jiangsu Province Hospital

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李宏丽 Li Hongli	交银国际（亚洲）有限公司总经理 General Manager, BOCOM International (Asia) Co., Ltd.
余世新 Yu Shixin	招商局海通贸易有限公司总经理 General Manager, China Merchants Hoi Tung Trading Co., Ltd.
周海冰 Zhou Haibing	北京大数长胜资产管理有限公司首席战略官 CSO, Beijing Great Numbers Asset Management Co., Ltd.
刘　浩 Liu Hao	浩悦资本有限公司创始人兼首席执行官 Founder & CEO, HaoYue Capital Ltd.
蔡大庆 Cai Daqing	珠海夏尔巴股权投资管理有限公司创始人 / 管理合伙人 Founder & Managing Partner, Sherpa Venture Capital
H.J. Jiang	泰福资本创始管理合伙人 Managing Partner, TF Capital
张蕾娣 Zhang Leidi	国寿股权投资有限公司董事总经理 Managing Director, China Life Private Equity Investment Co., Ltd.
王闽川 Wang Minchuan	三正健康投资管理有限公司合伙人、董事总经理 Partner & Managing Director, 3H Health Investment Management Ltd.

方　敏 Fang Min	华平投资合伙人、中国医疗健康投资负责人 Managing Director & Head of Healthcare Investment, Warburg Pincus
郑效东 Zheng Xiaodong	上海东富龙科技股份有限公司董事长 Chairman of the Board, Shanghai Tofflon Science and Technology Co., Ltd.
王锦刚 Wang Jingang	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.
谭凌实 Tan Lingshi	缔脉生物医药科技（上海）有限公司董事长兼首席执行官 Chairman of the Board & CEO, dMed Biopharmaceutical Co., Ltd.
张天泽 Zhang Tianze	零氪科技（北京）有限公司首席执行官 CEO, LinkDoc Co., Ltd.
洪　浩 Hong Hao	凯莱英医药集团（天津）股份有限公司董事长兼首席执行官 Chairman of the Board & CEO, Asymchem Laboratories (Tianjin) Co., Ltd.
闻丹忆 Wen Danyi	上海立迪生物技术股份有限公司董事长兼执行总裁 Chairman of the Board & CEO, Shanghai LIDE Biotech Co., Ltd.
陈志红 Chen Zhihong	浙江九洲药业股份有限公司总经理 General Manager, Zhejiang Jiuzhou Pharmaceutical Co., Ltd.
陈志红 Chen Zhihong	浙江九洲药业股份有限公司总经理 General Manager, Zhejiang Jiuzhou Pharmaceutical Co., Ltd.
宋青春 Song Qingchun	北京春天医药科技发展有限公司总经理 General Manager, Proswell Medical Co., Ltd.
温书豪 Wen Shuhao	深圳晶泰科技有限公司董事长 Chairman of the Board, XtalPi Inc.
刘　川 Liu Chuan	北京科林利康医学研究有限公司董事长兼首席科学官 Chairman of the Board & Chief Scientific Officer, Clinical Service Center
陈永清 Chen Yongqing	国信医药科技（北京）有限公司董事长兼总裁 Chairman of the Board & President, GX Pharma Technology (Beijing) Co., Ltd.
宓子厚 Mi Zihou	艾昆纬亚太区总裁 President, Asia Pacific, IQVIA
高思华 Gao Sihua	北京中医药大学原校长 Former President, Beijing University of Chinese Medicine
张伯礼 Zhang Boli	天津中医药大学校长，中国工程院院士 President, Tianjin University of Traditional Chinese Medicine, Academician, Chinese Academy of Engineering
吴春福 Wu Chunfu	沈阳药科大学原党委书记 Former Secretary of the Party Committee, Shenyang Pharmaceutical University
刘俊义 Liu Junyi	北京大学药学院原院长 Former Dean, Peking University School of Pharmaceutical Sciences
陆伟跃 Lu Weiyue	复旦大学药学院原党委书记 Former Secretary of the Party Committee, School of Pharmacy Fudan University
刘克良 Liu Keliang	中国人民解放军军事医学科学院毒物药物研究所原所长 Former Director, Institute of Pharmacology and Toxicology Academy of Military Medical Sciences
李卓荣 Li Zhuorong	中国医学科学院北京协和医学院医药生物技术研究所副所长 Deputy Director, Institute of Medicinal Biotechnology, Chinese Academy of Medical Sciences & Peking Union Medical College
陈建峰 Chen Jianfeng	北京市纳微化结构药物工程技术研究中心，中国工程院秘书长，北京化工大学副校长，中国工程院院士 General Secretary, Beijing Nanostructured Drug Engineering & Technology Center, Chinese Academy of Engineering Vice President, Beijing University of Chemical Technology, Academician, Chinese Academy of Engineering
肖瑞平 Xiao Ruiping	北京大学分子医学南京转化研究院副院长 Deputy Dean, PKU-Nanjing Joint Institute of Translational Medicine
施一公 Shi Yigong	西湖大学校长 President, Westlake University

重要活动
Important Events

第十一届理事会第二次会议（2020 年 9 月 26 日 · 苏州）
The Second Meeting of 11th PhIRDA Board of Directors (September 26, 2020, Suzhou)

2019–2020 年度会长宋瑞霖为 2020–2021 年度会长任晋生颁发证书
2019-2020 PhIRDA Annual Chairman Song Ruilin presented certificate to 2020-2021 PhIRDA Annual Chairman Ren Jinsheng

监事蒋华良发言
Dr. Jiang Hualiang, Supervisor of PhIRDA, made a speech

监事邵蓉发言
Ms. Shao Rong, Supervisor of PhIRDA, made a speech

监事舒畅发言
Mr. Shu Chang, Supervisor of PhIRDA, made a speech

鲁晓缇副秘书长主持会议
Ms. Lu Xiaoti, PhIRDA Deputy Secretary-General chaired the meeting

冯岚秘书长作工作报告
Ms. Feng Lan, PhIRDA Secretary-General delivered a work report

国际创新药物监管专委会发起人何如意发言
Dr. He Ruyi, Sponsor of International Regulatory Science Specialty Committee, made a speech

会场全景
Plenary Meeting

参会代表合影
Photograph of Representatives

中国医药创新促进会专业委员会活动（8 月 – 9 月）

Activities of PhIRDA Specialty Committees (August - September)

中国医药创新促进会
医药创新投资专业委员会第三届第一次工作会议
（2020 年 8 月 20 日 · 深圳）
The First Meeting of 3rd PhIRDA Pharmaceutical Innovation Investment Specialty Committee
(August 20, 2020, Shenzhen)

中国医药创新促进会
心血管药物临床研究专业委员会成立大会
（2020 年 8 月 24 日 · 任丘）
Inaugurating Meeting of PhIRDA Clinical Research on Cardiovascular Drugs Specialty Committee
(August 24, 2020, Renqiu)

中国医药创新促进会
国际创新药物监管专业委员会成立大会
（2020 年 9 月 27 日 · 苏州）
Inaugurating Meeting of PhIRDA International Regulatory Science Specialty Committee
(September 27, 2020, Suzhou)

中国医药创新促进会
医药政策专业委员会第三届第一次工作会议
（2020 年 9 月 29 日 · 苏州）
The First Meeting of 3rd PhIRDA Medicinal Policy Specialty Committee
(September 29, 2020, Suzhou)

2019 年中国罕见病大会（2019 年 10 月 19 日 · 北京）

2019 China Conference on Rare Diseases (October 19, 2019, Beijing)

2019 年 10 月 19 日，由中国罕见病联盟主办，中国药促会等机构承办的“2019 年中国罕见病大会”在北京举行，国家卫生健康委员会副主任王贺胜、中国医院协会会长刘谦、国家医疗保障局副局长李滔、国家药品监督管理局副局长徐景和等领导出席大会，并就各部门的职责阐述对罕见病管理的政策与措施。中国药促会会长宋瑞霖在大会开幕式上就“如何打造良好的国内罕见病防控生态环境”组织了主题讨论，同与会嘉宾深入探讨，推动罕见病事业发展。大会吸引了来自行政部门和海内外科研院所、医药协 / 学会、医疗机构、高等院校等机构的知名专家学者 1600 余人参会，获得了参会者的一致好评，收到了社会各界的强烈反响。

Hosted by China Alliance for Rare Diseases (CARD) and organized by PhIRDA etc., 2019 China Conference on Rare Diseases was held in Beijing on October 19, 2019. Wang Hesheng, Vice-minister of National Health Commission, Liu Qian, President of Chinese Hospital Association, Li Tao, Deputy Director of the National Healthcare Security Administration and Xu Jinghe, Deputy Commissioner of National Medical Products Association and other government officials participated the conference and explained policies and measures for rare disease management regarding the responsibilities of each department. Song Ruilin, Chairman of PhIRDA, chaired the panel discussion on cultivating an ecosystem for the prevention and control of rare diseases in China and had a fruitful discussion with the panelists. The conference attracted more than 1,600 well-known experts and scholars from administrative departments, scientific research institutes at home and abroad, medical associations/societies, medical institutions, colleges and universities, etc., receiving praise from all of the participants.

领导致辞

Welcome Remarks by Leaders

第二届中国生物医药创新投资人论坛
（2020 年 8 月 20 日 · 深圳）
The Second China BioMed Innovation Investors Forum
(August 20, 2020, Shenzhen)

中国医药创新促进会医药创新投资专业委员会联合高特佳投资集团、坪山区人民政府共同主办的第二届中国生物医药创新投资人论坛在深圳举办。本次论坛旨在帮助社会各界更好地了解创业板证券发行上市最新政策，将生物医药产业和创业板紧密相连，为金融领域和生物医药领域专家和学者汇聚一堂共话我国生物医药产业创新和可持续发展搭建了对话平台。

The Second China BioMed Innovation Investors Forum, co-hosted by PhIRDA Pharmaceutical Innovation Investment Specialty Committee, GTJA Investment Group and People's Government of Pingshan District was held in Shenzhen. The forum aims to help all the stakeholders to better understand the latest policies for the issuance and listing of securities on the ChiNext, closely link the biopharmaceutical industry and ChiNext and build a platform to bring together experts and scholars in the financial and biopharmaceutical fields to discuss the innovation and sustainable development of biopharmaceutical industry in China.

会议现场

Plenary Meeting

第五届中国医药创新与投资大会（2020 年 9 月 27 日 −29 日 · 苏州）

2020 China BioMed Innovation and Investment Conference (September 27-29, 2020, Suzhou)

由中国药促会联合中国医疗器械行业协会、香港交易所和艾美达医药咨询共同主办的第五届中国医药创新与投资大会在苏州工业园区召开。大会设置了上市公司、非上市公司、医疗器械、国际云路演、罕见病、创新研发服务、AI+ 生物医药、大数据 + 智慧医疗等 13 个项目路演专场以及科创板、创业板、投资人经验分享、创新药准入政策分享、投资并购、资本市场创新服务、医药创新城市发展和当前形势下如何提高中国药物创新国际价值等 8 个分论坛，现场展示 105 个创新项目，吸引近 3000 位医药与投资界人士注册参会，其中药品及器械研发、生产和服务机构超过 800 家，投资和金融服务相关机构 300 余家。一对一商务邀约洽谈系统累计为参会者提供 830 桌次洽谈服务，有效地提升了交流效率。大会囊括医药产业宏观政策、医药产业投资趋势及经验分享、全球资本市场及上市相关金融和法律服务咨询、临床数据全球首发和国内外百余家机构（项目）路演，成为亚太地区具有广泛影响力的、权威多元、规模性的医药创新与投资界高端年度盛会。

开幕式会场全景

Plenary Meeting of Opening Ceremony

Co-hosted by China Pharmaceutical Innovation and Research Development Association (PhIRDA), China Association for Medical Devices Industry (CAMDI), Hong Kong Exchanges and Clearing Limited (HKEX) and iMeta Health Information Consulting, 2020 China BioMed Innovation and Investment Conference (2020 CBIIC) was held in Suzhou Industrial Park. 2020 CBIIC set 13 parallel roadshow sessions including Listed Company, Non-Listed Company, Medical Devices, Virtual International Projects, Rare Diseases and Orphan Drugs, R&D Service Company, AI+BioMed, WIT-MED+Big Data etc., and 8 forums including SSE STAR Market, ChiNext, Investors' Experience Sharing, Access to New Drug Policy Sharing, Financing M&A, Capital Market Innovation Services, Biomedical Innovation Cities Development and Leverage the Global Value of Pharmaceutical Innovations from China. 105 pharmaceutical innovative projects were presented on-site, attracting over 3,000 representatives from more than 800 pharmaceutical and medical devices companies, 300 investment institutions to participate in this event. The One-on-One Partnering System provided participants with more effective communication, having facilitated 830 match meetings during the 3-day conference. Including analysis on macro policies of pharmaceutical industry, experience sharing and trends of investment, law and financial consulting of global capital market and listing, clinical trial data release and over 100 roadshows from domestic and foreign companies, 2020 CBIIC has grown into the influential, authoritative and diversified annual grand conference in Asia-Pacific region.

多位重量级嘉宾亮相大会开幕式

KOLs Participated in the Opening Ceremony

商务部原部长、

中国外商投资企业协会会长陈德铭

Chen Deming, Former Minister of Commerce of the People's Republic of China, Chairman of China Association of Enterprises with Foreign Investment

全国政协经济委员会主任、

原中国银监会主席尚福林

Shang Fulin, Director of Economic Committee of CPPCC, Former Chairman of the China Banking Regulatory Commission

中国药促会执行会长宋瑞霖

Song Ruilin, Executive President of PhIRDA

香港交易所行政总裁李小加

Charles Li, Chief Executive of HKEX

中国药促会会长、先声药业董事长任晋生

Ren Jinsheng, Chairman of PhIRDA& Chairman of the Board of Simcere Pharmaceutical

苏州市市长李亚平

Li Yaping, Mayor of Suzhou People's Municipal Government

中国药促会候任会长、齐鲁制药集团总裁李燕

Li Yan, Chairman-elected of PhIRDA,
President of Qilu Pharmaceutical Group

深圳证券交易所党委副书记、总经理沙雁

Sha Yan, Deputy Secretary of the Party Committee, President & CEO of Shenzhen Stock Exchange

摩根大通投资银行全球主席 Elizabeth Myers

Elizabeth Myers, Global Chairman of Investment Banking, Equity Capital Markets at J.P. Morgan

首都医科大学附属北京天坛医院院长王拥军

Wang Yongjun, President of Beijing Tian Tan Hospital, Capital Medical University

中国药理学会理事长张永祥

Zhang Yongxiang, Chairman of Chinese Pharmacological Society

“投资与医药创新”主题讨论

Panel: Investment and Pharmaceutical Innovation

“全球医药创新发展趋势”主题讨论

Panel: Global Trends on Pharmaceutical Innovation R&D

首届医药创新城市发展论坛（2020 年 9 月 27 日 · 苏州）

Biomedical Innovation Cities Development Forum

(September 27, 2020, Suzhou)

由中国药促会和 RDPAC 共同发起、IQVIA 作为项目研究合作方的“中国最具投资价值的生物医药创新城市研究”项目成果在论坛发布。论坛揭晓了中国最具投资价值生物医药创新城市排名和生物药、医疗器械、医疗服务、医疗大数据、最具潜力生物医药五个细分领域创新城市榜单，并对十大创新城市授牌。来自北京、上海、广州等十余座城市的政府部门代表以及医药创新企业、投资机构和相关媒体共同见证了论坛盛况。

Initiated by PhIRDA and China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee (RDPAC) and conducted by IQVIA, Study on China Biomedical Innovation Cities with Most Investment Value was released on the Biomedical Innovation Cities Development Forum of 2020 CBIIC. The Forum released the ranking list of China Biomedical Innovation Cities with Most Investment Value and the list of Representative Innovation Cities evaluated by 5 subcategories including biological drugs, medical devices, medical services, medical big data and the biopharmaceutical with the most potentials. Top 10 China Biomedical Innovation Cities with Most Investment Value were awarded. Representatives from government, pharmaceutical innovation companies, investment institutions and pharmaceutical press in more than ten cities including Beijing, Shanghai, Guangzhou, etc. also participated in and witnessed the event.

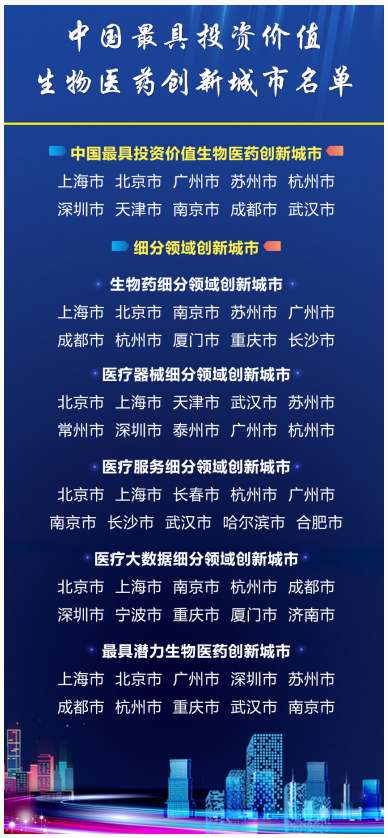
发布仪式

Study Release Conference of “China Biomedical Innovation Cities with Most Investment Value”

中国最具投资价值生物医药创新城市授牌仪式

（上海市 北京市 广州市 苏州市 杭州市 深圳市 南京市 成都市 武汉市）

Awarding Ceremony of China Biomedical Innovation Cities with Most Investment Value
(Shanghai, Beijing, Guangzhou, Suzhou, Hangzhou, Shenzhen, Nanjing, Chengdu, Wuhan)



宋瑞霖会长受聘为全国政协参政议政人才库特聘专家

Chairman Song Ruilin was offered appointment as the Expert of the Talent Pool for State Affairs of Chinese People's Political Consultative Conference (CPPCC)

全国政协参政议政人才库特聘专家聘书颁发仪式现场

Award Ceremony of Expert of the Talent Pool for State Affairs of CPPCC

宋瑞霖会长长期从事医药卫生领域的法律、政策研究，带领中国药促会积极参与药品审评审批制度和国家医疗保障制度改革，为完善我国医药创新政策环境做出了积极贡献。

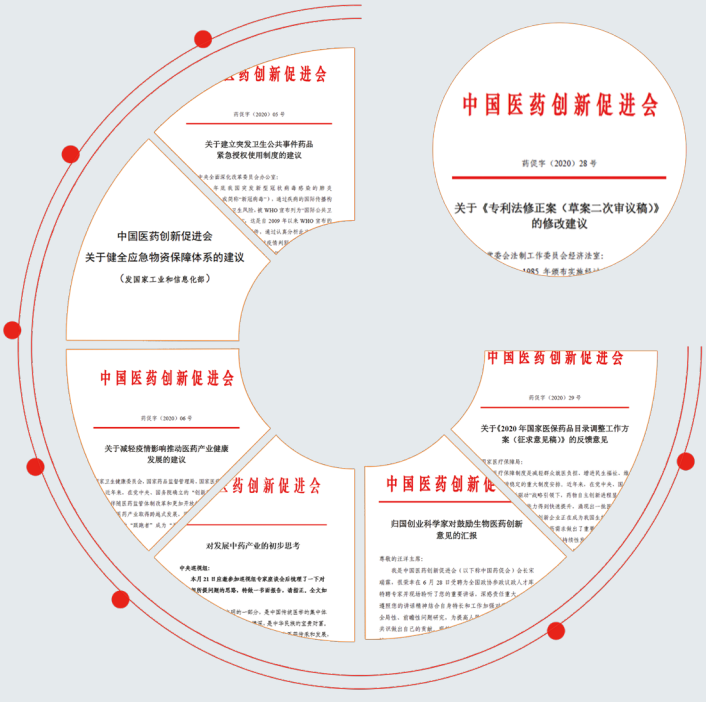
Chairman Song Ruilin has been engaging in health policy research and legal studies for long time. He has made great contribution in leading PhIRDA engage in optimizing the reform of drug review and approval system, medical insurance reimbursement system and policy environment for pharmaceutical innovation in China.

开展政策研讨 积极建言献策

Making Discussions on Medical Policies & Providing Suggestions

深入研究行业热点和痛点问题，持续调动并整合专家及会员企业力量，为政府有关部门献计献策，促进中国医药创新事业蓬勃发展。

PhIRDA made in-depth study on industry hotspots and problems, continue to mobilize and integrate the strength of experts and members, provide suggestions for relevant government departments, and promote the flourishing development of pharmaceutical innovation in China.



国际交流活动

International Cooperation and Exchanges

宋瑞霖会长会见美国药品研究与制造商协会（PhRMA）执行副总裁兼首席医疗官 Richard Moscicki

（2019 年 10 月 19 日 · 北京）

PhIRDA Chairman Song Ruilin met with Richard Moscicki, Chief Medical Officer and Executive Vice President of PhRMA (October 19, 2019, Beijing)

冯岚秘书长会见澳大利亚生物技术协会（AusBiotech）主席 Julie Phillips（2019 年 10 月 30 日 · 澳大利亚墨尔本）

PhIRDA Secretary General Feng Lan met with Julie Phillips, Chairman of AusBiotech (October 30, 2019, Melbourne, Australia)

宋瑞霖会长应邀出席第 38 届摩根大通健康产业大会，并作为主要嘉宾参与讨论（2020 年 1 月 15 日 · 美国旧金山）

PhIRDA Chairman Song Ruilin attended the 38th Annual J.P. Morgan Healthcare Conference and participated panel discussion (January 15, 2020, San Francisco, USA)

线上活动
Virtual Events

第十一届中国医院药学政策论坛（2020 年 7 月 17 日）
The 11th China Hospital Pharmacy Policy Forum (July 17, 2020)

中国药促会和中国药师协会共同主办的第十一届中国医院药学政策论坛以线上形式顺利召开。本届药学论坛邀请到多位权威专家，从多角度多层面围绕国家医保目录调整、药学服务模式创新等前沿问题进行解读并展开深入交流。

Co-hosted by PhIRDA and Chinese Pharmacists Association, the 11th China Hospital Pharmacy Policy Forum was successfully held virtually. The forum invited authoritative experts to interpret and conduct in-depth exchanges on cutting-edge topics including the adjustment of NRDL and pharmaceutical service models from multiple angles and levels.

“新版《药品注册管理办法》与临床试验指导政策系列讲座”四期线上宣讲活动（2020 年 4–5 月）

Serial Webinars on Newly Revised *Provisions for Drug Registration* and Clinical Trial Guidance (April-May, 2020)

“新版《药品注册管理办法》与临床试验指导政策系列讲座”宣讲活动

Series of Lectures on Clinical Trial Guidance and New Provisions for Drug Registration

本系列宣讲活动邀请到国家药品监督管理局注册司综合处李江宁处长、药品审评中心药理毒理学部王庆利部长、药品审评中心化药临床二部谢松梅副部长和药品审评中心化药药学二部许真玉副部长就新版《药品注册管理办法》与临床试验相关指导政策进行深入解读和介绍。

Serial webinars invited Li Ning, Director of Department of Drug Registration of NMPA, Wang Qingli, Director of Department of Pharmacology and Toxicology, CDE, NMPA, Xie Songmei, Director of Clinical Medicine Department II, CDE, NMPA, and Xu Yuzhen, Deputy Director of Chemical and Pharmaceutical Department II, CDE, NMPA, to make in-depth interpretation and introduction of the newly revised *Provisions for Drug Registration* and the guidance policies related to clinical trials.

“生物科技生态圈对话香港资本市场” 系列研讨会
（2020 年 6 月 5 日和 2020 年 7 月 6 日）

Dialogues with the Biotech Community Webinar Series
(June 5 & July 6, 2020)

中国药促会与香港交易所共同举办“生物科技生态圈对话香港资本市场”系列研讨会

Dialogues with the Biotech Community Webinar Series Co-hosted by PhIRDA and HKEX

本系列研讨会邀请到抗疫前线医学专家、生物医药企业领袖、医疗数据领域嘉宾和投资机构高级管理者分别就 “疫情下医疗大数据的分析与应用” 以及“全球疫情下的医药健康创新发展与香港资本市场新机遇”等热点话题进行线上分享和交流。在线参会者突破 20 万人。

The Webinar Series invited COVID-19 front-line medical experts, leaders of biopharmaceutical enterprises, professionals on medical data field and senior executives from investment institutions, to focus on the analysis and application of medical big data and development of pharmaceutical innovation and new opportunities in Hong Kong capital market amidst the COVID-19 pandemic. The number of online audiences exceeded 20,000.

“人类遗传资源管理政策解读线上培训”线上培训（2020 年 5 月 30 日）

Virtual Workshop of the Policies of Human Genetic Resource Administration (May 30, 2020)

中国药促会主办人类遗传资源管理与实施线上培训（2020 年 5 月 30 日）

Virtual Workshop on the Implementation of Regulations on Management of Human Genetic Resources

本次线上活动特邀到中国人类遗传资源管理办公室相关同志和军科院军事医学研究院研究员张永祥进行政策解读，在线参会者超过 1.5 万人。

Head of China Human Genetic Resources Administration Office and Zhang Yongxiang, Researcher of Academy of Military Medical Sciences made speeches in the workshop. The total number of online audiences exceeded 15,000.

AI 智能开启药物研发新引擎（2020 年 5 月 29 日）

AI Opens a New Engine for Drug R&D(29 May, 2020)

中国医药创新促进会、中欧国际工商学院联合发起并主办了主题为“AI 智能开启药物研发新引擎”的云对话，就人工智能在医药产业研发中的作用进行深度解读与讨论。

PhIRDA and China Europe International Business School (CEIBS) jointly hosted a virtual meeting themed "AI Opens a New Engine for Drug R&D" to discuss the role of artificial intelligence plays in pharmaceutical industry R&D.

大事记（2019 年 10 月 –2020 年 9 月）

——2019 年——

10 月 19 日

由中国罕见病联盟主办，我会等机构承办的 2019 中国罕见病大会在北京举行。期间，宋瑞霖会长会见了美国药品研究与制造商协会（PhRMA）执行副总裁兼首席医疗官 Richard Moscicki。

10 月 30 日

冯岚秘书长会见了澳大利亚生物技术协会（AusBiotech）主席 Julie Phillips。

11 月 2 日

由我会和贝达药业共同主办的“凯美纳成果发布八周年学术峰会”在北京举行。

11 月 6 日

由我会和国家卫健委国际交流与合作中心主办，复星国际承办的中国国际进口博览会“科技赋能 健康未来”第二届虹桥国际健康科技创新论坛在上海举行。

12 月 6 日

我会与南京市投资促进领导小组办公室签署战略合作协议。

12 月 19 日

我会与中国科学院上海药物研究所、中国医学科学院药物研究所联合北京天坛医院、北京大学第一医院等临床试验机构共同建立中药注射剂再评价第三方评估平台，向国家药品监督管理局提出《关于提升中药注射剂质量工作方案的建议》。

——2020 年——

1 月 12 日

我会与世易医健（eChinaHealth）、美国临床肿瘤学会（ASCO）共同主办的 ASCO Direct“肿瘤突破：科学与技术的交汇”国际会议在美国旧金山举行。

1 月 15 日

宋瑞霖会长应邀出席在美国旧金山举行的第 38 届摩根大通健康产业大会，并参与宏观角度剖析中国医药产业创新发展的现状与未来主题讨论。

2 月 25 日

我会分别向中共中央全面深化改革委员会办公室和国家工业和信息化部提出《关于建立我国突发卫生公共事件药品紧急授权使用制度的建议》和《关于健全应急物资保障体系的建议》。

3 月 3 日

我会向国家药品监督管理局、国家医疗保障局和国家卫生健康委员会三部门提出《关于减轻疫情影响推动医药产业健康发展的建议》。

3 月 30 日

我会向国家药品监督管理局提出《关于尽快制定重大突发传染病疫情药物临床试验指南的建议》。

4 月 8 日

我会与 APAC 13 个行业协会共同撰写的《2020 年亚洲医药市场与监管报告》在第九届亚洲制药组织合作会议上发布。

4 月 16 日

由宋瑞霖会长撰写的《中国药品监管改革成果和对全球医药创新的贡献》在国际媒体 PharmaBoardroom 发布。

4 月 24 日

西安新通药物研究有限公司、应世生物科技（上海）有限公司加入我会。

6 月 28 日

宋瑞霖会长受聘为全国政协参政议政人才库特聘专家。

6 月 28 日

我会向驻国家药品监督管理局中央巡视组提出《对发展中药产业的初步思考》。

6 月 29 日

国家市场监督管理总局原党组书记、副局长毕井泉同志赴我会调研。

7 月 3 日

我会提出的《关于优化创新环境，吸引更多海外人才回国发展的几点建议》上报全国政协主席汪洋同志，并以政协摘报的形式上报党中央国务院。

7 月 7 日

北京康辰药业股份有限公司、和铂医药（苏州）有限公司、亘喜生物科技（上海）有限公司、和其瑞医药（南京）有限公司、科望（上海）生物医药科技有限公司、国信医药科技（北京）有限公司、北京大学分子医学南京转化研究院、西湖大学、艾昆纬企业管理咨询（上海）有限公司加入我会。

7 月 17 日

我会与中国药师协会共同主办的“第十一届中国医院药学政策论坛”召开。

7 月 29 日

我会生物药工作组成立，聚焦当前生物药和生物类似药研发和产业化面临的重点和难点问题，以促进产业良性发展。

8 月 8 日

我会向国家医疗保障局提出《2020 年国家医保药品目录调整工作方案（征求意见稿）》意见和建议。

8 月 10 日

我会向全国人大常委会法制工作委员会经济法室提出《专利法修正案（草案二次审议稿）》修改建议。

8 月 16 日

我会组织召开“中药再评价专家研讨会”，就传统中药走上现代化和中药注射剂再评价形成相关共识，报送国家药品监督管理局。

8 月 20 日

中国医药创新促进会医药创新投资专业委员会在深圳坪山召开换届会议。

8 月 20 日

第二届中国生物医药创新投资人论坛在深圳坪山召开。

8 月 24 日

中国医药创新促进会心血管药物临床研究专业委员会成立。北大一院心内及心脏中心主任霍勇当选第一届主任委员。

8 月 28 日

苏州泽璟生物制药股份有限公司、苏州开拓药业股份有限公司、华平投资加入我会。

9 月 2 日

我会召开 2020 年度联络秘书工作会议。

9 月 26 日

我会第十一届理事会第二次会议在苏州召开。先声药业董事长任晋生当选 2020-2021 年度会长。

9 月 26 日

新兴际华医药控股有限公司加入我会。

9 月 27-29 日

由我会联合中国医疗器械行业协会、香港交易所和艾美达医药咨询共同主办的第五届中国医药创新与投资大会在苏州召开。

9 月 27 日

首届医药创新城市发展论坛在苏州召开。由我会和 RDPAC 共同发起、IQVIA 作为项目研究合作方的“中国最具投资价值的生物医药创新城市研究”项目成果在论坛发布。

9 月 27 日

中国医药创新促进会国际创新药物监管专业委员会成立。原国家食品药品监督管理总局药品审评中心首席科学家何如意当选第一届主任委员。

9 月 29 日

中国医药创新促进会医药政策专业委员会在苏州召开换届会议。北京医院药学部主任胡欣当选第三届主任委员。

Remarkable Events (October, 2019 - September, 2020)

—— 2019 ——

October 19

2019 China Conference on Rare Diseases, hosted by China Alliance for Rare Diseases (CARD) and organized by PhIRDA etc., was held in Beijing. During the meeting, PhIRDA Chairman Song Ruilin met with Richard Moscicki, Chief Medical Officer and Executive Vice President of PhRMA.

October 30

PhIRDA Secretary General Feng Lan met with Julie Phillips, Chairman of AusBiotech.

November 2

PhIRDA and Beta Pharmaceuticals co-hosted the 8th Listing Anniversary Academic Summit of Conmana in Beijing.

November 6

The Second Hongqiao International Health Technology Innovation Forum themed Technology Energizes the Future of Health, hosted by PhIRDA and International Health Exchange and Cooperation Center NHC PRC (IHECC), organized by Shanghai Fosun Pharmaceutical, was successfully held on the China International Import Expo (CIIE) in Shanghai.

December 6

PhIRDA signed a strategic cooperation agreement with Leading Group Office of Nanjing Municipal Investment Promotion Bureau.

December 19

PhIRDA established a third-part TCM injections safety re-evaluation platform with Shanghai Institute of Materia Medica, Chinese Academy of Sciences, Institute of Medicine, Chinese Academy of Medical Sciences, and clinical institutions including Beijing Tiantan Hospital, Capital Medical University, Peking University First Hospital, etc., to propose *Suggestions on Improving the Quality of TCM Injections Work Plan* to NMPA.

2020

January 12

International Conference ASCO Direct "Oncology Breakthrough: Where Science Meets Technology", co-hosted by PhIRDA, eChinaHealth and ASCO, was successfully held in San Francisco, USA.

January 15

PhIRDA Chairman Song Ruilin attended the 38th Annual J.P. Morgan Healthcare Conference and participated in panel discussion on current situation and future of development of Chinese pharmaceutical industry from a macro perspective.

February 25

PhIRDA submitted proposals *Suggestions on Establishing an Emergency Authorization System for the Use of Drugs in Public Health Emergencies in China and Suggestions on Improving the Emergency Supplies System* to Central Committee for Deepening Overall Reform and Ministry of Industry and Information Technology, PRC, respectively.

March 3

PhIRDA submitted *Suggestions on Mitigating the Impact of the COVID-19 Pandemic and Promoting the Healthy Development of the Pharmaceutical Industry* to the NMPA, National Healthcare Security Administration and the National Health Commission, PRC.

March 30

PhIRDA submitted Suggestions on *Urgent Formulating Guidelines for Clinical Drug Trials for Major Infectious Disease Outbreaks* to the NMPA, PRC.

April 8

The *Market Information survey of Pharmaceutical Market & Regulatory Environment Report 2020*, co-drafted by PhIRDA and 13 industrial associations, was released in 9th Asia Partnership Conference of Pharmaceutical Associations (APAC).

April 16

Article *China's Regulatory Reform and Its Contribution to Global Pharmaceutical Innovation* by Dr. Song Ruilin, Chairman of PhIRDA, was published on international media *PharmaBoardroom*.

April 24

Xi'an Xintong Pharmaceutical Research Co., Ltd and InxMed (Shanghai) Co., Ltd officially joined PhIRDA.

May 19-20

PhIRDA Chairman Song Ruilin led the team to Suzhou and Nanjing for investigation, and held a seminar with PhIRDA members.

June 28

PhIRDA Chairman Song Ruilin was offered appointment as Expert of the Talent Pool for State Affairs of Chinese People's Political Consultative Conference (CPPCC).

June 28

PhIRDA proposed *Thoughts on the Development of Traditional Chinese Medicine Industry* to Central Leading Group for Inspection Work in NMPA.

June 29

Bi Jingquan, Former Secretary of Party Group and Deputy Director-General of State Administration for Market Regulation, visited PhIRDA.

July 3

PhIRDA's *Suggestions on Improving Innovation Environment and Attracting Overseas Talents Back to China* were reported to Wang Yang, Chairman of the Chinese People's Political Consultative Conference National Committee, and briefed to the CPC Central Committee and the State Council.

July 7

Beijing Konruns Pharmaceutical Co., Ltd., Harbour Biomed, Gracell Biotechnologies (Shanghai) Co., Ltd., Hope Medicine (Nanjing) Co., Ltd., Elpiscience Biopharma, Ltd., GX Pharma Technology (Beijing) Co., Ltd., PKU-Nanjing Joint Institute of Translational Medicine, Westlake University, and IQVIA Enterprise Management Consulting (Shanghai) Co., Ltd. officially joined PhIRDA.

July 17

The 11th China Hospital Pharmacy Policy Forum, co-hosted by PhIRDA and Chinese Pharmacists Association (CPA), was successfully held.

July 29

Focusing on the key issues and difficulties in R&D and industrialization of biological medicine and biosimilars, PhIRDA established Biological Medicine Working Group to promote the healthy development of the industry.

August 8

PhIRDA submitted opinions and suggestions on the *Work Plan for the Adjustment of the National Reimbursement Drug List in 2020 (Draft)* to the National Healthcare Security Administration.

August 10

PhIRDA proposed suggestions for the *Amendment to the Patent Law of the People's Republic of China (Draft for Second Deliberation)* to the Economic Law Department of Legislative Affairs Commission, National People's Congress (NPC), PRC.

August 16

PhIRDA organized the Expert Seminar on the Safety Re-evaluation of Traditional Chinese Medicine (TCM) to reach a consensus on the modernization of TCM and the safety re-evaluation of TCM injections, and submitted report to NMPA.

August 20

The First Meeting of 3rd PhIRDA Pharmaceutical Innovation Investment Specialty Committee was held in Pingshan, Shenzhen.

August 20

The Second China BioMed Innovation Investors Forum was held in Pingshan, Shenzhen.

August 24

PhIRDA Clinical Research on Cardiovascular Drugs Specialty Committee was established. Huo Yong, Director of Cardiology Department and Heart Center, Peking University First Hospital, was elected as the Chairman of the first session of the Specialty Committee.

August 28

Suzhou Zelgen Biopharmaceuticals Co., Ltd., Kintor Pharmaceutical Co., Ltd., and Warburg Pincus officially joined PhIRDA.

September 2

2020 Annual PhIRDA Contact Representative Meeting was held.

September 26

The second meeting of the 11th Board of Directors was held in Suzhou. Mr. Ren Jinsheng, Chairman of the Board of Simcere Pharmaceutical, was elected as 2020-2021 PhIRDA Annual Chairman.

September 26

Xinxing Cathay International Group Co., Ltd. officially joined PhIRDA.

September 27-29

The 2020 China BioMed Innovation and Investment Conference (2020 CBIIC), hosted by PhIRDA, CAMDI, HKEX and iMeta Health Information Consulting Co., Ltd.(iMeta), was held in Suzhou

September 27

The first Biomedical Innovation Cities Development Forum & Study Release Conference of "China Biomedical Innovation Cities with Most Investment Value", initiated by PhIRDA and RDPAC and conducted by IQVIA, was held in Suzhou.

September 27

PhIRDA International Regulatory Science Specialty Committee was established. Dr. He Ruyi, Former Chief Scientist of Center for Drug Evaluation, CFDA, was elected as the Chairman of the first session of the Specialty Committee.

September 29

The Medicinal Policy Specialty Committee held its new session meeting in Suzhou. Hu Xin, Director of Department of Pharmacy, Beijing Hospital, was elected as the Chairman of the third session of the Specialty Committee.

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和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。

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，个人社会信用记录良好；
（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的，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 日内报登记管理机关核准。

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　本会经登记管理机关办理注销登记手续后即为终止。

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关的监督下，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关核准之日起生效。

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.

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 Assembly15 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 be 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 11th 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.

中国医药创新促进会 2019-2020 年度工作报告暨 2020-2021 年度工作建议

——— 2020 年 9 月 26 日第十一届理事会第二次会议

中国医药创新促进会秘书长 冯岚

各位理事：

受会长委托，我向理事会报告中国医药创新促进会（以下称“我会”）2019-2020 年度主要工作，并对 2020-2021 年度重点工作提出建议，请各位审议。

生物医药产业作为关乎全人类健康福祉的国家战略性支柱产业，是全面带动我国经济社会发展的重要推动力。据世界卫生组织官网统计的最新数据显示，自 2020 年新冠肺炎疫情席卷全球以来，累计确诊病例超 3000 万，并且仍然以每日 30 万例的速度增长，累计死亡近 100 万人。面对新冠肺炎疫情全球爆发，有效药物和疫苗更是人类战胜疫情，全面重启国际社会往来的决胜武器。

近年来，我会始终将推动中国医药创新发展作为自身肩负的使命，为医药产业各创新主体搭建国际交流合作平台探索新思路、开拓新路径、提供新方法，以解决事关我国医药产业生死存亡和可持续发展的全局性、长期性问题。在国家创新驱动发展战略和资本市场多元化改革的双重引领和支持下，我国生物医药产业重大创新成果竞相涌现，并且已经进入与世界先进国家并跑阶段。在此次抗击新冠肺炎疫情过程中，我会及各会员单位围绕完善疫情防控政策体系建设、治疗、疫苗研发、疫情防控以及后疫情时代生物医药产业可持续发展等多个领域开展专项科研攻关，为统筹推进疫情防控和经济社会发展提供了有力支撑、做出了重大贡献。在此，向全体会员单位表示衷心感谢！我会 2019-2020 年度主要工作完成情况如下：

第一部分 2019–2020 年度主要工作回顾

自 2019 年 9 月 20 日换届改选并召开第十一届理事会第一次会议以来，我会紧跟时代步伐，始终围绕“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，充分发挥专业委员会资源优势，不断深入发挥为政府决策建言献策作用，在为会员及行业服务能力和水平、创办品牌特色活动、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，促进支部党建工作与我会工作深度结合

我会党支部在中国工业经济联合会党委的指导下，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，持续有序开展党员教育学习及党的组织生活工作。过去一年中我会党支部持续深度开展“不忘初心、牢记使命”主题教育活动，不断将学习教育、检视问题、整改落实等各项工作学在深处、干在实处；此外，根据党中央的要求，认真学习宣传贯彻领会党的十九届四中全会精神、2020 年全国两会重要讲话精神。党员同志还在抗疫阶段率先作出贡献，发挥应有党员先锋模范作用。党支部通过组织不同角度的学习及活动，进一步提高党员党性，不断促进支部党建工作与我会业务工作深度结合，从行业协会视角推动我党事业全面发展。过去一年我会党支部发展了一名预备党员，吸纳两名党员新同志，党员队伍在不断壮大。

二、深入研究行业热点和痛点问题，持续调动并整合专家及会员单位力量，为政府有关部门献计献策，促进中国医药创新产业蓬勃发展

（一）继续推动深化药品监管体制改革，对《药品管理法》等配套法规及指导原则提出修订意见

我会围绕《药品注册管理办法（修订稿）》和《药品生产监督管理办法（征求意见稿）》修订工作，组织会员单位认真分析现行药品注册监管与药品许可持有企业实际状况存在的差异，坚持强化药品研制、注册和上市后监管为主，建议持续优化药品注册审评审批制度和药品生产许可制度，并向国家有关部门提出建设性建议。

2020 年为全面落实法律要求并细化药品监管改革要求，我会积极参与药品审评审批制度改革相关征求意见的研究，组织会员企业和相关力量对药品注册分类、现场核查、关联审评、加速审批、上市后变更等相关配套文件，以及疫情期间药物临床试验管理的指导原则等重要文件提出修订意见。

（二）聚焦完善我国医保用药管理、积极推动国产创新药实时准入医保目录，组织研讨并建言献策

1、基本医疗保险用药管理暂行办法

4 月 29 日，国家医保局发布了《基本医疗保险用药管理暂行办法（征求意见稿）》（以下称“管理办法”）并公开征求意见。我会在深入开展调研后，建议明确以“鼓励自主创新药物的可及与可获得”为原则，并提出了续约期内各级医疗机构不再进行二次议价，以确保国家谈判的权威性等具体建议。我会提出的大部分建议均在《管理办法》中被采纳。

2、对 2020 年国家医保药品目录调整工作方案提出建议

8 月初，国家医保局发布了《2020 年国家医保药品目录调整工作方案（征求意见稿）》（以下称“工作方案”），其中对拟新增药品范围的时间限制为 2019 年 12 月 31 日。为了使国家医保药品目录动态调整能够进一步鼓励中国本土医药创新，我会特别邀请专业媒体和十余家创新药企负责人同时发声并正式向国家医保局提出合理可行建议：医保准入谈判的最终目标是满足人民健康和临床需求以及患者用药可及性，不应当简单地以药品获批时间节点作为限制；同时，建议以顶层设计为依托，加强医保药品目录动态调整的制度建设，如增加企业沟通交流渠道和申诉机制，调出目录药品名单设置公示期，适当给予企业补充材料的机会等。工作方案正式发布后上述建议均被采纳。国家医保局将 2020 年新药准入时间放宽至 8 月 17 日的这一做法是国产创新药最终实现“随批、随谈、随进”快速纳入医保目录的巨大进步。

（三）针对疫情期间影响医药产业创新发展的关键问题进行调研，向政府有关部门提出符合我国国情的政策建议

疫情期间我会就影响医药产业创新发展的若干关键问题向医药企业、科研机构、医疗机构、投资和金融机构及其他相关单位发出调查问卷百余封，在充分借鉴国际先进经验并结合我国国情及医药产业现状的基础上，召开会长会议线上会议充分研究讨论，形成了《关于建立突发卫生公共事件药品紧急授权使用的建议》和《关于减轻疫情影响推动医药产业健康发展的建议》并分别上报中央深改委和国家卫健委、国家药监局、国家医保局等政府有关部门。此外，我会还结合此次疫情，对关于加强应对突发公共卫生事件的医药产业政策进行了系统的梳理和研究，为未来提出对《突发事件防治法》和《中华人民共和国传染病防治法》等相关条例修订建议奠定了基础。

（四）高度关注专利期限补偿和专利纠纷早期解决机制的落实情况，积极参与《专利法修正案（草案二次审议稿）》的修改，深入开展相关课题研究

1、对《专利法修正案（草案二次审议稿）》提出修改建议

为强化知识产权保护，推动我国医药创新发展，我会结合药品审批和药品专利纠纷司法审判实践，并综合药品专利领域专家和会员代表意见，重点对药品审评和专利纠纷解决的适用法律及防止滥用诉权，等待期败诉赔偿机制等规章提出修改意见。

2、受国家药监局委托，深入开展生物制品专利纠纷早期解决机制研究

我会多次受国家药品监督管理局政策法规司和药品注册管理司委托，对中国建立生物药专利链接制度展开深入调研并召开座谈会。我会在借鉴国际经验的基础上，结合中国国情、产业实际现状和未来发展趋势，围绕明确生物制品专利链接制度的内涵和实施主体、生物制品原研药专利信息登记和公示制度、生物制品专利纠纷早期解决程序等重点内容，向国家药监局提出了建立符合中国特色生物制品专利链接制度的建议。

近期，国家药监局和国家知识产权局发布的《药品专利纠纷早期解决机制实施办法（试行）（征求意见稿）》，大部分内容参考了我会提出的建议。

（五）高度关注中药产业发展，专门成立中药注射剂再评价第三方评估平台，积极推动中药再评价工作

为推动中药产业创新发展，我会与中国科学院上海药物研究所、中国医学科学院药物研究所联合北京天坛医院、北京大学第一医院等临床试验机构共同建立中药注射剂再评价第三方评估平台，拟定了中药注射剂再评价设计实施方案，对中药注射剂的有效性和安全性进行系统性的评价。8 月 16 日下午，我会组织召开“中药再评价专家研讨会”，邀请业内知名药学专家、中医专家、西医临床专家和政策专家共同探讨传统中药走上现代化和中药注射剂再评价相关技术问题，会议形成相关共识已报送国家药品监督管理局。

（六）聚焦当前生物药和生物类似药研发和产业化面临的重点和难点问题，组建生物药工作组，促进产业良性发展

为搭建行业发展的沟通交流平台，我会组建了生物药工作组，由科研院所和生物药研发等 23 家会员单位构成，共同探讨和研究当前生物药和生物类似药产业化和市场准入过程中面临的重点和难点问题，促进生物制药相关企业的交流合作和共同进步。

（七）长期从事医药卫生领域法律、政策研究，协助政府有关部门推动药品审评审批制度和国家医疗保障制度改革，宋瑞霖会长受聘成为全国政协参政议政人才库特聘专家，并就进一步完善我国医药创新政策环境提出建议

2020 年 6 月 28 日，宋瑞霖会长受聘为全国政协参政议政人才库特聘专家，并借此契机将《关于优化创新环境，吸引更多海外人才回国发展的几点建议》上报全国政协主席汪洋同志。建议稿得到汪洋同志的高度认可，并以政协摘报的形式上报党中央国务院。此建议稿为后期医保政策的调整奠定了良好基础。

三、发起“中国最具投资价值生物医药创新城市”评选活动，引领产业创新发展和城市转型升级、提质增效，助力医药创新生态环境的改善

我会携手中国外商投资企业协会药品研制和开发行业委员会（RDPAC）作为“中国最具投资价值生物医药创新城市评价”项目联合发起人，艾昆纬（IQVIA）作为项目研究服务合作方，通过对国内外生物医药产业发展领先城市和近 25 个权威性城市评价体系进行研究，总结出以城市为核心，致力生物医药产业创新发展的 6 大必备要素的“回形针式”体系，涵盖 80 个创新能力评价指标，最终选定 28 个省市的 72 个城市进行综合评选。评选结果将在 9 月 27 日下午举办的医药创新城市发展论坛上全球发布。除总体排名前十的城市外，还将对医药行业细分领域表现突出的城市授予相应的奖项。

四、不断丰富和完善专业委员会建设，汇聚不同专业领域专家力量，为推动中国医药产业创新和可持续发展贡献新的力量

根据我会第十一届理事会第一次会议审议通过的相关决议和《中国医药创新促进会专业委员会管理办法》的相关规定，2019 年我会各专业委员会开始统筹规划换届选举（成立）相关工作，并启动了各专业委员会领导班子和委员的遴选工作。医药创新投资专业委员会已于 8 月 20 日在深圳成功换届，心血管药物临床研究专业委员会已于 8 月 24 日在河北任丘召开了成立大会，国际创新药物监管专业委员会和医药政策专业委员会将分别于 9 月 27 和 9 月 29 日在苏州召开成立大会和换届会议。由于受新冠肺炎疫情影响，药物研发、创新研发服务、药物临床试验、脑神经药物临床研究、抗肿瘤药物临床研究和医药企业合规专业委员会也将在今年内陆续完成换届（成立）相关工作。未来，我会将依托专业委员会专家资源优势，继续深耕药品监管、医药投资和药物研发等领域，继续为我国各医药创新主体提供全方位价值服务和我国医药产业领跑全球做出新的更大贡献。

五、继往开来，举办丰富多彩、形式多样的线上线下会议，为医药产业各创新主体提供更多价值服务

（一）第四届中国医药创新与投资大会（以下称“投资大会”）

第四届投资大会于 2019 年 9 月 21-23 日在苏州工业园区成功举办。第四届投资大会在往届基础上新设科创板、罕见病等主题论坛，特邀国家药品监管局有关负责人权威解读新修订的《药品管理法》；全球顶级药物研发科学家和全球金融市场四大证券交易平台——港交所、纳斯达克交易所、伦交所和上交所掌舵人首次共聚中国，热议全球医药创新及创新融资平台对医药创新领域的融资支持政策和未来发展趋势。

今年第五届投资大会将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发展助力生物医药产业创新发展的新篇章，并新设创业板、医药创新城市发展、创新药准入政策分享等分论坛，同期举办国际云路演专场继续为投资大会赋能，为国内外参会者提供更多价值服务。

（二）第二届中国生物医药创新投资人论坛（以下称“投资人论坛”）

第二届投资人论坛已于 2020 年 8 月 20 日在深圳坪山顺利召开。第二届投资人论坛深度聚焦深交所创业板注册制改革，邀请深圳证券交易所上市推广部华南区郑文才副主任及各市场参与方围绕创业板改革过程中可能遇到的问题、当前国际形势下生物医药产业与资本界如何跨界合作，共同推动我国生物医药产业创新和可持续发展等热点话题进行深入交流，为创业板改革助力生物医药产业创新发展贡献了力量。

（三）第十一届中国医院药学政策论坛（以下称“药学论坛”）

为更好地探讨医院药学及卫生政策，提升临床药师综合能力和管理水平，探索医院药学服务新模式，我会和中国药师协会共同主办的第十一届中国医院药学政策论坛已于 2020 年 7 月 17 日在线上召开。多位权威专家、知名学者以云端分享及对话的方式，多角度多层面地围绕如何积极引导药学服务模式转变，深入探讨医院药学服务模式新模式，推进国家医药卫生体制改革政策贯彻落实，帮助药师寻找自身职能定位、提升价值地位，从而推动医院药师药学服务水平与人才能力建设，协助推动医药产业创新发展。

（四）举办《药品管理法》等相关法律法规线上培训

为配合新修订《药品管理法》、《药品注册管理办法》、《中华人民共和国人类遗传资源管理条例》等法律法规的贯彻实施，我会先后邀请国家药品监督管理局注册司综合处李江宁处长、药品审评中心药理毒理学部王庆利部长、药品审评中心化药药学二部许真玉副部长、药品审评中心化药临床二部谢松梅副部长，以及中国人类遗传资源管理办公室相关同志和军科院军事医学研究院张永祥研究员，分别围绕药品注册管理办法及配套文件、指导原则以及人类遗传资源管理政策等五个主题进行线上政策宣讲和培训，为社会各界提供了权威政策解读和与药品监管部门沟通交流的机会。累计宣讲活动观看量超万人次。

（五）持续关注香港资本市场改革，共同举办系列活动

我会与香港交易所围绕疫情下医疗大数据分析与应用、后疫情时代中国医药研发、香港资本市场多元化助力生物科技上市公司发展等主题共同举办的“生物科技生态圈对话香港资本市场系列”线上活动通过人民日报健康时报等多个平台进行全网直播，累计观看量超 20 万人次。

六、通过创办品牌评选活动，在权威期刊发文、接受权威媒体访谈等方式，向世界宣传我国医药创新成果

（一）成功举办第四届医药创新品牌评选活动

2019 年，我会与苏州工业园区联合举办的“独墅湖杯”医药创新品牌评选受到行业内高度认可和广泛关注。经过业内专家推荐并通过评审专家委员会的严格评定，评选出以罗沙司他为代表的多个真正具有创新价值的临床急需品种；以顶级华人科学家刘勇军博士为代表的一批在研发、临床等领域具有非凡建树的创新人物，颁奖典礼在苏州广播电视总台演播大厅隆重举办，全网直播，活跃于医药行业的知名专家、学者、企业家等 400 余位嘉宾见证了各奖项揭晓盛况。

（二）通过多种方式在国际期刊和杂志宣传中国医药改革发展，增进国际社会对中国医药产业发展的认识

我会宋瑞霖会长受邀作为 PharmaBoardroom 全球领袖平台专家，针对中国药品监管改革成果和对全球医药创新的贡献发表文章。此外，宋瑞霖会长还多次接受包括香港南华早报等国内外权威媒体的采访，介绍中国医药创新发展及药品监管改革，分析中国生物医药产业未来发展趋势，鼓励国内外加强医药产业创新交流与合作。

七、深入开展国际医药交流，推动全球医药产业相互交流与合作

（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 18 个 ICH 工作组推荐 36 名专家（包括 13 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 57 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

我会领导受邀参加 J.P. 摩根健康产业大会、亚洲制药组织合作会议（APAC）、中英药物警戒圆桌会议、第六届中国医疗峰会、APEC 生物医药产业协会新冠时期伦理合规研讨会、澳大利亚国际生物科技周（Global Biotech VIP Week）、中日医药健康交流会等创新、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。

八、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、编辑医药行业最新动态消息，精选当天重磅国内医药政策、国际药物研发成果、全球医药行业热点新闻，编辑《医药信息简报》，通过邮件的形式定向发送至会员单位以及业内专家、政府部门、合作机构处。2019 年共发送《医药信息简报》233 篇，受众累计达 37 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活动、医药行业最新热点新闻，包含政策解读、创新型医药企业最新动态、药物研发以及医药投融资并购趋势，并且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，聚焦行业痛点、难点、热点问题，筛选并推送深度分析文章，受到业界广泛关注。截至 2020 年 9 月，我会订阅号关注人数 15136 人；投资大会服务号关注人数 7562 人。

九、推动罕见病战略体系建设

2019 年 10 月，由中国罕见病联盟主办，我会承办的中国罕见病大会在北京顺利举行。国家卫生健康委员会副主任王贺胜，十三届全国人大教科文卫委员会副主任委员、中国医院协会会长刘谦，国家医疗保障局副局长李滔，国家药品监督管理局副局长徐景和等领导受邀出席。大会旨在积极联通政府部门、医疗机构、医药企业和患者组织，为推动罕见病防治事业发展、特别是推动我国罕见病临床、科研与孤儿药开发的协同创新上提供新动能、注入新动力。《关于提高我国罕见病防治和保障水平的几点建议》已上报党中央。

十、发起成立由中国科学院和中国工程院院士领衔的中国医药创新促进会医药创新科学委员会，为共建共享创新和可持续发展的产业生态建言献策

为推动我国医药创新高质量发展，进一步完善和优化我国医药创新环境，我会发起成立了由中国科学院院士和中国工程院院士领衔的覆盖生命科学、医学、医药卫生、药物研发等领域的 17 位资深专家的“中国医药创新促进会医药创新科学委员会”，以构建国家高端智库，共建共享创新和可持续发展的产业生态建言献策。

十一、全面贯彻落实党的十九大精神，踊跃投身脱贫攻坚事业，为全面建成小康社会贡献应有力量

参与脱贫攻坚，既是我会的重要责任，又是我会服务国家、服务社会、服务群众、服务行业的重要体现。我会结合自身情况，重点关注产业扶贫，参与河南省郑州市中牟县助农项目，从帮助贫困人口解决最直接、最现实、最紧迫的问题入手，为坚决打赢脱贫攻坚战，全面建成小康社会贡献应有力量。

第二部分 2020–2021 年度重点工作建议

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

随着党员队伍不断壮大，我会党支部需要将“不忘初心、牢记使命”主题教育工作常态化，举办更加丰富多元的党员集中学习教育活动，进一步武装党员思想理论头脑，切实抓好教育学习成果转化；需要以习近平新时代中国特色社会主义思想为指引，在当今日益复杂的国际环境中，以更加清晰的头脑和明确的方向，深刻认识我国在医药创新领域已经取得的成绩和面临的严峻问题，并在工作中找到解决问题的方法和建议调整的政策，不断投身于中国医药创新事业发展中，为党和国家做出更加卓越的贡献。

二、继续发挥行业智库作用，推荐、组织专家参与 ICH 相关工作组及指南修订工作

我会将继续按照 IFPMA 秘书处和国家药监局 ICH 办公室要求，推荐行业内权威专家参与 ICH 指导原则的制修订工作，加强国际合作，积极参与国际标准和规则制定，配合国家药监局相关部门做好 ICH 相关指导原则在中国转化实施的培训工作；为中国医药产业争取更多在国际中发声机会，不断推动中国制药行业标准与国际接轨，并加速推进 ICH 指导原则在国内的落地转化实施工作。

三、积极拓展与国内外相关机构合作，推动国内医药产业创新能力，打造有国际影响力的医药创新品牌活动

（一）设立“盖伦中国奖”，助力中国品牌在全球的传扬和发展，为增强我国医药创新国际竞争力贡献力量

盖伦奖于 1970 年在法国创立，被业内公认为是制药和生物医疗行业的最高荣誉，旨在褒奖在医疗科学领域所

取得卓越贡献的研究与创新成果，被誉为“医药界的诺贝尔奖”，已先后有十六个国家设立盖伦奖。为进一步加强“独墅湖杯”医药创新品牌评选的国际影响力，推动国内知名医药品牌跻身国际舞台，我会与盖伦基金会达成优化品牌评选的合作意向，届时“盖伦奖”将与“独墅湖杯”医药创新品牌评选深度融合，汲取各自奖项之优势，对促进中国医药创新做出突出贡献的个人和组织以及在中国研发上市的创新产品予以表彰，打造具有中国特色兼具强大国际影响力的医药创新品牌评选活动。目前盖伦奖的引入和本土化相关申报工作正在有条不紊的进行，预计 2021 年全新升级的品牌评选活动将以王者姿态重回医药人的视野。

（二）继续拓展与各国驻华使领馆、行业协会的合作交流活动

继续拓展与各国驻华使领馆、政府机构和行业协会之间的产业交流合作，在科研、临床、产业、政策多方面开展交流与合作，适时组织项目对接、出访考察等国际交流活动，为会员企业寻求海外合作机会，进一步提高中国医药企业的国际竞争力，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，共同推动新药研发趋势、医药卫生领域合作，推动国际药品监管体系改革，搭建国际医药创新领域交流的平台。

（三）积极开展医药产品走向“一带一路”沿线国家市场策略研究，推动中国及“一带一路”沿线国家医药产业界交流，构建医药经贸合作新格局

为推动中国及“一带一路”沿线国家医药产业界深入交流，满足沿线国家药物使用需求，促进医药产业进出口贸易，我会拟开展《医药产品走向“一带一路”沿线国家市场策略研究》，将以中、美、欧等发达国家及地区获批上市的创新药进入“一带一路”沿线国家需进行的临床试验、上市审批、生产及市场准入相关政策作为重点进行研究，深化中国和“一带一路”沿线国家间医药经济合作与往来，有助于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。

四、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

（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，继续推进药品知识产权保护相关政策的落地，向国家有关部门提出建设性建议，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，以及促进医保支付品种落地使用。

（四）开展探索多层次保障机制研究，鼓励“医保”+“商保”的支付模式，为创新药支付开拓创新思路，实现社保和商保优势互补，引导保险业深度融合多层次医疗保障体系建设。

（五）以建言“十四五”、推动医药创新为主题，主动开展企业和产业调研，为推动医药产业结构调整和我国医药创新科技成果转化提供决策思考。

创新的号角已经吹响！我会邀请您一道，为我国医药产业各创新主体提供新的便利，让医药产业全链条携手赋能医药创新，为让更多创新成果能够早日惠及全球百姓做出新的更大贡献！

2019-2020 Annual Work Report & 2020-2021 Work Proposal for China Pharmaceutical Innovation and Research Development Association

—— The Second Meeting of 11th Board of Directors, September 26, 2020

Feng Lan, Secretary-General of PhIRDA

Dear All Directors:

Entrusted by the Chairman, I hereby report to the Board of Directors on 2019-2020 main work and 2020-2021 work proposal of China Pharmaceutical Innovation and Research Development Association (hereinafter referred to as "PhIRDA").

As a national strategic pillar industry related to the health and well-being of all mankind, the biopharmaceutical industry is an important driving force for China's economic and social development in an all-round way. According to the latest statistics on the official website of the World Health Organization, since the outbreak of COVID-19, the total number of confirmed cases has exceeded 30 million, which is still growing at a rate of 300,000 cases per day, and the death toll has been close to 1 million people. The key to win the fight against COVID-19 and fully restart international exchanges is effective drugs and vaccines.

Shouldering the mission of promoting innovative development of China's pharmaceutical industry, PhIRDA has built an international exchange and cooperation platform for various innovation entities in the pharmaceutical industry, explored new ideas, developed new paths, and provided new methods for them, and tried to solve the overall and long-term problems regarding to the survival and sustainable development of China's pharmaceutical industry. The national innovation-driven development strategy and the capital market diversification reform hastened the emergency of a large number of major innovation achievements and spurred China's biopharmaceutical industry to keep pace with the world's advanced countries. While fighting against COVID-19, PhIRDA and members have kept special scientific research on fields such as pandemic prevention and control policy system improvement, treatment, vaccine R&D, pandemic prevention and control, and sustainable development of the biopharmaceutical industry in the post-COVID-19 era, providing a strong support and making a great contribution to overall pandemic prevention and control and economic and social development. I hereby would like to express my heartfelt thanks to all PhIRDA members! The main work completed by PhIRDA in 2019-2020 is reported as follows:

Part I. Review of Major Work in 2019-2020

Since the term change and the first meeting of the 11th Board of Directors on September 20, 2019, PhIRDA has kept up with the pace of the times 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 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 improving the capability and level of serving members and the industry, 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, promote the deep integration of the Party building work of the Party branch with the work of PhIRDA

Under the guidance of the Party committee of China Federation of Industrial Economics 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. In the past year, the Party branch continued to carry out the education themed with "remaining true to the original aspiration and keeping mission firmly in mind" in depth and put various work such as learning and teaching, examining, and rectification implementation on a deep and firm footing. Moreover, according to the requirements of the CPC Central Committee, the Party branch conscientiously studied, publicized and implemented

the spirit of the Fourth Plenary Session of the 19th CPC Central Committee and the spirit of the important speeches delivered at the National People's Congress and the Chinese Political Consultative Conference (NPC & CPPCC) in 2020. Party members also took the lead in making contributions in the anti-pandemic stage and played their due vanguard and exemplary role. By organizing learning and activities from different perspectives, the Party branch further improved the Party spirit of Party members, continuously promoted the in-depth integration of the Party building work of the branch with the business work of PhIRDA, and boosted the overall development of the Party's cause. In the past year, the Party branch developed a probationary Party member and admitted two new Party members so that the Party member team was constantly expanding.

II. Deeply study industry hotspots and pain points, continue to mobilize and integrate the strength of experts and PhIRDA members, offer advice and suggestions for relevant government departments, and promote the vigorous development of China's pharmaceutical innovation industry

(I) Continue to promote the reform of the drug regulatory system to go in depth, and propose amendments to the *Drug Administration Law* and other supporting regulations and guiding principles

Focusing on the *Provisions for Drug Registration (Revised Draft)* and the *Provisions for the Supervision and Administration of Drug Production (Draft for Comment)*, PhIRDA organized members to carefully analyze whether the current drug registration supervision fails to comply with the actual status of marketing authorization holders, adhered to strengthening drug development, registration and post-marketing supervision, advised to continue to optimize the drug registration review and approval system and the drug production licensing system, and proposed constructive suggestions to the relevant government departments.

In 2020, in order to fully implement legal requirements and refine drug regulatory reform requirements, PhIRDA actively participated in the research on soliciting opinions for the reform of the drug review and approval system and organized PhIRDA members and related forces to propose amendments for the relevant supporting documents on classification of drug registration, on-site verification, associated review, accelerated approval, and post-marketing changes as well as important documents such as the guiding principles for drug clinical trial management during the pandemic period.

(II) Focus on improving the management of drugs included in the National Reimbursement Drug List (NRDL), actively promote the real-time access of domestically-made innovative drugs into the NRDL, and organize discussions and offer advice and suggestions

1. Interim Measures for the Administration of Essential Drugs of Medicare

On April 29, the *National Healthcare Security Administration (NHSA)* issued the Interim Measures for the Administration of Essential Drugs of Medicare (Draft for Comment) (hereinafter referred to as "Administration Measures") and solicited public opinions. After conducting in-depth investigations, PhIRDA suggested that the principle of "encouraging the accessibility and availability of independent innovative drugs" should be clearly stated and that medical institutions at all levels would no longer conduct secondary bargaining during the renewal period to ensure the authority of national negotiations. Most of the suggestions put forward by PhIRDA were adopted in the *Administration Measures*.

2. Advance a work adjustment proposal for the NRDL

In early August, the NHSA issued the *Work Adjustment Scheme of the National Reimbursement Drug List (Draft for Comment)* (hereinafter referred to as "Work Scheme"), in which the time limit for new drugs to be added into the NRDL was adjusted to December 31, 2019. In order to enable the dynamic adjustment of the NRDL to further encourage domestic pharmaceutical innovation, PhIRDA especially invited professional media and heads of more than 10 innovative pharmaceutical enterprises to jointly put forward a reasonable and feasible suggestion that the time node of drug approval should not be simply used as the limit to prevent a drug from being included into the NRDL as the ultimate objective of medical insurance access negotiations is to meet the health and clinical needs of the people and make drugs easy to be obtained. They also advised the NHSA to strengthen construction of the system for dynamic adjustment of the NRDL relying on top-level design, such as increasing enterprise communication channels and appeal mechanisms, calling out a list of drugs in the NRDL and setting a publicity period, and giving enterprises an opportunity to supply materials appropriately. All the above suggestions were adopted in the Work Scheme that was officially released. The NHSA extended the time limit for new drugs to be added into the NRDL in 2020 to August 17, which was regarded as a huge progress on the way to realize the rapid inclusion of domestically-made innovative drugs into the NRDL once they are approved and negotiated.

(III) Survey key issues affecting the innovative development

of the pharmaceutical industry during the pandemic and put forward policy recommendations in line with China's national conditions to relevant government departments

During the pandemic, PhIRDA sent more than 100 questionnaires to pharmaceutical enterprises, scientific research institutions, medical institutions, investment and financial institutions, and other related units on several key issues affecting the innovative development of the pharmaceutical industry. On the basis of making full use of international advanced experiences and combining with China's national conditions and the pharmaceutical industry's current status, PhIRDA held an online Chairman Meeting, at which the *Suggestions on Establishing an Emergency Authorization System for the Use of Drugs in Public Health Emergencies* and *Suggestions on Mitigating the Impact of the COVID-19 Pandemic and Promoting the Healthy Development of the Pharmaceutical Industry* were formed through full studies and discussions and reported to relevant departments such as the Central Committee for Deepening Overall Reform (CCDOR), the National Health Commission (NHC), the National Medical Products Administration (NMPA) and the NHSA respectively. Moreover, in conjunction with the pandemic, PhIRDA systematically sorted out and studied the pharmaceutical industry policies on strengthening response to public health emergencies, laying a solid foundation for revising the *Law of the People's Republic of China on Emergency Prevention and Control*, the *Law of the People's Republic of China on the Prevention and Treatment of Communicable Diseases* and other relevant ordinances.

(IV) Pay close attention to the implementation of drug patent restoration and early settlement mechanisms for patent disputes, actively participate in the revision of the Amendment to the *Patent Law of the People's Republic of China (Draft for Second Deliberation)*, and conduct in-depth studies on related topics

1. Make a suggestion for revision of the Amendment to the *Patent Law of the People's Republic of China (Draft for Second Deliberation)*

In order to strengthen the protection of intellectual property rights and promote the innovative development of China's pharmaceutical industry, PhIRDA, in combination with the practice of drug approval and judicial trial of drug patent disputes and in consideration of the opinions of experts and member representatives in the field of drug patents, proposed amendments to laws and regulations such as the applicable laws for drug review and patent dispute resolution, prevention of abuse of process, and the waiting period compensation mechanism for loss of litigation.

2. Entrusted by the NMPA, conduct in-depth studies on the early settlement mechanism of patent disputes for biological products

Entrusted by the Department of Policies and Regulations and Department of Drug Registration of NMPA, PhIRDA conducted in-depth investigations and held symposiums on establishing a domestic patent linkage system for biological drugs. On the basis of drawing on international experiences and combining with China's national conditions, actual industrial status and future development trends, PhIRDA, around clarifying the connotation and implementation subjects of the patent linkage system 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, advised the NMPA to establish a patent linkage system for biological products with Chinese characteristics.

The suggestions put forward by PhIRDA were adopted in the *Implementation Provisions for the Early Settlement Mechanism for Drug Patent Disputes (Trial) (Draft for Comment)* issued by the NMPA and China National Intellectual Property Administration (CNIPA) recently.

(V) Pay close attention to the development of the traditional Chinese medicine (TCM) industry, set up a third-part TCM injections safety re-evaluation platform, and actively promote the re-evaluation of TCM

In order to promote the innovative development of the TCM industry, PhIRDA worked together with Shanghai Institute of Materia Medica, Chinese Academy of Sciences, Institute of Materia Medica, Chinese Academy of Medical Sciences, and clinical trial institutions such as Beijing Tiantan Hospital and Peking University First Hospital, etc. to establish a third-part TCM injections safety re-evaluation platform and worked out an implementation plan for the re-evaluation design of TCM injections to systematically evaluate the efficacy and safety of TCM injections. On the afternoon of August 16, PhIRDA organized an "Expert Seminar on Safety Re-evaluation of TCM", where well-known pharmacy experts, Chinese medicine experts, Western medicine clinical experts and policy experts in the industry were invited to discuss technical issues related to the modernization of TCM and the safety re-evaluation of TCM injections, and submitted the consensuses reached at the seminar to the NMPA.

(VI) Focus on the key and difficult issues currently encountered in the R&D and industrialization of biological drugs and biosimilars, establish a Biological Medicine

Working Group, promote the benign development of the industry

In order to build a communication platform for the development of the industry, PhIRDA established a Biological Medicine Working Group, which is composed of 23 PhIRDA members including scientific research institutes and biological drug R&D institutions. They are intended to jointly discuss and study the key and difficult issues currently encountered in the industrialization and market access of biological drugs and biosimilars and promote the exchange, cooperation and common progress of biopharmaceutical-related enterprises.

(VII) Maintain long-term studies on laws and policies in the field of medicine and health and assist relevant government departments to promote the reform of the drug review and approval system and the national healthcare security system. Chairman Song Ruilin was offered appointment as an Expert of the Talent Pool for State Affairs of Chinese People's Political Consultative Conference (CPPCC) for participating in the administration and discussion of state affairs and made a suggestion on further improving China's policy environment for pharmaceutical innovation.

On June 28, 2020, Chairman Song Ruilin was offered appointment as an Expert of the Talent Pool for State Affairs of Chinese People's Political Consultative Conference (CPPCC) for participating in the administration and discussion of state affairs and took this opportunity to submit the *Suggestions on Improving Innovation Environment and Attracting Overseas Talents Back to China* to Comrade Wang Yang, Chairman of the CPPCC. The proposed draft was highly recognized by Comrade Wang Yang and submitted to the CPC Central Committee and the State Council in the form of a CPPCC summary. This draft laid a good foundation for the later adjustment of the healthcare security policy.

III. Initiate the activity of selecting "China Biomedical Innovation Cities with Most Investment Value" to lead industrial innovation and development, urban transformation and upgrading, improve quality and efficiency, and help improve the ecological environment for pharmaceutical innovation

Co-hosted by PhIRDA and R&D-based Pharmaceutical Association Committee (RDPAC), conducted by IQVIA, "China Biomedical Innovation Cities with Most Investment Value" built a biopharmaceutical industry development evaluation systems of leading cities and studied nearly 25 authoritative cities at home and abroad, worked out a "paperclip" system cored on cities, with 6 essential elements for the innovative development of biopharmaceutical industry and covering 80 innovation ability evaluation indicators and finally selected 72 cities in 28 provinces and municipalities for comprehensive selection. The selection results will be released globally at the Biomedical Innovation Cities Development Forum on the afternoon of September 27. In addition to the top ten cities in the comprehensive ranking, cities with outstanding performance in subcategories of the pharmaceutical industry will also be awarded corresponding awards.

IV. Continuously enrich and improve PhIRDA Specialty Committees, gather together experts in different professional fields, and contribute new forces to the promotion of innovative and sustainable development of China's pharmaceutical industry

In accordance with the relevant resolutions deliberated and approved at the first meeting of the 11th Board of Directors of PhIRDA and the *Administrative Measures on the Specialty Committees of PhIRDA*, in 2019, PhIRDA began to plan the work related to the term change (establishment) of PhIRDA Specialty Committees, as a whole and started the selection of leadership ranks and members for the Specialty Committees. The Pharmaceutical Innovation Investment Specialty Committee was successfully re-elected in Shenzhen on August 20. The Cardiovascular Drugs Specialty Committee was held an inaugurating meeting in Renqiu, Hebei on August 24. The International Regulatory Science Specialty Committee and the Medicinal Policy Specialty Committee will be held an inaugurating meeting and a term change meeting in Suzhou on September 27 and 29 respectively. Although affected by COVID-19, Drug R&D Specialty Committee, Innovation R&D Services Specialty Committee, Clinical Trial Research Specialty Committee, Clinical Research on Cranial Nerve Drugs Specialty Committee, Clinical Research on Oncology Drugs Specialty Committee and Ethics and Business Compliance Specialty Committee will also be completed term change (establishment) in succession within this year. In the future, PhIRDA will, relying on the advantageous expert resources of specialty committees, continue to deepen the fields of drug administration, pharmaceutical investment and drug R&D, provide all-round value services for domestic pharmaceutical innovation subjects, and make greater contributions to helping the domestic pharmaceutical industry lead the world.

V. Carry forward the past and forge ahead into the future, and hold colorful and diverse online and

offline conferences to provide more value services for various innovative entities in the pharmaceutical industry

(I) 2019 China BioMed Innovation and Investment Conference (hereinafter referred to as "CBIIC")

2019 China BioMed Innovation and Investment Conference was successfully held in Suzhou Industrial Park (SIP) on September 21-23, 2019. On the basis of previous sessions, 2019 CBIIC set up theme forums such as SSE STAR Market Forum and Rare Diseases and Orphan Drugs Roadshow, and specially invited relevant people in charge of the NMPA to give an authoritative interpretation of the newly revised *Drug Administration Law*. The world's top drug R&D scientists and leaders of the four major securities trading platforms in the global financial market - Hong Kong Exchanges and Clearing Limited (HKEX), National Association of Securities Dealers Automated Quotation (NASDAQ), London Stock Exchange (LSE), and Shanghai Stock Exchange (SSE) gathered for the first time in China to discuss global pharmaceutical innovation as well as financing support policies and future development trends of innovative financing platforms for pharmaceutical innovation.

2020 CBIIC to be held this year will bring together China's three major stock exchanges- HKEX, SSE and Shenzhen Stock Exchange (SZSE), which will jointly discuss 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, the Virtual International Roadshows to be held will also continue to enable the Investment Conference and provide more value services for domestic and foreign participants.

(II) The Second China BioMed Innovation Investors Forum (hereinafter referred to as "Investor Forum")

The Second China BioMed Innovation Investors Forum was successfully held in Pingshan, Shenzhen on August 20, 2020. The Investor Forum focused on the reform of the system of registering on SZSE ChiNext, where Zheng Wencai, Deputy Director of the South China District of Marketing Department of SZSE, and various market participants were invited to conduct in-depth exchanges on hot topics, such as the problems that may be encountered during the ChiNext reform process, how to achieve cross-border cooperation between the biopharmaceutical industry and the capital community under the current international situation, and joint promotion of the innovative and sustainable development of the biopharmaceutical industry in China, helping the ChiNext reform promote the innovative development of the biopharmaceutical industry.

(III) The 11th China Hospital Pharmacy Policy Forum (hereinafter referred to as "Forum")

In order to better discuss hospital pharmacy and health policies, improve the comprehensive ability and management of clinical pharmacists, and explore new models of hospital pharmacy services, the 11th China Hospital Pharmacy Policy Forum, co-hosted by PhIRDA and Chinese Pharmacists Association (CPA), was held on July 17, 2020. In the form of cloud sharing and dialogue, a number of authoritative experts and well-known scholars, around how to actively guide the transformation of pharmacy service models, conducted multi-angle and multi-level discussions on promoting the implementation of policies concerning the national medical and health system reform and helping pharmacists look for their own functional positioning and enhance their value status through new hospital pharmacy service models, so as to promote the hospital pharmacist and pharmacy service and talent capacity building and assist in promoting the innovative development of the pharmaceutical industry.

(IV) Organize online training on the *Drug Administration Law* and other relevant laws and regulations

In order to cope with the implementation of the newly revised *Drug Administration Law*, the *Provisions for Drug Registration*, the *Regulations of the People's Republic of China on the Management of Human Genetic Resources* and other laws and regulations, PhIRDA successively invited Li Jiangning, Director of Division of General Affairs, Department of Drug Registration of NMPA, Wang Qingli, Director of Department of Pharmacology and Toxicology of the Center for Drug Evaluation (CDE), NMPA, Xu Zhenyu, Deputy Director of Department II of Chemical Medicine and Pharmacy of CDE, Xie Songmei, Deputy Director of Clinical Department II of Chemical Drugs of CDE, NMPA, Head of China Human Genetic Resources Administration Office (CHGRAO), and Zhang Yongxiang, Researcher of Academy of Military Medical Sciences, PLA, to give online policy presentations and training on five themes including drug registration administration regulations and supporting documents, guidelines, and human genetic resources management policies, providing all walks of life with an opportunity to learn about authoritative policy interpretations and communicate with the drug regulatory departments. The online policy presentations received more than 10,000 views.

(V) Continue to pay attention to the reform of Hong Kong's capital market and jointly organize a series of activities

The Dialogues with the Biotech Community Webinar Series, jointly organized by PhIRDA and HKEX around topics such as the analysis and application of healthcare big data under the pandemic, China's pharmaceutical R&D in the POST-COVID 19 Era, and Hong Kong's capital market to help the development of listed biotech companies by diversified means, was live broadcasted on multiple platforms such as People.cn and Jksb.com.cn and received more than 200,000 views.

VI. Publicize China's pharmaceutical innovation achievements to the world by hosting Selection Activities, publishing articles in authoritative journals, and accepting interviews from authoritative media

(I) Successfully hold the 2019 "Dushu Lake Prize" Selection Activities of China Pharmaceutical Innovation Brand

2019 "Dushu Lake Prize" Selection Activities of China Pharmaceutical Innovation Brand, jointly organized by PhIRDA and Suzhou Industrial Park (SIP), was highly recognized and widely concerned in the industry. After recommended by industry experts and strictly evaluated by the expert review committee, a number of clinically urgently needed varieties with real innovative value represented by Roxadustat Capsule as well as a group of innovative figures with extraordinary achievements in the fields of R&D and clinical trial represented by top Chinese scientist Dr. Liu Yongjun were selected. The award ceremony was grandly held in the studio of Suzhou Broadcasting System (SBS) and live broadcasted on the Internet, where more than 400 guests, including well-known experts, scholars, and entrepreneurs active in the pharmaceutical industry, witnessed the grand announcement of each award.

(II) Publicize the Chinese pharmaceutical reform and development on international journals and magazines in various ways to enhance the international community's understanding of the development of China's pharmaceutical industry

PhIRDA Chairman Song Ruilin was invited, as an expert of the global leader platform PharmaBoardroom, to publish articles on the achievements of China's drug regulatory reform and its contribution to global pharmaceutical innovation. Moreover, Chairman Song Ruilin, in the interviews from authoritative media at home and abroad, including South China Morning Post, introduced China's pharmaceutical innovation development and drug regulatory reform, analyzed the future development trend of China's biopharmaceutical industry, and encouraged domestic and foreign exchanges and cooperation in the pharmaceutical industry.

VII. 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 36 experts (including 13 Leaders and 7 Alternate Leaders) to 18 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 57 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

The leaders of PhIRDA were invited to participate in Annual J.P. Morgan Healthcare Conference, Asia Partnership Conference of Pharmaceutical Associations (APAC), China-UK Pharmacovigilance Roundtable, China Healthcare Summit 2019, Special Webinar/Teleconference Session for APEC Biopharmaceutical Industry Associations: Reinforcing Business Ethics and Integrity amidst COVID-19, Global Biotech VIP Week, Global Biotech VIP Week, China-Japan Medical and Health Exchange 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 adinistration experience from other countries and regions.

VIII. Continuously improve the pharmaceutical information service capability

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

PhIRDA insisted on collecting, sorting out and editing the latest news of the pharmaceutical industry on a daily basis, edited heavyweight domestic pharmaceutical policies, international drug R&D results, and breaking news of the global pharmaceutical industry into *Daily Pharmaceutical Information Brief*, and sent it to PhIRDA members as well as industry experts, government departments, and cooperative agencies by e-mail. In 2019, a total of 233 pieces of *Daily Pharmaceutical Information Brief* were issued for 370,000 readers.

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

PhIRDA released its activities, latest breaking news of the pharmaceutical industry, policy interpretations, latest developments of innovative pharmaceutical enterprises, drug R&D, and pharmaceutical investment, financing and M&A trends to all walks of life through public publicity channels such as its official WeChat and official website, and official WeChat of China BioMed Innovation and Investment Conference (CBIIC), and widely publicized its opinions and suggestions on medical policy research, focused on industry pain points, difficulties, and hotspots, and screened and pushed in-depth analysis articles through WeChat and official website platforms, which received widespread attention from the industry. As of September 2020, PhIRDA Subscription has been followed by 15,136 people and 7,562 for CBIIC WeChat.

IX. Promote the construction of a strategic system for rare diseases

In October 2019, China Conference on Rare Diseases, hosted by China Alliance for Rare Diseases and organized by PhIRDA, was successfully held in Beijing. Wang Hesheng, Vice-Minister of the NHC, Liu Qian, Vice-Chairman of Education, Science, Culture & Health Committee of the NPC & President of Chinese Hospital Association, Li Tao, Deputy Director of the NHSA, Xu Jinghe, NMPA Deputy Commissioner and other leaders were invited to participate. CBIIC was aimed at keeping government departments, medical institutions, pharmaceutical enterprises and patient organizations in contact to provide new kinetic energy and inject new impetus to the promotion of rare disease prevention and treatment, especially collaborative innovation in clinical trial of rare diseases, scientific research, and development of orphan drugs. The *Several Recommendations on Improving the Level of Rare Disease Prevention, Treatment and Healthcare* was reported to the CPC Central Committee.

X. Initiate the establishment of the Scientific Committee on Pharmaceutical Innovation of PhIRDA led by academicians of the Chinese Academy of Sciences (CAS) and the Chinese Academy of Engineering (CAE), which is intended to offer advice and suggestions for the joint construction, sharing and sustainable development of the industrial ecology

In order to promote the high-quality development of China's pharmaceutical innovation and further improve and optimize China's pharmaceutical innovation environment, PhIRDA initiated the establishment of "Scientific Committee on Pharmaceutical Innovation of PhIRDA" consisting of 17 senior experts in the fields of life sciences, medicine science, medicine and health, and drug R&D under the leadership of academicians of the CAS and the CAE. It is intended to build a national high-end think tank and offer advice and suggestions for the joint construction, sharing and sustainable development of the industrial ecology.

XI. Fully implement the spirit of the 19th National Congress of the Communist Party of China, actively participate in poverty alleviation, and contribute to building a well-off society in an all-round way

Participation in poverty alleviation not only is an important responsibility of PhIRDA, but also reflects PhIRDA is committed to serving the country, serving the society, serving the people, and serving the industry. PhIRDA, combining with its own situation and focusing on industrial targeted poverty alleviation, participated in the agricultural aid project in Zhongmu County, Zhengzhou City, Henan Province. Starting from helping the poor to solve the most direct, realistic and pressing problems, PhIRDA made due contributions to winning the fight against poverty and building a well-off society in an all-round way.

Part II. Proposal for Key Work in 2020-2021

I. Further strengthen construction of the Party organization and create a new situation for Party

building based on the actual work of PhIRDA

With the continuous increase of Party members, the Party branch of PhIRDA needs to normalize the education work on the theme of "remaining true to the original aspiration and keeping mission firmly in mind", organize richer and more diverse intensive learning and education activities for Party members, help Party members arm their mind with thoughts and theories, and earnestly grasp the transformation of education and learning achievements. In today's increasingly complex international environment, the Party branch, under the guidance of Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era, needs to keep a clearer mind and a definitive direction, deeply understand the achievements made and severe problems faced by China in the field of pharmaceutical innovation, find solutions to problems and policies for suggestion adjustment in work, devote itself to the development of China's pharmaceutical innovation business, and make more outstanding contributions to the Party and the country.

II. Continue to play the role as an industry think tank, and recommend and organize experts to participate in ICH-related EWGs and guideline revision

In accordance with the requirements of the Secretariat of the IFPMA and the ICH Office of the NMPA, PhIRDA will continue to recommend authoritative experts in the industry to participate in the formulation and revision of ICH guidelines, strengthen international cooperation, actively participate in the formulation of international standards and rules, and cooperate with relevant departments of the NMPA to complete the implementation and training of ICH-related guidelines in China. Moreover, PhIRDA will strive for international discourse power for the China's pharmaceutical industry, continue to promote China's pharmaceutical industry standards to comply with international standards, and accelerate the implementation of ICH guidelines in China.

III. Actively expand cooperation with relevant institutions at home and abroad, promote the innovation capability of the domestic pharmaceutical industry, and create an internationally influential brand activity for pharmaceutical innovation

(I) Establish "Prix Galien China Awards" to help the spread and development of Chinese brands in the world, and contribute to enhancing the international competitiveness of China's pharmaceutical innovation

The Prix Galien Awards, initiated in France in 1970, is recognized by the industry as the highest honor in the pharmaceutical and biopharmaceutical industry. It aims to commend the studies and innovation achievements with outstanding contributions in the field of medical science. It is hailed as the "Nobel in the field of medicine" and has been extended to 16 countries. In order to further strengthen the international influence of "Dushu Lake Prize" Selection Activities of China Pharmaceutical Innovation Brand, and promote domestic well-known pharmaceutical brands to squeeze into the international stage, PhIRDA reached a cooperation intention with the Galien Foundation on optimizing the brand selection. The Prix Galien Awards and "Dushu Lake Prize"are expected to deeply integrate with each other, complement with each other, 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, and create a brand selection activity for pharmaceutical innovation with Chinese characteristics and a strong international influence. Currently, the work of introducing into and localizing the Prix Galien Awards is being carried out in an orderly manner. It is expected that a newly upgraded brand selection activity will return to the pharmaceutical industry as a king.

(II) Continue to expand cooperation and exchanges with foreign embassies and consulates in China and industry associations

Continue to expand industrial exchanges and cooperation with foreign embassies and consulates in China, government agencies and industry associations, carry out exchanges and cooperation in scientific research, clinical trial, industry, and policies, organize project docking, visits and inspections, and other international exchange activities in a timely manner, seek overseas cooperation opportunities for members, further enhance the international competitiveness of China's pharmaceutical companies, promote China's pharmaceutical industry to deeply integrate into the international community in the fields of trade, investment and technology, jointly promote cooperation in new drug R&D trends as well as medicine and health, promote the reform of the international drug regulatory system and build a platform for exchanges in the field of international pharmaceutical innovation.

(III) Actively study strategies for exporting pharmaceutical products to countries along the Belt and Road Initiative (BRI), promote exchanges on the pharmaceutical industry between China and countries along the BRI, and build a new pattern of pharmaceutical economic and trade cooperation

In order to promote in-depth exchanges on the pharmaceutical industry between China and countries along the BRI , meet the needs for drug use of countries along the BRI, and promote the import and export trade of the pharmaceutical industry, PhIRDA plans to carry out the *Research on Market Strategies for Pharmaceutical Products into Countries along the Belt and Road*, focus on studying the policies concerning clinical trials, marketing approval, production and market access required for exporting marketed innovative drugs from developed countries and regions such as China, the United States, and Europe to countries along the BRI, and deepen pharmaceutical economic cooperation and exchanges between China and countries along the BRI, which will help China's pharmaceutical industry to form a new pattern of wide-field, deep-level, high-level, and all-round foreign trade cooperation.

IV. 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

(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, continue to promote the implementation of policies related to drug intellectual property protection, and put forward constructive suggestions to relevant national departments 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 security 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 NRDL.

(IV) Study the exploration of a multi-level security mechanism, encourage the payment model of "healthcare insurance" + "commercial insurance", develop innovative ideas for innovating in drug payment, complement social insurance with commercial insurance, and guide the insurance industry to deeply integrate with the multi-level healthcare security system construction.

(V) Take the initiative to carry out enterprise and industry research according to the theme of offering advice to the "14th Five-Year Plan" and promoting pharmaceutical innovation, and provide decision-making references for promoting the structural adjustment of the pharmaceutical industry and the transformation of China’s scientific and technological achievements on pharmaceutical innovation.

The innovation has been sounded! PhIRDA hereby invites you to work together to provide new conveniences for all innovative entities in China's pharmaceutical industry, let the entire chain of the pharmaceutical industry to enable pharmaceutical innovation, and make new and greater contributions to allowing more innovative achievements to benefit people around the world as soon as possible!