药促会官网
Official Website of PhIRDA

药促会微信公众号
Official WeChat Account of PhIRDA

会员名录
PhIRDA Members

会刊
Association Journal of PhIRDA

创　新 | 产业化 | 国际化

INNOVATION | INDUSTRIALIZATION | INTERNATIONALIZATION

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PhIRDA 中国药促会

2022-2023

中国医药创新促进会

协会会刊

CHINA PHARMACEUTICAL INNOVATION AND RESEARCH DEVELOPMENT ASSOCIATION JOURNAL

会长寄语
MESSAGE FROM CHAIRMAN OF PHIRDA

团结协作，破局创新

会长

随着社会和生活方式的改变以及人口老龄化，慢性复杂性疾病加剧了用药需求；新冠疫情肆虐全球，新发突发传染病缺乏有效药物，给全人类生命健康带来了严重威胁与挑战，充分体现了医药创新研发对于人类生存和健康的重要意义，凸显了加快生物医药领域原始创新和攻克核心技术的紧迫性。当前，新一轮科技革命和产业变革正在重塑世界，对科技创新提出了更高要求。大数据与人工智能、合成生物学、基因编辑、细胞疗法等新兴技术和疗法在制药领域的深度交叉融合，促使医药产业新理念、新技术、新模式和新业态不断涌现，深刻地改变着药物研发的思路和方向，推动创新药物研发进入变革时代。

当前，我国已成为全球第二大药品市场，仅次于美国。近年来，在政策、资金、技术、人才等因素的共同作用下，在新药专项实施、药品审评审批改革、大力吸引海外人才回流等多重举措下，我国医药产业创新能力显著提升，创新药获批数量激增；我国创新药研发企业开始走出国门，开拓海外市场，跨国研发合作频现；生物医药领域的中国制造、中国创新也正在加速影响、融入全球的生物制药行业。然而，与发达国家相比，仍存在缺乏原创理论、原创技术、原创新药的问题。我国研发的大部分新药仍为国外已有新药的跟进，多为快速模仿创新品种，自主发现的药物作用新靶标、新机制和在此基础上发展的原创新药基本空白； PROTAC技术、基于大数据和人工智能的药物设计、精准治疗、基因治疗、细胞治疗等前沿引领技术均由国外首先提出。近年来，新药研发全球化以及我国鼓励药品“全球新”、接受境外临床试验数据等一系列改革举措，助推我国生物医药创新，也给我国的生物医药创新提出了更高要求；而国际形势的日趋复杂、美国《国家生物技术和生物制造计划》等法案的相继出台，对我国生物医药走向海外增加了一定的变数，也提醒我们在生物医药领域也面临潜在的关键核心技术“卡脖子”风险。我国生物医药的发展面临前所未有的挑战。

会长寄语 Message from Chairman of PhIRDA

药促会自1988年成立以来，走过了几十余年的风雨历程，近年来更是获得飞速发展，会员单位从几十余家快速发展到180余家，集聚了制药企业、科研院所、资本等各单位，构建基础研究、药物研发、生产、使用以及投融资的全链条组织构架，涵盖教育、技术、人才、资本等创新生态要素。并在药品监管、审评审批、产业政策制定、集采等方面为推动我国医药政策体系完善和创新环境改善建言献策，在推动国家生物医药改革发展和政策制定方面正发挥越来越大的作用；同时，药促会积极走出国门，在相关国际组织为中国医药发声，提升了中国医药创新的世界影响力和话语权。在这个变革的时代，会员们加强互动，团结协作，产学研深度融合，营造生物医药良好创新生态；会员们同舟共济，共克时坚，更好应对新形势、新挑战。如何更好地推动上述合作，也是药促会不断努力前行的方向。

道阻且长，行则将至。在接下来的一年里，我将与中国药促会的会员们一起秉承 “创新、产业化、国际化”的宗旨，进一步汇聚国内创新医药的中坚力量，搭建药物研发的国际国内交流平台，踔厉奋发、笃行不怠，继续做好产业与政府的桥梁，促进医药产业全链条携手赋能医药创新，不断推进中国医药产业创新加速、创新破局，质、量齐飞，不断改善我国医药产业生态环境。相信通过我们的努力，能使我国的创新药物早日从模仿创新向原始创新跨越，为全球患者带来更多的中国方案。

会长寄语 Message from Chairman of PhIRDA

Innovation: Work Together and Break Through Difficulties

With changes in society, people’s lifestyles and an aging population as the background, chronic and complex diseases have exacerbated the need for medication; The COVID-19 is ravaging around the world. However, effective drugs fall short of the demand of coping with the pandemic, which poses serious threats and challenges to the life and health of all mankind and fully reflects the importance of pharmaceutical innovation and R＆D to people’s survival and health, highlighting the urgency of accelerating original innovation and overcoming core technologies in the field of biopharmaceuticals. At present, a new round of scientific and technological revolution and industrial transformation is reshaping the world, putting forward higher and stricter requirements for scientific and technological innovation. The deep cross-integration of big data with emerging technologies and therapies including artificial intelligence, synthetic biology, gene editing, and cell therapy in the pharmaceutical field has promoted the continuous emergence of new concepts, technologies, models and formats of business in the pharmaceutical industry, profoundly changing the philosophy and direction of the R＆D of drugs, and pushing forward the innovative drug R＆D into an new era of change.

Nowadays, China has become the world’s second largest pharmaceutical market, second only to the United States. In recent years, in the series of the combined strategies, funds, technology, talents and other factors, including the special implementation of new drugs, drug review and approval reform, and return of talents, China has gained prominent momentum in the innovation ability of its pharmaceutical industry and the number of innovative drugs approval has surged. China’s innovative drug R&D enterprises began to go abroad to explore overseas markets. As a result, cross-border R&D cooperation has frequently emerged; China’s manufacturing and innovation in the biopharmaceutical field are also accelerating their impact and integration into the global biopharmaceutical industry. However, compared with developed countries, there remains a lack of original theories, technologies and innovative drugs in China. Not a few new drugs are still following the steps of existing foreign drugs, and mostly are fast-follow of innovative varieties. Few self-discovered new targets and mechanisms of drug effects and original innovative drugs on this basis are developed. While PROTAC technology, drug design based on big data and AI, precision therapy, gene therapy, cell therapy and other cutting-edge leading technologies were first proposed by foreign countries over the past few years, the globalization of new drug R＆D and a set of reformative strategies including China’s encouragement of “first-in-class” of drugs, acceptance of overseas clinical trial data have boosted China’s biopharmaceutical innovation, which, at the same time, put forward higher requirements for China’s biopharmaceutical innovation. The increasingly complex international situation and the successive introduction of the US National Biotechnology and Biomanufacturing Plan and other bills have added certain variables for China’s biopharmaceuticals to go overseas, and also reminded us of the “being-strangled” risk due to key core technologies and stranglehold problems in biopharmaceuticals. The development of biopharmaceuticals in China is facing unprecedented challenges.

会长寄语 Message from Chairman of PhIRDA

Since its establishment in 1988, China Pharmaceutical Innovation and Research Development Association (PhIRDA) has gone through decades of efforts, and in recent years, it has also achieved rapid development, with members developing at a rather swift pace from dozens to more than 180, which contains pharmaceutical enterprises, scientific research institutes, capital and other units, covering the whole chain organizational structure of basic research, drug R&D, production, use, investment and financing while also including innovative ecological elements like education, technology, talents and capital. In the perspectives of drug supervision, review and approval, industrial policy formulation, centralized procurement, it provides suggestions and strategies for promoting the improvement of China's pharmaceutical policy system and innovation environment, and is playing an increasingly important role in promoting the reform and development of national biopharmaceuticals as well as policy formulation. At the same time, the PhIRDA has taken active steps in going abroad to speak out for Chinese pharmaceuticals in relevant international organizations, enhancing the world influence and discourse power of China's pharmaceutical innovation. In this era full of changes, members have strengthened their interactions, unity and cooperation, and deeply integrated industry, education and research to create a good innovation environment for biopharmaceuticals. Members are in the same boat to overcome the times and better cope with the new situation and new challenges. How to better promote the above cooperation is also the destination that PhIRDA continues to strive for.

Though the road ahead is dangerous and difficult, we can only achieve our goals with constant efforts. In the following year, I will work together with the members of PhIRDA, with the aim of "innovation, industrialization and internationalization", to further gather the backbone of domestic innovative pharmaceuticals, build a platform for both international and domestic exchanges of drug R&D. We will continue to work hard in a steadfast manner, give full play to our role in bridging the industry and the government and promote the whole chain of the pharmaceutical industry to work together to empower pharmaceutical innovation, continuously promoting the acceleration of innovation and breakthrough of innovation in China's pharmaceutical industry, with quality and quantity surging ahead at the same pace, and constantly improving the environment of China's pharmaceutical industry. We believe that through our efforts, we can make China's innovative drugs leap from imitation to original innovation in the foreseeable future, and provide more "Chinese solutions" to help patients around the world.

目 录 Contents

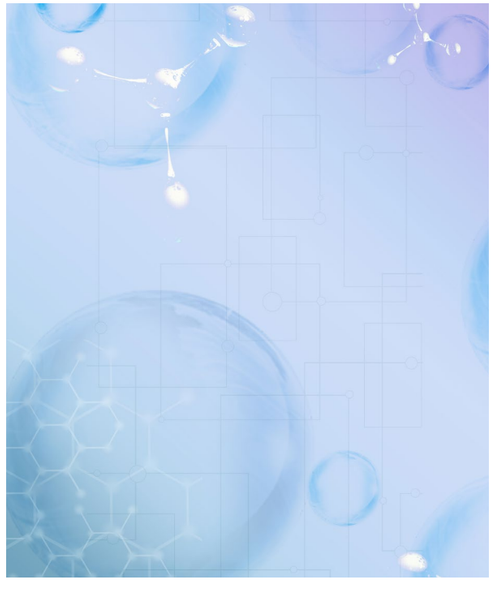
中国医药创新促进会简介

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 182 家。中国药促会已成立了药物研发、药物临床试验研究、医药政策、医药创新投资、创新研发服务、心血管药物临床研究、国际创新药物监管、抗肿瘤药物临床研究、脑神经药物临床研究、医药企业合规、糖尿病与代谢性疾病药物临床研究专业委员会，形成了以创新为核心，以促进创新为目标的涵盖药物研发、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

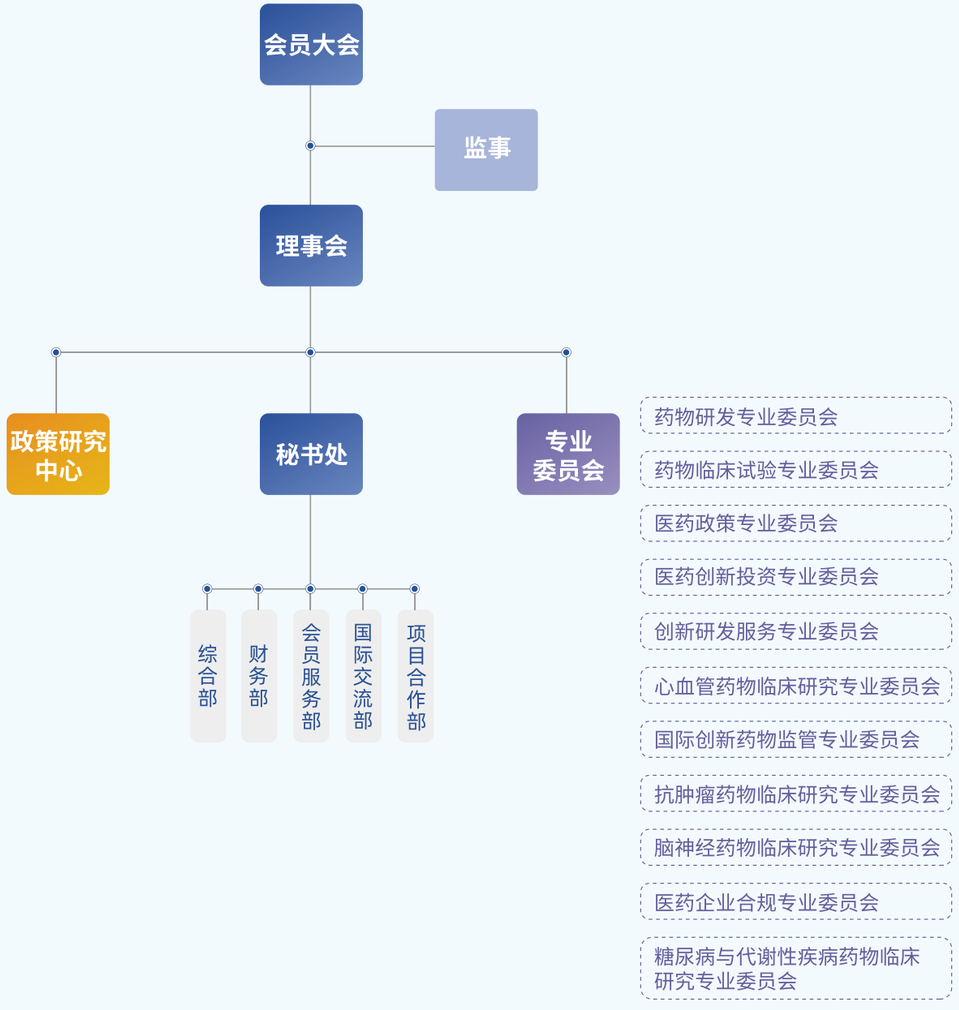
Founded in 1988, China Pharmaceutical Innovation and Research Development Association (PhIRDA), formerly named China Pharmaceutical Industry Research and Development Association, is registered as a non-profit 4A social organization by the Ministry of Civil Affairs of China at national level.

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 182 members mainly consists of pharmaceutical R&D enterprises, research institutions, clinical institutions, R&D Services companies and investment institutions focusing on pharmaceutical innovation. Moreover, PhIRDA has established the following Specialty Committees: Drug R&D, Clinical Trial Research, Medicinal Policy, Pharmaceutical Innovation Investment and Innovation R&D Services, Clinical Research on Cardiovascular Drugs, International Regulatory Science, Clinical Research on Oncology Drugs, Clinical Research on Cranial Nerve Drugs, Ethics and Business Compliance, Clinical Research on Diabetes and Metabolic Diseases, forming a fully functional organization structure focusing on innovation, aiming to promote the development of innovation, covering the whole industrial chain, including drug R&D, manufacturing, using, investment and capital market. PhIRDA is also a member of International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) to continuously broaden channels of international collaboration.

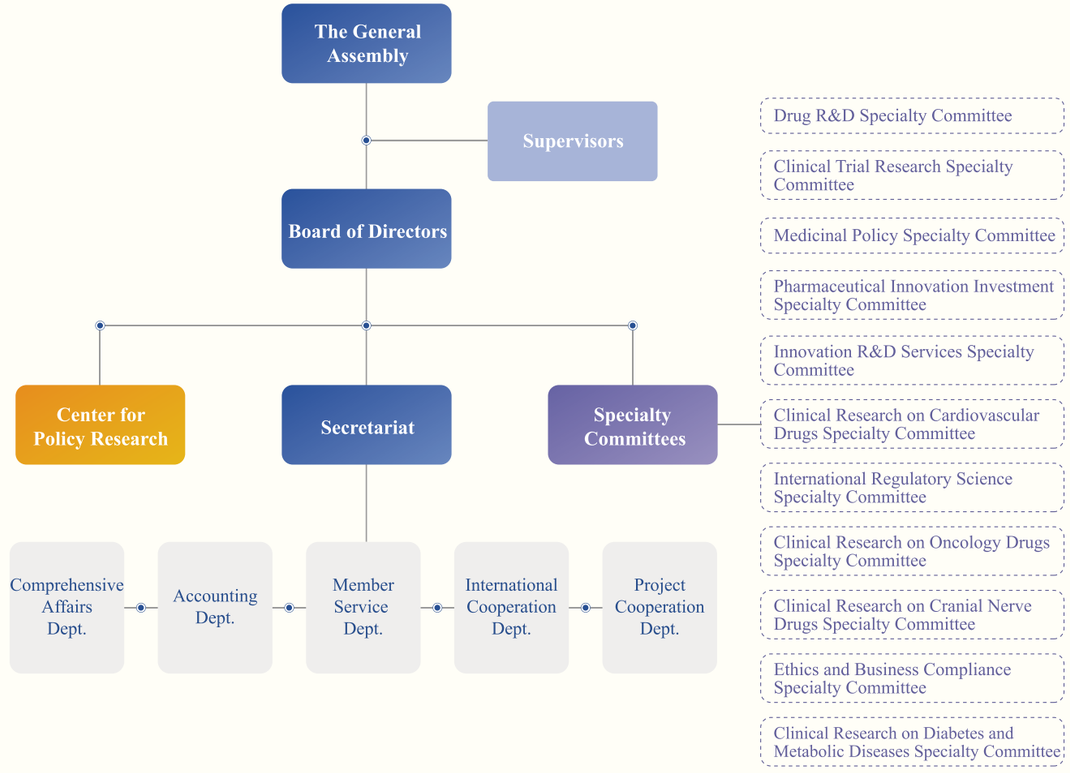
Major work of PhIRDA includes: first, to conduct policy researches, propose valuable suggestions on healthcare reform and the development of pharmaceutical industry; second, to promote communication and innovative development of our members and even the whole pharmaceutical industry through forums, press-conferences,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

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

机构设置



Organizational Structure of PhIRDA



中国医药创新促进会医药创新科学委员会专家名单

Expert List of PhIRDA Pharmaceutical Innovation Scientific Committee

桑国卫 荣誉主任
中国工程院院士

Honorary Chairman, Sang Guowei
Academician of Chinese Academy of Engineering

陈凯先 主任
中国科学院院士

Chairman, Chen Kaixian
Academician of Chinese Academy of Sciences

魏于全 委员
中国科学院院士

Member, Wei Yuquan
Academician of Chinese Academy of Sciences

裴 钢 委员
中国科学院院士
发展中国家科学院院士

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

曹雪涛 委员
中国工程院院士

Member, Cao Xuetao
Academician of Chinese Academy of Engineering

丁 健 委员
中国工程院院士
发展中国家科学院院士

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

程 京 委员
中国工程院院士

Member, Cheng Jing
Academician of Chinese Academy of Engineering

王晓东 委员
中国科学院外籍院士

Member, Wang Xiaodong
Foreign Academician of Chinese Academy of Sciences

王广基 委员
中国工程院院士

Member, Wang Guangji
Academician of Chinese Academy of Engineering

葛均波 委员
中国科学院院士

Member, Ge Junbo
Academician of Chinese Academy of Sciences

王松灵 委员
中国科学院院士

Member, Wang Songling
Academician of Chinese Academy of Sciences

丁文江 委员
中国工程院院士

Member, Ding Wenjiang
Academician of Chinese Academy of Engineering

岳建民 委员
中国科学院院士

Member, Yue Jianmin
Academician of Chinese Academy of Sciences

樊　嘉 委员
中国科学院院士

Member, Fan Jia
Academician of Chinese Academy of Sciences

王　锐 委员
中国工程院院士

Member, Wang Rui
Academician of Chinese Academy of Engineering

李校堃 委员
中国工程院院士

Member, Li Xiaokun
Academician of Chinese Academy of Engineering

会领导介绍

INTRODUCTION OF PHIRDA LEADERSHIP

会领导介绍
Introduction of PhIRDA Leadership

第九届会员大会以来历任会长
Chairman of PhIRDA Since the 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
天士力创始人
天士力控股集团董事局终身荣誉主席
天士力大健康产业投资集团董事长

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

孙飘扬
2014-2015年度会长
江苏恒瑞医药股份有限公司董事长

Sun Piaoyang
Annual Chairman 2014-2015
Chairman of the Board, Jiangsu Hengrui Pharmaceuticals Co., Ltd.

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

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

丁列明
2016-2017年度会长
贝达药业股份有限公司
董事长兼CEO

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

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

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

刘殿波
2018-2019年度会长
绿叶生命科学集团董事局主席

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

宋瑞霖
2019-2020年度会长
中国医药创新促进会执行会长

Song Ruilin
Annual Chairman 2019-2020
Executive President of China Pharmaceutical Innovation and Research Development Association

任晋生
2020-2021年度会长
先声药业集团有限公司
董事长兼首席执行官

Ren Jinsheng
Annual Chairman 2020-2021
Chairman and Chief Executive Officer, Simcere Pharmaceutical Group Limited

李　燕
2021-2022年度会长
齐鲁制药集团有限公司总裁

Li Yan
Annual Chairman 2021-2022
President, Qilu Pharmaceutical Group Co., Ltd.

现任会领导
Current Leadership of PhIRDA

李　佳 会长
中国科学院上海药物研究所所长

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

宋瑞霖 执行会长
中国医药创新促进会

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

张抒扬 副会长
北京协和医院院长

Zhang Shuyang, Vice President
President, Peking Union Medical College Hospital

陈启宇 副会长
复星国际执行董事兼联席首席执行官
复星医药董事

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

孙飘扬 副会长
江苏恒瑞医药股份有限公司董事长

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

丁列明 副会长
贝达药业股份有限公司
董事长兼CEO

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

蒋建东 副会长
中国工程院院士
中国医学科学院药物研究院院长

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

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绿叶生命科学集团董事局主席

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

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先声药业集团有限公司
董事长兼首席执行官

Ren Jinsheng, Vice President
Chairman and Chief Executive Officer, Simcere Pharmaceutical Group Limited

李　燕 副会长
齐鲁制药集团有限公司总裁

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

柯尊洪 副会长
成都康弘药业集团股份有限公司
董事长

Ke Zunhong, Vice President
Chairman of the Board, Chengdu Kanghong Pharmaceutical Group Co., Ltd.

闫凯境 副会长
天士力医药集团股份有限公司
董事长

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Chairman of the Board, Tasly Pharmaceutical Group Co., Ltd.

赵　勇 副会长
上海医药党委副书记、副总裁

Zhao Yong, Vice President
Deputy Secretary of the Party Committee & Vice President, SPH

吴晓滨 副会长
百济神州总裁、首席运营官和中国区总经理

Wu Xiaobin, Vice President
President, Chief Operating Officer & General Manager – China, BeiGene Ltd.

冯　岚 秘书长
中国医药创新促进会

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

专业委员会介绍

中国药促会目前已成立11个专业委员会，依托专业委员会专家及委员资源优势，我会在药械研发、临床研究、行业监管、政策研究、投融资、药械数字化和合规等方面开展了大量卓有成效的工作，受到社会各界广泛关注和好评。此外，我会还将组建医药数字化及创新疗法专业委员会和创新医疗器械专业委员会，为会员单位和整个药械产业提供更多元的价值服务。

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

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

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

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

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

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

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

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

Introduction of Specialty Committees

At present, PhIRDA has established 11 Specialty Committees. Relying on the resources of experts and members, PhIRDA has conducted a great deal of effective work in the research and development of drugs and medical devices, clinical research, industry supervision, policy research, investment and financing, digitization of drugs and medical devices and compliance, etc., receiving widely concerned and praised from society. In addition, PhIRDA will also set up Digitalization in Pharmaceutical and Innovative Therapy Specialty Committee and Innovative Medical Devices Specialty Committee to provide more diversified and valuable services for PhIRDA members and the entire pharmaceutical industry.

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

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

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

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

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

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

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

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

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

杨大俊 主任委员
亚盛医药董事长兼首席执行官

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

鲁先平 副主任委员
深圳微芯生物科技股份有限公司
董事长、总裁

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

俞德超 副主任委员
信达生物制药（苏州）有限公司
董事长兼总裁

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

王印祥 副主任委员
北京加科思新药研发有限公司
董事长兼首席执行官

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

房健民 副主任委员
荣昌生物联合创始人、首席执行官
兼首席科学官

Vice-Chairman, Fang Jianmin
Co-Founder, CEO & CSO of RemeGen

陈　力 副主任委员
华领医药技术（上海）有限公司
创始人、董事长、首席执行官

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

张　丹 副主任委员
昆翎医药联合创始人
兼首席战略官

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

王晓良 副主任委员
中国医学科学院药物研究院副院长

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

薛　群 副主任委员
北海康成制药有限公司创始人
董事长兼首席执行官

Vice-Chairman, Xue Qun
Founder, Chairman and CEO, CANbridge Pharmaceuticals Inc.

阎水忠 副主任委员
再鼎医药（上海）有限公司
全球研发首席运营官

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

任　进 副主任委员
中国科学院上海药物研究所药物
安全评价研究中心主任、研究员

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

彭少平 秘书长
先声药业集团南京研究院负责人

Secretary-General, Peng Shaoping
Executive Dean of Nanjing R&D Center

第三届药物临床试验专业委员会
The 3rd Clinical Trial Research Specialty Committee

崔一民 主任委员
北京大学临床药理研究所所长

Chairman, Cui Yimin
Director of Institute of Clinical Pharmacology, Peking University

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首都医科大学附属北京世纪坛医院
药物I期临床试验研究室主任

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

李海燕 副主任委员
北京大学第三医院
药物临床试验机构主任

Vice-Chairman, Li Haiyan
Director of Clinical Research Center, Peking University Third Hospital

李可欣 副主任委员
北京医院临床试验研究原中心主任

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

胡　蓓 副主任委员
北京协和医院创新药物临床药代药效研究北京市重点实验室主任

Vice-Chairman, Hu Bei
Director of Beijing Key Laboratory of Clinical Pharmacokinetics and Pharmacodynamics of Innovative Drugs, Peking Union Medical College Hospital

郭　彤 副主任委员
艾昆纬大中华区业务拓展
副总裁

Vice-Chairman, Guo Tong
Vice President of Business Development, IQVIA

阳国平 秘书长
中南大学湘雅三医院
临床药理中心主任

Secretary-General, Yang Guoping
Director of Center of Clinical Pharmacology, Third Xiangya Hospital of Central South University

第三届医药政策专业委员会
The 3rd Medicinal Policy Specialty Committee

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复旦大学公共卫生学院
卫生经济学教授

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

胡　欣 主任委员
北京医院药学部主任药师
首席专家

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

刘军帅 副主任委员
国家罕见病诊疗与保障专家
委员会委员

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

邵　蓉 副主任委员
中国药科大学教授
国家药物政策与医药产业
经济研究中心执行副主任

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

宣建伟 副主任委员
中山大学医药经济研究所所长

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

武志昂 副主任委员
沈阳药科大学亦弘商学院院长

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

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国家卫生健康委药物与卫生
技术评估中心副主任

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

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首都医科大学附属北京儿童医院
药学部主任

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

第四届医药创新投资专业委员会
The 4th Pharmaceutical Innovation Investment Specialty Committee

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中国医学科学院北京协和医院
主任药师

Vice-Chairman, Mei Dan
Chief Pharmacist of Pharmacy, Peking Union Medical College Hospital

冯婉玉 副主任委员
北京大学医学部药物评价中心
副主任

Vice-Chairman, Feng Wanyu
Deputy Director of Peking University Health Science Center's Institute for Drug Evaluation

赵志刚 副主任委员
首都医科大学附属北京天坛医院
药学部主任

Vice-Chairman, Zhao Zhigang
Director of Department of Pharmacy, Beijing Tian Tan Hospital, Capital Medical University

冯　毅 副主任委员
四川科伦药业股份有限公司
研发副总裁兼首席战略官

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

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先声药业有限公司
党委书记兼副总裁

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Secretary of Party Committee & Vice President of Simcere Pharmaceutical Group

梁颍宇 主任委员
启明创投主管合伙人

Chairman, Nisa Leung
Managing Partner of Qiming Venture Partners

杜　莹 副主任委员
再鼎医药董事长兼首席执行官

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

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博远资本创始合伙人

Vice-Chairman, Kevin Chen
Founding Partner of Biotrack Capital

李凯军 副主任委员
醴泽资本管理合伙人

Vice-Chairman, Kevin Li
Managing Partner of LYZZ Capital

朱晋桥 副主任委员
倚锋资本董事长

Vice-Chairman, Zhu Jinqiao
Chairman of EFung Capital

储慧斌 副主任委员
海捷投资控股集团首席合伙人

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

方　敏 副主任委员
华平投资合伙人
中国医疗健康投资负责人

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

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国寿股权投资管委会主任

Vice-Chairman, Zhang leidi
Head of Management Committee, China Life Private Equity Investment Co., Ltd.

王 珣 副主任委员
华盖医疗投资首席投资官

Vice-Chairman, Wang xun
CIO, Huagai Healthcare Fund

黄晓华 副主任委员
招商局健康产业控股有限公司
总经理

Vice-Chairman, Huang xiaohua
General Manager, China Merchants Health Care Holdings Co., Ltd.

陈 侃 秘书长
启明创投合伙人

Secretary-General, Chen kan
Partner of Qiming Venture Partners

第二届创新研发服务专业委员会
The 2nd Innovation R&D Services Specialty Committee

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上海立迪生物技术股份有限公司
董事长兼执行总裁

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

甄 岭 副主任委员
昆翎医药全球董事长兼首席执行官

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

宋青春 副主任委员
北京春天医药科技发展有限公司
创始人兼总经理

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

王 斌 副主任委员
浙江九洲药业股份有限公司
高级副总裁

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

李 明 副主任委员
滬港中科国际生物科技有限公司
首席执行官

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

马 健 副主任委员
深圳晶泰科技有限公司
联合创始人、首席执行官

Vice-Chairman, Ma Jian
Co-Founder&CEO of XtalPi

刘 熠 秘书长
缔脉生物高级副总裁
首席医学官

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

第一届心血管药物临床研究专业委员会
The 1st Clinical Research on Cardiovascular Drugs Specialty Committee

葛均波 名誉主任委员
中国科学院院士
上海复旦大学附属中山医院
心内科主任

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

霍　勇 主任委员
北京大学第一医院心内科首席专家

Chairman, Huo Yong
Chief Expert of Cardiology Department, Peking University First Hospital

袁祖贻 副主任委员
西安交通大学第一附属医院
心血管病医院院长

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

陈纪言 副主任委员
广东省人民医院首席专家

Vice-Chairman, Chen Jiyan
Chief Expert of Guangdong Provincial People's Hospital

周玉杰 副主任委员
首都医科大学附属北京安贞医院
常务副院长

Vice-Chairman, Zhou Yujie
Executive President of Beijing Anzhen Hospital, Capital Medical University

荆志成 副主任委员
北京协和医院心内科主任

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

耿美玉 副主任委员
中国科学院上海药物研究所
学术所长

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

傅向华 副主任委员
河北医科大学第二医院
心血管内科首席专家

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

周达新 副主任委员
上海复旦大学附属中山医院
心内科副主任

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

高晓丽 秘书长
宝石花（天津）国际医疗健康
有限公司副总经理

Secretary-General, Gao Xiaoli
Vice President of Gnertect Gem Flower International Healthcare Co., Ltd.

第一届国际创新药物监管专业委员会
The 1st International Regulatory Science Specialty Committee

何如意 主任委员
荣昌生物首席医学官、国投创新医疗健康首席科学家、前国家食品药品监督管理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

陈少羽 副主任委员
美国安诺波特律师事务所驻上海代表处管理合伙人

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

杜　涛 副主任委员
深圳埃格林医药有限公司董事长

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

杜　新 副主任委员
深圳埃格林医药有限公司
首席执行官

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

李　宁 副主任委员
上海君实生物首席执行官

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

赵孝斌 副主任委员兼秘书长
浙江海昶生物医药有限公司总裁

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

第二届抗肿瘤药物临床研究专业委员会
The 2nd Clinical Research on Oncology Drugs Specialty Committee

管忠震 顾问
中山大学肿瘤医院肿瘤内科教授

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

秦叔逵 顾问
解放军东部战区总医院全军肿瘤中心主任

Counselor, Qin Shukui
Director of PLA Cancer Center

孙飘扬 顾问
江苏恒瑞医药股份有限公司董事长

Counselor, Sun Piaoyang
Chairman of the Board, Jiangsu Hengrui Pharmaceuticals Co., Ltd.

孙 燕 顾问
中国工程院院士

Counselor, Sun Yan
Academician of the Chinese Academy of Engineering

吴一龙 顾问
广东省人民医院终身主任

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

于金明 顾问
中国工程院院士

Counselor, Yu Jinming
Academician of Chinese Academy of Engineering

李 进 主任委员
同济大学附属东方医院肿瘤医学部主任

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

徐兵河 副主任委员
中国工程院院士

Vice-Chairman, Xu Binghe
Academician of Chinese Academy of Engineering

马 军 副主任委员
哈尔滨血液病肿瘤研究所所长

Vice-Chairman, Ma Jun
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Chairman of the Board & CEO, Beijing InnoCare Pharma Tech Co., Ltd.

房健民
Fang Jianmin
荣昌生物制药（烟台）股份有限公司首席执行官兼首席科学官
CEO & Chief Scientific Officer, RemeGen, Ltd.

赵　宏
Zhao Hong
赛生药业控股有限公司总裁、
首席执行官
President & CEO, SciClone Pharmaceuticals (Holdings) Limited

梁文青
Liang Wenqing
长风药业股份有限公司董事长、
总经理
Chairman of the Board & General Manager, CF PharmTech, Inc.

张登科
Zhang Dengke
西安新通药物研究股份有限公司
董事长兼总经理
Chairman of the Board & General Manager, Xi'an Xintong Pharmaceutical Research Co., Ltd.

王在琪
Wang Zaiqi
应世生物科技（南京）有限公司董事长兼首席执行官
Chairman of the Board & CEO, InxMed (Nanjing) Co., Ltd.

王劲松
Wang Jinsong
和铂医药创始人、董事长
兼首席执行官
Founder, Chairman of the Board & CEO, Harbour BioMed

曹　卫
Cao Wei
亘喜生物科技（上海）有限公司
创始人、董事长兼首席执行官
Founder, Chairman of the Board & CEO, Gracell Biotechnologies (Shanghai) Co., Ltd.

肖瑞平
Xiao Ruiping
和其瑞医药（南京）有限公司
创始人、董事长
Founder & Chairman of the Board, Hope Medicine (Nanjing) Co., Ltd.

盛泽林
Sheng Zelin
苏州泽璟生物制药股份有限公司
董事长、总经理
Chairman of the Board & General Manager, Suzhou Zelgen Biopharmaceuticals Co., Ltd.

童友之
Tong Youzhi
开拓药业创始人、董事长
兼首席执行官
Founder, Chairman of the Board & CEO, Kintor Pharmaceutical Limited

王建平
Wang Jianping
新兴际华医药控股有限公司
党委书记、董事长
Secretary of the Party Committee & Chairman, Xinxing Cathay International Pharmaceutical Holdings Co., Ltd.

杜锦豪
Du Jinhao
上海艾力斯医药科技股份有限公司董事长
Chairman of the Board, Shanghai Allist Pharmaceuticals Co., Ltd.

袁征宇
Yuan Zhengyu
上海盟科药业股份有限公司总经理
General Manager, Shanghai MicuRx Pharmaceutical Co., Ltd.

景书谦
Jing Shuqian
鸿运华宁（杭州）生物医药
有限公司董事长兼首席执行官
Chairman of the Board & CEO, Gmax Biopharm LLC.

王智瑶
Wang Zhiyao
拜奥新管理（上海）有限公司总经理
General Manager, BioShin (Shanghai) Consulting Services Co., Ltd.

潘　柯
Pan Ke
江苏亚虹医药科技股份有限公司
创始人、董事长及首席执行官
Founder, Chairman of the Board & CEO, Jiangsu Asieris Pharmaceuticals Co., Ltd.

赵孝斌
Zhao Xiaobin
浙江海昶生物医药技术有限公司
创始人、总裁
Founder & President, Zhejiang Haichang Biotech Co., Ltd.

黄岳升
Huang Yuesheng
北京五和博澳药业股份有限公司
董事长
Chairman of the Board, Beijing Wehand-Bio Pharmaceutical Co., Ltd.

史晓峰
Shi Xiaofeng
远大医药（中国）有限公司董事长
Chairman of the Board, Grand Pharma (China) Co., Ltd.

吕向阳
Lv Xiangyang
来凯医药科技（上海）有限公司
创始人，董事长兼CEO
Founder, Chairman of the Board & CEO, Laekna Therapeutics Shanghai Co., Ltd.

向　宇
Xiang Yu
上海琅钰健康科技(集团)有限公司
首席执行官
CEO, RareStone Group Co., Ltd.

赵大尧
Zhao Dayao
上海蔼睦医疗科技有限公司
首席执行官
CEO, Shanghai AffaMed Therapeutics Co., Ltd.

徐　敏
Xu Min
派格生物医药(苏州)股份有限公司创始人、董事长兼首席执行官
Founder, Chairman of the Board & CEO, Pegbio. Co., Ltd.

张晓雷
Zhang Xiaolei
瓴路药业(上海)有限责任公司
联合创始人兼首席执行官
Co-Founder & CEO, Overland Pharmaceutical (Shanghai) Co., Ltd.

秦东辉
Qin Donghui
辉诺生物医药科技(杭州)有限公司董事长兼首席执行官
Chairman of the Board & CEO, Phaeno Therapeutics Co., Ltd.

董瑞平
Dong Ruiping
上海海和药物研究开发股份有限公司首席执行官
CEO, Haihe Biopharma Co., Ltd.

梁　果
Liang Guo
四川三叶草生物制药有限公司
首席执行官兼董事
CEO & Board Director, Clover Biopharmaceuticals, Inc.

张成城
Zhang Chengcheng
北京谷神生命健康科技有限公司
董事长
Chairman of the Board, Beijing GuShen Life Health Science Technology Co., Ltd.

刘利平
Liu Liping
深圳君圣泰生物技术有限公司
创始人、首席执行官
Founder & CEO, Shenzhen HighTide Biopharmaceutical Ltd.

夏国尧
Xia Guoyao
上海礼邦医药科技有限公司
首席执行官
CEO, Alebund Pharmaceuticals Ltd.

徐　霆
Xu Ting
江苏康宁杰瑞生物制药有限公司
董事长兼总裁
Chairman of the Board & President, Jiangsu Alphamab Biopharmaceuticals Co., Ltd.

龚兆龙
Gong Zhaolong
思路迪(北京)医药科技有限公司
董事长兼首席执行官
Chairman of the Board & CEO, 3D Medicines Inc.

刘滨磊
Liu Binlei
武汉滨会生物科技股份有限公司
创始人、董事长兼总经理
Founder, Chairman of the Board & General Manager, Binhui Biopharmaceutical Co., Ltd.

贾祥波
Jia Xiangbo
无锡智康弘义生物科技有限公司
创始人、董事长
Founder & Chairman of the Board, Wuxi Biocity Biopharmaceutics Co., Ltd.

王轶喆
Wang Yizhe
上海联拓生物科技有限公司
首席执行官
CEO, LianBio China

王庆华
Wang Qinghua
上海银诺医药技术有限公司
创始人、董事长、CEO
Founder, Chairman of the Board & CEO, Innogen Pharmaceutical Technology Co., Ltd.

丁师哲
Ding Shizhe
启元生物(杭州)有限公司总经理
General Manager, E-nitiate Biopharmaceuticals (Hangzhou) Co., Ltd.

陈东浩
Chen Donghao
杭州畅溪制药有限公司首席执行官
CEO, Hangzhou Chance Pharmaceutical Ltd.

吴功雄
Wu Gongxiong
远森制药(北京)有限公司董事长
Chairman, LongWood Pharmaceuticals

牟晓盾
Mou Xiaodun
正序(上海)生物科技有限公司
首席执行官
CEO, CorrectSequence Therapeutics

吕　梁
Lv Liang
华东医药股份有限公司
董事长、总经理
Chairman, President, Huadong Medicine Co., Ltd.

甘忠如
Gan Zhongru
甘李药业股份有限公司董事长
Chairman, Gan & Lee Pharmaceuticals.

黄映辉
Huang Yinghui
苏州映辉医药科技有限公司
创始人、董事长
Founder & Chairman of the Board, Suzhou Infinory Pharmaceuticals, LLC

张峰
Zhang Feng
南京优科生物医药股份有限公司
董事长
Chairman, Nanjing YOKO Biomedical Co., Ltd.

郑效东
Zheng Xiaodong
东富龙科技集团股份有限公司
董事长
Chairman of the Board, Tofflon Science and Technology Group Co., Ltd.

吉朋松
Ji Pengsong
上海安翰医疗技术有限公司董事长
Chairman of the Board, Ankon Medical Technologies Co., Ltd.

郑立谋
Zheng Limou
厦门艾德生物医药科技股份有限公司董事长
Chairman of the Board, Amoy Diagnostics Co., Ltd.

杨　霞
Yang Xia
山西锦波生物医药股份有限公司
董事长兼功能蛋白研究院院长
Chairman and Dean of Functional Protein Research Institute, Shanxi Jinbo Bio-Pharmaceutical Co., Ltd.

赵立见
Zhao Lijian
深圳华大基因股份有限公司CEO
CEO, BGI Genomics Co., Ltd.

毛　琳
Mao Lin
南京普济生物有限公司董事长
Chairman, Nanjing Pregene Biotechnology Co., Ltd.

孙毅勇
Sun Yiyong
上海微创电生理医疗科技股份有限公司总裁
President, Shanghai MicroPort EP MedTech Co., Ltd.

田明明
Tian Mingming
江苏德威兰医疗器械股份有限公司董事长
Chairman, JiangSu Deviceland Medical Instrument Co., Ltd.

楼胜琼
Lou Shengqiong
杭州瑞普基因科技有限公司
总经理
General Manager, Hangzhou Repugene Technology Co., Ltd.

任　用
Ren Yong
江苏先声医学诊断有限公司CEO
CEO, Jiangsu Simcere Diagnostics Co., Ltd.

张天泽
Zhang Tianze
零氪科技(北京)有限公司
首席执行官
CEO, LinkDoc Technology Co., Ltd.

温书豪
Wen Shuhao
晶泰科技联合创始人、董事长
Co-Founder and Chairman, XtalPi

孙　巍
Sun Wei
北京无疆脑智科技有限公司
创始人兼董事长
Founder & Chairman of the Board, Beijing Infinite Brain Technology Co., Ltd.

成晓亮 Cheng Xiaoliang	江苏品生医疗科技集团有限公司 总裁 President, Jiangsu Qlife Medical Technology Group Co., Ltd.
季序我 Ji Xuwo	普瑞基准科技（北京）有限公司 创始人兼首席执行官 Founder & CEO, Precision Scientific (Beijing) Co., Ltd.
陈　宽 Chen Kuan	推想医疗科技股份有限公司 董事长兼首席执行官 Chairman of the Board & CEO, Infervision Medical Technology Co., Ltd.
王承志 Wang Chengzhi	北京镁伽机器人科技有限公司 首席科学家 Chief Scientific Officer, MegaRobo Technologies Co., Ltd.
何　骑 He Qi	上海腾迈医药科技有限公司 联合创始人、首席执行官 Co-founder & CEO, TandemAI Shanghai Co., Ltd.
储慧斌 Chu Huibin	海捷投资控股集团首席合伙人 Chief Partner, Hiyield Investment Holding Group
李振福 Li Zhenfu	北京德福悦安投资顾问有限公司 董事长 Chairman of the Board, GL Capital Group
李　茜 Li Qian	平安银行医疗健康金融事业部总裁 President, Finance SBU of Healthcare Industries of Ping An Bank
陈鹏辉 Chen Penghui	博远资本创始合伙人 Founding Partner, Biotrack Capital
姚江涛 Yao Jiangtao	中航信托股份有限公司董事长 Chairman of the Board, AVIC Trust Co., Ltd.
王晓滨 Wang Xiaobin	宝石花医疗健康投资控股集团有限公司副董事长 Vice Chairman, Gem Flower Healthcare Investment Holding Group Co., Ltd.
赵　群 Zhao Qun	苏州工业园区元禾原点创业投资管理有限公司合伙人 Partner, SIP Oriza Seed Fund Management Co., Ltd.
施　毅 Shi Yi	礼来亚洲基金创始人及管理合伙人 Founder & Managing Partner, Lilly Asia Ventures
黄晓华 Huang Xiaohua	招商局健康产业控股有限公司 总经理 General Manager, China Merchants Health Care Holdings Co., Ltd.
张丽萍 Zhang Liping	北京大数长胜资产管理有限公司 董事长 Chairman of the Board, Beijing Great Numbers Asset Management Co., Ltd.
蒋翔仁 Jiang Xiangren	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管委会主任 Head of Management Committee, 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, Warburg Pincus
陈志行 Chen Zhixing	大钲资本合伙人 Partner, Centurium Capital
许小林 Xu Xiaolin	华盖医疗投资管理（北京）有限公司 创始合伙人、董事长 Founding Partner, Huagai Healthcare Fund
甄　岭 Zhen Ling	昆翎全球董事长兼首席执行官 Global Chairman and CEO, ClinChoice
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.
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 President & CEO, Shanghai LIDE Biotech Co., Ltd.
花莉蓉 Hua Lirong	浙江九洲药业股份有限公司董事长 Chairman of the Board, Zhejiang Jiuzhou Pharmaceutical Co., Ltd.
黄纯莹 Huang Chunying	东曜药业有限公司执行董事 Executive Director, TOT Biopharma Co., Ltd.
宋青春 Song Qingchun	北京春天医药科技发展有限公司董事长 Chairman of the Board, PROSWELL MEDICAL COMPANY
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
姜　海 Jiang Hai	润东医药研发（上海）有限公司总裁 President, Rundo International Pharmaceuticals Research & Development Co., Ltd.
宓子厚 Mi Zihou	艾昆纬亚太区总裁 President, Asia Pacific, IQVIA
曹晓春 Cao Xiaochun	杭州泰格医药科技股份有限公司 总裁 President, Hangzhou Tigermed Consulting Co., Ltd.
齐学兵 Qi Xuebing	北京海金格医药科技股份有限公司 董事长 Chairman of the Board, Beijing Highthink Pharmaceutical Technology Service Co., Ltd.
李　明 Li Ming	滬港中科国际生物科技有限公司 首席执行官 CEO, ZSHK Laboratories Limited
何映珂 He Yingke	源健优科生物科技（上海）有限公司首席执行官 CEO, Yuanjianyouke Biotechnology (Shanghai) Co., Ltd.
李玉玲 Li Yuling	浙江健新原力制药有限公司首席执行官 CEO, Zhejiang Innoforce Pharmaceuticals Co., Ltd.
焦　鹏 Jiao Peng	上海碧博生物医药工程有限公司董事长、首席执行官 Chairman & CEO, BiBo Biopharma Engineering Co., Ltd.

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
中国工程院院士，天津中医药大学名誉校长
Academician, Chinese Academy of Engineering, Honorary President, Tianjin University of Traditional Chinese Medicine

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

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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
Beijing Nanostructured Drug Engineering & Technology Center, General Secretary of the 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

阿吉艾克拜尔·艾萨
Haji Akber Aisa
中国科学院新疆理化技术研究所学术副所长
Academic Deputy Director, Xinjiang Technical Institute of Physics and Chemistry, Chinese Academy of Sciences

重要活动
Important Events

重要活动（2021年10月-2022年9月）
Important Events (October, 2021 - September, 2022)

中国药促会党组织建设
PhIRDA Party Organization Construction

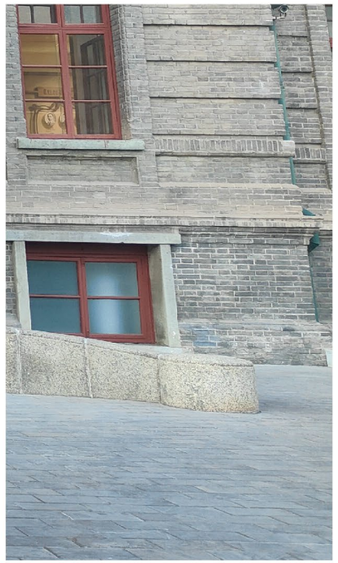
中国药促会党支部始终以习近平新时代中国特色社会主义思想为统领，认真有序开展党建工作，通过内容丰富、形式创新的线上线下学习方式和实践活动，不断提升党员素质、保持党员先进性，增强党组织生活的感染力、吸引力、针对性和实效性，切实把学习成效转化为推动协会发展的强大力量。党支部全体党员同志积极参加“国资委行业协会学习贯彻党的十九届六中全会精神网络培训班”，认真按时完成学习任务，并获得培训班结业证书。

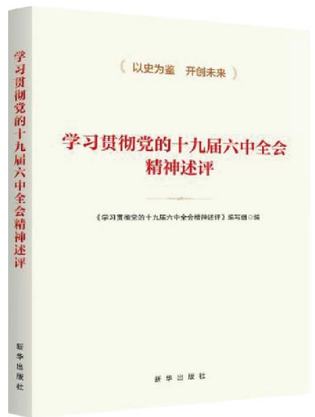
中国药促会党支部按上级党组织要求及统一部署，开展支部换届工作，将布局在服务高质量发展新篇章的党建工作不断优化升级。

Guided by the Xi Jinping Thought on Socialism with Chinese Characteristics in a New Era, the Party branch of PhIRDA has conscientiously and orderly carried out the Party building work, constantly improved the quality of Party members, maintained their advanced nature, enhanced the appeal, attraction, pertinence and effectiveness of the Party branch, and earnestly transformed the learning results into a powerful force to promote the development of PhIRDA through online and offline learning methods and practical activities with rich content and innovative forms. All Party members of the Party branch actively participated in the “State-owned Assets Supervision and Administration Commission (SASAC) Industry Association Learning and Implementing the spirit of the 6th Plenary Session of the 19th CPC Central Committee Network Training Class”, conscientiously completed the learning tasks on time, and obtained the training class completion certificate.

According to the requirements and unified deployment of the higher Party organization, the Party branch of PhIRDA has changed the term of office, and continuously optimized and upgraded the Party building work laid out in the new chapter of the development of high-quality services.

部分党员赴北大红楼参观学习
Some Party members visited and studied at Peking University Red Tower





深入学习贯彻习近平总书记重要讲话精神，坚定不移贯彻落实党中央重大决策部署
Thoroughly studied and implemented the principles of President Xi’s important speeches and unswervingly implemented the major decisions and plans of the CPC Central Committee

重点工作会议
Important Meetings

2022年会长会议扩大会议（2022年3月25日）
2022 PhIRDA President Board Meeting（March 25, 2022）

我会2021-2022年度会长李燕，执行会长宋瑞霖，副会长陈启宇、孙飘扬、丁列明、蒋建东、刘殿波、任晋生、柯尊洪、闫凯境、赵勇、张抒扬、吴晓滨，秘书长冯岚，监事蒋华良、邵蓉、舒畅，以及受邀副会长单位代表出席会议。**会议总结了十一届三次理事会以来的重点工作成果，并确定了2022年重点工作。**

2021-2022 Annual Chairman Li Yan, Executive President Song Ruilin, Deputy-Chairmen Chen Qiyu, Sun Piaoyang, Ding Lieming, Jiang Jiandong, Liu Dianbo, Ren Jinsheng, Ke Zunhong, Yan Kaijing, Zhao Yong, Zhang Shuyang, Wu Xiaobin, Secretary-General Feng Lan, Supervior Jiang Hualiang, Shao Rong, Shu Chang, and invited representatives of Vice-President members attended the meeting. **The meeting summarized the results of the work priorities since Third Meeting of the 11th Board of Directors and identified priorities for 2022.**

第十一届理事会第四次会议（2022年9月22日）
The 4th Meeting of the 11th Board of Directors (September 22, 2022)

我会会领导李燕、宋瑞霖、李佳、张抒扬、孙飘扬、丁列明、蒋建东、刘殿波、柯尊洪、闫凯境、赵勇、吴晓滨、冯岚，监事蒋华良、邵蓉、舒畅以及第十一届理事及理事代表等共70余人出席会议。

2021-2022年度会长李燕向理事会做工作报告并提出未来工作建议。会议选举中国科学院上海药物研究所所长李佳为中国医药创新促进会2022-2023年度会长，推选北京协和医院院长张抒扬为候任年度会长。与会代表围绕我会2022-2023年度重点工作展开讨论并达成共识。

More than 70 representatives attended the meeting, including PhIRDA leaders Li Yan, Song Ruilin, Li Jia, Zhang Shuyang, Sun Piao-yang, Ding Lieming, Jiang Jiandong, Liu Dianbo, Ke Zunhong, Yan Kaijing, Zhao Yong, Wu Xiaobin, Feng Lan, supervisors Jiang Hualiang, Shao Rong, Shu Chang and members and representatives of the 11th Board of Directors.

Li Yan, 2021-2022 Annual Chairman, delivered a work report to the Board of Directors and put forward suggestions for future work. The meeting elected Li Jia, Director of Shanghai Institute of Materia Medica, Chinese Academy of Sciences, as the 2022-2023 Annual Chairman, and elected Zhang Shuyang, President of Peking Union Medical College Hospital (PUMCH) as Chairman-elected. Participants discussed and reached consensus on the key work of PhIRDA in 2022-2023.

李燕 2021-2022年度会长
Li Yan, 2021-2022 Annual Chairman

李佳 2022-2023年度会长
Li Jia, 2022-2023 Annual Chairman

张抒扬 候任年度会长
Zhang Shuyang, Chairman-elected

会议现场
Plenary Meeting

品牌活动，精彩纷呈
Grand Activities, Fascinating and Wonderful

2021年中国罕见病大会（2021年12月18日-19日·北京）
2021 China Conference on Rare Diseases (December 18-19, 2021·Beijing)

2021年12月18日-19日，由国家卫生健康委、中国红十字会总会指导，中国罕见病联盟、中国红十字基金会、中国医药创新促进会、中国医院协会共同主办的“2021年中国罕见病大会”在北京举行。全国人大常委会副委员长、中国红十字会会长陈竺发来贺信，共和国勋章获得者、国家罕见病诊疗与保障专家委员会顾问钟南山院士，全国人大常委会科教文卫副主任委员、中国医院协会会长刘谦，国家药品监督管理局副局长陈时飞，国家医疗保障局副局长李滔，工业和信息化部副部长王江平，国家卫生健康委副主任李斌分别致辞。

大会以“因罕而聚，为爱同行”为主题，围绕罕见病防治与保障政策、药物创新与研发、临床诊疗、基础研究、真实世界研究和信息技术应用等主题开展研讨和交流，助力我国罕见病防治与保障事业迈上新台阶，受到了社会各界的广泛关注。

On December 18, 2021, guided by the National Health Commission (NHC) and the Red Cross Society of China (RCSC), hosted by China Alliance for Rare Diseases (CARD), the Chinese Red Cross Foundation, Chinese Hospital Association and PhIRDA, the 2021 China Conference on Rare Diseases (CCRD) was held in Beijing. Chen Zhu, Vice Chairman of the Standing Committee of the NPC, and President of RCSC, sent a congratulatory letter to CCRD. Academician Zhong Nanshan, winner of the Medal of the Republic and consultant of the National Committee of Experts on the Diagnosis, Treatment and Guarantee of Rare Diseases, Liu Qian, Deputy Director of Science, Education, Culture and Health of the Standing Committee of the NPC and President of the Chinese Hospital Association, Wang Jiangping, Vice Minister of the Ministry of Industry and Information Technology, Li Bin, Deputy Director of NPC, Chen Shifei, Deputy Commissioner of NMPA, Li Tao, Deputy Director of the National Healthcare Security Administration and other relevant leaders attended CCRD and delivered speeches.

With the theme of “Gathered by Rare Diseases and Work Together for Love”, participants discussed topics including rare diseases prevention and control and security policy, drug innovation and research and development, basic research, clinical diagnosis and treatment, research and real world application of information technology, so as to promote rare diseases prevention and control and security in our country to a new level, receiving widespread attention from all walks of life.

2022中国医药创新政策论坛（2022年7月23日·济南）
2022 China Pharmaceutical Innovation Policy Forum (July 23, 2022·Jinan)

2022年7月23日，由我会医药政策专业委员会和艾美达医药咨询共同主办的“2022中国医药创新政策论坛”在山东济南召开。本届论坛以“医药创新生态　新阶段与新征程”为主题，邀请了20多位来自政府相关部门人员及医保、医药卫生管理、药学、药物经济学专家学者与产业界企业代表，共同围绕医药创新发展趋势、政策导向、创新药价值等热点问题展开深入探讨。

On July 23, 2022, the 2022 Forum on China’s Pharmaceutical Innovation Policies, co-hosted by PhIRDA Medicinal Policy Specialty Committee and iMeta, was successfully held in Jinan, Shandong Province. Themed with “New Ecology, New Stage and New Journey of Pharmaceutical Innovation”, the forum invited senior officials from regulatory agencies, experts and scholars in medical insurance, pharmacy and pharmaceutical economics, and representatives of enterprises in the industry conducted in-depth discussions on hot issues including the development trend of pharmaceutical innovation, policy orientation and the value of innovative drugs.


胡　欣 Hu Xin

中国药促会医药政策专委会主任委员、北京医院药学部主任医师、首席专家
Chairman of PhIRDA Medicinal Policy Specialty Committee, Chief Pharmacist & Chief Expert of Beijing Hospital Pharmacy Department


方来英 Fang Laiying

全国政协委员、中国医院协会副会长
Member of the National Committee of CPPCC, Vice-President of Chinese Hospital Association


何如意 He Ruyi

中国药促会国际创新药物监管委员会主任委员、荣昌生物首席医学官、国投创新医疗健康首席科学家
Chairman of PhIRDA International Regulatory Science Specialty Committee, CMO of RemeGen, CSO of SDIC


会议现场 Plenary Meeting

上海合作组织医药合作发展大会（2022年9月8日·北京）

Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference (September 8, 2022·Beijing)

由上海合作组织睦邻友好合作委员会、上海合作组织秘书处、乌兹别克斯坦共和国驻华使馆和我会共同主办的“上海合作组织医药合作发展大会”于9月8日在京召开。本次大会是上合组织成员国家首次在上合组织框架下举办的医药领域合作会议，是加强上合组织国家间医药卫生领域交流的重要平台，对未来上合组织内建立紧密的合作关系具有重要意义。

Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference, co-hosted by Good-Neighborliness, Friendship and Cooperation Committee of the Shanghai Cooperation Organization, Secretariat of the Shanghai Cooperation Organization, Embassy of the Republic of Uzbekistan in the People's Republic of China, and China Pharmaceutical Innovation and Research Development Association, was successfully held in Beijing, China on September 8, 2022. As the first conference in pharmaceutical industry under the framework of the Shanghai Cooperation Organization, the conference built a platform for cooperation and exchange of pharmaceutical and healthcare industry, being of great significance to promote close cooperation within the Shanghai Cooperation Organization.

致辞
Remarks

崔　丽
上合组织睦邻友好合作委员会副主席
Cui Li, Vice-President of the Good-Neighborliness, Friendship and Cooperation Committee of the Shanghai Cooperation Organization

阿尔济耶夫
乌兹别克斯坦共和国驻华大使
Farhod Arziev, Ambassador of Republic of Uzbekistan to China

宋瑞霖
中国医药创新促进会执行会长
Song Ruilin, Executive President of PhIRDA

张　明
上合组织秘书长
Zhang Ming, Secretary-General of Shanghai Cooperation Organization

伊尔霍姆·乌拉洛夫
乌兹别克斯坦共和国驻华使馆临时代办
Ilkhom Uralov, Charge d'affaires of Republic of Uzbekistan to China

上合组织国家监管、医药产业界代表汇聚一堂

Representatives from Regulatory and Pharmaceutical Industries of SCO Countries Gather Here

“加强国际医药产业合作、推动上合框架下的药品监管互认”主题讨论
Panel Discussion under the Topic of “Strengthen International Cooperation in Pharmaceutical Industry and Promote Mutual Recognition of Drug Regulation”

《推动建立上合组织框架下医药产业合作倡议》发布仪式
Announcing Ceremony of the *Initiative to Promote and Establish Pharmaceutical Industry Cooperation under the Framework of the Shanghai Cooperation Organization*

参会嘉宾合影
Group Photo of Guests

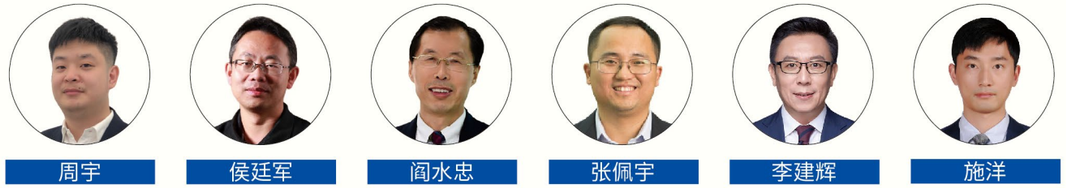
“医药创新说”系列主题直播（2022年5月-8月）
Series theme Live Streams of “Pharmaceutical Innovation”

2022年5月以来，我会多个专业委员会聚焦当前医药创新全链条堵点问题及行业热点重磅话题，组织策划了多场包括多组学和人工智能等现代技术手段、药械创新跨界融合、资本市场多层次改革助力药械产业高质量发展、创新药出海、国际多中心临床和生物样本活库促进新药研发成果转化等主题的“医药创新说”线上直播活动，并联合相关合作单位和知名媒体进行全方位的宣传报道和推流转播。“医药创新说”的强势回归再度引发业界的高度关注和社会各方的好评认可，视频直播及回放累计观看近13万人次，累计曝光21余万次。

Since May 2022, several specialty committees of PhIRDA, focusing on blocking points in the whole chain of pharmaceutical innovation and hot topics in the industry, having organized several online live streams on topics including multiple omics, artificial intelligence and modern technology means, cross-border integration of innovation in pharmaceutical and equipment industry, and the development facilitated by multi-level capital market reform, “go global” of innovative drugs, international multi-national clinical and biobank repository promoted the transformation of new drug research and development, and cooperated with relevant cooperative units and well-known media to carry out a full range of publicity and broadcast. The strong return of “Pharmaceutical Innovation” has once again aroused high concern of the industry and the praise and recognition of all parties in the society. The total number of people watching the online live streams and replays is nearly 130,000, and the total exposure is more than 210,000 times.

2022年“医药创新说”嘉宾
Speakers of 2022 "Pharmaceutical Innovation" Live Streams


胡志斌 梁晗 张伟 邹灵龙 黄晓莉 唐艳旻


周宇 侯廷军 阎水忠 张佩宇 李建辉 施洋


薛冰 王亚宁 吴一龙 杨大俊 李进 宋瑞霖


苏慰国 周彩存 柴柯辰 李凯军 吴玉九 黄国滨


梁颖宇 闻丹忆 张太平 朱畴文 朱明华

政策研究，发挥高端智库作用
Conduct Policy Research and Leverage the Role of High-end Think Tank

高质量完成政府委托项目
Completed Government Commissioned Projects with High Quality

科技部重大专项司委托我会开展“新药创制重大专项骨干企业创新能力评估”课题研究项目

Completed the project of “Evaluation of Innovation Ability of Key Enterprises of Major Special Project of New Drug Research and Development” commissioned by the Department of Major Science and Technology Project of the Ministry of Science and Technology (MoST)

为持续深入实施国家创新驱动发展战略提供智力支持，科学定位创新主体活力与水平，我会运用科学评估方法，并建立客观科学的评价体系，对本土企业创新能力进行全面梳理、分析与评价，评估结果全面且客观地反映我国现阶段医药创新潜能以及面临的挑战。课题研究成果受到政府部门领导及行业专家的高度认可和肯定。

In order to provide a theoretical basis and intellectual support for continuous and in-depth implementation of the national pharmaceutical innovation strategy, determine the vitality and level of innovative bodies, PhIRDA adopted a scientific evaluation method and a complete evaluation system comprehensively sorted out, analyzed and evaluated the innovation capability of domestic enterprises; the evaluation results comprehensively and objectively reflected the potential and challenges of pharmaceutical innovation in China at this stage. The research findings were highly recognized and affirmed by MoST and industry experts.

北京市卫生健康委员会委托我会开展“北京市研究型病房项目评估”工作

Beijing Municipal Health Commission (BHC) commissioned PhIRDA to conduct the Beijing Research-oriented Ward Evaluation Project

我会对北京市首批10家研究型病房建设示范单位展开评估，组建了来自协会、医院、企业多方，涵盖医药产业政策、医院管理、临床研究、科研管理、产业代表的评估专家组，通过对标先进国家研究型医院建设经验，充分分析首都的经济、政策、医疗等系统环境，对目标单位的主要建设成效进行综合评价，有针对性地提出若干政策建议。北京市卫健委相关领导对评估工作和研究成果给予高度肯定，并以此制定北京市研究型医院及研究型病房进一步改革的行动方案征求意见稿。

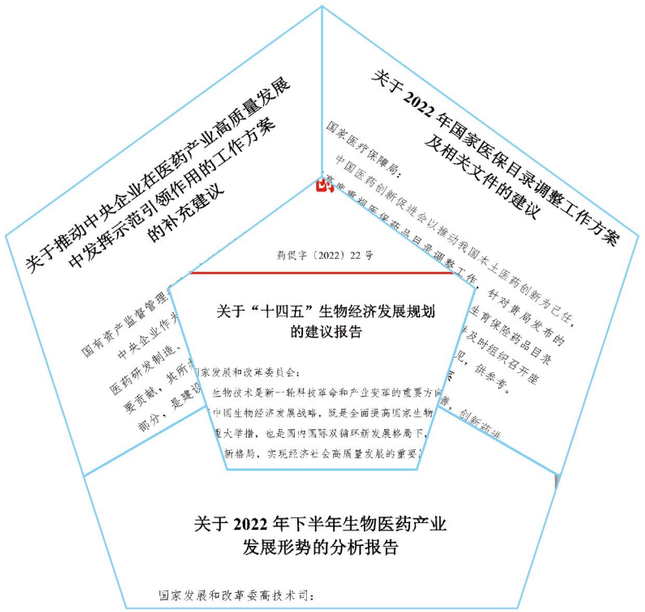
In order to better build research-oriented wards and drive the innovative development of pharmaceutical industry with high-level clinical research, PhIRDA evaluated the first 10 demonstration units for research-oriented ward construction in Beijing, established an evaluation expert group consisting of experts in pharmaceutical industry policies, hospital management, clinical research and scientific research management and industry representatives from industry associations, hospitals and enterprises. In accordance with the experience on constructing research-oriented hospitals of advanced countries, the group fully analyzed the economic, policy, medical and other system environments of the capital city, comprehensively evaluated the main construction achievements of target units, and put forward several policy recommendations in a targeted manner. The relevant leaders of BHC highly affirmed the evaluation work and research findings, and formulated an action plan for further reform (draft for comments) of Beijing’s research-oriented hospitals and research-oriented wards based on the research.

积极建言献策

Actively Offer Advice

围绕我国医药政策与医药产业发展相关热点、堵点问题，深入开展研究，向国家和政府有关部门提出适合我国国情、符合行业发展需求的可操作性意见和建议，助力医药行业高质量创新发展。

Based on hot topics and blocking problems related to the pharmaceutical policy and the pharmaceutical industry development, PhIRDA conducted in-depth research to put forward feasible opinions and suggestions suitable to China's national conditions and meet the development needs of the pharmaceutical industry to help the high-quality innovative development of the pharmaceutical industry.



中国医药创新促进会

关于强化药品监管能力，推动创新药高质量发展的建议

针对国际社会对中国临床数据的质疑之声紧急召开座谈会并提交相关建议

In response to the international community's doubts about China's clinical data, an urgent symposium was held and relevant suggestions were submitted.

贡献专家智慧

Contribute Expert Wisdom

我会入选的专家名单
Selected PhIRDA Experts


陈凯先院士


王广基院士


张伯礼院士


蒋建东院士


肖伟院士


宋瑞霖执行会长

国家药监局成立中药管理战略决策专家咨询委员会，我会医药创新科学委员会主任陈凯先院士、委员王广基院士，第十届会员大会副会长张伯礼院士，协会副会长、2017-2018年度会长蒋建东院士，会员单位江苏康缘药业股份有限公司董事长肖伟院士以及执行会长宋瑞霖入选。

NMPA announced the establishment of the Expert Advisory Committee for Strategic Decision Making of Traditional Chinese Medicine Management, and several experts of PhIRDA were selected to join the Expert Advisory Committee, including Director and Member of the Pharmaceutical Innovation Scientific Committee of PhIRDA, Academician Chen Kaixian, Academician Wang Guangji, Academician Zhang Boli, Vice President of the 10th General Assembly of PhIRDA, Academician Jiang Jiandong, Vice President and 2017-2018 Annual Chairman, Academician Xiao Wei, Chairman of PhIRDA member Jiangsu Kanion Pharmaceutical, and PhIRDA Executive President Song Ruilin.

发表重要研究成果
Publish Important Research Findings

中国药促会、RDPAC共同召开《构建中国医药创新生态系统（2021-2025）》报告发布会

PhIRDA and RDPAC jointly held the press conference of the report *Building China's Pharmaceutical Innovation Ecosystem (2021-2025)*

发表文章《中国医药创新面临的挑战及其应对》

通过发表学术文章，使研究成果能够为政策制定提供科学依据和有价值的参考，共建完善的医药创新生态系统。

Publish the article *Challenges to China's Pharmaceutical Innovation and Its Response*

By publishing academic articles, the research findings were leveraged to provide scientific basis and valuable reference for policy making and build a better pharmaceutical innovation ecosystem.

我会抗肿瘤药物临床研究专业委员会发布《2021年度中国抗肿瘤新药临床研究评述》

围绕当前潜力靶点机制、国内研发现状进行全面阐述，给出学术简评。一方面引导投资人和研发机构合理投入研发资源，避免同质化研发造成资源挤兑；另一方面呼吁相关主体关注填补临床空白、满足患者临床需求的相关领域，合理配置新药研发资源，构建可持续发展的良性药械创新生态环境。

PhIRDA Clinical Research on Oncology Drugs Specialty Committee issued the *2021 Review of Clinical Research on New Anti-tumor Drugs in China*

Based on the current potential target mechanism and current status of domestic research and development, a brief academic review was conducted. On the one hand, investors and R&D institutions were guided to invest R&D resources rationally to avoid resource crowding caused by homogenized R&D. On the other hand, it called on relevant bodies to pay attention on the fields related to filling the clinical gaps and meeting the clinical needs of patients, rationally allocating new drug research and development resources, and building a good ecological environment for sustainable development of pharmaceutical and equipment innovation.

商业保险专题出版

我会参与中国发展研究基金会(CDRF)课题，就商业保险专题撰写《商业健康险与医药产业的融合发展》课题研究报告，相关书籍《“十四五”时期商业健康保险发展研究》已正式出版。

Commercial Insurance Special Publication

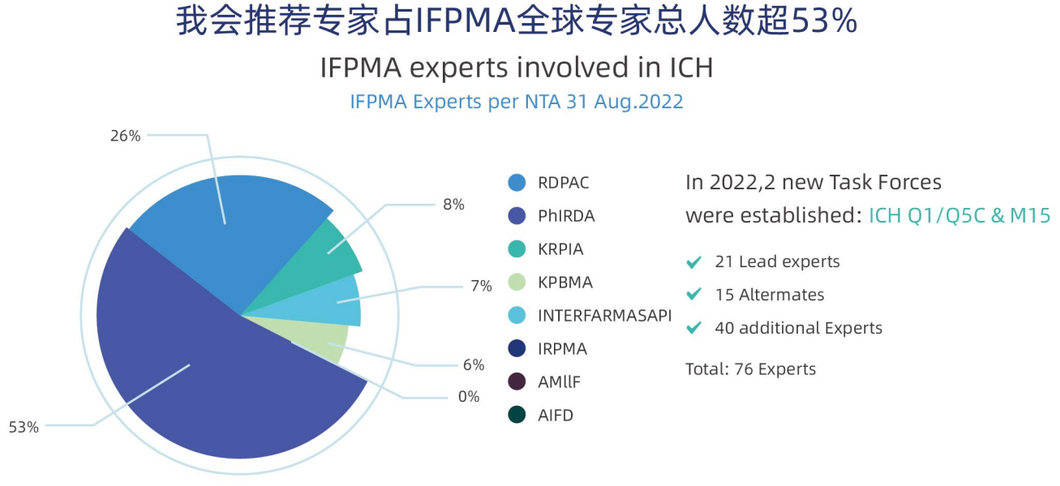
PhIRAD participated in China Development Research Foundation (CDRF) project, and wrote the report *Integrated Development of Commercial Health Insurance and Pharmaceutical Industry*. Relevant book *Building China's Pharmaceutical Innovation Ecosystem (2021-2025)* is now official published.

国际交流
International Events

积极参与国际规则制定
Actively Participate in International Rule-making

我会积极组织专家开展与国际接轨的药品监管标准、政策等研究与制定工作，推动ICH指导原则转化实施。截至2022年9月30日，IFPMA官网信息显示：我会已向IFPMA 21个ICH工作组推荐43名专家（包括14名组长，9名候补组长），推荐的专家在IFPMA全球专家总人数中占比超过53%。

PhIRDA 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. According to IFPMA's official website, as of September 30, 2022, PhIRDA has recommended 43 experts (including 14 Leaders and 9 Alternate Leaders) to 21 Task Force of the IFPMA, accounting for more than 53% of the total number of IFPMA experts worldwide.



中国药促会IFPMA ICH专家工作组组长名单
PhIRDA IFPMA ICH EWG Leaders List

1	Q1/Q5C: Targeted Revisions of the Stability Guideline Series	赵孝斌 ZHAO Xiaobin 浙江海昶生物医药有限公司创始人、总裁 Founder & President of Zhejiang Haichang Biotech Co., Ltd.
2	Q2(R2)/Q14：分析方法验证/分析方法开发 Q2(R2)/Q14: Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation	徐菊芳 XU Jufang 长风药业股份有限公司分析总监 Analytical Director, CF PharmTech, Inc.
3	Q5A(R2)：来源于人或动物细胞系的生物技术产品的病毒安全性评价 Q5A(R2): Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin	巩 威 GONG Wei 上海复宏汉霖生物技术股份有限公司副总经理 Deputy General Manager, Shanghai Henlius Biotech. Inc.
4	Q9(R1)：质量风险管理 Q9(R1): Quality Risk Management	屠志浩 TU Zhihao 再鼎医药（上海）有限公司GxP质量副总裁 Vice President, MAH Quality Responsible Person, Zai Laboratory
5	S12：基因治疗产品的非临床生物分布研究 S12: Non-clinical Biodistribution Studies for Gene Therapy Products	许 田 XU Tian 上海复星医药（集团）股份有限公司首席科学顾问 Chief Scientific Advisor, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.
6	E2D(R1)：上市后安全性数据的管理：快速报告的定义和标准 E2D(R1): Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting	孟 渊 MENG Yuan 天境生物科技（上海）有限公司医学办公室负责人 Head of Medical Office, I-Mab Biopharma Co., Ltd.
7	E8：临床试验的一般性考虑 E8: Revision of General Considerations for CT	闫 慧 YAN Hui 缔脉生物医药科技（上海）有限公司原监管与战略高级副总裁 Former Senior Vice President Regulatory Affairs & Strategy, dMed Biopharmaceutical Co., Ltd.

中国药促会IFPMA ICH专家工作组组长名单
PhIRDA IFPMA ICH EWG Leaders List

8	E11A：儿科外推 E11A: Pediatric Extrapolation	史 军 SHI Jun 启元生物（杭州）有限公司首席医学官 Chief Medical Officer, E-nitiate Biopharmaceuticals (Hangzhou) Co.,Ltd.
9	E17：多区域临床试验计划与设计的一般原则 E17: General Principles for Planning and Design of Multi-Regional Clinical Trials	吴一龙 WU Yilong 广东省人民医院首席专家 Chief Expert, Guangdong Provincial People's Hospital
10	E19：安全性数据收集的优化 E19: Optimisation of Safety Data Collection	张 丹 ZHANG Dan 昆翎医药首席战略官 Chief Strategy Officer, ClinChoice, Inc.
11	M11：结构化统一临床电子方案 M11: Clinical electronic Structured Harmonized Protocol (CeSHarP) Opportunity for Discussion Purposes	王兴河 WANG Xinghe 首都医科大学附属北京世纪坛医院《国家药物与医疗器械临床试验机构》办公室主任、兼药物I期临床试验办公室主任 Chief Physician/Professor, Director of General Office of National Drug & Medical Device Clinical Trial Institute, Director of Phase I Clinical Trial Center, Beijing Shijitan Hospital, Capital Medical University
12	M12：药物相互作用研究 M12: Drug Interaction Studies	陶晓路 TAO Xiaolu 和铂医药（苏州）有限公司转化与早期开发高级副总裁 Senior Vice President of Translational Development & Portfolio Management, Harbour BioMed (Suzhou) Co., Ltd.
13	M13：普通口服固体制剂的生物等效性 M13: Bioequivalence for Immediate-Release Solid Oral Dosage Forms	王志云 WANG Zhiyun 再鼎医药（上海）有限公司小分子药学高级副总裁 Senior Vice President, Small Molecule CMC, Zai Laboratory
14	M14: General Principles on Planning and Designing Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of A Medicine	王存林 WANG Cunlin 苏州亚盛药业有限公司安全和药物警戒副总裁 Vice President, Safety & Pharmacovigilance, Ascentage Pharma Group Corp. Ltd.

首届亚洲医疗健康高峰论坛（2021年11月24日·香港）

1st Asia Summit on Global Health (24 November, 2021, Hong Kong)

2021年11月24日，由我会作为重要战略合作伙伴支持、香港特区政府及香港贸易发展局合办的“首届亚洲医疗健康高峰论坛”在港举行。与会代表就全球在公共卫生、医疗科技、国际商贸合作及投资等方面的最新情况进行深入交流，共同探讨全球医疗健康新趋势、后疫情时代相关产业的政策法规，探索医疗、科技和公共卫生等领域的合作商机。

On 24 November 2021, the 1st Asia Summit on Global Health, co-hosted by the Hong Kong Special Administrative Region Government and the Hong Kong Trade Development Council (HKTDC), supported by PhIRDA as an important strategic partner, was held in Hong Kong. The participants conducted in-depth exchanges on the latest developments in global public health, medical science and technology, international business cooperation and investment, discussed new trends in global healthcare, policies and regulations of relevant industries in the post-pandemic era, and explored business opportunities for cooperation in medical, science and technology and public health.

合影留念（左：宋瑞霖 右：张明）
Photograph (Left: Song Ruilin, right: Zhang Ming)

宋瑞霖执行会长拜访上海合作组织秘书长张明（2022年4月12日·北京）

PhIRDA Executive President Song Ruilin met with Secretary-General of the Shanghai Cooperation Organization Zhang Ming (April 12, 2022, Beijing)

中日邦交正常化50周年纪念活动之“中日医药交流活动”（2022年9月29日·中国和日本）

The “China-Japan Pharmaceutical Exchange Activity” commemorating the 50th anniversary of the normalization of China-Japan diplomatic relations. (September 29, 2022, China and Japan)

我会受邀参加中日邦交正常化50周年纪念活动之“中日医药交流活动”，宋瑞霖执行会长作了题为“中日医药产业发展新机遇”的主旨报告。中日两国药品监管机构、行业协会及相关临床机构及企业的广泛深入交流，能够有力促进两国药品监管机构合作和医药产业高质量发展，为增进中日两国人民健康福祉发挥积极作用。

PhIRDA was invited to participate in the “China-Japan Pharmaceutical Exchange Activity” commemorating the 50th anniversary of the normalization of China-Japan diplomatic relations. Executive President Song Ruilin delivered a keynote speech entitled “New Opportunities for the Development of China-Japan Pharmaceutical Industry”. Representatives from Chinese and Japanese drug regulatory agencies, industry associations, and relevant clinical institutions and enterprises conducted extensive and in-depth exchanges, effectively promoting the cooperation between the two countries’ drug regulatory agencies and high-quality development of the pharmaceutical industry, playing a positive role in improving the health and well-being of the Chinese and Japanese people.

交流活动东京现场
Meeting in Tokyo

大事记

REMARKABLE EVENTS

中国医药创新促进会大事记（2021年10月-2022年9月）

2021年 10月

10月29日

我会与RDPAC共同召开《构建中国医药创新生态系统（2021-2025）》报告发布会。

2021年 11月

11月6日

我会与国家卫生健康委国际交流与合作中心共同主办的进博会平行论坛——第四届虹桥国际健康科技创新论坛在上海举行。

11月24日

由我会作为重要战略合作伙伴支持、香港特区政府及香港贸易发展局合办的“首届亚洲医疗健康高峰论坛”召开。

2021年 12月

12月17日

我会糖尿病与代谢性疾病药物临床研究专业委员会第一届第二次工作会议召开。

12月18日

由国家卫生健康委、中国红十字会总会指导，中国罕见病联盟与我会共同主办的2021年中国罕见病大会在北京举行。

由我会和亚盛医药共同主办的“重大新药创制”专项成果发布暨耐立克全球首发上市会在苏州召开。

2022年 1月

1月26日

思路迪（北京）医药科技有限公司、江苏康宁杰瑞生物制药有限公司、北京大钲管理咨询有限公司、杭州泰格医药科技股份有限公司、北京海金格医药科技股份有限公司、北京无疆脑智科技有限公司、江苏品生医疗科技集团有限公司、普瑞基准科技（北京）有限公司、推想医疗科技股份有限公司和北京镁伽机器人科技有限公司加入我会。

2022年 2月

2月16日

我会针对国际社会对中国临床数据的质疑之声紧急组织召开“中国新药研发临床数据管理”座谈会，并提交《关于强化药品监管能力，推动创新药高质量发展》建议至有关部门。

2022年 3月

3月5日

我会脑神经药物临床研究专业委员会召开“AI辅助神经重症监护课题”专家论证会。

3月10日

我会政策研究中心在《医学与哲学》发表文章《中国医药创新面临的挑战及其应对》，助力中国医药应对创新挑战。

3月24日

我会与北爱尔兰投资发展署共同主办的“英国北爱尔兰生命与健康科学行业研讨会”召开。

3月25日

中国医药创新促进会2022年会长会议召开。

2022年 4月

4月12日

宋瑞霖执行会长拜访上海合作组织秘书长张明。

2022年 5月

5月5日

武汉滨会生物科技股份有限公司、无锡智康弘义生物科技有限公司、上海联拓生物科技有限公司和滬港中科国际生物科技有限公司加入我会。

5月13日

我会抗肿瘤药物临床研究专业委员会发布《2021年度中国抗肿瘤新药临床研究评述》。

5月20日

2022年“医药创新说”系列主题线上直播拉开序幕，首期活动由我会医药数字化及创新疗法专业委员会（筹）主办，主题为“多组学技术与医药创新跨界融合新机遇”。

5月27日

我会医药创新投资专业委员会主办的“医药创新说——科创板助力生物医药产业高质量发展”线上召开。

2022年 6月

6月10日

我会医药数字化及创新疗法专业委员会（筹）主办的“医药创新说——人工智能与药物研发跨界融合新机遇”线上召开。

6月14日

我会向国家发展和改革委员会递交《关于“十四五”生物经济发展规划的建议报告》。

6月15日

我会医药企业合规专业委员会联合中国药科大学药品监管科学研究院、中国医药报社共同主办的“紫金医药合规论坛”系列线上活动召开，第一期主题为“药品研发注册合规专题”。

6月17日

我会医药创新投资专业委员会主办的“医药创新说——创业板助力生物医药产业高质量发展”线上召开。

6月24日

我会药物临床试验专业委员会、国际创新药物监管专业委员会、药物研发专业委员会和抗肿瘤药物临床研究专业委员会联合主办的“医药创新说——疫情和创新药出海背景下的临床试验策略：新形势、新进展与新方法”线上召开。

6月27日

我会向国家发展和改革委高技术司递交《关于2022年下半年生物医药产业发展形势的分析报告》。

6月28日

我会医药创新科学委员会主任陈凯先院士、委员王广基院士，第十届会员大会副会长张伯礼院士，我会副会长、2017-2018年度会长蒋建东院士，会员单位江苏康缘药业股份有限公司董事长肖伟院士以及执行会长宋瑞霖入选国家药品监督管理局中药管理战略决策专家咨询委员会，为推动中药科学监管贡献力量。

6月29日

我会抗肿瘤药物临床研究专业委员会与药物研发专业委员会联合主办的“医药创新说——如何提升国产新药创新水平”线上召开。

6月30日

由我会支持、新加坡经济发展局主办的“中国生物医药产业东盟市场发展研讨会”召开。

2022年 7月

7月1日

我会医药创新投资专业委员会主办的“医药创新说——北交所助力生物医药产业高质量发展”线上召开。

7月8日

我会医药创新投资专业委员会主办的“医药创新说——医疗健康产业创新与投资展望”线上召开。

7月15日

“紫金医药合规论坛”系列线上活动第二期召开，主题为“医疗机构药物临床试验与使用合规专题”。

7月23日

我会医药政策专业委员会主办的“2022中国医药创新政策论坛”在山东济南召开。

2022年 8月

8月11日

我会受北京市卫生健康委员会委托，完成首批10家研究型病房示范单位评估工作。

由我会支持、香港交易所主办的“2022年香港交易所生物科技峰会”召开。

8月12日

我会受科技部重大专项司委托的“新药创制重大专项骨干企业创新能力评估”课题研究项目完成结题。

启明维创创业投资管理（上海）有限公司当选我会第十一届理事单位；中国科学院新疆理化技术研究所、上海银诺医药技术有限公司、启元生物（杭州）有限公司、源健优科生物科技（上海）有限公司、浙江健新原力制药有限公司、杭州瑞普基因科技有限公司、江苏先声医学诊断有限公司、上海腾迈医药科技有限公司和华盖医疗投资管理（北京）有限公司加入我会。

8月15日

“紫金医药合规论坛”系列线上活动第三期召开，主题为“药品注册核查与合规专题”。

8月18日

我会会同烟台市政府等机构主办的“2022医药创新与发展国际会议”在山东烟台召开。

8月23日

2022年部分会员单位联络秘书工作会议召开。

8月27日

我会创新研发服务专业委员会主办的“医药创新说——建好、用好生物样本活库，为新药研发转化增速、增效”线上召开。

8月31日

截至8月31日，IFPMA官网信息显示：我会已向IFPMA　21个ICH工作组推荐43名专家，推荐的专家在IFPMA全球专家总人数中占比超过53%。

2022年 9月

9月8日

由中国医药创新促进会、上海合作组织睦邻友好合作委员会、上海合作组织秘书处、乌兹别克斯坦共和国驻华使馆共同主办的“上海合作组织医药合作发展大会”在北京召开。

9月15日

“紫金医药合规论坛”系列线上活动第四期召开，主题为“药品生产质量合规专题”。

9月22日

我会第十一届理事会第四次会议召开，中国科学院上海药物研究所所长李佳当选2022-2023年度会长，推选北京协和医院院长张抒扬为候任会长。

杭州畅溪制药有限公司、远森制药（北京）有限公司、正序（上海）生物科技有限公司、华东医药股份有限公司、山西锦波生物医药股份有限公司、深圳华大基因股份有限公司、南京普济生物有限公司、上海微创电生理医疗科技股份有限公司、江苏德威兰医疗器械股份有限公司、上海碧博生物医药工程有限公司加入我会。

9月29日

我会受邀参加中日邦交正常化50周年纪念活动之“中日医药交流活动”。

Remarkable Events of PhIRDA (October, 2021 - September, 2022)

2021 Oct.

October 24

PhIRDA jointly held the press conference with RDPAC on the report “Building China’s Pharmaceutical Innovation Ecosystem (2021-2025)”.

2021 Nov.

November 6

The 4th Hongqiao International Health Technology Innovation Forum, co-hosted by PhIRDA and International Health Exchange and Cooperation Center NHC PRC (IHECC), was successfully held on the China International Import Expo (CIIE) in Shanghai.

November 24

The 1st Asia Summit on Global Health, co-hosted by the HKSAR Government and the Hong Kong Trade Development Council (HKTDC), and supported by PhIRDA as an important strategic partner, was successfully held.

2021 Dec.

December 17

The Second Meeting of the 1st PhIRDA Clinical Research on Diabetes and Metabolic Diseases Specialty Committee was successfully held.

December 18

2021 China Conference on Rare Diseases, guided by National Health Commission (NHC) and the Red Cross Society of China (RCSC), and co-hosted by China Alliance for Rare Diseases (CARD) and PhIRDA, was successfully held in Beijing.

The “Major New Drug Research and Development” Special Achievement Release, as well as the global debut of Olverembatinib, co-hosted by PhIRAD and Ascentage Pharma, was successfully held in Suzhou.

2022 Jan.

January 26

3D Medicines, Alphamab Oncology, Centurium Capital, Tigermed, Highthinkmed, IBT, Qlife, Precision Scientific, Infer Vision, Megarobo joined PhIRDA.

2022 Feb.

February 16

In response to the voices of the international community questioning Chinese clinical data, PhIRDA urgently organized a symposium on “Clinical Data Management of New Drug Research and Development in China”, and submitted suggestions on “Strengthening Drug Supervision Capacity and Promoting High-quality Development of Innovative Drugs” to relevant departments.

2022 Mar.

March 5

The expert argumentation meeting of “AI-assisted Neurological Intensive Care Project” was successfully held by PhIRDA Clinical Research on Cranial Nerve Drugs Specialty Committee.

March 10

PhIRDA Center for Policy Research published the article *Challenges to China's Pharmaceutical Innovation and Its Response* in the journal *Medicine and Philosophy*, helping Chinese pharmaceutical deal with innovation challenges.

March 24

Northern Ireland Life and Health Sciences Industry Seminar, co-hosted by PhIRDA and Invest NI, was successfully held.

March 25

Meeting of 2022 PhIRDA Presidents Board was successfully held.

2022

Apr.

April 12

Executive President Song Ruilin met with SCO General-Secretary Zhang Ming.

2022

May

May 5

Binhui Biopharm, Biocitypharma, LianBio, and ZSHK Laboratories Limited joined PhIRDA.

May 13

PhIRDA Clinical Research on Oncology Drugs Specialty Committee issued *2021 Review of Clinical Research on New Anti-tumor Drugs in China*.

May 20

2022 series of themed online live streams "Pharmaceutical Innovation" was kicked off. The first one was hosted by PhIRDA Digital Medicine and Innovative Therapy Specialty Committee (preparatory) with the theme "New Opportunities for Cross-boundary Integration of Multi-omics Technology and Medicine Innovation".

May 27

"Pharmaceutical Innovation—SSE STAR Market Promotes High-quality Development of Biomedical Industry", hosted by PhIRDA Pharmaceutical Innovation Investment Specialty Committee, was held virtually.

2022

Jun.

June 10

"Pharmaceutical Innovation--New Opportunities for Cross-boundary Integration of AI and Drug R&D", hosted by PhIRDA Digital Medicine and Innovative Therapy Specialty Committee (preparatory), was held virtually.

June 14

PhIRDA submitted *Proposal Report on the 14th Five-Year Plan for Bioeconomy Development* to the National Development and Reform Commission.

June 15

"Zijin Pharmaceutical Compliance Forum", a series of online activities, hosted by PhIRDA Ethics and Business Compliance Specialty Committee, the Institute of Pharmaceutical Regulatory Sciences of China Pharmaceutical University and China Pharmaceutical News Agency, was successfully held virtually. The topic of the 1st Phase was "Drug R&D Registration Compliance".

June 17

"Pharmaceutical Innovation--ChiNext Promotes High-quality Development of Biomedical Industry", hosted by PhIRDA Pharmaceutical Innovation Investment Specialty Committee, was held virtually.

June 24

"Pharmaceutical Innovation--Clinical Trial Strategies under the Circumstances of Epidemic and Innovative Drug Go Global: New Situation, New Progress and New Method", hosted by PhIRDA Specialty Committees of Drug R&D, Clinical Trial Research, International Regulatory Science and Clinical Research on Oncology Drugs, was held virtually.

June 27

PhIRDA submitted the *Analysis Report on the Development Situation of the Biomedical Industry in the Second Half of 2022* to the Department of Innovation and High-Tech Development, the National Development and Reform Commission.

Academician Chen Kaixian, Director of PhIRDA Pharmaceutical Innovation Scientific Committee, Academician Wang Guangji, Member of PhIRDA Pharmaceutical Innovation Scientific Committee , Academician Zhang Boli, Vice President of the 10th General Assembly of PhIRDA, Academician Jiang Jiandong, Vice President and PhIRDA Annual Chairman of 2017-2018, Academician Xiao Wei, Chairman of PhIRDA Member Jiangsu Kanion Pharmaceutical, and Executive President Song Ruilin were selected to join the Expert Advisory Committee for Strategic Decision Making of Traditional Chinese Medicine Management, NMPA.

June 29

"Pharmaceutical Innovation--How to Improve the Innovation Level of Domestic New Drugs", co-hosted by PhIRDA Drug R&D Specialty Committee and Clinical Research on Oncology Drugs Specialty Committee, was held virtually.

June 30

Seminar on the Development of China's Biopharmaceutical Industry in ASEAN Market, hosted by Singapore Economic Development Board (EDB), supported by PhIRDA, was successfully held.

2022

Jul.

July 1

"Pharmaceutical Innovation--Beijing Stock Exchange Promotes High-quality Development of Bioeconomy", hosted by PhIRDA Pharmaceutical Innovation Investment Specialty Committee, was held virtually.

July 8

"Pharmaceutical Innovation--Innovation and Investment Outlook of Medical and Healthcare Industry", hosted by PhIRDA Pharmaceutical Innovation Investment Specialty Committee, was held virtually.

July 15

The 2nd Phase of "Zijin Pharmaceutical Compliance Forum" series of online activities with the topic of Compliance of Drug Clinical Trials and Use in Medical Institutions, was held virtually.

July 23

2022 China Pharmaceutical Innovation Policy Forum, hosted by PhIRDA Medicinal Policy Specialty Committee, was successfully held in Jinan, Shandong.

2022

Aug.

August 11

Entrusted by Beijing Municipal Health Commission, PhIRDA evaluated the first 10 demonstration units for research-oriented ward construction in Beijing.

Biotech Summit 2022, hosted by HKEX and supported by PhIRDA, was successfully held.

August 12

Entrusted by the Department of Major Science and Technology Project of Ministry of Science and Technology (MoST), PhIRDA completed the project of "Evaluation of Innovation Ability of Key Enterprises of Major Project of New Drug Research and Development".

Qiming Venture Partners was elected the 11th Director of PhIRDA; Xinjiang Technical Institute of Physics and Chemistry, Chinese Academy of Sciences, Innogen, E-nitiate Bio, Yuanjianyouke Biotechnology (Shanghai) Co., Ltd., Innoforce, Repugene Technology, Simcere Diagnoisis, TandemAI, Beijing HuaGai Healthcare Investment Management Co., Ltd. joined PhIRDA.

August 15

The 3rd Phase of "Zijin Pharmaceutical Compliance Forum" series of online activities with the topic of Compliance of Drug Registration and Inspection, was held virtually.

August 18

2022 International Conference on Pharmaceutical Innovation and Development, hosted by PhIRDA, The People's Government of Yantai etc., was successfully held in Yantai, Shandong.

August 23

2022 Annual Contact Representatives Meeting of some members was successfully held.

August 27

"Pharmaceutical Innovation--Build and Make Good Use of Living Biological Samples, Accelerate and Improve the Transformation Efficiency of New Drug R&D", hosted by PhIRDA Innovation R&D Services Specialty Committee, was held virtually.

August 31

As of August 31, IFPMA website shows that PhIRDA has recommended 43 experts to 21 ICH Task Force of IFPMA, accounting for more than 53% of the total number of IFPMA experts worldwide .

2022

Sept.

September 8

Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference, co-hosted by Good-Neighborliness, Friendship and Cooperation Committee of the Shanghai Cooperation Organization, Secretariat of the Shanghai Cooperation Organization, Embassy of the Republic of Uzbekistan in the People's Republic of China, China Pharmaceutical Innovation and Research Development Association, was held in Beijing, China on September 8, 2022.

September 15

The 4th Phase of "Zijin Pharmaceutical Compliance Forum" series of online activities with the topic of Drug Production Quality Compliance was held virtually.

September 22

The 4th Meeting of the 11th Board of Directors of PhIRDA was successfully held, during which Li Jia, Director of Shanghai Institute of Materia Medica, Chinese Academy of Sciences, was elected as the Annual Chairman of PhIRDA of the year 2022-2023, and Zhang Shuyang, President of Peking Union Medical College Hospital (PUMCH) was elected as Chairman-elected.

Chance Pharmaceuticals, LongWood Pharmaceuticals, CorrectSequence Therapeutics, Huadong Medicine, Shanxi Jinbo Bio-Pharmaceutical Co., Ltd., BGI Genomics, Changsha Puji Biotechnology Co., Ltd., Shanghai MicroPort EP MedTech Co., Ltd., JiangSu Deviceland Medical Instrument Co., Ltd., and Bibo Pharma joined PhIRDA.

September 29

PhIRDA was invited to participate in the "China-Japan Pharmaceutical Exchange Activity" commemorating the 50th anniversary of the normalization of China-Japan diplomatic relations.

章　程

CONSTITUTION

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2021~2022年度工作报告暨2022~2023年度工作建议

----2022年9月22日第11届理事会第4次会议

2022年是党的二十大召开之年，是“十四五”规划的关键之年，同时也是中国医药创新面临重重困境的一年。受新冠疫情影响，国内经济持续低迷，企业融资困难，临床研发管线多有暂停或终止的情况发生；受地缘政治因素影响，国际环境发生巨大变化，创新药 “出海”之路屡屡受阻。面对国内外复杂多变的政策和经济环境，中国医药创新促进会（以下称“我会”）今年重点围绕我国生物医药创新领域的“卡脖子”相关问题，就药品监管相关法律法规及政策修订、推动我国医药产品布局国际化、从全链条角度思考和优化我国创新药械政策环境等多方面开展专项研究。此外，我会秘书处还不断加强内部管理及分支机构建设，为各项重点工作提供有力保障。2021~2022年度重点工作完成情况如下：

第一部分
2021~2022年度主要工作回顾

自2021年9月24日第十一届三次理事会召开以来，我会围绕加强党建、优化组织架构、为政府部门完善医药政策建言献策、搭建产业界高端交流合作平台、促进产业创新与国际化接轨等方面开展了卓有成效的工作。具体工作内容如下：

一、以习近平新时代中国特色社会主义思想为统领，推动党建工作高质量发展，进一步促进支部党建与我会日常工作深度结合

我会党支部在国资委党委和中国工经联党委的坚强领导下，深入学习贯彻习近平新时代中国特色社会主义思想，按照上级党委要求，认真有序开展党建工作，通过丰富的实践活动与互动学习方式不断提升支部党员党性修养，并切实把学习成效转化为推动我会发展的强大力量。截至目前，中国药促会党支部共有正式党员11人、积极分子2人，占员工总数的54%。

我会党支部在年度内还进一步完善了多项党建工作规章制度，以加强党的全面领导为统领，并按照上级党组织的安排，开展支部换届工作，将布局在服务高质量发展新篇章的党建工作不断优化升级。此外，支部积极贯彻“我为群众办实事”的工作精神，在日常工作中以为产业、为会员解决实际问题为己任，稳步推进我会各项工作，不断为行业发声，为致力于中国医药创新的有志之士提供交流合作、互利共赢平台。

二、为顺应时代发展，更好发挥我会核心价值、提升会员服务水平，经理事会决议，特设政策研究中心、会员服务部，以丰富我会组织架构

（一）设立政策研究中心，凝聚国内外医药政策与医药产业领域研究精英，打造国内一流、国际知名的第三方智库

研究中心将凝聚国内外医药政策与医药产业领域研究精英，与国内外政策、法规研究机构以及咨询机构合作，打造国内一流、国际知名的第三方智库，研究和探讨我国医药政策与医药产业发展相关热点问题，以期为政府及其有关部门建言献策，为行业发展提供战略咨询。

（二）设立会员服务部，为会员单位提供全方位服务与支持

会员服务部在秘书处的直接领导下，将持续创新会员服务形式，开拓完善会员服务新渠道，强化与会员单位沟通联系，及时主动了解会员单位需求，反映行业共性问题，切实为服务好会员单位发挥桥梁和纽带作用。

三、发挥高端智库作用，开展医药政策研究，为我国医改事业、完善医药政策和产业发展建言献策

（一）完成“新药创制重大专项骨干企业创新能力评估”工作，科学定位创新主体活力与水平

受科技部重大专项司委托，我会今年开展了“新药创制重大专项骨干企业创新能力评估”工作。组建专家委员会，特别聘请蒋华良院士和蒋建东院士作为评估专家委员会联席主席，汇集了药物研发科学家、临床医生、以及战略专家等智力资源；以国际视野坚持创新引领，运用科学评估方法及完整的评价体系，对本土企业创新能力进行全面梳理、分析与评价；评估结果全面且客观地反映我国现阶段医药创新潜能以及面临的挑战。课题研究成果受到科技部与行业专家的高度认可和肯定，为持续深入实施国家医药创新战略发展方向提供理论基础和智力支持。

（二）针对医药源头创新和临床研究能力建设，开展北京市研究型病房项目评估工作，推动产业全链条创新协同发展

为更好地建设研究型病房，以高水平临床研究带动医药产业创新发展，受北京市卫健委委托，我会对北京市首批10家研究型病房建设示范单位展开评估。组建了来自行业协会、医院、企业多方，涵盖医药产业政策、医院管理、临床研究、科研管理、产业代表的评估专家组，通过对标先进国家研究型医院建设经验，充分分析首都的经济、政策、医疗等系统环境，对目标单位的主要建设成效进行综合评价，有针对性地提出若干政策建议。北京市卫健委相关领导对评估工作和研究成果给予高度肯定，并以此制定北京市研究型医院及研究型病房进一步改革的行动方案，目前尚处于征求政府部门及评估单位意见中。

（三）梳理总结“卡脖子”问题，为推动关键核心技术攻关铺垫良好基础

我会积极配合国家科技评估中心，研究分析新药创制领域面临的“卡脖子”关键技术与特征、攻关关键技术的组织实施与管理模式，剖析其中存在的突出问题。初步提出了“中国医药产业存在的卡脖子技术及解决策略”，为长期攻关生物医药这一战略性领域的关键技术组织策略与体制机制建设奠定基础。

（四）科学研判我国生物医药产业中期发展形势，为我国生物经济高质量发展建言献策

受国家发改委高技术司委托，我会开展了2022年上半年产业形势分析工作，梳理重点企业的生产经营状况，针对创新药企业面临的实际困难和制度障碍，提出建议措施。同时，在“关于生物经济和生物医药产业专题座谈会”中，就有关情况进行汇报和反馈。

同时，我会受邀参加国家发改委“十四五”生物经济发展规划座谈会，并递交《关于“十四五”生物经济发展规划的建议报告》，提出要利用细胞治疗药物和天然药物优势，把握历史机遇加强基础建设，对产业后端发展提出建议。

四、发挥政府与行业联系的桥梁纽带作用，参与重要政策法规学习与修订工作，推动政策体系完善和医药创新环境改善

（一）高度重视《药品管理法实施条例》修订工作，促进符合产业现状和发展趋势的诸多政策以

法规形式加以固化

2022年5月9日，《药品管理法实施条例》修订草案征求意见稿发布后，我会多次受邀参加由国家药监局举办的系列座谈会，与各级药品监管部门、国内外药品生产经营企业、其他行业学会协会和专家学者，围绕焦点问题进行深入研讨。同时，政策研究中心积极征求各会员单位及专家委员会意见和建议，组织团队成员逐条学习、认真研究，并提出修改意见，助力打造市场化、法治化、国际化的监管环境。

（二）关注人类遗传资源监管法制化进程，加强部门间政策协调，促进遗传资源监管与医药创新发展的有机统一

2022年3月22日，科技部发布了《人类遗传资源管理条例实施细则（征求意见稿）》，我会及时整理分析各会员单位和专业委员会专家的意见和建议，向科技部反馈行业普遍关心的具体实施问题，切实缩短中国医药研发、注册与审批与全球尚存的“时间差”，保障监管的科学性、高效性。

（三）不断拓展服务内涵和外延，我会多位专家入选国家药监局中药管理战略决策专家咨询委员会，为推动中药科学监管贡献力量

2022年6月，国家药监局发布成立中药管理战略决策专家咨询委员会，我会医药创新科学委员会主任陈凯先院士、委员王广基院士，第十届会员大会副会长张伯礼院士，我会副会长、2017-2018年度会长蒋建东院士，会员单位江苏康缘药业股份有限公司董事长肖伟院士以及执行会长宋瑞霖入选，这将为深化中药审评审批制度改革，保障和促进中药重大监管决策的科学权威性贡献专家智慧。

（四）充分发挥行业协会定位优势，提供政府与产业沟通对话平台，搭建桥梁纽带促进沟通交流

针对2022年国家医保目录调整工作方案广泛征求会员企业意见形成行业建议，推进基于药品价值的科学决策，呼吁建立公平公开的标准和程序，改善续约规则，持续推动医保政策不断完善。我会还积极组织会员单位相关负责人参加由国家药监局药品审评中心召开的系列研讨会，推动相关工作不断改进和完善。

五、围绕行业重大问题，自主开展多项课题研究，研究成果包括研究报告、学术文章、意见建议、出版刊物等，积极拓宽发声渠道，扩大影响力

（一）围绕制约行业发展的痛点、难点，组织召开专题会议，深入沟通交流并设立研究方向

针对美国FDA召开肿瘤药物咨询委员会（ODAC）中提到中国临床研究存在欺诈和不够标准的问题，我会及时组织创新企业召开了“中国新药研发临床数据管理座谈会”，并向国家药监部门递交《关于强化药品监管能力，推动创新药高质量发展的建议》；应邀与RDPAC共同举办了“创新药支付改革”闭门研讨会，与行业专家学者、中外企业代表，对创新药的价值评估和定价、医保改革与多方支付体系建设等话题深入探讨。后期我会还将针对以上两个重大议题设立相应的研究课题。

（二）通过发表学术文章、出版研究报告，使研究成果能够为政策制定提供科学依据和有价值的参考，共建完善的医药创新生态系统

在《医学与哲学》期刊发表学术文章《中国医药创新面临的挑战及其应对》；《商业健康险与医药产业的融合发展》课题研究报告将由中国发展出版社正式出版；《构建中国医药创新生态系统（2021-2025）》报告将由中国法制出版社正式出版，目前处于校审阶段。

（三）已完成的研究课题形成建议报告提交至相关部门，积极拓宽发声渠道

一是向国家药品监督管理局科技和国际合作司提交《关于药品医疗器械真实世界数据有关规则研究的建议报告》，持续推进监管创新；二是今年两会期间，通过两会代表提出关于疏通创新药进入医疗机构堵点的一系列建议，受到媒体及社会各层面的高度关注。

六、深入开展国际医药交流，推动全球医药监管标准互认，打造多方共赢的国际合作机制，为扩大中国医药创新的世界影响力做出积极贡献

（一）积极参与国际规则制定，组织专家开展与国际接轨的药品监管标准、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 21个ICH工作组推荐43名专家（包括14名组长，9名候补组长），推荐的专家在IFPMA全球专家总人数中占比超过53%。

受国家药品监督管理局ICH工作办公室委托，我会已对59个ICH指导原则征求会员单位意见，及时反馈行业意见，推动ICH指导原则在我国的顺利转化实施。此外，受药审中心委托，我会还积极开展ICH指导原则专家工作组的招募工作，目前已有46位专家被纳入21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）加强中国与一带一路沿线国家医药领域合作交流，搭建与上合组织国家医药卫生监管部门多样化沟通平台，为提升各国卫生健康保障和人民福祉水平贡献力量

为推动我国医药创新产品“走出去”，加强中国与一带一路沿线国家医药领域合作交流、推动建立平衡高效的国际药品监管体系互认机制，我会现已开展《医药产品走向“一带一路”沿线国家市场策略II期研究》，充分发挥自身产业优势，积极参加“一带一路”卫生健康合作座谈会等高端会议，展示中国医药创新成果及药监改革成就。

为进一步贯彻落实习近平总书记在上海合作组织峰会上提出的“构建卫生健康共同体”重要倡议，深化全球卫生合作，提供重要公共产品，增进各国民众健康福祉，我会与上合组织睦邻友好合作委员会、上合组织秘书处、乌兹别克斯坦共和国驻华大使馆于2022年9月8日共同主办“上海合作组织医药合作发展大会”。这是在上合组织框架下首次召开的医药产业合作大会，来自十几个上合国家的使馆派员参会，上合组织秘书长张明、中国上合睦委会副主席崔丽、上合组织轮值主席国乌兹别克斯坦驻华大使及我会负责人在会上致辞，多个国家的卫生/药监部门官员发表演讲，20个国家的各界人士线上参会。本次会议为未来中国创新药与上合以及“一带一路”国家市场深入务实合作奠定了良好基础。

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

在全球新冠疫情大流行期间，我会积极拓展国际事务新领域，与美、加、英、澳、日、荷、白俄罗斯、乌兹别克斯坦、新加坡等各国驻华使领馆及IFPMA、APAC、上合组织、知识产权法庭与国际医药企业联盟协会（INTERPAT）等国际组织保持紧密联系，共同推动全球医药产业相互交流与合作；与英国北爱尔兰投资发展署（Invest Northern Ireland）共同主办英国北爱尔兰生命与健康科学行业研讨会，搭建中英两国生物医药产业合作交流平台，助力中国生物医药企业“出海”。

此外，我会领导还受邀参加中国生物医药企业东盟市场拓展会议、第十一届亚洲制药组织合作会议（APAC）、第八届中国医疗峰会、APEC中小企业伦理合规论坛、加拿大安大略省生物科学创新投资峰会、首届亚洲医疗健康高峰论坛、IFPMA商业伦理合规委员会（eBIC）研讨会等创新、投资、监管类主题国际会议及研讨会，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，增加世界对我国医药创新领域的了解和认可，并向其它国家和地区学习先进监管经验。

七、不断丰富和完善专业委员会设置，探索搭建主题化、常态化、品牌化的特色活动平台，为推动我国创新药械产业高质量和可持续发展贡献新的力量

2022年4月以来，我会多个专业委员会围绕行业热点重磅话题，组织策划了包括药械创新跨界融合、创新药出海等主题在内的共计9期“医药创新说”线上直播活动，引发业界的高度关注和社会各方的好评认可，视频直播及回放累计观看近4万人次，文字报道累计曝光19余万次。

2022年6月以来，医药企业合规专委会联合中国药科大学药品监管科学研究院、中国医药报社共同主办多期“紫金医药合规论坛”系列线上活动，以促进行业健康发展。

2022年5月，抗肿瘤药物临床研究专业委员会携手30余位肿瘤领域专家，发布《2021年度中国抗肿瘤新药临床研究评述》，围绕当前潜力靶点机制、国内研发现状进行了全面阐述，给出学术简评。

2022年6月，脑神经药物临床研究专业委员会联合天坛医院牵头开展“替尼泊苷联合顺铂或卡铂在复发型脑胶质瘤患者中的有效性、安全性和耐受性的单臂、开放、多中心、真实世界研究”，为满足患者临床用药需求贡献绵薄之力。

经国家药品监督管理局药品审评中心批准，糖尿病与代谢性疾病药物临床研究专业委员会将牵头协助国家药品监督管理局制定《1型糖尿病非胰岛素药物研发技术指导原则》及《钳夹试验评价胰岛素药代动力学和药效动力学指导原则》两项指导原则。

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

（一）中国医药创新与投资大会

第六届中国医药创新与投资大会（以下称“投资大会”）于2021年9月25~27日在苏州成功举办。第六届投资大会在往届基础上新设医药数字化及创新疗法论坛和创新药基础研究与成果转化路演专场，同期举办深交所创业板专题座谈会和国际云路演专场，为参会者提供更多价值服务。第六届投资大会累计吸引国内外115家优秀企业现场或云端路演，医药企业、投资机构等代表2000余人参会，为参会者提供614桌次一对一邀约洽谈服务，受到业界广泛好评。

（二）罕见病大会

2021年12月18日，由国家卫生健康委员会、中国红十字会总会指导，中国罕见病联盟与我会联合主办的2021年中国罕见病大会在北京隆重召开。全国人大常委会副委员长、中国红十字会会长陈竺向大会致贺信。共和国勋章获得者、国家罕见病诊疗与保障专家委员会顾问钟南山院士，全国人大常委会科教文卫副主任委员、中国医院协会会长刘谦，工业和信息化部副部长王江平，国家卫生健康委员会副主任李斌，国家药品监督管理局副局长陈时飞，国家医疗保障局副局长李滔等相关领导出席大会并致辞。大会紧紧围绕罕见病诊疗和保障等重点内容展开研讨，助力我国罕见病防治与保障事业迈上新台阶。

（三）2022中国医药创新政策论坛

2022年7月23日，2022中国医药创新政策论坛在山东济南成功召开。论坛以“医药创新生态 新阶段 与新征程”为主题，邀请监管机构相关负责人及医保、药学、药物经济学专家学者与产业界企业代表共聚一堂，围绕医药创新发展趋势、政策导向、创新药价值等热点问题进行多角度、多方位的解读和讨论，深入研究医药创新全链条各环节政策，呼吁构建有利于药械产业高质量发展的创新生态环境。

九、践行医药行业社会责任，全力推动援藏工作

今年8月我会组织会员单位为“西藏人人健康”进藏义诊活动捐赠针对藏区高发疾病的特定药物，捐赠信息一经发出，会员单位积极响应、踊跃参与，包括齐鲁制药、恒瑞医药、绿叶制药、天士力、先声药业、上海医药、康弘药业、信立泰药业和亚宝药业在内的多家会员单位在几小时内捐齐了本次活动所需全部药品。

十、了解医药产业政策前沿动态、传递行业发展声音，不断提升医药信息服务能力

我会团队成员每日坚持搜集整理全球医药政策、药物研发成果、医药行业热点新闻等医药行业最新动态消息，按照国内资讯每日一次、国际资讯每周一次的频率，通过邮件向会员单位以及业内专家、政府部门、合作机构发送信息简报。年度内共发送简报信息330余篇。通过官网、微信公众号、视频号、抖音等多种宣传渠道及新媒体矩阵广泛宣传我会对医药政策的研究意见和建议，向社会各界发布我会重点工作、重要活动，筛选并推送深度分析文章，受到业界广泛关注。目前，我会订阅号关注总人数24000余人，年度内净增3600余人。

在全体药促会同仁的不懈努力奋斗下，我会已经成为政府部门“用得上”、会员单位“靠得住”、行业专家“信得过”的行业协会。2022年前三季度经理事会表决共发展新会员单位33家，涵盖药物、器械、数字化、CXO企业及投资机构、科研院所等。我会会员单位在各自领域深耕细作，不断强化核心竞争力并持续开拓海外市场，形成了一批高质量发展的医药上市公司群体，国际地位和影响力显著提升，已经成为世界医药创新格局中不可或缺的中坚力量。

第二部分
2022~2023年度重点工作建议

继续秉承办会宗旨，坚持党的领导，牢牢把握“创新、产业化、国际化”的发展主线，整合并合理配置各方医药创新要素力量，持续改善我国医药产业生态环境，建议2022-2023年度着重围绕以下几个方面开展相关工作：

一、进一步加强党组织建设，结合我会工作实际开创党建工作新局面

新一年我会将持续以习近平新时代中国特色社会主义思想为指引，贯彻落实中央全面从严治党的要求，不断提高党建工作质量和水平；继续加强党员学习教育工作，认真学习习近平总书记重要讲话精神，从提高政治站位、感悟真理力量、推动工作实践的角度加强学习；从协会角度以真挚情怀不断增进民生福祉，全方位推动产业的高质量创新发展，为实现第二个百年奋斗目标、实现中华民族伟大复兴的中国梦而不懈奋斗。

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

（一）高质量完成科技部重大专项司委托开展的《我国创新药物研发和转化能力国际对比研究及发展前沿跟踪》课题研究工作。该课题将邀请蒋建东院士、宋瑞霖执行会长、李佳所长等专家为顾问，通过梳理国际国内创新药物研发的技术现状和发展趋势，以及对我国创新药物研发重点单位的优势技术进行摸底调研，量化分析各项技术的发展水

平和国内外差距等。

（二）继续完善和推动创新生态体系建设，认真研究医药创新强国战略，聚焦重大核心发展领域，主攻薄弱环节，建设国际化创新生态环境，促进产业提质升级，巩固生物医药产业在国民经济中的战略性地位。

（三）开展中国新药临床研发全球布局策略研究，推动中国积极参与国际多中心临床试验，促进中国整体临床研究和管理能力提升、加速融入国际化进程。

（四）加快友好型创新药支付体系建设，深化基本医保创新药支付方式改革，厘清边界，定位商业健康险的功能价值及创新支付方式，推动医保、商保协同发展，提升创新药的可及性。

（五）聚焦罕见病药物领域，积极开展推动国家药物政策立法研究，从国家层面建立激励罕见病药物创新研发、患者诊疗、报销与支付等完善的法律保障体系。

三、时刻关注行业发展存在的主要问题，继续推进创新药价值与支付、创新药出海与国际化、监管制度相关课题的研究工作

（一）成立“参照药品遴选方法学共识”项目课题组，解决参照药品遴选因缺乏规范对创新药谈判准入产生的不利影响，助力卫生技术评估和循证决策证据水平的整体提升。

（二）成立“创新药医保准入与创新支付”项目课题组，探索建立符合医保功能定位、多方治理的友好型创新药医保准入与支付机制。

（三）成立“创新药全球布局与定价策略研究”项目课题组，通过对全球主要药品市场环境和准入政策扫描，分析不同国家地区对药品价格的干预与定价影响，为国内药品监管制度深化改革建言献策提供有力支持。

（四）设立“建立中国特色的创新药支付保障体系研究”课题，以期从体系建设的顶层设计，到从体现创新药价值、基本医保准入制度、多层次保障体系与多元创新支付等多维度提出建议。

（五）开展“药品上市许可持有人制度研究”，进一步厘清各相关主体权责义务，推进MAH制度在中国更好地稳固实施。

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

（一）加强与上合组织和“一带一路”沿线国家医药产业合作交流，首先推动建立东盟、上合组织框架下的多边或者双边的医药产业合作，推动国际药品审批监管合作，建立更加高效共赢的国际药品研发合作模式，加快推动我国医药产业实现国际化，为共同构建人类卫生健康共同体做出积极贡献。

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

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

五、充分发挥专业委员会资源优势，汇聚不同专业领域专家力量，为促进整个医药产业跨界交流探索新思路、开拓新路径、提供新方法

成立医药数字化及创新疗法专业委员会，创办中国药械产业数字化创新高峰论坛；成立创新医疗器械专业委员会，以构建政策引导、科研投入、行业协同的创新器械发展格局；创办中国糖尿病和代谢性疾病药物器械研发创新大会，聚焦糖尿病和代谢性疾病领域临床需求，满足产业需求；修订《中国医药创新促进会医药企业伦理准则》，呼吁构建良性合规的药械产业发展生态环境；联合专业权威媒体和国际知名咨询机构，适时推出并发布药械产业投资研究报告，为社会各界提供专业的药械产业投资资讯和信息服务。

六、发起成立多组学技术应用平台，推动现代化技术手段与药械研发深度融合，服务药械产业高质量发展

“神农计划”是我会联合会员单位品生医疗出资设立、面向社会开展的、具有严格入选标准的项目，以推动分子表型组学在创新药物靶点发现、治疗机理、伴随诊断及疗效评估领域应用研究，加速“个性化治疗”进程。“神农计划”将为会员单位及其他医药领域创新主体提供技术平台，支持高质量的创新药物研发项目，为更精准地探寻妇幼、肿瘤、心血管、神经系统等疾病领域的疾病分子表型层面信息，更高效率的靶点挖掘和药物设计提供可能。

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

为激励中国自主创新，引导中国医药创新向原创创新、颠覆性技术创新转变，反映中国医药创新当前取得的成果和全球贡献，我会与盖伦基金会将共同举办盖伦奖系列评选活动，表彰在医药基础研究、前沿技术和药物研发、成果转化技术创新领域做出突出贡献的科学家和科学工作者。由于科技主管部门对奖项设置的严格管理，目前我会计划与香港生物医药创新协会展开合作并在香港特区政府的支持下推动此项工作。同时，特邀国内、外知名专家组建盖伦奖评审委员会，加速推进完成奖项评选前期各项筹备工作，确保评选活动顺利召开。

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

（一）中国医药创新与投资大会

投资大会作为我会匠心打造的品牌盛会，每年在日程设置、嘉宾邀请、项目筛选、特色服务等方面都在不断优化升级、开拓创新。在延续大会开幕式、路演专场、主题论坛和相关闭门会议设置的同时，第七届投资大会还将增设近万平米专题展区，更好地为药械企业、医疗机构、地方政府、投资人、专业媒体和参会观众搭建丰富多样的交流合作平台，助力企业品牌影响力提升的同时，帮助企业和临床机构、地方政府等相关机构建立联系，在人才引入、招商引资、资源共享等领域挖掘潜在合作机会。

（二）其他会议和活动

我会将继续与国内外各相关机构鼎力合作，办好一年一度的中国医药创新政策论坛和中国罕见病大会等活动，并以各专业委员会工作重点为切入点，结合学术研究方向，继续深度开展各专业领域

活动，服务医药创新关键环节，推动我国生物医药发展和医学技术进步。

九、继续推动医疗助藏项目

我会将携手援助西藏发展基金会等相关机构和中国红十字基金会共同发起医疗助藏项目合作，项目计划为期五年，具体内容包括：组织专家赴藏区义诊，开展藏区高原重点疾病早筛及后期的诊断治疗、康复管理；开展基层医疗人员培训、向西藏农牧民干部群众宣传普及应急救护知识、掌握自救与他救技能，普及高原病预防、治疗、康复及日常健康管理知识；在基层乡村建设南丁格尔健康驿站（救护站），提升西藏基层群众医疗卫生保障水平；探索推动人工智能辅助诊疗技术赋能西藏医疗事业发展，提升西藏地区基层医疗机构诊疗水平等公益活动。此项工作得到援助西藏发展基金会理事长、第十一世班禅额尔德尼•确吉杰布高度认可和中国红十字会会长、全国人大常委会副委员长陈竺的大力支持。

在全球疫情蔓延、经济下滑以及俄乌冲突等复杂国际环境中，中国的医药创新面临前所未有的机遇和挑战。我会将在完成既定工作目标的同时，持续思考中国医药发展的出路和未来，不断整合配置创新资源，逆水行舟、攻坚克难，稳步提升我国医药创新力量的国际地位和话语权。未来，我会仍将不忘初心，牢牢把握“创新、产业化、国际化”的发展主线，做好产业与政府的桥梁，让医药产业全链条携手赋能医药创新，不断推进中国医药产业创新加速、创新破局，质、量齐飞。

2021-2022 Annual Work Report & 2022-2023 Work Proposal for China Pharmaceutical Innovation and Research Development Association

---- The Fourth Meeting of 11th Board of Directors, September 22, 2022

2022 is the key year of the “14th Five-Year Plan”, when the 20th National Congress of the CPC is held and China’s pharmaceutical innovation faces many difficulties. The COVID-19 epidemic made the domestic economy continuously depressed, companies difficult in financing, and clinical research and development management lines often suspended or terminated; geopolitical factors brought tremendous changes to the international environment and obstructed innovative drugs from “going global”. In the face of the complex and changing policy and economic environment at home and abroad, China Pharmaceutical Innovation and Research Development Association (hereinafter referred to as “PhIRDA”) will conduct special researches focusing on “crucial key” problems in China’s biopharmaceutical innovation, revision of laws, regulations and policies related to drug regulation, promotion of internationalized distribution of China’s pharmaceutical products, and thinking and optimization of the policy environment for innovative pharmaceuticals and devices from the perspective of the whole chain. In addition, the Secretariat of PhIRDA has also continuously strengthened internal management and branch building to strongly support various focuses of work. The main work completed by PhIRDA in 2021-2022 is reported as follows:

Part I. Review of Major Work in 2021-2022

Since the Third Meeting of the 11th Board of Directors was held on September 24, 2021, PhIRDA has made fruitful efforts around strengthening Party building, optimizing the organizational structure, offering advice and suggestions for government departments to improve pharmaceutical policies, building high-end exchange and cooperation platforms for industry professionals, and promoting industrial innovation and international integration. The work contents are detailed as follows:

I. Under the command of Xi Jinping Thought on Socialism with Chinese Characteristics in a New Era, boost the high-quality development of Party building work, and promote the deep integration of the Party building work of the Party branch with the routine work of PhIRDA

Under the strong leadership of the Party committee of the State-owned Assets Supervision and Administration Commission (SASAC) and the Party committee of China Federation of Industrial Economics (CFIE), the Party branch of PhIRDA deeply studied and implemented the Xi Jinping Thought on Socialism with Chinese Characteristics in a New Era, carried out Party building work in a conscientious and orderly manner as required by the higher Party committee, continuously improved the Party spirit of the branch’s Party members through rich practical activities and interactive learning methods, and effectively transformed the learning outcomes into a powerful force to promote the development of PhIRDA. By far, the Party branch has had 11 full members and 2 activists, accounting for 54% of the total number of employees.

Moreover, the Party branch further improved a number of rules and regulations on Party building during the year. Under the command of strengthening the overall leadership of the Party and in accordance with the arrangement of the higher Party organization, it changed the term of office and constantly optimized and upgraded the Party building work that serves high-quality development. Actively implementing the working spirit of “I do practical things for the masses” and shouldering the duty of solving practical problems for the industry and members, the Party branch steadily promoted all work of PhIRDA, constantly spoke for the industry, and provided a platform for communication, win-win cooperation, and mutual benefits for ambitious people committed to

China's pharmaceutical innovation.

II. To conform to the times, give better play to the core values of PhIRDA and improve the level of services for members, set up Center for Policy Research and Member Service Department in accordance with the resolution of the Board of Directors to enrich the organizational structure

(I) Set up Center for Policy Research, gather together domestic and foreign research elites in the fields of pharmaceutical policy and pharmaceutical industry, and build a domestic first-class and internationally well-known third-party think tank

Center for Policy Research will gather together domestic and foreign research elites in the fields of pharmaceutical policy and pharmaceutical industry, cooperate with domestic and foreign policy and regulation research institutions and advisory bodies, and build a domestic first-class and internationally renowned third-party think tank to research and discuss hot issues related to China's pharmaceutical policy and pharmaceutical industry development, with a view to offer advice and suggestions to the government and its relevant departments and provide strategic advice for the development of the industry.

(II) Set up Member Service Department to provide all-round services and support for members

Under the direct leadership of the Secretariat, the Member Service Department will continue to innovate in the form of member services, create and improve new channels for member services, strengthen communication with members, take the initiative to understand the needs of members in a timely manner, reflect common problems in the industry, and effectively play a role as a bridge and link for serving members.

III. Play the role of a high-end think tank, conduct research on pharmaceutical policies, and offer advice and suggestions for China's drug regulation reform, improvement of pharmaceutical policies and development of the industry

(I) Complete the project of "Evaluation of Innovation Ability of Key Enterprises of Major Special Project of New Drug Research and Development", determining the vitality and level of innovation subjects in a scientific manner

Entrusted by the Department of Major Science and Technology Project under the Ministry of Science and Technology (MoST), PhIRDA conducted the work of "Evaluation of Innovation Ability of Key Enterprises of Major Special Project of New Drug Research and Development". An expert committee was established, with Academician Jiang Hualiang and Academician Jiang Jiandong specially invited as the co-chairmen and bringing together intellectual resources including drug research and development scientists, clinicians, and strategic experts; adhering to innovation orientation from an international perspective, the innovation capability of local enterprises was comprehensively sorted out, analyzed and evaluated using a scientific evaluation method and a complete evaluation system; the evaluation results comprehensively and objectively reflected the potential and challenges of pharmaceutical innovation in China at this stage. The research findings were highly recognized and affirmed by MoST and industry experts, and provided a theoretical basis and intellectual support for continuous and in-depth implementation of the national pharmaceutical innovation strategy.

(II) Aiming at the source innovation of pharmaceutical industry and the construction of clinical research capacity, carry out the Beijing Research-oriented Ward Evaluation Project and promote the innovation and coordinated development of the whole industry chain

Entrusted by Beijing Municipal Health Commission (BHC), PhIRDA evaluated the first 10 demonstration units for research-oriented ward construction in Beijing, in order to better build research-oriented wards and drive the innovative development of pharmaceutical industry with high-level clinical research. An evaluation expert group was established, consisting of experts in pharmaceutical industry policies, hospital management, clinical research and scientific research management and industry representatives from industry associations, hospitals and enterprises. In accordance with the experience on constructing research-oriented hospitals of advanced countries, the group fully analyzed the economic, policy, medical and other system environments of the capital city, comprehensively evaluated the main construction achievements of target units, and put forward several policy recommendations in a targeted manner. The relevant leaders of BHC highly affirmed the evaluation work and research findings, and formulated an action plan for further reform of Beijing's research-oriented hospitals and research-oriented wards based on this, which is still in the stage of soliciting comments from government departments and evaluation units.

(III) Sort out and summarize "critical key" problems, laying a good foundation for tackling key problems in core technologies

PhIRDA actively cooperated with the National Center for Science and Technology Evaluation (NCSTE) to study and analyze "critical key" technologies in the field of new drug research and development and their characteristics and tackle key problems in the mode of organizing, implementing and managing key technologies, and analyze outstanding problems herein. PhIRDA preliminarily put forward "Critical Key Technologies in China's Pharmaceutical Industry and Solutions", laying the foundation for tackling key problems in making key technology organization strategies and establishing systems and mechanisms in the strategic field of biopharmaceutical industry in the long term.

(IV) Scientifically study and judge the medium-term development of China's biopharmaceutical industry and offer advice and suggestions for the high-quality development of China's bioeconomy

Entrusted by the Department of Innovation and High-Tech Development, the National Development and Reform Commission (NDRC), PhIRDA analyzed the industrial situation in the first half of 2022, sorted out the production and operation of key enterprises, and put forward suggestions and measures against the actual difficulties and institutional obstacles faced by innovative pharmaceutical enterprises. Meanwhile, PhIRDA reported and fed back relevant information at the "Symposium on Bioeconomy and Biopharmaceutical Industry".

Upon invitation, PhIRDA participated in the NDRC Symposium on Bioeconomy Development Planning in the "14th Five-Year Plan" Period and submitted the *Proposal on Bioeconomy Development Planning in the "14th Five-Year Plan" Period*, proposing to take advantages of cell therapy drugs and natural drugs, seize the historical opportunity to strengthen infrastructure construction, and put forward suggestions on the back-end development of the industry.

IV. Play the role as a bridge between the government and the industry, participate in the learning and revision of important policies and regulations, and promote the improvement of the policy system and the pharmaceutical innovation environment

(I) Attach great importance to the revision of the *Regulations for the Implementation of the Drug Administration Law,* and promote many policies conforming to the current situation and development trend of the industry to be solidified in the form of laws and regulations

After the draft for comments on the revised *Regulations for the Implementation of the Drug Administration Law* was released on May 9, 2022, PhIRDA was repeatedly invited to participate in a series of symposiums held by NMPA to deeply discuss focus issues with drug regulatory authorities at all levels, domestic and foreign drug production and marketing enterprises, other industry associations, and experts and scholars. Meanwhile, the Center for Policy Research actively solicited comments

and suggestions from members and expert committees, organized team members to seriously learn and research item by item, and put forward suggestions for revision, so as to help create a market-oriented, legalized and international regulatory environment.

(II) Pay attention to the legalization process of supervision over human genetic resources, strengthen policy coordination among departments, and promote the organic unity of supervision over genetic resources with pharmaceutical innovation and development

After MoST issued the *Detailed Rules for the Implementation of the Regulations on the Administration of Human Genetic Resources* (Draft for Comments) on March 22, 2022, PhIRDA timely collated and analyzed the comments and suggestions from members and experts of specialty committees and fed back the specific implementation issues of general concern in the industry to MoST to effectively shorten the existing "time difference" between China's pharmaceutical research and development, registration and approval and the world's and ensure scientific and efficient supervision.

(III) Continuously expand the connotation and extension of services so that several experts of PhIRDA are selected to join the Expert Advisory Committee for Strategic Decision Making of Traditional Chinese Medicine Management of NMPA, contributing to promoting the scientific supervision of traditional Chinese medicine (TCM)

After NMPA announced the establishment of the Expert Advisory Committee for Strategic Decision Making of Traditional Chinese Medicine Management in June 2022, several experts of PhIRDA were selected to join the Expert Advisory Committee, including Academician Chen Kaixian and Academician Wang Guangji, Director and Member of the Pharmaceutical Innovation Scientific Committee of PhIRDA, Academician Zhang Boli, Vice President of the 10th General Assembly of PhIRDA, Academician Jiang Jiandong, Vice President and 2017-2018 Annual Chairman, Academician Xiao Wei, Chairman of PhIRDA member Jiangsu Kanion Pharmaceutical, and Executive President Song Ruilin. This encouraged these experts contribute their wisdom to deepening the reform of the TCM review and approval system and ensuring and promoting the scientific authority of major regulatory decisions on TCM.

(IV) Give full play to the positional advantage of industry associations, provide a platform for communication between the government and industry, and build a bridge to promote communication and exchanges

PhIRDA extensively solicited comments from members on the 2022 work program for adjustment of the National Drug Reimbursement List (NDRL) and formed industry suggestions, called for the establishment of fair and open standards and procedures and improvement of renewal rules, and continued to promote the continuous improvement of medical insurance policies. PhIRDA also actively organized relevant leaders of members to participate in a series of symposiums held by the Center for Drug Evaluation (CDE) of NMPA and promoted the continuous improvement and perfection of relevant work.

V. Independently establish and research multiple projects around major issues in the industry, generate research findings including research reports, academic articles, suggestions, and publications, actively broaden speak-out channels, and expand the influence

(I) Organize and hold thematic meetings on the pain points and difficulties that restrict the development of the industry, conduct in-depth communication and establish research directions

In view of the fraud and lack of standards in China's clinical research mentioned in the Oncology Drugs Advisory Committee (ODAC) Conference convened by the US FDA, PhIRDA timely organized innovative enterprises to hold the "Symposium on Management of New Drug Research and Development Clinical Data in China" and submitted the *Suggestions on Strengthening Drug Regulatory Capacity and Promoting the High Quality Development of Innovative Drugs* to the national drug regulatory authority; jointly held a closed door seminar with RDPAC on "Innovative Drug Payment Reform" upon invitation to deeply discuss topics including value evaluation and pricing of innovative drugs, medical insurance reform, and multi-party payment system construction with industry experts and scholars as well as Chinese and foreign enterprise representatives. Later, PhIRDA will set up corresponding research projects for the above two major topics under discussion.

(II) Make research findings a scientific basis and valuable reference for policy formulation by publishing academic articles and research reports, and jointly build a sound ecosystem for pharmaceutical innovation

The academic article *Challenges to China's Pharmaceutical Innovation and Its Response* was published in the journal *Medicine and Philosophy*; the research report *Integrated Development of Commercial Health Insurance and Pharmaceutical Industry* will be officially published by China Development Press; the report *Building China's Pharmaceutical Innovation Ecosystem (2021-2025)* will be officially published by China Legal Publishing House, which is currently in the proofreading stage.

(III) Form and submit proposal reports of completed research projects to relevant departments and actively broaden speak-out channels

First, submitted the *Proposal Report on the Research of Relevant Rules for Real World Data of Pharmaceuticals and Medical Devices* to the Department of Science, Technology and International Cooperation of NMPA and continued to promote innovation in supervision; second, put forward a series of suggestions on unblocking the way for innovative drugs to enter medical institutions through deputies to the National People's Congress and the Chinese Political Consultative Conference (NPC & CPPCC), drawing much attention from the media and all walks of life.

VI. Deeply carry out international exchanges on pharmaceutical industry, promote global mutual recognition of pharmaceutical regulatory standards, create a win-win international cooperation mechanism, and make positive contributions to expanding the world influence of China's pharmaceutical innovation

(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 43 experts (including 14 Leaders and 9 Alternate Leaders) to 21 ICH Expert Working Groups (EWGs) of the IFPMA since 2017, accounting for more than 53% of the total number of IFPMA experts worldwide.

Entrusted by the ICH Office of the NMPA, PhIRDA solicited opinions from PhIRDA members and timely fed back industry opinions on 59 ICH guidelines to promote the smooth implementation of ICH guidelines in China. Entrusted by the Center for Drug Evaluation (CDE), PhIRDA actively recruited experts for ICH EWGs. By far, 46 experts recommended by PhIRDA have been included in 21 CDE ICH EWGs, and the experts for other EWGs are under further selection.

(II) Strengthen cooperation and exchanges in the pharmaceutical field between China and countries along the Belt and Road, build a diversified communication platform with the medical and health regulatory authorities of SCO countries, and contribute to improving the health security and people's well-being in all countries

To promote China's innovative pharmaceutical products to "go global", strengthen cooperation and exchanges in the pharmaceutical field between China and countries along the Belt and Road, and promote the establishment of a balanced and efficient international recognition

mechanism for drug regulatory systems, PhIRDA has carried out *Phase II Research on Market Strategies for Pharmaceutical Products to Enter Countries along the Belt and Road*, given full play to its industrial advantages, and actively participated in high-end conferences including the "Belt and Road" Health Cooperation Symposium to demonstrate China's achievements in pharmaceutical innovation and drug regulatory reform.

To further implement the important initiative of "Building a Global Community of Health for All" put forward by General Secretary Xi Jinping at the SCO Summit, deepen global cooperation on health, provide important public goods, and enhance the health and well-being of people in all countries, PhIRDA co-hosted the "SCO Pharmaceutical Cooperation Development Conference" with the Good-Neighborliness, Friendship and Cooperation Commission (GNFCC) of SCO, the Secretariat of SCO, and the Embassy of the Republic of Uzbekistan in China on September 8, 2022. This is the first pharmaceutical industry cooperation conference held under the framework of SCO. Embassies of more than a dozen of SCO countries in China sent representatives to attend the conference, SCO Secretary General Zhang Ming, GNFCC Vice President Cui Li, Ambassador to China of SCO Rotating Chairman Uzbekistan and PhIRDA leader delivered speeches at the conference, officials of health/drug regulatory departments of many countries made speeches, and people from all walks of life in 20 countries attended the conference online. This conference laid a good foundation for China's in-depth practical cooperation on innovative drugs with countries of SCO and along the "Belt and Road" in the future.

(III) 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

When the COVID-19 pandemic swept the world, PhIRDA actively expanded new areas of international affairs, and maintained close contact and jointly promoted mutual exchanges and cooperation on the global pharmaceutical industry with embassies and consulates of the US, Canada, Britain, Australia, Japan, the Netherlands, Belarus, Uzbekistan, Singapore and other countries in China, as well as international organizations such as IFPMA, APAC, SCO, and INTERPAT; co-hosted the Northern Ireland Life and Health Science Industry Seminar with the Invest Northern Ireland to build a Sino-UK cooperation and exchange platform for the biopharmaceutical industry and help Chinese biopharmaceutical enterprises to "go global".

Upon invitation, leaders of PhIRDA participated in international conferences and seminars themed with innovation, investment and supervision, including ASEAN Market Development Conference of Chinese Biopharmaceutical Enterprises, 11th Asia Partnership Conference of Pharmaceutical Associations (APAC) Conference, 8th China Healthcare Summit, APEC SME Ethics and Compliance Forum, Ontario Bioscience Innovation Investment Summit, 1st Asian Summit on Global Health, and Seminar of IFPMA Ethics and Business Integrity Committee (eBIC). Through keynote reports and roundtable discussions, PhIRDA showed China's achievements in drug regulatory reform and pharmaceutical innovation and development to the world, enabled the world to more understand and recognize China's pharmaceutical innovation, and learned advanced regulatory experience from other countries and regions.

VII. Continuously enrich and improve PhIRDA Specialty Committees, explore and establish thematic, normalized, and brand-based special activity platforms, and contributed new forces to the promotion of the innovation and sustainable development of China's pharmaceutical and health industry

Since April 2022, several specialty committees of PhIRDA have organized and planned a total of nine online live streams "Pharmaceutical Innovation" themed with cross-border integration of pharmaceutical and medical device innovation and export of innovative drugs, drawing much attention and praises from the industry and all walks of life and with nearly 40,000 watches and replays and more than 190,000 reads of written reports.

Since June 2022, the Ethics and Business Compliance Specialty Committee has co-hosted several online activities of "Zijin Pharmaceutical Compliance Forum" with the Institute of Pharmaceutical Regulatory Sciences of China Pharmaceutical University and China Pharmaceutical News Agency in order to boost the healthy development of the industry.

In May 2022, the Clinical Research on Oncology Drugs Specialty Committee joined hands with more than 30 experts in the field of oncology to issue the *2021 Review of Clinical Research on New Anti-tumor Drugs in China*, making comprehensive description and brief academic evaluation around the current potential target mechanism and the current status of domestic research and development.

In June 2022, the Clinical Research on Cranial Nerve Drugs Specialty Committee worked with Beijing Tiantan Hospital to lead a "Single-arm, open, multi-center, real-world study on the effectiveness, safety and tolerance of teniposide in combination with cisplatin or carboplatin in patients with recurrent brain glioma", contributing to meeting the clinical drug needs of patients.

Approved by CDE of NMPA, the Clinical Research on Diabetes and Metabolic Diseases Specialty Committee will take the lead in assisting NMPA in formulating two guidelines - *Technical Guidelines on the Research and Development of Non-insulin Drugs for Type 1 Diabetes and Guidelines on Evaluation of the Pharmacokinetics and Pharmacodynamics of Insulin by Clamp Test*.

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

(I) China BioMed Innovation and Investment Conference

The 6th China BioMed Innovation and Investment Conference (hereinafter referred to as "CBIIC") was successfully held in Suzhou from September 25 to 27, 2021. The 6th CBIIC will be enriched by the Digitalization in Pharma and Innovative Therapy Forum, and Fundamental Research & Transformation of New Drugs Roadshow. Meanwhile, Reform of the ChiNext Seminar and Virtual International Roadshow were held to provide more valuable services for participants. The 6th CBIIC attracted a total of 115 outstanding enterprises that conducted the on-site or virtual roadshows, and nearly 2,000 representatives of pharmaceutical enterprises and investment institutions present, delivering the services of one-on-one negotiation upon invitation for 614 person-times. The 6th CBIIC was widely acclaimed by industry professionals.

(II) China Conference on Rare Diseases

On December 18, 2021, under the guidance of the National Health Commission (NHC) and the Red Cross Society of China (RCSC), China Alliance for Rare Diseases (CARD) worked with PhIRDA to hold the 2021 China Conference on Rare Diseases (CCRD) in Beijing. Chen Zhu, Vice Chairman of the Standing Committee of the NPC, and President of RCSC, sent a congratulatory letter to CCRD. Academician Zhong Nanshan, winner of the Medal of the Republic and consultant of the National Committee of Experts on the Diagnosis, Treatment and Guarantee of Rare Diseases, Liu Qian, Deputy Director of Science, Education, Culture and Health of the Standing Committee of the NPC and President of the Chinese Hospital Association, Wang Jiangping, Vice Minister of the Ministry of Industry and Information Technology, Li Bin, Deputy Director of NPC, Chen Shifei, Deputy Commissioner of NMPA, Li Tao, Deputy Director of the National Healthcare Security Administration and other relevant leaders attended CCRD and delivered speeches. The participants had a heated discussion focusing on the diagnosis, treatment and security of rare diseases and other key contents, helping China's rare disease prevention, control and security to step onto a new level.

(III) 2022 Forum on China's Pharmaceutical Innovation Policies

On July 23, 2022, the 2022 Forum on China's Pharmaceutical Innovation Policies was successfully held in Jinan, Shandong Province. The forum is themed with "New Ecology, New Stage and New Journey of Pharmaceutical Innovation", at which relevant heads of regulatory agencies, experts and scholars in medical insurance, pharmacy and pharmaceutical economics, and representatives of enterprises in the industry conducted multi-angle and multi-dimensional interpretation and discussion on hot issues including the development trend of pharmaceutical innovation, policy orientation, and value of innovative drugs, deeply studied policies in all links of the whole chain of pharmaceutical innovation, and called for the establishment of an innovative ecological environment conducive to the high-quality development of the pharmaceutical industry.

IX. Fulfill the social responsibility of the pharmaceutical industry and make every effort to promote the aid to Tibet

This August, PhIRDA organized members to donate specific drugs for high-incidence diseases in Tibet for the free diagnosis and treatment activity "Making All People in Tibet Healthy". Once the donation information was sent, members actively responded and actively participated. Qilu Pharmaceutical, Hengrui Pharmaceuticals, Luye Pharma, Tasly, Simcere, Shanghai Pharma, Kanghong Pharmaceutical, Salubrisl, Yabao Pharmaceutical and other members donated all the medicines needed for this activity within a few hours.

X. Get to know the cutting-edge trends of pharmaceutical industry policies, convey the voice of industry development, and constantly improve the pharmaceutical information service capability

Adhering to collecting and sorting out the latest news of the pharmaceutical industry, including global pharmaceutical policies, drug research and development achievements, and hot news of the pharmaceutical industry every day, the team members of PhIRDA sent information briefings on domestic information once a day and international information once a week to members, industry experts, government departments, and cooperative organizations by email. More than 330 briefings were sent during the year. PhIRDA widely publicized its opinions and suggestions on medical and pharmaceutical policy research, released its work focuses and important activities to all walks of life, and screened and pushed in-depth analysis articles through its official website, WeChat official account, WeChat video channel, Tik Tok and other publicity channels and new media matrix, which received widespread attention from the industry. By far, PhIRDA Subscription has been followed by more than 24,000 people, with a net increase of 3,600 people in the year.

With the unremitting efforts of all colleagues, PhIRDA has become an industry association "useful" for government departments and with "reliable" members, and "trustworthy" industry experts. In the first three quarters of 2022, 33 new members were selected by the Board of Directors by vote, covering pharmaceuticals, devices, digitization, CXO enterprises and investment institutions, and scientific research institutes. The members of PhIRDA have deeply and intensively cultivated their respective fields, constantly strengthened their core competitiveness and continued to exploit overseas markets. Some of them have grown into high-quality listed pharmaceutical companies, significantly improved their international status and influence, and become an indispensable hard core in the global pharmaceutical innovation pattern.

Part II. Proposal for Key Work in 2022-2023

Continuing to uphold the original tenet, adhere to the leadership of the Party, firmly grasp the main development line of "Innovation, Industrialization and Internationalization", integrate and rationally allocate the forces of various pharmaceutical innovation elements, and constantly improve the ecological environment of China's pharmaceutical industry, PhIRDA is suggested to focus on the following aspects of work in 2022-2023:

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

In the new year, PhIRDA will continue to act under the guidance of Xi Jinping Thought on Socialism with Chinese Characteristics in a New Era, implement the requirements of the CPC Central Committee to comprehensively and strictly govern the Party, and continuously improve the quality and level of Party building; continue to strengthen learning and education of Party members, conscientiously learn the spirit of General Secretary Xi Jinping's important speeches, and strengthen learning from the perspective of improving the political consciousness, apprehending the power of truth, and promoting work practice; continue to improve the people's well-being and livelihood with sincere feelings, promote the high-quality innovation and development of the industry in an all-round way, and make unremitting efforts to achieve the Second Centenary Goal and realize the Chinese dream of the great rejuvenation of the Chinese nation.

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

(I) Complete the research project *International Comparative Research on China's Innovative Drug R&D and Transformation Capacity and Tracking of Development Frontier* entrusted by the Department of Major Science and Technology Project of MoST with high quality. Academician Jiang Jiandong, Executive President Song Ruilin, Director Li Jia and other experts will be invited as consultants for this project. They will sort out the technical status and development trend of international and domestic innovative drug research and development, survey the superior technologies of key units of innovative drug research and development, and conduct a quantitative analysis of the development level of various technologies and the gap between China and other countries.

(II) Continue to improve and promote the construction of an innovation ecosystem, seriously study the strategy of strengthening China through pharmaceutical innovation, focus on major core development areas, target weak links, build an international ecological environment for innovation, promote industrial upgrading, and consolidate the strategic position of the biopharmaceutical industry in the national economy.

(III) Research the global layout strategy of China's clinical research and development of new drugs, promote China to actively participate in international multi-center clinical trials, boost the improvement of China's overall clinical research and management capability, and accelerate the process of internationalization.

(IV) Accelerate the construction of a friendly payment system for innovative drugs, deepen the reform of payment for innovative drugs by basic medical insurance, clarify the boundary, determine the functional value and innovative payment mode of commercial health insurance, promote the coordinated development of medical insurance and commercial insurance, and improve the accessibility of innovative drugs.

(V) Focus on the field of orphan drugs, actively carry out research on promoting national pharmaceutical policy legislation, and establish a sound legal security system at the national level to encourage innovative research and development of orphan drugs, diagnosis and treatment of patients, reimbursement and payment.

III. Always pay attention to the main problems existing in the development of the industry, and continue to promote research on the value and payment of innovative drugs, export and internationalization of innovative drugs, regulatory systems, etc.

(I) Establish a research project group for "Consensus on Methodology for Reference Drug Selection", eliminate

the adverse impact of reference drug selection on the negotiation and access of innovative drugs due to lack of standards, and help improve the overall level of evidence for health technology assessment and evidence-based decision-making.

(II) Establish a research project group for "Medical Insurance Access and Payment for Innovative Drugs", and explore the establishment of a friendly multiparty-governed medical insurance access and payment mechanism for innovative medicines that conforms to the functional orientation of medical insurance.

(III) Establish a research project group for "Research on the Global Layout and Pricing Strategy of Innovative Drugs", and analyze the intervention and pricing influence on drug prices in different countries and regions through scanning the global major pharmaceutical market environments and their access policies, so as to provide strong support and suggestions for deepening the domestic drug regulatory system reform.

(IV) Establish a research project "Research on the Establishment of an Innovative Drug Payment Guarantee System with Chinese Characteristics", aiming to offer suggestions from multiple dimensions, including top-level design of system construction, reflection of the value of innovative drugs, basic medical insurance access system, multi-level security system and diversified innovative payment.

(V) Carry out "Research on the Drug Marketing Authorization Holder (MAH) System", further clarify the rights, responsibilities and obligations of all relevant subjects and promote the better and stable implementation of the MAH system in China.

IV. Actively expand exchanges and cooperation with relevant foreign institutions, and steadily enhance the international status and say of China's pharmaceutical innovation forces

(I) Strengthen cooperation and exchanges with countries of SCO and along the "Belt and Road" in the pharmaceutical industry, first promote the establishment of multilateral or bilateral pharmaceutical industry cooperation under the framework of ASEAN and SCO, promote international cooperation on pharmaceutical approval and supervision, establish a more efficient and win-win international cooperation model for pharmaceutical research and development, accelerate the internationalization of China's pharmaceutical industry, and make positive contributions to co-building a community of human health.

(II) Continue to expand cooperation and exchanges with embassies and consulates of various countries in China, industry associations and social organizations. PhIRDA will recommend authoritative experts in the industry to participate in the formulation and revision of ICH guidelines in accordance with the requirements of the Secretariat of the IFPMA and the ICH Office of the NMPA, and urge Chinese experts to participate in the formulation of international standards and rules and speak out on the international stage; cooperate with the NMPA to complete the transformation and implementation of ICH-related guidelines in China, and steadily promote China's pharmaceutical industry standards to comply with international standards.

(III) Integrate and rationally allocate resources to further help Chinese pharmaceutical enterprises improve their international competitiveness, help members to acquire more opportunities of new drug R&D and overseas cooperation in the medical and health field, and promote the deep integration of China's pharmaceutical industry with the global pharmaceutical industry in the areas of trade, investment and technology, etc.

V. Give full play to the resource advantages of PhIRDA Specialty Committees, gather together experts in different professional fields, and explore new ideas, develop new paths, and provide new methods for promoting cross-border exchanges in the pharmaceutical industry

PhIRDA will set up Digital Medicine and Innovative Therapy Specialty Committee, and create a Digital Innovation Summit Forum for China's Pharmaceutical and Medical Device Industries; set up Innovative Medical Devices Specialty Committee to build an innovative device development pattern guided by policies, with scientific research investment and in coordination with the industry; create a China R&D Innovation Conference for Pharmaceuticals and Medical Devices for Diabetes and Metabolic Diseases to focus on the clinical needs of diabetes and metabolic diseases and meet the industrial needs; revise the Code of Ethics for Pharmaceutical Enterprises of PhIRDA and call for building a benign and compliant ecological environment for the development of pharmaceutical and medical device industries; cooperate with professional authoritative media and internationally renowned advisory bodies to timely launch and release research reports for investment in the pharmaceutical industry so as to provide professional pharmaceutical industry investment information and services for all walks of life.

VI. Initiate the establishment of a multi-omics technology application platform, promote the deep integration of modern technological means with pharmaceutical research and development, and serve the high-quality development of pharmaceutical and medical device industries

"SINON" is a project funded and established by PhIRDA and its member Qlife, oriented to the society and with strict inclusion criteria, and aims to promote the application research of molecular phenotypeomics in fields including discovery of innovative drug targets, mechanism of treatment, concomitant diagnosis and efficacy evaluation and to accelerate the process of "personalized treatment". "SINON" will provide a technological platform for members and other innovative subjects in the pharmaceutical field, support high-quality innovative pharmaceutical research and development projects, and make it possible to more accurately seek the molecular phenotype information of maternal and children diseases, cancer, cardiovascular diseases, nervous system disease, and other diseases and to conduct more efficient target mining and drug design.

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

To stimulate independent innovation in China, guide China's pharmaceutical innovation to focus on original innovation and disruptive technological innovation, and reflect the current achievements and global contributions of China's pharmaceutical innovation, PhIRDA will work with the Galien Foundation to hold the Prix Galien selection series to commend scientists and scientific workers who have made outstanding contributions in the fields of pharmaceutical basic research, cutting-edge technology and drug R&D, and technological innovation in outcome transformation. Due to the strict management of award setting by the competent authority for science and technology, PhIRDA plans to cooperate with the HK Bio-Med Innotech Association to promote this work with the support of the Government of Hong Kong SAR. Meanwhile, domestic and foreign well-known experts are invited to form a Galien Award Review Committee to accelerate completion of all preparations prior to award selection and ensure the smooth holding of the activity.

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

(I) China BioMed Innovation and Investment Conference

CBIIC is a brand conference created by PhIRDA, with its schedule setting, guest invitation, project screening, and characteristic services constantly optimized, upgraded, and innovated every year. In continuation of the opening ceremony, roadshow, theme forum and closed-door meeting, the 7th CBIIC will add a nearly 10,000-m^2 theme display area as a rich and diverse communication and

cooperation platform for pharmaceutical and medical enterprises, medical institutions, local governments, investors, professional media and visitors. In addition to assisting enterprises to enhance their brand influence, it will help enterprises, clinical institutions, local governments and relevant institutions to come into contact and tap potential cooperation opportunities in talent introduction, business and investment solicitation, resource sharing, etc.

(II) Other meetings and activities

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

IX. Continue to promote the medical aid to Tibet

PhIRDA will join hands with Tibet Development Fund (TDF), the Chinese Red Cross Foundation and other relevant agencies to initiate five-year cooperation on medical aid to Tibet, with specific contents including: organizing experts to provide free diagnosis and treatment in the Tibetan area and carrying out early screening of key altitude sicknesses in the Tibetan area as well as later diagnosis, treatment, and rehabilitation administration; training primary medical staff, publicizing and popularizing emergency rescue knowledge to the cadres and masses in Tibet and helping them to master skills of saving their life by themselves and others, and popularizing knowledge on prevention, treatment, rehabilitation, and daily health management of altitude sicknesses; building Nightingale health stations (rescue stations) in villages and improving the grassroots medical and health protection level in Tibet; exploring and promoting AI-assisted diagnosis and treatment technology to enable the development of Tibet's medical treatment and improving the diagnosis and treatment level of primary medical institutions in the Tibet area. This work was greatly recognized by the 11th Panchen Erdeni Qoigyi Gyaibo, Board Chairman of TDF, and vigorously supported by Chen Zhu, Vice Chairman of the Standing Committee of the NPC, and President of RCSC.

In the complex international environment such as global epidemic spread, economic decline, and Russia-Ukraine conflict, China's pharmaceutical innovation ushers in unprecedented opportunities and challenges. While accomplishing the set objectives of work, PhIRDA will keep thinking about the way out and future of China's pharmaceutical development, continuously integrate and allocate innovative resources, sail against the current and surmount difficulties, and steadily improve the international status and discourse power of China's pharmaceutical innovation force. In the future, PhIRDA will remain true to the original aspiration, firmly hold the main development line of "Innovation, Industrialization and Internationalization", serve as a bridge between the industry and government, promote the entire pharmaceutical industry chain to enable pharmaceutical innovation, and constantly boost China's pharmaceutical industry to accelerate and make breakthroughs in innovation and improve both quality and quantity.